

US3412184 (Prod: New Horizons Clinical Research)

Generated By: KC Joubran

Generated On: 09 Jun 2021 17:30:24

All time stamps listed in this document are displayed in GMT

US3412184

Form: Participant Creation

Data signed: (b) (4) 16 Apr 2021 14:34:06

Generated On: 09 Jun 2021 17:30:24

[Participant ID](#)

US3412184

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

US3412184

Folder: Screening

Form: Visit Date

Data signed: (b) (4) 13 Feb 2021 04:54:06

Generated On: 09 Jun 2021 17:30:24

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	10 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 04:54:06

Generated On: 09 Jun 2021 17:30:24

Date of Birth (MMM yyyy)	(b) (6) 1947
Age	73
Age Units	YEARS
Age (Derived)	73
Sex	Female <input checked="" type="radio"/> Male <input type="radio"/>
Ethnicity	Hispanic or Latino <input type="radio"/> Not Hispanic or Latino <input checked="" type="radio"/> Not Reported <input type="radio"/> Unknown <input type="radio"/>
Race (Check All That Apply)	
White	False
Black	True
Asian	False
American Indian or Alaska Native	False
Native Hawaiian or other Pacific Islander	False
Other	False
If race is Other, specify _____	
Unknown	False
Not reported	False

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Folder: Screening

Form: Enrollment

Data signed: (b) (4) 13 Feb 2021 04:54:06

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Date of Informed Consent (<i>dd MMM yyyy</i>)	10 AUG 2020
Month and Year of Informed Consent (derived)	AUG 2020
Year of Informed Consent (derived)	2020
Protocol Version	Amendment 1 <input checked="" type="radio"/>
	Amendment 2 <input type="radio"/>
	Amendment 3 <input type="radio"/>
	Amendment 4 <input type="radio"/>
	Amendment 5 <input type="radio"/>
Was participant enrolled in the study?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
If No, indicate reason for screen fail	Withdrew Consent <input type="radio"/>
	Inclusion/Exclusion <input type="radio"/>
	Cohort Full <input type="radio"/>
	Other <input type="radio"/>
If reason for screen fail is Other, specify	
Was this participant screened previously?	Yes <input type="radio"/>
	No <input checked="" type="radio"/>
If Yes, previous participant number	
Enrollment Trigger	1

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Folder: Screening

Form: Inclusion/Exclusion Criteria Summary

Data signed: (b) (4) 13 Feb 2021 04:54:06

Generated On: 09 Jun 2021 17:30:24

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 04:54:06

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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 04:54:06

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Condition	OSTEOARTHRITIS BI-LATERAL KNEES
Start date (dd MMM yyyy)	UN UNK 2010
Start date completely unknown	False
Condition ongoing at study entry	Yes <input checked="" type="radio"/> No <input type="radio"/>
If No, please specify the stop date (dd MMM yyyy)	
Stop date completely unknown	False
Start Month and Year (derived)	JAN 2010
Start Year (derived)	2010
Stop Month and Year (derived)	
Stop Year (derived)	

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Folder: Screening

Form: Medical History (3)

Data signed: (b) (4) 13 Feb 2021 04:54:06

Generated On: 09 Jun 2021 17:30:24

Condition	POST-MENOPAUSAL
Start date (dd MMM yyyy)	UN UNK 1996
Start date completely unknown	False
Condition ongoing at study entry	Yes <input checked="" type="radio"/> No <input type="radio"/>
If No, please specify the stop date (dd MMM yyyy)	
Stop date completely unknown	False
Start Month and Year (derived)	JAN 1996
Start Year (derived)	1996
Stop Month and Year (derived)	
Stop Year (derived)	

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Folder: Screening

Form: Vital Signs

Data signed: (b) (4) 13 Feb 2021 04:54:06

Generated On: 09 Jun 2021 17:30:24

Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (dd MMM yyyy)	10 AUG 2020
Time of assessment (00:00-23:59)	09:37 (24 HR)
Vital Signs Date and Time (derived)	10 AUG 2020 09:37
Height (xxx.x)	165.6 cm
Weight (xxx.x)	88.1 kg
BMI (xxx.x)	32.12590 kg/m ²
BMI units	KG/M2
Temperature (xxx.x)	ND - Not Done
Route of measurement	Oral <input type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	ND - Not Done
Pulse units	BPM
Respiratory Rate (xxx)	ND - Not Done
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	ND - Not Done
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	ND - Not Done
Diastolic Blood Pressure units	MMHG
Height (derived)	
Weight (derived)	

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Folder: Screening

Form: Physical Examination

Data signed: (b) (4) 13 Feb 2021 04:54:06

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Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

10 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: Childbearing Potential

Data signed: (b) (4) 13 Feb 2021 04:54:06

Generated On: 09 Jun 2021 17:30:24

Date of assessment (dd MMM yyyy) 10 AUG 2020

Is the participant of childbearing potential? Yes ☐
No ☒

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

If Partner medically sterile or Other, specify _____

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

Date of surgery unknown False

If Post-menopausal, date of last menstruation (dd MMM yyyy) UN UNK 1996

Date of last menstruation unknown False

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Folder: Screening

Form: Risk of Exposure

Data signed: (b) (4) 13 Feb 2021 04:54:06

Generated On: 09 Jun 2021 17:30:24

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

HAS HEALTH CARE WORKER
COME TO HOUSE FOR
HUSBAND

Location and Living Circumstances Risk (check all that apply)

No Risk Identified False

Resides in Nursing Home or Assisted Living Facility False

PRODUCTION RELEASE (v12.003
EAB) (1725)

12 of 2073

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Folder: Screening

Form: Risk of Exposure

Data signed: (b) (4) 13 Feb 2021 04:54:06

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Resides in Multi-family dwelling (e.g., cohabitation in dwelling with > 5 people, includes grandparents living with children < 18yrs)	False
Resides in high density housing (e.g., high rise apartments with shared entrances or elevators)	False
Resides in low density, multi-family setting without (e.g., apartments complex without shared entrances or elevators, duplexes)	False
Resides in a single family home (i.e., detached housing)	True
Other	True
Specify	LIVES IN (b) (6)

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Folder: Visit 1 Day 1

Form: Visit Date

Data signed: (b) (4) 13 Feb 2021 02:43:24

Generated On: 09 Jun 2021 17:30:24

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	10 AUG 2020
Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>
Folder OID	VISIT1

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Folder: Visit 1 Day 1

Form: Randomization

Data signed: (b) (4) 13 Feb 2021 02:43:24

Generated On: 09 Jun 2021 17:30:24

What was the date of randomization? (dd MMM yyyy) 10 AUG 2020

What was the participant's randomization number? 185180

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 ☒

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Data signed: (b) (4) 13 Feb 2021 02:43:24

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Height	ND - Not Done
Weight	ND - Not Done

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Data signed: (b) (4) 13 Feb 2021 02:43:24

Generated On: 09 Jun 2021 17:30:24

Height	ND - Not Done
Weight	ND - Not Done
Timepoint	Pre-Dose <input checked="" type="radio"/> Post-Dose <input type="radio"/>
Were vital signs assessed?	Yes <input checked="" type="radio"/> No <input type="radio"/>
Date of assessment (dd MMM yyyy)	10 AUG 2020
Time of assessment (00:00-23:59)	09:37 (24 HR)
Vital Signs Date and Time (derived)	10 AUG 2020 09:37
Temperature (xxx.x)	36.3 C
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)	14 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	138 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	86 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 02:43:24

Generated On: 09 Jun 2021 17:30:24

Height	ND - Not Done
Weight	ND - Not Done
Timepoint	Pre-Dose <input type="radio"/> Post-Dose <input checked="" type="radio"/>
Were vital signs assessed?	Yes <input checked="" type="radio"/> No <input type="radio"/>
Date of assessment (dd MMM yyyy)	10 AUG 2020
Time of assessment (00:00-23:59)	11:06 (24 HR)
Vital Signs Date and Time (derived)	10 AUG 2020 11:06
Temperature (xxx.x)	97.7 F
Route of measurement	Oral <input checked="" type="radio"/> Axillary <input type="radio"/> Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	68 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	140 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	85 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 02:43:23

Generated On: 09 Jun 2021 17:30:24

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 02:43:23

Generated On: 09 Jun 2021 17:30:24

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) 10 AUG 2020

What was the treatment time? (00:00-23:59) 10:35 (24 HR)

Treatment Date and Time (derived) 10 AUG 2020 10:35

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 02:43:23

Generated On: 09 Jun 2021 17:30:24

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

Collection date (dd MMM yyyy)	10 AUG 2020
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Collection time (00:00-23:59)	10:00 (24 HR)
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Collection date and time (derived)	10 AUG 2020 10:00
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US3412184

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab

Data signed: (b) (4) 13 Feb 2021 02:43:23

Generated On: 09 Jun 2021 17:30:24

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

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Folder: Visit 1 Day 1

Form: Continuing

Data signed: (b) (4) 13 Feb 2021 02:43:23

Generated On: 09 Jun 2021 17:30:24

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 17:30:24

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

97.7 °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

10 AUG 2020 11:07

PC Open Date & Time

10 AUG 2020 10:55

PC Close Date & Time

10 AUG 2020 13:25

US3412184

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 17:30:24

TIMEPOINT

DAY 1, AFTER VACCINATION
(AT HOME)

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

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

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

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

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

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

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

Was **TEMPERATURE** taken? Yes ☒ No ☐

Please record your **TEMPERATURE** in °F 98.0 °F

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

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

PC Time Stamp	10 AUG 2020 21:14
PC Open Date & Time	10 AUG 2020 14:20
PC Close Date & Time	11 AUG 2020 11:59

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Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 17:30:24

TIMEPOINT

DAY 2

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

98.0 °F

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

Yes ☐

No ☒

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

PC Time Stamp

12 AUG 2020 09:40

PC Open Date & Time

11 AUG 2020 12:00

PC Close Date & Time

12 AUG 2020 11:59

US3412184

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 17:30:24

TIMEPOINT

DAY 3

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☐

No ☐

Please record your **TEMPERATURE** in °F

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

Yes ☐

No ☐

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

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

To **PREVENT** pain or fever from occurring

PC Time Stamp

PC Open Date & Time

12 AUG 2020 12:00

PC Close Date & Time

13 AUG 2020 11:59

US3412184

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 17:30:24

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

97.4 °F

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

Yes ☐

No ☒

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

PC Time Stamp

13 AUG 2020 12:40

PC Open Date & Time

13 AUG 2020 12:00

PC Close Date & Time

14 AUG 2020 11:59

US3412184

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 17:30:24

TIMEPOINT

DAY 5

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

98.0 °F

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

Yes ☐

No ☒

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

PC Time Stamp

14 AUG 2020 20:49

PC Open Date & Time

14 AUG 2020 12:00

PC Close Date & Time

15 AUG 2020 11:59

US3412184

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 17:30:24

TIMEPOINT

DAY 6

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.6 °F

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

Yes ☐

No ☒

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

PC Time Stamp

15 AUG 2020 23:48

PC Open Date & Time

15 AUG 2020 12:00

PC Close Date & Time

16 AUG 2020 11:59

US3412184

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 17:30:24

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

95.6 °F

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

Yes ☐

No ☒

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

PC Time Stamp

16 AUG 2020 22:30

PC Open Date & Time

16 AUG 2020 12:00

PC Close Date & Time

17 AUG 2020 11:59

US3412184

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 17:30:24

TIMEPOINT

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

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

10 AUG 2020 11:12

PC Open Date & Time

10 AUG 2020 10:55

PC Close Date & Time

10 AUG 2020 13:25

US3412184

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 17:30:24

TIMEPOINT

DAY 1, AFTER VACCINATION
(AT HOME)

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

Please select one response below

None ☒

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

Please select one response below

None ☒

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

10 AUG 2020 21:16

PC Open Date & Time

10 AUG 2020 14:20

PC Close Date & Time

11 AUG 2020 11:59

US3412184

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 17:30:24

TIMEPOINT

DAY 2

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

12 AUG 2020 09:41

PC Open Date & Time

11 AUG 2020 12:00

PC Close Date & Time

12 AUG 2020 11:59

US3412184

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 17:30:24

TIMEPOINT

DAY 3

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

None ☐

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☐

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

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

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

Yes ☐

No ☐

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

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

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

None ☐

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

PC Open Date & Time

12 AUG 2020 12:00

PC Close Date & Time

13 AUG 2020 11:59

US3412184

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 17:30:24

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

13 AUG 2020 12:40

PC Open Date & Time

13 AUG 2020 12:00

PC Close Date & Time

14 AUG 2020 11:59

US3412184

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 17:30:24

TIMEPOINT

DAY 5

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

14 AUG 2020 20:50

PC Open Date & Time

14 AUG 2020 12:00

PC Close Date & Time

15 AUG 2020 11:59

US3412184

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 17:30:24

TIMEPOINT

DAY 6

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

15 AUG 2020 23:48

PC Open Date & Time

15 AUG 2020 12:00

PC Close Date & Time

16 AUG 2020 11:59

US3412184

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 17:30:24

TIMEPOINT

DAY 7

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

16 AUG 2020 22:31

PC Open Date & Time

16 AUG 2020 12:00

PC Close Date & Time

17 AUG 2020 11:59

US3412184

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:30:24

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 ☐

US3412184

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:30:24

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

No ☒

Yes ☐

PC Time stamp	10 AUG 2020 11:13
PC Open Date & Time	10 AUG 2020 10:55
PC Close Date & Time	10 AUG 2020 13:25

US3412184

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:30:24

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 ☐

US3412184

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:30:24

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

No ☒

Yes ☐

PC Time stamp	10 AUG 2020 21:17
PC Open Date & Time	10 AUG 2020 14:20
PC Close Date & Time	11 AUG 2020 11:59

US3412184

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:30:24

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 ☒

US3412184

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:30:24

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

US3412184

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:30:24

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 ☐

US3412184

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:30:24

Yes ☐

PC Time stamp

PC Open Date & Time

12 AUG 2020 12:00

PC Close Date & Time

13 AUG 2020 11:59

US3412184

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:30:24

TIMEPOINT

DAY 4

HEADACHE

None ☒

No interference with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

FATIGUE

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

NAUSEA/VOMITING

None ☒

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

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

Prevents daily activity, requires
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity
not requiring medical attention ☐

Prevents daily activity and
requires medical attention ☐

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

No ☒

PRODUCTION RELEASE (v12.003

48 of 2073

EAB) (1725)

US3412184

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:30:24

Yes <input type="checkbox"/>	
PC Time stamp	13 AUG 2020 12:41
PC Open Date & Time	13 AUG 2020 12:00
PC Close Date & Time	14 AUG 2020 11:59

US3412184

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:30:24

TIMEPOINT

DAY 5

HEADACHE

None ☒

No interference with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

FATIGUE

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

NAUSEA/VOMITING

None ☒

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

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

Prevents daily activity, requires
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity
not requiring medical attention ☐

Prevents daily activity and
requires medical attention ☐

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

No ☒

PRODUCTION RELEASE (v12.003

50 of 2073

EAB) (1725)

US3412184

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:30:24

Yes <input type="checkbox"/>	
PC Time stamp	14 AUG 2020 20:50
PC Open Date & Time	14 AUG 2020 12:00
PC Close Date & Time	15 AUG 2020 11:59

US3412184

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:30:24

TIMEPOINT

DAY 6

HEADACHE

None ☒

No interference with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

FATIGUE

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

NAUSEA/VOMITING

None ☒

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

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

Prevents daily activity, requires
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity
not requiring medical attention ☐

Prevents daily activity and
requires medical attention ☐

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

No ☒

PRODUCTION RELEASE (v12.003

52 of 2073

EAB) (1725)

US3412184

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:30:24

Yes <input type="checkbox"/>	
PC Time stamp	15 AUG 2020 23:49
PC Open Date & Time	15 AUG 2020 12:00
PC Close Date & Time	16 AUG 2020 11:59

US3412184

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:30:24

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 ☒

US3412184

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:30:24

Yes <input type="checkbox"/>	
PC Time stamp	16 AUG 2020 22:32
PC Open Date & Time	16 AUG 2020 12:00
PC Close Date & Time	17 AUG 2020 11:59

US3412184

Folder: Safety Call Day 8 (1)

Form: Safety Call

Data signed: (b) (4) 13 Feb 2021 04:54:06

Generated On: 09 Jun 2021 17:30:24

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

17 AUG 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3412184

Folder: Safety Call Day 8 (1)

Form: Continuing

Data signed: (b) (4) 13 Feb 2021 04:54:06

Generated On: 09 Jun 2021 17:30:24

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3412184

Folder: Safety Call Day 15 (1)

Form: Safety Call

Data signed: (b) (4) 13 Feb 2021 04:54:06

Generated On: 09 Jun 2021 17:30:24

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

US3412184

Folder: Safety Call Day 15 (1)

Form: Continuing

Data signed: (b) (4) 13 Feb 2021 04:54:06

Generated On: 09 Jun 2021 17:30:24

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3412184

Folder: Safety Call Day 22 (1)

Form: Safety Call

Data signed: (b) (4) 13 Feb 2021 04:54:06

Generated On: 09 Jun 2021 17:30:24

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

US3412184

Folder: Safety Call Day 22 (1)

Form: Continuing

Data signed: (b) (4) 13 Feb 2021 04:54:06

Generated On: 09 Jun 2021 17:30:24

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3412184

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Data signed: (b) (4) 13 Feb 2021 02:43:25

Generated On: 09 Jun 2021 17:30:24

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

US3412184

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Data signed: (b) (4) 13 Feb 2021 02:43:26

Generated On: 09 Jun 2021 17:30:24

Timepoint	Pre-Dose <input checked="" type="radio"/>
	Post-Dose <input type="radio"/>
Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (dd MMM yyyy)	08 SEP 2020
Time of assessment (00:00-23:59)	07:50 (24 HR)
Vital Signs Date and Time (derived)	08 SEP 2020 07:50
Temperature (xxx.x)	36.9 C
Route of measurement	Oral <input checked="" type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	78 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	140 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	78 mmHg
Diastolic Blood Pressure units	MMHG

US3412184

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Data signed: (b) (4) 13 Feb 2021 02:43:26

Generated On: 09 Jun 2021 17:30:24

Timepoint	Pre-Dose <input type="checkbox"/>
	Post-Dose <input checked="" type="checkbox"/>
Were vital signs assessed?	Yes <input checked="" type="checkbox"/>
	No <input type="checkbox"/>
Date of assessment (dd MMM yyyy)	08 SEP 2020
Time of assessment (00:00-23:59)	09:46 (24 HR)
Vital Signs Date and Time (derived)	08 SEP 2020 09:46
Temperature (xxx.x)	97.5 F
Route of measurement	Oral <input checked="" type="checkbox"/>
	Axillary <input type="checkbox"/>
	Other <input type="checkbox"/>
If Other, specify	
Pulse (xxx)	76 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	140 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	80 mmHg
Diastolic Blood Pressure units	MMHG

US3412184

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Data signed: (b) (4) 13 Feb 2021 02:43:25

Generated On: 09 Jun 2021 17:30:24

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

08 SEP 2020

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

US3412184

Folder: Visit 2 Day 29 (1)

Form: Exposure

Data signed: (b) (4) 13 Feb 2021 02:43:25

Generated On: 09 Jun 2021 17:30:24

Was study treatment given? Yes ☒ No ☐

If No, reason not given

Participant declined due to Adverse Event ☐

Physician withheld dose due to Adverse Event ☐

Death ☐

Lost To Follow-Up ☐

Physician Decision ☐

Pregnancy ☐

Protocol Deviation ☐

Study Terminated by Sponsor ☐

Withdrawal of Consent by Participant ☐

Confirmed COVID-19 ☐

Other ☐

If reason is Physician Decision, Withdrawal of Consent by Participant, Protocol Deviation, or Other, specify

What was the study treatment? MRNA-1273 OR PLACEBO

What was the treatment date? (dd MMM yyyy) 08 SEP 2020

What was the treatment time? (00:00-23:59) 09:15 (24 HR)

Treatment Date and Time (derived) 08 SEP 2020 09:15

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

What was the frequency of the study treatment dosing? ONCE

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

US3412184

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 13 Feb 2021 02:43:25

Generated On: 09 Jun 2021 17:30:24

Was the sample collected?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Collection date (dd MMM yyyy)	08 SEP 2020
Collection time (00:00-23:59)	08:31 (24 HR)
Collection date and time (derived)	08 SEP 2020 08:31

US3412184

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab

Data signed: (b) (4) 13 Feb 2021 02:43:24

Generated On: 09 Jun 2021 17:30:24

Collection date (dd MMM yyyy)			08 SEP 2020
Lab Test	Was the sample collected?	Collection time (00:00 - 23:59)	Collection date and time (derived)
Nasopharyngeal Swab 1	Yes	08:35	08 SEP 2020 08:35
Nasopharyngeal Swab 2	No		

US3412184

Folder: Visit 2 Day 29 (1)

Form: Continuing

Data signed: (b) (4) 13 Feb 2021 02:43:25

Generated On: 09 Jun 2021 17:30:24

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3412184

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 17:30:24

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

08 SEP 2020 09:57

PC Open Date & Time

08 SEP 2020 09:35

PC Close Date & Time

08 SEP 2020 12:05

US3412184

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 17:30:24

TIMEPOINT

DAY 1, AFTER VACCINATION
(AT HOME)

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

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

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

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

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

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

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

Was **TEMPERATURE** taken? Yes ☒ No ☐

Please record your **TEMPERATURE** in °F 97.3 °F

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

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

PC Time Stamp	08 SEP 2020 20:36
PC Open Date & Time	08 SEP 2020 13:00
PC Close Date & Time	09 SEP 2020 11:59

US3412184

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 17:30:24

TIMEPOINT

DAY 2

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

98.0 °F

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

Yes ☐

No ☒

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

PC Time Stamp

09 SEP 2020 16:11

PC Open Date & Time

09 SEP 2020 12:00

PC Close Date & Time

10 SEP 2020 11:59

US3412184

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 17:30:24

TIMEPOINT

DAY 3

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☐

No ☐

Please record your **TEMPERATURE** in °F

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

Yes ☐

No ☐

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

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

To **PREVENT** pain or fever from occurring

PC Time Stamp

PC Open Date & Time

10 SEP 2020 12:00

PC Close Date & Time

11 SEP 2020 11:59

US3412184

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 17:30:24

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

97.3 °F

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

Yes ☐

No ☒

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

PC Time Stamp

11 SEP 2020 23:59

PC Open Date & Time

11 SEP 2020 12:00

PC Close Date & Time

12 SEP 2020 11:59

US3412184

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 17:30:24

TIMEPOINT

DAY 5

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.4 °F

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

Yes ☐

No ☒

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

PC Time Stamp

12 SEP 2020 12:00

PC Open Date & Time

12 SEP 2020 12:00

PC Close Date & Time

13 SEP 2020 11:59

US3412184

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 17:30:24

TIMEPOINT

DAY 6

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.3 °F

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

Yes ☐

No ☒

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

PC Time Stamp

13 SEP 2020 19:33

PC Open Date & Time

13 SEP 2020 12:00

PC Close Date & Time

14 SEP 2020 11:59

US3412184

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 17:30:24

TIMEPOINT

DAY 7

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.6 °F

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

Yes ☐

No ☒

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

PC Time Stamp

15 SEP 2020 06:33

PC Open Date & Time

14 SEP 2020 12:00

PC Close Date & Time

15 SEP 2020 11:59

US3412184

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 17:30:24

TIMEPOINT

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

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

08 SEP 2020 09:57

PC Open Date & Time

08 SEP 2020 09:35

PC Close Date & Time

08 SEP 2020 12:05

US3412184

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 17:30:24

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

08 SEP 2020 20:37

PC Open Date & Time

08 SEP 2020 13:00

PC Close Date & Time

09 SEP 2020 11:59

US3412184

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 17:30:24

TIMEPOINT

DAY 2

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

09 SEP 2020 16:12

PC Open Date & Time

09 SEP 2020 12:00

PC Close Date & Time

10 SEP 2020 11:59

US3412184

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 17:30:24

TIMEPOINT

DAY 3

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

None ☐

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☐

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

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

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

Yes ☐

No ☐

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

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

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

None ☐

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

PC Open Date & Time

10 SEP 2020 12:00

PC Close Date & Time

11 SEP 2020 11:59

US3412184

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 17:30:24

TIMEPOINT

DAY 4

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

12 SEP 2020 00:00

PC Open Date & Time

11 SEP 2020 12:00

PC Close Date & Time

12 SEP 2020 11:59

US3412184

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 17:30:24

TIMEPOINT

DAY 5

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

12 SEP 2020 12:01

PC Open Date & Time

12 SEP 2020 12:00

PC Close Date & Time

13 SEP 2020 11:59

US3412184

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 17:30:24

TIMEPOINT

DAY 6

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

13 SEP 2020 19:33

PC Open Date & Time

13 SEP 2020 12:00

PC Close Date & Time

14 SEP 2020 11:59

US3412184

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 17:30:24

TIMEPOINT

DAY 7

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

15 SEP 2020 06:33

PC Open Date & Time

14 SEP 2020 12:00

PC Close Date & Time

15 SEP 2020 11:59

US3412184

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:30:24

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 ☐

US3412184

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:30:24

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

No ☒

Yes ☐

PC Time stamp	08 SEP 2020 09:58
PC Open Date & Time	08 SEP 2020 09:35
PC Close Date & Time	08 SEP 2020 12:05

US3412184

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:30:24

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 ☐

US3412184

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:30:24

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

No ☒

Yes ☐

PC Time stamp	08 SEP 2020 20:38
PC Open Date & Time	08 SEP 2020 13:00
PC Close Date & Time	09 SEP 2020 11:59

US3412184

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:30:24

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 ☒

US3412184

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:30:24

Yes <input type="checkbox"/>	
PC Time stamp	09 SEP 2020 16:12
PC Open Date & Time	09 SEP 2020 12:00
PC Close Date & Time	10 SEP 2020 11:59

US3412184

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:30:24

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 ☐

US3412184

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:30:24

Yes ☐

PC Time stamp

PC Open Date & Time

10 SEP 2020 12:00

PC Close Date & Time

11 SEP 2020 11:59

US3412184

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:30:24

TIMEPOINT

DAY 4

HEADACHE

None ☒

No interference with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

FATIGUE

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

NAUSEA/VOMITING

None ☒

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

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

Prevents daily activity, requires
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity
not requiring medical attention ☐

Prevents daily activity and
requires medical attention ☐

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

No ☒

PRODUCTION RELEASE (v12.003

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EAB) (1725)

US3412184

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:30:24

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

US3412184

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:30:24

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 ☒

US3412184

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:30:24

Yes <input type="checkbox"/>	
PC Time stamp	12 SEP 2020 12:02
PC Open Date & Time	12 SEP 2020 12:00
PC Close Date & Time	13 SEP 2020 11:59

US3412184

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:30:24

TIMEPOINT

DAY 6

HEADACHE

None ☒

No interference with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

FATIGUE

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

NAUSEA/VOMITING

None ☒

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

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

Prevents daily activity, requires
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity
not requiring medical attention ☐

Prevents daily activity and
requires medical attention ☐

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

No ☒

PRODUCTION RELEASE (v12.003

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EAB) (1725)

US3412184

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:30:24

Yes <input type="checkbox"/>	
PC Time stamp	13 SEP 2020 19:34
PC Open Date & Time	13 SEP 2020 12:00
PC Close Date & Time	14 SEP 2020 11:59

US3412184

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:30:24

TIMEPOINT

DAY 7

HEADACHE

None ☒

No interference with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

FATIGUE

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

NAUSEA/VOMITING

None ☒

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

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

Prevents daily activity, requires
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity
not requiring medical attention ☐

Prevents daily activity and
requires medical attention ☐

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

No ☒

PRODUCTION RELEASE (v12.003

100 of 2073

EAB) (1725)

US3412184

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:30:24

Yes <input type="checkbox"/>	
PC Time stamp	15 SEP 2020 06:35
PC Open Date & Time	14 SEP 2020 12:00
PC Close Date & Time	15 SEP 2020 11:59

US3412184

Folder: Safety Call Day 36 (1)

Form: Safety Call

Data signed: (b) (4) 13 Feb 2021 04:54:06

Generated On: 09 Jun 2021 17:30:24

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

15 SEP 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3412184

Folder: Safety Call Day 36 (1)

Form: Continuing

Data signed: (b) (4) 13 Feb 2021 04:54:06

Generated On: 09 Jun 2021 17:30:24

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3412184

Folder: Safety Call Day 43 (1)

Form: Safety Call

Data signed: (b) (4) 13 Feb 2021 02:43:22

Generated On: 09 Jun 2021 17:30:24

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

22 SEP 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3412184

Folder: Safety Call Day 43 (1)

Form: Continuing

Data signed: (b) (4) 13 Feb 2021 02:43:22

Generated On: 09 Jun 2021 17:30:24

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3412184

Folder: Safety Call Day 50 (1)

Form: Safety Call

Data signed: (b) (4) 13 Feb 2021 02:43:22

Generated On: 09 Jun 2021 17:30:24

Was Contact Attempted? Yes ☒
No ☐

Date of Contact or Contact Attempt (dd MMM yyyy) 29 SEP 2020

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

Comments

If Contact Not Made, please provide Comments

US3412184

Folder: Safety Call Day 50 (1)

Form: Continuing

Data signed: (b) (4) 13 Feb 2021 02:43:22

Generated On: 09 Jun 2021 17:30:24

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3412184

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Data signed: (b) (4) 13 Feb 2021 02:43:28

Generated On: 09 Jun 2021 17:30:24

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	06 OCT 2020
Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>
Folder OID	VISIT3

US3412184

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Data signed: (b) (4) 13 Feb 2021 02:43:28

Generated On: 09 Jun 2021 17:30:24

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) _____

US3412184

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Data signed: (b) (4) 13 Feb 2021 02:43:28

Generated On: 09 Jun 2021 17:30:24

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.

US3412184

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 13 Feb 2021 02:43:27

Generated On: 09 Jun 2021 17:30:24

Was the sample collected?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Collection date (dd MMM yyyy)	06 OCT 2020
Collection time (00:00-23:59)	10:43 (24 HR)
Collection date and time (derived)	06 OCT 2020 10:43

US3412184

Folder: Visit 3 Day 57 (1)

Form: Continuing

Data signed: (b) (4) 13 Feb 2021 02:43:27

Generated On: 09 Jun 2021 17:30:24

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3412184

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:30:24

TIMEPOINT	DAY 64
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input 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 type="radio"/> Yes <input checked="" type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	True
Chills	True
Cough	False
Shortness of breath	False
Difficulty breathing	False
Fatigue	True
Muscle aches	False
Body aches	True
Headache	True
New loss of taste	False
New loss of smell	False
Sore throat	False
Congestion	False
Runny nose	False
Nausea	False
Vomiting	False
Diarrhea	False
Please contact your study clinic immediately. Click below to confirm that you have read this message 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"/>
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	10 OCT 2020 06:38:00
Patient Cloud Open Date & Time	10 OCT 2020 00:01
PRODUCTION RELEASE (v12.003 EAB) (1725)	
113 of 2073	

US3412184

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:30:24

[Patient Cloud Close Date & Time](#)

14 OCT 2020 23:59

US3412184

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:30:24

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

21 OCT 2020 22:36:35

Patient Cloud Open Date & Time

17 OCT 2020 00:01

Patient Cloud Close Date & Time

21 OCT 2020 23:59

US3412184

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:30:24

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

26 OCT 2020 12:14:21

Patient Cloud Open Date & Time

24 OCT 2020 00:01

Patient Cloud Close Date & Time

28 OCT 2020 23:59

US3412184

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:30:24

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 <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 NOV 2020 07:58:43
Patient Cloud Open Date & Time	07 NOV 2020 00:01
Patient Cloud Close Date & Time	11 NOV 2020 23:59

US3412184

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:30:24

TIMEPOINT	DAY 99
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input 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 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"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	14 NOV 2020 08:16:55
Patient Cloud Open Date & Time	14 NOV 2020 00:01
Patient Cloud Close Date & Time	18 NOV 2020 23:59

US3412184

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:30:24

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

US3412184

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:30:24

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

US3412184

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:30:24

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 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"/>

US3412184

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:30:24

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
Patient Cloud Open Date & Time	25 NOV 2020 00:01
Patient Cloud Close Date & Time	29 NOV 2020 23:59

US3412184

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:30:24

TIMEPOINT	DAY 117
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

US3412184

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:30:24

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

[Patient Cloud Open Date & Time](#)

02 DEC 2020 00:01

[Patient Cloud Close Date & Time](#)

06 DEC 2020 23:59

US3412184

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:30:24

TIMEPOINT

DAY 124

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

10 DEC 2020 13:07:38

Patient Cloud Open Date & Time

09 DEC 2020 00:01

Patient Cloud Close Date & Time

13 DEC 2020 23:59

US3412184

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:30:24

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

16 DEC 2020 00:02:13

Patient Cloud Open Date & Time

16 DEC 2020 00:01

Patient Cloud Close Date & Time

20 DEC 2020 23:59

US3412184

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:30:24

TIMEPOINT

DAY 138

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

23 DEC 2020 00:01:33

Patient Cloud Open Date & Time

23 DEC 2020 00:01

Patient Cloud Close Date & Time

27 DEC 2020 23:59

US3412184

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:30:24

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

30 DEC 2020 06:39:59

Patient Cloud Open Date & Time

30 DEC 2020 00:01

Patient Cloud Close Date & Time

03 JAN 2021 23:59

US3412184

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:30:24

TIMEPOINT

DAY 152

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

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

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

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

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

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

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

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

US3412184

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:30:24

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
Patient Cloud Open Date & Time	06 JAN 2021 00:01
Patient Cloud Close Date & Time	10 JAN 2021 23:59

US3412184

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:30:24

TIMEPOINT

DAY 159

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

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

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

US3412184

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:30:24

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

[Patient Cloud Open Date & Time](#)

13 JAN 2021 00:01

[Patient Cloud Close Date & Time](#)

17 JAN 2021 23:59

US3412184

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:30:24

TIMEPOINT	DAY 166
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

US3412184

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:30:24

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

[Patient Cloud Close Date & Time](#)

24 JAN 2021 23:59

US3412184

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:30:24

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

US3412184

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:30:24

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

[Patient Cloud Close Date & Time](#)

31 JAN 2021 23:59

US3412184

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:30:24

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 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	05 FEB 2021 12:04:17
Patient Cloud Open Date & Time	03 FEB 2021 00:01
Patient Cloud Close Date & Time	07 FEB 2021 23:59

US3412184

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:30:24

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	10 FEB 2021 00:01:31
Patient Cloud Open Date & Time	10 FEB 2021 00:01
Patient Cloud Close Date & Time	14 FEB 2021 23:59

US3412184

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:30:24

TIMEPOINT

DAY 194

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

17 FEB 2021 00:01:33

Patient Cloud Open Date & Time

17 FEB 2021 00:01

Patient Cloud Close Date & Time

21 FEB 2021 23:59

US3412184

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:30:24

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

24 FEB 2021 17:10:25

Patient Cloud Open Date & Time

24 FEB 2021 00:01

Patient Cloud Close Date & Time

28 FEB 2021 23:59

US3412184

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:30:24

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

07 MAR 2021 12:10:44

Patient Cloud Open Date & Time

03 MAR 2021 00:01

Patient Cloud Close Date & Time

07 MAR 2021 23:59

US3412184

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:30:24

TIMEPOINT

DAY 215

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

10 MAR 2021 00:02:41

Patient Cloud Open Date & Time

10 MAR 2021 00:01

Patient Cloud Close Date & Time

14 MAR 2021 23:59

US3412184

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:30:24

TIMEPOINT

DAY 222

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

17 MAR 2021 00:04:24

Patient Cloud Open Date & Time

17 MAR 2021 00:01

Patient Cloud Close Date & Time

21 MAR 2021 23:59

US3412184

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:30:24

TIMEPOINT

DAY 229

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

24 MAR 2021 23:34:20

Patient Cloud Open Date & Time

24 MAR 2021 00:01

Patient Cloud Close Date & Time

28 MAR 2021 23:59

US3412184

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:30:24

TIMEPOINT

DAY 236

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

02 APR 2021 10:22:46

Patient Cloud Open Date & Time

31 MAR 2021 00:01

Patient Cloud Close Date & Time

04 APR 2021 23:59

US3412184

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:30:24

TIMEPOINT

DAY 243

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

08 APR 2021 20:50:38

Patient Cloud Open Date & Time

07 APR 2021 00:01

Patient Cloud Close Date & Time

11 APR 2021 23:59

US3412184

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:30:24

TIMEPOINT

DAY 250

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

15 APR 2021 07:45:48

Patient Cloud Open Date & Time

14 APR 2021 00:01

Patient Cloud Close Date & Time

18 APR 2021 23:59

US3412184

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:30:24

TIMEPOINT

DAY 257

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

21 APR 2021 06:47:14

Patient Cloud Open Date & Time

21 APR 2021 00:01

Patient Cloud Close Date & Time

25 APR 2021 23:59

US3412184

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:30:24

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

US3412184

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:30:24

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

[Patient Cloud Close Date & Time](#)

02 MAY 2021 23:59

US3412184

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:30:24

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 ☐

US3412184

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:30:24

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

[Patient Cloud Open Date & Time](#)

05 MAY 2021 00:01

[Patient Cloud Close Date & Time](#)

09 MAY 2021 23:59

US3412184

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:30:24

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 ☐

US3412184

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:30:24

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

[Patient Cloud Open Date & Time](#)

12 MAY 2021 00:01

[Patient Cloud Close Date & Time](#)

16 MAY 2021 23:59

US3412184

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:30:24

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 ☐

US3412184

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:30:24

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

[Patient Cloud Open Date & Time](#)

19 MAY 2021 00:01

[Patient Cloud Close Date & Time](#)

23 MAY 2021 23:59

US3412184

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:30:24

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

US3412184

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:30:24

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

[Patient Cloud Open Date & Time](#)

26 MAY 2021 00:01

[Patient Cloud Close Date & Time](#)

30 MAY 2021 23:59

US3412184

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:30:24

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 ☐

US3412184

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:30:24

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

US3412184

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:30:24

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

US3412184

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:30:24

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

US3412184

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:30:24

TIMEPOINT	DAY 313
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

US3412184

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:30:24

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

US3412184

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:30:24

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

US3412184

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:30:24

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

US3412184

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:30:24

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

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 ☐

US3412184

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:30:24

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

US3412184

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:30:24

TIMEPOINT	DAY 334
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>

US3412184

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:30:24

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

US3412184

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:30:24

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

US3412184

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:30:24

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

US3412184

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:30:24

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

US3412184

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:30:24

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

US3412184

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:30:24

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 ☐

US3412184

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:30:24

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

US3412184

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:30:24

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 ☐

US3412184

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:30:24

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

US3412184

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:30:24

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 ☐

US3412184

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:30:24

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
Patient Cloud Open Date & Time	11 AUG 2021 00:01
Patient Cloud Close Date & Time	15 AUG 2021 23:59

US3412184

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:30:24

TIMEPOINT

DAY 376

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3412184

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:30:24

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

US3412184

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:30:24

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 ☐

US3412184

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:30:24

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

US3412184

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:30:24

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

US3412184

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:30:24

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

US3412184

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:30:24

TIMEPOINT

DAY 397

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3412184

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:30:24

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

US3412184

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:30:24

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 ☐

US3412184

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:30:24

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

US3412184

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:30:24

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

US3412184

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:30:24

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

[Patient Cloud Open Date & Time](#)

22 SEP 2021 00:01

[Patient Cloud Close Date & Time](#)

26 SEP 2021 23:59

US3412184

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:30:24

TIMEPOINT	DAY 418
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>

US3412184

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:30:24

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

US3412184

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:30:24

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

US3412184

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:30:24

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

US3412184

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:30:24

TIMEPOINT

DAY 432

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3412184

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:30:24

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
Patient Cloud Open Date & Time	13 OCT 2021 00:01
Patient Cloud Close Date & Time	17 OCT 2021 23:59

US3412184

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:30:24

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 ☐

US3412184

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:30:24

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

US3412184

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:30:24

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

US3412184

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:30:24

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

US3412184

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:30:24

TIMEPOINT

DAY 453

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3412184

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:30:24

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

[Patient Cloud Open Date & Time](#)

03 NOV 2021 00:01

[Patient Cloud Close Date & Time](#)

07 NOV 2021 23:59

US3412184

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:30:24

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

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 ☐

US3412184

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:30:24

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

US3412184

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:30:24

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

US3412184

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:30:24

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
Patient Cloud Open Date & Time	17 NOV 2021 00:01
Patient Cloud Close Date & Time	21 NOV 2021 23:59

US3412184

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:30:24

TIMEPOINT

DAY 474

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

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

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

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

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

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

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

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

US3412184

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:30:24

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

US3412184

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:30:24

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

US3412184

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:30:24

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

US3412184

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:30:24

TIMEPOINT	DAY 488
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

US3412184

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:30:24

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

US3412184

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:30:24

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 ☐

US3412184

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:30:24

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
Patient Cloud Open Date & Time	15 DEC 2021 00:01
Patient Cloud Close Date & Time	19 DEC 2021 23:59

US3412184

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:30:24

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 ☐

US3412184

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:30:24

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
Patient Cloud Open Date & Time	22 DEC 2021 00:01
Patient Cloud Close Date & Time	26 DEC 2021 23:59

US3412184

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:30:24

TIMEPOINT

DAY 509

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3412184

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:30:24

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

[Patient Cloud Open Date & Time](#)

29 DEC 2021 00:01

[Patient Cloud Close Date & Time](#)

02 JAN 2022 23:59

US3412184

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:30:24

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

US3412184

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:30:24

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

US3412184

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:30:24

TIMEPOINT

DAY 523

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3412184

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:30:24

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

US3412184

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:30:24

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 ☐

US3412184

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:30:24

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

US3412184

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:30:24

TIMEPOINT

DAY 537

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3412184

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:30:24

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

[Patient Cloud Open Date & Time](#)

26 JAN 2022 00:01

[Patient Cloud Close Date & Time](#)

30 JAN 2022 23:59

US3412184

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:30:24

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

US3412184

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:30:24

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

[Patient Cloud Open Date & Time](#)

02 FEB 2022 00:01

[Patient Cloud Close Date & Time](#)

06 FEB 2022 23:59

US3412184

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:30:24

TIMEPOINT

DAY 551

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3412184

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:30:24

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

[Patient Cloud Open Date & Time](#)

09 FEB 2022 00:01

[Patient Cloud Close Date & Time](#)

13 FEB 2022 23:59

US3412184

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:30:24

TIMEPOINT

DAY 558

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

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

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

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

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

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

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

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

US3412184

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:30:24

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

[Patient Cloud Open Date & Time](#)

16 FEB 2022 00:01

[Patient Cloud Close Date & Time](#)

20 FEB 2022 23:59

US3412184

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:30:24

TIMEPOINT

DAY 565

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

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

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

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

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

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

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

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

US3412184

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:30:24

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

US3412184

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:30:24

TIMEPOINT

DAY 572

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

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

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

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

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

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

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

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

US3412184

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:30:24

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

US3412184

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:30:24

TIMEPOINT

DAY 579

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3412184

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:30:24

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

[Patient Cloud Open Date & Time](#)

09 MAR 2022 00:01

[Patient Cloud Close Date & Time](#)

13 MAR 2022 23:59

US3412184

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:30:24

TIMEPOINT

DAY 586

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3412184

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:30:24

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

[Patient Cloud Open Date & Time](#)

16 MAR 2022 00:01

[Patient Cloud Close Date & Time](#)

20 MAR 2022 23:59

US3412184

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:30:24

TIMEPOINT

DAY 593

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3412184

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:30:24

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

[Patient Cloud Open Date & Time](#)

23 MAR 2022 00:01

[Patient Cloud Close Date & Time](#)

27 MAR 2022 23:59

US3412184

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:30:24

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

US3412184

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:30:24

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

[Patient Cloud Open Date & Time](#)

30 MAR 2022 00:01

[Patient Cloud Close Date & Time](#)

03 APR 2022 23:59

US3412184

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:30:24

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

US3412184

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:30:24

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

US3412184

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:30:24

TIMEPOINT	DAY 614
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

US3412184

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:30:24

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
Patient Cloud Open Date & Time	13 APR 2022 00:01
Patient Cloud Close Date & Time	17 APR 2022 23:59

US3412184

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:30:24

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

US3412184

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:30:24

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

[Patient Cloud Open Date & Time](#)

20 APR 2022 00:01

[Patient Cloud Close Date & Time](#)

24 APR 2022 23:59

US3412184

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:30:24

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 ☐

US3412184

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:30:24

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

[Patient Cloud Open Date & Time](#)

27 APR 2022 00:01

[Patient Cloud Close Date & Time](#)

01 MAY 2022 23:59

US3412184

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:30:24

TIMEPOINT	DAY 635
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

US3412184

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:30:24

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

[Patient Cloud Open Date & Time](#)

04 MAY 2022 00:01

[Patient Cloud Close Date & Time](#)

08 MAY 2022 23:59

US3412184

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:30:24

TIMEPOINT

DAY 642

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3412184

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:30:24

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

[Patient Cloud Open Date & Time](#)

11 MAY 2022 00:01

[Patient Cloud Close Date & Time](#)

15 MAY 2022 23:59

US3412184

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:30:24

TIMEPOINT

DAY 649

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3412184

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:30:24

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

US3412184

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:30:24

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

US3412184

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:30:24

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

[Patient Cloud Open Date & Time](#)

25 MAY 2022 00:01

[Patient Cloud Close Date & Time](#)

29 MAY 2022 23:59

US3412184

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:30:24

TIMEPOINT

DAY 663

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3412184

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:30:24

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

US3412184

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:30:24

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

US3412184

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:30:24

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

US3412184

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:30:24

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°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 ☐

US3412184

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:30:24

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

US3412184

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:30:24

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

US3412184

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:30:24

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
Patient Cloud Open Date & Time	22 JUN 2022 00:01
Patient Cloud Close Date & Time	26 JUN 2022 23:59

US3412184

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:30:24

TIMEPOINT	DAY 691
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>

US3412184

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:30:24

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

US3412184

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:30:24

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 ☐

US3412184

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:30:24

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

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10 JUL 2022 23:59

US3412184

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:30:24

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 ☐

US3412184

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:30:24

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

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17 JUL 2022 23:59

US3412184

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:30:24

TIMEPOINT	DAY 712
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

US3412184

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:30:24

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

US3412184

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:30:24

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

US3412184

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:30:24

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
Patient Cloud Open Date & Time	27 JUL 2022 00:01
Patient Cloud Close Date & Time	31 JUL 2022 23:59

US3412184

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:30:24

TIMEPOINT	DAY 726
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

US3412184

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:30:24

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

[Patient Cloud Open Date & Time](#)

03 AUG 2022 00:01

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07 AUG 2022 23:59

US3412184

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:30:24

TIMEPOINT	DAY 733
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>

US3412184

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:30:24

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

US3412184

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:30:24

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

US3412184

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:30:24

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

US3412184

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:30:24

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

US3412184

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:30:24

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

US3412184

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:30:24

TIMEPOINT

DAY 754

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

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

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

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

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

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

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

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

US3412184

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:30:24

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

US3412184

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:30:24

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 ☐

US3412184

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:30:24

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

[Patient Cloud Open Date & Time](#)

07 SEP 2022 00:01

[Patient Cloud Close Date & Time](#)

11 SEP 2022 23:59

US3412184

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:30:24

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

US3412184

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:30:24

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

[Patient Cloud Open Date & Time](#)

14 SEP 2022 00:01

[Patient Cloud Close Date & Time](#)

18 SEP 2022 23:59

US3412184

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:30:24

TIMEPOINT

DAY 775

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3412184

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:30:24

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

[Patient Cloud Open Date & Time](#)

21 SEP 2022 00:01

[Patient Cloud Close Date & Time](#)

25 SEP 2022 23:59

US3412184

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:30:24

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 ☐

US3412184

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:30:24

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

US3412184

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:30:24

TIMEPOINT

DAY 789

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3412184

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:30:24

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

[Patient Cloud Open Date & Time](#)

05 OCT 2022 00:01

[Patient Cloud Close Date & Time](#)

09 OCT 2022 23:59

US3412184

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:30:24

TIMEPOINT	DAY 796
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

US3412184

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:30:24

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

[Patient Cloud Open Date & Time](#)

12 OCT 2022 00:01

[Patient Cloud Close Date & Time](#)

16 OCT 2022 23:59

US3412184

Folder: Cosmetic Injections and Dermal Fillers

Form: Cosmetic Injection_ Dermal Filler eDiary

Generated On: 09 Jun 2021 17:30:24

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		07 MAR 2021 12:11:02

US3412184

Folder: Safety Call Day 85 (1)

Form: Safety Call

Data signed: (b) (4) 10 Mar 2021 19:34:57

Generated On: 09 Jun 2021 17:30:24

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

3 NOV 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3412184

Folder: Safety Call Day 85 (1)

Form: Continuing

Data signed: (b) (4) 10 Mar 2021 19:34:57

Generated On: 09 Jun 2021 17:30:24

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3412184

Folder: Safety Call Day 119 (1)

Form: Safety Call

Data signed: (b) (4) 16 Apr 2021 14:34:07

Generated On: 09 Jun 2021 17:30:24

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

7 DEC 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3412184

Folder: Safety Call Day 119 (1)

Form: Continuing

Data signed: (b) (4) 16 Apr 2021 14:34:07

Generated On: 09 Jun 2021 17:30:24

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3412184

Folder: Safety Call Day 149 (1)

Form: Safety Call

Data signed: (b) (4) 16 Apr 2021 14:34:07

Generated On: 09 Jun 2021 17:30:24

Was Contact Attempted? Yes ☒
No ☐

Date of Contact or Contact Attempt (dd MMM yyyy) 6 JAN 2021

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

Comments

If Contact Not Made, please provide Comments

US3412184

Folder: Safety Call Day 149 (1)

Form: Continuing

Data signed: (b) (4) 16 Apr 2021 14:34:07

Generated On: 09 Jun 2021 17:30:24

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3412184

Folder: Safety Call Day 179 (1)

Form: Safety Call

Data signed: (b) (4) 16 Apr 2021 14:34:07

Generated On: 09 Jun 2021 17:30:24

Was Contact Attempted? Yes ☒
No ☐

Date of Contact or Contact Attempt (dd MMM yyyy) 5 FEB 2021

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

Comments

If Contact Not Made, please provide Comments

US3412184

Folder: Safety Call Day 179 (1)

Form: Continuing

Data signed: (b) (4) 16 Apr 2021 14:34:07

Generated On: 09 Jun 2021 17:30:24

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3412184

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Data signed: (b) (4) 16 Apr 2021 14:34:07

Generated On: 09 Jun 2021 17:30:24

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

Visit date (dd MMM yyyy)	02 MAR 2021
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Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>

Folder OID	VISIT4
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US3412184

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Data signed: (b) (4) 16 Apr 2021 14:34:07

Generated On: 09 Jun 2021 17:30:24

Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (dd MMM yyyy)	02 MAR 2021
Time of assessment (00:00-23:59)	11:24 (24 HR)
Vital Signs Date and Time (derived)	02 MAR 2021 11:24
Temperature (xxx.x)	36.8 C
Route of measurement	Oral <input checked="" type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	91 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
Height (derived)	
Weight (derived)	

US3412184

Folder: Visit 4 Day 209 (1)

Form: Physical Examination

Data signed: (b) (4) 16 Apr 2021 14:34:07

Generated On: 09 Jun 2021 17:30:24

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.

US3412184

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 16 Apr 2021 14:34:07

Generated On: 09 Jun 2021 17:30:24

Was the sample collected?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Collection date (dd MMM yyyy)	02 MAR 2021
Collection time (00:00-23:59)	11:34 (24 HR)
Collection date and time (derived)	02 MAR 2021 11:34

US3412184

Folder: Visit 4 Day 209 (1)

Form: Continuing

Data signed: (b) (4) 16 Apr 2021 14:34:07

Generated On: 09 Jun 2021 17:30:24

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3412184

Folder: Safety Call Day 239 (1)

Form: Safety Call

Data signed: (b) (4) 16 Apr 2021 14:34:07

Generated On: 09 Jun 2021 17:30:24

Was Contact Attempted? Yes ☒
No ☐

Date of Contact or Contact Attempt (dd MMM yyyy) 02 APR 2021

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

Comments

If Contact Not Made, please provide Comments

US3412184

Folder: Safety Call Day 239 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:30:24

Is the participant continuing to the next visit?

Yes ☐

No ☐

Continuing Flag

US3412184

Folder: Covid-19 Assessment (1)

Form: COVID-19 Contact

Generated On: 09 Jun 2021 17:30:24

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"/>

US3412184

Folder: Covid-19 Assessment (1)

Form: Generate Next COVID-19 Assessment

Generated On: 09 Jun 2021 17:30:24

Generate Next COVID-19 Assessment

Yes ☐

No ☐

US3412184

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

Form: Visit Date

Data signed: (b) (4) 16 Apr 2021 14:34:07

Generated On: 09 Jun 2021 17:30:24

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

Visit date (dd MMM yyyy)	5 JAN 2021
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Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>

Folder OID	UNBLND_DECIDE
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US3412184

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

Form: Unblinding

Data signed: (b) (4) 16 Apr 2021 14:34:07

Generated On: 09 Jun 2021 17:30:24

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

US3412184

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

Form: Vital Signs - Dosing

Data signed: (b) (4) 16 Apr 2021 14:34:07

Generated On: 09 Jun 2021 17:30:24

Height	166.5 cm
Weight	87 kg
BMI (xxx.x)	31.38273

US3412184

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

Form: Vital Signs - Dosing (1)

Data signed: (b) (4) 16 Apr 2021 14:34:07

Generated On: 09 Jun 2021 17:30:24

Height	166.5 cm
Weight	87 kg
BMI (xxx.x)	31.38273
Timepoint	Pre-Dose <input checked="" type="radio"/> Post-Dose <input type="radio"/>
Were vital signs assessed?	Yes <input checked="" type="radio"/> No <input type="radio"/>
Date of assessment (dd MMM yyyy)	05 JAN 2021
Time of assessment (00:00-23:59)	12:50 (24 HR)
Vital Signs Date and Time (derived)	05 JAN 2021 12:50
Temperature (xxx.x)	37 C
Route of measurement	Oral <input checked="" type="radio"/> Axillary <input type="radio"/> Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	87 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	14 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	122 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	84 mmHg
Diastolic Blood Pressure units	MMHG

US3412184

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

Form: Vital Signs - Dosing (2)

Data signed: (b) (4) 16 Apr 2021 14:34:07

Generated On: 09 Jun 2021 17:30:24

Height	166.5 cm
Weight	87 kg
BMI (xxx.x)	31.38273
Timepoint	Pre-Dose <input type="radio"/> Post-Dose <input checked="" type="radio"/>
Were vital signs assessed?	Yes <input checked="" type="radio"/> No <input type="radio"/>
Date of assessment (dd MMM yyyy)	05 JAN 2021
Time of assessment (00:00-23:59)	13:39 (24 HR)
Vital Signs Date and Time (derived)	05 JAN 2021 13:39
Temperature (xxx.x)	98.6 F
Route of measurement	Oral <input checked="" type="radio"/> Axillary <input type="radio"/> Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	74 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	130 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	72 mmHg
Diastolic Blood Pressure units	MMHG

US3412184

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

Form: Physical Examination

Data signed: (b) (4) 16 Apr 2021 14:34:07

Generated On: 09 Jun 2021 17:30:24

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

05 JAN 2021

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

US3412184

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

Form: Exposure

Data signed: (b) (4) 16 Apr 2021 14:34:07

Generated On: 09 Jun 2021 17:30:24

Was study treatment given? Yes ☒ No ☐

If No, reason not given

Participant declined due to Adverse Event ☐

Physician withheld dose due to Adverse Event ☐

Death ☐

Lost To Follow-Up ☐

Physician Decision ☐

Pregnancy ☐

Protocol Deviation ☐

Study Terminated by Sponsor ☐

Withdrawal of Consent by Participant ☐

Confirmed COVID-19 ☐

Other ☐

If reason is Physician Decision, Withdrawal of Consent by Participant, Protocol Deviation, or Other, specify

What was the study treatment? (Unblinded) MRNA-1273

What was the treatment date? (dd MMM yyyy) 05 JAN 2021

What was the treatment time? (00:00-23:59) 13:05 (24 HR)

Treatment Date and Time (derived) 05 JAN 2021 13:05

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

US3412184

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

Form: Immunogenicity Assessment

Data signed: (b) (4) 16 Apr 2021 14:34:07

Generated On: 09 Jun 2021 17:30:24

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

Collection date (dd MMM yyyy)	05 JAN 2021
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Collection time (00:00-23:59)	12:21 (24 HR)
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Collection date and time (derived)	05 JAN 2021 12:21
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US3412184

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

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Data signed: (b) (4) 16 Apr 2021 14:34:07

Generated On: 09 Jun 2021 17:30:24

Was the sample collected?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Collection date (dd MMM yyyy)	05 JAN 2021
Collection time (00:00 - 23:59)	12:59
Collection Date and Time (derived)	05 JAN 2021 12:59

US3412184

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

Form: Continuing

Data signed: (b) (4) 16 Apr 2021 14:34:07

Generated On: 09 Jun 2021 17:30:24

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3412184

Folder: Safety Call OL-D8 (1)

Form: Safety Call

Data signed: (b) (4) 10 Mar 2021 19:34:57

Generated On: 09 Jun 2021 17:30:24

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

13 JAN 2021

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3412184

Folder: Safety Call OL-D8 (1)

Form: Continuing

Data signed: (b) (4) 10 Mar 2021 19:34:57

Generated On: 09 Jun 2021 17:30:24

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

US3412184

Folder: OL-D29 (1)

Form: Visit Date

Data signed: (b) (4) 16 Apr 2021 14:34:06

Generated On: 09 Jun 2021 17:30:24

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	2 FEB 2021
Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>
Folder OID	OLD29

US3412184

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Data signed: (b) (4) 16 Apr 2021 14:34:06

Generated On: 09 Jun 2021 17:30:24

Timepoint	Pre-Dose <input checked="" type="radio"/>
	Post-Dose <input type="radio"/>
Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (dd MMM yyyy)	2 FEB 2021
Time of assessment (00:00-23:59)	11:34 (24 HR)
Vital Signs Date and Time (derived)	2 FEB 2021 11:34
Temperature (xxx.x)	36.8 C
Route of measurement	Oral <input checked="" type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	87 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	12 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	118 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	74 mmHg
Diastolic Blood Pressure units	MMHG

US3412184

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Data signed: (b) (4) 16 Apr 2021 14:34:06

Generated On: 09 Jun 2021 17:30:24

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)	2 FEB 2021
Time of assessment (00:00-23:59)	13:03 (24 HR)
Vital Signs Date and Time (derived)	2 FEB 2021 13:03
Temperature (xxx.x)	98.8 F
Route of measurement	Oral <input checked="" type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	82 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	18 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	132 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	90 mmHg
Diastolic Blood Pressure units	MMHG

US3412184

Folder: OL-D29 (1)

Form: Physical Examination

Data signed: (b) (4) 16 Apr 2021 14:34:06

Generated On: 09 Jun 2021 17:30:24

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

2 FEB 2021

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

US3412184

Folder: OL-D29 (1)

Form: Exposure

Data signed: (b) (4) 16 Apr 2021 14:34:06

Generated On: 09 Jun 2021 17:30:24

Was study treatment given? Yes ☒ No ☐

If No, reason not given

Participant declined due to Adverse Event ☐

Physician withheld dose due to Adverse Event ☐

Death ☐

Lost To Follow-Up ☐

Physician Decision ☐

Pregnancy ☐

Protocol Deviation ☐

Study Terminated by Sponsor ☐

Withdrawal of Consent by Participant ☐

Confirmed COVID-19 ☐

Other ☐

If reason is Physician Decision, Withdrawal of Consent by Participant, Protocol Deviation, or Other, specify

What was the study treatment? (Unblinded) MRNA-1273

What was the treatment date? (dd MMM yyyy) 2 FEB 2021

What was the treatment time? (00:00-23:59) 12:28 (24 HR)

Treatment Date and Time (derived) 2 FEB 2021 12:28

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

US3412184

Folder: OL-D29 (1)

Form: Continuing

Data signed: (b) (4) 16 Apr 2021 14:34:06

Generated On: 09 Jun 2021 17:30:24

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3412184

Folder: Safety Call OL-D36 (1)

Form: Safety Call

Data signed: (b) (4) 10 Mar 2021 19:34:57

Generated On: 09 Jun 2021 17:30:24

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

9 FEB 2021

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3412184

Folder: Safety Call OL-D36 (1)

Form: Continuing

Data signed: (b) (4) 10 Mar 2021 19:34:57

Generated On: 09 Jun 2021 17:30:24

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3412184

Folder: OL-D57 (1)

Form: Visit Date

Data signed: (b) (4) 16 Apr 2021 14:34:06

Generated On: 09 Jun 2021 17:30:24

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	02 MAR 2021
Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>
Folder OID	OLD57

US3412184

Folder: OL-D57 (1)

Form: Vital Signs

Data signed: (b) (4) 16 Apr 2021 14:34:07

Generated On: 09 Jun 2021 17:30:24

Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (<i>dd MMM yyyy</i>)	02 MAR 2021
Time of assessment (<i>00:00-23:59</i>)	11:24 (24 HR)
Vital Signs Date and Time (derived)	02 MAR 2021 11:24
Temperature (<i>xxx.x</i>)	36.8 C
Route of measurement	Oral <input checked="" type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	
Pulse (<i>xxx</i>)	91 beats/min
Pulse units	BPM
Respiratory Rate (<i>xxx</i>)	16 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>)	80 mmHg
Diastolic Blood Pressure units	MMHG
Height (derived)	
Weight (derived)	

US3412184

Folder: OL-D57 (1)

Form: Physical Examination

Data signed: (b) (4) 16 Apr 2021 14:34:06

Generated On: 09 Jun 2021 17:30:24

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: OL-D57 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 16 Apr 2021 14:34:06

Generated On: 09 Jun 2021 17:30:24

Was the sample collected?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Collection date (dd MMM yyyy)	02 MAR 2021
Collection time (00:00-23:59)	11:34 (24 HR)
Collection date and time (derived)	02 MAR 2021 11:34

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Folder: Adverse Events

Form: Adverse Events Summary

Data signed: (b) (4) 15 Mar 2021 15:34:10

Generated On: 09 Jun 2021 17:30:24

Did the participant experience any adverse events?

Yes ☒

No ☐

If Yes, enter details on the Adverse Events form.

US3412184

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:30:24

AEID	USA-US061-2020-MRNA-1273-P30 1000002
Adverse event	RIGHT BREAST DUCTAL CARCINOMA IN SITU
Was this a medically-attended AE?	Yes <input checked="" type="radio"/> No <input type="radio"/>
Was this a Solicited Adverse Reaction?	Yes <input type="radio"/> No <input checked="" type="radio"/>
Is this event a confirmed diagnosis of Symptomatic Covid-19?	Yes <input type="radio"/> No <input checked="" type="radio"/>
Start date (dd MMM yyyy)	12 AUG 2020
Start time (00:00-23:59)	
AE start date and time (derived)	
Ongoing?	Yes <input checked="" type="radio"/> No <input type="radio"/>
If not Ongoing, end date (dd MMM yyyy)	
End time (00:00-23:59)	
AE End Date and Time (derived)	
Severity	Grade 1/Mild <input type="radio"/> Grade 2/Moderate <input checked="" type="radio"/> Grade 3/Severe <input type="radio"/> Grade 4 <input type="radio"/>
Is the adverse event serious?	Yes <input checked="" type="radio"/> No <input type="radio"/>
AE is serious due To (check all that apply)	
Death	False
Life threatening	False
Requires inpatient or prolongation of existing Hospitalization	False
Hospital Admission Date (dd MMM yyyy)	
Hospital Discharge Date (dd MMM yyyy)	
Admitted to ICU?	Yes <input type="radio"/> No <input type="radio"/> Unknown <input type="radio"/>
Number of Days in ICU	
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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:30:24

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

US3412184

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:30:24

SUBJECT CONTACTED FOR
TELEPHONE VISIT @ 17:30. SHE
NOTES SHE HAD A
MAMMOGRAM AND BIOPSY
LAST WEEK OF HER RIGHT
BREAST ON 12-AUG-2020. SHE
WAS INFORMED THAT THEY
FOUND STAGE 0 BREAST
CANCER (NO INVOLVEMENT
OF LYMPH NODES).
BONE MINERAL DENSITY SCAN
IS IN THE NORMAL RANGE
MRI BREAST BILATERAL W WO
BREAS-ICD-10-CM. D05.11-
INTRADUCTAL CARCINOMA IN
SITU OF RIGHT
BREAST-ICD-10-CM
THE CLIP PLACED AT TIME OF
BIOPSY IS PRESENT IN THE
POSTERIOR
RETROAREOLAR/6:00 PART OF
THE RIGHT BREAST. WITH THE
PATIENT PRONE, THIS IS 9.5 CM
POSTERIOR TO THE NIPPLE.
THERE IS A MINIMAL
ILL-DEFINES 5MM SIZE AREA
OF ENHANCEMENT AT THE
LEVEL OF THE CLIP. NO
EVIDENCE OF MULTICENTRIC
OR MULTIFOCAL
ABNORMALITY. NO
SUSPICIOUS ENHANCEMENT
PRESENT ELSEWHERE IN
EITHER BREAST. NO EVIDENCE
OF AXILLARY OR INTERNAL
MAMMARY CHAIN
ADENOPATHY. KNOWN BIOPSY

US3412184

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:30:24

PROVEN MALIGNANCY. NO
EVIDENCE OF MULTICENTRIC
OR MULTIFOCAL
ABNORMALITY. MINIMAL
POSTBIOPSY CHANGES ON THE
RIGHT ARE PRESENT

SUBJECT IS TAKING PART IN
ANOTHER PHARMACEUTICAL
TRIAL FOR ARIMIDEX FOR
BREAST CANCER. THIS WAS
APPROVED BY THE MEDICAL
MONITOR THAT SUBJECT CAN
CONTINUE WITH FOLLOW UP
AND SITE WILL DOCUMENT
THE PROTOCOL DEVIATION.

SUBJECT WAS UNBLINDED ON
05JAN2021 AND WAS FOUND TO
HAVE RECEIVED THE
PLACEBO. SUBJECT RECEIVED
1ST DOSE OF MRNA-1273 ON
13JAN2021 AND THE 2ND DOSE
ON 02FEB2021.

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)	

US3412184

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:30:24

AEID

Adverse event

INJECTION SITE PAIN (LEFT
ARM)

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)

5 JAN 2021

Start time (00:00-23:59)

14:00 (24 HR)

AE start date and time (derived)

5 JAN 2021 14:00

Ongoing?

Yes ☐

No ☒

If not Ongoing, end date (dd MMM yyyy)

7 JAN 2021

End time (00:00-23:59)

AE End Date and Time (derived)

Severity

Grade 1/Mild ☒

Grade 2/Moderate ☐

Grade 3/Severe ☐

Grade 4 ☐

Is the adverse event serious?

Yes ☐

No ☒

AE is serious due To (check all that apply)

Death False

Life threatening False

Requires inpatient or prolongation of existing Hospitalization False

Hospital Admission Date (dd MMM yyyy)

Hospital Discharge Date (dd MMM yyyy)

Admitted to ICU?

Yes ☐

No ☐

Unknown ☐

Number of Days in ICU

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:30:24

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

US3412184

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination Summary

Data signed: (b) (4) 12 Apr 2021 14:37:59

Generated On: 09 Jun 2021 17:30:24

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

Yes ☒

No ☐

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

US3412184

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Data signed: (b) (4) 12 Apr 2021 14:20:12

Generated On: 09 Jun 2021 17:30:24

Name of Medication ADVIL

Prophylaxis Yes ☐
No ☒

Indication OSTEOARTHRITIS OF KNEE

Dose per administration 200

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Data signed: (b) (4) 12 Apr 2021 14:20:12

Generated On: 09 Jun 2021 17:30:24

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

US3412184

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Data signed: (b) (4) 12 Apr 2021 14:20:12

Generated On: 09 Jun 2021 17:30:24

Name of Medication MULTIVITAMIN

Prophylaxis Yes ☒
No ☐

Indication GENERAL HEALTH

Dose per administration 1

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Data signed: (b) (4) 12 Apr 2021 14:20:12

Generated On: 09 Jun 2021 17:30:24

	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	UN UNK 2000	
Start date completely unknown	False	
Ongoing?	Yes	<input checked="" type="radio"/>
	No	<input type="radio"/>
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived)	1	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input checked="" type="radio"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Data signed: (b) (4) 12 Apr 2021 14:20:12

Generated On: 09 Jun 2021 17:30:24

Name of Medication OMEGA 3 (FISH OIL)

Prophylaxis Yes ☒
No ☐

Indication GENERAL HEALTH

Dose per administration 1000

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

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EAB) (1725)

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Data signed: (b) (4) 12 Apr 2021 14:20:12

Generated On: 09 Jun 2021 17:30:24

	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	UN UNK 2000	
Start date completely unknown	False	
Ongoing?	Yes	<input checked="" type="radio"/>
	No	<input type="radio"/>
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived)	1	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input checked="" type="radio"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Data signed: (b) (4) 12 Apr 2021 14:20:12

Generated On: 09 Jun 2021 17:30:24

Name of Medication VITAMIN D3

Prophylaxis Yes ☒
No ☐

Indication GENERAL HEALTH

Dose per administration 1000

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Data signed: (b) (4) 12 Apr 2021 14:20:12

Generated On: 09 Jun 2021 17:30:24

	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	UN	UNK 2000
Start date completely unknown	False	
Ongoing?	Yes	<input checked="" type="radio"/>
	No	<input type="radio"/>
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived)	1	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input checked="" type="radio"/>

US3412184

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Data signed: (b) (4) 12 Apr 2021 14:20:12

Generated On: 09 Jun 2021 17:30:24

Name of Medication ANASTRAZOLE

Prophylaxis Yes ☐
No ☒

Indication BREAST CANCER

Dose per administration 1

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Data signed: (b) (4) 12 Apr 2021 14:20:12

Generated On: 09 Jun 2021 17:30:24

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

US3412184

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Data signed: (b) (4) 12 Apr 2021 14:20:12

Generated On: 09 Jun 2021 17:30:24

Name of Medication IBUPROFEN

Prophylaxis Yes ☐
No ☒

Indication OA

Dose per administration 400

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

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EAB) (1725)

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Data signed: (b) (4) 12 Apr 2021 14:20:12

Generated On: 09 Jun 2021 17:30:24

	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	UN	UNK 2020
Start date completely unknown	False	
Ongoing?	Yes	<input checked="" type="radio"/>
	No	<input type="radio"/>
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived)	1	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input checked="" type="radio"/>

US3412184

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures Summary

Data signed: (b) (4) 12 Apr 2021 14:37:59

Generated On: 09 Jun 2021 17:30:24

Were any concomitant procedures performed?

Yes ☒

No ☐

If yes, please complete Concomitant Procedures form.

US3412184

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures

Data signed: (b) (4) 16 Apr 2021 13:31:16

Generated On: 09 Jun 2021 17:30:24

Procedure/Surgery date (dd MMM yyyy)	Procedure/Surgery	Indication	If indication is Other, specify
12 AUG 2020	MAM STEROTACTIC LOC BREAST BIOPSY RIGHT	Diagnostic	
16 SEP 2020	DX BONE DENSITY AXIAL SKELETON	Diagnostic	
17 SEP 2020	MRI BREAST BILATERAL W WO CONTRAST W CAD	Diagnostic	

US3412184

Folder: End of Study (1)

Form: Dosing Discontinuation

Generated On: 09 Jun 2021 17:30:24

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

US3412184

Folder: End of Study (1)

Form: End of Study / Study Discontinuation

Generated On: 09 Jun 2021 17:30:24

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 ☐

US3412184

Folder: SAE USA-US061-2020-MRNA-1273-P301000002

Form: Safety Report Form

Data signed: (b) (4) 16 Apr 2021 14:34:07

Generated On: 09 Jun 2021 17:30:24

SAEID	USA-US061-2020-MRNA-1273-P301000002
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 type="radio"/> No <input checked="" type="radio"/>
Persistent or significant disability or incapacity	Yes <input type="radio"/> No <input checked="" type="radio"/>
Congenital anomaly or birth defect	Yes <input type="radio"/> No <input checked="" type="radio"/>
Other medically important event	Yes <input checked="" type="radio"/> No <input type="radio"/>
Investigator's First Name	GREGORY
Investigator's Last Name	GOTTSCHLICH
Site Address: Street	4260 GLENDALE MILFORD ROAD
Site Address: City	CINCINNATI
Site Address: State	
Site Address: Postal Code	45242
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	6

US3412184

Folder: SAE USA-US061-2020-MRNA-1273-P301000002

Form: Safety Report Form (1)

Data signed: (b) (4) 16 Apr 2021 14:34:07

Generated On: 09 Jun 2021 17:30:24

SAEID	USA-US061-2020-MRNA-1273-P301000002
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 type="radio"/> No <input checked="" type="radio"/>
Persistent or significant disability or incapacity	Yes <input type="radio"/> No <input checked="" type="radio"/>
Congenital anomaly or birth defect	Yes <input type="radio"/> No <input checked="" type="radio"/>
Other medically important event	Yes <input checked="" type="radio"/> No <input type="radio"/>
Investigator's First Name	GREGORY
Investigator's Last Name	GOTTSCHLICH
Site Address: Street	4260 GLENDALE MILFORD ROAD
Site Address: City	CINCINNATI
Site Address: State	
Site Address: Postal Code	45242
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	6
Date of submission (Pre-filled from custom function)	18/AUG/2020 09:46
Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.	True

US3412184

Folder: SAE USA-US061-2020-MRNA-1273-P301000002

Form: Safety Report Form (2)

Data signed: (b) (4) 16 Apr 2021 14:34:07

Generated On: 09 Jun 2021 17:30:24

SAEID	USA-US061-2020-MRNA-1273-P301000002
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 type="radio"/> No <input checked="" type="radio"/>
Persistent or significant disability or incapacity	Yes <input type="radio"/> No <input checked="" type="radio"/>
Congenital anomaly or birth defect	Yes <input type="radio"/> No <input checked="" type="radio"/>
Other medically important event	Yes <input checked="" type="radio"/> No <input type="radio"/>
Investigator's First Name	GREGORY
Investigator's Last Name	GOTTSCHLICH
Site Address: Street	4260 GLENDALE MILFORD ROAD
Site Address: City	CINCINNATI
Site Address: State	
Site Address: Postal Code	45242
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	6
Date of submission (Pre-filled from custom function)	22/OCT/2020 10:00
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.	True

US3412184

Folder: SAE USA-US061-2020-MRNA-1273-P301000002

Form: Safety Report Form (3)

Data signed: (b) (4) 16 Apr 2021 14:34:07

Generated On: 09 Jun 2021 17:30:24

SAEID	USA-US061-2020-MRNA-1273-P301000002
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 type="radio"/> No <input checked="" type="radio"/>
Persistent or significant disability or incapacity	Yes <input type="radio"/> No <input checked="" type="radio"/>
Congenital anomaly or birth defect	Yes <input type="radio"/> No <input checked="" type="radio"/>
Other medically important event	Yes <input checked="" type="radio"/> No <input type="radio"/>
Investigator's First Name	GREGORY
Investigator's Last Name	GOTTSCHLICH
Site Address: Street	4260 GLENDALE MILFORD ROAD
Site Address: City	CINCINNATI
Site Address: State	
Site Address: Postal Code	45242
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	6
Date of submission (Pre-filled from custom function)	11/NOV/2020 15:33
Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.	True

US3412184

Folder: SAE USA-US061-2020-MRNA-1273-P301000002

Form: Safety Report Form (4)

Data signed: (b) (4) 16 Apr 2021 14:34:07

Generated On: 09 Jun 2021 17:30:24

SAEID	USA-US061-2020-MRNA-1273-P301000002
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 type="radio"/> No <input checked="" type="radio"/>
Persistent or significant disability or incapacity	Yes <input type="radio"/> No <input checked="" type="radio"/>
Congenital anomaly or birth defect	Yes <input type="radio"/> No <input checked="" type="radio"/>
Other medically important event	Yes <input checked="" type="radio"/> No <input type="radio"/>
Investigator's First Name	GREGORY
Investigator's Last Name	GOTTSCHLICH
Site Address: Street	4260 GLENDALE MILFORD ROAD
Site Address: City	CINCINNATI
Site Address: State	
Site Address: Postal Code	45242
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	6
Date of submission (Pre-filled from custom function)	25/NOV/2020 12:59
Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.	True

US3412184

Folder: SAE USA-US061-2020-MRNA-1273-P301000002

Form: Safety Report Form (5)

Data signed: (b) (4) 16 Apr 2021 14:34:07

Generated On: 09 Jun 2021 17:30:24

SAEID	USA-US061-2020-MRNA-1273-P301000002
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 type="radio"/> No <input checked="" type="radio"/>
Persistent or significant disability or incapacity	Yes <input type="radio"/> No <input checked="" type="radio"/>
Congenital anomaly or birth defect	Yes <input type="radio"/> No <input checked="" type="radio"/>
Other medically important event	Yes <input checked="" type="radio"/> No <input type="radio"/>
Investigator's First Name	GREGORY
Investigator's Last Name	GOTTSCHLICH
Site Address: Street	4260 GLENDALE MILFORD ROAD
Site Address: City	CINCINNATI
Site Address: State	
Site Address: Postal Code	45242
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	6
Date of submission (Pre-filled from custom function)	29/JAN/2021 11:51
Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.	True

US3412184

Folder: SAE USA-US061-2020-MRNA-1273-P301000002

Form: Safety Report Form (6)

Data signed: (b) (4) 16 Apr 2021 14:34:07

Generated On: 09 Jun 2021 17:30:24

SAEID	USA-US061-2020-MRNA-1273-P301000002
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 type="radio"/> No <input checked="" type="radio"/>
Persistent or significant disability or incapacity	Yes <input type="radio"/> No <input checked="" type="radio"/>
Congenital anomaly or birth defect	Yes <input type="radio"/> No <input checked="" type="radio"/>
Other medically important event	Yes <input checked="" type="radio"/> No <input type="radio"/>
Investigator's First Name	GREGORY
Investigator's Last Name	GOTTSCHLICH
Site Address: Street	4260 GLENDALE MILFORD ROAD
Site Address: City	CINCINNATI
Site Address: State	
Site Address: Postal Code	45242
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	6
Date of submission (Pre-filled from custom function)	18/FEB/2021 17:17
Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.	True

Audit

US3412184 (Prod: New Horizons Clinical Research)

US3412184

Form: Participant Creation

Generated On: 09 Jun 2021 17:30:24

[Participant ID](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:34:07
User entered 'US3412184'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	10 Aug 2020 13:19:45

US3412184

Folder: Screening

Form: Visit Date

Generated On: 09 Jun 2021 17:30:24

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:28:47
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 04:54:06
User entered 'Yes (Y)'	Steven Anderson (b) (4)	10 Aug 2020 14:35:41

US3412184

Folder: Screening

Form: Visit Date

Generated On: 09 Jun 2021 17:30:24

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:28:47
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 04:54:06
User entered '10 AUG 2020'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	10 Aug 2020 13:19:46

US3412184

Folder: Screening

Form: Visit Date

Generated On: 09 Jun 2021 17:30:24

[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 12:28:47
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 04:54:06
User entered 'Clinic (Clinic)'	Steven Anderson (b) (4)	10 Aug 2020 14:35:41

US3412184

Folder: Screening

Form: Visit Date

Generated On: 09 Jun 2021 17:30:24

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:28:47
User entered 'SCRN'	System	10 Aug 2020 14:35:41

US3412184

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 17:30:24

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:28:47
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 04:54:06
User entered (b) (6) 1947'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	10 Aug 2020 13:19:47

US3412184

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 17:30:24

[Age](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:28:47
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 04:54:06
User entered '73'	Steven Anderson (b) (4)	10 Aug 2020 14:36:10

US3412184

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 17:30:24

[Age Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:28:47
User entered 'YEARS'	System	10 Aug 2020 14:36:10

US3412184

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 17:30:24

[Age \(Derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:28:47
User entered '73'	System	10 Aug 2020 14:36:25

US3412184

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 17:30:24

[Sex](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:28:47
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 04:54:06
User entered 'Female (F)'	Steven Anderson (b) (4)	10 Aug 2020 14:36:10

US3412184

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 17:30:24

[Ethnicity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:28:47
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 04:54:06
User entered 'Not Hispanic or Latino (NOT HISPANIC OR LATINO)'	Steven Anderson (b) (4)	10 Aug 2020 14:36:10

US3412184

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 17:30:24

[White](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:28:47
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 04:54:06
User entered '0' reason for change: Data Entry Error	(b) (4)	
	Melissa Fuson (b) (4)	23 Sep 2020 16:26:45
User entered '1' reason for change: Data Entry Error	(b) (4)	
	Melissa Fuson (b) (4)	23 Sep 2020 15:49:54
User entered '0'	(b) (4)	
	Steven Anderson (b) (4)	10 Aug 2020 14:36:10
	(b) (4)	

US3412184

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 17:30:24

[Black](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:28:47
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 04:54:06
User entered '1' reason for change: Data Entry Error	(b) (4)	
	Melissa Fuson (b) (4)	23 Sep 2020 16:26:45
User entered '0' reason for change: Data Entry Error	(b) (4)	
	Melissa Fuson (b) (4)	23 Sep 2020 15:49:54
User entered '1'	(b) (4)	
	Steven Anderson (b) (4)	10 Aug 2020 14:36:10
	(b) (4)	

US3412184

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 17:30:24

[Asian](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:28:47
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 04:54:06
User entered '0'	Steven Anderson (b) (4)	10 Aug 2020 14:36:10

US3412184

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 17:30:24

[American Indian or Alaska Native](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:28:47
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 04:54:06
User entered '0'	Steven Anderson (b) (4)	10 Aug 2020 14:36:10

US3412184

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 17:30:24

[Native Hawaiian or other Pacific Islander](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:28:47
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 04:54:06
User entered '0'	Steven Anderson (b) (4)	10 Aug 2020 14:36:10

US3412184

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 17:30:24

[Other](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:28:47
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 04:54:06
User entered '0'	Steven Anderson (b) (4)	10 Aug 2020 14:36:10

US3412184

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 17:30:24

[If race is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:28:47
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 04:54:06
User entered empty.	Steven Anderson (b) (4)	10 Aug 2020 14:36:10

US3412184

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 17:30:24

[Unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:28:47
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 04:54:06
User entered '0'	Steven Anderson (b) (4)	10 Aug 2020 14:36:10

US3412184

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 17:30:24

[Not reported](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:28:47
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 04:54:06
User entered '0'	Steven Anderson (b) (4)	10 Aug 2020 14:36:10

US3412184

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 17:30:24

Date of Informed Consent (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:28:47
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 04:54:06
User entered '10 Aug 2020'	Steven Anderson (b) (4)	10 Aug 2020 14:36:25

US3412184

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 17:30:24

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:28:47
User entered 'Aug 2020'	System	10 Aug 2020 14:36:25

US3412184

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 17:30:24

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:28:47
User entered '2020'	System	10 Aug 2020 14:36:25

US3412184

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 17:30:24

[Protocol Version](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:28:47
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 04:54:06
User entered 'Amendment 1 (1)'	Steven Anderson (b) (4)	10 Aug 2020 14:36:25

US3412184

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 17:30:24

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:28:47
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 04:54:06
User entered 'Yes (Y)'	Steven Anderson (b) (4)	10 Aug 2020 14:36:25

US3412184

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 17:30:24

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:28:47
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 04:54:06
User entered empty.	Steven Anderson (b) (4)	10 Aug 2020 14:36:25

US3412184

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 17:30:24

If reason for screen fail is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:28:47
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 04:54:06
User entered empty.	Steven Anderson (b) (4)	10 Aug 2020 14:36:25

US3412184

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 17:30:24

[Was this participant screened previously?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:28:47
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 04:54:06
User entered 'No (N)'	Steven Anderson (b) (4)	10 Aug 2020 14:36:25

US3412184

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 17:30:24

[If Yes, previous participant number](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:28:47
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 04:54:06
User entered empty.	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	10 Aug 2020 13:19:46

US3412184

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 17:30:24

[Enrollment Trigger](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:28:47
User entered 'I'	System	10 Aug 2020 14:36:31

US3412184

Folder: Screening

Form: Inclusion/Exclusion Criteria Summary

Generated On: 09 Jun 2021 17:30:24

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:28:47
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 04:54:06
User entered 'Yes (Y)'	Steven Anderson (b) (4)	10 Aug 2020 14:36:31

US3412184

Folder: Screening

Form: Medical History Summary

Generated On: 09 Jun 2021 17:30:24

[Were any significant conditions reported?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:28:47
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 04:54:06
User entered 'Yes (Y)'	Steven Anderson (b) (4)	17 Aug 2020 23:31:05

US3412184

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 17:30:24

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:28:47
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 04:54:06
User coded data point as SOC: Musculoskeletal and connective tissue disorders, HLGT: Joint disorders, HLT: Osteoarthritis, PT: Osteoarthritis, LLT: Osteoarthritis knees - version MedDRA\23.0.	Coder Import (b) (4)	23 Nov 2020 21:38:27
User coded data point as Term Coded data point by User: Coder System - version MedDRA\23.0.	Coder Import (b) (4)	23 Nov 2020 21:38:27
User closed query 'Per DM CLR: Please specify the location of OSTEOARTHRITIS. Review and update medical history diagnosis as appropriate and ensure update to MHx is reconciled with any corresponding AE or ConMed entries, if applicable.	(b) (4), (b) (6)	15 Oct 2020 11:45:12
' (Site from DM).		
Data point term sent to Coder	System	13 Oct 2020 21:38:55
Query 'Per DM CLR: Please specify the location of OSTEOARTHRITIS. Review and update medical history diagnosis as appropriate and ensure update to MHx is reconciled with any corresponding AE or ConMed entries, if applicable.	Steven Anderson (b) (4)	13 Oct 2020 21:38:16
' answered with 'has been updated with location' (Site from DM).	(b) (4)	
Coding entries removed.	Steven Anderson (b) (4)	13 Oct 2020 21:38:06
User entered 'OSTEOARTHRITIS Bi-lateral knees' reason for change: Data Entry Error	(b) (4)	
User opened query 'Per DM CLR: Please specify the location of OSTEOARTHRITIS. Review and update medical history diagnosis as appropriate and ensure update to MHx is reconciled with any corresponding AE or ConMed entries, if applicable.	Steven Anderson (b) (4)	13 Oct 2020 21:38:06
' (Site from DM).	(b) (4)	
User coded data point as SOC: Musculoskeletal and connective tissue disorders, HLGT: Joint disorders, HLT: Osteoarthritis, PT: Osteoarthritis, LLT: Osteoarthritis - version MedDRA\23.0.	(b) (4), (b) (6)	26 Sep 2020 16:42:53
User coded data point as Term Coded data point by User: Coder System - version MedDRA\23.0.		
Data point term sent to Coder	Coder Import (b) (4)	17 Aug 2020 23:33:18
	(b) (4)	
	Coder Import (b) (4)	17 Aug 2020 23:33:18
	(b) (4)	
	System	17 Aug 2020 23:32:12

US3412184

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 17:30:24

[Condition](#)

Audit	User	Time (GMT)
User entered 'Osteoarthritis'	Steven Anderson (b) (4) (b) (4)	17 Aug 2020 23:31:33

US3412184

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 17:30:24

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:28:47
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 04:54:06
User entered 'un UNK 2010'	Steven Anderson (b) (4)	17 Aug 2020 23:31:33

US3412184

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 17:30:24

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:28:47
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 04:54:06
User entered '0'	Steven Anderson (b) (4)	17 Aug 2020 23:31:33

US3412184

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 17:30:24

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:28:47
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 04:54:06
User entered 'Yes (Y)'	Steven Anderson (b) (4)	17 Aug 2020 23:31:33

US3412184

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 17:30:24

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:28:47
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 04:54:06
User entered empty.	Steven Anderson (b) (4)	17 Aug 2020 23:31:33

US3412184

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 17:30:24

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:28:47
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 04:54:06
User entered '0'	Steven Anderson (b) (4)	17 Aug 2020 23:31:33

US3412184

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 17:30:24

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:28:47
User entered 'Jan 2010'	System	17 Aug 2020 23:31:33

US3412184

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 17:30:24

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:28:47
User entered '2010'	System	17 Aug 2020 23:31:33

US3412184

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 17:30:24

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:28:47
User entered empty.	System	17 Aug 2020 23:31:33

US3412184

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 17:30:24

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:28:47
User entered empty.	System	17 Aug 2020 23:31:33

US3412184

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 17:30:24

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:28:47
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 04:54:06
User coded data point as SOC: Social circumstances, HLT: Age related factors, HLT: Age related issues, PT: Postmenopause, LLT: Postmenopause - version MedDRA\\23.0.	Coder Import (b) (4)	13 Oct 2020 21:40:23
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	13 Oct 2020 21:40:23
Data point term sent to Coder	System	13 Oct 2020 21:38:55
User entered 'Post-menopausal'	Steven Anderson (b) (4)	13 Oct 2020 21:38:55

US3412184

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 17:30:24

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:28:47
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 04:54:06
User entered 'un UNK 1996'	Steven Anderson (b) (4)	13 Oct 2020 21:38:55

US3412184

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 17:30:24

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:28:47
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 04:54:06
User entered '0'	Steven Anderson (b) (4)	13 Oct 2020 21:38:55

US3412184

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 17:30:24

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:28:47
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 04:54:06
User entered 'Yes (Y)'	Steven Anderson (b) (4)	13 Oct 2020 21:38:55

US3412184

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 17:30:24

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:28:47
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 04:54:06
User entered empty.	Steven Anderson (b) (4)	13 Oct 2020 21:38:55

US3412184

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 17:30:24

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:28:47
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 04:54:06
User entered '0'	Steven Anderson (b) (4)	13 Oct 2020 21:38:55

US3412184

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 17:30:24

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:28:47
User entered 'Jan 1996'	System	13 Oct 2020 21:38:55

US3412184

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 17:30:24

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:28:47
User entered '1996'	System	13 Oct 2020 21:38:55

US3412184

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 17:30:24

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:28:47
User entered empty.	System	13 Oct 2020 21:38:55

US3412184

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 17:30:24

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:28:47
User entered empty.	System	13 Oct 2020 21:38:55

US3412184

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:30:24

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:28:47
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 04:54:06
User entered 'Yes (Y)'	Steven Anderson (b) (4)	17 Aug 2020 23:33:03

US3412184

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:30:24

Date of assessment (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:28:47
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 04:54:06
User closed query 'The Vital Signs Date is not equal to Visit Date. Please review and reconcile.' (Site from System).	(b) (4)	17 Aug 2020 23:33:25
Query 'The Vital Signs Date is not equal to Visit Date. Please review and reconcile.' answered by data change (Site from System).	System	17 Aug 2020 23:33:25
User closed query 'Screening Vital Signs is not within 28 days of Visit 1. Please reconcile or confirm dates.' (Site from System).	System	17 Aug 2020 23:33:25
Query 'Screening Vital Signs is not within 28 days of Visit 1. Please reconcile or confirm dates.' answered by data change (Site from System).	System	17 Aug 2020 23:33:25
User entered '10 Aug 2020' reason for change: Data Entry Error	Steven Anderson (b) (4)	17 Aug 2020 23:33:25
User opened query 'The Vital Signs Date is not equal to Visit Date. Please review and reconcile.' (Site from System).	(b) (4)	17 Aug 2020 23:33:03
User opened query 'Screening Vital Signs is not within 28 days of Visit 1. Please reconcile or confirm dates.' (Site from System).	System	17 Aug 2020 23:33:03
User entered '17 Aug 2020'	Steven Anderson (b) (4)	17 Aug 2020 23:33:03

US3412184

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:30:24

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:28:47
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 04:54:06
User entered '09:37'	Steven Anderson (b) (4)	17 Aug 2020 23:33:03

US3412184

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:30:24

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:28:47
User entered '10 Aug 2020 09:37'	System	17 Aug 2020 23:33:25
User entered '17 Aug 2020 09:37'	System	17 Aug 2020 23:33:03

US3412184

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:30:24

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:28:47
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 04:54:06
User entered '165.6' cm	Steven Anderson (b) (4)	17 Aug 2020 23:33:03
DataPoint set to visible.	System	10 Aug 2020 14:36:31

US3412184

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:30:24

Weight (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:28:47
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 04:54:06
User entered '88.1' kg	Steven Anderson (b) (4)	17 Aug 2020 23:33:03
DataPoint set to visible.	System	10 Aug 2020 14:36:31

US3412184

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:30:24

BMI (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:28:47
Amendment Manager: User entered '32.12590'	System	16 Sep 2020 23:49:32
User entered '32.1'	System	17 Aug 2020 23:33:03
DataPoint set to visible.	System	10 Aug 2020 14:36:31

US3412184

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:30:24

[BMI units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:28:47
User entered 'kg/m2'	System	17 Aug 2020 23:33:03
DataPoint set to visible.	System	10 Aug 2020 14:36:31

US3412184

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:30:24

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:28:47
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 04:54:06
User closed query 'Data entered is non-conformant. Please correct.' (Site from System).	(b) (4)	17 Aug 2020 23:33:25
User entered missing code ND - Not Done; reason for change Data Entry Error	System	17 Aug 2020 23:33:25
User opened query 'Data entered is non-conformant. Please correct.' (Site from System).	Steven Anderson (b) (4)	17 Aug 2020 23:33:03
User entered '3nd' (non-conformant).	(b) (4)	17 Aug 2020 23:33:03

US3412184

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:30:24

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:28:47
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 04:54:06
User closed query 'Data is required. Please provide.' (Site from System).	(b) (4) (b) (4), (b) (6)	18 Aug 2020 19:38:05
Query 'Data is required. Please provide.' answered with 'na' (Site from System).	Steven Anderson (b) (4)	17 Aug 2020 23:33:34
User opened query 'Data is required. Please provide.' (Site from System).	(b) (4)	
User entered empty.	System	17 Aug 2020 23:33:03
	Steven Anderson (b) (4)	17 Aug 2020 23:33:03
	(b) (4)	

US3412184

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:30:24

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:28:47
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 04:54:06
User entered empty.	Steven Anderson (b) (4)	17 Aug 2020 23:33:03

US3412184

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:30:24

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:28:47
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 04:54:06
User entered missing code ND - Not Done.	Steven Anderson (b) (4)	17 Aug 2020 23:33:03

US3412184

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:30:24

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:28:47
User entered 'bpm'	System	17 Aug 2020 23:33:03

US3412184

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:30:24

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:28:47
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 04:54:06
User entered missing code ND - Not Done.	Steven Anderson (b) (4)	17 Aug 2020 23:33:03

US3412184

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:30:24

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:28:47
User entered 'breaths/min'	System	17 Aug 2020 23:33:03

US3412184

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:30:24

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:28:47
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 04:54:06
User entered missing code ND - Not Done.	Steven Anderson (b) (4)	17 Aug 2020 23:33:03

US3412184

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:30:24

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:28:47
User entered 'mmHg'	System	17 Aug 2020 23:33:03

US3412184

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:30:24

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:28:47
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 04:54:06
User entered missing code ND - Not Done.	Steven Anderson (b) (4)	17 Aug 2020 23:33:03

US3412184

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:30:24

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:28:47
User entered 'mmHg'	System	17 Aug 2020 23:33:03

US3412184

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:30:24

[Height \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:28:47

US3412184

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:30:24

[Weight \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:28:47

US3412184

Folder: Screening

Form: Physical Examination

Generated On: 09 Jun 2021 17:30:24

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:28:47
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 04:54:06
User entered 'Yes (Y)'	Steven Anderson (b) (4)	17 Aug 2020 23:33:45

US3412184

Folder: Screening

Form: Physical Examination

Generated On: 09 Jun 2021 17:30:24

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:28:47
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 04:54:06
Query 'The Physical Examination Date is prior to the Screening Visit Date. Please review and reconcile.' canceled (Site from System).	(b) (4) (b) (4), (b) (6)	11 Sep 2020 18:07:29
User opened query 'The Physical Examination Date is prior to the Screening Visit Date. Please review and reconcile.' (Site from System).	System	08 Sep 2020 12:53:06
User entered '10 Aug 2020'	Steven Anderson (b) (4) (b) (4)	17 Aug 2020 23:33:45

US3412184

Folder: Screening

Form: Childbearing Potential

Generated On: 09 Jun 2021 17:30:24

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:28:47
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 04:54:06
User entered '10 Aug 2020'	Steven Anderson (b) (4)	17 Aug 2020 23:34:17

US3412184

Folder: Screening

Form: Childbearing Potential

Generated On: 09 Jun 2021 17:30:24

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:28:47
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 04:54:06
User entered 'No (N)'	Steven Anderson (b) (4)	17 Aug 2020 23:34:17

US3412184

Folder: Screening

Form: Childbearing Potential

Generated On: 09 Jun 2021 17:30:24

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:28:47
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 04:54:06
User closed query 'Per DM CLR: Please review this condition as this is not recorded in MH ecrf. Record this condition in MH ecrf as appropriate. ' (Site from DM).	(b) (4) (b) (4), (b) (6)	15 Oct 2020 11:45:32
Query 'Per DM CLR: Please review this condition as this is not recorded in MH ecrf. Record this condition in MH ecrf as appropriate. ' answered with 'this has been recorded in med history' (Site from DM).	Steven Anderson (b) (4) (b) (4)	13 Oct 2020 21:39:44
User opened query 'Per DM CLR: Please review this condition as this is not recorded in MH ecrf. Record this condition in MH ecrf as appropriate. ' (Site from DM).	(b) (4), (b) (6)	08 Oct 2020 05:32:49
User entered 'Post-menopausal (POST-MENOPAUSAL)'	Steven Anderson (b) (4) (b) (4)	17 Aug 2020 23:34:17

US3412184

Folder: Screening

Form: Childbearing Potential

Generated On: 09 Jun 2021 17:30:24

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:28:47
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 04:54:06
User entered empty.	Steven Anderson (b) (4)	17 Aug 2020 23:34:17

US3412184

Folder: Screening

Form: Childbearing Potential

Generated On: 09 Jun 2021 17:30:24

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:28:47
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 04:54:06
User entered empty.	Steven Anderson (b) (4)	17 Aug 2020 23:34:17

US3412184

Folder: Screening

Form: Childbearing Potential

Generated On: 09 Jun 2021 17:30:24

[Date of surgery unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:28:47
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 04:54:06
User entered '0'	Steven Anderson (b) (4)	17 Aug 2020 23:34:17

US3412184

Folder: Screening

Form: Childbearing Potential

Generated On: 09 Jun 2021 17:30:24

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:28:47
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 04:54:06
User entered 'un UNK 1996'	Steven Anderson (b) (4)	17 Aug 2020 23:34:17

US3412184

Folder: Screening

Form: Childbearing Potential

Generated On: 09 Jun 2021 17:30:24

[Date of last menstruation unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:28:47
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 04:54:06
User entered '0'	Steven Anderson (b) (4)	17 Aug 2020 23:34:17

US3412184

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:30:24

[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 12:28:47
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 04:54:06
User entered 'No (N)'	Steven Anderson (b) (4)	17 Aug 2020 23:37:43

US3412184

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:30:24

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 12:28:47
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 04:54:06
User entered 'No (N)'	Steven Anderson (b) (4)	17 Aug 2020 23:37:43

US3412184

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:30:24

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 12:28:47
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 04:54:06
User entered 'No (N)'	Steven Anderson (b) (4)	17 Aug 2020 23:37:43

US3412184

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:30:24

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 12:28:47
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 04:54:06
User entered 'No (N)'	Steven Anderson (b) (4)	17 Aug 2020 23:37:43

US3412184

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:30:24

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 12:28:47
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 04:54:06
User entered 'No (N)'	Steven Anderson (b) (4)	17 Aug 2020 23:37:43

US3412184

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:30:24

[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 12:28:47
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 04:54:06
User entered 'No (N)'	Steven Anderson (b) (4)	17 Aug 2020 23:37:43

US3412184

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:30:24

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 12:28:47
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 04:54:06
User entered 'No (N)'	Steven Anderson (b) (4)	17 Aug 2020 23:37:43

US3412184

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:30:24

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 12:28:47
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 04:54:06
User entered 'No (N)'	Steven Anderson (b) (4)	17 Aug 2020 23:37:43

US3412184

Folder: Screening

Form: Risk of Exposure

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[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 12:28:47
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 04:54:06
User entered 'No (N)'	Steven Anderson (b) (4)	17 Aug 2020 23:37:43

US3412184

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:30:24

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 12:28:47
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 04:54:06
User entered 'No (N)'	Steven Anderson (b) (4)	17 Aug 2020 23:37:43

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Folder: Screening

Form: Risk of Exposure

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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 12:28:47
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 04:54:06
User entered 'No (N)'	Steven Anderson (b) (4)	17 Aug 2020 23:37:43

US3412184

Folder: Screening

Form: Risk of Exposure

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Other

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:28:47
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 04:54:06
User entered 'Yes (Y)'	Steven Anderson (b) (4)	17 Aug 2020 23:37:43

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Folder: Screening

Form: Risk of Exposure

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[Specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:28:47
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 04:54:06
User entered 'Has health care worker come to house for husband'	Steven Anderson (b) (4)	17 Aug 2020 23:37:43

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Folder: Screening

Form: Risk of Exposure

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No Risk Identified

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:28:47
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 04:54:06
User entered '0'	Steven Anderson (b) (4)	17 Aug 2020 23:37:43

US3412184

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:30:24

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:28:47
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 04:54:06
User entered '0'	Steven Anderson (b) (4)	17 Aug 2020 23:37:43

US3412184

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:30:24

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 12:28:47
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 04:54:06
User entered '0'	Steven Anderson (b) (4)	17 Aug 2020 23:37:43

US3412184

Folder: Screening

Form: Risk of Exposure

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[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 12:28:47
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 04:54:06
User entered '0'	Steven Anderson (b) (4)	17 Aug 2020 23:37:43

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Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:30:24

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 12:28:47
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 04:54:06
User entered '0'	Steven Anderson (b) (4)	17 Aug 2020 23:37:43

US3412184

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:30:24

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:28:47
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 04:54:06
User entered 'I'	Steven Anderson (b) (4)	17 Aug 2020 23:37:43

US3412184

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:30:24

Other

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:28:47
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 04:54:06
User entered '1' reason for change: Data Entry Error	(b) (4)	
	Melissa Fuson (b) (4)	23 Sep 2020 16:00:36
User entered '0'	(b) (4)	
	Steven Anderson (b) (4)	17 Aug 2020 23:37:43
	(b) (4)	

US3412184

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:30:24

[Specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:28:47
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 04:54:06
User entered 'Lives in (b) (6) ' reason for change:	Melissa Fuson (b) (4)	23 Sep 2020 16:00:36
Data Entry Error	(b) (4)	
User entered empty.	Steven Anderson (b) (4)	17 Aug 2020 23:37:43

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Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 09 Jun 2021 17:30:24

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:06:09
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 02:43:30
User entered 'Yes (Y)'	Steven Anderson (b) (4)	10 Aug 2020 14:36:47

US3412184

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 09 Jun 2021 17:30:24

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:06:09
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 02:43:30
User entered '10 Aug 2020'	Steven Anderson (b) (4)	10 Aug 2020 14:36:47

US3412184

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 09 Jun 2021 17:30:24

[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 20:06:09
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 02:43:30
User entered 'Clinic (Clinic)'	Steven Anderson (b) (4)	10 Aug 2020 14:36:47

US3412184

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 09 Jun 2021 17:30:24

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:06:09
User entered 'VISIT1'	System	10 Aug 2020 14:36:47

US3412184

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 17:30:24

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:06:09
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 02:43:30
User entered '10 AUG 2020'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	10 Aug 2020 14:14:26

US3412184

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 17:30:24

What was the participant's randomization number?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:06:09
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 02:43:30
Amendment Manager: User closed query 'Data entered is non-conformant. Please correct.' (Site from System).	(b) (4)	21 Aug 2020 03:13:21
Amendment Manager: Data point set to conformant.	System	21 Aug 2020 03:13:21
User opened query 'Data entered is non-conformant. Please correct.' (Site from System).	System	10 Aug 2020 14:14:26
User entered '185180' (non-conformant).	RWS_ENDPOINT ENDPOINT (b) (4)	10 Aug 2020 14:14:26

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Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 17:30:24

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:06:09
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 02:43:30
User entered '>=65 years (3)'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	10 Aug 2020 14:14:26

US3412184

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 17:30:24

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 20:06:09
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 02:43:30
User entered 'No (N)'	Steven Anderson (b) (4)	10 Aug 2020 14:37:00

US3412184

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 17:30:24

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 20:06:09
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 02:43:30
User entered 'No (N)'	Steven Anderson (b) (4)	10 Aug 2020 14:37:00

US3412184

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 17:30:24

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:06:09
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 02:43:30
User entered 'No (N)'	Steven Anderson (b) (4)	10 Aug 2020 14:37:00

US3412184

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 17:30:24

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:06:09
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 02:43:30
User entered 'No (N)'	Steven Anderson (b) (4)	10 Aug 2020 14:37:00

US3412184

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 17:30:24

[Liver Disease](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:06:09
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 02:43:30
User entered 'No (N)'	Steven Anderson (b) (4)	10 Aug 2020 14:37:00

US3412184

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 17:30:24

[Height](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:06:09
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 02:43:30
User entered missing code ND - Not Done.	Steven Anderson (b) (4)	17 Aug 2020 23:40:05

US3412184

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 17:30:24

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:06:09
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 02:43:30
User entered missing code ND - Not Done.	Steven Anderson (b) (4)	17 Aug 2020 23:40:05

US3412184

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 17:30:24

[Height](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:06:09
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 02:43:30
User entered missing code ND - Not Done.	Steven Anderson (b) (4)	17 Aug 2020 23:40:05

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 17:30:24

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:06:09
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 02:43:30
User entered missing code ND - Not Done.	Steven Anderson (b) (4)	17 Aug 2020 23:40:05

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:30:24

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:06:09
User accepted default value 'Pre-Dose (PREDOSE)'	Steven Anderson (b) (4)	17 Aug 2020 23:40:05
	(b) (4)	

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:30:24

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:06:09
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 02:43:30
User entered 'Yes (Y)'	Steven Anderson (b) (4)	17 Aug 2020 23:40:05

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:30:24

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:06:09
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 02:43:30
User entered '10 Aug 2020'	Steven Anderson (b) (4)	17 Aug 2020 23:40:05

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:30:24

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:06:09
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 02:43:30
User entered '09:37'	Steven Anderson (b) (4)	17 Aug 2020 23:40:05

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:30:24

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:06:09
User entered '10 Aug 2020 09:37'	System	17 Aug 2020 23:40:05

US3412184

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:30:24

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:06:09
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 02:43:30
User entered '36.3' C	Steven Anderson (b) (4)	17 Aug 2020 23:40:05

US3412184

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:30:24

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:06:09
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 02:43:30
User entered 'Oral (Oral)'	Steven Anderson (b) (4)	17 Aug 2020 23:40:05

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:30:24

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:06:09
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 02:43:30
User entered empty.	Steven Anderson (b) (4)	17 Aug 2020 23:40:05

US3412184

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:30:24

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:06:09
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 02:43:30
User entered '66'	Steven Anderson (b) (4)	17 Aug 2020 23:40:05

US3412184

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:30:24

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:06:09
User entered 'bpm'	System	17 Aug 2020 23:40:05

US3412184

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:30:24

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:06:09
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 02:43:30
User entered '14'	Steven Anderson (b) (4)	17 Aug 2020 23:40:05

US3412184

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:30:24

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:06:09
User entered 'breaths/min'	System	17 Aug 2020 23:40:05

US3412184

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:30:24

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:06:09
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 02:43:30
User entered '138'	Steven Anderson (b) (4)	17 Aug 2020 23:40:05

US3412184

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:30:24

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:06:09
User entered 'mmHg'	System	17 Aug 2020 23:40:05

US3412184

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:30:24

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:06:09
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 02:43:30
User entered '86'	Steven Anderson (b) (4)	17 Aug 2020 23:40:05

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:30:24

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:06:09
User entered 'mmHg'	System	17 Aug 2020 23:40:05

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 17:30:24

[Height](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:06:09
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 02:43:30
User entered missing code ND - Not Done.	Steven Anderson (b) (4)	17 Aug 2020 23:40:05

US3412184

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 17:30:24

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:06:09
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 02:43:30
User entered missing code ND - Not Done.	Steven Anderson (b) (4)	17 Aug 2020 23:40:05

US3412184

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:30:24

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:06:09
User accepted default value 'Post-Dose (POSTDOSE)'	Steven Anderson (b) (4)	17 Aug 2020 23:40:05

US3412184

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:30:24

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:06:09
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 02:43:30
User entered 'Yes (Y)'	Steven Anderson (b) (4)	17 Aug 2020 23:40:05

US3412184

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:30:24

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:06:09
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 02:43:30
User entered '10 Aug 2020'	Steven Anderson (b) (4)	17 Aug 2020 23:40:05

US3412184

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:30:24

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:06:09
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 02:43:30
Amendment Manager: Query closed during migration process because the edit check no longer exists in target version.	(b) (4)	21 Aug 2020 03:13:18
User opened query 'Post-dose vital signs time is prior to or less than 60 minutes after the Dose Time. Please review and reconcile.' (Site from System).		17 Aug 2020 23:40:05
User entered '11:06'	Steven Anderson (b) (4)	17 Aug 2020 23:40:05
	(b) (4)	

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:30:24

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:06:09
User entered '10 Aug 2020 11:06'	System	17 Aug 2020 23:40:05

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:30:24

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:06:09
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 02:43:30
User entered '97.7' F	Steven Anderson (b) (4)	17 Aug 2020 23:40:05

US3412184

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:30:24

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:06:09
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 02:43:30
User entered 'Oral (Oral)'	Steven Anderson (b) (4)	17 Aug 2020 23:40:05

US3412184

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:30:24

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:06:09
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 02:43:30
User entered empty.	Steven Anderson (b) (4)	17 Aug 2020 23:40:05

US3412184

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:30:24

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:06:09
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 02:43:30
User entered '68'	Steven Anderson (b) (4)	17 Aug 2020 23:40:05

US3412184

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:30:24

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:06:09
User entered 'bpm'	System	17 Aug 2020 23:40:05

US3412184

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:30:24

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:06:09
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 02:43:30
User entered '16'	Steven Anderson (b) (4)	17 Aug 2020 23:40:05

US3412184

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:30:24

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:06:09
User entered 'breaths/min'	System	17 Aug 2020 23:40:05

US3412184

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:30:24

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:06:09
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 02:43:30
User entered '140'	Steven Anderson (b) (4)	17 Aug 2020 23:40:05

US3412184

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:30:24

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:06:09
User entered 'mmHg'	System	17 Aug 2020 23:40:05

US3412184

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:30:24

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:06:09
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 02:43:30
User entered '85'	Steven Anderson (b) (4)	17 Aug 2020 23:40:05

US3412184

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:30:24

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:06:09
User entered 'mmHg'	System	17 Aug 2020 23:40:05

US3412184

Folder: Visit 1 Day 1

Form: Physical Examination

Generated On: 09 Jun 2021 17:30:24

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:06:09
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 02:43:30
User entered 'No (N)'	Steven Anderson (b) (4)	17 Aug 2020 23:40:12

US3412184

Folder: Visit 1 Day 1

Form: Physical Examination

Generated On: 09 Jun 2021 17:30:24

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:06:09
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 02:43:30
User entered empty.	Steven Anderson (b) (4)	17 Aug 2020 23:40:12

US3412184

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 17:30:24

[Was study treatment given?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:06:09
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 02:43:30
User entered 'Yes (Y)'	Steven Anderson (b) (4)	10 Aug 2020 14:48:00

US3412184

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 17:30:24

[If No, reason not given](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:06:09
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 02:43:30
User entered empty.	Steven Anderson (b) (4)	10 Aug 2020 14:48:00

US3412184

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 17:30:24

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 20:06:09
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 02:43:30
User entered empty.	Steven Anderson (b) (4)	10 Aug 2020 14:48:00

US3412184

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 17:30:24

[What was the study treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:06:09
User entered 'MRNA-1273 OR PLACEBO'	System	10 Aug 2020 14:48:00

US3412184

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 17:30:24

What was the treatment date? (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:06:09
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 02:43:30
User entered '10 Aug 2020'	Steven Anderson (b) (4)	10 Aug 2020 14:48:00

US3412184

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 17:30:24

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:06:09
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 02:43:30
User entered '10:35'	Steven Anderson (b) (4)	10 Aug 2020 14:48:00

US3412184

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 17:30:24

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:06:09
User entered '10 Aug 2020 10:35'	System	10 Aug 2020 14:48:00

US3412184

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 17:30:24

Which arm was used to give treatment?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:06:09
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 02:43:30
User entered 'Left Arm (LEFT ARM)'	Steven Anderson (b) (4)	10 Aug 2020 14:48:00

US3412184

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 17:30:24

[What was the frequency of the study treatment dosing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:06:09
User entered 'ONCE'	System	10 Aug 2020 14:48:00

US3412184

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 17:30:24

What was the route of administration for the study treatment?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:06:09
User entered 'INTRAMUSCULAR'	System	10 Aug 2020 14:48:00

US3412184

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:30:24

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:06:09
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 02:43:30
User entered 'Yes (Y)'	Steven Anderson (b) (4)	17 Aug 2020 23:40:28

US3412184

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:30:24

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:06:09
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 02:43:30
User entered '10 Aug 2020'	Steven Anderson (b) (4)	17 Aug 2020 23:40:28

US3412184

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:30:24

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:06:09
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 02:43:30
User entered '10:00'	Steven Anderson (b) (4)	17 Aug 2020 23:40:28

US3412184

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:30:24

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:06:09
User entered '10 Aug 2020 10:00'	System	17 Aug 2020 23:40:28

US3412184

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab

Generated On: 09 Jun 2021 17:30:24

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:06:09
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 02:43:30
User entered '10 Aug 2020'	Steven Anderson (b) (4)	17 Aug 2020 23:40:46

US3412184

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 17:30:24

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:06:09
User accepted default value 'Nasopharyngeal Swab 1 (NASAL1)'	Steven Anderson (b) (4)	17 Aug 2020 23:40:46

US3412184

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 17:30:24

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:06:09
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 02:43:30
User entered 'Yes (Y)'	Steven Anderson (b) (4)	17 Aug 2020 23:40:46

US3412184

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 17:30:24

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:06:09
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 02:43:30
User entered '10:09'	Steven Anderson (b) (4)	17 Aug 2020 23:40:46

US3412184

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 17:30:24

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:06:09
User entered '10 Aug 2020 10:09'	System	17 Aug 2020 23:40:46

US3412184

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 17:30:24

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:06:09
User accepted default value 'Nasopharyngeal Swab 2 (NASAL2)'	Steven Anderson (b) (4)	17 Aug 2020 23:40:46

US3412184

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 17:30:24

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:06:09
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 02:43:30
User entered 'No (N)'	Steven Anderson (b) (4)	17 Aug 2020 23:40:46

US3412184

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 17:30:24

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:06:09
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 02:43:30
User entered empty.	Steven Anderson (b) (4)	17 Aug 2020 23:40:46

US3412184

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 17:30:24

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:06:09
User entered empty.	System	17 Aug 2020 23:40:46

US3412184

Folder: Visit 1 Day 1

Form: Continuing

Generated On: 09 Jun 2021 17:30:24

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:06:09
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 02:43:30
User entered 'Yes (Y)'	Steven Anderson (b) (4)	17 Aug 2020 23:40:52

US3412184

Folder: Visit 1 Day 1

Form: Continuing

Generated On: 09 Jun 2021 17:30:24

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:06:09
User entered 'I'	System	17 Aug 2020 23:40:52

US3412184

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 17:30:24

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:31:53
Data entry locked.	System	10 Aug 2020 14:48:00
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	10 Aug 2020 14:48:00

US3412184

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 17:30:24

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:31:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (63C78D1B-A891-413A-BA58-C2E172B44955)', Time: '2020-08-10T11:07:18', User OID: 'PatientReportedOutcome (US3412184)', ODM File OID: '262e2caa-520e-4f39-9f61-9b2da846cc75'	System	10 Aug 2020 15:07:54
User entered 'Yes (Y)'	System	10 Aug 2020 15:07:54

US3412184

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 17:30:24

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:31:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (63C78D1B-A891-413A-BA58-C2E172B44955)', Time: '2020-08-10T11:07:27', User OID: 'PatientReportedOutcome (US3412184)', ODM File OID: '262e2caa-520e-4f39-9f61-9b2da846cc75' User entered '97.7'	System	10 Aug 2020 15:07:54
	System	10 Aug 2020 15:07:54

US3412184

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 17:30:24

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:31:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (63C78D1B-A891-413A-BA58-C2E172B44955)', Time: '2020-08-10T11:07:44', User OID: 'PatientReportedOutcome (US3412184)', ODM File OID: '262e2caa-520e-4f39-9f61-9b2da846cc75'	System	10 Aug 2020 15:07:54
User entered 'No (N)'	System	10 Aug 2020 15:07:54

US3412184

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 17:30:24

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:31:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (63C78D1B-A891-413A-BA58-C2E172B44955)', Time: '2020-08-10T11:07:51', User OID: 'PatientReportedOutcome (US3412184)', ODM File OID: '262e2caa-520e-4f39-9f61-9b2da846cc75'	System	10 Aug 2020 15:07:54
User entered '10 Aug 2020 11:07'	System	10 Aug 2020 15:07:54

US3412184

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 17:30:24

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:31:53
User entered '10 Aug 2020 10:55'	System	10 Aug 2020 14:48:00

US3412184

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 17:30:24

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:31:53
User entered '10 Aug 2020 13:25'	System	10 Aug 2020 14:48:00

US3412184

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 17:30:24

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:31:53
Data entry locked.	System	10 Aug 2020 14:48:00
User entered 'Day 1, after vaccination (at home)'	System	10 Aug 2020 14:48:00

US3412184

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 17:30:24

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:31:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (63C78D1B-A891-413A-BA58-C2E172B44955)', Time: '2020-08-10T21:13:52', User OID: 'PatientReportedOutcome (US3412184)', ODM File OID: '96ea2e5b-0241-4038-ba10-2297b8b0f81d' User entered 'Yes (Y)'	System	11 Aug 2020 01:14:16
	System	11 Aug 2020 01:14:16

US3412184

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 17:30:24

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:31:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (63C78D1B-A891-413A-BA58-C2E172B44955)', Time: '2020-08-10T21:14:03', User OID: 'PatientReportedOutcome (US3412184)', ODM File OID: '96ea2e5b-0241-4038-ba10-2297b8b0f81d' User entered '98.0'	System	11 Aug 2020 01:14:16
	System	11 Aug 2020 01:14:16

US3412184

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 17:30:24

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:31:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (63C78D1B-A891-413A-BA58-C2E172B44955)', Time: '2020-08-10T21:14:09', User OID: 'PatientReportedOutcome (US3412184)', ODM File OID: '96ea2e5b-0241-4038-ba10-2297b8b0f81d' User entered 'No (N)'	System	11 Aug 2020 01:14:16
	System	11 Aug 2020 01:14:16

US3412184

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 17:30:24

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:31:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (63C78D1B-A891-413A-BA58-C2E172B44955)', Time: '2020-08-10T21:14:14', User OID: 'PatientReportedOutcome (US3412184)', ODM File OID: '96ea2e5b-0241-4038-ba10-2297b8b0f81d' User entered '10 Aug 2020 21:14'	System	11 Aug 2020 01:14:16
	System	11 Aug 2020 01:14:16

US3412184

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 17:30:24

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:31:53
User entered '10 Aug 2020 14:20'	System	10 Aug 2020 14:48:00

US3412184

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 17:30:24

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:31:53
User entered '11 Aug 2020 11:59'	System	10 Aug 2020 14:48:00

US3412184

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 17:30:24

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:31:53
Data entry locked.	System	10 Aug 2020 14:48:00
User entered 'Day 2'	System	10 Aug 2020 14:48:00

US3412184

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 17:30:24

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:31:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (63C78D1B-A891-413A-BA58-C2E172B44955)', Time: '2020-08-12T09:40:20', User OID: 'PatientReportedOutcome (US3412184)', ODM File OID: '904425ef-4fa3-4bb4-b27f-b4d39a3e5221' User entered 'Yes (Y)'	System	12 Aug 2020 13:40:46
	System	12 Aug 2020 13:40:46

US3412184

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 17:30:24

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:31:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (63C78D1B-A891-413A-BA58-C2E172B44955)', Time: '2020-08-12T09:40:30', User OID: 'PatientReportedOutcome (US3412184)', ODM File OID: '904425ef-4fa3-4bb4-b27f-b4d39a3e5221' User entered '98.0'	System	12 Aug 2020 13:40:46
	System	12 Aug 2020 13:40:46

US3412184

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 17:30:24

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:31:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (63C78D1B-A891-413A-BA58-C2E172B44955)', Time: '2020-08-12T09:40:36', User OID: 'PatientReportedOutcome (US3412184)', ODM File OID: '904425ef-4fa3-4bb4-b27f-b4d39a3e5221'	System	12 Aug 2020 13:40:46
User entered 'No (N)'	System	12 Aug 2020 13:40:46

US3412184

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 17:30:24

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:31:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (63C78D1B-A891-413A-BA58-C2E172B44955)', Time: '2020-08-12T09:40:43', User OID: 'PatientReportedOutcome (US3412184)', ODM File OID: '904425ef-4fa3-4bb4-b27f-b4d39a3e5221' User entered '12 Aug 2020 09:40'	System	12 Aug 2020 13:40:46
	System	12 Aug 2020 13:40:46

US3412184

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 17:30:24

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:31:53
User entered '11 Aug 2020 12:00'	System	10 Aug 2020 14:48:00

US3412184

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 17:30:24

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:31:53
User entered '12 Aug 2020 11:59'	System	10 Aug 2020 14:48:00

US3412184

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 17:30:24

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:31:53
Data entry locked.	System	10 Aug 2020 14:48:00
User entered 'Day 3'	System	10 Aug 2020 14:48:00

US3412184

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 17:30:24

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:31:53

US3412184

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 17:30:24

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:31:53

US3412184

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 17:30:24

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:31:53

US3412184

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 17:30:24

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:31:53

US3412184

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 17:30:24

To **PREVENT** pain or fever from occurring

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:31:53

US3412184

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 17:30:24

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:31:53

US3412184

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 17:30:24

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:31:53
User entered '12 Aug 2020 12:00'	System	10 Aug 2020 14:48:00

US3412184

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 17:30:24

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:31:53
User entered '13 Aug 2020 11:59'	System	10 Aug 2020 14:48:00

US3412184

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 17:30:24

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:31:53
Data entry locked.	System	10 Aug 2020 14:48:00
User entered 'Day 4'	System	10 Aug 2020 14:48:00

US3412184

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 17:30:24

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:31:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (63C78D1B-A891-413A-BA58-C2E172B44955)', Time: '2020-08-13T12:39:58', User OID: 'PatientReportedOutcome (US3412184)', ODM File OID: '442c87cd-904f-4fc0-8b2c-7d39510dcf3d' User entered 'Yes (Y)'	System	13 Aug 2020 16:40:17
	System	13 Aug 2020 16:40:17

US3412184

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 17:30:24

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:31:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (63C78D1B-A891-413A-BA58-C2E172B44955)', Time: '2020-08-13T12:40:05', User OID: 'PatientReportedOutcome (US3412184)', ODM File OID: '442c87cd-904f-4fc0-8b2c-7d39510dcf3d' User entered '97.4'	System	13 Aug 2020 16:40:17
	System	13 Aug 2020 16:40:17

US3412184

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 17:30:24

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:31:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (63C78D1B-A891-413A-BA58-C2E172B44955)', Time: '2020-08-13T12:40:10', User OID: 'PatientReportedOutcome (US3412184)', ODM File OID: '442c87cd-904f-4fc0-8b2c-7d39510dcf3d' User entered 'No (N)'	System	13 Aug 2020 16:40:17
	System	13 Aug 2020 16:40:17

US3412184

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 17:30:24

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:31:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (63C78D1B-A891-413A-BA58-C2E172B44955)', Time: '2020-08-13T12:40:15', User OID: 'PatientReportedOutcome (US3412184)', ODM File OID: '442c87cd-904f-4fc0-8b2c-7d39510dcf3d' User entered '13 Aug 2020 12:40'	System	13 Aug 2020 16:40:17
	System	13 Aug 2020 16:40:17

US3412184

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 17:30:24

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:31:53
User entered '13 Aug 2020 12:00'	System	10 Aug 2020 14:48:00

US3412184

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 17:30:24

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:31:53
User entered '14 Aug 2020 11:59'	System	10 Aug 2020 14:48:00

US3412184

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 17:30:24

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:31:53
Data entry locked.	System	10 Aug 2020 14:48:00
User entered 'Day 5'	System	10 Aug 2020 14:48:00

US3412184

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 17:30:24

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:31:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (63C78D1B-A891-413A-BA58-C2E172B44955)', Time: '2020-08-14T20:49:29', User OID: 'PatientReportedOutcome (US3412184)', ODM File OID: '2a97dbbe-5e1f-4c4f-b239-41a5db5165d9' User entered 'Yes (Y)'	System	15 Aug 2020 00:49:58
	System	15 Aug 2020 00:49:58

US3412184

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 17:30:24

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:31:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (63C78D1B-A891-413A-BA58-C2E172B44955)', Time: '2020-08-14T20:49:36', User OID: 'PatientReportedOutcome (US3412184)', ODM File OID: '2a97dbbe-5e1f-4c4f-b239-41a5db5165d9'	System	15 Aug 2020 00:49:58
User entered '98.0'	System	15 Aug 2020 00:49:58

US3412184

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 17:30:24

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:31:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (63C78D1B-A891-413A-BA58-C2E172B44955)', Time: '2020-08-14T20:49:51', User OID: 'PatientReportedOutcome (US3412184)', ODM File OID: '2a97dbbe-5e1f-4c4f-b239-41a5db5165d9'	System	15 Aug 2020 00:49:58
User entered 'No (N)'	System	15 Aug 2020 00:49:58

US3412184

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 17:30:24

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:31:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (63C78D1B-A891-413A-BA58-C2E172B44955)', Time: '2020-08-14T20:49:55', User OID: 'PatientReportedOutcome (US3412184)', ODM File OID: '2a97dbbe-5e1f-4c4f-b239-41a5db5165d9'	System	15 Aug 2020 00:49:58
User entered '14 Aug 2020 20:49'	System	15 Aug 2020 00:49:58

US3412184

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 17:30:24

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:31:53
User entered '14 Aug 2020 12:00'	System	10 Aug 2020 14:48:00

US3412184

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 17:30:24

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:31:53
User entered '15 Aug 2020 11:59'	System	10 Aug 2020 14:48:00

US3412184

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 17:30:24

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:31:53
Data entry locked.	System	10 Aug 2020 14:48:00
User entered 'Day 6'	System	10 Aug 2020 14:48:00

US3412184

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 17:30:24

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:31:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (63C78D1B-A891-413A-BA58-C2E172B44955)', Time: '2020-08-15T23:48:02', User OID: 'PatientReportedOutcome (US3412184)', ODM File OID: 'eb2fcb6a-b94c-461c-874a-8e2128967a34' User entered 'Yes (Y)'	System	16 Aug 2020 03:48:26
	System	16 Aug 2020 03:48:26

US3412184

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 17:30:24

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:31:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (63C78D1B-A891-413A-BA58-C2E172B44955)', Time: '2020-08-15T23:48:09', User OID: 'PatientReportedOutcome (US3412184)', ODM File OID: 'eb2fcb6a-b94c-461c-874a-8e2128967a34' User entered '97.6'	System	16 Aug 2020 03:48:26
	System	16 Aug 2020 03:48:26

US3412184

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 17:30:24

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:31:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (63C78D1B-A891-413A-BA58-C2E172B44955)', Time: '2020-08-15T23:48:16', User OID: 'PatientReportedOutcome (US3412184)', ODM File OID: 'eb2fcb6a-b94c-461c-874a-8e2128967a34'	System	16 Aug 2020 03:48:26
User entered 'No (N)'	System	16 Aug 2020 03:48:26

US3412184

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 17:30:24

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:31:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (63C78D1B-A891-413A-BA58-C2E172B44955)', Time: '2020-08-15T23:48:20', User OID: 'PatientReportedOutcome (US3412184)', ODM File OID: 'eb2fcb6a-b94c-461c-874a-8e2128967a34'	System	16 Aug 2020 03:48:26
User entered '15 Aug 2020 23:48'	System	16 Aug 2020 03:48:26

US3412184

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 17:30:24

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:31:53
User entered '15 Aug 2020 12:00'	System	10 Aug 2020 14:48:00

US3412184

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 17:30:24

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:31:53
User entered '16 Aug 2020 11:59'	System	10 Aug 2020 14:48:00

US3412184

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 17:30:24

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:31:53
Data entry locked.	System	10 Aug 2020 14:48:00
User entered 'Day 7'	System	10 Aug 2020 14:48:00

US3412184

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 17:30:24

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:31:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (63C78D1B-A891-413A-BA58-C2E172B44955)', Time: '2020-08-16T22:30:41', User OID: 'PatientReportedOutcome (US3412184)', ODM File OID: '58ffdb31-85f4-40ea-901b-25df75918a76'	System	17 Aug 2020 02:31:02
User entered 'Yes (Y)'	System	17 Aug 2020 02:31:02

US3412184

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 17:30:24

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:31:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (63C78D1B-A891-413A-BA58-C2E172B44955)', Time: '2020-08-16T22:30:49', User OID: 'PatientReportedOutcome (US3412184)', ODM File OID: '58ffdb31-85f4-40ea-901b-25df75918a76'	System	17 Aug 2020 02:31:02
User entered '95.6'	System	17 Aug 2020 02:31:02

US3412184

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 17:30:24

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:31:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (63C78D1B-A891-413A-BA58-C2E172B44955)', Time: '2020-08-16T22:30:55', User OID: 'PatientReportedOutcome (US3412184)', ODM File OID: '58ffdb31-85f4-40ea-901b-25df75918a76'	System	17 Aug 2020 02:31:02
User entered 'No (N)'	System	17 Aug 2020 02:31:02

US3412184

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 17:30:24

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:31:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (63C78D1B-A891-413A-BA58-C2E172B44955)', Time: '2020-08-16T22:30:58', User OID: 'PatientReportedOutcome (US3412184)', ODM File OID: '58ffdb31-85f4-40ea-901b-25df75918a76'	System	17 Aug 2020 02:31:02
User entered '16 Aug 2020 22:30'	System	17 Aug 2020 02:31:02

US3412184

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 17:30:24

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:31:53
User entered '16 Aug 2020 12:00'	System	10 Aug 2020 14:48:00

US3412184

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 17:30:24

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:31:53
User entered '17 Aug 2020 11:59'	System	10 Aug 2020 14:48:00

US3412184

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 17:30:24

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:31:53
Data entry locked.	System	10 Aug 2020 14:48:00
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	10 Aug 2020 14:48:00

US3412184

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 17:30:24

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 10:31:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (63C78D1B-A891-413A-BA58-C2E172B44955)', Time: '2020-08-10T11:11:52', User OID: 'PatientReportedOutcome (US3412184)', ODM File OID: '520c77e9-f9c8-47d9-a623-16ff5f66db22'	System	10 Aug 2020 15:12:32
User entered 'None (1)'	System	10 Aug 2020 15:12:32

US3412184

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 17:30:24

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:31:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (63C78D1B-A891-413A-BA58-C2E172B44955)', Time: '2020-08-10T11:12:00', User OID: 'PatientReportedOutcome (US3412184)', ODM File OID: '520c77e9-f9c8-47d9-a623-16ff5f66db22'	System	10 Aug 2020 15:12:32
User entered 'No (N)'	System	10 Aug 2020 15:12:32

US3412184

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 17:30:24

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:31:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (63C78D1B-A891-413A-BA58-C2E172B44955)', Time: '2020-08-10T11:12:06', User OID: 'PatientReportedOutcome (US3412184)', ODM File OID: '520c77e9-f9c8-47d9-a623-16ff5f66db22'	System	10 Aug 2020 15:12:32
User entered 'No (N)'	System	10 Aug 2020 15:12:32

US3412184

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 17:30:24

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 10:31:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (63C78D1B-A891-413A-BA58-C2E172B44955)', Time: '2020-08-10T11:12:24', User OID: 'PatientReportedOutcome (US3412184)', ODM File OID: '520c77e9-f9c8-47d9-a623-16ff5f66db22'	System	10 Aug 2020 15:12:32
User entered 'None (1)'	System	10 Aug 2020 15:12:32

US3412184

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 17:30:24

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:31:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (63C78D1B-A891-413A-BA58-C2E172B44955)', Time: '2020-08-10T11:12:27', User OID: 'PatientReportedOutcome (US3412184)', ODM File OID: '520c77e9-f9c8-47d9-a623-16ff5f66db22'	System	10 Aug 2020 15:12:32
User entered '10 Aug 2020 11:12'	System	10 Aug 2020 15:12:32

US3412184

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 17:30:24

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:31:53
User entered '10 Aug 2020 10:55'	System	10 Aug 2020 14:48:00

US3412184

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 17:30:24

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:31:53
User entered '10 Aug 2020 13:25'	System	10 Aug 2020 14:48:00

US3412184

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 17:30:24

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:31:53
Data entry locked.	System	10 Aug 2020 14:48:00
User entered 'Day 1, after vaccination (at home)'	System	10 Aug 2020 14:48:00

US3412184

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 17:30:24

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 10:31:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (63C78D1B-A891-413A-BA58-C2E172B44955)', Time: '2020-08-10T21:16:11', User OID: 'PatientReportedOutcome (US3412184)', ODM File OID: '0e616c63-4dbf-40b7-8e58-33def0a6f542'	System	11 Aug 2020 01:16:52
User entered 'None (1)'	System	11 Aug 2020 01:16:52

US3412184

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 17:30:24

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:31:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (63C78D1B-A891-413A-BA58-C2E172B44955)', Time: '2020-08-10T21:16:31', User OID: 'PatientReportedOutcome (US3412184)', ODM File OID: '0e616c63-4dbf-40b7-8e58-33def0a6f542' User entered 'No (N)'	System	11 Aug 2020 01:16:52
	System	11 Aug 2020 01:16:52

US3412184

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 17:30:24

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:31:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (63C78D1B-A891-413A-BA58-C2E172B44955)', Time: '2020-08-10T21:16:38', User OID: 'PatientReportedOutcome (US3412184)', ODM File OID: '0e616c63-4dbf-40b7-8e58-33def0a6f542' User entered 'No (N)'	System	11 Aug 2020 01:16:52
	System	11 Aug 2020 01:16:52

US3412184

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 17:30:24

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 10:31:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (63C78D1B-A891-413A-BA58-C2E172B44955)', Time: '2020-08-10T21:16:45', User OID: 'PatientReportedOutcome (US3412184)', ODM File OID: '0e616c63-4dbf-40b7-8e58-33def0a6f542'	System	11 Aug 2020 01:16:52
User entered 'None (1)'	System	11 Aug 2020 01:16:52

US3412184

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 17:30:24

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:31:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (63C78D1B-A891-413A-BA58-C2E172B44955)', Time: '2020-08-10T21:16:49', User OID: 'PatientReportedOutcome (US3412184)', ODM File OID: '0e616c63-4dbf-40b7-8e58-33def0a6f542'	System	11 Aug 2020 01:16:52
User entered '10 Aug 2020 21:16'	System	11 Aug 2020 01:16:52

US3412184

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 17:30:24

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:31:53
User entered '10 Aug 2020 14:20'	System	10 Aug 2020 14:48:00

US3412184

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 17:30:24

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:31:53
User entered '11 Aug 2020 11:59'	System	10 Aug 2020 14:48:00

US3412184

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 17:30:24

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:31:53
Data entry locked.	System	10 Aug 2020 14:48:00
User entered 'Day 2'	System	10 Aug 2020 14:48:00

US3412184

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 17:30:24

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 10:31:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (63C78D1B-A891-413A-BA58-C2E172B44955)', Time: '2020-08-12T09:40:49', User OID: 'PatientReportedOutcome (US3412184)', ODM File OID: '57529f0a-074e-489f-8d81-21674f44e74c' User entered 'None (1)'	System	12 Aug 2020 13:41:06
	System	12 Aug 2020 13:41:06

US3412184

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 17:30:24

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:31:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (63C78D1B-A891-413A-BA58-C2E172B44955)', Time: '2020-08-12T09:40:53', User OID: 'PatientReportedOutcome (US3412184)', ODM File OID: '57529f0a-074e-489f-8d81-21674f44e74c' User entered 'No (N)'	System	12 Aug 2020 13:41:06
	System	12 Aug 2020 13:41:06

US3412184

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 17:30:24

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:31:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (63C78D1B-A891-413A-BA58-C2E172B44955)', Time: '2020-08-12T09:40:56', User OID: 'PatientReportedOutcome (US3412184)', ODM File OID: '57529f0a-074e-489f-8d81-21674f44e74c' User entered 'No (N)'	System	12 Aug 2020 13:41:06
	System	12 Aug 2020 13:41:06

US3412184

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 17:30:24

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 10:31:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (63C78D1B-A891-413A-BA58-C2E172B44955)', Time: '2020-08-12T09:41:01', User OID: 'PatientReportedOutcome (US3412184)', ODM File OID: '57529f0a-074e-489f-8d81-21674f44e74c' User entered 'None (1)'	System	12 Aug 2020 13:41:06
	System	12 Aug 2020 13:41:06

US3412184

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 17:30:24

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:31:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (63C78D1B-A891-413A-BA58-C2E172B44955)', Time: '2020-08-12T09:41:04', User OID: 'PatientReportedOutcome (US3412184)', ODM File OID: '57529f0a-074e-489f-8d81-21674f44e74c' User entered '12 Aug 2020 09:41'	System	12 Aug 2020 13:41:06
	System	12 Aug 2020 13:41:06

US3412184

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 17:30:24

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:31:53
User entered '11 Aug 2020 12:00'	System	10 Aug 2020 14:48:00

US3412184

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 17:30:24

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:31:53
User entered '12 Aug 2020 11:59'	System	10 Aug 2020 14:48:00

US3412184

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 17:30:24

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:31:53
Data entry locked.	System	10 Aug 2020 14:48:00
User entered 'Day 3'	System	10 Aug 2020 14:48:00

US3412184

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 17:30:24

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 10:31:53

US3412184

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 17:30:24

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:31:53

US3412184

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 17:30:24

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 10:31:53

US3412184

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 17:30:24

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:31:53

US3412184

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 17:30:24

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 10:31:53

US3412184

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 17:30:24

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 10:31:53

US3412184

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 17:30:24

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:31:53

US3412184

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 17:30:24

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:31:53
User entered '12 Aug 2020 12:00'	System	10 Aug 2020 14:48:00

US3412184

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 17:30:24

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:31:53
User entered '13 Aug 2020 11:59'	System	10 Aug 2020 14:48:00

US3412184

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 17:30:24

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:31:53
Data entry locked.	System	10 Aug 2020 14:48:00
User entered 'Day 4'	System	10 Aug 2020 14:48:00

US3412184

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 17:30:24

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 10:31:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (63C78D1B-A891-413A-BA58-C2E172B44955)', Time: '2020-08-13T12:40:19', User OID: 'PatientReportedOutcome (US3412184)', ODM File OID: 'c6027e8a-db68-4b7f-a606-eba4e7512e67' User entered 'None (1)'	System	13 Aug 2020 16:40:34
	System	13 Aug 2020 16:40:34

US3412184

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 17:30:24

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:31:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (63C78D1B-A891-413A-BA58-C2E172B44955)', Time: '2020-08-13T12:40:22', User OID: 'PatientReportedOutcome (US3412184)', ODM File OID: 'c6027e8a-db68-4b7f-a606-eba4e7512e67' User entered 'No (N)'	System	13 Aug 2020 16:40:34
	System	13 Aug 2020 16:40:34

US3412184

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 17:30:24

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:31:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (63C78D1B-A891-413A-BA58-C2E172B44955)', Time: '2020-08-13T12:40:25', User OID: 'PatientReportedOutcome (US3412184)', ODM File OID: 'c6027e8a-db68-4b7f-a606-eba4e7512e67' User entered 'No (N)'	System	13 Aug 2020 16:40:34
	System	13 Aug 2020 16:40:34

US3412184

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 17:30:24

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 10:31:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (63C78D1B-A891-413A-BA58-C2E172B44955)', Time: '2020-08-13T12:40:27', User OID: 'PatientReportedOutcome (US3412184)', ODM File OID: 'c6027e8a-db68-4b7f-a606-eba4e7512e67' User entered 'None (1)'	System	13 Aug 2020 16:40:34
	System	13 Aug 2020 16:40:34

US3412184

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 17:30:24

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:31:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (63C78D1B-A891-413A-BA58-C2E172B44955)', Time: '2020-08-13T12:40:30', User OID: 'PatientReportedOutcome (US3412184)', ODM File OID: 'c6027e8a-db68-4b7f-a606-eba4e7512e67'	System	13 Aug 2020 16:40:34
User entered '13 Aug 2020 12:40'	System	13 Aug 2020 16:40:34

US3412184

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 17:30:24

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:31:53
User entered '13 Aug 2020 12:00'	System	10 Aug 2020 14:48:00

US3412184

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 17:30:24

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:31:53
User entered '14 Aug 2020 11:59'	System	10 Aug 2020 14:48:00

US3412184

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 17:30:24

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:31:53
Data entry locked.	System	10 Aug 2020 14:48:00
User entered 'Day 5'	System	10 Aug 2020 14:48:00

US3412184

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 17:30:24

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 10:31:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (63C78D1B-A891-413A-BA58-C2E172B44955)', Time: '2020-08-14T20:50:02', User OID: 'PatientReportedOutcome (US3412184)', ODM File OID: '043bf993-41b9-4e96-b532-049b4c993433'	System	15 Aug 2020 00:50:25
User entered 'None (1)'	System	15 Aug 2020 00:50:25

US3412184

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 17:30:24

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:31:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (63C78D1B-A891-413A-BA58-C2E172B44955)', Time: '2020-08-14T20:50:08', User OID: 'PatientReportedOutcome (US3412184)', ODM File OID: '043bf993-41b9-4e96-b532-049b4c993433'	System	15 Aug 2020 00:50:25
User entered 'No (N)'	System	15 Aug 2020 00:50:25

US3412184

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 17:30:24

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:31:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (63C78D1B-A891-413A-BA58-C2E172B44955)', Time: '2020-08-14T20:50:13', User OID: 'PatientReportedOutcome (US3412184)', ODM File OID: '043bf993-41b9-4e96-b532-049b4c993433'	System	15 Aug 2020 00:50:25
User entered 'No (N)'	System	15 Aug 2020 00:50:25

US3412184

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 17:30:24

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 10:31:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (63C78D1B-A891-413A-BA58-C2E172B44955)', Time: '2020-08-14T20:50:20', User OID: 'PatientReportedOutcome (US3412184)', ODM File OID: '043bf993-41b9-4e96-b532-049b4c993433'	System	15 Aug 2020 00:50:25
User entered 'None (1)'	System	15 Aug 2020 00:50:25

US3412184

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 17:30:24

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:31:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (63C78D1B-A891-413A-BA58-C2E172B44955)', Time: '2020-08-14T20:50:24', User OID: 'PatientReportedOutcome (US3412184)', ODM File OID: '043bf993-41b9-4e96-b532-049b4c993433'	System	15 Aug 2020 00:50:25
User entered '14 Aug 2020 20:50'	System	15 Aug 2020 00:50:25

US3412184

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 17:30:24

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:31:53
User entered '14 Aug 2020 12:00'	System	10 Aug 2020 14:48:00

US3412184

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 17:30:24

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:31:53
User entered '15 Aug 2020 11:59'	System	10 Aug 2020 14:48:00

US3412184

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 17:30:24

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:31:53
Data entry locked.	System	10 Aug 2020 14:48:00
User entered 'Day 6'	System	10 Aug 2020 14:48:00

US3412184

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 17:30:24

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 10:31:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (63C78D1B-A891-413A-BA58-C2E172B44955)', Time: '2020-08-15T23:48:26', User OID: 'PatientReportedOutcome (US3412184)', ODM File OID: '6d2f3ae2-7f24-4fb7-9062-cad85fd9cc7f' User entered 'None (1)'	System	16 Aug 2020 03:48:48
	System	16 Aug 2020 03:48:48

US3412184

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 17:30:24

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:31:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (63C78D1B-A891-413A-BA58-C2E172B44955)', Time: '2020-08-15T23:48:30', User OID: 'PatientReportedOutcome (US3412184)', ODM File OID: '6d2f3ae2-7f24-4fb7-9062-cad85fd9cc7f' User entered 'No (N)'	System	16 Aug 2020 03:48:48
	System	16 Aug 2020 03:48:48

US3412184

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 17:30:24

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:31:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (63C78D1B-A891-413A-BA58-C2E172B44955)', Time: '2020-08-15T23:48:37', User OID: 'PatientReportedOutcome (US3412184)', ODM File OID: '6d2f3ae2-7f24-4fb7-9062-cad85fd9cc7f' User entered 'No (N)'	System	16 Aug 2020 03:48:48
	System	16 Aug 2020 03:48:48

US3412184

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 17:30:24

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 10:31:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (63C78D1B-A891-413A-BA58-C2E172B44955)', Time: '2020-08-15T23:48:44', User OID: 'PatientReportedOutcome (US3412184)', ODM File OID: '6d2f3ae2-7f24-4fb7-9062-cad85fd9cc7f' User entered 'None (1)'	System	16 Aug 2020 03:48:48
	System	16 Aug 2020 03:48:48

US3412184

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 17:30:24

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:31:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (63C78D1B-A891-413A-BA58-C2E172B44955)', Time: '2020-08-15T23:48:47', User OID: 'PatientReportedOutcome (US3412184)', ODM File OID: '6d2f3ae2-7f24-4fb7-9062-cad85fd9cc7f' User entered '15 Aug 2020 23:48'	System	16 Aug 2020 03:48:48
	System	16 Aug 2020 03:48:48

US3412184

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 17:30:24

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:31:53
User entered '15 Aug 2020 12:00'	System	10 Aug 2020 14:48:00

US3412184

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 17:30:24

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:31:53
User entered '16 Aug 2020 11:59'	System	10 Aug 2020 14:48:00

US3412184

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 17:30:24

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:31:53
Data entry locked.	System	10 Aug 2020 14:48:00
User entered 'Day 7'	System	10 Aug 2020 14:48:00

US3412184

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 17:30:24

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 10:31:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (63C78D1B-A891-413A-BA58-C2E172B44955)', Time: '2020-08-16T22:31:04', User OID: 'PatientReportedOutcome (US3412184)', ODM File OID: 'f9dad119-f419-413d-af2d-1289f73982c3'	System	17 Aug 2020 02:31:34
User entered 'None (1)'	System	17 Aug 2020 02:31:34

US3412184

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 17:30:24

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:31:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (63C78D1B-A891-413A-BA58-C2E172B44955)', Time: '2020-08-16T22:31:12', User OID: 'PatientReportedOutcome (US3412184)', ODM File OID: 'f9dad119-f419-413d-af2d-1289f73982c3'	System	17 Aug 2020 02:31:34
User entered 'No (N)'	System	17 Aug 2020 02:31:34

US3412184

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 17:30:24

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:31:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (63C78D1B-A891-413A-BA58-C2E172B44955)', Time: '2020-08-16T22:31:21', User OID: 'PatientReportedOutcome (US3412184)', ODM File OID: 'f9dad119-f419-413d-af2d-1289f73982c3' User entered 'No (N)'	System	17 Aug 2020 02:31:34
	System	17 Aug 2020 02:31:34

US3412184

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 17:30:24

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 10:31:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (63C78D1B-A891-413A-BA58-C2E172B44955)', Time: '2020-08-16T22:31:28', User OID: 'PatientReportedOutcome (US3412184)', ODM File OID: 'f9dad119-f419-413d-af2d-1289f73982c3' User entered 'None (1)'	System	17 Aug 2020 02:31:34
	System	17 Aug 2020 02:31:34

US3412184

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 17:30:24

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:31:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (63C78D1B-A891-413A-BA58-C2E172B44955)', Time: '2020-08-16T22:31:31', User OID: 'PatientReportedOutcome (US3412184)', ODM File OID: 'f9dad119-f419-413d-af2d-1289f73982c3'	System	17 Aug 2020 02:31:34
User entered '16 Aug 2020 22:31'	System	17 Aug 2020 02:31:34

US3412184

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 17:30:24

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:31:53
User entered '16 Aug 2020 12:00'	System	10 Aug 2020 14:48:00

US3412184

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 17:30:24

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:31:53
User entered '17 Aug 2020 11:59'	System	10 Aug 2020 14:48:00

US3412184

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:30:24

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:31:53
Data entry locked.	System	10 Aug 2020 14:48:00
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	10 Aug 2020 14:48:00

US3412184

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:30:24

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:31:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (63C78D1B-A891-413A-BA58-C2E172B44955)', Time: '2020-08-10T11:12:47', User OID: 'PatientReportedOutcome (US3412184)', ODM File OID: '34d373b1-68b0-4079-be81-b1f36938ed0f' User entered 'None (0)'	System	10 Aug 2020 15:13:19
	System	10 Aug 2020 15:13:19

US3412184

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:30:24

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:31:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (63C78D1B-A891-413A-BA58-C2E172B44955)', Time: '2020-08-10T11:12:49', User OID: 'PatientReportedOutcome (US3412184)', ODM File OID: '34d373b1-68b0-4079-be81-b1f36938ed0f' User entered 'None (0)'	System	10 Aug 2020 15:13:19
	System	10 Aug 2020 15:13:19

US3412184

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:30:24

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:31:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (63C78D1B-A891-413A-BA58-C2E172B44955)', Time: '2020-08-10T11:12:52', User OID: 'PatientReportedOutcome (US3412184)', ODM File OID: '34d373b1-68b0-4079-be81-b1f36938ed0f' User entered 'None (0)'	System	10 Aug 2020 15:13:19
	System	10 Aug 2020 15:13:19

US3412184

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:30:24

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:31:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (63C78D1B-A891-413A-BA58-C2E172B44955)', Time: '2020-08-10T11:13:04', User OID: 'PatientReportedOutcome (US3412184)', ODM File OID: '34d373b1-68b0-4079-be81-b1f36938ed0f' User entered 'None (0)'	System	10 Aug 2020 15:13:19
	System	10 Aug 2020 15:13:19

US3412184

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:30:24

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:31:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (63C78D1B-A891-413A-BA58-C2E172B44955)', Time: '2020-08-10T11:13:06', User OID: 'PatientReportedOutcome (US3412184)', ODM File OID: '34d373b1-68b0-4079-be81-b1f36938ed0f' User entered 'None (0)'	System	10 Aug 2020 15:13:19
	System	10 Aug 2020 15:13:19

US3412184

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:30:24

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:31:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (63C78D1B-A891-413A-BA58-C2E172B44955)', Time: '2020-08-10T11:13:08', User OID: 'PatientReportedOutcome (US3412184)', ODM File OID: '34d373b1-68b0-4079-be81-b1f36938ed0f' User entered 'None (0)'	System	10 Aug 2020 15:13:19
	System	10 Aug 2020 15:13:19

US3412184

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:30:24

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 10:31:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (63C78D1B-A891-413A-BA58-C2E172B44955)', Time: '2020-08-10T11:13:13', User OID: 'PatientReportedOutcome (US3412184)', ODM File OID: '34d373b1-68b0-4079-be81-b1f36938ed0f' User entered 'No (N)'	System	10 Aug 2020 15:13:19
	System	10 Aug 2020 15:13:19

US3412184

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:30:24

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:31:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (63C78D1B-A891-413A-BA58-C2E172B44955)', Time: '2020-08-10T11:13:16', User OID: 'PatientReportedOutcome (US3412184)', ODM File OID: '34d373b1-68b0-4079-be81-b1f36938ed0f' User entered '10 Aug 2020 11:13'	System	10 Aug 2020 15:13:19
	System	10 Aug 2020 15:13:19

US3412184

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:30:24

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:31:53
User entered '10 Aug 2020 10:55'	System	10 Aug 2020 14:48:00

US3412184

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:30:24

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:31:53
User entered '10 Aug 2020 13:25'	System	10 Aug 2020 14:48:00

US3412184

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:30:24

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:31:53
Data entry locked.	System	10 Aug 2020 14:48:00
User entered 'Day 1, after vaccination (at home)'	System	10 Aug 2020 14:48:00

US3412184

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:30:24

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:31:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (63C78D1B-A891-413A-BA58-C2E172B44955)', Time: '2020-08-10T21:16:54', User OID: 'PatientReportedOutcome (US3412184)', ODM File OID: 'c15be117-7434-4bd5-bda2-19c686d753c1' User entered 'None (0)'	System	11 Aug 2020 01:17:31
	System	11 Aug 2020 01:17:31

US3412184

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:30:24

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:31:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (63C78D1B-A891-413A-BA58-C2E172B44955)', Time: '2020-08-10T21:16:59', User OID: 'PatientReportedOutcome (US3412184)', ODM File OID: 'c15be117-7434-4bd5-bda2-19c686d753c1' User entered 'None (0)'	System	11 Aug 2020 01:17:31
	System	11 Aug 2020 01:17:31

US3412184

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:30:24

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:31:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (63C78D1B-A891-413A-BA58-C2E172B44955)', Time: '2020-08-10T21:17:07', User OID: 'PatientReportedOutcome (US3412184)', ODM File OID: 'c15be117-7434-4bd5-bda2-19c686d753c1' User entered 'None (0)'	System	11 Aug 2020 01:17:31
	System	11 Aug 2020 01:17:31

US3412184

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:30:24

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:31:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (63C78D1B-A891-413A-BA58-C2E172B44955)', Time: '2020-08-10T21:17:10', User OID: 'PatientReportedOutcome (US3412184)', ODM File OID: 'c15be117-7434-4bd5-bda2-19c686d753c1' User entered 'None (0)'	System	11 Aug 2020 01:17:31
	System	11 Aug 2020 01:17:31

US3412184

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:30:24

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:31:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (63C78D1B-A891-413A-BA58-C2E172B44955)', Time: '2020-08-10T21:17:13', User OID: 'PatientReportedOutcome (US3412184)', ODM File OID: 'c15be117-7434-4bd5-bda2-19c686d753c1' User entered 'None (0)'	System	11 Aug 2020 01:17:31
	System	11 Aug 2020 01:17:31

US3412184

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:30:24

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:31:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (63C78D1B-A891-413A-BA58-C2E172B44955)', Time: '2020-08-10T21:17:16', User OID: 'PatientReportedOutcome (US3412184)', ODM File OID: 'c15be117-7434-4bd5-bda2-19c686d753c1' User entered 'None (0)'	System	11 Aug 2020 01:17:31
	System	11 Aug 2020 01:17:31

US3412184

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:30:24

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 10:31:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (63C78D1B-A891-413A-BA58-C2E172B44955)', Time: '2020-08-10T21:17:24', User OID: 'PatientReportedOutcome (US3412184)', ODM File OID: 'c15be117-7434-4bd5-bda2-19c686d753c1' User entered 'No (N)'	System	11 Aug 2020 01:17:31
	System	11 Aug 2020 01:17:31

US3412184

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:30:24

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:31:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (63C78D1B-A891-413A-BA58-C2E172B44955)', Time: '2020-08-10T21:17:28', User OID: 'PatientReportedOutcome (US3412184)', ODM File OID: 'c15be117-7434-4bd5-bda2-19c686d753c1' User entered '10 Aug 2020 21:17'	System	11 Aug 2020 01:17:31
	System	11 Aug 2020 01:17:31

US3412184

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:30:24

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:31:53
User entered '10 Aug 2020 14:20'	System	10 Aug 2020 14:48:00

US3412184

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:30:24

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:31:53
User entered '11 Aug 2020 11:59'	System	10 Aug 2020 14:48:00

US3412184

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:30:24

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:31:53
Data entry locked.	System	10 Aug 2020 14:48:00
User entered 'Day 2'	System	10 Aug 2020 14:48:00

US3412184

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:30:24

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:31:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (63C78D1B-A891-413A-BA58-C2E172B44955)', Time: '2020-08-12T09:41:11', User OID: 'PatientReportedOutcome (US3412184)', ODM File OID: 'b26a818f-55f8-402f-b998-e3efbfc194cf'	System	12 Aug 2020 13:41:34
User entered 'None (0)'	System	12 Aug 2020 13:41:34

US3412184

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:30:24

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:31:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (63C78D1B-A891-413A-BA58-C2E172B44955)', Time: '2020-08-12T09:41:14', User OID: 'PatientReportedOutcome (US3412184)', ODM File OID: 'b26a818f-55f8-402f-b998-e3efbfc194cf' User entered 'None (0)'	System	12 Aug 2020 13:41:34
	System	12 Aug 2020 13:41:34

US3412184

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:30:24

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:31:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (63C78D1B-A891-413A-BA58-C2E172B44955)', Time: '2020-08-12T09:41:17', User OID: 'PatientReportedOutcome (US3412184)', ODM File OID: 'b26a818f-55f8-402f-b998-e3efbfc194cf'	System	12 Aug 2020 13:41:34
User entered 'None (0)'	System	12 Aug 2020 13:41:34

US3412184

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:30:24

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:31:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (63C78D1B-A891-413A-BA58-C2E172B44955)', Time: '2020-08-12T09:41:20', User OID: 'PatientReportedOutcome (US3412184)', ODM File OID: 'b26a818f-55f8-402f-b998-e3efbfc194cf' User entered 'None (0)'	System	12 Aug 2020 13:41:34
	System	12 Aug 2020 13:41:34

US3412184

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:30:24

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:31:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (63C78D1B-A891-413A-BA58-C2E172B44955)', Time: '2020-08-12T09:41:23', User OID: 'PatientReportedOutcome (US3412184)', ODM File OID: 'b26a818f-55f8-402f-b998-e3efbfc194cf'	System	12 Aug 2020 13:41:34
User entered 'None (0)'	System	12 Aug 2020 13:41:34

US3412184

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:30:24

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:31:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (63C78D1B-A891-413A-BA58-C2E172B44955)', Time: '2020-08-12T09:41:25', User OID: 'PatientReportedOutcome (US3412184)', ODM File OID: 'b26a818f-55f8-402f-b998-e3efbfc194cf' User entered 'None (0)'	System	12 Aug 2020 13:41:34
	System	12 Aug 2020 13:41:34

US3412184

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:30:24

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 10:31:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (63C78D1B-A891-413A-BA58-C2E172B44955)', Time: '2020-08-12T09:41:29', User OID: 'PatientReportedOutcome (US3412184)', ODM File OID: 'b26a818f-55f8-402f-b998-e3efbfc194cf' User entered 'No (N)'	System	12 Aug 2020 13:41:34
	System	12 Aug 2020 13:41:34

US3412184

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:30:24

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:31:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (63C78D1B-A891-413A-BA58-C2E172B44955)', Time: '2020-08-12T09:41:32', User OID: 'PatientReportedOutcome (US3412184)', ODM File OID: 'b26a818f-55f8-402f-b998-e3efbfc194cf'	System	12 Aug 2020 13:41:34
User entered '12 Aug 2020 09:41'	System	12 Aug 2020 13:41:34

US3412184

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:30:24

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:31:53
User entered '11 Aug 2020 12:00'	System	10 Aug 2020 14:48:00

US3412184

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:30:24

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:31:53
User entered '12 Aug 2020 11:59'	System	10 Aug 2020 14:48:00

US3412184

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:30:24

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:31:53
Data entry locked.	System	10 Aug 2020 14:48:00
User entered 'Day 3'	System	10 Aug 2020 14:48:00

US3412184

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:30:24

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:31:53

US3412184

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:30:24

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:31:53

US3412184

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:30:24

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:31:53

US3412184

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:30:24

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:31:53

US3412184

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:30:24

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:31:53

US3412184

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:30:24

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:31:53

US3412184

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:30:24

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 10:31:53

US3412184

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:30:24

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:31:53

US3412184

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:30:24

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:31:53
User entered '12 Aug 2020 12:00'	System	10 Aug 2020 14:48:00

US3412184

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:30:24

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:31:53
User entered '13 Aug 2020 11:59'	System	10 Aug 2020 14:48:00

US3412184

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:30:24

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:31:53
Data entry locked.	System	10 Aug 2020 14:48:00
User entered 'Day 4'	System	10 Aug 2020 14:48:00

US3412184

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:30:24

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:31:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (63C78D1B-A891-413A-BA58-C2E172B44955)', Time: '2020-08-13T12:40:35', User OID: 'PatientReportedOutcome (US3412184)', ODM File OID: 'e1592033-4fbd-4acc-b587-d4c25a5a0bcf'	System	13 Aug 2020 16:41:02
User entered 'None (0)'	System	13 Aug 2020 16:41:02

US3412184

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:30:24

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:31:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (63C78D1B-A891-413A-BA58-C2E172B44955)', Time: '2020-08-13T12:40:40', User OID: 'PatientReportedOutcome (US3412184)', ODM File OID: 'e1592033-4fbd-4acc-b587-d4c25a5a0bcf' User entered 'None (0)'	System	13 Aug 2020 16:41:02
	System	13 Aug 2020 16:41:02

US3412184

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:30:24

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:31:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (63C78D1B-A891-413A-BA58-C2E172B44955)', Time: '2020-08-13T12:40:44', User OID: 'PatientReportedOutcome (US3412184)', ODM File OID: 'e1592033-4fbd-4acc-b587-d4c25a5a0bcf' User entered 'None (0)'	System	13 Aug 2020 16:41:02
	System	13 Aug 2020 16:41:02

US3412184

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:30:24

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:31:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (63C78D1B-A891-413A-BA58-C2E172B44955)', Time: '2020-08-13T12:40:47', User OID: 'PatientReportedOutcome (US3412184)', ODM File OID: 'e1592033-4fbd-4acc-b587-d4c25a5a0bcf' User entered 'None (0)'	System	13 Aug 2020 16:41:02
	System	13 Aug 2020 16:41:02

US3412184

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:30:24

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:31:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (63C78D1B-A891-413A-BA58-C2E172B44955)', Time: '2020-08-13T12:40:49', User OID: 'PatientReportedOutcome (US3412184)', ODM File OID: 'e1592033-4fbd-4acc-b587-d4c25a5a0bcf' User entered 'None (0)'	System	13 Aug 2020 16:41:02
	System	13 Aug 2020 16:41:02

US3412184

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:30:24

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:31:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (63C78D1B-A891-413A-BA58-C2E172B44955)', Time: '2020-08-13T12:40:52', User OID: 'PatientReportedOutcome (US3412184)', ODM File OID: 'e1592033-4fbd-4acc-b587-d4c25a5a0bcf' User entered 'None (0)'	System	13 Aug 2020 16:41:02
	System	13 Aug 2020 16:41:02

US3412184

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:30:24

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 10:31:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (63C78D1B-A891-413A-BA58-C2E172B44955)', Time: '2020-08-13T12:40:59', User OID: 'PatientReportedOutcome (US3412184)', ODM File OID: 'e1592033-4fbd-4acc-b587-d4c25a5a0bcf' User entered 'No (N)'	System	13 Aug 2020 16:41:02
	System	13 Aug 2020 16:41:02

US3412184

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:30:24

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:31:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (63C78D1B-A891-413A-BA58-C2E172B44955)', Time: '2020-08-13T12:41:01', User OID: 'PatientReportedOutcome (US3412184)', ODM File OID: 'e1592033-4fbd-4acc-b587-d4c25a5a0bcf' User entered '13 Aug 2020 12:41'	System	13 Aug 2020 16:41:02
	System	13 Aug 2020 16:41:02

US3412184

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:30:24

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:31:53
User entered '13 Aug 2020 12:00'	System	10 Aug 2020 14:48:00

US3412184

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:30:24

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:31:53
User entered '14 Aug 2020 11:59'	System	10 Aug 2020 14:48:00

US3412184

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:30:24

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:31:53
Data entry locked.	System	10 Aug 2020 14:48:00
User entered 'Day 5'	System	10 Aug 2020 14:48:00

US3412184

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:30:24

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:31:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (63C78D1B-A891-413A-BA58-C2E172B44955)', Time: '2020-08-14T20:50:29', User OID: 'PatientReportedOutcome (US3412184)', ODM File OID: 'dc1a34cc-e000-4ff6-a91c-6e8e7c354fce' User entered 'None (0)'	System	15 Aug 2020 00:51:01
	System	15 Aug 2020 00:51:01

US3412184

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:30:24

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:31:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (63C78D1B-A891-413A-BA58-C2E172B44955)', Time: '2020-08-14T20:50:31', User OID: 'PatientReportedOutcome (US3412184)', ODM File OID: 'dc1a34cc-e000-4ff6-a91c-6e8e7c354fce' User entered 'None (0)'	System	15 Aug 2020 00:51:01
	System	15 Aug 2020 00:51:01

US3412184

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:30:24

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:31:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (63C78D1B-A891-413A-BA58-C2E172B44955)', Time: '2020-08-14T20:50:34', User OID: 'PatientReportedOutcome (US3412184)', ODM File OID: 'dc1a34cc-e000-4ff6-a91c-6e8e7c354fce'	System	15 Aug 2020 00:51:01
User entered 'None (0)'	System	15 Aug 2020 00:51:01

US3412184

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:30:24

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:31:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (63C78D1B-A891-413A-BA58-C2E172B44955)', Time: '2020-08-14T20:50:36', User OID: 'PatientReportedOutcome (US3412184)', ODM File OID: 'dc1a34cc-e000-4ff6-a91c-6e8e7c354fce'	System	15 Aug 2020 00:51:01
User entered 'None (0)'	System	15 Aug 2020 00:51:01

US3412184

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:30:24

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:31:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (63C78D1B-A891-413A-BA58-C2E172B44955)', Time: '2020-08-14T20:50:38', User OID: 'PatientReportedOutcome (US3412184)', ODM File OID: 'dc1a34cc-e000-4ff6-a91c-6e8e7c354fce'	System	15 Aug 2020 00:51:01
User entered 'None (0)'	System	15 Aug 2020 00:51:01

US3412184

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:30:24

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:31:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (63C78D1B-A891-413A-BA58-C2E172B44955)', Time: '2020-08-14T20:50:41', User OID: 'PatientReportedOutcome (US3412184)', ODM File OID: 'dc1a34cc-e000-4ff6-a91c-6e8e7c354fce' User entered 'None (0)'	System	15 Aug 2020 00:51:01
	System	15 Aug 2020 00:51:01

US3412184

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:30:24

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 10:31:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (63C78D1B-A891-413A-BA58-C2E172B44955)', Time: '2020-08-14T20:50:56', User OID: 'PatientReportedOutcome (US3412184)', ODM File OID: 'dc1a34cc-e000-4ff6-a91c-6e8e7c354fce' User entered 'No (N)'	System	15 Aug 2020 00:51:01
	System	15 Aug 2020 00:51:01

US3412184

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:30:24

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:31:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (63C78D1B-A891-413A-BA58-C2E172B44955)', Time: '2020-08-14T20:50:59', User OID: 'PatientReportedOutcome (US3412184)', ODM File OID: 'dc1a34cc-e000-4ff6-a91c-6e8e7c354fce'	System	15 Aug 2020 00:51:01
User entered '14 Aug 2020 20:50'	System	15 Aug 2020 00:51:01

US3412184

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:30:24

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:31:53
User entered '14 Aug 2020 12:00'	System	10 Aug 2020 14:48:00

US3412184

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:30:24

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:31:53
User entered '15 Aug 2020 11:59'	System	10 Aug 2020 14:48:00

US3412184

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:30:24

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:31:53
Data entry locked.	System	10 Aug 2020 14:48:00
User entered 'Day 6'	System	10 Aug 2020 14:48:00

US3412184

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:30:24

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:31:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (63C78D1B-A891-413A-BA58-C2E172B44955)', Time: '2020-08-15T23:48:52', User OID: 'PatientReportedOutcome (US3412184)', ODM File OID: '015ec42f-0d96-44fb-8cf9-b8a5ce033ac0' User entered 'None (0)'	System	16 Aug 2020 03:49:32
	System	16 Aug 2020 03:49:32

US3412184

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:30:24

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:31:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (63C78D1B-A891-413A-BA58-C2E172B44955)', Time: '2020-08-15T23:48:55', User OID: 'PatientReportedOutcome (US3412184)', ODM File OID: '015ec42f-0d96-44fb-8cf9-b8a5ce033ac0' User entered 'None (0)'	System	16 Aug 2020 03:49:32
	System	16 Aug 2020 03:49:32

US3412184

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:30:24

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:31:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (63C78D1B-A891-413A-BA58-C2E172B44955)', Time: '2020-08-15T23:48:58', User OID: 'PatientReportedOutcome (US3412184)', ODM File OID: '015ec42f-0d96-44fb-8cf9-b8a5ce033ac0'	System	16 Aug 2020 03:49:32
User entered 'None (0)'	System	16 Aug 2020 03:49:32

US3412184

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:30:24

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:31:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (63C78D1B-A891-413A-BA58-C2E172B44955)', Time: '2020-08-15T23:49:00', User OID: 'PatientReportedOutcome (US3412184)', ODM File OID: '015ec42f-0d96-44fb-8cf9-b8a5ce033ac0' User entered 'None (0)'	System	16 Aug 2020 03:49:32
	System	16 Aug 2020 03:49:32

US3412184

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:30:24

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:31:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (63C78D1B-A891-413A-BA58-C2E172B44955)', Time: '2020-08-15T23:49:03', User OID: 'PatientReportedOutcome (US3412184)', ODM File OID: '015ec42f-0d96-44fb-8cf9-b8a5ce033ac0'	System	16 Aug 2020 03:49:32
User entered 'None (0)'	System	16 Aug 2020 03:49:32

US3412184

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:30:24

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:31:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (63C78D1B-A891-413A-BA58-C2E172B44955)', Time: '2020-08-15T23:49:06', User OID: 'PatientReportedOutcome (US3412184)', ODM File OID: '015ec42f-0d96-44fb-8cf9-b8a5ce033ac0' User entered 'None (0)'	System	16 Aug 2020 03:49:32
	System	16 Aug 2020 03:49:32

US3412184

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:30:24

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 10:31:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (63C78D1B-A891-413A-BA58-C2E172B44955)', Time: '2020-08-15T23:49:12', User OID: 'PatientReportedOutcome (US3412184)', ODM File OID: '015ec42f-0d96-44fb-8cf9-b8a5ce033ac0' User entered 'No (N)'	System	16 Aug 2020 03:49:32
	System	16 Aug 2020 03:49:32

US3412184

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:30:24

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:31:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (63C78D1B-A891-413A-BA58-C2E172B44955)', Time: '2020-08-15T23:49:27', User OID: 'PatientReportedOutcome (US3412184)', ODM File OID: '015ec42f-0d96-44fb-8cf9-b8a5ce033ac0' User entered '15 Aug 2020 23:49'	System	16 Aug 2020 03:49:32
	System	16 Aug 2020 03:49:32

US3412184

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:30:24

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:31:53
User entered '15 Aug 2020 12:00'	System	10 Aug 2020 14:48:00

US3412184

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:30:24

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:31:53
User entered '16 Aug 2020 11:59'	System	10 Aug 2020 14:48:00

US3412184

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:30:24

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:31:53
Data entry locked.	System	10 Aug 2020 14:48:00
User entered 'Day 7'	System	10 Aug 2020 14:48:00

US3412184

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:30:24

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:31:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (63C78D1B-A891-413A-BA58-C2E172B44955)', Time: '2020-08-16T22:31:36', User OID: 'PatientReportedOutcome (US3412184)', ODM File OID: 'd9fecebd-fb06-4599-82e8-1b10bae0a6fb' User entered 'None (0)'	System	17 Aug 2020 02:32:25
	System	17 Aug 2020 02:32:25

US3412184

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:30:24

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:31:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (63C78D1B-A891-413A-BA58-C2E172B44955)', Time: '2020-08-16T22:31:42', User OID: 'PatientReportedOutcome (US3412184)', ODM File OID: 'd9fecebd-fb06-4599-82e8-1b10bae0a6fb' User entered 'None (0)'	System	17 Aug 2020 02:32:25
	System	17 Aug 2020 02:32:25

US3412184

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:30:24

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:31:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (63C78D1B-A891-413A-BA58-C2E172B44955)', Time: '2020-08-16T22:31:45', User OID: 'PatientReportedOutcome (US3412184)', ODM File OID: 'd9fecebd-fb06-4599-82e8-1b10bae0a6fb' User entered 'None (0)'	System	17 Aug 2020 02:32:25
	System	17 Aug 2020 02:32:25

US3412184

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:30:24

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:31:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (63C78D1B-A891-413A-BA58-C2E172B44955)', Time: '2020-08-16T22:31:48', User OID: 'PatientReportedOutcome (US3412184)', ODM File OID: 'd9fecebd-fb06-4599-82e8-1b10bae0a6fb' User entered 'None (0)'	System	17 Aug 2020 02:32:25
	System	17 Aug 2020 02:32:25

US3412184

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:30:24

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:31:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (63C78D1B-A891-413A-BA58-C2E172B44955)', Time: '2020-08-16T22:31:51', User OID: 'PatientReportedOutcome (US3412184)', ODM File OID: 'd9fecebd-fb06-4599-82e8-1b10bae0a6fb' User entered 'None (0)'	System	17 Aug 2020 02:32:25
	System	17 Aug 2020 02:32:25

US3412184

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:30:24

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:31:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (63C78D1B-A891-413A-BA58-C2E172B44955)', Time: '2020-08-16T22:31:54', User OID: 'PatientReportedOutcome (US3412184)', ODM File OID: 'd9fecebd-fb06-4599-82e8-1b10bae0a6fb' User entered 'None (0)'	System	17 Aug 2020 02:32:25
	System	17 Aug 2020 02:32:25

US3412184

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:30:24

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 10:31:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (63C78D1B-A891-413A-BA58-C2E172B44955)', Time: '2020-08-16T22:32:19', User OID: 'PatientReportedOutcome (US3412184)', ODM File OID: 'd9fecebd-fb06-4599-82e8-1b10bae0a6fb' User entered 'No (N)'	System	17 Aug 2020 02:32:25
	System	17 Aug 2020 02:32:25

US3412184

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:30:24

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:31:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (63C78D1B-A891-413A-BA58-C2E172B44955)', Time: '2020-08-16T22:32:22', User OID: 'PatientReportedOutcome (US3412184)', ODM File OID: 'd9fecebd-fb06-4599-82e8-1b10bae0a6fb' User entered '16 Aug 2020 22:32'	System	17 Aug 2020 02:32:25
	System	17 Aug 2020 02:32:25

US3412184

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:30:24

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:31:53
User entered '16 Aug 2020 12:00'	System	10 Aug 2020 14:48:00

US3412184

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:30:24

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:31:53
User entered '17 Aug 2020 11:59'	System	10 Aug 2020 14:48:00

US3412184

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:30:24

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:06:09
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 04:54:06
User entered 'Yes (Y)'	Steven Anderson (b) (4)	17 Aug 2020 23:41:15

US3412184

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:30:24

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:06:09
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 04:54:06
User entered '17 Aug 2020'	Steven Anderson (b) (4)	17 Aug 2020 23:41:15

US3412184

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:30:24

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:06:09
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 04:54:06
User entered 'Contact Made (CONTACT MADE)'	Steven Anderson (b) (4)	17 Aug 2020 23:41:15

US3412184

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:30:24

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:06:09
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 04:54:06
User entered empty.	Steven Anderson (b) (4)	17 Aug 2020 23:41:15

US3412184

Folder: Safety Call Day 8 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:30:24

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:06:09
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 04:54:06
User entered 'Yes (Y)'	Steven Anderson (b) (4)	17 Aug 2020 23:42:15

US3412184

Folder: Safety Call Day 8 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:30:24

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:06:09
User entered 'I'	System	17 Aug 2020 23:42:15

US3412184

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:30:24

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:06:09
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 04:54:06
User entered 'Yes (Y)'	Steven Anderson (b) (4)	24 Aug 2020 21:31:36

US3412184

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:30:24

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:06:09
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 04:54:06
User entered '24 Aug 2020'	Steven Anderson (b) (4)	24 Aug 2020 21:31:36

US3412184

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:30:24

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:06:09
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 04:54:06
User entered 'Contact Made (CONTACT MADE)'	Steven Anderson (b) (4)	24 Aug 2020 21:31:36

US3412184

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:30:24

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:06:09
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 04:54:06
User entered empty.	Steven Anderson (b) (4)	24 Aug 2020 21:31:36

US3412184

Folder: Safety Call Day 15 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:30:24

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:06:09
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 04:54:06
User entered 'Yes (Y)'	Steven Anderson (b) (4)	24 Aug 2020 21:31:41

US3412184

Folder: Safety Call Day 15 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:30:24

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:06:09
User entered 'I'	System	24 Aug 2020 21:31:41

US3412184

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:30:24

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:06:09
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 04:54:06
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	01 Sep 2020 12:45:28

US3412184

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:30:24

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:06:09
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 04:54:06
User entered '31 Aug 2020'	(b) (4) (b) (4), (b) (6)	01 Sep 2020 12:45:28

US3412184

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:30:24

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:06:09
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 04:54:06
User entered 'Contact Made (CONTACT MADE)'	(b) (4) (b) (4), (b) (6)	01 Sep 2020 12:45:28

US3412184

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:30:24

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:06:09
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 04:54:06
User entered empty.	(b) (4) (b) (4), (b) (6)	01 Sep 2020 12:45:28

US3412184

Folder: Safety Call Day 22 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:30:24

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:06:09
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 04:54:06
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	01 Sep 2020 12:45:32

US3412184

Folder: Safety Call Day 22 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:30:24

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:06:09
User entered 'I'	System	01 Sep 2020 12:45:32

US3412184

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 09 Jun 2021 17:30:24

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:06:09
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 02:43:30
User entered 'Yes (Y)'	Steven Anderson (b) (4)	08 Sep 2020 12:53:06

US3412184

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 09 Jun 2021 17:30:24

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:06:09
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 02:43:30
User entered '08 Sep 2020'	Steven Anderson (b) (4)	08 Sep 2020 12:53:06

US3412184

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 09 Jun 2021 17:30:24

[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 20:06:09
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 02:43:30
User entered 'Clinic (Clinic)'	Steven Anderson (b) (4)	08 Sep 2020 12:53:06

US3412184

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 09 Jun 2021 17:30:24

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:06:09
User entered 'VISIT2'	System	08 Sep 2020 12:53:06

US3412184

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:30:24

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:06:09
User accepted default value 'Pre-Dose (PREDOSE)'	Steven Anderson (b) (4)	08 Sep 2020 12:53:57
	(b) (4)	

US3412184

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:30:24

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:06:09
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 02:43:30
User entered 'Yes (Y)'	Steven Anderson (b) (4)	08 Sep 2020 12:53:57

US3412184

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:30:24

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:06:09
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 02:43:30
User entered '08 Sep 2020'	Steven Anderson (b) (4)	08 Sep 2020 12:53:57

US3412184

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:30:24

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:06:09
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 02:43:30
User entered '07:50'	Steven Anderson (b) (4)	08 Sep 2020 12:53:57

US3412184

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:30:24

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:06:09
User entered '08 Sep 2020 07:50'	System	08 Sep 2020 12:53:57

US3412184

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:30:24

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:06:09
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 02:43:30
User entered '36.9' C	Steven Anderson (b) (4)	08 Sep 2020 12:53:57

US3412184

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:30:24

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:06:09
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 02:43:30
User entered 'Oral (Oral)'	Steven Anderson (b) (4)	08 Sep 2020 12:53:57

US3412184

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:30:24

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:06:09
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 02:43:30
User entered empty.	Steven Anderson (b) (4)	08 Sep 2020 12:53:57

US3412184

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:30:24

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:06:09
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 02:43:30
User entered '78'	Steven Anderson (b) (4)	08 Sep 2020 12:53:57

US3412184

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:30:24

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:06:09
User entered 'bpm'	System	08 Sep 2020 12:53:57

US3412184

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:30:24

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:06:09
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 02:43:30
User entered '16'	Steven Anderson (b) (4)	08 Sep 2020 12:53:57

US3412184

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:30:24

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:06:09
User entered 'breaths/min'	System	08 Sep 2020 12:53:57

US3412184

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:30:24

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:06:09
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 02:43:30
User entered '140'	Steven Anderson (b) (4)	08 Sep 2020 12:53:57

US3412184

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:30:24

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:06:09
User entered 'mmHg'	System	08 Sep 2020 12:53:57

US3412184

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:30:24

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:06:09
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 02:43:30
User entered '78'	Steven Anderson (b) (4)	08 Sep 2020 12:53:57

US3412184

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:30:24

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:06:09
User entered 'mmHg'	System	08 Sep 2020 12:53:57

US3412184

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:30:24

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:06:09
User accepted default value 'Post-Dose (POSTDOSE)'	Steven Anderson (b) (4)	08 Sep 2020 12:53:57

US3412184

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:30:24

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:06:09
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 02:43:30
User closed query 'Data is required. Please complete.' (Site from System).	(b) (4)	08 Sep 2020 13:56:47
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	08 Sep 2020 13:56:47
User entered 'Yes (Y)' reason for change: Data Entry Error	Mylene Asmar-Rios (b) (4)	08 Sep 2020 13:56:47
User opened query 'Data is required. Please complete.' (Site from System).	System	08 Sep 2020 12:53:57
User entered empty.	Steven Anderson (b) (4)	08 Sep 2020 12:53:57

US3412184

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:30:24

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:06:09
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 02:43:30
User entered '08 Sep 2020' reason for change: Data Entry Error	(b) (4)	08 Sep 2020 13:56:47
User entered empty.	Mylene Asmar-Rios (b) (4)	08 Sep 2020 12:53:57
	(b) (4)	

US3412184

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:30:24

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:06:09
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 02:43:30
User entered '09:46' reason for change: Data Entry Error	(b) (4)	08 Sep 2020 13:56:47
User entered empty.	Mylene Asmar-Rios (b) (4)	08 Sep 2020 12:53:57
	(b) (4)	

US3412184

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:30:24

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:06:09
User entered '08 Sep 2020 09:46'	System	08 Sep 2020 13:56:47
User entered empty.	System	08 Sep 2020 12:53:57

US3412184

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:30:24

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:06:09
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 02:43:30
User entered '97.5' F reason for change: Data Entry Error	(b) (4)	08 Sep 2020 13:56:47
User entered empty.	Mylene Asmar-Rios (b) (4)	08 Sep 2020 12:53:57
	(b) (4)	

US3412184

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:30:24

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:06:09
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 02:43:30
User entered 'Oral (Oral)' reason for change: Data Entry Error	(b) (4)	08 Sep 2020 13:56:47
User entered empty.	Mylene Asmar-Rios (b) (4)	08 Sep 2020 12:53:57
	(b) (4)	

US3412184

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:30:24

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:06:09
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 02:43:30
User entered empty.	Steven Anderson (b) (4)	08 Sep 2020 12:53:57

US3412184

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:30:24

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:06:09
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 02:43:30
User entered '76' reason for change: Data Entry Error	(b) (4)	08 Sep 2020 13:56:47
User entered empty.	Mylene Asmar-Rios (b) (4)	08 Sep 2020 12:53:57
	(b) (4)	

US3412184

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:30:24

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:06:09
User entered 'bpm'	System	08 Sep 2020 13:56:47
User entered empty.	System	08 Sep 2020 12:53:57

US3412184

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:30:24

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:06:09
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 02:43:30
User entered '16' reason for change: Data Entry Error	(b) (4)	08 Sep 2020 13:56:47
User entered empty.	Mylene Asmar-Rios (b) (4)	08 Sep 2020 12:53:57
	(b) (4)	

US3412184

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:30:24

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:06:09
User entered 'breaths/min'	System	08 Sep 2020 13:56:47
User entered empty.	System	08 Sep 2020 12:53:57

US3412184

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:30:24

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:06:09
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 02:43:30
User entered '140' reason for change: Data Entry Error	(b) (4)	08 Sep 2020 13:56:47
User entered empty.	Mylene Asmar-Rios (b) (4)	08 Sep 2020 12:53:57
	(b) (4)	

US3412184

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:30:24

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:06:09
User entered 'mmHg'	System	08 Sep 2020 13:56:47
User entered empty.	System	08 Sep 2020 12:53:57

US3412184

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:30:24

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:06:09
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 02:43:30
User entered '80' reason for change: Data Entry Error	(b) (4)	08 Sep 2020 13:56:47
User entered empty.	Mylene Asmar-Rios (b) (4)	08 Sep 2020 12:53:57
	(b) (4)	

US3412184

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:30:24

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:06:09
User entered 'mmHg'	System	08 Sep 2020 13:56:47
User entered empty.	System	08 Sep 2020 12:53:57

US3412184

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 17:30:24

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:06:09
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 02:43:30
User entered 'Yes (Y)'	Steven Anderson (b) (4)	08 Sep 2020 12:54:10

US3412184

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 17:30:24

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:06:09
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 02:43:30
User entered '08 Sep 2020'	Steven Anderson (b) (4)	08 Sep 2020 12:54:10

US3412184

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 17:30:24

[Was study treatment given?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:06:09
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 02:43:30
User entered 'Yes (Y)'	Mylene Asmar-Rios (b) (4)	08 Sep 2020 13:55:06

US3412184

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 17:30:24

[If No, reason not given](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:06:09
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 02:43:30
User entered empty.	Mylene Asmar-Rios (b) (4)	08 Sep 2020 13:55:06

US3412184

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 17:30:24

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 20:06:09
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 02:43:30
User entered empty.	Mylene Asmar-Rios (b) (4)	08 Sep 2020 13:55:06

US3412184

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 17:30:24

[What was the study treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:06:09
User entered 'MRNA-1273 OR PLACEBO'	System	08 Sep 2020 13:55:06

US3412184

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 17:30:24

What was the treatment date? (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:06:09
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 02:43:30
User entered '08 Sep 2020'	Mylene Asmar-Rios (b) (4)	08 Sep 2020 13:55:06

US3412184

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 17:30:24

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:06:09
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 02:43:30
User entered '09:15'	Mylene Asmar-Rios (b) (4)	08 Sep 2020 13:55:06

US3412184

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 17:30:24

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:06:09
User entered '08 Sep 2020 09:15'	System	08 Sep 2020 13:55:06

US3412184

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 17:30:24

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:06:09
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 02:43:30
User entered 'Left Arm (LEFT ARM)'	Mylene Asmar-Rios	08 Sep 2020 13:55:06

US3412184

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 17:30:24

What was the frequency of the study treatment dosing?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:06:09
User entered 'ONCE'	System	08 Sep 2020 13:55:06

US3412184

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 17:30:24

What was the route of administration for the study treatment?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:06:09
User entered 'INTRAMUSCULAR'	System	08 Sep 2020 13:55:06

US3412184

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:30:24

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:06:09
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 02:43:30
User entered 'Yes (Y)'	Steven Anderson (b) (4)	08 Sep 2020 12:54:33

US3412184

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:30:24

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:06:09
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 02:43:30
User entered '08 Sep 2020'	Steven Anderson (b) (4)	08 Sep 2020 12:54:33

US3412184

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:30:24

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:06:09
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 02:43:30
User entered '08:31'	Steven Anderson (b) (4)	08 Sep 2020 12:54:33

US3412184

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:30:24

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:06:09
User entered '08 Sep 2020 08:31'	System	08 Sep 2020 12:54:33

US3412184

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab

Generated On: 09 Jun 2021 17:30:24

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:06:09
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 02:43:30
User entered '08 Sep 2020'	Steven Anderson (b) (4)	08 Sep 2020 12:54:54

US3412184

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 17:30:24

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:06:09
User accepted default value 'Nasopharyngeal Swab 1 (NASAL1)'	Steven Anderson (b) (4)	08 Sep 2020 12:54:54

US3412184

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 17:30:24

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:06:09
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 02:43:30
User entered 'Yes (Y)'	Steven Anderson (b) (4)	08 Sep 2020 12:54:54

US3412184

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 17:30:24

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:06:09
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 02:43:30
User entered '08:35'	Steven Anderson (b) (4)	08 Sep 2020 12:54:54

US3412184

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 17:30:24

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:06:09
User entered '08 Sep 2020 08:35'	System	08 Sep 2020 12:54:54

US3412184

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 17:30:24

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:06:09
User accepted default value 'Nasopharyngeal Swab 2 (NASAL2)'	Steven Anderson (b) (4)	08 Sep 2020 12:54:54

US3412184

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 17:30:24

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:06:09
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 02:43:30
User entered 'No (N)'	Steven Anderson (b) (4)	08 Sep 2020 12:54:54

US3412184

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 17:30:24

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:06:09
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 02:43:30
User entered empty.	Steven Anderson (b) (4)	08 Sep 2020 12:54:54

US3412184

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 17:30:24

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:06:09
User entered empty.	System	08 Sep 2020 12:54:54

US3412184

Folder: Visit 2 Day 29 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:30:24

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:06:09
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 02:43:30
User entered 'Yes (Y)'	Steven Anderson (b) (4)	08 Sep 2020 12:55:00

US3412184

Folder: Visit 2 Day 29 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:30:24

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:06:09
User entered 'I'	System	08 Sep 2020 12:55:00

US3412184

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 17:30:24

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:31:53
Data entry locked.	System	08 Sep 2020 13:55:06
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	08 Sep 2020 13:55:06

US3412184

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 17:30:24

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:31:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (63C78D1B-A891-413A-BA58-C2E172B44955)', Time: '2020-09-08T09:56:37', User OID: 'PatientReportedOutcome (US3412184)', ODM File OID: '12e26ba2-a110-4d78-af6a-0b261d56fe9c' User entered 'Yes (Y)'	System	08 Sep 2020 13:57:09
	System	08 Sep 2020 13:57:09

US3412184

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 17:30:24

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:31:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (63C78D1B-A891-413A-BA58-C2E172B44955)', Time: '2020-09-08T09:56:46', User OID: 'PatientReportedOutcome (US3412184)', ODM File OID: '12e26ba2-a110-4d78-af6a-0b261d56fe9c' User entered '97.5'	System	08 Sep 2020 13:57:09
	System	08 Sep 2020 13:57:09

US3412184

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 17:30:24

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:31:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (63C78D1B-A891-413A-BA58-C2E172B44955)', Time: '2020-09-08T09:56:59', User OID: 'PatientReportedOutcome (US3412184)', ODM File OID: '12e26ba2-a110-4d78-af6a-0b261d56fe9c' User entered 'No (N)'	System	08 Sep 2020 13:57:09
	System	08 Sep 2020 13:57:09

US3412184

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 17:30:24

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:31:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (63C78D1B-A891-413A-BA58-C2E172B44955)', Time: '2020-09-08T09:57:04', User OID: 'PatientReportedOutcome (US3412184)', ODM File OID: '12e26ba2-a110-4d78-af6a-0b261d56fe9c' User entered '08 Sep 2020 09:57'	System	08 Sep 2020 13:57:09
	System	08 Sep 2020 13:57:09

US3412184

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 17:30:24

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:31:53
User entered '08 Sep 2020 09:35'	System	08 Sep 2020 13:55:06

US3412184

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 17:30:24

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:31:53
User entered '08 Sep 2020 12:05'	System	08 Sep 2020 13:55:06

US3412184

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 17:30:24

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:31:53
Data entry locked.	System	08 Sep 2020 13:55:06
User entered 'Day 1, after vaccination (at home)'	System	08 Sep 2020 13:55:06

US3412184

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 17:30:24

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:31:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (63C78D1B-A891-413A-BA58-C2E172B44955)', Time: '2020-09-08T20:36:29', User OID: 'PatientReportedOutcome (US3412184)', ODM File OID: '03d8e9f9-1d7e-40a5-ba6e-2e110a280b36' User entered 'Yes (Y)'	System	09 Sep 2020 00:36:48
	System	09 Sep 2020 00:36:48

US3412184

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 17:30:24

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:31:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (63C78D1B-A891-413A-BA58-C2E172B44955)', Time: '2020-09-08T20:36:37', User OID: 'PatientReportedOutcome (US3412184)', ODM File OID: '03d8e9f9-1d7e-40a5-ba6e-2e110a280b36' User entered '97.3'	System	09 Sep 2020 00:36:48
	System	09 Sep 2020 00:36:48

US3412184

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 17:30:24

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:31:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (63C78D1B-A891-413A-BA58-C2E172B44955)', Time: '2020-09-08T20:36:42', User OID: 'PatientReportedOutcome (US3412184)', ODM File OID: '03d8e9f9-1d7e-40a5-ba6e-2e110a280b36' User entered 'No (N)'	System	09 Sep 2020 00:36:48
	System	09 Sep 2020 00:36:48

US3412184

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 17:30:24

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:31:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (63C78D1B-A891-413A-BA58-C2E172B44955)', Time: '2020-09-08T20:36:46', User OID: 'PatientReportedOutcome (US3412184)', ODM File OID: '03d8e9f9-1d7e-40a5-ba6e-2e110a280b36'	System	09 Sep 2020 00:36:48
User entered '08 Sep 2020 20:36'	System	09 Sep 2020 00:36:48

US3412184

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 17:30:24

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:31:53
User entered '08 Sep 2020 13:00'	System	08 Sep 2020 13:55:06

US3412184

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 17:30:24

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:31:53
User entered '09 Sep 2020 11:59'	System	08 Sep 2020 13:55:06

US3412184

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 17:30:24

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:31:53
Data entry locked.	System	08 Sep 2020 13:55:06
User entered 'Day 2'	System	08 Sep 2020 13:55:06

US3412184

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 17:30:24

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:31:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (63C78D1B-A891-413A-BA58-C2E172B44955)', Time: '2020-09-09T16:11:00', User OID: 'PatientReportedOutcome (US3412184)', ODM File OID: '99129417-8489-42cc-b354-a2010fd01309'	System	09 Sep 2020 20:11:46
User entered 'Yes (Y)'	System	09 Sep 2020 20:11:46

US3412184

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 17:30:24

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:31:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (63C78D1B-A891-413A-BA58-C2E172B44955)', Time: '2020-09-09T16:11:33', User OID: 'PatientReportedOutcome (US3412184)', ODM File OID: '99129417-8489-42cc-b354-a2010fd01309'	System	09 Sep 2020 20:11:46
User entered '98.0'	System	09 Sep 2020 20:11:46

US3412184

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 17:30:24

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:31:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (63C78D1B-A891-413A-BA58-C2E172B44955)', Time: '2020-09-09T16:11:37', User OID: 'PatientReportedOutcome (US3412184)', ODM File OID: '99129417-8489-42cc-b354-a2010fd01309'	System	09 Sep 2020 20:11:46
User entered 'No (N)'	System	09 Sep 2020 20:11:46

US3412184

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 17:30:24

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:31:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (63C78D1B-A891-413A-BA58-C2E172B44955)', Time: '2020-09-09T16:11:41', User OID: 'PatientReportedOutcome (US3412184)', ODM File OID: '99129417-8489-42cc-b354-a2010fd01309'	System	09 Sep 2020 20:11:46
User entered '09 Sep 2020 16:11'	System	09 Sep 2020 20:11:46

US3412184

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 17:30:24

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:31:53
User entered '09 Sep 2020 12:00'	System	08 Sep 2020 13:55:06

US3412184

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 17:30:24

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:31:53
User entered '10 Sep 2020 11:59'	System	08 Sep 2020 13:55:06

US3412184

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 17:30:24

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:31:53
Data entry locked.	System	08 Sep 2020 13:55:06
User entered 'Day 3'	System	08 Sep 2020 13:55:06

US3412184

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 17:30:24

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:31:53

US3412184

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 17:30:24

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:31:53

US3412184

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 17:30:24

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:31:53

US3412184

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 17:30:24

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:31:53

US3412184

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 17:30:24

To **PREVENT** pain or fever from occurring

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:31:53

US3412184

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 17:30:24

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:31:53

US3412184

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 17:30:24

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:31:53
User entered '10 Sep 2020 12:00'	System	08 Sep 2020 13:55:06

US3412184

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 17:30:24

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:31:53
User entered '11 Sep 2020 11:59'	System	08 Sep 2020 13:55:06

US3412184

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 17:30:24

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:31:53
Data entry locked.	System	08 Sep 2020 13:55:06
User entered 'Day 4'	System	08 Sep 2020 13:55:06

US3412184

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 17:30:24

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:31:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (63C78D1B-A891-413A-BA58-C2E172B44955)', Time: '2020-09-11T23:59:29', User OID: 'PatientReportedOutcome (US3412184)', ODM File OID: '68ea595f-04f0-4fdc-9b83-8501ad901dc2'	System	12 Sep 2020 03:59:50
User entered 'Yes (Y)'	System	12 Sep 2020 03:59:50

US3412184

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 17:30:24

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:31:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (63C78D1B-A891-413A-BA58-C2E172B44955)', Time: '2020-09-11T23:59:37', User OID: 'PatientReportedOutcome (US3412184)', ODM File OID: '68ea595f-04f0-4fdc-9b83-8501ad901dc2'	System	12 Sep 2020 03:59:50
User entered '97.3'	System	12 Sep 2020 03:59:50

US3412184

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 17:30:24

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:31:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (63C78D1B-A891-413A-BA58-C2E172B44955)', Time: '2020-09-11T23:59:44', User OID: 'PatientReportedOutcome (US3412184)', ODM File OID: '68ea595f-04f0-4fdc-9b83-8501ad901dc2'	System	12 Sep 2020 03:59:50
User entered 'No (N)'	System	12 Sep 2020 03:59:50

US3412184

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 17:30:24

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:31:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (63C78D1B-A891-413A-BA58-C2E172B44955)', Time: '2020-09-11T23:59:48', User OID: 'PatientReportedOutcome (US3412184)', ODM File OID: '68ea595f-04f0-4fdc-9b83-8501ad901dc2'	System	12 Sep 2020 03:59:50
User entered '11 Sep 2020 23:59'	System	12 Sep 2020 03:59:50

US3412184

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 17:30:24

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:31:53
User entered '11 Sep 2020 12:00'	System	08 Sep 2020 13:55:06

US3412184

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 17:30:24

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:31:53
User entered '12 Sep 2020 11:59'	System	08 Sep 2020 13:55:06

US3412184

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 17:30:24

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:31:53
Data entry locked.	System	08 Sep 2020 13:55:06
User entered 'Day 5'	System	08 Sep 2020 13:55:06

US3412184

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 17:30:24

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:31:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (63C78D1B-A891-413A-BA58-C2E172B44955)', Time: '2020-09-12T12:00:23', User OID: 'PatientReportedOutcome (US3412184)', ODM File OID: '2b554587-0c09-4ab9-b429-3826c4ca77a9' User entered 'Yes (Y)'	System	12 Sep 2020 16:02:19
	System	12 Sep 2020 16:02:19

US3412184

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 17:30:24

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:31:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (63C78D1B-A891-413A-BA58-C2E172B44955)', Time: '2020-09-12T12:00:30', User OID: 'PatientReportedOutcome (US3412184)', ODM File OID: '2b554587-0c09-4ab9-b429-3826c4ca77a9' User entered '97.4'	System	12 Sep 2020 16:02:19
	System	12 Sep 2020 16:02:19

US3412184

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 17:30:24

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:31:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (63C78D1B-A891-413A-BA58-C2E172B44955)', Time: '2020-09-12T12:00:36', User OID: 'PatientReportedOutcome (US3412184)', ODM File OID: '2b554587-0c09-4ab9-b429-3826c4ca77a9' User entered 'No (N)'	System	12 Sep 2020 16:02:19
	System	12 Sep 2020 16:02:19

US3412184

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 17:30:24

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:31:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (63C78D1B-A891-413A-BA58-C2E172B44955)', Time: '2020-09-12T12:00:43', User OID: 'PatientReportedOutcome (US3412184)', ODM File OID: '2b554587-0c09-4ab9-b429-3826c4ca77a9'	System	12 Sep 2020 16:02:19
User entered '12 Sep 2020 12:00'	System	12 Sep 2020 16:02:19

US3412184

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 17:30:24

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:31:53
User entered '12 Sep 2020 12:00'	System	08 Sep 2020 13:55:06

US3412184

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 17:30:24

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:31:53
User entered '13 Sep 2020 11:59'	System	08 Sep 2020 13:55:06

US3412184

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 17:30:24

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:31:53
Data entry locked.	System	08 Sep 2020 13:55:06
User entered 'Day 6'	System	08 Sep 2020 13:55:06

US3412184

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 17:30:24

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:31:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (63C78D1B-A891-413A-BA58-C2E172B44955)', Time: '2020-09-13T19:33:17', User OID: 'PatientReportedOutcome (US3412184)', ODM File OID: 'addb8dfd-d5be-45f3-9603-60b85895d39d' User entered 'Yes (Y)'	System	13 Sep 2020 23:33:36
	System	13 Sep 2020 23:33:36

US3412184

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 17:30:24

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:31:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (63C78D1B-A891-413A-BA58-C2E172B44955)', Time: '2020-09-13T19:33:23', User OID: 'PatientReportedOutcome (US3412184)', ODM File OID: 'addb8dfd-d5be-45f3-9603-60b85895d39d' User entered '97.3'	System	13 Sep 2020 23:33:36
	System	13 Sep 2020 23:33:36

US3412184

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 17:30:24

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:31:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (63C78D1B-A891-413A-BA58-C2E172B44955)', Time: '2020-09-13T19:33:26', User OID: 'PatientReportedOutcome (US3412184)', ODM File OID: 'addb8dfd-d5be-45f3-9603-60b85895d39d' User entered 'No (N)'	System	13 Sep 2020 23:33:36
	System	13 Sep 2020 23:33:36

US3412184

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 17:30:24

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:31:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (63C78D1B-A891-413A-BA58-C2E172B44955)', Time: '2020-09-13T19:33:31', User OID: 'PatientReportedOutcome (US3412184)', ODM File OID: 'addb8dfd-d5be-45f3-9603-60b85895d39d' User entered '13 Sep 2020 19:33'	System	13 Sep 2020 23:33:36
	System	13 Sep 2020 23:33:36

US3412184

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 17:30:24

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:31:53
User entered '13 Sep 2020 12:00'	System	08 Sep 2020 13:55:06

US3412184

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 17:30:24

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:31:53
User entered '14 Sep 2020 11:59'	System	08 Sep 2020 13:55:06

US3412184

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 17:30:24

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:31:53
Data entry locked.	System	08 Sep 2020 13:55:06
User entered 'Day 7'	System	08 Sep 2020 13:55:06

US3412184

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 17:30:24

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:31:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (63C78D1B-A891-413A-BA58-C2E172B44955)', Time: '2020-09-15T06:33:11', User OID: 'PatientReportedOutcome (US3412184)', ODM File OID: '8a246b6e-a15e-48e2-9017-2a009d628a49' User entered 'Yes (Y)'	System	15 Sep 2020 10:33:33
	System	15 Sep 2020 10:33:33

US3412184

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 17:30:24

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:31:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (63C78D1B-A891-413A-BA58-C2E172B44955)', Time: '2020-09-15T06:33:20', User OID: 'PatientReportedOutcome (US3412184)', ODM File OID: '8a246b6e-a15e-48e2-9017-2a009d628a49' User entered '97.6'	System	15 Sep 2020 10:33:33
	System	15 Sep 2020 10:33:33

US3412184

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 17:30:24

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:31:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (63C78D1B-A891-413A-BA58-C2E172B44955)', Time: '2020-09-15T06:33:27', User OID: 'PatientReportedOutcome (US3412184)', ODM File OID: '8a246b6e-a15e-48e2-9017-2a009d628a49'	System	15 Sep 2020 10:33:33
User entered 'No (N)'	System	15 Sep 2020 10:33:33

US3412184

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 17:30:24

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:31:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (63C78D1B-A891-413A-BA58-C2E172B44955)', Time: '2020-09-15T06:33:31', User OID: 'PatientReportedOutcome (US3412184)', ODM File OID: '8a246b6e-a15e-48e2-9017-2a009d628a49' User entered '15 Sep 2020 06:33'	System	15 Sep 2020 10:33:33
	System	15 Sep 2020 10:33:33

US3412184

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 17:30:24

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:31:53
User entered '14 Sep 2020 12:00'	System	08 Sep 2020 13:55:06

US3412184

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 17:30:24

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:31:53
User entered '15 Sep 2020 11:59'	System	08 Sep 2020 13:55:06

US3412184

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 17:30:24

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:31:53
Data entry locked.	System	08 Sep 2020 13:55:06
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	08 Sep 2020 13:55:06

US3412184

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 17:30:24

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 10:31:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (63C78D1B-A891-413A-BA58-C2E172B44955)', Time: '2020-09-08T09:57:19', User OID: 'PatientReportedOutcome (US3412184)', ODM File OID: 'b481ceb9-e184-4aa1-8b15-b2fba7b082bc' User entered 'None (1)'	System	08 Sep 2020 13:57:43
	System	08 Sep 2020 13:57:43

US3412184

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 17:30:24

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:31:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (63C78D1B-A891-413A-BA58-C2E172B44955)', Time: '2020-09-08T09:57:27', User OID: 'PatientReportedOutcome (US3412184)', ODM File OID: 'b481ceb9-e184-4aa1-8b15-b2fba7b082bc' User entered 'No (N)'	System	08 Sep 2020 13:57:43
	System	08 Sep 2020 13:57:43

US3412184

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 17:30:24

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:31:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (63C78D1B-A891-413A-BA58-C2E172B44955)', Time: '2020-09-08T09:57:31', User OID: 'PatientReportedOutcome (US3412184)', ODM File OID: 'b481ceb9-e184-4aa1-8b15-b2fba7b082bc' User entered 'No (N)'	System	08 Sep 2020 13:57:43
	System	08 Sep 2020 13:57:43

US3412184

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 17:30:24

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 10:31:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (63C78D1B-A891-413A-BA58-C2E172B44955)', Time: '2020-09-08T09:57:38', User OID: 'PatientReportedOutcome (US3412184)', ODM File OID: 'b481ceb9-e184-4aa1-8b15-b2fba7b082bc' User entered 'None (1)'	System	08 Sep 2020 13:57:43
	System	08 Sep 2020 13:57:43

US3412184

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 17:30:24

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:31:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (63C78D1B-A891-413A-BA58-C2E172B44955)', Time: '2020-09-08T09:57:41', User OID: 'PatientReportedOutcome (US3412184)', ODM File OID: 'b481ceb9-e184-4aa1-8b15-b2fba7b082bc' User entered '08 Sep 2020 09:57'	System	08 Sep 2020 13:57:43
	System	08 Sep 2020 13:57:43

US3412184

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 17:30:24

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:31:53
User entered '08 Sep 2020 09:35'	System	08 Sep 2020 13:55:06

US3412184

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 17:30:24

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:31:53
User entered '08 Sep 2020 12:05'	System	08 Sep 2020 13:55:06

US3412184

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 17:30:24

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:31:53
Data entry locked.	System	08 Sep 2020 13:55:06
User entered 'Day 1, after vaccination (at home)'	System	08 Sep 2020 13:55:06

US3412184

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 17:30:24

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 10:31:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (63C78D1B-A891-413A-BA58-C2E172B44955)', Time: '2020-09-08T20:36:51', User OID: 'PatientReportedOutcome (US3412184)', ODM File OID: '24ea786f-41a7-4e3d-a0ef-7bb5eae36bc1' User entered 'None (1)'	System	09 Sep 2020 00:37:12
	System	09 Sep 2020 00:37:12

US3412184

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 17:30:24

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:31:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (63C78D1B-A891-413A-BA58-C2E172B44955)', Time: '2020-09-08T20:36:57', User OID: 'PatientReportedOutcome (US3412184)', ODM File OID: '24ea786f-41a7-4e3d-a0ef-7bb5eae36bc1' User entered 'No (N)'	System	09 Sep 2020 00:37:12
	System	09 Sep 2020 00:37:12

US3412184

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 17:30:24

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:31:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (63C78D1B-A891-413A-BA58-C2E172B44955)', Time: '2020-09-08T20:37:00', User OID: 'PatientReportedOutcome (US3412184)', ODM File OID: '24ea786f-41a7-4e3d-a0ef-7bb5eae36bc1' User entered 'No (N)'	System	09 Sep 2020 00:37:12
	System	09 Sep 2020 00:37:12

US3412184

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 17:30:24

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 10:31:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (63C78D1B-A891-413A-BA58-C2E172B44955)', Time: '2020-09-08T20:37:04', User OID: 'PatientReportedOutcome (US3412184)', ODM File OID: '24ea786f-41a7-4e3d-a0ef-7bb5eae36bc1' User entered 'None (1)'	System	09 Sep 2020 00:37:12
	System	09 Sep 2020 00:37:12

US3412184

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 17:30:24

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:31:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (63C78D1B-A891-413A-BA58-C2E172B44955)', Time: '2020-09-08T20:37:07', User OID: 'PatientReportedOutcome (US3412184)', ODM File OID: '24ea786f-41a7-4e3d-a0ef-7bb5eae36bc1' User entered '08 Sep 2020 20:37'	System	09 Sep 2020 00:37:12
	System	09 Sep 2020 00:37:12

US3412184

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 17:30:24

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:31:53
User entered '08 Sep 2020 13:00'	System	08 Sep 2020 13:55:06

US3412184

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 17:30:24

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:31:53
User entered '09 Sep 2020 11:59'	System	08 Sep 2020 13:55:06

US3412184

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 17:30:24

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:31:53
Data entry locked.	System	08 Sep 2020 13:55:06
User entered 'Day 2'	System	08 Sep 2020 13:55:06

US3412184

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 17:30:24

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 10:31:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (63C78D1B-A891-413A-BA58-C2E172B44955)', Time: '2020-09-09T16:11:55', User OID: 'PatientReportedOutcome (US3412184)', ODM File OID: 'a1255f74-faad-4797-843c-36b91da769eb' User entered 'None (1)'	System	09 Sep 2020 20:12:16
	System	09 Sep 2020 20:12:16

US3412184

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 17:30:24

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:31:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (63C78D1B-A891-413A-BA58-C2E172B44955)', Time: '2020-09-09T16:11:59', User OID: 'PatientReportedOutcome (US3412184)', ODM File OID: 'a1255f74-faad-4797-843c-36b91da769eb' User entered 'No (N)'	System	09 Sep 2020 20:12:16
	System	09 Sep 2020 20:12:16

US3412184

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 17:30:24

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:31:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (63C78D1B-A891-413A-BA58-C2E172B44955)', Time: '2020-09-09T16:12:03', User OID: 'PatientReportedOutcome (US3412184)', ODM File OID: 'a1255f74-faad-4797-843c-36b91da769eb' User entered 'No (N)'	System	09 Sep 2020 20:12:16
	System	09 Sep 2020 20:12:16

US3412184

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 17:30:24

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 10:31:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (63C78D1B-A891-413A-BA58-C2E172B44955)', Time: '2020-09-09T16:12:10', User OID: 'PatientReportedOutcome (US3412184)', ODM File OID: 'a1255f74-faad-4797-843c-36b91da769eb' User entered 'None (1)'	System	09 Sep 2020 20:12:16
	System	09 Sep 2020 20:12:16

US3412184

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 17:30:24

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:31:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (63C78D1B-A891-413A-BA58-C2E172B44955)', Time: '2020-09-09T16:12:13', User OID: 'PatientReportedOutcome (US3412184)', ODM File OID: 'a1255f74-faad-4797-843c-36b91da769eb' User entered '09 Sep 2020 16:12'	System	09 Sep 2020 20:12:16
	System	09 Sep 2020 20:12:16

US3412184

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 17:30:24

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:31:53
User entered '09 Sep 2020 12:00'	System	08 Sep 2020 13:55:06

US3412184

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 17:30:24

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:31:53
User entered '10 Sep 2020 11:59'	System	08 Sep 2020 13:55:06

US3412184

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 17:30:24

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:31:53
Data entry locked.	System	08 Sep 2020 13:55:06
User entered 'Day 3'	System	08 Sep 2020 13:55:06

US3412184

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 17:30:24

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 10:31:53

US3412184

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 17:30:24

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:31:53

US3412184

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 17:30:24

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 10:31:53

US3412184

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 17:30:24

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:31:53

US3412184

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 17:30:24

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 10:31:53

US3412184

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 17:30:24

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 10:31:53

US3412184

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 17:30:24

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:31:53

US3412184

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 17:30:24

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:31:53
User entered '10 Sep 2020 12:00'	System	08 Sep 2020 13:55:06

US3412184

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 17:30:24

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:31:53
User entered '11 Sep 2020 11:59'	System	08 Sep 2020 13:55:06

US3412184

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 17:30:24

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:31:53
Data entry locked.	System	08 Sep 2020 13:55:06
User entered 'Day 4'	System	08 Sep 2020 13:55:06

US3412184

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 17:30:24

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 10:31:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (63C78D1B-A891-413A-BA58-C2E172B44955)', Time: '2020-09-11T23:59:53', User OID: 'PatientReportedOutcome (US3412184)', ODM File OID: '26e3094b-72eb-4a30-950f-7e5c05523536' User entered 'None (1)'	System	12 Sep 2020 04:00:11
	System	12 Sep 2020 04:00:11

US3412184

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 17:30:24

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:31:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (63C78D1B-A891-413A-BA58-C2E172B44955)', Time: '2020-09-11T23:59:58', User OID: 'PatientReportedOutcome (US3412184)', ODM File OID: '26e3094b-72eb-4a30-950f-7e5c05523536' User entered 'No (N)'	System	12 Sep 2020 04:00:11
	System	12 Sep 2020 04:00:11

US3412184

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 17:30:24

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:31:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (63C78D1B-A891-413A-BA58-C2E172B44955)', Time: '2020-09-12T00:00:02', User OID: 'PatientReportedOutcome (US3412184)', ODM File OID: '26e3094b-72eb-4a30-950f-7e5c05523536' User entered 'No (N)'	System	12 Sep 2020 04:00:11
	System	12 Sep 2020 04:00:11

US3412184

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 17:30:24

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 10:31:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (63C78D1B-A891-413A-BA58-C2E172B44955)', Time: '2020-09-12T00:00:06', User OID: 'PatientReportedOutcome (US3412184)', ODM File OID: '26e3094b-72eb-4a30-950f-7e5c05523536' User entered 'None (1)'	System	12 Sep 2020 04:00:11
	System	12 Sep 2020 04:00:11

US3412184

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 17:30:24

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:31:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (63C78D1B-A891-413A-BA58-C2E172B44955)', Time: '2020-09-12T00:00:09', User OID: 'PatientReportedOutcome (US3412184)', ODM File OID: '26e3094b-72eb-4a30-950f-7e5c05523536'	System	12 Sep 2020 04:00:11
User entered '12 Sep 2020 00:00'	System	12 Sep 2020 04:00:11

US3412184

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 17:30:24

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:31:53
User entered '11 Sep 2020 12:00'	System	08 Sep 2020 13:55:06

US3412184

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 17:30:24

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:31:53
User entered '12 Sep 2020 11:59'	System	08 Sep 2020 13:55:06

US3412184

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 17:30:24

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:31:53
Data entry locked.	System	08 Sep 2020 13:55:06
User entered 'Day 5'	System	08 Sep 2020 13:55:06

US3412184

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 17:30:24

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 10:31:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (63C78D1B-A891-413A-BA58-C2E172B44955)', Time: '2020-09-12T12:00:53', User OID: 'PatientReportedOutcome (US3412184)', ODM File OID: '08742a21-6826-4a66-9cf6-e1326ceec6bc' User entered 'None (1)'	System	12 Sep 2020 16:04:19
	System	12 Sep 2020 16:04:19

US3412184

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 17:30:24

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:31:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (63C78D1B-A891-413A-BA58-C2E172B44955)', Time: '2020-09-12T12:00:58', User OID: 'PatientReportedOutcome (US3412184)', ODM File OID: '08742a21-6826-4a66-9cf6-e1326ceec6bc' User entered 'No (N)'	System	12 Sep 2020 16:04:19
	System	12 Sep 2020 16:04:19

US3412184

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 17:30:24

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:31:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (63C78D1B-A891-413A-BA58-C2E172B44955)', Time: '2020-09-12T12:01:03', User OID: 'PatientReportedOutcome (US3412184)', ODM File OID: '08742a21-6826-4a66-9cf6-e1326ceec6bc' User entered 'No (N)'	System	12 Sep 2020 16:04:19
	System	12 Sep 2020 16:04:19

US3412184

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 17:30:24

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 10:31:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (63C78D1B-A891-413A-BA58-C2E172B44955)', Time: '2020-09-12T12:01:07', User OID: 'PatientReportedOutcome (US3412184)', ODM File OID: '08742a21-6826-4a66-9cf6-e1326ceec6bc' User entered 'None (1)'	System	12 Sep 2020 16:04:19
	System	12 Sep 2020 16:04:19

US3412184

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 17:30:24

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:31:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (63C78D1B-A891-413A-BA58-C2E172B44955)', Time: '2020-09-12T12:01:16', User OID: 'PatientReportedOutcome (US3412184)', ODM File OID: '08742a21-6826-4a66-9cf6-e1326ceec6bc' User entered '12 Sep 2020 12:01'	System	12 Sep 2020 16:04:19
	System	12 Sep 2020 16:04:19

US3412184

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 17:30:24

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:31:53
User entered '12 Sep 2020 12:00'	System	08 Sep 2020 13:55:06

US3412184

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 17:30:24

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:31:53
User entered '13 Sep 2020 11:59'	System	08 Sep 2020 13:55:06

US3412184

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 17:30:24

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:31:53
Data entry locked.	System	08 Sep 2020 13:55:06
User entered 'Day 6'	System	08 Sep 2020 13:55:06

US3412184

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 17:30:24

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 10:31:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (63C78D1B-A891-413A-BA58-C2E172B44955)', Time: '2020-09-13T19:33:37', User OID: 'PatientReportedOutcome (US3412184)', ODM File OID: '80aa49e2-9747-4822-b70b-4b1e54a3a6be' User entered 'None (1)'	System	13 Sep 2020 23:33:55
	System	13 Sep 2020 23:33:55

US3412184

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 17:30:24

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:31:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (63C78D1B-A891-413A-BA58-C2E172B44955)', Time: '2020-09-13T19:33:41', User OID: 'PatientReportedOutcome (US3412184)', ODM File OID: '80aa49e2-9747-4822-b70b-4b1e54a3a6be' User entered 'No (N)'	System	13 Sep 2020 23:33:55
	System	13 Sep 2020 23:33:55

US3412184

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 17:30:24

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:31:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (63C78D1B-A891-413A-BA58-C2E172B44955)', Time: '2020-09-13T19:33:46', User OID: 'PatientReportedOutcome (US3412184)', ODM File OID: '80aa49e2-9747-4822-b70b-4b1e54a3a6be' User entered 'No (N)'	System	13 Sep 2020 23:33:55
	System	13 Sep 2020 23:33:55

US3412184

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 17:30:24

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 10:31:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (63C78D1B-A891-413A-BA58-C2E172B44955)', Time: '2020-09-13T19:33:51', User OID: 'PatientReportedOutcome (US3412184)', ODM File OID: '80aa49e2-9747-4822-b70b-4b1e54a3a6be' User entered 'None (1)'	System	13 Sep 2020 23:33:55
	System	13 Sep 2020 23:33:55

US3412184

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 17:30:24

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:31:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (63C78D1B-A891-413A-BA58-C2E172B44955)', Time: '2020-09-13T19:33:53', User OID: 'PatientReportedOutcome (US3412184)', ODM File OID: '80aa49e2-9747-4822-b70b-4b1e54a3a6be' User entered '13 Sep 2020 19:33'	System	13 Sep 2020 23:33:55
	System	13 Sep 2020 23:33:55

US3412184

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 17:30:24

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:31:53
User entered '13 Sep 2020 12:00'	System	08 Sep 2020 13:55:06

US3412184

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 17:30:24

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:31:53
User entered '14 Sep 2020 11:59'	System	08 Sep 2020 13:55:06

US3412184

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 17:30:24

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:31:53
Data entry locked.	System	08 Sep 2020 13:55:06
User entered 'Day 7'	System	08 Sep 2020 13:55:06

US3412184

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 17:30:24

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 10:31:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (63C78D1B-A891-413A-BA58-C2E172B44955)', Time: '2020-09-15T06:33:35', User OID: 'PatientReportedOutcome (US3412184)', ODM File OID: 'be4849fe-dd61-46e4-8dce-facb280599f6' User entered 'None (1)'	System	15 Sep 2020 10:34:01
	System	15 Sep 2020 10:34:01

US3412184

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 17:30:24

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:31:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (63C78D1B-A891-413A-BA58-C2E172B44955)', Time: '2020-09-15T06:33:41', User OID: 'PatientReportedOutcome (US3412184)', ODM File OID: 'be4849fe-dd61-46e4-8dce-facb280599f6' User entered 'No (N)'	System	15 Sep 2020 10:34:01
	System	15 Sep 2020 10:34:01

US3412184

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 17:30:24

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:31:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (63C78D1B-A891-413A-BA58-C2E172B44955)', Time: '2020-09-15T06:33:49', User OID: 'PatientReportedOutcome (US3412184)', ODM File OID: 'be4849fe-dd61-46e4-8dce-facb280599f6' User entered 'No (N)'	System	15 Sep 2020 10:34:01
	System	15 Sep 2020 10:34:01

US3412184

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 17:30:24

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 10:31:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (63C78D1B-A891-413A-BA58-C2E172B44955)', Time: '2020-09-15T06:33:54', User OID: 'PatientReportedOutcome (US3412184)', ODM File OID: 'be4849fe-dd61-46e4-8dce-facb280599f6' User entered 'None (1)'	System	15 Sep 2020 10:34:01
	System	15 Sep 2020 10:34:01

US3412184

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 17:30:24

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:31:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (63C78D1B-A891-413A-BA58-C2E172B44955)', Time: '2020-09-15T06:33:57', User OID: 'PatientReportedOutcome (US3412184)', ODM File OID: 'be4849fe-dd61-46e4-8dce-facb280599f6' User entered '15 Sep 2020 06:33'	System	15 Sep 2020 10:34:01
	System	15 Sep 2020 10:34:01

US3412184

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 17:30:24

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:31:53
User entered '14 Sep 2020 12:00'	System	08 Sep 2020 13:55:06

US3412184

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 17:30:24

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:31:53
User entered '15 Sep 2020 11:59'	System	08 Sep 2020 13:55:06

US3412184

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:30:24

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:31:53
Data entry locked.	System	08 Sep 2020 13:55:06
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	08 Sep 2020 13:55:06

US3412184

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:30:24

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:31:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (63C78D1B-A891-413A-BA58-C2E172B44955)', Time: '2020-09-08T09:57:46', User OID: 'PatientReportedOutcome (US3412184)', ODM File OID: 'f97735ed-83ad-4ffd-aa20-8161026f676d' User entered 'None (0)'	System	08 Sep 2020 13:58:09
	System	08 Sep 2020 13:58:09

US3412184

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:30:24

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:31:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (63C78D1B-A891-413A-BA58-C2E172B44955)', Time: '2020-09-08T09:57:49', User OID: 'PatientReportedOutcome (US3412184)', ODM File OID: 'f97735ed-83ad-4ffd-aa20-8161026f676d' User entered 'None (0)'	System	08 Sep 2020 13:58:09
	System	08 Sep 2020 13:58:09

US3412184

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:30:24

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:31:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (63C78D1B-A891-413A-BA58-C2E172B44955)', Time: '2020-09-08T09:57:52', User OID: 'PatientReportedOutcome (US3412184)', ODM File OID: 'f97735ed-83ad-4ffd-aa20-8161026f676d' User entered 'None (0)'	System	08 Sep 2020 13:58:09
	System	08 Sep 2020 13:58:09

US3412184

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:30:24

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:31:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (63C78D1B-A891-413A-BA58-C2E172B44955)', Time: '2020-09-08T09:57:55', User OID: 'PatientReportedOutcome (US3412184)', ODM File OID: 'f97735ed-83ad-4ffd-aa20-8161026f676d' User entered 'None (0)'	System	08 Sep 2020 13:58:09
	System	08 Sep 2020 13:58:09

US3412184

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:30:24

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:31:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (63C78D1B-A891-413A-BA58-C2E172B44955)', Time: '2020-09-08T09:57:58', User OID: 'PatientReportedOutcome (US3412184)', ODM File OID: 'f97735ed-83ad-4ffd-aa20-8161026f676d' User entered 'None (0)'	System	08 Sep 2020 13:58:09
	System	08 Sep 2020 13:58:09

US3412184

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:30:24

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:31:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (63C78D1B-A891-413A-BA58-C2E172B44955)', Time: '2020-09-08T09:58:00', User OID: 'PatientReportedOutcome (US3412184)', ODM File OID: 'f97735ed-83ad-4ffd-aa20-8161026f676d' User entered 'None (0)'	System	08 Sep 2020 13:58:09
	System	08 Sep 2020 13:58:09

US3412184

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:30:24

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 10:31:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (63C78D1B-A891-413A-BA58-C2E172B44955)', Time: '2020-09-08T09:58:04', User OID: 'PatientReportedOutcome (US3412184)', ODM File OID: 'f97735ed-83ad-4ffd-aa20-8161026f676d' User entered 'No (N)'	System	08 Sep 2020 13:58:09
	System	08 Sep 2020 13:58:09

US3412184

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:30:24

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:31:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (63C78D1B-A891-413A-BA58-C2E172B44955)', Time: '2020-09-08T09:58:07', User OID: 'PatientReportedOutcome (US3412184)', ODM File OID: 'f97735ed-83ad-4ffd-aa20-8161026f676d' User entered '08 Sep 2020 09:58'	System	08 Sep 2020 13:58:09
	System	08 Sep 2020 13:58:09

US3412184

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:30:24

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:31:53
User entered '08 Sep 2020 09:35'	System	08 Sep 2020 13:55:06

US3412184

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:30:24

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:31:53
User entered '08 Sep 2020 12:05'	System	08 Sep 2020 13:55:06

US3412184

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:30:24

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:31:53
Data entry locked.	System	08 Sep 2020 13:55:06
User entered 'Day 1, after vaccination (at home)'	System	08 Sep 2020 13:55:06

US3412184

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:30:24

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:31:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (63C78D1B-A891-413A-BA58-C2E172B44955)', Time: '2020-09-08T20:37:35', User OID: 'PatientReportedOutcome (US3412184)', ODM File OID: '364af106-36e4-4850-9fac-9afdae440e68' User entered 'None (0)'	System	09 Sep 2020 00:38:16
	System	09 Sep 2020 00:38:16

US3412184

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:30:24

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:31:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (63C78D1B-A891-413A-BA58-C2E172B44955)', Time: '2020-09-08T20:37:38', User OID: 'PatientReportedOutcome (US3412184)', ODM File OID: '364af106-36e4-4850-9fac-9afdae440e68' User entered 'None (0)'	System	09 Sep 2020 00:38:16
	System	09 Sep 2020 00:38:16

US3412184

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:30:24

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:31:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (63C78D1B-A891-413A-BA58-C2E172B44955)', Time: '2020-09-08T20:37:41', User OID: 'PatientReportedOutcome (US3412184)', ODM File OID: '364af106-36e4-4850-9fac-9afdae440e68' User entered 'None (0)'	System	09 Sep 2020 00:38:16
	System	09 Sep 2020 00:38:16

US3412184

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:30:24

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:31:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (63C78D1B-A891-413A-BA58-C2E172B44955)', Time: '2020-09-08T20:37:44', User OID: 'PatientReportedOutcome (US3412184)', ODM File OID: '364af106-36e4-4850-9fac-9afdae440e68' User entered 'None (0)'	System	09 Sep 2020 00:38:16
	System	09 Sep 2020 00:38:16

US3412184

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:30:24

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:31:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (63C78D1B-A891-413A-BA58-C2E172B44955)', Time: '2020-09-08T20:37:47', User OID: 'PatientReportedOutcome (US3412184)', ODM File OID: '364af106-36e4-4850-9fac-9afdae440e68' User entered 'None (0)'	System	09 Sep 2020 00:38:16
	System	09 Sep 2020 00:38:16

US3412184

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:30:24

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:31:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (63C78D1B-A891-413A-BA58-C2E172B44955)', Time: '2020-09-08T20:37:49', User OID: 'PatientReportedOutcome (US3412184)', ODM File OID: '364af106-36e4-4850-9fac-9afdae440e68' User entered 'None (0)'	System	09 Sep 2020 00:38:16
	System	09 Sep 2020 00:38:16

US3412184

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:30:24

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 10:31:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (63C78D1B-A891-413A-BA58-C2E172B44955)', Time: '2020-09-08T20:37:53', User OID: 'PatientReportedOutcome (US3412184)', ODM File OID: '364af106-36e4-4850-9fac-9afdae440e68' User entered 'No (N)'	System	09 Sep 2020 00:38:16
	System	09 Sep 2020 00:38:16

US3412184

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:30:24

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:31:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (63C78D1B-A891-413A-BA58-C2E172B44955)', Time: '2020-09-08T20:38:11', User OID: 'PatientReportedOutcome (US3412184)', ODM File OID: '364af106-36e4-4850-9fac-9afdae440e68'	System	09 Sep 2020 00:38:16
User entered '08 Sep 2020 20:38'	System	09 Sep 2020 00:38:16

US3412184

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:30:24

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:31:53
User entered '08 Sep 2020 13:00'	System	08 Sep 2020 13:55:06

US3412184

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:30:24

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:31:53
User entered '09 Sep 2020 11:59'	System	08 Sep 2020 13:55:06

US3412184

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:30:24

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:31:53
Data entry locked.	System	08 Sep 2020 13:55:06
User entered 'Day 2'	System	08 Sep 2020 13:55:06

US3412184

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:30:24

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:31:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (63C78D1B-A891-413A-BA58-C2E172B44955)', Time: '2020-09-09T16:12:18', User OID: 'PatientReportedOutcome (US3412184)', ODM File OID: '31694c1c-1ebf-4b4f-9a1e-aa6468a7c74b' User entered 'None (0)'	System	09 Sep 2020 20:12:47
	System	09 Sep 2020 20:12:47

US3412184

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:30:24

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:31:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (63C78D1B-A891-413A-BA58-C2E172B44955)', Time: '2020-09-09T16:12:20', User OID: 'PatientReportedOutcome (US3412184)', ODM File OID: '31694c1c-1ebf-4b4f-9a1e-aa6468a7c74b' User entered 'None (0)'	System	09 Sep 2020 20:12:47
	System	09 Sep 2020 20:12:47

US3412184

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:30:24

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:31:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (63C78D1B-A891-413A-BA58-C2E172B44955)', Time: '2020-09-09T16:12:23', User OID: 'PatientReportedOutcome (US3412184)', ODM File OID: '31694c1c-1ebf-4b4f-9a1e-aa6468a7c74b' User entered 'None (0)'	System	09 Sep 2020 20:12:47
	System	09 Sep 2020 20:12:47

US3412184

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:30:24

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:31:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (63C78D1B-A891-413A-BA58-C2E172B44955)', Time: '2020-09-09T16:12:26', User OID: 'PatientReportedOutcome (US3412184)', ODM File OID: '31694c1c-1ebf-4b4f-9a1e-aa6468a7c74b' User entered 'None (0)'	System	09 Sep 2020 20:12:47
	System	09 Sep 2020 20:12:47

US3412184

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:30:24

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:31:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (63C78D1B-A891-413A-BA58-C2E172B44955)', Time: '2020-09-09T16:12:29', User OID: 'PatientReportedOutcome (US3412184)', ODM File OID: '31694c1c-1ebf-4b4f-9a1e-aa6468a7c74b' User entered 'None (0)'	System	09 Sep 2020 20:12:47
	System	09 Sep 2020 20:12:47

US3412184

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:30:24

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:31:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (63C78D1B-A891-413A-BA58-C2E172B44955)', Time: '2020-09-09T16:12:33', User OID: 'PatientReportedOutcome (US3412184)', ODM File OID: '31694c1c-1ebf-4b4f-9a1e-aa6468a7c74b' User entered 'None (0)'	System	09 Sep 2020 20:12:47
	System	09 Sep 2020 20:12:47

US3412184

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:30:24

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 10:31:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (63C78D1B-A891-413A-BA58-C2E172B44955)', Time: '2020-09-09T16:12:37', User OID: 'PatientReportedOutcome (US3412184)', ODM File OID: '31694c1c-1ebf-4b4f-9a1e-aa6468a7c74b' User entered 'No (N)'	System	09 Sep 2020 20:12:47
	System	09 Sep 2020 20:12:47

US3412184

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:30:24

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:31:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (63C78D1B-A891-413A-BA58-C2E172B44955)', Time: '2020-09-09T16:12:41', User OID: 'PatientReportedOutcome (US3412184)', ODM File OID: '31694c1c-1ebf-4b4f-9a1e-aa6468a7c74b'	System	09 Sep 2020 20:12:47
User entered '09 Sep 2020 16:12'	System	09 Sep 2020 20:12:47

US3412184

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:30:24

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:31:53
User entered '09 Sep 2020 12:00'	System	08 Sep 2020 13:55:06

US3412184

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:30:24

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:31:53
User entered '10 Sep 2020 11:59'	System	08 Sep 2020 13:55:06

US3412184

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:30:24

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:31:53
Data entry locked.	System	08 Sep 2020 13:55:06
User entered 'Day 3'	System	08 Sep 2020 13:55:06

US3412184

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:30:24

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:31:53

US3412184

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:30:24

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:31:53

US3412184

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:30:24

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:31:53

US3412184

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:30:24

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:31:53

US3412184

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:30:24

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:31:53

US3412184

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:30:24

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:31:53

US3412184

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:30:24

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 10:31:53

US3412184

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:30:24

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:31:53

US3412184

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:30:24

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:31:53
User entered '10 Sep 2020 12:00'	System	08 Sep 2020 13:55:06

US3412184

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:30:24

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:31:53
User entered '11 Sep 2020 11:59'	System	08 Sep 2020 13:55:06

US3412184

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:30:24

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:31:53
Data entry locked.	System	08 Sep 2020 13:55:06
User entered 'Day 4'	System	08 Sep 2020 13:55:06

US3412184

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:30:24

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:31:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (63C78D1B-A891-413A-BA58-C2E172B44955)', Time: '2020-09-12T00:00:16', User OID: 'PatientReportedOutcome (US3412184)', ODM File OID: '1a0569ca-3dc0-4792-a35a-02357a5f6c30' User entered 'None (0)'	System	12 Sep 2020 04:00:46
	System	12 Sep 2020 04:00:46

US3412184

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:30:24

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:31:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (63C78D1B-A891-413A-BA58-C2E172B44955)', Time: '2020-09-12T00:00:19', User OID: 'PatientReportedOutcome (US3412184)', ODM File OID: '1a0569ca-3dc0-4792-a35a-02357a5f6c30' User entered 'None (0)'	System	12 Sep 2020 04:00:46
	System	12 Sep 2020 04:00:46

US3412184

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:30:24

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:31:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (63C78D1B-A891-413A-BA58-C2E172B44955)', Time: '2020-09-12T00:00:23', User OID: 'PatientReportedOutcome (US3412184)', ODM File OID: '1a0569ca-3dc0-4792-a35a-02357a5f6c30' User entered 'None (0)'	System	12 Sep 2020 04:00:46
	System	12 Sep 2020 04:00:46

US3412184

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:30:24

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:31:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (63C78D1B-A891-413A-BA58-C2E172B44955)', Time: '2020-09-12T00:00:26', User OID: 'PatientReportedOutcome (US3412184)', ODM File OID: '1a0569ca-3dc0-4792-a35a-02357a5f6c30' User entered 'None (0)'	System	12 Sep 2020 04:00:46
	System	12 Sep 2020 04:00:46

US3412184

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:30:24

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:31:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (63C78D1B-A891-413A-BA58-C2E172B44955)', Time: '2020-09-12T00:00:29', User OID: 'PatientReportedOutcome (US3412184)', ODM File OID: '1a0569ca-3dc0-4792-a35a-02357a5f6c30' User entered 'None (0)'	System	12 Sep 2020 04:00:46
	System	12 Sep 2020 04:00:46

US3412184

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:30:24

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:31:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (63C78D1B-A891-413A-BA58-C2E172B44955)', Time: '2020-09-12T00:00:33', User OID: 'PatientReportedOutcome (US3412184)', ODM File OID: '1a0569ca-3dc0-4792-a35a-02357a5f6c30' User entered 'None (0)'	System	12 Sep 2020 04:00:46
	System	12 Sep 2020 04:00:46

US3412184

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:30:24

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 10:31:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (63C78D1B-A891-413A-BA58-C2E172B44955)', Time: '2020-09-12T00:00:40', User OID: 'PatientReportedOutcome (US3412184)', ODM File OID: '1a0569ca-3dc0-4792-a35a-02357a5f6c30' User entered 'No (N)'	System	12 Sep 2020 04:00:46
	System	12 Sep 2020 04:00:46

US3412184

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:30:24

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:31:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (63C78D1B-A891-413A-BA58-C2E172B44955)', Time: '2020-09-12T00:00:43', User OID: 'PatientReportedOutcome (US3412184)', ODM File OID: '1a0569ca-3dc0-4792-a35a-02357a5f6c30'	System	12 Sep 2020 04:00:46
User entered '12 Sep 2020 00:00'	System	12 Sep 2020 04:00:46

US3412184

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:30:24

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:31:53
User entered '11 Sep 2020 12:00'	System	08 Sep 2020 13:55:06

US3412184

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:30:24

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:31:53
User entered '12 Sep 2020 11:59'	System	08 Sep 2020 13:55:06

US3412184

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:30:24

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:31:53
Data entry locked.	System	08 Sep 2020 13:55:06
User entered 'Day 5'	System	08 Sep 2020 13:55:06

US3412184

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:30:24

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:31:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (63C78D1B-A891-413A-BA58-C2E172B44955)', Time: '2020-09-12T12:01:35', User OID: 'PatientReportedOutcome (US3412184)', ODM File OID: '9ca47502-b5be-4d96-af14-eb0cd68e0156' User entered 'None (0)'	System	12 Sep 2020 16:07:20
	System	12 Sep 2020 16:07:20

US3412184

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:30:24

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:31:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (63C78D1B-A891-413A-BA58-C2E172B44955)', Time: '2020-09-12T12:01:39', User OID: 'PatientReportedOutcome (US3412184)', ODM File OID: '9ca47502-b5be-4d96-af14-eb0cd68e0156' User entered 'None (0)'	System	12 Sep 2020 16:07:20
	System	12 Sep 2020 16:07:20

US3412184

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:30:24

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:31:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (63C78D1B-A891-413A-BA58-C2E172B44955)', Time: '2020-09-12T12:01:53', User OID: 'PatientReportedOutcome (US3412184)', ODM File OID: '9ca47502-b5be-4d96-af14-eb0cd68e0156' User entered 'None (0)'	System	12 Sep 2020 16:07:20
	System	12 Sep 2020 16:07:20

US3412184

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:30:24

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:31:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (63C78D1B-A891-413A-BA58-C2E172B44955)', Time: '2020-09-12T12:02:02', User OID: 'PatientReportedOutcome (US3412184)', ODM File OID: '9ca47502-b5be-4d96-af14-eb0cd68e0156' User entered 'None (0)'	System	12 Sep 2020 16:07:20
	System	12 Sep 2020 16:07:20

US3412184

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:30:24

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:31:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (63C78D1B-A891-413A-BA58-C2E172B44955)', Time: '2020-09-12T12:02:05', User OID: 'PatientReportedOutcome (US3412184)', ODM File OID: '9ca47502-b5be-4d96-af14-eb0cd68e0156' User entered 'None (0)'	System	12 Sep 2020 16:07:20
	System	12 Sep 2020 16:07:20

US3412184

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:30:24

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:31:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (63C78D1B-A891-413A-BA58-C2E172B44955)', Time: '2020-09-12T12:02:08', User OID: 'PatientReportedOutcome (US3412184)', ODM File OID: '9ca47502-b5be-4d96-af14-eb0cd68e0156' User entered 'None (0)'	System	12 Sep 2020 16:07:20
	System	12 Sep 2020 16:07:20

US3412184

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:30:24

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 10:31:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (63C78D1B-A891-413A-BA58-C2E172B44955)', Time: '2020-09-12T12:02:13', User OID: 'PatientReportedOutcome (US3412184)', ODM File OID: '9ca47502-b5be-4d96-af14-eb0cd68e0156' User entered 'No (N)'	System	12 Sep 2020 16:07:20
	System	12 Sep 2020 16:07:20

US3412184

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:30:24

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:31:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (63C78D1B-A891-413A-BA58-C2E172B44955)', Time: '2020-09-12T12:02:16', User OID: 'PatientReportedOutcome (US3412184)', ODM File OID: '9ca47502-b5be-4d96-af14-eb0cd68e0156'	System	12 Sep 2020 16:07:20
User entered '12 Sep 2020 12:02'	System	12 Sep 2020 16:07:20

US3412184

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:30:24

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:31:53
User entered '12 Sep 2020 12:00'	System	08 Sep 2020 13:55:06

US3412184

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:30:24

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:31:53
User entered '13 Sep 2020 11:59'	System	08 Sep 2020 13:55:06

US3412184

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:30:24

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:31:53
Data entry locked.	System	08 Sep 2020 13:55:06
User entered 'Day 6'	System	08 Sep 2020 13:55:06

US3412184

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:30:24

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:31:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (63C78D1B-A891-413A-BA58-C2E172B44955)', Time: '2020-09-13T19:34:08', User OID: 'PatientReportedOutcome (US3412184)', ODM File OID: 'b3e66049-02c5-46b5-b545-5dbafe4ec987' User entered 'None (0)'	System	13 Sep 2020 23:34:43
	System	13 Sep 2020 23:34:43

US3412184

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:30:24

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:31:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (63C78D1B-A891-413A-BA58-C2E172B44955)', Time: '2020-09-13T19:34:17', User OID: 'PatientReportedOutcome (US3412184)', ODM File OID: 'b3e66049-02c5-46b5-b545-5dbafe4ec987' User entered 'None (0)'	System	13 Sep 2020 23:34:43
	System	13 Sep 2020 23:34:43

US3412184

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:30:24

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:31:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (63C78D1B-A891-413A-BA58-C2E172B44955)', Time: '2020-09-13T19:34:23', User OID: 'PatientReportedOutcome (US3412184)', ODM File OID: 'b3e66049-02c5-46b5-b545-5dbafe4ec987' User entered 'None (0)'	System	13 Sep 2020 23:34:43
	System	13 Sep 2020 23:34:43

US3412184

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:30:24

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:31:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (63C78D1B-A891-413A-BA58-C2E172B44955)', Time: '2020-09-13T19:34:26', User OID: 'PatientReportedOutcome (US3412184)', ODM File OID: 'b3e66049-02c5-46b5-b545-5dbafe4ec987' User entered 'None (0)'	System	13 Sep 2020 23:34:43
	System	13 Sep 2020 23:34:43

US3412184

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:30:24

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:31:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (63C78D1B-A891-413A-BA58-C2E172B44955)', Time: '2020-09-13T19:34:31', User OID: 'PatientReportedOutcome (US3412184)', ODM File OID: 'b3e66049-02c5-46b5-b545-5dbafe4ec987'	System	13 Sep 2020 23:34:43
User entered 'None (0)'	System	13 Sep 2020 23:34:43

US3412184

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:30:24

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:31:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (63C78D1B-A891-413A-BA58-C2E172B44955)', Time: '2020-09-13T19:34:34', User OID: 'PatientReportedOutcome (US3412184)', ODM File OID: 'b3e66049-02c5-46b5-b545-5dbafe4ec987' User entered 'None (0)'	System	13 Sep 2020 23:34:43
	System	13 Sep 2020 23:34:43

US3412184

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:30:24

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 10:31:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (63C78D1B-A891-413A-BA58-C2E172B44955)', Time: '2020-09-13T19:34:38', User OID: 'PatientReportedOutcome (US3412184)', ODM File OID: 'b3e66049-02c5-46b5-b545-5dbafe4ec987' User entered 'No (N)'	System	13 Sep 2020 23:34:43
	System	13 Sep 2020 23:34:43

US3412184

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:30:24

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:31:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (63C78D1B-A891-413A-BA58-C2E172B44955)', Time: '2020-09-13T19:34:41', User OID: 'PatientReportedOutcome (US3412184)', ODM File OID: 'b3e66049-02c5-46b5-b545-5dbafe4ec987'	System	13 Sep 2020 23:34:43
User entered '13 Sep 2020 19:34'	System	13 Sep 2020 23:34:43

US3412184

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:30:24

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:31:53
User entered '13 Sep 2020 12:00'	System	08 Sep 2020 13:55:06

US3412184

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:30:24

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:31:53
User entered '14 Sep 2020 11:59'	System	08 Sep 2020 13:55:06

US3412184

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:30:24

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:31:53
Data entry locked.	System	08 Sep 2020 13:55:06
User entered 'Day 7'	System	08 Sep 2020 13:55:06

US3412184

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:30:24

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:31:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (63C78D1B-A891-413A-BA58-C2E172B44955)', Time: '2020-09-15T06:34:09', User OID: 'PatientReportedOutcome (US3412184)', ODM File OID: 'beb3d972-56cc-4cdd-8c02-60bc23c0e512' User entered 'None (0)'	System	15 Sep 2020 10:35:13
	System	15 Sep 2020 10:35:13

US3412184

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:30:24

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:31:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (63C78D1B-A891-413A-BA58-C2E172B44955)', Time: '2020-09-15T06:34:32', User OID: 'PatientReportedOutcome (US3412184)', ODM File OID: 'beb3d972-56cc-4cdd-8c02-60bc23c0e512' User entered 'None (0)'	System	15 Sep 2020 10:35:13
	System	15 Sep 2020 10:35:13

US3412184

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:30:24

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:31:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (63C78D1B-A891-413A-BA58-C2E172B44955)', Time: '2020-09-15T06:34:40', User OID: 'PatientReportedOutcome (US3412184)', ODM File OID: 'beb3d972-56cc-4cdd-8c02-60bc23c0e512' User entered 'None (0)'	System	15 Sep 2020 10:35:13
	System	15 Sep 2020 10:35:13

US3412184

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:30:24

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:31:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (63C78D1B-A891-413A-BA58-C2E172B44955)', Time: '2020-09-15T06:34:43', User OID: 'PatientReportedOutcome (US3412184)', ODM File OID: 'beb3d972-56cc-4cdd-8c02-60bc23c0e512' User entered 'None (0)'	System	15 Sep 2020 10:35:13
	System	15 Sep 2020 10:35:13

US3412184

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:30:24

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:31:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (63C78D1B-A891-413A-BA58-C2E172B44955)', Time: '2020-09-15T06:34:46', User OID: 'PatientReportedOutcome (US3412184)', ODM File OID: 'beb3d972-56cc-4cdd-8c02-60bc23c0e512' User entered 'None (0)'	System	15 Sep 2020 10:35:13
	System	15 Sep 2020 10:35:13

US3412184

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:30:24

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:31:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (63C78D1B-A891-413A-BA58-C2E172B44955)', Time: '2020-09-15T06:34:49', User OID: 'PatientReportedOutcome (US3412184)', ODM File OID: 'beb3d972-56cc-4cdd-8c02-60bc23c0e512' User entered 'None (0)'	System	15 Sep 2020 10:35:13
	System	15 Sep 2020 10:35:13

US3412184

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:30:24

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 10:31:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (63C78D1B-A891-413A-BA58-C2E172B44955)', Time: '2020-09-15T06:35:01', User OID: 'PatientReportedOutcome (US3412184)', ODM File OID: 'beb3d972-56cc-4cdd-8c02-60bc23c0e512' User entered 'No (N)'	System	15 Sep 2020 10:35:13
	System	15 Sep 2020 10:35:13

US3412184

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:30:24

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:31:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (63C78D1B-A891-413A-BA58-C2E172B44955)', Time: '2020-09-15T06:35:11', User OID: 'PatientReportedOutcome (US3412184)', ODM File OID: 'beb3d972-56cc-4cdd-8c02-60bc23c0e512'	System	15 Sep 2020 10:35:13
User entered '15 Sep 2020 06:35'	System	15 Sep 2020 10:35:13

US3412184

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:30:24

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:31:53
User entered '14 Sep 2020 12:00'	System	08 Sep 2020 13:55:06

US3412184

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:30:24

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:31:53
User entered '15 Sep 2020 11:59'	System	08 Sep 2020 13:55:06

US3412184

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:30:24

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:06:09
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 04:54:06
User entered 'Yes (Y)'	Melissa Fuson (b) (4)	23 Sep 2020 16:34:22

US3412184

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:30:24

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:06:09
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 04:54:06
User entered '15 Sep 2020'	Melissa Fuson (b) (4)	23 Sep 2020 16:34:22

US3412184

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:30:24

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:06:09
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 04:54:06
User entered 'Contact Made (CONTACT MADE)'	Melissa Fuson (b) (4)	23 Sep 2020 16:34:22

US3412184

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:30:24

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:06:09
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 04:54:06
User entered empty.	Melissa Fuson (b) (4)	23 Sep 2020 16:34:22

US3412184

Folder: Safety Call Day 36 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:30:24

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:06:09
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 04:54:06
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	15 Sep 2020 20:30:27

US3412184

Folder: Safety Call Day 36 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:30:24

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:06:09
User entered 'I'	System	15 Sep 2020 20:30:27

US3412184

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:30:24

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:06:09
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 02:43:30
User entered 'Yes (Y)'	Mason Urban (b) (4)	22 Sep 2020 18:55:10

US3412184

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:30:24

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:06:09
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 02:43:30
User entered '22 Sep 2020'	Mason Urban (b) (4)	22 Sep 2020 18:55:10

US3412184

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:30:24

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:06:09
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 02:43:30
User entered 'Contact Made (CONTACT MADE)'	Mason Urban (b) (4)	22 Sep 2020 18:55:10

US3412184

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:30:24

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:06:09
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 02:43:30
User entered empty.	Mason Urban (b) (4)	22 Sep 2020 18:55:10

US3412184

Folder: Safety Call Day 43 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:30:24

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:06:09
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 02:43:30
User entered 'Yes (Y)'	Mason Urban (b) (4)	22 Sep 2020 18:55:25

US3412184

Folder: Safety Call Day 43 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:30:24

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:06:09
User entered 'I'	System	22 Sep 2020 18:55:25

US3412184

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:30:24

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:06:09
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 02:43:30
User entered 'Yes (Y)'	Mason Urban (b) (4)	29 Sep 2020 18:55:34

US3412184

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:30:24

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:06:09
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 02:43:30
User entered '29 Sep 2020'	Mason Urban (b) (4)	29 Sep 2020 18:55:34

US3412184

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:30:24

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:06:09
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 02:43:30
User entered 'Contact Made (CONTACT MADE)'	Mason Urban (b) (4)	29 Sep 2020 18:55:34

US3412184

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:30:24

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:06:09
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 02:43:30
User entered empty.	Mason Urban (b) (4)	29 Sep 2020 18:55:34

US3412184

Folder: Safety Call Day 50 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:30:24

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:06:09
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 02:43:30
User entered 'Yes (Y)'	Mason Urban (b) (4)	29 Sep 2020 18:55:38

US3412184

Folder: Safety Call Day 50 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:30:24

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:06:09
User entered 'I'	System	29 Sep 2020 18:55:38

US3412184

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 09 Jun 2021 17:30:24

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:06:09
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 02:43:30
User entered 'Yes (Y)'	Steven Anderson (b) (4)	06 Oct 2020 16:31:07

US3412184

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 09 Jun 2021 17:30:24

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:06:09
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 02:43:30
User entered '06 Oct 2020'	Steven Anderson (b) (4)	06 Oct 2020 16:31:07

US3412184

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 09 Jun 2021 17:30:24

[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 20:06:09
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 02:43:30
User entered 'Clinic (Clinic)'	Steven Anderson (b) (4)	06 Oct 2020 16:31:07

US3412184

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 09 Jun 2021 17:30:24

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:06:09
User entered 'VISIT3'	System	06 Oct 2020 16:31:07

US3412184

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:30:24

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:06:09
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 02:43:30
User entered 'No (N)'	Steven Anderson (b) (4)	06 Oct 2020 16:31:18

US3412184

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:30:24

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:06:09
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 02:43:30
User entered empty.	Steven Anderson (b) (4)	06 Oct 2020 16:31:18

US3412184

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:30:24

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:06:09
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 02:43:30
User entered empty.	Steven Anderson (b) (4)	06 Oct 2020 16:31:18

US3412184

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:30:24

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:06:09
User entered empty.	System	06 Oct 2020 16:31:18

US3412184

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:30:24

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:06:09
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 02:43:30
User entered empty.	Steven Anderson (b) (4)	06 Oct 2020 16:31:18

US3412184

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:30:24

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:06:09
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 02:43:30
User entered empty.	Steven Anderson (b) (4)	06 Oct 2020 16:31:18

US3412184

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:30:24

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:06:09
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 02:43:30
User entered empty.	Steven Anderson (b) (4)	06 Oct 2020 16:31:18

US3412184

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:30:24

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:06:09
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 02:43:30
User entered empty.	Steven Anderson (b) (4)	06 Oct 2020 16:31:18

US3412184

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:30:24

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:06:09
User entered empty.	System	06 Oct 2020 16:31:18

US3412184

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:30:24

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:06:09
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 02:43:30
User entered empty.	Steven Anderson (b) (4)	06 Oct 2020 16:31:18

US3412184

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:30:24

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:06:09
User entered empty.	System	06 Oct 2020 16:31:18

US3412184

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:30:24

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:06:09
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 02:43:30
User entered empty.	Steven Anderson (b) (4)	06 Oct 2020 16:31:18

US3412184

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:30:24

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:06:09
User entered empty.	System	06 Oct 2020 16:31:18

US3412184

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:30:24

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:06:09
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 02:43:30
User entered empty.	Steven Anderson (b) (4)	06 Oct 2020 16:31:18

US3412184

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:30:24

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:06:09
User entered empty.	System	06 Oct 2020 16:31:18

US3412184

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:30:24

[Height \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:06:09

US3412184

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:30:24

[Weight \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:06:09

US3412184

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 17:30:24

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:06:09
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 02:43:30
User entered 'No (N)' reason for change: Data Entry Error	Melissa Fuson (b) (4)	24 Nov 2020 16:18:30
User entered 'Yes (Y)'	Steven Anderson (b) (4)	06 Oct 2020 16:31:33

US3412184

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 17:30:24

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:06:09
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 02:43:30
User entered empty; reason for change Data Entry Error	Melissa Fuson (b) (4)	24 Nov 2020 16:18:30
User entered '06 Oct 2020'	Steven Anderson (b) (4)	06 Oct 2020 16:31:33

US3412184

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:30:24

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:06:09
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 02:43:30
User entered 'Yes (Y)'	Steven Anderson (b) (4)	06 Oct 2020 16:31:50

US3412184

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:30:24

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:06:09
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 02:43:30
User entered '06 Oct 2020'	Steven Anderson (b) (4)	06 Oct 2020 16:31:50

US3412184

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:30:24

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:06:09
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 02:43:30
User entered '10:43'	Steven Anderson (b) (4)	06 Oct 2020 16:31:50

US3412184

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:30:24

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:06:09
User entered '06 Oct 2020 10:43'	System	06 Oct 2020 16:31:50

US3412184

Folder: Visit 3 Day 57 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:30:24

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:06:09
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 02:43:30
User entered 'Yes (Y)'	Steven Anderson (b) (4)	06 Oct 2020 16:31:57

US3412184

Folder: Visit 3 Day 57 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:30:24

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:06:09
User entered 'I'	System	06 Oct 2020 16:31:57

US3412184

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:30:24

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:31:53
Data entry locked.	System	10 Aug 2020 14:48:00
User entered 'Day 64'	System	10 Aug 2020 14:48:00

US3412184

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:30:24

[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 10:31:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (63C78D1B-A891-413A-BA58-C2E172B44955)', Time: '2020-10-10T06:36:18', User OID: 'PatientReportedOutcome (US3412184)', ODM File OID: '849b2e3c-e3ba-48db-96ea-7a1059d8c69d'	System	10 Oct 2020 10:38:11
User entered 'Yes (Y)'	System	10 Oct 2020 10:38:11

US3412184

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:30:24

Have you been exposed to someone with 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 10:31:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (63C78D1B-A891-413A-BA58-C2E172B44955)', Time: '2020-10-10T06:36:26', User OID: 'PatientReportedOutcome (US3412184)', ODM File OID: '849b2e3c-e3ba-48db-96ea-7a1059d8c69d'	System	10 Oct 2020 10:38:11
User entered 'No (N)'	System	10 Oct 2020 10:38:11

US3412184

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:30:24

[Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:31:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (63C78D1B-A891-413A-BA58-C2E172B44955)', Time: '2020-10-10T06:36:39', User OID: 'PatientReportedOutcome (US3412184)', ODM File OID: '849b2e3c-e3ba-48db-96ea-7a1059d8c69d' User entered 'Yes (Y)'	System	10 Oct 2020 10:38:11
	System	10 Oct 2020 10:38:11

US3412184

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:30:24

Fever (Temperature \geq 100.4°F/38°C)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:31:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (63C78D1B-A891-413A-BA58-C2E172B44955)', Time: '2020-10-10T06:37:08', User OID: 'PatientReportedOutcome (US3412184)', ODM File OID: '849b2e3c-e3ba-48db-96ea-7a1059d8c69d' User entered '1'	System	10 Oct 2020 10:38:11
	System	10 Oct 2020 10:38:11

US3412184

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:30:24

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:31:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (63C78D1B-A891-413A-BA58-C2E172B44955)', Time: '2020-10-10T06:37:08', User OID: 'PatientReportedOutcome (US3412184)', ODM File OID: '849b2e3c-e3ba-48db-96ea-7a1059d8c69d' User entered '1'	System	10 Oct 2020 10:38:11
	System	10 Oct 2020 10:38:11

US3412184

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:30:24

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:31:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (63C78D1B-A891-413A-BA58-C2E172B44955)', Time: '2020-10-10T06:37:08', User OID: 'PatientReportedOutcome (US3412184)', ODM File OID: '849b2e3c-e3ba-48db-96ea-7a1059d8c69d' User entered '0'	System	10 Oct 2020 10:38:11
	System	10 Oct 2020 10:38:11

US3412184

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:30:24

[Shortness of breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:31:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (63C78D1B-A891-413A-BA58-C2E172B44955)', Time: '2020-10-10T06:37:08', User OID: 'PatientReportedOutcome (US3412184)', ODM File OID: '849b2e3c-e3ba-48db-96ea-7a1059d8c69d' User entered '0'	System	10 Oct 2020 10:38:11
	System	10 Oct 2020 10:38:11

US3412184

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:30:24

[Difficulty breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:31:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (63C78D1B-A891-413A-BA58-C2E172B44955)', Time: '2020-10-10T06:37:08', User OID: 'PatientReportedOutcome (US3412184)', ODM File OID: '849b2e3c-e3ba-48db-96ea-7a1059d8c69d' User entered '0'	System	10 Oct 2020 10:38:11
	System	10 Oct 2020 10:38:11

US3412184

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:30:24

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:31:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (63C78D1B-A891-413A-BA58-C2E172B44955)', Time: '2020-10-10T06:37:08', User OID: 'PatientReportedOutcome (US3412184)', ODM File OID: '849b2e3c-e3ba-48db-96ea-7a1059d8c69d' User entered '1'	System	10 Oct 2020 10:38:11
	System	10 Oct 2020 10:38:11

US3412184

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:30:24

[Muscle aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:31:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (63C78D1B-A891-413A-BA58-C2E172B44955)', Time: '2020-10-10T06:37:08', User OID: 'PatientReportedOutcome (US3412184)', ODM File OID: '849b2e3c-e3ba-48db-96ea-7a1059d8c69d' User entered '0'	System	10 Oct 2020 10:38:11
	System	10 Oct 2020 10:38:11

US3412184

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:30:24

[Body aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:31:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (63C78D1B-A891-413A-BA58-C2E172B44955)', Time: '2020-10-10T06:37:08', User OID: 'PatientReportedOutcome (US3412184)', ODM File OID: '849b2e3c-e3ba-48db-96ea-7a1059d8c69d' User entered '1'	System	10 Oct 2020 10:38:11
	System	10 Oct 2020 10:38:11

US3412184

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:30:24

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:31:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (63C78D1B-A891-413A-BA58-C2E172B44955)', Time: '2020-10-10T06:37:08', User OID: 'PatientReportedOutcome (US3412184)', ODM File OID: '849b2e3c-e3ba-48db-96ea-7a1059d8c69d' User entered '1'	System	10 Oct 2020 10:38:11
	System	10 Oct 2020 10:38:11

US3412184

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:30:24

[New loss of taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:31:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (63C78D1B-A891-413A-BA58-C2E172B44955)', Time: '2020-10-10T06:37:08', User OID: 'PatientReportedOutcome (US3412184)', ODM File OID: '849b2e3c-e3ba-48db-96ea-7a1059d8c69d' User entered '0'	System	10 Oct 2020 10:38:11
	System	10 Oct 2020 10:38:11

US3412184

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:30:24

[New loss of smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:31:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (63C78D1B-A891-413A-BA58-C2E172B44955)', Time: '2020-10-10T06:37:08', User OID: 'PatientReportedOutcome (US3412184)', ODM File OID: '849b2e3c-e3ba-48db-96ea-7a1059d8c69d' User entered '0'	System	10 Oct 2020 10:38:11
	System	10 Oct 2020 10:38:11

US3412184

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:30:24

[Sore throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:31:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (63C78D1B-A891-413A-BA58-C2E172B44955)', Time: '2020-10-10T06:37:08', User OID: 'PatientReportedOutcome (US3412184)', ODM File OID: '849b2e3c-e3ba-48db-96ea-7a1059d8c69d' User entered '0'	System	10 Oct 2020 10:38:11
	System	10 Oct 2020 10:38:11

US3412184

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:30:24

[Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:31:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (63C78D1B-A891-413A-BA58-C2E172B44955)', Time: '2020-10-10T06:37:08', User OID: 'PatientReportedOutcome (US3412184)', ODM File OID: '849b2e3c-e3ba-48db-96ea-7a1059d8c69d' User entered '0'	System	10 Oct 2020 10:38:11
	System	10 Oct 2020 10:38:11

US3412184

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:30:24

[Runny nose](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:31:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (63C78D1B-A891-413A-BA58-C2E172B44955)', Time: '2020-10-10T06:37:08', User OID: 'PatientReportedOutcome (US3412184)', ODM File OID: '849b2e3c-e3ba-48db-96ea-7a1059d8c69d' User entered '0'	System	10 Oct 2020 10:38:11
	System	10 Oct 2020 10:38:11

US3412184

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:30:24

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:31:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (63C78D1B-A891-413A-BA58-C2E172B44955)', Time: '2020-10-10T06:37:08', User OID: 'PatientReportedOutcome (US3412184)', ODM File OID: '849b2e3c-e3ba-48db-96ea-7a1059d8c69d' User entered '0'	System	10 Oct 2020 10:38:11
	System	10 Oct 2020 10:38:11

US3412184

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:30:24

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:31:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (63C78D1B-A891-413A-BA58-C2E172B44955)', Time: '2020-10-10T06:37:08', User OID: 'PatientReportedOutcome (US3412184)', ODM File OID: '849b2e3c-e3ba-48db-96ea-7a1059d8c69d' User entered '0'	System	10 Oct 2020 10:38:11
	System	10 Oct 2020 10:38:11

US3412184

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:30:24

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:31:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (63C78D1B-A891-413A-BA58-C2E172B44955)', Time: '2020-10-10T06:37:08', User OID: 'PatientReportedOutcome (US3412184)', ODM File OID: '849b2e3c-e3ba-48db-96ea-7a1059d8c69d' User entered '0'	System	10 Oct 2020 10:38:11
	System	10 Oct 2020 10:38:11

US3412184

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:30:24

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:31:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (63C78D1B-A891-413A-BA58-C2E172B44955)', Time: '2020-10-10T06:37:24', User OID: 'PatientReportedOutcome (US3412184)', ODM File OID: '849b2e3c-e3ba-48db-96ea-7a1059d8c69d'	System	10 Oct 2020 10:38:11
User entered 'I confirm I have read this message and will call the study clinic immediately (9)'	System	10 Oct 2020 10:38:11

US3412184

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:30:24

[Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:31:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (63C78D1B-A891-413A-BA58-C2E172B44955)', Time: '2020-10-10T06:37:38', User OID: 'PatientReportedOutcome (US3412184)', ODM File OID: '849b2e3c-e3ba-48db-96ea-7a1059d8c69d' User entered 'Yes (Y)'	System	10 Oct 2020 10:38:11
	System	10 Oct 2020 10:38:11

US3412184

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:30:24

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:31:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (63C78D1B-A891-413A-BA58-C2E172B44955)', Time: '2020-10-10T06:37:50', User OID: 'PatientReportedOutcome (US3412184)', ODM File OID: '849b2e3c-e3ba-48db-96ea-7a1059d8c69d'	System	10 Oct 2020 10:38:11
User entered 'I confirm I have read this message and will call the study clinic immediately (9)'	System	10 Oct 2020 10:38:11

US3412184

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:30:24

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:31:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (63C78D1B-A891-413A-BA58-C2E172B44955)', Time: '2020-10-10T06:38:00', User OID: 'PatientReportedOutcome (US3412184)', ODM File OID: '849b2e3c-e3ba-48db-96ea-7a1059d8c69d' User entered '10 Oct 2020 06:38:00'	System	10 Oct 2020 10:38:11
	System	10 Oct 2020 10:38:11

US3412184

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:30:24

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:31:53
Data entry locked.	System	10 Aug 2020 14:48:00
User entered '10 Oct 2020 00:01'	System	10 Aug 2020 14:48:00

US3412184

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:30:24

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:31:53
Data entry locked.	System	10 Aug 2020 14:48:00
User entered '14 Oct 2020 23:59'	System	10 Aug 2020 14:48:00

US3412184

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:30:24

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:31:53
Data entry locked.	System	10 Aug 2020 14:48:00
User entered 'Day 71'	System	10 Aug 2020 14:48:00

US3412184

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:30:24

[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 10:31:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (63C78D1B-A891-413A-BA58-C2E172B44955)', Time: '2020-10-21T22:36:23', User OID: 'PatientReportedOutcome (US3412184)', ODM File OID: 'd5475de7-1003-4c32-bcca-69f9088ba718' User entered 'No (N)'	System	22 Oct 2020 02:36:39
	System	22 Oct 2020 02:36:39

US3412184

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:30:24

Have you been exposed to someone with 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 10:31:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (63C78D1B-A891-413A-BA58-C2E172B44955)', Time: '2020-10-21T22:36:32', User OID: 'PatientReportedOutcome (US3412184)', ODM File OID: 'd5475de7-1003-4c32-bcca-69f9088ba718'	System	22 Oct 2020 02:36:39
User entered 'No (N)'	System	22 Oct 2020 02:36:39

US3412184

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:30:24

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:31:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (63C78D1B-A891-413A-BA58-C2E172B44955)', Time: '2020-10-21T22:36:35', User OID: 'PatientReportedOutcome (US3412184)', ODM File OID: 'd5475de7-1003-4c32-bcca-69f9088ba718' User entered '21 Oct 2020 22:36:35'	System	22 Oct 2020 02:36:39
	System	22 Oct 2020 02:36:39

US3412184

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:30:24

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:31:53
Data entry locked.	System	10 Aug 2020 14:48:00
User entered '17 Oct 2020 00:01'	System	10 Aug 2020 14:48:00

US3412184

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:30:24

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:31:53
Data entry locked.	System	10 Aug 2020 14:48:00
User entered '21 Oct 2020 23:59'	System	10 Aug 2020 14:48:00

US3412184

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:30:24

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:31:53
Data entry locked.	System	10 Aug 2020 14:48:00
User entered 'Day 78'	System	10 Aug 2020 14:48:00

US3412184

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:30:24

[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 10:31:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (63C78D1B-A891-413A-BA58-C2E172B44955)', Time: '2020-10-26T12:14:11', User OID: 'PatientReportedOutcome (US3412184)', ODM File OID: '3d134859-9fb2-483a-9908-32135da4bfa0'	System	26 Oct 2020 16:14:24
User entered 'No (N)'	System	26 Oct 2020 16:14:24

US3412184

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:30:24

Have you been exposed to someone with 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 10:31:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (63C78D1B-A891-413A-BA58-C2E172B44955)', Time: '2020-10-26T12:14:16', User OID: 'PatientReportedOutcome (US3412184)', ODM File OID: '3d134859-9fb2-483a-9908-32135da4bfa0'	System	26 Oct 2020 16:14:24
User entered 'No (N)'	System	26 Oct 2020 16:14:24

US3412184

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:30:24

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:31:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (63C78D1B-A891-413A-BA58-C2E172B44955)', Time: '2020-10-26T12:14:21', User OID: 'PatientReportedOutcome (US3412184)', ODM File OID: '3d134859-9fb2-483a-9908-32135da4bfa0' User entered '26 Oct 2020 12:14:21'	System	26 Oct 2020 16:14:24
	System	26 Oct 2020 16:14:24

US3412184

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:30:24

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:31:53
Data entry locked.	System	10 Aug 2020 14:48:00
User entered '24 Oct 2020 00:01'	System	10 Aug 2020 14:48:00

US3412184

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:30:24

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:31:53
Data entry locked.	System	10 Aug 2020 14:48:00
User entered '28 Oct 2020 23:59'	System	10 Aug 2020 14:48:00

US3412184

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:30:24

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:31:53
Data entry locked.	System	10 Aug 2020 14:48:00
User entered 'Day 92'	System	10 Aug 2020 14:48:00

US3412184

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:30:24

[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 10:31:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (63C78D1B-A891-413A-BA58-C2E172B44955)', Time: '2020-11-07T07:58:25', User OID: 'PatientReportedOutcome (US3412184)', ODM File OID: '9fa1d38d-851b-4a73-8462-c11d251eb0b6' User entered 'No (N)'	System	07 Nov 2020 12:58:47
	System	07 Nov 2020 12:58:47

US3412184

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:30:24

Have you been exposed to someone with 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 10:31:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (63C78D1B-A891-413A-BA58-C2E172B44955)', Time: '2020-11-07T07:58:33', User OID: 'PatientReportedOutcome (US3412184)', ODM File OID: '9fa1d38d-851b-4a73-8462-c11d251eb0b6'	System	07 Nov 2020 12:58:47
User entered 'No (N)'	System	07 Nov 2020 12:58:47

US3412184

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:30:24

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:31:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (63C78D1B-A891-413A-BA58-C2E172B44955)', Time: '2020-11-07T07:58:43', User OID: 'PatientReportedOutcome (US3412184)', ODM File OID: '9fa1d38d-851b-4a73-8462-c11d251eb0b6' User entered '07 Nov 2020 07:58:43'	System	07 Nov 2020 12:58:47
	System	07 Nov 2020 12:58:47

US3412184

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:30:24

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:31:53
Data entry locked.	System	10 Aug 2020 14:48:00
User entered '07 Nov 2020 00:01'	System	10 Aug 2020 14:48:00

US3412184

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:30:24

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:31:53
Data entry locked.	System	10 Aug 2020 14:48:00
User entered '11 Nov 2020 23:59'	System	10 Aug 2020 14:48:00

US3412184

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:30:24

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:31:53
Data entry locked.	System	10 Aug 2020 14:48:00
User entered 'Day 99'	System	10 Aug 2020 14:48:00

US3412184

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:30:24

[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 10:31:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (63C78D1B-A891-413A-BA58-C2E172B44955)', Time: '2020-11-14T08:15:26', User OID: 'PatientReportedOutcome (US3412184)', ODM File OID: '66ceb045-b310-49c9-97be-1960b88504f7'	System	14 Nov 2020 13:17:07
User entered 'No (N)'	System	14 Nov 2020 13:17:07

US3412184

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:30:24

[Have you been exposed to someone with 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 10:31:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (63C78D1B-A891-413A-BA58-C2E172B44955)', Time: '2020-11-14T08:16:41', User OID: 'PatientReportedOutcome (US3412184)', ODM File OID: '66ceb045-b310-49c9-97be-1960b88504f7'	System	14 Nov 2020 13:17:07
User entered 'Yes (Y)'	System	14 Nov 2020 13:17:07

US3412184

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:30:24

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:31:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (63C78D1B-A891-413A-BA58-C2E172B44955)', Time: '2020-11-14T08:16:52', User OID: 'PatientReportedOutcome (US3412184)', ODM File OID: '66ceb045-b310-49c9-97be-1960b88504f7'	System	14 Nov 2020 13:17:07
User entered 'I confirm I have read this message and will call the study clinic immediately (9)'	System	14 Nov 2020 13:17:07

US3412184

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:30:24

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:31:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (63C78D1B-A891-413A-BA58-C2E172B44955)', Time: '2020-11-14T08:16:55', User OID: 'PatientReportedOutcome (US3412184)', ODM File OID: '66ceb045-b310-49c9-97be-1960b88504f7' User entered '14 Nov 2020 08:16:55'	System	14 Nov 2020 13:17:07
	System	14 Nov 2020 13:17:07

US3412184

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:30:24

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:31:53
Data entry locked.	System	10 Aug 2020 14:48:00
User entered '14 Nov 2020 00:01'	System	10 Aug 2020 14:48:00

US3412184

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:30:24

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:31:53
Data entry locked.	System	10 Aug 2020 14:48:00
User entered '18 Nov 2020 23:59'	System	10 Aug 2020 14:48:00

US3412184

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:30:24

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:57:13
Amendment Manager: User entered 'Day 103'	System	19 Nov 2020 16:57:13

US3412184

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:30:24

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:57:13
Amendment Manager: User entered '18 Nov 2020 00:01'	System	19 Nov 2020 16:57:13

US3412184

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:30:24

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:57:13
Amendment Manager: User entered '22 Nov 2020 23:59'	System	19 Nov 2020 16:57:13

US3412184

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:30:24

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:57:13
Amendment Manager: User entered 'Day 110'	System	19 Nov 2020 16:57:13

US3412184

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:30:24

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:57:13
Amendment Manager: User entered '25 Nov 2020 00:01'	System	19 Nov 2020 16:57:13

US3412184

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:30:24

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:57:13
Amendment Manager: User entered '29 Nov 2020 23:59'	System	19 Nov 2020 16:57:13

US3412184

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:30:24

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:57:13
Amendment Manager: User entered 'Day 117'	System	19 Nov 2020 16:57:13

US3412184

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:30:24

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:57:13
Amendment Manager: User entered '02 Dec 2020 00:01'	System	19 Nov 2020 16:57:13

US3412184

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:30:24

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:57:13
Amendment Manager: User entered '06 Dec 2020 23:59'	System	19 Nov 2020 16:57:13

US3412184

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:30:24

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:57:13
Amendment Manager: User entered 'Day 124'	System	19 Nov 2020 16:57:13

US3412184

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:30:24

[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 (B13BC002-54ED-4590-9644-D0F236AFA2A2)', Time: '2020-12-10T13:07:15', User OID: 'PatientReportedOutcome (US3412184)', ODM File OID: 'b6f8d19a-6d91-4452-b84c-d8f9bfd34af0'	System	10 Dec 2020 18:07:41
User entered 'No (N)'	System	10 Dec 2020 18:07:41

US3412184

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:30:24

Have you been exposed to someone with 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 (B13BC002-54ED-4590-9644-D0F236AFA2A2)', Time: '2020-12-10T13:07:34', User OID: 'PatientReportedOutcome (US3412184)', ODM File OID: 'b6f8d19a-6d91-4452-b84c-d8f9bfd34af0'	System	10 Dec 2020 18:07:41
User entered 'No (N)'	System	10 Dec 2020 18:07:41

US3412184

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:30:24

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B13BC002-54ED-4590-9644-D0F236AFA2A2)', Time: '2020-12-10T13:07:38', User OID: 'PatientReportedOutcome (US3412184)', ODM File OID: 'b6f8d19a-6d91-4452-b84c-d8f9bfd34af0' User entered '10 Dec 2020 13:07:38'	System	10 Dec 2020 18:07:41
	System	10 Dec 2020 18:07:41

US3412184

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:30:24

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:57:13
Amendment Manager: User entered '09 Dec 2020 00:01'	System	19 Nov 2020 16:57:13

US3412184

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:30:24

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:57:13
Amendment Manager: User entered '13 Dec 2020 23:59'	System	19 Nov 2020 16:57:13

US3412184

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:30:24

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:57:13
Amendment Manager: User entered 'Day 131'	System	19 Nov 2020 16:57:13

US3412184

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:30:24

[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 (B13BC002-54ED-4590-9644-D0F236AFA2A2)', Time: '2020-12-16T00:01:49', User OID: 'PatientReportedOutcome (US3412184)', ODM File OID: 'de4f1844-447f-49f8-84d1-d50c660c0e8c'	System	16 Dec 2020 05:02:19
User entered 'No (N)'	System	16 Dec 2020 05:02:19

US3412184

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:30:24

Have you been exposed to someone with 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 (B13BC002-54ED-4590-9644-D0F236AFA2A2)', Time: '2020-12-16T00:02:01', User OID: 'PatientReportedOutcome (US3412184)', ODM File OID: 'de4f1844-447f-49f8-84d1-d50c660c0e8c'	System	16 Dec 2020 05:02:19
User entered 'No (N)'	System	16 Dec 2020 05:02:19

US3412184

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:30:24

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B13BC002-54ED-4590-9644-D0F236AFA2A2)', Time: '2020-12-16T00:02:13', User OID: 'PatientReportedOutcome (US3412184)', ODM File OID: 'de4f1844-447f-49f8-84d1-d50c660c0e8c' User entered '16 Dec 2020 00:02:13'	System	16 Dec 2020 05:02:19
	System	16 Dec 2020 05:02:19

US3412184

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:30:24

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:57:13
Amendment Manager: User entered '16 Dec 2020 00:01'	System	19 Nov 2020 16:57:13

US3412184

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:30:24

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:57:13
Amendment Manager: User entered '20 Dec 2020 23:59'	System	19 Nov 2020 16:57:13

US3412184

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:30:24

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:57:13
Amendment Manager: User entered 'Day 138'	System	19 Nov 2020 16:57:13

US3412184

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:30:24

[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 (B13BC002-54ED-4590-9644-D0F236AFA2A2)', Time: '2020-12-23T00:01:21', User OID: 'PatientReportedOutcome (US3412184)', ODM File OID: '5613995b-7d65-438e-9f92-9fc5493dafdb' User entered 'No (N)'	System	23 Dec 2020 05:01:45
	System	23 Dec 2020 05:01:45

US3412184

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:30:24

Have you been exposed to someone with 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 (B13BC002-54ED-4590-9644-D0F236AFA2A2)', Time: '2020-12-23T00:01:26', User OID: 'PatientReportedOutcome (US3412184)', ODM File OID: '5613995b-7d65-438e-9f92-9fc5493dafdb'	System	23 Dec 2020 05:01:45
User entered 'No (N)'	System	23 Dec 2020 05:01:45

US3412184

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:30:24

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B13BC002-54ED-4590-9644-D0F236AFA2A2)', Time: '2020-12-23T00:01:33', User OID: 'PatientReportedOutcome (US3412184)', ODM File OID: '5613995b-7d65-438e-9f92-9fc5493dafdb' User entered '23 Dec 2020 00:01:33'	System	23 Dec 2020 05:01:45
	System	23 Dec 2020 05:01:45

US3412184

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:30:24

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:57:13
Amendment Manager: User entered '23 Dec 2020 00:01'	System	19 Nov 2020 16:57:13

US3412184

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:30:24

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:57:13
Amendment Manager: User entered '27 Dec 2020 23:59'	System	19 Nov 2020 16:57:13

US3412184

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:30:24

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:57:13
Amendment Manager: User entered 'Day 145'	System	19 Nov 2020 16:57:13

US3412184

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:30:24

[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 (B13BC002-54ED-4590-9644-D0F236AFA2A2)', Time: '2020-12-30T06:39:48', User OID: 'PatientReportedOutcome (US3412184)', ODM File OID: '66bdf063-ccc9-4b68-98be-595cbd0d431d' User entered 'No (N)'	System	30 Dec 2020 11:40:01
	System	30 Dec 2020 11:40:01

US3412184

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:30:24

Have you been exposed to someone with 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 (B13BC002-54ED-4590-9644-D0F236AFA2A2)', Time: '2020-12-30T06:39:52', User OID: 'PatientReportedOutcome (US3412184)', ODM File OID: '66bdf063-ccc9-4b68-98be-595cbd0d431d' User entered 'No (N)'	System	30 Dec 2020 11:40:01
	System	30 Dec 2020 11:40:01

US3412184

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:30:24

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B13BC002-54ED-4590-9644-D0F236AFA2A2)', Time: '2020-12-30T06:39:59', User OID: 'PatientReportedOutcome (US3412184)', ODM File OID: '66bdf063-ccc9-4b68-98be-595cbd0d431d' User entered '30 Dec 2020 06:39:59'	System	30 Dec 2020 11:40:01
	System	30 Dec 2020 11:40:01

US3412184

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:30:24

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:57:13
Amendment Manager: User entered '30 Dec 2020 00:01'	System	19 Nov 2020 16:57:13

US3412184

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:30:24

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:57:13
Amendment Manager: User entered '03 Jan 2021 23:59'	System	19 Nov 2020 16:57:13

US3412184

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:30:24

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:57:13
Amendment Manager: User entered 'Day 152'	System	19 Nov 2020 16:57:13

US3412184

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:30:24

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:57:13
Amendment Manager: User entered '06 Jan 2021 00:01'	System	19 Nov 2020 16:57:13

US3412184

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:30:24

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:57:13
Amendment Manager: User entered '10 Jan 2021 23:59'	System	19 Nov 2020 16:57:13

US3412184

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:30:24

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:57:13
Amendment Manager: User entered 'Day 159'	System	19 Nov 2020 16:57:13

US3412184

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:30:24

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:57:13
Amendment Manager: User entered '13 Jan 2021 00:01'	System	19 Nov 2020 16:57:13

US3412184

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:30:24

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:57:13
Amendment Manager: User entered '17 Jan 2021 23:59'	System	19 Nov 2020 16:57:13

US3412184

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:30:24

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:57:13
Amendment Manager: User entered 'Day 166'	System	19 Nov 2020 16:57:13

US3412184

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:30:24

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:57:13
Amendment Manager: User entered '20 Jan 2021 00:01'	System	19 Nov 2020 16:57:13

US3412184

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:30:24

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:57:13
Amendment Manager: User entered '24 Jan 2021 23:59'	System	19 Nov 2020 16:57:13

US3412184

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:30:24

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:57:13
Amendment Manager: User entered 'Day 173'	System	19 Nov 2020 16:57:13

US3412184

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:30:24

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:57:13
Amendment Manager: User entered '27 Jan 2021 00:01'	System	19 Nov 2020 16:57:13

US3412184

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:30:24

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:57:13
Amendment Manager: User entered '31 Jan 2021 23:59'	System	19 Nov 2020 16:57:13

US3412184

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:30:24

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:57:13
Amendment Manager: User entered 'Day 180'	System	19 Nov 2020 16:57:13

US3412184

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:30:24

[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 (BE2239D8-5851-41C8-9E0D-0EFE22431A8D)', Time: '2021-02-05T12:03:39', User OID: 'PatientReportedOutcome (US3412184)', ODM File OID: '2fd09216-da55-4654-ad6a-9f0b82e14138' User entered 'Yes (Y)'	System	05 Feb 2021 17:09:05
	System	05 Feb 2021 17:09:05

US3412184

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:30:24

Have you been exposed to someone with 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 (BE2239D8-5851-41C8-9E0D-0EFE22431A8D)', Time: '2021-02-05T12:03:45', User OID: 'PatientReportedOutcome (US3412184)', ODM File OID: '2fd09216-da55-4654-ad6a-9f0b82e14138'	System	05 Feb 2021 17:09:05
User entered 'No (N)'	System	05 Feb 2021 17:09:05

US3412184

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:30:24

[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 (BE2239D8-5851-41C8-9E0D-0EFE22431A8D)', Time: '2021-02-05T12:03:52', User OID: 'PatientReportedOutcome (US3412184)', ODM File OID: '2fd09216-da55-4654-ad6a-9f0b82e14138' User entered 'No (N)'	System	05 Feb 2021 17:09:05
	System	05 Feb 2021 17:09:05

US3412184

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:30:24

[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 (BE2239D8-5851-41C8-9E0D-0EFE22431A8D)', Time: '2021-02-05T12:04:02', User OID: 'PatientReportedOutcome (US3412184)', ODM File OID: '2fd09216-da55-4654-ad6a-9f0b82e14138' User entered 'Yes (Y)'	System	05 Feb 2021 17:09:05
	System	05 Feb 2021 17:09:05

US3412184

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:30:24

[Please 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 (BE2239D8-5851-41C8-9E0D-0EFE22431A8D)', Time: '2021-02-05T12:04:14', User OID: 'PatientReportedOutcome (US3412184)', ODM File OID: '2fd09216-da55-4654-ad6a-9f0b82e14138'	System	05 Feb 2021 17:09:05
User entered 'I confirm I have read this message and will call the study clinic immediately (9)'	System	05 Feb 2021 17:09:05

US3412184

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:30:24

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (BE2239D8-5851-41C8-9E0D-0EFE22431A8D)', Time: '2021-02-05T12:04:17', User OID: 'PatientReportedOutcome (US3412184)', ODM File OID: '2fd09216-da55-4654-ad6a-9f0b82e14138' User entered '05 Feb 2021 12:04:17'	System	05 Feb 2021 17:09:05
	System	05 Feb 2021 17:09:05

US3412184

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:30:24

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:57:13
Amendment Manager: User entered '03 Feb 2021 00:01'	System	19 Nov 2020 16:57:13

US3412184

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:30:24

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:57:13
Amendment Manager: User entered '07 Feb 2021 23:59'	System	19 Nov 2020 16:57:13

US3412184

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:30:24

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:57:13
Amendment Manager: User entered 'Day 187'	System	19 Nov 2020 16:57:13

US3412184

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:30:24

[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 (BE2239D8-5851-41C8-9E0D-0EFE22431A8D)', Time: '2021-02-10T00:01:18', User OID: 'PatientReportedOutcome (US3412184)', ODM File OID: '000614f0-0bc9-4f60-824f-8d23d744fdbbc'	System	10 Feb 2021 05:02:21
User entered 'No (N)'	System	10 Feb 2021 05:02:21

US3412184

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:30:24

Have you been exposed to someone with 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 (BE2239D8-5851-41C8-9E0D-0EFE22431A8D)', Time: '2021-02-10T00:01:27', User OID: 'PatientReportedOutcome (US3412184)', ODM File OID: '000614f0-0bc9-4f60-824f-8d23d744fdbbc'	System	10 Feb 2021 05:02:21
User entered 'No (N)'	System	10 Feb 2021 05:02:21

US3412184

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:30:24

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (BE2239D8-5851-41C8-9E0D-0EFE22431A8D)', Time: '2021-02-10T00:01:31', User OID: 'PatientReportedOutcome (US3412184)', ODM File OID: '000614f0-0bc9-4f60-824f-8d23d744fdbbc' User entered '10 Feb 2021 00:01:31'	System	10 Feb 2021 05:02:21
	System	10 Feb 2021 05:02:21

US3412184

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:30:24

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:57:13
Amendment Manager: User entered '10 Feb 2021 00:01'	System	19 Nov 2020 16:57:13

US3412184

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:30:24

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:57:13
Amendment Manager: User entered '14 Feb 2021 23:59'	System	19 Nov 2020 16:57:13

US3412184

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:30:24

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:57:13
Amendment Manager: User entered 'Day 194'	System	19 Nov 2020 16:57:13

US3412184

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:30:24

[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 (BE2239D8-5851-41C8-9E0D-0EFE22431A8D)', Time: '2021-02-17T00:01:23', User OID: 'PatientReportedOutcome (US3412184)', ODM File OID: '759ef98e-dcf3-406c-b45d-ca7c38651eb7' User entered 'No (N)'	System	17 Feb 2021 05:03:18
	System	17 Feb 2021 05:03:18

US3412184

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:30:24

Have you been exposed to someone with 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 (BE2239D8-5851-41C8-9E0D-0EFE22431A8D)', Time: '2021-02-17T00:01:29', User OID: 'PatientReportedOutcome (US3412184)', ODM File OID: '759ef98e-dcf3-406c-b45d-ca7c38651eb7'	System	17 Feb 2021 05:03:18
User entered 'No (N)'	System	17 Feb 2021 05:03:18

US3412184

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:30:24

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (BE2239D8-5851-41C8-9E0D-0EFE22431A8D)', Time: '2021-02-17T00:01:33', User OID: 'PatientReportedOutcome (US3412184)', ODM File OID: '759ef98e-dcf3-406c-b45d-ca7c38651eb7' User entered '17 Feb 2021 00:01:33'	System	17 Feb 2021 05:03:18
	System	17 Feb 2021 05:03:18

US3412184

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:30:24

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:57:13
Amendment Manager: User entered '17 Feb 2021 00:01'	System	19 Nov 2020 16:57:13

US3412184

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:30:24

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:57:13
Amendment Manager: User entered '21 Feb 2021 23:59'	System	19 Nov 2020 16:57:13

US3412184

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:30:24

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:57:13
Amendment Manager: User entered 'Day 201'	System	19 Nov 2020 16:57:13

US3412184

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:30:24

[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 (BE2239D8-5851-41C8-9E0D-0EFE22431A8D)', Time: '2021-02-24T12:10:14-05:00', User OID: 'PatientReportedOutcome (US3412184)', ODM File OID: '63ffb099-0a3e-4f1d-bac1-e17ffddddd513'	System	24 Feb 2021 17:19:26
User entered 'No (N)'	System	24 Feb 2021 17:19:26

US3412184

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:30:24

Have you been exposed to someone with 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 (BE2239D8-5851-41C8-9E0D-0EFE22431A8D)', Time: '2021-02-24T12:10:19-05:00', User OID: 'PatientReportedOutcome (US3412184)', ODM File OID: '63ffb099-0a3e-4f1d-bac1-e17ffddddd513'	System	24 Feb 2021 17:19:26
User entered 'No (N)'	System	24 Feb 2021 17:19:26

US3412184

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:30:24

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (BE2239D8-5851-41C8-9E0D-0EFE22431A8D)', Time: '2021-02-24T12:10:25-05:00', User OID: 'PatientReportedOutcome (US3412184)', ODM File OID: '63ffb099-0a3e-4f1d-bac1-e17ffddddd513'	System	24 Feb 2021 17:19:26
User entered '24 Feb 2021 17:10:25'	System	24 Feb 2021 17:19:26

US3412184

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:30:24

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:57:13
Amendment Manager: User entered '24 Feb 2021 00:01'	System	19 Nov 2020 16:57:13

US3412184

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:30:24

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:57:13
Amendment Manager: User entered '28 Feb 2021 23:59'	System	19 Nov 2020 16:57:13

US3412184

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:30:24

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:57:13
Amendment Manager: User entered 'Day 208'	System	19 Nov 2020 16:57:13

US3412184

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:30:24

[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 (BE2239D8-5851-41C8-9E0D-0EFE22431A8D)', Time: '2021-03-07T12:10:37-05:00', User OID: 'PatientReportedOutcome (US3412184)', ODM File OID: '7ce9d97f-c748-4a2e-818a-ea91bfeb5574'	System	07 Mar 2021 17:14:50
User entered 'No (N)'	System	07 Mar 2021 17:14:50

US3412184

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:30:24

Have you been exposed to someone with 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 (BE2239D8-5851-41C8-9E0D-0EFE22431A8D)', Time: '2021-03-07T12:10:41-05:00', User OID: 'PatientReportedOutcome (US3412184)', ODM File OID: '7ce9d97f-c748-4a2e-818a-ea91bfeb5574'	System	07 Mar 2021 17:14:50
User entered 'No (N)'	System	07 Mar 2021 17:14:50

US3412184

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:30:24

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (BE2239D8-5851-41C8-9E0D-0EFE22431A8D)', Time: '2021-03-07T12:10:44-05:00', User OID: 'PatientReportedOutcome (US3412184)', ODM File OID: '7ce9d97f-c748-4a2e-818a-ea91bfeb5574' User entered '07 Mar 2021 12:10:44'	System	07 Mar 2021 17:14:50
	System	07 Mar 2021 17:14:50

US3412184

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:30:24

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:57:13
Amendment Manager: User entered '03 Mar 2021 00:01'	System	19 Nov 2020 16:57:13

US3412184

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:30:24

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:57:13
Amendment Manager: User entered '07 Mar 2021 23:59'	System	19 Nov 2020 16:57:13

US3412184

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:30:24

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:57:13
Amendment Manager: User entered 'Day 215'	System	19 Nov 2020 16:57:13

US3412184

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:30:24

[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 (BE2239D8-5851-41C8-9E0D-0EFE22431A8D)', Time: '2021-03-10T00:02:28-05:00', User OID: 'PatientReportedOutcome (US3412184)', ODM File OID: '8eed759a-62c1-42f3-9595-167123b609a1'	System	10 Mar 2021 05:04:18
User entered 'No (N)'	System	10 Mar 2021 05:04:18

US3412184

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:30:24

Have you been exposed to someone with 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 (BE2239D8-5851-41C8-9E0D-0EFE22431A8D)', Time: '2021-03-10T00:02:36-05:00', User OID: 'PatientReportedOutcome (US3412184)', ODM File OID: '8eed759a-62c1-42f3-9595-167123b609a1'	System	10 Mar 2021 05:04:18
User entered 'No (N)'	System	10 Mar 2021 05:04:18

US3412184

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:30:24

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (BE2239D8-5851-41C8-9E0D-0EFE22431A8D)', Time: '2021-03-10T00:02:41-05:00', User OID: 'PatientReportedOutcome (US3412184)', ODM File OID: '8eed759a-62c1-42f3-9595-167123b609a1' User entered '10 Mar 2021 00:02:41'	System	10 Mar 2021 05:04:18
	System	10 Mar 2021 05:04:18

US3412184

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:30:24

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:57:13
Amendment Manager: User entered '10 Mar 2021 00:01'	System	19 Nov 2020 16:57:13

US3412184

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:30:24

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:57:13
Amendment Manager: User entered '14 Mar 2021 23:59'	System	19 Nov 2020 16:57:13

US3412184

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:30:24

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:57:13
Amendment Manager: User entered 'Day 222'	System	19 Nov 2020 16:57:13

US3412184

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:30:24

[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 (BE2239D8-5851-41C8-9E0D-0EFE22431A8D)', Time: '2021-03-17T00:04:10-04:00', User OID: 'PatientReportedOutcome (US3412184)', ODM File OID: '10897bf1-0f48-4509-af34-bcaaaf77a9b'	System	17 Mar 2021 04:05:08
User entered 'No (N)'	System	17 Mar 2021 04:05:08

US3412184

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:30:24

Have you been exposed to someone with 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 (BE2239D8-5851-41C8-9E0D-0EFE22431A8D)', Time: '2021-03-17T00:04:20-04:00', User OID: 'PatientReportedOutcome (US3412184)', ODM File OID: '10897bf1-0f48-4509-af34-bcaaaf77a9b'	System	17 Mar 2021 04:05:08
User entered 'No (N)'	System	17 Mar 2021 04:05:08

US3412184

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:30:24

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (BE2239D8-5851-41C8-9E0D-0EFE22431A8D)', Time: '2021-03-17T00:04:24-04:00', User OID: 'PatientReportedOutcome (US3412184)', ODM File OID: '10897bf1-0f48-4509-af34-bcaaaf77a9b' User entered '17 Mar 2021 00:04:24'	System	17 Mar 2021 04:05:08
	System	17 Mar 2021 04:05:08

US3412184

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:30:24

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:57:13
Amendment Manager: User entered '17 Mar 2021 00:01'	System	19 Nov 2020 16:57:13

US3412184

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:30:24

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:57:13
Amendment Manager: User entered '21 Mar 2021 23:59'	System	19 Nov 2020 16:57:13

US3412184

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:30:24

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:57:13
Amendment Manager: User entered 'Day 229'	System	19 Nov 2020 16:57:13

US3412184

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:30:24

[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 (BE2239D8-5851-41C8-9E0D-0EFE22431A8D)', Time: '2021-03-24T23:34:12-04:00', User OID: 'PatientReportedOutcome (US3412184)', ODM File OID: '00f3aaa0-e7c8-49f4-844d-5163ed1659e7'	System	25 Mar 2021 03:34:25
User entered 'No (N)'	System	25 Mar 2021 03:34:25

US3412184

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:30:24

[Have you been exposed to someone with 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 (BE2239D8-5851-41C8-9E0D-0EFE22431A8D)', Time: '2021-03-24T23:34:17-04:00', User OID: 'PatientReportedOutcome (US3412184)', ODM File OID: '00f3aaa0-e7c8-49f4-844d-5163ed1659e7'	System	25 Mar 2021 03:34:25
User entered 'No (N)'	System	25 Mar 2021 03:34:25

US3412184

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:30:24

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (BE2239D8-5851-41C8-9E0D-0EFE22431A8D)', Time: '2021-03-24T23:34:20-04:00', User OID: 'PatientReportedOutcome (US3412184)', ODM File OID: '00f3aaa0-e7c8-49f4-844d-5163ed1659e7' User entered '24 Mar 2021 23:34:20'	System	25 Mar 2021 03:34:25

US3412184

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:30:24

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:57:13
Amendment Manager: User entered '24 Mar 2021 00:01'	System	19 Nov 2020 16:57:13

US3412184

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:30:24

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:57:13
Amendment Manager: User entered '28 Mar 2021 23:59'	System	19 Nov 2020 16:57:13

US3412184

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:30:24

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:57:13
Amendment Manager: User entered 'Day 236'	System	19 Nov 2020 16:57:13

US3412184

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:30:24

[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 (BE2239D8-5851-41C8-9E0D-0EFE22431A8D)', Time: '2021-04-02T10:22:40-04:00', User OID: 'PatientReportedOutcome (US3412184)', ODM File OID: '6f9e534a-4b8b-4839-a9fa-c598537dd164'	System	02 Apr 2021 14:22:49
User entered 'No (N)'	System	02 Apr 2021 14:22:49

US3412184

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:30:24

Have you been exposed to someone with 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 (BE2239D8-5851-41C8-9E0D-0EFE22431A8D)', Time: '2021-04-02T10:22:43-04:00', User OID: 'PatientReportedOutcome (US3412184)', ODM File OID: '6f9e534a-4b8b-4839-a9fa-c598537dd164'	System	02 Apr 2021 14:22:49
User entered 'No (N)'	System	02 Apr 2021 14:22:49

US3412184

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:30:24

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (BE2239D8-5851-41C8-9E0D-0EFE22431A8D)', Time: '2021-04-02T10:22:46-04:00', User OID: 'PatientReportedOutcome (US3412184)', ODM File OID: '6f9e534a-4b8b-4839-a9fa-c598537dd164'	System	02 Apr 2021 14:22:49
User entered '02 Apr 2021 10:22:46'	System	02 Apr 2021 14:22:49

US3412184

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:30:24

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:57:13
Amendment Manager: User entered '31 Mar 2021 00:01'	System	19 Nov 2020 16:57:13

US3412184

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:30:24

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:57:13
Amendment Manager: User entered '04 Apr 2021 23:59'	System	19 Nov 2020 16:57:13

US3412184

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:30:24

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:57:13
Amendment Manager: User entered 'Day 243'	System	19 Nov 2020 16:57:13

US3412184

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:30:24

[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 (BE2239D8-5851-41C8-9E0D-0EFE22431A8D)', Time: '2021-04-08T20:50:32-04:00', User OID: 'PatientReportedOutcome (US3412184)', ODM File OID: '5d6ace1d-2204-4805-97e8-30443d0ed58a' User entered 'No (N)'	System	09 Apr 2021 00:50:41
	System	09 Apr 2021 00:50:41

US3412184

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:30:24

[Have you been exposed to someone with 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 (BE2239D8-5851-41C8-9E0D-0EFE22431A8D)', Time: '2021-04-08T20:50:35-04:00', User OID: 'PatientReportedOutcome (US3412184)', ODM File OID: '5d6ace1d-2204-4805-97e8-30443d0ed58a' User entered 'No (N)'	System	09 Apr 2021 00:50:41

US3412184

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:30:24

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (BE2239D8-5851-41C8-9E0D-0EFE22431A8D)', Time: '2021-04-08T20:50:38-04:00', User OID: 'PatientReportedOutcome (US3412184)', ODM File OID: '5d6ace1d-2204-4805-97e8-30443d0ed58a'	System	09 Apr 2021 00:50:41
User entered '08 Apr 2021 20:50:38'	System	09 Apr 2021 00:50:41

US3412184

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:30:24

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:57:13
Amendment Manager: User entered '07 Apr 2021 00:01'	System	19 Nov 2020 16:57:13

US3412184

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:30:24

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:57:13
Amendment Manager: User entered '11 Apr 2021 23:59'	System	19 Nov 2020 16:57:13

US3412184

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:30:24

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:57:13
Amendment Manager: User entered 'Day 250'	System	19 Nov 2020 16:57:13

US3412184

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:30:24

[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 (BE2239D8-5851-41C8-9E0D-0EFE22431A8D)', Time: '2021-04-15T07:45:40-04:00', User OID: 'PatientReportedOutcome (US3412184)', ODM File OID: '69da705b-b20e-4780-a65f-418237778b02'	System	15 Apr 2021 11:45:52
User entered 'No (N)'	System	15 Apr 2021 11:45:52

US3412184

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:30:24

Have you been exposed to someone with 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 (BE2239D8-5851-41C8-9E0D-0EFE22431A8D)', Time: '2021-04-15T07:45:45-04:00', User OID: 'PatientReportedOutcome (US3412184)', ODM File OID: '69da705b-b20e-4780-a65f-418237778b02'	System	15 Apr 2021 11:45:52
User entered 'No (N)'	System	15 Apr 2021 11:45:52

US3412184

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:30:24

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (BE2239D8-5851-41C8-9E0D-0EFE22431A8D)', Time: '2021-04-15T07:45:48-04:00', User OID: 'PatientReportedOutcome (US3412184)', ODM File OID: '69da705b-b20e-4780-a65f-418237778b02'	System	15 Apr 2021 11:45:52
User entered '15 Apr 2021 07:45:48'	System	15 Apr 2021 11:45:52

US3412184

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:30:24

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:57:13
Amendment Manager: User entered '14 Apr 2021 00:01'	System	19 Nov 2020 16:57:13

US3412184

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:30:24

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:57:13
Amendment Manager: User entered '18 Apr 2021 23:59'	System	19 Nov 2020 16:57:13

US3412184

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:30:24

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:57:13
Amendment Manager: User entered 'Day 257'	System	19 Nov 2020 16:57:13

US3412184

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:30:24

[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 (BE2239D8-5851-41C8-9E0D-0EFE22431A8D)', Time: '2021-04-21T06:47:05-04:00', User OID: 'PatientReportedOutcome (US3412184)', ODM File OID: '452bbf96-b7f5-4562-802e-4224fafb9e05'	System	21 Apr 2021 10:47:16
User entered 'No (N)'	System	21 Apr 2021 10:47:16

US3412184

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:30:24

[Have you been exposed to someone with 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 (BE2239D8-5851-41C8-9E0D-0EFE22431A8D)', Time: '2021-04-21T06:47:10-04:00', User OID: 'PatientReportedOutcome (US3412184)', ODM File OID: '452bbf96-b7f5-4562-802e-4224fafb9e05'	System	21 Apr 2021 10:47:16
User entered 'No (N)'	System	21 Apr 2021 10:47:16

US3412184

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:30:24

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (BE2239D8-5851-41C8-9E0D-0EFE22431A8D)', Time: '2021-04-21T06:47:14-04:00', User OID: 'PatientReportedOutcome (US3412184)', ODM File OID: '452bbf96-b7f5-4562-802e-4224fafb9e05'	System	21 Apr 2021 10:47:16
User entered '21 Apr 2021 06:47:14'	System	21 Apr 2021 10:47:16

US3412184

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:30:24

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:57:13
Amendment Manager: User entered '21 Apr 2021 00:01'	System	19 Nov 2020 16:57:13

US3412184

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:30:24

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:57:13
Amendment Manager: User entered '25 Apr 2021 23:59'	System	19 Nov 2020 16:57:13

US3412184

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:30:24

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:57:13
Amendment Manager: User entered 'Day 264'	System	19 Nov 2020 16:57:13

US3412184

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:30:24

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:57:13
Amendment Manager: User entered '28 Apr 2021 00:01'	System	19 Nov 2020 16:57:13

US3412184

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:30:24

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:57:13
Amendment Manager: User entered '02 May 2021 23:59'	System	19 Nov 2020 16:57:13

US3412184

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:30:24

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:57:13
Amendment Manager: User entered 'Day 271'	System	19 Nov 2020 16:57:13

US3412184

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:30:24

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:57:13
Amendment Manager: User entered '05 May 2021 00:01'	System	19 Nov 2020 16:57:13

US3412184

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:30:24

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:57:13
Amendment Manager: User entered '09 May 2021 23:59'	System	19 Nov 2020 16:57:13

US3412184

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:30:24

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:57:13
Amendment Manager: User entered 'Day 278'	System	19 Nov 2020 16:57:13

US3412184

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:30:24

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:57:13
Amendment Manager: User entered '12 May 2021 00:01'	System	19 Nov 2020 16:57:13

US3412184

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:30:24

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:57:13
Amendment Manager: User entered '16 May 2021 23:59'	System	19 Nov 2020 16:57:13

US3412184

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:30:24

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:57:13
Amendment Manager: User entered 'Day 285'	System	19 Nov 2020 16:57:13

US3412184

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:30:24

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:57:13
Amendment Manager: User entered '19 May 2021 00:01'	System	19 Nov 2020 16:57:13

US3412184

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:30:24

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:57:13
Amendment Manager: User entered '23 May 2021 23:59'	System	19 Nov 2020 16:57:13

US3412184

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:30:24

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:57:13
Amendment Manager: User entered 'Day 292'	System	19 Nov 2020 16:57:13

US3412184

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:30:24

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:57:13
Amendment Manager: User entered '26 May 2021 00:01'	System	19 Nov 2020 16:57:13

US3412184

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:30:24

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:57:13
Amendment Manager: User entered '30 May 2021 23:59'	System	19 Nov 2020 16:57:13

US3412184

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:30:24

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:57:13
Amendment Manager: User entered 'Day 299'	System	19 Nov 2020 16:57:13

US3412184

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:30:24

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:57:13
Amendment Manager: User entered '02 Jun 2021 00:01'	System	19 Nov 2020 16:57:13

US3412184

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:30:24

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:57:13
Amendment Manager: User entered '06 Jun 2021 23:59'	System	19 Nov 2020 16:57:13

US3412184

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:30:24

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:57:13
Amendment Manager: User entered 'Day 306'	System	19 Nov 2020 16:57:13

US3412184

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:30:24

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:57:13
Amendment Manager: User entered '09 Jun 2021 00:01'	System	19 Nov 2020 16:57:13

US3412184

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:30:24

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:57:13
Amendment Manager: User entered '13 Jun 2021 23:59'	System	19 Nov 2020 16:57:13

US3412184

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:30:24

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:57:13
Amendment Manager: User entered 'Day 313'	System	19 Nov 2020 16:57:13

US3412184

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:30:24

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:57:13
Amendment Manager: User entered '16 Jun 2021 00:01'	System	19 Nov 2020 16:57:13

US3412184

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:30:24

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:57:13
Amendment Manager: User entered '20 Jun 2021 23:59'	System	19 Nov 2020 16:57:13

US3412184

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:30:24

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:57:13
Amendment Manager: User entered 'Day 320'	System	19 Nov 2020 16:57:13

US3412184

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:30:24

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:57:13
Amendment Manager: User entered '23 Jun 2021 00:01'	System	19 Nov 2020 16:57:13

US3412184

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

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[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:57:13
Amendment Manager: User entered '27 Jun 2021 23:59'	System	19 Nov 2020 16:57:13

US3412184

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:30:24

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:57:13
Amendment Manager: User entered 'Day 327'	System	19 Nov 2020 16:57:13

US3412184

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:30:24

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:57:13
Amendment Manager: User entered '30 Jun 2021 00:01'	System	19 Nov 2020 16:57:13

US3412184

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:30:24

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:57:13
Amendment Manager: User entered '04 Jul 2021 23:59'	System	19 Nov 2020 16:57:13

US3412184

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:30:24

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:57:13
Amendment Manager: User entered 'Day 334'	System	19 Nov 2020 16:57:13

US3412184

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:30:24

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:57:13
Amendment Manager: User entered '07 Jul 2021 00:01'	System	19 Nov 2020 16:57:13

US3412184

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:30:24

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:57:13
Amendment Manager: User entered '11 Jul 2021 23:59'	System	19 Nov 2020 16:57:13

US3412184

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:30:24

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:57:13
Amendment Manager: User entered 'Day 341'	System	19 Nov 2020 16:57:13

US3412184

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:30:24

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:57:13
Amendment Manager: User entered '14 Jul 2021 00:01'	System	19 Nov 2020 16:57:13

US3412184

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:30:24

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:57:13
Amendment Manager: User entered '18 Jul 2021 23:59'	System	19 Nov 2020 16:57:13

US3412184

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:30:24

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:57:13
Amendment Manager: User entered 'Day 348'	System	19 Nov 2020 16:57:13

US3412184

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:30:24

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:57:13
Amendment Manager: User entered '21 Jul 2021 00:01'	System	19 Nov 2020 16:57:13

US3412184

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:30:24

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:57:13
Amendment Manager: User entered '25 Jul 2021 23:59'	System	19 Nov 2020 16:57:13

US3412184

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:30:24

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:57:13
Amendment Manager: User entered 'Day 355'	System	19 Nov 2020 16:57:13

US3412184

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:30:24

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:57:13
Amendment Manager: User entered '28 Jul 2021 00:01'	System	19 Nov 2020 16:57:13

US3412184

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:30:24

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:57:13
Amendment Manager: User entered '01 Aug 2021 23:59'	System	19 Nov 2020 16:57:13

US3412184

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:30:24

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:57:13
Amendment Manager: User entered 'Day 362'	System	19 Nov 2020 16:57:13

US3412184

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:30:24

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:57:13
Amendment Manager: User entered '04 Aug 2021 00:01'	System	19 Nov 2020 16:57:13

US3412184

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:30:24

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:57:13
Amendment Manager: User entered '08 Aug 2021 23:59'	System	19 Nov 2020 16:57:13

US3412184

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:30:24

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:57:13
Amendment Manager: User entered 'Day 369'	System	19 Nov 2020 16:57:13

US3412184

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:30:24

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:57:13
Amendment Manager: User entered '11 Aug 2021 00:01'	System	19 Nov 2020 16:57:13

US3412184

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

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[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:57:13
Amendment Manager: User entered '15 Aug 2021 23:59'	System	19 Nov 2020 16:57:13

US3412184

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:30:24

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:57:13
Amendment Manager: User entered 'Day 376'	System	19 Nov 2020 16:57:13

US3412184

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:30:24

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:57:13
Amendment Manager: User entered '18 Aug 2021 00:01'	System	19 Nov 2020 16:57:13

US3412184

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:30:24

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:57:13
Amendment Manager: User entered '22 Aug 2021 23:59'	System	19 Nov 2020 16:57:13

US3412184

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

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TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:57:13
Amendment Manager: User entered 'Day 383'	System	19 Nov 2020 16:57:13

US3412184

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:30:24

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:57:13
Amendment Manager: User entered '25 Aug 2021 00:01'	System	19 Nov 2020 16:57:13

US3412184

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:30:24

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:57:13
Amendment Manager: User entered '29 Aug 2021 23:59'	System	19 Nov 2020 16:57:13

US3412184

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:30:24

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:57:13
Amendment Manager: User entered 'Day 390'	System	19 Nov 2020 16:57:13

US3412184

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:30:24

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:57:13
Amendment Manager: User entered '01 Sep 2021 00:01'	System	19 Nov 2020 16:57:13

US3412184

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:30:24

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:57:13
Amendment Manager: User entered '05 Sep 2021 23:59'	System	19 Nov 2020 16:57:13

US3412184

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:30:24

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:57:13
Amendment Manager: User entered 'Day 397'	System	19 Nov 2020 16:57:13

US3412184

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:30:24

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:57:13
Amendment Manager: User entered '08 Sep 2021 00:01'	System	19 Nov 2020 16:57:13

US3412184

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

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[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:57:13
Amendment Manager: User entered '12 Sep 2021 23:59'	System	19 Nov 2020 16:57:13

US3412184

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

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TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:57:13
Amendment Manager: User entered 'Day 404'	System	19 Nov 2020 16:57:13

US3412184

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:30:24

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:57:13
Amendment Manager: User entered '15 Sep 2021 00:01'	System	19 Nov 2020 16:57:13

US3412184

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:30:24

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:57:13
Amendment Manager: User entered '19 Sep 2021 23:59'	System	19 Nov 2020 16:57:13

US3412184

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:30:24

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:57:13
Amendment Manager: User entered 'Day 411'	System	19 Nov 2020 16:57:13

US3412184

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:30:24

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:57:13
Amendment Manager: User entered '22 Sep 2021 00:01'	System	19 Nov 2020 16:57:13

US3412184

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:30:24

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:57:13
Amendment Manager: User entered '26 Sep 2021 23:59'	System	19 Nov 2020 16:57:13

US3412184

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:30:24

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:57:13
Amendment Manager: User entered 'Day 418'	System	19 Nov 2020 16:57:13

US3412184

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:30:24

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:57:13
Amendment Manager: User entered '29 Sep 2021 00:01'	System	19 Nov 2020 16:57:13

US3412184

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:30:24

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:57:13
Amendment Manager: User entered '03 Oct 2021 23:59'	System	19 Nov 2020 16:57:13

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Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:30:24

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:57:13
Amendment Manager: User entered 'Day 425'	System	19 Nov 2020 16:57:13

US3412184

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:30:24

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:57:13
Amendment Manager: User entered '06 Oct 2021 00:01'	System	19 Nov 2020 16:57:13

US3412184

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:30:24

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:57:13
Amendment Manager: User entered '10 Oct 2021 23:59'	System	19 Nov 2020 16:57:13

US3412184

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:30:24

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:57:13
Amendment Manager: User entered 'Day 432'	System	19 Nov 2020 16:57:13

US3412184

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:30:24

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:57:13
Amendment Manager: User entered '13 Oct 2021 00:01'	System	19 Nov 2020 16:57:13

US3412184

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:30:24

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:57:13
Amendment Manager: User entered '17 Oct 2021 23:59'	System	19 Nov 2020 16:57:13

US3412184

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:30:24

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:57:13
Amendment Manager: User entered 'Day 439'	System	19 Nov 2020 16:57:13

US3412184

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:30:24

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:57:13
Amendment Manager: User entered '20 Oct 2021 00:01'	System	19 Nov 2020 16:57:13

US3412184

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:30:24

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:57:13
Amendment Manager: User entered '24 Oct 2021 23:59'	System	19 Nov 2020 16:57:13

US3412184

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:30:24

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:57:13
Amendment Manager: User entered 'Day 446'	System	19 Nov 2020 16:57:13

US3412184

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:30:24

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:57:13
Amendment Manager: User entered '27 Oct 2021 00:01'	System	19 Nov 2020 16:57:13

US3412184

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:30:24

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:57:13
Amendment Manager: User entered '31 Oct 2021 23:59'	System	19 Nov 2020 16:57:13

US3412184

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:30:24

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:57:13
Amendment Manager: User entered 'Day 453'	System	19 Nov 2020 16:57:13

US3412184

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:30:24

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:57:13
Amendment Manager: User entered '03 Nov 2021 00:01'	System	19 Nov 2020 16:57:13

US3412184

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:30:24

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:57:13
Amendment Manager: User entered '07 Nov 2021 23:59'	System	19 Nov 2020 16:57:13

US3412184

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:30:24

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:57:13
Amendment Manager: User entered 'Day 460'	System	19 Nov 2020 16:57:13

US3412184

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:30:24

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:57:13
Amendment Manager: User entered '10 Nov 2021 00:01'	System	19 Nov 2020 16:57:13

US3412184

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:30:24

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:57:13
Amendment Manager: User entered '14 Nov 2021 23:59'	System	19 Nov 2020 16:57:13

US3412184

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:30:24

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:57:13
Amendment Manager: User entered 'Day 467'	System	19 Nov 2020 16:57:13

US3412184

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:30:24

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:57:13
Amendment Manager: User entered '17 Nov 2021 00:01'	System	19 Nov 2020 16:57:13

US3412184

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:30:24

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:57:13
Amendment Manager: User entered '21 Nov 2021 23:59'	System	19 Nov 2020 16:57:13

US3412184

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:30:24

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:57:13
Amendment Manager: User entered 'Day 474'	System	19 Nov 2020 16:57:13

US3412184

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:30:24

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:57:13
Amendment Manager: User entered '24 Nov 2021 00:01'	System	19 Nov 2020 16:57:13

US3412184

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:30:24

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:57:13
Amendment Manager: User entered '28 Nov 2021 23:59'	System	19 Nov 2020 16:57:13

US3412184

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:30:24

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:57:13
Amendment Manager: User entered 'Day 481'	System	19 Nov 2020 16:57:13

US3412184

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:30:24

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:57:13
Amendment Manager: User entered '01 Dec 2021 00:01'	System	19 Nov 2020 16:57:13

US3412184

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:30:24

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:57:13
Amendment Manager: User entered '05 Dec 2021 23:59'	System	19 Nov 2020 16:57:13

US3412184

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:30:24

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:57:13
Amendment Manager: User entered 'Day 488'	System	19 Nov 2020 16:57:13

US3412184

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:30:24

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:57:13
Amendment Manager: User entered '08 Dec 2021 00:01'	System	19 Nov 2020 16:57:13

US3412184

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:30:24

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:57:13
Amendment Manager: User entered '12 Dec 2021 23:59'	System	19 Nov 2020 16:57:13

US3412184

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:30:24

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:57:13
Amendment Manager: User entered 'Day 495'	System	19 Nov 2020 16:57:13

US3412184

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:30:24

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:57:13
Amendment Manager: User entered '15 Dec 2021 00:01'	System	19 Nov 2020 16:57:13

US3412184

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:30:24

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:57:13
Amendment Manager: User entered '19 Dec 2021 23:59'	System	19 Nov 2020 16:57:13

US3412184

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:30:24

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:57:13
Amendment Manager: User entered 'Day 502'	System	19 Nov 2020 16:57:13

US3412184

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:30:24

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:57:13
Amendment Manager: User entered '22 Dec 2021 00:01'	System	19 Nov 2020 16:57:13

US3412184

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:30:24

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:57:13
Amendment Manager: User entered '26 Dec 2021 23:59'	System	19 Nov 2020 16:57:13

US3412184

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:30:24

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:57:13
Amendment Manager: User entered 'Day 509'	System	19 Nov 2020 16:57:13

US3412184

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:30:24

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:57:13
Amendment Manager: User entered '29 Dec 2021 00:01'	System	19 Nov 2020 16:57:13

US3412184

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:30:24

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:57:13
Amendment Manager: User entered '02 Jan 2022 23:59'	System	19 Nov 2020 16:57:13

US3412184

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:30:24

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:57:13
Amendment Manager: User entered 'Day 516'	System	19 Nov 2020 16:57:13

US3412184

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:30:24

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:57:13
Amendment Manager: User entered '05 Jan 2022 00:01'	System	19 Nov 2020 16:57:13

US3412184

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:30:24

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:57:13
Amendment Manager: User entered '09 Jan 2022 23:59'	System	19 Nov 2020 16:57:13

US3412184

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:30:24

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:57:13
Amendment Manager: User entered 'Day 523'	System	19 Nov 2020 16:57:13

US3412184

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:30:24

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:57:13
Amendment Manager: User entered '12 Jan 2022 00:01'	System	19 Nov 2020 16:57:13

US3412184

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:30:24

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:57:13
Amendment Manager: User entered '16 Jan 2022 23:59'	System	19 Nov 2020 16:57:13

US3412184

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:30:24

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:57:13
Amendment Manager: User entered 'Day 530'	System	19 Nov 2020 16:57:13

US3412184

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:30:24

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:57:13
Amendment Manager: User entered '19 Jan 2022 00:01'	System	19 Nov 2020 16:57:13

US3412184

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:30:24

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:57:13
Amendment Manager: User entered '23 Jan 2022 23:59'	System	19 Nov 2020 16:57:13

US3412184

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:30:24

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:57:13
Amendment Manager: User entered 'Day 537'	System	19 Nov 2020 16:57:13

US3412184

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:30:24

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:57:13
Amendment Manager: User entered '26 Jan 2022 00:01'	System	19 Nov 2020 16:57:13

US3412184

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:30:24

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:57:13
Amendment Manager: User entered '30 Jan 2022 23:59'	System	19 Nov 2020 16:57:13

US3412184

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:30:24

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:57:13
Amendment Manager: User entered 'Day 544'	System	19 Nov 2020 16:57:13

US3412184

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:30:24

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:57:13
Amendment Manager: User entered '02 Feb 2022 00:01'	System	19 Nov 2020 16:57:13

US3412184

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:30:24

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:57:13
Amendment Manager: User entered '06 Feb 2022 23:59'	System	19 Nov 2020 16:57:13

US3412184

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:30:24

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:57:13
Amendment Manager: User entered 'Day 551'	System	19 Nov 2020 16:57:13

US3412184

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:30:24

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:57:13
Amendment Manager: User entered '09 Feb 2022 00:01'	System	19 Nov 2020 16:57:13

US3412184

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:30:24

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:57:13
Amendment Manager: User entered '13 Feb 2022 23:59'	System	19 Nov 2020 16:57:13

US3412184

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:30:24

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:57:13
Amendment Manager: User entered 'Day 558'	System	19 Nov 2020 16:57:13

US3412184

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:30:24

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:57:13
Amendment Manager: User entered '16 Feb 2022 00:01'	System	19 Nov 2020 16:57:13

US3412184

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:30:24

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:57:13
Amendment Manager: User entered '20 Feb 2022 23:59'	System	19 Nov 2020 16:57:13

US3412184

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:30:24

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:57:13
Amendment Manager: User entered 'Day 565'	System	19 Nov 2020 16:57:13

US3412184

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:30:24

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:57:13
Amendment Manager: User entered '23 Feb 2022 00:01'	System	19 Nov 2020 16:57:13

US3412184

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:30:24

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:57:13
Amendment Manager: User entered '27 Feb 2022 23:59'	System	19 Nov 2020 16:57:13

US3412184

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:30:24

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:57:13
Amendment Manager: User entered 'Day 572'	System	19 Nov 2020 16:57:13

US3412184

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:30:24

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:57:13
Amendment Manager: User entered '02 Mar 2022 00:01'	System	19 Nov 2020 16:57:13

US3412184

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:30:24

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:57:13
Amendment Manager: User entered '06 Mar 2022 23:59'	System	19 Nov 2020 16:57:13

US3412184

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:30:24

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:57:13
Amendment Manager: User entered 'Day 579'	System	19 Nov 2020 16:57:13

US3412184

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:30:24

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:57:13
Amendment Manager: User entered '09 Mar 2022 00:01'	System	19 Nov 2020 16:57:13

US3412184

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:30:24

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:57:13
Amendment Manager: User entered '13 Mar 2022 23:59'	System	19 Nov 2020 16:57:13

US3412184

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:30:24

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:57:13
Amendment Manager: User entered 'Day 586'	System	19 Nov 2020 16:57:13

US3412184

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:30:24

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:57:13
Amendment Manager: User entered '16 Mar 2022 00:01'	System	19 Nov 2020 16:57:13

US3412184

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:30:24

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:57:13
Amendment Manager: User entered '20 Mar 2022 23:59'	System	19 Nov 2020 16:57:13

US3412184

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:30:24

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:57:13
Amendment Manager: User entered 'Day 593'	System	19 Nov 2020 16:57:13

US3412184

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:30:24

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:57:13
Amendment Manager: User entered '23 Mar 2022 00:01'	System	19 Nov 2020 16:57:13

US3412184

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:30:24

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:57:13
Amendment Manager: User entered '27 Mar 2022 23:59'	System	19 Nov 2020 16:57:13

US3412184

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:30:24

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:57:13
Amendment Manager: User entered 'Day 600'	System	19 Nov 2020 16:57:13

US3412184

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:30:24

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:57:13
Amendment Manager: User entered '30 Mar 2022 00:01'	System	19 Nov 2020 16:57:13

US3412184

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:30:24

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:57:13
Amendment Manager: User entered '03 Apr 2022 23:59'	System	19 Nov 2020 16:57:13

US3412184

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:30:24

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:57:13
Amendment Manager: User entered 'Day 607'	System	19 Nov 2020 16:57:13

US3412184

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:30:24

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:57:13
Amendment Manager: User entered '06 Apr 2022 00:01'	System	19 Nov 2020 16:57:13

US3412184

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:30:24

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:57:13
Amendment Manager: User entered '10 Apr 2022 23:59'	System	19 Nov 2020 16:57:13

US3412184

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:30:24

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:57:13
Amendment Manager: User entered 'Day 614'	System	19 Nov 2020 16:57:13

US3412184

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:30:24

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:57:13
Amendment Manager: User entered '13 Apr 2022 00:01'	System	19 Nov 2020 16:57:13

US3412184

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:30:24

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:57:13
Amendment Manager: User entered '17 Apr 2022 23:59'	System	19 Nov 2020 16:57:13

US3412184

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:30:24

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:57:13
Amendment Manager: User entered 'Day 621'	System	19 Nov 2020 16:57:13

US3412184

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:30:24

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:57:13
Amendment Manager: User entered '20 Apr 2022 00:01'	System	19 Nov 2020 16:57:13

US3412184

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:30:24

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:57:13
Amendment Manager: User entered '24 Apr 2022 23:59'	System	19 Nov 2020 16:57:13

US3412184

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:30:24

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:57:13
Amendment Manager: User entered 'Day 628'	System	19 Nov 2020 16:57:13

US3412184

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:30:24

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:57:13
Amendment Manager: User entered '27 Apr 2022 00:01'	System	19 Nov 2020 16:57:13

US3412184

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:30:24

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:57:13
Amendment Manager: User entered '01 May 2022 23:59'	System	19 Nov 2020 16:57:13

US3412184

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:30:24

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:57:13
Amendment Manager: User entered 'Day 635'	System	19 Nov 2020 16:57:13

US3412184

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:30:24

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:57:13
Amendment Manager: User entered '04 May 2022 00:01'	System	19 Nov 2020 16:57:13

US3412184

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:30:24

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:57:13
Amendment Manager: User entered '08 May 2022 23:59'	System	19 Nov 2020 16:57:13

US3412184

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:30:24

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:57:13
Amendment Manager: User entered 'Day 642'	System	19 Nov 2020 16:57:13

US3412184

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:30:24

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:57:13
Amendment Manager: User entered '11 May 2022 00:01'	System	19 Nov 2020 16:57:13

US3412184

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:30:24

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:57:13
Amendment Manager: User entered '15 May 2022 23:59'	System	19 Nov 2020 16:57:13

US3412184

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:30:24

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:57:13
Amendment Manager: User entered 'Day 649'	System	19 Nov 2020 16:57:13

US3412184

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:30:24

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:57:13
Amendment Manager: User entered '18 May 2022 00:01'	System	19 Nov 2020 16:57:13

US3412184

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:30:24

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:57:13
Amendment Manager: User entered '22 May 2022 23:59'	System	19 Nov 2020 16:57:13

US3412184

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:30:24

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:57:13
Amendment Manager: User entered 'Day 656'	System	19 Nov 2020 16:57:13

US3412184

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:30:24

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:57:13
Amendment Manager: User entered '25 May 2022 00:01'	System	19 Nov 2020 16:57:13

US3412184

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:30:24

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:57:13
Amendment Manager: User entered '29 May 2022 23:59'	System	19 Nov 2020 16:57:13

US3412184

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:30:24

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:57:13
Amendment Manager: User entered 'Day 663'	System	19 Nov 2020 16:57:13

US3412184

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:30:24

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:57:13
Amendment Manager: User entered '01 Jun 2022 00:01'	System	19 Nov 2020 16:57:13

US3412184

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:30:24

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:57:13
Amendment Manager: User entered '05 Jun 2022 23:59'	System	19 Nov 2020 16:57:13

US3412184

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:30:24

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:57:13
Amendment Manager: User entered 'Day 670'	System	19 Nov 2020 16:57:13

US3412184

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:30:24

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:57:13
Amendment Manager: User entered '08 Jun 2022 00:01'	System	19 Nov 2020 16:57:13

US3412184

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:30:24

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:57:13
Amendment Manager: User entered '12 Jun 2022 23:59'	System	19 Nov 2020 16:57:13

US3412184

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:30:24

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:57:13
Amendment Manager: User entered 'Day 677'	System	19 Nov 2020 16:57:13

US3412184

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:30:24

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:57:13
Amendment Manager: User entered '15 Jun 2022 00:01'	System	19 Nov 2020 16:57:13

US3412184

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:30:24

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:57:13
Amendment Manager: User entered '19 Jun 2022 23:59'	System	19 Nov 2020 16:57:13

US3412184

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:30:24

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:57:13
Amendment Manager: User entered 'Day 684'	System	19 Nov 2020 16:57:13

US3412184

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:30:24

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:57:13
Amendment Manager: User entered '22 Jun 2022 00:01'	System	19 Nov 2020 16:57:13

US3412184

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:30:24

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:57:13
Amendment Manager: User entered '26 Jun 2022 23:59'	System	19 Nov 2020 16:57:13

US3412184

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:30:24

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:57:13
Amendment Manager: User entered 'Day 691'	System	19 Nov 2020 16:57:13

US3412184

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:30:24

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:57:13
Amendment Manager: User entered '29 Jun 2022 00:01'	System	19 Nov 2020 16:57:13

US3412184

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:30:24

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:57:13
Amendment Manager: User entered '03 Jul 2022 23:59'	System	19 Nov 2020 16:57:13

US3412184

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:30:24

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:57:13
Amendment Manager: User entered 'Day 698'	System	19 Nov 2020 16:57:13

US3412184

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:30:24

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:57:13
Amendment Manager: User entered '06 Jul 2022 00:01'	System	19 Nov 2020 16:57:13

US3412184

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:30:24

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:57:13
Amendment Manager: User entered '10 Jul 2022 23:59'	System	19 Nov 2020 16:57:13

US3412184

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:30:24

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:57:13
Amendment Manager: User entered 'Day 705'	System	19 Nov 2020 16:57:13

US3412184

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:30:24

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:57:13
Amendment Manager: User entered '13 Jul 2022 00:01'	System	19 Nov 2020 16:57:13

US3412184

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:30:24

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:57:13
Amendment Manager: User entered '17 Jul 2022 23:59'	System	19 Nov 2020 16:57:13

US3412184

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:30:24

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:57:13
Amendment Manager: User entered 'Day 712'	System	19 Nov 2020 16:57:13

US3412184

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:30:24

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:57:13
Amendment Manager: User entered '20 Jul 2022 00:01'	System	19 Nov 2020 16:57:13

US3412184

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:30:24

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:57:13
Amendment Manager: User entered '24 Jul 2022 23:59'	System	19 Nov 2020 16:57:13

US3412184

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:30:24

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:57:13
Amendment Manager: User entered 'Day 719'	System	19 Nov 2020 16:57:13

US3412184

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:30:24

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:57:13
Amendment Manager: User entered '27 Jul 2022 00:01'	System	19 Nov 2020 16:57:13

US3412184

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:30:24

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:57:13
Amendment Manager: User entered '31 Jul 2022 23:59'	System	19 Nov 2020 16:57:13

US3412184

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:30:24

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:57:13
Amendment Manager: User entered 'Day 726'	System	19 Nov 2020 16:57:13

US3412184

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:30:24

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:57:13
Amendment Manager: User entered '03 Aug 2022 00:01'	System	19 Nov 2020 16:57:13

US3412184

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:30:24

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:57:13
Amendment Manager: User entered '07 Aug 2022 23:59'	System	19 Nov 2020 16:57:13

US3412184

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:30:24

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:57:13
Amendment Manager: User entered 'Day 733'	System	19 Nov 2020 16:57:13

US3412184

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:30:24

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:57:13
Amendment Manager: User entered '10 Aug 2022 00:01'	System	19 Nov 2020 16:57:13

US3412184

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:30:24

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:57:13
Amendment Manager: User entered '14 Aug 2022 23:59'	System	19 Nov 2020 16:57:13

US3412184

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:30:24

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:57:13
Amendment Manager: User entered 'Day 740'	System	19 Nov 2020 16:57:13

US3412184

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:30:24

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:57:13
Amendment Manager: User entered '17 Aug 2022 00:01'	System	19 Nov 2020 16:57:13

US3412184

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:30:24

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:57:13
Amendment Manager: User entered '21 Aug 2022 23:59'	System	19 Nov 2020 16:57:13

US3412184

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:30:24

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:57:13
Amendment Manager: User entered 'Day 747'	System	19 Nov 2020 16:57:13

US3412184

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:30:24

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:57:13
Amendment Manager: User entered '24 Aug 2022 00:01'	System	19 Nov 2020 16:57:13

US3412184

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:30:24

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:57:13
Amendment Manager: User entered '28 Aug 2022 23:59'	System	19 Nov 2020 16:57:13

US3412184

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:30:24

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:57:13
Amendment Manager: User entered 'Day 754'	System	19 Nov 2020 16:57:13

US3412184

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:30:24

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:57:13
Amendment Manager: User entered '31 Aug 2022 00:01'	System	19 Nov 2020 16:57:13

US3412184

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:30:24

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:57:13
Amendment Manager: User entered '04 Sep 2022 23:59'	System	19 Nov 2020 16:57:13

US3412184

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:30:24

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:57:13
Amendment Manager: User entered 'Day 761'	System	19 Nov 2020 16:57:13

US3412184

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:30:24

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:57:13
Amendment Manager: User entered '07 Sep 2022 00:01'	System	19 Nov 2020 16:57:13

US3412184

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:30:24

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:57:13
Amendment Manager: User entered '11 Sep 2022 23:59'	System	19 Nov 2020 16:57:13

US3412184

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:30:24

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:57:13
Amendment Manager: User entered 'Day 768'	System	19 Nov 2020 16:57:13

US3412184

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:30:24

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:57:13
Amendment Manager: User entered '14 Sep 2022 00:01'	System	19 Nov 2020 16:57:13

US3412184

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:30:24

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:57:13
Amendment Manager: User entered '18 Sep 2022 23:59'	System	19 Nov 2020 16:57:13

US3412184

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:30:24

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:57:13
Amendment Manager: User entered 'Day 775'	System	19 Nov 2020 16:57:13

US3412184

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:30:24

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:57:13
Amendment Manager: User entered '21 Sep 2022 00:01'	System	19 Nov 2020 16:57:13

US3412184

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:30:24

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:57:13
Amendment Manager: User entered '25 Sep 2022 23:59'	System	19 Nov 2020 16:57:13

US3412184

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:30:24

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:57:13
Amendment Manager: User entered 'Day 782'	System	19 Nov 2020 16:57:13

US3412184

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:30:24

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:57:13
Amendment Manager: User entered '28 Sep 2022 00:01'	System	19 Nov 2020 16:57:13

US3412184

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:30:24

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:57:13
Amendment Manager: User entered '02 Oct 2022 23:59'	System	19 Nov 2020 16:57:13

US3412184

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:30:24

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:57:13
Amendment Manager: User entered 'Day 789'	System	19 Nov 2020 16:57:13

US3412184

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:30:24

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:57:13
Amendment Manager: User entered '05 Oct 2022 00:01'	System	19 Nov 2020 16:57:13

US3412184

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:30:24

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:57:13
Amendment Manager: User entered '09 Oct 2022 23:59'	System	19 Nov 2020 16:57:13

US3412184

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:30:24

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:57:13
Amendment Manager: User entered 'Day 796'	System	19 Nov 2020 16:57:13

US3412184

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:30:24

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:57:13
Amendment Manager: User entered '12 Oct 2022 00:01'	System	19 Nov 2020 16:57:13

US3412184

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:30:24

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:57:13
Amendment Manager: User entered '16 Oct 2022 23:59'	System	19 Nov 2020 16:57:13

US3412184

Folder: Cosmetic Injections and Dermal Fillers

Form: Cosmetic Injection_ Dermal Filler eDiary (1)

Generated On: 09 Jun 2021 17:30:24

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 00:16:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (BE2239D8-5851-41C8-9E0D-0EFE22431A8D)', Time: '2021-03-07T12:10:56-05:00', User OID: 'PatientReportedOutcome (US3412184)', ODM File OID: '7a3d2016-861a-43cf-86c6-f3ddb3ca3637'	System	07 Mar 2021 17:14:57
User entered 'No (N)'	System	07 Mar 2021 17:14:57

US3412184

Folder: Cosmetic Injections and Dermal Fillers

Form: Cosmetic Injection_ Dermal Filler eDiary (1)

Generated On: 09 Jun 2021 17:30:24

[Date & Time of Submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 00:16:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (BE2239D8-5851-41C8-9E0D-0EFE22431A8D)', Time: '2021-03-07T12:11:02-05:00', User OID: 'PatientReportedOutcome (US3412184)', ODM File OID: '7a3d2016-861a-43cf-86c6-f3ddb3ca3637' User entered '07 Mar 2021 12:11:02'	System	07 Mar 2021 17:14:57
	System	07 Mar 2021 17:14:57

US3412184

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:30:24

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:06:09
User signature succeeded.	Richard Powell (b) (4)	10 Mar 2021 19:34:57
User entered 'Yes (Y)'	Mason Urban (b) (4)	03 Nov 2020 21:09:52

US3412184

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:30:24

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:06:09
User signature succeeded.	Richard Powell (b) (4)	10 Mar 2021 19:34:57
User entered '3 Nov 2020'	Mason Urban (b) (4)	03 Nov 2020 21:09:52

US3412184

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:30:24

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:06:09
User signature succeeded.	Richard Powell (b) (4)	10 Mar 2021 19:34:57
User entered 'Contact Made (CONTACT MADE)'	Mason Urban (b) (4)	03 Nov 2020 21:09:52

US3412184

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:30:24

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:06:09
User signature succeeded.	Richard Powell (b) (4)	10 Mar 2021 19:34:57
User entered empty.	Mason Urban (b) (4)	03 Nov 2020 21:09:52

US3412184

Folder: Safety Call Day 85 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:30:24

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:06:09
User signature succeeded.	Richard Powell (b) (4)	10 Mar 2021 19:34:57
User entered 'Yes (Y)'	Mason Urban (b) (4)	03 Nov 2020 21:10:07

US3412184

Folder: Safety Call Day 85 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:30:24

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:06:09
User entered 'I'	System	03 Nov 2020 21:10:07

US3412184

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:30:24

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:38:49
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:34:07
User entered 'Yes (Y)'	Mason Urban (b) (4)	08 Dec 2020 17:32:58

US3412184

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:30:24

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:38:49
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:34:07
User entered '7 Dec 2020'	Mason Urban (b) (4)	08 Dec 2020 17:32:58

US3412184

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:30:24

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:38:49
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:34:07
User entered 'Contact Made (CONTACT MADE)'	Mason Urban (b) (4)	08 Dec 2020 17:32:58

US3412184

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:30:24

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:38:49
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:34:07
User entered empty.	Mason Urban (b) (4)	08 Dec 2020 17:32:58

US3412184

Folder: Safety Call Day 119 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:30:24

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:38:49
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:34:07
User entered 'Yes (Y)'	Mason Urban (b) (4)	08 Dec 2020 17:33:04

US3412184

Folder: Safety Call Day 119 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:30:24

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:38:49
User entered 'I'	System	08 Dec 2020 17:33:04

US3412184

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:30:24

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:38:49
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:34:07
User entered 'Yes (Y)'	Mason Urban (b) (4)	06 Jan 2021 15:39:30

US3412184

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:30:24

Date of Contact or Contact Attempt (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:38:49
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:34:07
User entered '6 Jan 2021'	Mason Urban (b) (4)	06 Jan 2021 15:39:30

US3412184

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:30:24

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:38:49
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:34:07
User entered 'Contact Made (CONTACT MADE)'	Mason Urban (b) (4)	06 Jan 2021 15:39:30

US3412184

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:30:24

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:38:49
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:34:07
User entered empty.	Mason Urban (b) (4)	06 Jan 2021 15:39:30

US3412184

Folder: Safety Call Day 149 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:30:24

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:38:49
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:34:07
User entered 'Yes (Y)'	Mason Urban (b) (4)	06 Jan 2021 15:39:36

US3412184

Folder: Safety Call Day 149 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:30:24

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:38:49
User entered 'I'	System	06 Jan 2021 15:39:36

US3412184

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:30:24

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:38:49
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:34:07
User entered 'Yes (Y)'	Mason Urban (b) (4)	05 Feb 2021 17:09:05

US3412184

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:30:24

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:38:49
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:34:07
User entered '5 Feb 2021'	Mason Urban (b) (4)	05 Feb 2021 17:09:05

US3412184

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:30:24

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:38:49
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:34:07
User entered 'Contact Made (CONTACT MADE)'	Mason Urban (b) (4)	05 Feb 2021 17:09:05

US3412184

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:30:24

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:38:49
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:34:07
User entered empty.	Mason Urban (b) (4)	05 Feb 2021 17:09:05

US3412184

Folder: Safety Call Day 179 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:30:24

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:38:49
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:34:07
User entered 'Yes (Y)'	Mason Urban (b) (4)	05 Feb 2021 17:09:09

US3412184

Folder: Safety Call Day 179 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:30:24

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:38:49
User entered 'I'	System	05 Feb 2021 17:09:09

US3412184

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Generated On: 09 Jun 2021 17:30:24

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:28:47
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:34:07
User entered 'Yes (Y)'	Andrea Newlands (b) (4)	29 Mar 2021 13:37:52

US3412184

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Generated On: 09 Jun 2021 17:30:24

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:28:47
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:34:07
User entered '02 Mar 2021'	Andrea Newlands (b) (4)	29 Mar 2021 13:37:52

US3412184

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Generated On: 09 Jun 2021 17:30:24

[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 12:28:47
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:34:07
User entered 'Clinic (Clinic)'	Andrea Newlands (b) (4)	29 Mar 2021 13:37:52

US3412184

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Generated On: 09 Jun 2021 17:30:24

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:28:47
User entered 'VISIT4'	System	29 Mar 2021 13:37:52

US3412184

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:30:24

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:28:47
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:34:07
User entered 'Yes (Y)'	Andrea Newlands (b) (4)	30 Mar 2021 15:37:50

US3412184

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:30:24

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:28:47
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:34:07
User entered '02 Mar 2021'	Andrea Newlands (b) (4)	30 Mar 2021 15:37:50

US3412184

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:30:24

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:28:47
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:34:07
User entered '11:24'	Andrea Newlands (b) (4)	30 Mar 2021 15:37:50

US3412184

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:30:24

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:28:47
User entered '02 Mar 2021 11:24'	System	30 Mar 2021 15:37:50

US3412184

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:30:24

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:28:47
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:34:07
User entered '36.8' C	Andrea Newlands (b) (4)	30 Mar 2021 15:37:50

US3412184

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:30:24

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:28:47
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:34:07
User entered 'Oral (Oral)'	Andrea Newlands (b) (4)	30 Mar 2021 15:37:50

US3412184

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:30:24

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:28:47
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:34:07
User entered empty.	Andrea Newlands (b) (4)	30 Mar 2021 15:37:50

US3412184

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:30:24

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:28:47
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:34:07
User entered '91'	Andrea Newlands (b) (4)	30 Mar 2021 15:37:50

US3412184

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:30:24

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:28:47
User entered 'bpm'	System	30 Mar 2021 15:37:50

US3412184

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:30:24

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:28:47
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:34:07
User entered '16'	Andrea Newlands (b) (4)	30 Mar 2021 15:37:50

US3412184

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:30:24

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:28:47
User entered 'breaths/min'	System	30 Mar 2021 15:37:50

US3412184

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:30:24

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:28:47
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:34:07
User entered '122'	Andrea Newlands (b) (4)	30 Mar 2021 15:37:50

US3412184

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:30:24

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:28:47
User entered 'mmHg'	System	30 Mar 2021 15:37:50

US3412184

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:30:24

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:28:47
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:34:07
User entered '80'	Andrea Newlands (b) (4)	30 Mar 2021 15:37:50

US3412184

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:30:24

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:28:47
User entered 'mmHg'	System	30 Mar 2021 15:37:50

US3412184

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:30:24

[Height \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:28:47

US3412184

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:30:24

[Weight \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:28:47

US3412184

Folder: Visit 4 Day 209 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 17:30:24

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:28:47
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:34:07
User entered 'No (N)'	Andrea Newlands (b) (4)	29 Mar 2021 13:41:47

US3412184

Folder: Visit 4 Day 209 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 17:30:24

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:28:47
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:34:07
User entered empty.	Andrea Newlands (b) (4)	29 Mar 2021 13:41:47

US3412184

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:30:24

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:28:47
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:34:07
User entered 'Yes (Y)'	Andrea Newlands (b) (4)	29 Mar 2021 13:43:28

US3412184

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:30:24

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:28:47
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:34:07
User entered '02 Mar 2021'	Andrea Newlands (b) (4)	29 Mar 2021 13:43:28

US3412184

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:30:24

Collection time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:28:47
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:34:07
User entered '11:34'	Andrea Newlands (b) (4)	29 Mar 2021 13:43:28

US3412184

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:30:24

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:28:47
User entered '02 Mar 2021 11:34'	System	29 Mar 2021 13:43:28

US3412184

Folder: Visit 4 Day 209 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:30:24

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:28:47
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:34:07
User entered 'Yes (Y)'	Andrea Newlands (b) (4)	29 Mar 2021 13:43:34

US3412184

Folder: Visit 4 Day 209 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:30:24

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:28:47
User entered 'I'	System	29 Mar 2021 13:43:34

US3412184

Folder: Safety Call Day 239 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:30:24

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:34:07
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	02 Apr 2021 13:55:07

US3412184

Folder: Safety Call Day 239 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:30:24

Date of Contact or Contact Attempt (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:34:07
User closed query 'Safety Call Day 239 'Date of Contact or Contact Attempt' is less than 207 days or greater than 213 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)	15 Apr 2021 15:04:41
Query 'Safety Call Day 239 'Date of Contact or Contact Attempt' is less than 207 days or greater than 213 days after Visit 2 Treatment Date on the Exposure Form. Please review and reconcile, or clarify.' answered with 'date is correct, pd noted' (Site from System).	Andrea Newlands (b) (4) (b) (4)	09 Apr 2021 12:33:03
User opened query 'Safety Call Day 239 'Date of Contact or Contact Attempt' is less than 207 days or greater than 213 days after Visit 2 Treatment Date on the Exposure Form. Please review and reconcile, or clarify.' (Site from System).	System	02 Apr 2021 13:55:07
User entered '02 Apr 2021'	(b) (4), (b) (6)	02 Apr 2021 13:55:07

US3412184

Folder: Safety Call Day 239 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:30:24

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:34:07
	(b) (4)	
User entered 'Contact Made (CONTACT MADE)'	Andrea Newlands (b) (4)	09 Apr 2021 12:31:03
reason for change: Data Entry Error	(b) (4)	
User entered 'Contact Not Made (CONTACT NOT	(b) (4), (b) (6)	02 Apr 2021 13:55:07
MADE)'		

US3412184

Folder: Safety Call Day 239 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:30:24

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:34:07
	(b) (4)	
User entered empty; reason for change Data Entry Error	Andrea Newlands (b) (4)	09 Apr 2021 12:31:03
	(b) (4)	
User entered 'Left VM on 02 APR 2021.'	(b) (4), (b) (6)	02 Apr 2021 13:55:07

US3412184

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

Form: Visit Date

Generated On: 09 Jun 2021 17:30:24

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 06:01:34
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:34:07
User entered 'Yes (Y)'	Mason Urban (b) (4)	12 Jan 2021 19:22:32

US3412184

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

Form: Visit Date

Generated On: 09 Jun 2021 17:30:24

Visit date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 06:01:34
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:34:07
User closed query 'Per GCL Lab Reconciliation: Antibody-mediated Immunogenicity: Sample dated 05Jan2021 is reported under OL-1 visit in PPD Central lab, however the same is missing in EDC. Please review if the sample has been collected then update the details under appropriate visit. Please confirm date of sample. Else clarify, thank you.' (Site from DM).	(b) (4), (b) (6)	22 Feb 2021 11:30:02
User closed query 'Per GCL Lab Reconciliation: Swab: Sample dated 05-JAN-2021 is reported under OL-1 visit in PPD portal; however, the same is missing in EDC. Kindly review if the sample was collected, if yes, update the data as appropriate under Central Laboratory - Nasopharyngeal Swab (Single) eCRF initiated under Participant Decision Visit / OL-D1 eCRF, else clarify. ' (Site from DM).		22 Feb 2021 11:29:59
Query 'Per GCL Lab Reconciliation: Antibody-mediated Immunogenicity: Sample dated 05Jan2021 is reported under OL-1 visit in PPD Central lab, however the same is missing in EDC. Please review if the sample has been collected then update the details under appropriate visit. Please confirm date of sample. Else clarify, thank you.' answered with 'updated' (Site from DM).	Andrea Newlands (b) (4)	17 Feb 2021 23:48:43
Query 'Per GCL Lab Reconciliation: Swab: Sample dated 05-JAN-2021 is reported under OL-1 visit in PPD portal; however, the same is missing in EDC. Kindly review if the sample was collected, if yes, update the data as appropriate under Central Laboratory - Nasopharyngeal Swab (Single) eCRF initiated under Participant Decision Visit / OL-D1 eCRF, else clarify. ' answered with 'updated' (Site from DM).	Andrea Newlands (b) (4)	17 Feb 2021 23:48:39

US3412184

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

Form: Visit Date

Generated On: 09 Jun 2021 17:30:24

Visit date (dd MMM yyyy)

Audit	User	Time (GMT)
User opened query 'Per GCL Lab Reconciliation: Antibody-mediated Immunogenicity: Sample dated 05Jan2021 is reported under OL-1 visit in PPD Central lab, however the same is missing in EDC. Please review if the sample has been collected then update the details under appropriate visit. Please confirm date of sample. Else clarify, thank you.' (Site from DM).	(b) (4), (b) (6)	08 Feb 2021 16:07:11
User opened query 'Per GCL Lab Reconciliation: Swab: Sample dated 05-JAN-2021 is reported under OL-1 visit in PPD portal; however, the same is missing in EDC. Kindly review if the sample was collected, if yes, update the data as appropriate under Central Laboratory - Nasopharyngeal Swab (Single) eCRF initiated under Participant Decision Visit / OL-D1 eCRF, else clarify. ' (Site from DM).		08 Feb 2021 10:23:13
User entered '5 Jan 2021'	Mason Urban (b) (4) (b) (4)	12 Jan 2021 19:22:32

US3412184

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

Form: Visit Date

Generated On: 09 Jun 2021 17:30:24

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 06:01:34
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:34:07
User entered 'Clinic (Clinic)'	Mason Urban (b) (4)	12 Jan 2021 19:22:32

US3412184

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

Form: Visit Date

Generated On: 09 Jun 2021 17:30:24

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 06:01:34
User entered 'UNBLND_DECIDE'	System	12 Jan 2021 19:22:32

US3412184

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

Form: Unblinding

Generated On: 09 Jun 2021 17:30:24

Date of updated informed consent (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 06:01:34
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:34:07
User entered '5 Jan 2021'	Mason Urban (b) (4)	12 Jan 2021 19:22:55

US3412184

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

Form: Unblinding

Generated On: 09 Jun 2021 17:30:24

[N/A - Subject Unblinded under Amendment 5 and Discontinued from Study](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 06:01:34
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:34:07
User entered '0' WR# 5295537	(b) (4)	10 Mar 2021 16:55:28
Amendment Manager inserted this DataPoint.	System	06 Mar 2021 12:02:41

US3412184

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

Form: Unblinding

Generated On: 09 Jun 2021 17:30:24

[Was the participant unblinded?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 06:01:34
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:34:07
User entered 'Yes (Y)'	Mason Urban (b) (4)	12 Jan 2021 19:22:55

US3412184

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

Form: Unblinding

Generated On: 09 Jun 2021 17:30:24

[Under what version of the Protocol was the Participant unblinded?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 06:01:34
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:34:07
User entered 'AMENDMENT 6 OR LATER (AMENDMENT 6 OR LATER)' WR# 5295537	(b) (4)	10 Mar 2021 16:55:28
Amendment Manager inserted this DataPoint.	System	06 Mar 2021 12:02:41

US3412184

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

Form: Unblinding

Generated On: 09 Jun 2021 17:30:24

Date of unblinding (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 06:01:34
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:34:07
User entered '5 Jan 2021'	Mason Urban (b) (4)	12 Jan 2021 19:22:55

US3412184

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

Form: Unblinding

Generated On: 09 Jun 2021 17:30:24

[Participant randomization assignment](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 06:01:34
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:34:07
User entered 'Placebo (Placebo)'	Mason Urban (b) (4)	12 Jan 2021 19:22:55

US3412184

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

Form: Unblinding

Generated On: 09 Jun 2021 17:30:24

[Actual Dose 1](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 06:01:34
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:34:07
Amendment Manager: User entered 'Placebo (Placebo)'	(b) (4)	20 Jan 2021 11:32:39
User entered 'Placebo (Placebo)'	Mason Urban (b) (4)	12 Jan 2021 19:22:55
	(b) (4)	

US3412184

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

Form: Unblinding

Generated On: 09 Jun 2021 17:30:24

[Actual Dose 2](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 06:01:34
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:34:07
Amendment Manager: User entered 'Placebo (Placebo)'	(b) (4)	20 Jan 2021 11:32:39
User entered 'Placebo (Placebo)'	Mason Urban (b) (4)	12 Jan 2021 19:22:55
	(b) (4)	

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

Form: Unblinding

Generated On: 09 Jun 2021 17:30:24

[Will participant receive mRNA-1273?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 06:01:34
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:34:07
User entered 'Yes (Y)'	Mason Urban (b) (4)	12 Jan 2021 19:22:55

US3412184

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

Form: Unblinding

Generated On: 09 Jun 2021 17:30:24

[Placebo Only Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 06:01:34
User entered '1'	System	12 Jan 2021 19:22:55

US3412184

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

Form: Unblinding

Generated On: 09 Jun 2021 17:30:24

[Continuing with mRNA-1273](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 06:01:34
User entered 'I'	System	12 Jan 2021 19:22:55

US3412184

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

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 17:30:24

[Height](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 06:01:34
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:34:07
User entered '166.5' cm	Andrea Newlands (b) (4)	17 Feb 2021 23:45:05

US3412184

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

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 17:30:24

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 06:01:34
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:34:07
User entered '87' kg	Andrea Newlands (b) (4)	17 Feb 2021 23:45:05

US3412184

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

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 17:30:24

BMI (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 06:01:34
User entered '31.38273'	System	17 Feb 2021 23:45:05
DataPoint set to visible.	System	12 Jan 2021 19:22:55

US3412184

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

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 17:30:24

[Height](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 06:01:34
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:34:07
User entered '166.5' cm	Andrea Newlands (b) (4)	17 Feb 2021 23:45:05

US3412184

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

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 17:30:24

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 06:01:34
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:34:07
User entered '87' kg	Andrea Newlands (b) (4)	17 Feb 2021 23:45:05

US3412184

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

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 17:30:24

BMI (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 06:01:34
User entered '31.38273'	System	17 Feb 2021 23:45:05
DataPoint set to visible.	System	12 Jan 2021 19:22:55

US3412184

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

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:30:24

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 06:01:34
User accepted default value 'Pre-Dose (PREDOSE)'	Andrea Newlands (b) (4)	17 Feb 2021 23:45:05
	(b) (4)	

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

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:30:24

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 06:01:34
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:34:07
User closed query 'Data is required. Please complete.' (Site from System).	(b) (4)	17 Feb 2021 23:46:01
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	17 Feb 2021 23:46:01
User entered 'Yes (Y)' reason for change: Data Entry Error	Andrea Newlands (b) (4)	17 Feb 2021 23:46:01
User opened query 'Data is required. Please complete.' (Site from System).	(b) (4)	17 Feb 2021 23:45:05
User entered empty.	System	17 Feb 2021 23:45:05
	Andrea Newlands (b) (4)	17 Feb 2021 23:45:05
	(b) (4)	

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

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:30:24

[Date of assessment \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 06:01:34
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:34:07
User entered '05 Jan 2021' reason for change: Data Entry Error	(b) (4)	
	Andrea Newlands (b) (4)	17 Feb 2021 23:46:01
User entered empty.	(b) (4)	
	Andrea Newlands (b) (4)	17 Feb 2021 23:45:05
	(b) (4)	

US3412184

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

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:30:24

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 06:01:34
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:34:07
User entered '12:50' reason for change: Data Entry Error	Andrea Newlands (b) (4)	17 Feb 2021 23:46:01
User entered empty.	Andrea Newlands (b) (4)	17 Feb 2021 23:45:05

US3412184

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

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:30:24

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 06:01:34
User entered '05 Jan 2021 12:50'	System	17 Feb 2021 23:46:01
User entered empty.	System	17 Feb 2021 23:45:05

US3412184

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

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:30:24

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 06:01:34
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:34:07
User closed query 'Temperature reported is out of range >41.7C (107F) per protocol considered grade 3. Please indicate if CS/NCS and report as AE, if appropriate.' (Site from System).	(b) (4)	17 Feb 2021 23:46:12
Query 'Temperature reported is out of range >41.7C (107F) per protocol considered grade 3. Please indicate if CS/NCS and report as AE, if appropriate.' answered by data change (Site from System).	System	17 Feb 2021 23:46:12
User entered '37' C reason for change: Data Entry Error	Andrea Newlands (b) (4)	17 Feb 2021 23:46:12
User opened query 'Temperature reported is out of range >41.7C (107F) per protocol considered grade 3. Please indicate if CS/NCS and report as AE, if appropriate.' (Site from System).	(b) (4)	17 Feb 2021 23:46:01
User entered '97' C reason for change: Data Entry Error	System	17 Feb 2021 23:46:01
User entered empty.	Andrea Newlands (b) (4)	17 Feb 2021 23:45:05
	(b) (4)	

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

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:30:24

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 06:01:34
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:34:07
User entered 'Oral (Oral)' reason for change: Data Entry Error	Andrea Newlands (b) (4)	17 Feb 2021 23:46:01
User entered empty.	Andrea Newlands (b) (4)	17 Feb 2021 23:45:05

US3412184

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

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:30:24

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 06:01:34
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:34:07
User entered empty.	Andrea Newlands (b) (4)	17 Feb 2021 23:45:05

US3412184

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

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:30:24

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 06:01:34
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:34:07
User entered '87' reason for change: Data Entry Error	Andrea Newlands (b) (4)	17 Feb 2021 23:46:01
User entered empty.	Andrea Newlands (b) (4)	17 Feb 2021 23:45:05

US3412184

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

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:30:24

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 06:01:34
User entered 'bpm'	System	17 Feb 2021 23:46:01
User entered empty.	System	17 Feb 2021 23:45:05

US3412184

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

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:30:24

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 06:01:34
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:34:07
User entered '14' reason for change: Data Entry Error	Andrea Newlands (b) (4)	17 Feb 2021 23:46:01
User entered empty.	Andrea Newlands (b) (4)	17 Feb 2021 23:45:05

US3412184

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

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:30:24

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 06:01:34
User entered 'breaths/min'	System	17 Feb 2021 23:46:01
User entered empty.	System	17 Feb 2021 23:45:05

US3412184

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

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:30:24

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 06:01:34
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:34:07
User entered '122' reason for change: Data Entry Error	Andrea Newlands (b) (4)	17 Feb 2021 23:46:01
User entered empty.	Andrea Newlands (b) (4)	17 Feb 2021 23:45:05

US3412184

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

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:30:24

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 06:01:34
User entered 'mmHg'	System	17 Feb 2021 23:46:01
User entered empty.	System	17 Feb 2021 23:45:05

US3412184

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

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:30:24

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 06:01:34
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:34:07
User entered '84' reason for change: Data Entry Error	Andrea Newlands (b) (4)	17 Feb 2021 23:46:01
User entered empty.	Andrea Newlands (b) (4)	17 Feb 2021 23:45:05

US3412184

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

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:30:24

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 06:01:34
User entered 'mmHg'	System	17 Feb 2021 23:46:01
User entered empty.	System	17 Feb 2021 23:45:05

US3412184

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

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 17:30:24

[Height](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 06:01:34
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:34:07
User entered '166.5' cm	Andrea Newlands (b) (4)	17 Feb 2021 23:45:05

US3412184

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

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 17:30:24

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 06:01:34
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:34:07
User entered '87' kg	Andrea Newlands (b) (4)	17 Feb 2021 23:45:05

US3412184

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

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 17:30:24

BMI (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 06:01:34
User entered '31.38273'	System	17 Feb 2021 23:45:05
DataPoint set to visible.	System	12 Jan 2021 19:22:55

US3412184

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

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:30:24

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 06:01:34
User accepted default value 'Post-Dose (POSTDOSE)'	Andrea Newlands (b) (4) (b) (4)	17 Feb 2021 23:45:05

US3412184

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

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:30:24

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 06:01:34
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:34:07
User closed query 'Data is required. Please complete.' (Site from System).	(b) (4)	
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	17 Feb 2021 23:47:01
User entered 'Yes (Y)' reason for change: Data Entry Error	Andrea Newlands (b) (4)	17 Feb 2021 23:47:01
User opened query 'Data is required. Please complete.' (Site from System).	(b) (4)	
User entered empty.	System	17 Feb 2021 23:45:05
	Andrea Newlands (b) (4)	17 Feb 2021 23:45:05
	(b) (4)	

US3412184

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

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:30:24

[Date of assessment \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 06:01:34
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:34:07
User entered '05 Jan 2021' reason for change: Data Entry Error	(b) (4)	
	Andrea Newlands (b) (4)	17 Feb 2021 23:47:01
User entered empty.	(b) (4)	
	Andrea Newlands (b) (4)	17 Feb 2021 23:45:05
	(b) (4)	

US3412184

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

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:30:24

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 06:01:34
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:34:07
User entered '13:39' reason for change: Data Entry Error	Andrea Newlands (b) (4)	17 Feb 2021 23:47:01
User entered empty.	Andrea Newlands (b) (4)	17 Feb 2021 23:45:05

US3412184

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

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:30:24

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 06:01:34
User entered '05 Jan 2021 13:39'	System	17 Feb 2021 23:47:01
User entered empty.	System	17 Feb 2021 23:45:05

US3412184

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:30:24

[Temperature \(xxx.x\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 06:01:34
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:34:07
User entered '98.6' F reason for change: Data Entry Error	Andrea Newlands (b) (4)	17 Feb 2021 23:47:01
User entered empty.	Andrea Newlands (b) (4)	17 Feb 2021 23:45:05

US3412184

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:30:24

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 06:01:34
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:34:07
User entered 'Oral (Oral)' reason for change: Data Entry Error	Andrea Newlands (b) (4)	17 Feb 2021 23:47:01
User entered empty.	Andrea Newlands (b) (4)	17 Feb 2021 23:45:05

US3412184

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:30:24

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 06:01:34
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:34:07
User entered empty.	Andrea Newlands (b) (4)	17 Feb 2021 23:45:05

US3412184

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:30:24

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 06:01:34
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:34:07
User entered '74' reason for change: Data Entry Error	Andrea Newlands (b) (4)	17 Feb 2021 23:47:01
User entered empty.	Andrea Newlands (b) (4)	17 Feb 2021 23:45:05

US3412184

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:30:24

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 06:01:34
User entered 'bpm'	System	17 Feb 2021 23:47:01
User entered empty.	System	17 Feb 2021 23:45:05

US3412184

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:30:24

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 06:01:34
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:34:07
User entered '16' reason for change: Data Entry Error	Andrea Newlands (b) (4)	17 Feb 2021 23:47:01
User entered empty.	Andrea Newlands (b) (4)	17 Feb 2021 23:45:05

US3412184

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:30:24

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 06:01:34
User entered 'breaths/min'	System	17 Feb 2021 23:47:01
User entered empty.	System	17 Feb 2021 23:45:05

US3412184

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:30:24

[Systolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 06:01:34
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:34:07
User entered '130' reason for change: Data Entry Error	Andrea Newlands (b) (4)	17 Feb 2021 23:47:01
User entered empty.	Andrea Newlands (b) (4)	17 Feb 2021 23:45:05

US3412184

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:30:24

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 06:01:34
User entered 'mmHg'	System	17 Feb 2021 23:47:01
User entered empty.	System	17 Feb 2021 23:45:05

US3412184

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:30:24

[Diastolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 06:01:34
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:34:07
User entered '72' reason for change: Data Entry Error	Andrea Newlands (b) (4)	17 Feb 2021 23:47:01
User entered empty.	Andrea Newlands (b) (4)	17 Feb 2021 23:45:05

US3412184

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:30:24

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 06:01:34
User entered 'mmHg'	System	17 Feb 2021 23:47:01
User entered empty.	System	17 Feb 2021 23:45:05

US3412184

Folder: Participant Decision Visit / OL-D1 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 17:30:24

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 06:01:34
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:34:07
User entered 'Yes (Y)'	Andrea Newlands (b) (4)	17 Feb 2021 23:47:17

US3412184

Folder: Participant Decision Visit / OL-D1 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 17:30:24

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 06:01:34
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:34:07
User entered '05 Jan 2021'	Andrea Newlands (b) (4)	17 Feb 2021 23:47:17

US3412184

Folder: Participant Decision Visit / OL-D1 (1)

Form: Exposure

Generated On: 09 Jun 2021 17:30:24

[Was study treatment given?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 06:01:34
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:34:07
User entered 'Yes (Y)'	Andrea Newlands (b) (4)	17 Feb 2021 23:47:55

US3412184

Folder: Participant Decision Visit / OL-D1 (1)

Form: Exposure

Generated On: 09 Jun 2021 17:30:24

[If No, reason not given](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 06:01:34
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:34:07
User entered empty.	Andrea Newlands (b) (4)	17 Feb 2021 23:47:55

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Folder: Participant Decision Visit / OL-D1 (1)

Form: Exposure

Generated On: 09 Jun 2021 17:30:24

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)	26 Apr 2021 06:01:34
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:34:07
User entered empty.	Andrea Newlands (b) (4)	17 Feb 2021 23:47:55

US3412184

Folder: Participant Decision Visit / OL-D1 (1)

Form: Exposure

Generated On: 09 Jun 2021 17:30:24

[What was the study treatment? \(Unblinded\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 06:01:34
User entered 'mRNA-1273'	System	17 Feb 2021 23:47:55
DataPoint set to visible.	System	12 Jan 2021 19:22:55

US3412184

Folder: Participant Decision Visit / OL-D1 (1)

Form: Exposure

Generated On: 09 Jun 2021 17:30:24

What was the treatment date? (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 06:01:34
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:34:07
User entered '05 Jan 2021'	Andrea Newlands (b) (4)	17 Feb 2021 23:47:55

US3412184

Folder: Participant Decision Visit / OL-D1 (1)

Form: Exposure

Generated On: 09 Jun 2021 17:30:24

[What was the treatment time? \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 06:01:34
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:34:07
User entered '13:05'	Andrea Newlands (b) (4)	17 Feb 2021 23:47:55

US3412184

Folder: Participant Decision Visit / OL-D1 (1)

Form: Exposure

Generated On: 09 Jun 2021 17:30:24

[Treatment Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 06:01:34
User entered '05 Jan 2021 13:05'	System	17 Feb 2021 23:47:55

US3412184

Folder: Participant Decision Visit / OL-D1 (1)

Form: Exposure

Generated On: 09 Jun 2021 17:30:24

[Which arm was used to give treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 06:01:34
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:34:07
User entered 'Left Arm (LEFT ARM)'	Andrea Newlands (b) (4)	17 Feb 2021 23:47:55

US3412184

Folder: Participant Decision Visit / OL-D1 (1)

Form: Exposure

Generated On: 09 Jun 2021 17:30:24

[What was the frequency of the study treatment dosing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 06:01:34
User entered 'ONCE'	System	17 Feb 2021 23:47:55

US3412184

Folder: Participant Decision Visit / OL-D1 (1)

Form: Exposure

Generated On: 09 Jun 2021 17:30:24

[What was the route of administration for the study treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 06:01:34
User entered 'INTRAMUSCULAR'	System	17 Feb 2021 23:47:55

US3412184

Folder: Participant Decision Visit / OL-D1 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:30:24

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 06:01:34
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:34:07
User entered 'Yes (Y)'	Andrea Newlands (b) (4)	17 Feb 2021 23:48:18

US3412184

Folder: Participant Decision Visit / OL-D1 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:30:24

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 06:01:34
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:34:07
User entered '05 Jan 2021'	Andrea Newlands (b) (4)	17 Feb 2021 23:48:18

US3412184

Folder: Participant Decision Visit / OL-D1 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:30:24

[Collection time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 06:01:34
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:34:07
User entered '12:21'	Andrea Newlands (b) (4)	17 Feb 2021 23:48:18

US3412184

Folder: Participant Decision Visit / OL-D1 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:30:24

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 06:01:34
User entered '05 Jan 2021 12:21'	System	17 Feb 2021 23:48:18

US3412184

Folder: Participant Decision Visit / OL-D1 (1)

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 09 Jun 2021 17:30:24

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 06:01:34
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:34:07
User entered 'Yes (Y)'	Andrea Newlands (b) (4)	17 Feb 2021 23:48:30

US3412184

Folder: Participant Decision Visit / OL-D1 (1)

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 09 Jun 2021 17:30:24

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 06:01:34
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:34:07
User entered '05 Jan 2021'	Andrea Newlands (b) (4)	17 Feb 2021 23:48:30

US3412184

Folder: Participant Decision Visit / OL-D1 (1)

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 09 Jun 2021 17:30:24

[Collection time \(00:00 - 23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 06:01:34
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:34:07
User entered '12:59'	Andrea Newlands (b) (4)	17 Feb 2021 23:48:30

US3412184

Folder: Participant Decision Visit / OL-D1 (1)

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 09 Jun 2021 17:30:24

[Collection Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 06:01:34
User entered '05 Jan 2021 12:59'	System	17 Feb 2021 23:48:30

US3412184

Folder: Participant Decision Visit / OL-D1 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:30:24

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 06:01:34
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:34:07
User entered 'Yes (Y)'	Mason Urban (b) (4)	12 Jan 2021 19:23:02

US3412184

Folder: Participant Decision Visit / OL-D1 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:30:24

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 06:01:34
User entered 'I'	System	12 Jan 2021 19:23:02

US3412184

Folder: Safety Call OL-D8 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:30:24

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 06:01:34
User signature succeeded.	Richard Powell (b) (4)	10 Mar 2021 19:34:57
User entered 'Yes (Y)'	Mason Urban (b) (4)	13 Jan 2021 16:33:27

US3412184

Folder: Safety Call OL-D8 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:30:24

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 06:01:34
User signature succeeded.	Richard Powell (b) (4)	10 Mar 2021 19:34:57
User entered '13 Jan 2021'	Mason Urban (b) (4)	13 Jan 2021 16:33:27

US3412184

Folder: Safety Call OL-D8 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:30:24

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 06:01:34
User signature succeeded.	Richard Powell (b) (4)	10 Mar 2021 19:34:57
User entered 'Contact Made (CONTACT MADE)'	Mason Urban (b) (4)	13 Jan 2021 16:33:27

US3412184

Folder: Safety Call OL-D8 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:30:24

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 06:01:34
User signature succeeded.	Richard Powell (b) (4)	10 Mar 2021 19:34:57
User entered empty.	Mason Urban (b) (4)	13 Jan 2021 16:33:27

US3412184

Folder: Safety Call OL-D8 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:30:24

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 06:01:34
User signature succeeded.	Richard Powell (b) (4)	10 Mar 2021 19:34:57
User entered 'Yes (Y)'	Mason Urban (b) (4)	13 Jan 2021 16:33:31

US3412184

Folder: Safety Call OL-D8 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:30:24

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 06:01:34
User entered 'I'	System	13 Jan 2021 16:33:31

US3412184

Folder: Safety Call OL-D8 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:30:24

[OLD29 Placebo Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 06:01:34
User entered '1'	System	13 Jan 2021 16:33:31
DataPoint set to visible.	System	13 Jan 2021 16:33:31

US3412184

Folder: OL-D29 (1)

Form: Visit Date

Generated On: 09 Jun 2021 17:30:24

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 06:01:34
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:34:07
User entered 'Yes (Y)'	Melissa Fuson (b) (4)	03 Feb 2021 15:11:44

US3412184

Folder: OL-D29 (1)

Form: Visit Date

Generated On: 09 Jun 2021 17:30:24

[Visit date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 06:01:34
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:34:07
User entered '2 Feb 2021'	Melissa Fuson (b) (4)	03 Feb 2021 15:11:44

US3412184

Folder: OL-D29 (1)

Form: Visit Date

Generated On: 09 Jun 2021 17:30:24

[Was visit performed at the participant's home or at the clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 06:01:34
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:34:07
User entered 'Clinic (Clinic)'	Melissa Fuson (b) (4)	03 Feb 2021 15:11:44

US3412184

Folder: OL-D29 (1)

Form: Visit Date

Generated On: 09 Jun 2021 17:30:24

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 06:01:34
User entered 'OLD29'	System	03 Feb 2021 15:11:44

US3412184

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:30:24

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 06:01:34
User accepted default value 'Pre-Dose (PREDOSE)'	Melissa Fuson (b) (4) (b) (4)	03 Feb 2021 15:21:43

US3412184

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:30:24

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 06:01:34
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:34:07
User entered 'Yes (Y)'	Melissa Fuson (b) (4)	03 Feb 2021 15:21:43

US3412184

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:30:24

[Date of assessment \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 06:01:34
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:34:07
User entered '2 Feb 2021'	Melissa Fuson (b) (4)	03 Feb 2021 15:21:43

US3412184

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:30:24

Time of assessment (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 06:01:34
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:34:07
User closed query 'Data is required. Please provide.' (Site from System).	(b) (4)	17 Feb 2021 23:43:53
Query 'Data is required. Please provide.' answered by System	System	17 Feb 2021 23:43:53
data change (Site from System).		
User entered '11:34' reason for change: Data Entry Error	Andrea Newlands (b) (4)	17 Feb 2021 23:43:53
User opened query 'Data is required. Please provide.' (Site from System).	(b) (4)	03 Feb 2021 15:21:43
User entered empty.	System	
	Melissa Fuson (b) (4)	03 Feb 2021 15:21:43
	(b) (4)	

US3412184

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:30:24

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 06:01:34
User entered '2 Feb 2021 11:34'	System	17 Feb 2021 23:43:53
User entered empty.	System	03 Feb 2021 15:21:43

US3412184

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:30:24

[Temperature \(xxx.x\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 06:01:34
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:34:07
User entered '36.8' C	Melissa Fuson (b) (4)	03 Feb 2021 15:21:43

US3412184

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:30:24

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 06:01:34
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:34:07
User entered 'Oral (Oral)'	Melissa Fuson (b) (4)	03 Feb 2021 15:21:43

US3412184

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:30:24

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 06:01:34
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:34:07
User entered empty.	Melissa Fuson (b) (4)	03 Feb 2021 15:21:43

US3412184

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:30:24

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 06:01:34
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:34:07
User entered '87'	Melissa Fuson (b) (4)	03 Feb 2021 15:21:43

US3412184

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:30:24

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 06:01:34
User entered 'bpm'	System	03 Feb 2021 15:21:43

US3412184

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:30:24

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 06:01:34
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:34:07
User entered '12'	Melissa Fuson (b) (4)	03 Feb 2021 15:21:43

US3412184

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:30:24

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 06:01:34
User entered 'breaths/min'	System	03 Feb 2021 15:21:43

US3412184

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:30:24

[Systolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 06:01:34
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:34:07
User entered '118'	Melissa Fuson (b) (4)	03 Feb 2021 15:21:43

US3412184

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:30:24

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 06:01:34
User entered 'mmHg'	System	03 Feb 2021 15:21:43

US3412184

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:30:24

[Diastolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 06:01:34
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:34:07
User entered '74'	Melissa Fuson (b) (4)	03 Feb 2021 15:21:43

US3412184

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:30:24

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 06:01:34
User entered 'mmHg'	System	03 Feb 2021 15:21:43

US3412184

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:30:24

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 06:01:34
User accepted default value 'Post-Dose (POSTDOSE)'	Melissa Fuson (b) (4) (b) (4)	03 Feb 2021 15:21:43

US3412184

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:30:24

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 06:01:34
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:34:07
User entered 'Yes (Y)'	Melissa Fuson (b) (4)	03 Feb 2021 15:21:43

US3412184

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:30:24

[Date of assessment \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 06:01:34
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:34:07
User entered '2 Feb 2021'	Melissa Fuson (b) (4)	03 Feb 2021 15:21:43

US3412184

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:30:24

Time of assessment (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 06:01:34
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:34:07
User closed query 'Data is required. Please provide.' (Site from System).	(b) (4)	17 Feb 2021 23:44:04
Query 'Data is required. Please provide.' answered by System	System	17 Feb 2021 23:44:04
data change (Site from System).		
User entered '13:03' reason for change: Data Entry Error	Andrea Newlands (b) (4)	17 Feb 2021 23:44:04
User opened query 'Data is required. Please provide.' (Site from System).	(b) (4)	03 Feb 2021 15:21:43
User entered empty.	System	
	Melissa Fuson (b) (4)	03 Feb 2021 15:21:43
	(b) (4)	

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Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:30:24

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 06:01:34
User entered '2 Feb 2021 13:03'	System	17 Feb 2021 23:44:04
User entered empty.	System	03 Feb 2021 15:21:43

US3412184

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:30:24

[Temperature \(xxx.x\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 06:01:34
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:34:07
User entered '98.8' F	Melissa Fuson (b) (4)	03 Feb 2021 15:21:43

US3412184

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:30:24

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 06:01:34
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:34:07
User entered 'Oral (Oral)'	Melissa Fuson (b) (4)	03 Feb 2021 15:21:43

US3412184

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:30:24

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 06:01:34
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:34:07
User entered empty.	Melissa Fuson (b) (4)	03 Feb 2021 15:21:43

US3412184

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:30:24

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 06:01:34
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:34:07
User entered '82'	Melissa Fuson (b) (4)	03 Feb 2021 15:21:43

US3412184

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:30:24

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 06:01:34
User entered 'bpm'	System	03 Feb 2021 15:21:43

US3412184

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:30:24

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 06:01:34
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:34:07
User entered '18'	Melissa Fuson (b) (4)	03 Feb 2021 15:21:43

US3412184

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:30:24

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 06:01:34
User entered 'breaths/min'	System	03 Feb 2021 15:21:43

US3412184

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:30:24

[Systolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 06:01:34
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:34:07
User entered '132'	Melissa Fuson (b) (4)	03 Feb 2021 15:21:43

US3412184

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:30:24

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 06:01:34
User entered 'mmHg'	System	03 Feb 2021 15:21:43

US3412184

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:30:24

[Diastolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 06:01:34
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:34:07
User entered '90'	Melissa Fuson (b) (4)	03 Feb 2021 15:21:43

US3412184

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:30:24

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 06:01:34
User entered 'mmHg'	System	03 Feb 2021 15:21:43

US3412184

Folder: OL-D29 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 17:30:24

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 06:01:34
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:34:07
User entered 'Yes (Y)'	Melissa Fuson (b) (4)	03 Feb 2021 15:21:58

US3412184

Folder: OL-D29 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 17:30:24

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 06:01:34
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:34:07
User entered '2 Feb 2021'	Melissa Fuson (b) (4)	03 Feb 2021 15:21:58

US3412184

Folder: OL-D29 (1)

Form: Exposure

Generated On: 09 Jun 2021 17:30:24

[Was study treatment given?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 06:01:34
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:34:07
User entered 'Yes (Y)'	Melissa Fuson (b) (4)	03 Feb 2021 15:22:24

US3412184

Folder: OL-D29 (1)

Form: Exposure

Generated On: 09 Jun 2021 17:30:24

[If No, reason not given](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 06:01:34
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:34:07
User entered empty.	Melissa Fuson (b) (4)	03 Feb 2021 15:22:24

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Folder: OL-D29 (1)

Form: Exposure

Generated On: 09 Jun 2021 17:30:24

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)	26 Apr 2021 06:01:34
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:34:07
User entered empty.	Melissa Fuson (b) (4)	03 Feb 2021 15:22:24

US3412184

Folder: OL-D29 (1)

Form: Exposure

Generated On: 09 Jun 2021 17:30:24

[What was the study treatment? \(Unblinded\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 06:01:34
User entered 'mRNA-1273'	System	03 Feb 2021 15:22:24
DataPoint set to visible.	System	13 Jan 2021 16:33:31

US3412184

Folder: OL-D29 (1)

Form: Exposure

Generated On: 09 Jun 2021 17:30:24

[What was the treatment date? \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 06:01:34
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:34:07
User entered '2 Feb 2021'	Melissa Fuson (b) (4)	03 Feb 2021 15:22:24

US3412184

Folder: OL-D29 (1)

Form: Exposure

Generated On: 09 Jun 2021 17:30:24

[What was the treatment time? \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 06:01:34
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:34:07
User entered '12:28'	Melissa Fuson (b) (4)	03 Feb 2021 15:22:24

US3412184

Folder: OL-D29 (1)

Form: Exposure

Generated On: 09 Jun 2021 17:30:24

[Treatment Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 06:01:34
User entered '2 Feb 2021 12:28'	System	03 Feb 2021 15:22:24

US3412184

Folder: OL-D29 (1)

Form: Exposure

Generated On: 09 Jun 2021 17:30:24

[Which arm was used to give treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 06:01:34
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:34:07
User entered 'Left Arm (LEFT ARM)'	Melissa Fuson (b) (4)	03 Feb 2021 15:22:24

US3412184

Folder: OL-D29 (1)

Form: Exposure

Generated On: 09 Jun 2021 17:30:24

[What was the frequency of the study treatment dosing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 06:01:34
User entered 'ONCE'	System	03 Feb 2021 15:22:24

US3412184

Folder: OL-D29 (1)

Form: Exposure

Generated On: 09 Jun 2021 17:30:24

[What was the route of administration for the study treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 06:01:34
User entered 'INTRAMUSCULAR'	System	03 Feb 2021 15:22:24

US3412184

Folder: OL-D29 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:30:24

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 06:01:34
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:34:07
User entered 'Yes (Y)'	Melissa Fuson (b) (4)	03 Feb 2021 15:22:32

US3412184

Folder: OL-D29 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:30:24

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 06:01:34
User entered 'I'	System	03 Feb 2021 15:22:32

US3412184

Folder: Safety Call OL-D36 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:30:24

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 06:01:34
User signature succeeded.	Richard Powell (b) (4)	10 Mar 2021 19:34:57
User entered 'Yes (Y)'	Mason Urban (b) (4)	09 Feb 2021 20:52:35

US3412184

Folder: Safety Call OL-D36 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:30:24

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 06:01:34
User signature succeeded.	Richard Powell (b) (4)	10 Mar 2021 19:34:57
User entered '9 Feb 2021'	Mason Urban (b) (4)	09 Feb 2021 20:52:35

US3412184

Folder: Safety Call OL-D36 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:30:24

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 06:01:34
User signature succeeded.	Richard Powell (b) (4)	10 Mar 2021 19:34:57
User entered 'Contact Made (CONTACT MADE)'	Mason Urban (b) (4)	09 Feb 2021 20:52:35

US3412184

Folder: Safety Call OL-D36 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:30:24

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 06:01:34
User signature succeeded.	Richard Powell (b) (4)	10 Mar 2021 19:34:57
User entered empty.	Mason Urban (b) (4)	09 Feb 2021 20:52:35

US3412184

Folder: Safety Call OL-D36 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:30:24

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 06:01:34
User signature succeeded.	Richard Powell (b) (4)	10 Mar 2021 19:34:57
User entered 'Yes (Y)'	Mason Urban (b) (4)	09 Feb 2021 20:52:39

US3412184

Folder: Safety Call OL-D36 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:30:24

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 06:01:34
User entered 'I'	System	09 Feb 2021 20:52:39

US3412184

Folder: OL-D57 (1)

Form: Visit Date

Generated On: 09 Jun 2021 17:30:24

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 06:01:34
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:34:07
User entered 'Yes (Y)'	Andrea Newlands (b) (4)	02 Mar 2021 19:24:54

US3412184

Folder: OL-D57 (1)

Form: Visit Date

Generated On: 09 Jun 2021 17:30:24

[Visit date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 06:01:34
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:34:07
User entered '02 Mar 2021'	Andrea Newlands (b) (4)	02 Mar 2021 19:24:54

US3412184

Folder: OL-D57 (1)

Form: Visit Date

Generated On: 09 Jun 2021 17:30:24

[Was visit performed at the participant's home or at the clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 06:01:34
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:34:07
User entered 'Clinic (Clinic)'	Andrea Newlands (b) (4)	02 Mar 2021 19:24:54

US3412184

Folder: OL-D57 (1)

Form: Visit Date

Generated On: 09 Jun 2021 17:30:24

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 06:01:34
User entered 'OLD57'	System	02 Mar 2021 19:24:54

US3412184

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:30:24

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 06:01:34
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:34:07
User entered 'Yes (Y)'	Andrea Newlands (b) (4)	02 Mar 2021 19:26:19

US3412184

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:30:24

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 06:01:34
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:34:07
User entered '02 Mar 2021'	Andrea Newlands (b) (4)	02 Mar 2021 19:26:19

US3412184

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:30:24

[Time of assessment \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 06:01:34
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:34:07
User entered '11:24'	Andrea Newlands (b) (4)	02 Mar 2021 19:26:19

US3412184

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:30:24

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 06:01:34
User entered '02 Mar 2021 11:24'	System	02 Mar 2021 19:26:19

US3412184

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:30:24

[Temperature \(xxx.x\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 06:01:34
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:34:07
User entered '36.8' C	Andrea Newlands (b) (4)	02 Mar 2021 19:26:19

US3412184

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:30:24

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 06:01:34
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:34:07
User entered 'Oral (Oral)'	Andrea Newlands (b) (4)	02 Mar 2021 19:26:19

US3412184

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:30:24

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 06:01:34
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:34:07
User entered empty.	Andrea Newlands (b) (4)	02 Mar 2021 19:26:19

US3412184

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:30:24

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 06:01:34
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:34:07
User entered '91'	Andrea Newlands (b) (4)	02 Mar 2021 19:26:19

US3412184

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:30:24

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 06:01:34
User entered 'bpm'	System	02 Mar 2021 19:26:19

US3412184

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:30:24

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 06:01:34
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:34:07
User entered '16'	Andrea Newlands (b) (4)	02 Mar 2021 19:26:19

US3412184

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:30:24

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 06:01:34
User entered 'breaths/min'	System	02 Mar 2021 19:26:19

US3412184

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:30:24

[Systolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 06:01:34
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:34:07
User entered '122'	Andrea Newlands (b) (4)	02 Mar 2021 19:26:19

US3412184

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:30:24

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 06:01:34
User entered 'mmHg'	System	02 Mar 2021 19:26:19

US3412184

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:30:24

[Diastolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 06:01:34
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:34:07
User entered '80'	Andrea Newlands (b) (4)	02 Mar 2021 19:26:19

US3412184

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:30:24

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 06:01:34
User entered 'mmHg'	System	02 Mar 2021 19:26:19

US3412184

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:30:24

[Height \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 06:01:34

US3412184

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:30:24

[Weight \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 06:01:34

US3412184

Folder: OL-D57 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 17:30:24

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 06:01:34
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:34:07
User entered 'No (N)'	Andrea Newlands (b) (4)	02 Mar 2021 19:29:04

US3412184

Folder: OL-D57 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 17:30:24

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 06:01:34
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:34:07
User entered empty.	Andrea Newlands (b) (4)	02 Mar 2021 19:29:04

US3412184

Folder: OL-D57 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:30:24

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 06:01:34
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:34:07
User entered 'Yes (Y)'	Andrea Newlands (b) (4)	02 Mar 2021 19:29:14

US3412184

Folder: OL-D57 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:30:24

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 06:01:34
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:34:07
User entered '02 Mar 2021'	Andrea Newlands (b) (4)	02 Mar 2021 19:29:14

US3412184

Folder: OL-D57 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:30:24

[Collection time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 06:01:34
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:34:07
User entered '11:34'	Andrea Newlands (b) (4)	02 Mar 2021 19:29:14

US3412184

Folder: OL-D57 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:30:24

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 06:01:34
User entered '02 Mar 2021 11:34'	System	02 Mar 2021 19:29:14

US3412184

Folder: Adverse Events

Form: Adverse Events Summary

Generated On: 09 Jun 2021 17:30:24

[Did the participant experience any adverse events?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 06:41:35
User signature succeeded.	Richard Powell (b) (4)	15 Mar 2021 15:34:10
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Nov 2020 14:46:39
User entered 'Yes (Y)'	Steven Anderson (b) (4) (b) (4)	17 Aug 2020 23:42:22

US3412184

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:30:24

[AEID](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 14:46:56
Reviewed for Safety.		18 Aug 2020 13:45:03
User entered 'USA-US061-2020-mRNA-1273-P301000002'	System	18 Aug 2020 13:40:20
User entered 'New'	(b) (4), (b) (6)	18 Aug 2020 13:40:20

US3412184

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:30:24

[Adverse event](#)

Audit	User	Time (GMT)
User closed query 'PV Query: Please consider updating the event term to right breast ductal carcinoma in situ.' (Site from Safety).	(b) (4), (b) (6)	11 Nov 2020 15:33:04
User coded data point as SOC: Neoplasms benign, malignant and unspecified (incl cysts and polyps), HLGT: Breast neoplasms malignant and unspecified (incl nipple), HLT: Breast and nipple neoplasms malignant, PT: Intraductal proliferative breast lesion, LLT: Carcinoma in situ of breast ductal - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	11 Nov 2020 00:35:42
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\23.0. DataPoint Verified.	Coder Import (b) (4) (b) (4) (b) (4), (b) (6)	11 Nov 2020 00:35:42 10 Nov 2020 22:01:25
Data point term sent to Coder	System	10 Nov 2020 20:39:20
Query 'PV Query: Please consider updating the event term to right breast ductal carcinoma in situ.' answered with 'Term has been updated' (Site from Safety).	Steven Anderson (b) (4) (b) (4)	10 Nov 2020 20:38:31
Coding entries removed.	Steven Anderson (b) (4) (b) (4)	10 Nov 2020 20:38:21
User entered 'right breast ductal carcinoma in situ' reason for change: Data Entry Error	Steven Anderson (b) (4) (b) (4)	10 Nov 2020 20:38:21
User opened query 'PV Query: Please consider updating the event term to right breast ductal carcinoma in situ.' (Site from Safety).	(b) (4), (b) (6)	28 Oct 2020 13:59:09
User closed query 'Per MM, please review and confirm if the subject meets the criteria for discontinuation of study treatment, as per protocol 7.2' (Site from DM).		22 Oct 2020 04:49:36
Query 'Per MM, please review and confirm if the subject meets the criteria for discontinuation of study treatment, as per protocol 7.2' answered with 'This SAE was submitted to e-pip and per MM and sponsor subject was eligible to continue in the study. All documentation is filed in subject chart.' (Site from DM).	Steven Anderson (b) (4) (b) (4)	20 Oct 2020 21:38:24
User opened query 'Per MM, please review and confirm if the subject meets the criteria for discontinuation of study treatment, as per protocol 7.2' (Site from DM).	(b) (4), (b) (6)	05 Oct 2020 08:16:43

US3412184

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:30:24

[Adverse event](#)

Audit	User	Time (GMT)
User coded data point as SOC: Neoplasms benign, malignant and unspecified (incl cysts and polyps), HLGT: Breast neoplasms malignant and unspecified (incl nipple), HLT: Breast and nipple neoplasms malignant, PT: Breast cancer, LLT: Breast cancer - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	18 Aug 2020 07:56:17
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	18 Aug 2020 07:56:17
Data point term sent to Coder	System	17 Aug 2020 23:46:33
User entered 'Breast Cancer Stage 0'	Steven Anderson (b) (4) (b) (4)	17 Aug 2020 23:46:23

US3412184

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:30:24

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	13 Mar 2021 17:40:22
User closed query 'Per sponsor review, SAE involved medical care. Please update field accordingly.' (Site from DM).	(b) (4)	01 Feb 2021 17:57:08
Query 'Per sponsor review, SAE involved medical care. Please update field accordingly.' answered with 'this has been updated as it was a medically attended event' (Site from DM).	Steven Anderson (b) (4) (b) (4)	28 Jan 2021 15:54:48
DataPoint Un-verified.	Steven Anderson (b) (4) (b) (4)	28 Jan 2021 15:54:02
User entered 'Yes (Y)' reason for change: Data Entry Error	Steven Anderson (b) (4) (b) (4)	28 Jan 2021 15:54:02
User opened query 'Per sponsor review, SAE involved medical care. Please update field accordingly.' (Site from DM).	(b) (4), (b) (6)	30 Dec 2020 15:00:32
DataPoint Verified.	(b) (4)	05 Nov 2020 14:46:58
User entered 'No (N)'	Steven Anderson (b) (4) (b) (4)	17 Aug 2020 23:46:23

US3412184

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:30:24

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 14:47:00
User entered 'No (N)'	Steven Anderson (b) (4)	17 Aug 2020 23:46:23

US3412184

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:30:24

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 14:47:01
Query 'Per CDM, a response Yes/No is required for this field. Please update accordingly' canceled (Site from DM).		18 Sep 2020 14:54:17
User entered 'No (N)'	Steven Anderson (b) (4)	10 Sep 2020 16:32:36
User opened query 'Per CDM, a response Yes/No is required for this field. Please update accordingly' (Site from DM).	(b) (4) (b) (4), (b) (6)	10 Sep 2020 11:40:21
Amendment Manager inserted this DataPoint.	System	21 Aug 2020 03:13:19

US3412184

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:30:24

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 14:47:06
Query 'Adverse Event Start Date is before treatment date at Visit 2. Please review and reconcile. (per protocol any adverse event prior to first dose should be recorded as Medical History).' canceled (Site from System).		11 Sep 2020 17:25:46
User opened query 'Adverse Event Start Date is before treatment date at Visit 2. Please review and reconcile. (per protocol any adverse event prior to first dose should be recorded as Medical History).' (Site from System).	System	08 Sep 2020 13:55:06
User entered '12 Aug 2020'	Steven Anderson (b) (4) (b) (4)	17 Aug 2020 23:46:23

US3412184

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:30:24

[Start time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 14:47:08
User entered empty.	Steven Anderson (b) (4)	17 Aug 2020 23:46:23

US3412184

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:30:24

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	17 Aug 2020 23:46:23

US3412184

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:30:24

[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 14:47:10
User entered 'Yes (Y)'	Steven Anderson (b) (4)	17 Aug 2020 23:46:23

US3412184

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:30:24

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
User opened query 'PV Query: Please provide the event end date, when available. Please leave query open until end date is available. ' (Site from Safety).	(b) (4), (b) (6)	12 Apr 2021 16:34:52
Query 'PV Query: Please provide the event end date, when available. Please leave query open until end date is available. (Issued 21Sep2020- (b) (6))' canceled (Site from Safety).		12 Apr 2021 16:34:43
User opened query 'PV Query: Please provide the event end date, when available. Please leave query open until end date is available. (Issued 21Sep2020- (b) (6))' (Site from Safety).		12 Apr 2021 16:34:40
User closed query 'PV Query: Please provide the event end date, when available. Please leave query open until end date is available. ' (Site from Safety).		12 Apr 2021 16:34:31
Query 'PV Query: Please provide the event end date, when available. Please leave query open until end date is available. ' answered with 'please clarify which page as exposure ecrf on ol-d1 and ol-d29 have already been completed' (Site from Safety).	Andrea Newlands (b) (4) (b) (4)	09 Apr 2021 12:29:21
User opened query 'PV Query: Please provide the event end date, when available. Please leave query open until end date is available. ' (Site from Safety).	(b) (4), (b) (6)	20 Nov 2020 22:57:46
User closed query 'PV Query: Please provide the event end date, when available. Please leave query open until end date is available. ' (Site from Safety).		11 Nov 2020 15:33:07
DataPoint Verified.		10 Nov 2020 22:01:36
Query 'PV Query: Please provide the event end date, when available. Please leave query open until end date is available. ' answered with 'Site is not going to be leaving these queries open until end date is available. We are being flagged for having all these queries. Most of these may not even have end dates by study closure. ' (Site from Safety).	Steven Anderson (b) (4) (b) (4)	10 Nov 2020 20:24:23
User opened query 'PV Query: Please provide the event end date, when available. Please leave query open until end date is available. ' (Site from Safety).	(b) (4), (b) (6)	21 Sep 2020 11:49:55
User closed query 'PV Query: Please provide the event end date (recovered, returned to baseline, or, in the investigator's opinion, a new baseline has been achieved), when available.' (Site from Safety).		20 Sep 2020 20:32:51

US3412184

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:30:24

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
Query 'PV Query: Please provide the event end date (recovered, returned to baseline, or, in the investigator's opinion, a new baseline has been achieved), when available.' answered with 'SUBJECT HAS NOT RECIEVED RESULTS YET. ' (Site from Safety).	Mylene Asmar-Rios (b) (4)	18 Sep 2020 18:54:03
User opened query 'PV Query: Please provide the event end date (recovered, returned to baseline, or, in the investigator's opinion, a new baseline has been achieved), when available.' (Site from Safety).	(b) (4), (b) (6)	20 Aug 2020 12:50:39
User entered empty.	Steven Anderson (b) (4) (b) (4)	17 Aug 2020 23:46:23

US3412184

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:30:24

End time (00:00-23:59)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 14:47:19
User entered empty.	Steven Anderson (b) (4)	17 Aug 2020 23:46:23
	(b) (4)	

US3412184

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:30:24

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	17 Aug 2020 23:46:23

US3412184

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:30:24

[Severity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 14:47:21
User entered 'Grade 2/Moderate (Grade 2/Moderate)'	Steven Anderson (b) (4)	17 Aug 2020 23:46:23
	(b) (4)	

US3412184

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:30:24

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 14:47:23
User entered 'Yes (Y)'	Steven Anderson (b) (4)	17 Aug 2020 23:46:23

US3412184

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:30:24

[Death](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 14:47:28
User entered '0'	Steven Anderson (b) (4)	17 Aug 2020 23:46:23

US3412184

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:30:24

[Life threatening](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 14:47:30
User entered '0'	Steven Anderson (b) (4)	17 Aug 2020 23:46:23

US3412184

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:30:24

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 14:47:32
User entered '0'	Steven Anderson (b) (4)	17 Aug 2020 23:46:23

US3412184

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:30:24

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 14:47:34
User entered empty.	Steven Anderson (b) (4)	17 Aug 2020 23:46:23

US3412184

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:30:24

Hospital Discharge Date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 14:47:40
User entered empty.	Steven Anderson (b) (4)	17 Aug 2020 23:46:23

US3412184

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:30:24

[Admitted to ICU?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 14:47:41
User entered empty.	Steven Anderson (b) (4)	17 Aug 2020 23:46:23

US3412184

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:30:24

[Number of Days in ICU](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 14:47:46
User entered empty.	Steven Anderson (b) (4)	17 Aug 2020 23:46:23

US3412184

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:30:24

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 14:47:48
User entered '0'	Steven Anderson (b) (4)	17 Aug 2020 23:46:23

US3412184

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:30:24

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 14:47:50
User entered '0'	Steven Anderson (b) (4)	17 Aug 2020 23:46:23

US3412184

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:30:24

[Other medically important event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 14:47:52
User entered 'I'	Steven Anderson (b) (4)	17 Aug 2020 23:46:23

US3412184

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:30:24

[Relationship to investigational product](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 14:47:59
User entered 'Not Related (NOT RELATED)'	Steven Anderson (b) (4) (b) (4)	17 Aug 2020 23:46:23

US3412184

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:30:24

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 14:48:01
User entered 'Not Related (NOT RELATED)'	Steven Anderson (b) (4) (b) (4)	17 Aug 2020 23:46:23

US3412184

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:30:24

[Action taken with investigational product](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 14:48:03
User entered 'None (NONE)'	Steven Anderson (b) (4)	17 Aug 2020 23:46:23

US3412184

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:30:24

[None](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 22:02:36
User closed query 'None is checked, but Concomitant System Medication or Concomitant Procedure is also checked. Please correct.' (Site from System).		10 Nov 2020 20:29:00
User entered '0' reason for change: Data Entry Error Steven Anderson	(b) (4)	10 Nov 2020 20:29:00
User opened query 'None is checked, but Concomitant Medication or Concomitant Procedure is also checked. Please correct.' (Site from System).	(b) (4) System	10 Nov 2020 20:26:16
User entered '1'	Steven Anderson (b) (4)	17 Aug 2020 23:46:23

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[Concomitant Medication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Feb 2021 19:16:19
DataPoint Un-verified.	Steven Anderson (b) (4)	28 Jan 2021 15:54:02
User entered '1' reason for change: Data Entry Error	(b) (4)	28 Jan 2021 15:54:02
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 15:03:07
Query 'per ETRTR: When determined, please ensure to register any concomitant medication or procedure for this SAE, thanks.' canceled (Site from CRA).		06 Sep 2020 18:43:54
User opened query 'per ETRTR: When determined, please ensure to register any concomitant medication or procedure for this SAE, thanks.' (Site from CRA).		19 Aug 2020 21:29:28
User entered '0'	Steven Anderson (b) (4)	17 Aug 2020 23:46:23
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:30:24

[Concomitant Procedure](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	13 Mar 2021 17:40:40
User closed query 'If concomitant procedures are diagnostic and not therapeutic please remove check and update Con Procedures from AE to Diagnostic' (Site from CRA).	(b) (4)	11 Mar 2021 01:14:23
Query 'If concomitant procedures are diagnostic and not therapeutic please remove check and update Con Procedures from AE to Diagnostic' answered with 'updated' (Site from CRA).	Andrea Newlands (b) (4)	18 Feb 2021 13:44:27
User entered '0' reason for change: Data Entry Error	Andrea Newlands (b) (4)	18 Feb 2021 13:44:19
User opened query 'If concomitant procedures are diagnostic and not therapeutic please remove check and update Con Procedures from AE to Diagnostic' (Site from CRA).	(b) (4), (b) (6)	11 Feb 2021 19:26:19
User closed query 'Per DM CLR: RQ: Response noted, however, there is no therapeutic procedure recorded for this AE. Review response and update as appropriate. Otherwise, clarify.' (Site from DM).	(b) (4)	05 Feb 2021 11:18:28
User entered '1' reason for change: Data Entry Error	Steven Anderson (b) (4)	28 Jan 2021 16:05:37
Query 'Per DM CLR: RQ: Response noted, however, there is no therapeutic procedure recorded for this AE. Review response and update as appropriate. Otherwise, clarify.' answered with 'subject only started a con med no therapeutic procedure was completed' (Site from DM).	Steven Anderson (b) (4)	28 Jan 2021 15:55:23
DataPoint Un-verified.	Steven Anderson (b) (4)	28 Jan 2021 15:54:02
User entered '0' reason for change: Data Entry Error	Steven Anderson (b) (4)	28 Jan 2021 15:54:02
User opened query 'Per DM CLR: RQ: Response noted, however, there is no therapeutic procedure recorded for this AE. Review response and update as appropriate. Otherwise, clarify.' (Site from DM).	(b) (4), (b) (6)	13 Jan 2021 04:32:02
User closed query 'Per DM CLR: Other Action Taken = ConProc. However, the recorded procedure that match this AE were Diagnostic procedures rather than a Therapeutic procedures. Please update to record the therapeutic procedure for this AE as appropriate. Otherwise, clarify.' (Site from DM).	(b) (4)	14 Dec 2020 16:16:36

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Folder: Adverse Events

Form: Adverse Events (1)

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[Concomitant Procedure](#)

Audit	User	Time (GMT)
Query 'Per DM CLR: Other Action Taken = ConProc. However, the recorded procedure that match this AE were Diagnostic procedures rather than a Therapeutic procedures. Please update to record the therapeutic procedure for this AE as appropriate. Otherwise, clarify.' answered with 'UPDATED CON PROCEDURE TO OTHER FOR DIAGNOSTIC PROCEDURE' (Site from DM). User opened query 'Per DM CLR: Other Action Taken = ConProc. However, the recorded procedure that match this AE were Diagnostic procedures rather than a Therapeutic procedures. Please update to record the therapeutic procedure for this AE as appropriate. Otherwise, clarify.' (Site from DM). DataPoint Verified.	Melissa Fuson (b) (4) (b) (4)	11 Dec 2020 16:42:05
	(b) (4), (b) (6)	28 Nov 2020 17:56:26
		10 Nov 2020 22:02:36
User closed query 'Please consider adding MRI on 17 Sep 2020 to Concomitant Procedures page' (Site from CRA).		10 Nov 2020 22:01:46
Query 'Please consider adding MRI on 17 Sep 2020 to Concomitant Procedures page' answered with 'MRI has been added under con procedures.' (Site from CRA).	Steven Anderson (b) (4) (b) (4)	10 Nov 2020 20:28:48
User entered '1' reason for change: Data Entry Error	Steven Anderson (b) (4) (b) (4)	10 Nov 2020 20:26:16
User opened query 'Please consider adding MRI on 17 Sep 2020 to Concomitant Procedures page' (Site from CRA).	(b) (4), (b) (6)	05 Nov 2020 15:02:59
User entered '0'	Steven Anderson (b) (4) (b) (4)	17 Aug 2020 23:46:23

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[Outcome](#)

Audit	User	Time (GMT)
User opened query 'PV Query: Please provide the final event outcome, when available. If not expected to resolve, please confirm in your response. If resolution is expected, please keep query open until achieved.' (Site from Safety).	(b) (4), (b) (6)	20 Nov 2020 22:57:23
User closed query 'PV Query: Please provide the final event outcome, when available. If not expected to resolve, please confirm in your response. If resolution is expected, please keep query open until achieved.' (Site from Safety).		11 Nov 2020 15:33:22
DataPoint Verified.		10 Nov 2020 22:02:21
Query 'PV Query: Please provide the final event outcome, when available. If not expected to resolve, please confirm in your response. If resolution is expected, please keep query open until achieved.' answered with 'Site is not going to be leaving these queries open until end date is available. We are being flagged for having all these queries. Most of these may not even have end dates by study closure.' (Site from Safety).	Steven Anderson (b) (4)	10 Nov 2020 20:24:40
User opened query 'PV Query: Please provide the final event outcome, when available. If not expected to resolve, please confirm in your response. If resolution is expected, please keep query open until achieved.' (Site from Safety).	(b) (4), (b) (6)	20 Aug 2020 12:50:55
User closed query 'Data is required. Please complete.' (Site from System).	System	17 Aug 2020 23:46:59
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	17 Aug 2020 23:46:59
User entered 'Not Recovered/Not Resolved (NOT RECOVERED/NOT RESOLVED)' reason for change: Data Entry Error	Steven Anderson (b) (4)	17 Aug 2020 23:46:59
User opened query 'Data is required. Please complete.' (Site from System).	System	17 Aug 2020 23:46:23
User entered empty.	Steven Anderson (b) (4)	17 Aug 2020 23:46:23

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[If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 15:03:20
User entered empty.	Steven Anderson (b) (4) (b) (4)	17 Aug 2020 23:46:23

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Folder: Adverse Events

Form: Adverse Events (1)

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[Narrative](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	29 Apr 2021 15:37:28
User closed query 'PV Query: Please complete the exposure log with mRNA-1273 administration details ' (Site from Safety).		12 Apr 2021 16:39:54
Query 'PV Query: Please complete the exposure log with mRNA-1273 administration details ' answered with '*please clarify which page as exposure ecrf in ol-d1 and ol-d29 have already been compelted - accidentally responded to incorrect query above' (Site from Safety).	Andrea Newlands (b) (4)	09 Apr 2021 12:30:20
User opened query 'PV Query: Please complete the exposure log with mRNA-1273 administration details ' (Site from Safety).	(b) (4), (b) (6)	26 Feb 2021 14:17:51
User closed query 'Per DM CLR: SAE Narrative = SUBJECT IS TAKING PART IN ANOTHER PHARMACEUTICAL TRIAL FOR ARIMIDEX FOR BREAST CANCER . However, this is not recorded in the ConMed eCRF. Please review and ensure that this is captured in the appropriate eCRF. ' (Site from DM).		19 Feb 2021 04:30:39
User closed query 'PV Query: Please provide mRNA-1273 administration details once available.' (Site from Safety).		18 Feb 2021 22:17:07
User closed query 'PV Query: Please provide treatment given for the event including medical intervention and/or surgical treatments. Please add any treatment medications to the concomitant medication eCRF (including dates of administration, dose, units, frequency, route and indication). If no treatment was provided, please state so.' (Site from Safety).		18 Feb 2021 22:16:39
Query 'PV Query: Please provide treatment given for the event including medical intervention and/or surgical treatments. Please add any treatment medications to the concomitant medication eCRF (including dates of administration, dose, units, frequency, route and indication). If no treatment was provided, please state so.' answered with 'narrative already includes armidex conmed, subject has no other interventions' (Site from Safety).	Andrea Newlands (b) (4)	18 Feb 2021 13:46:04

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Folder: Adverse Events

Form: Adverse Events (1)

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[Narrative](#)

Audit	User	Time (GMT)
Query 'Per DM CLR: SAE Narrative = SUBJECT IS TAKING PART IN ANOTHER PHARMACEUTICAL TRIAL FOR ARIMIDEX FOR BREAST CANCER . However, this is not recorded in the ConMed eCRF. Please review and ensure that this is captured in the appropriate eCRF. ' answered with 'anastrozole already recorded in conmed ecrf' (Site from DM).	Andrea Newlands (b) (4)	18 Feb 2021 13:45:06
Query 'PV Query: Please provide mRNA-1273 administration details once available.' answered with 'updated' (Site from Safety).	Andrea Newlands (b) (4)	18 Feb 2021 13:29:26

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Folder: Adverse Events

Form: Adverse Events (1)

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[Narrative](#)

Audit	User	Time (GMT)
User entered 'SUBJECT CONTACTED FOR TELEPHONE VISIT @ 17:30. SHE NOTES SHE HAD A MAMMOGRAM AND BIOPSY LAST WEEK OF HER RIGHT BREAST ON 12-AUG-2020. SHE WAS INFORMED THAT THEY FOUND STAGE 0 BREAST CANCER (NO INVOLVEMENT OF LYMPH NODES). BONE MINERAL DENSITY SCAN IS IN THE NORMAL RANGE MRI BREAST BILATERAL W WO BREAS-ICD-10-CM. D05.11-INTRADUCTAL CARCINOMA IN SITU OF RIGHT BREAST-ICD-10-CM THE CLIP PLACED AT TIME OF BIOPSY IS PRESENT IN THE POSTERIOR RETROAREOLAR/6:00 PART OF THE RIGHT BREAST. WITH THE PATIENT PRONE, THIS IS 9.5 CM POSTERIOR TO THE NIPPLE. THERE IS A MINIMAL ILL-DEFINES 5MM SIZE AREA OF ENHANCEMENT AT THE LEVEL OF THE CLIP. NO EVIDENCE OF MULTICENTRIC OR MULTIFOCAL ABNORMALITY. NO SUSPICIOUS ENHANCEMENT PRESENT ELSEWHERE IN EITHER BREAST. NO EVIDENCE OF AXILLARY OR INTERNAL MAMMARY CHAIN ADENOPATHY. KNOWN BIOPSY PROVEN MALIGNANCY. NO EVIDENCE OF MULTICENTRIC OR MULTIFOCAL ABNORMALITY. MINIMAL POSTBIOPSY CHANGES ON THE RIGHT ARE PRESENT SUBJECT IS TAKING PART IN ANOTHER PHARMACEUTICAL TRIAL FOR ARIMIDEX FOR BREAST CANCER. THIS WAS APPROVED BY THE MEDICAL MONITOR THAT SUBJECT CAN CONTINUE WITH FOLLOW UP AND SITE WILL DOCUMENT THE PROTOCOL DEVIATION. Subject was unblinded on 05Jan2021 and was found to have received the placebo. Subject received 1st dose of mRNA-1273 on 13Jan2021 and the 2nd dose on 02Feb2021.' reason for change: Data Entry Error	Andrea Newlands (b) (4)	(b) (4) 18 Feb 2021 13:29:19

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[Narrative](#)

Audit	User	Time (GMT)
User opened query 'PV Query: Please provide mRNA-1273 administration details once available.' (Site from Safety).	(b) (4), (b) (6)	03 Feb 2021 15:22:35
User opened query 'Per DM CLR: SAE Narrative = SUBJECT IS TAKING PART IN ANOTHER PHARMACEUTICAL TRIAL FOR ARIMIDEX FOR BREAST CANCER . However, this is not recorded in the ConMed eCRF. Please review and ensure that this is captured in the appropriate eCRF. ' (Site from DM).		10 Dec 2020 05:19:24
DataPoint Un-verified.	Steven Anderson (b) (4) (b) (4)	24 Nov 2020 21:52:07

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Folder: Adverse Events

Form: Adverse Events (1)

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[Narrative](#)

Audit	User	Time (GMT)
User entered 'SUBJECT CONTACTED FOR TELEPHONE VISIT @ 17:30. SHE NOTES SHE HAD A MAMOGRAM AND BIOPSY LAST WEEK OF HER RIGHT BREAST ON 12-AUG-2020. SHE WAS INFORMED THAT THEY FOUND STAGE 0 BREAST CANCER (NO INVOLVEMENT OF LYMPH NODES). BONE MINERAL DENSITY SCAN IS IN THE NORMAL RANGE MRI BREAST BILATERAL W WO BREAS-ICD-10-CM. D05.11-INTRADUCTAL CARCINOMA IN SITU OF RIGHT BREAST-ICD-10-CM THE CLIP PLACED AT TIME OF BIOPSY IS PRESENT IN THE POSTERIOR RETROAREOLAR/6:00 PART OF THE RIGHT BREAST. WITH THE PATIENT PRONE, THIS IS 9.5 CM POSTERIOR TO THE NIPPLE. THERE IS A MINIMAL ILL-DEFINES 5MM SIZE AREA OF ENHANCEMENT AT THE LEVEL OF THE CLIP. NO EVIDENCE OF MULTICENTRIC OR MULTIFOCAL ABNORMALITY. NO SUSPICIOUS ENHANCEMENT PRESENT ELSEWHERE IN EITHER BREAST. NO EVIDENCE OF AXILLARY OR INTERNAL MAMMARY CHAIN ADENOPATHY. KNOWN BIOPSY PROVEN MALIGNANCY. NO EVIDENCE OF MULTICENTRIC OR MULTIFOCAL ABNORMALITY. MINIMAL POSTBIOPSY CHANGES ON THE RIGHT ARE PRESENT Subject is taking part in another pharmaceutical trial for arimidex for breast cancer. This was approved by the medical monitor that subject can continue with follow up and site will document the protocol deviation.' reason for change: Data Entry Error	Steven Anderson (b) (4)	24 Nov 2020 21:52:07

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Folder: Adverse Events

Form: Adverse Events (1)

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[Narrative](#)

Audit	User	Time (GMT)
User opened query 'PV Query: Please provide treatment given for the event including medical intervention and/or surgical treatments. Please add any treatment medications to the concomitant medication eCRF (including dates of administration, dose, units, frequency, route and indication). If no treatment was provided, please state so.' (Site from Safety).	(b) (4), (b) (6)	20 Nov 2020 22:57:30
User closed query 'PV Query: Please consider removing medical history of right breast ductal carcinoma in situ (ER positive) as it has been reported as a SAE.' (Site from Safety).		11 Nov 2020 15:33:18
User closed query 'PV Query: Please provide treatment given for the event including medical intervention and/or surgical treatments. Please add any treatment medications to the concomitant medication eCRF (including dates of administration, dose, units, frequency, route and indication). If no treatment was provided, please state so.' (Site from Safety).		11 Nov 2020 15:33:14
DataPoint Verified.		10 Nov 2020 22:02:36
User closed query 'please update narrative with MRI on 17 Sep 2020 and action/plan for treatment' (Site from CRA).		10 Nov 2020 22:02:11
Query 'please update narrative with MRI on 17 Sep 2020 and action/plan for treatment' answered with 'there has been no treatment plan as of yet. site is trying to follow up with patient to review plan of action.' (Site from CRA).	Steven Anderson (b) (4)	10 Nov 2020 20:28:12
Query 'PV Query: Please provide treatment given for the event including medical intervention and/or surgical treatments. Please add any treatment medications to the concomitant medication eCRF (including dates of administration, dose, units, frequency, route and indication). If no treatment was provided, please state so.' answered with 'there has been no treatment plan as of yet. site is trying to follow up with patient to review plan of action.' (Site from Safety).	Steven Anderson (b) (4)	10 Nov 2020 20:28:08

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[Narrative](#)

Audit	User	Time (GMT)
Query 'PV Query: Please consider removing medical history of right breast ductal carcinoma in situ (ER positive) as it has been reported as a SAE.' answered with 'medical history form has been updated.' (Site from Safety).	Steven Anderson (b) (4)	10 Nov 2020 20:26:59
User opened query 'please update narrative with MRI on 17 Sep 2020 and action/plan for treatment' (Site from CRA).	(b) (4), (b) (6)	05 Nov 2020 15:04:06
User closed query 'Please update narrative' (Site from CRA).		05 Nov 2020 15:04:06
User opened query 'PV Query: Please provide treatment given for the event including medical intervention and/or surgical treatments. Please add any treatment medications to the concomitant medication eCRF (including dates of administration, dose, units, frequency, route and indication). If no treatment was provided, please state so.' (Site from Safety).		28 Oct 2020 14:00:28
User opened query 'PV Query: Please consider removing medical history of right breast ductal carcinoma in situ (ER positive) as it has been reported as a SAE.' (Site from Safety).		28 Oct 2020 13:58:57
Query 'PV Query: Please provide treatment given for the event including medical intervention and/or surgical treatments. Please add any treatment medications to the concomitant medication eCRF (including dates of administration, dose, units, frequency, route and indication). If no treatment was provided, please state so.' canceled (Site from Safety).		28 Oct 2020 13:58:45
User opened query 'PV Query: Please provide treatment given for the event including medical intervention and/or surgical treatments. Please add any treatment medications to the concomitant medication eCRF (including dates of administration, dose, units, frequency, route and indication). If no treatment was provided, please state so.' (Site from Safety).		28 Oct 2020 13:58:23

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[Narrative](#)

Audit	User	Time (GMT)
User closed query 'PV Query: Please add concomitant medication received within 30 days prior to event (or >30 days if relevant to event) to concomitant medication eCRF (including dates of administration, dose, units, frequency, route and indication). If none, please state so.' (Site from Safety).	(b) (4), (b) (6)	22 Oct 2020 14:40:46
User closed query 'PV Query: Please provide records from oncology consultation appointment, when available, with patient identifiers redacted and subject ID added to Safety_Moderna@iqvia.com or fax to 866.599.1342. Please leave query unanswered until records sent or, if unable to obtain, please state so.' (Site from Safety).		22 Oct 2020 14:40:34
User closed query 'PV Query: Please provide treatment given for the event including medical intervention and/or surgical treatments. Please add any treatment medications to the concomitant medication eCRF (including dates of administration, dose, units, frequency, route and indication). If no treatment was provided, please state so.' (Site from Safety).		22 Oct 2020 14:40:20
User closed query 'PV Query: Please provide any relevant laboratory and diagnostic test results (including MRI). Please include units and reference ranges if applicable.' (Site from Safety).		22 Oct 2020 14:40:14
Query 'PV Query: Please provide any relevant laboratory and diagnostic test results (including MRI). Please include units and reference ranges if applicable.' answered with 'all results were input from procedures in site narrative along with con procedures updated as well' (Site from Safety).	Steven Anderson (b) (4)	21 Oct 2020 19:41:42
Query 'PV Query: Please add concomitant medication received within 30 days prior to event (or >30 days if relevant to event) to concomitant medication eCRF (including dates of administration, dose, units, frequency, route and indication). If none, please state so.' answered with 'Subject has not started any new medications. site will follow up with subject at the next phone call to see if status has changed.' (Site from Safety).	Steven Anderson (b) (4)	21 Oct 2020 19:29:25

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[Narrative](#)

Audit	User	Time (GMT)
Query 'PV Query: Please provide records from oncology consultation appointment, when available, with patient identifiers redacted and subject ID added to Safety_Moderna@iqvia.com or fax to 866.599.1342. Please leave query unanswered until records sent or, if unable to obtain, please state so.' answered with 'records are being sent to fax number provided' (Site from Safety).	Steven Anderson (b) (4)	21 Oct 2020 14:44:33
Query 'PV Query: Please provide treatment given for the event including medical intervention and/or surgical treatments. Please add any treatment medications to the concomitant medication eCRF (including dates of administration, dose, units, frequency, route and indication). If no treatment was provided, please state so.' answered with 'no treatment has been provided as of yet.' (Site from Safety).	Steven Anderson (b) (4)	21 Oct 2020 13:37:56
Query 'Please update narrative' answered with 'narrative has been updated with results from any procedure subject obtained.' (Site from CRA).	Steven Anderson (b) (4)	21 Oct 2020 13:37:18

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[Narrative](#)

Audit	User	Time (GMT)
User entered 'SUBJECT CONTACTED FOR TELEPHONE VISIT @ 17:30. SHE NOTES SHE HAD A MAMMOGRAM AND BIOPSY LAST WEEK OF HER RIGHT BREAST ON 12-AUG-2020. SHE WAS INFORMED THAT THEY FOUND STAGE 0 BREAST CANCER (NO INVOLVEMENT OF LYMPH NODES). Bone Mineral Density scan is in the normal range MRI Breast bilateral w wo breas-ICD-10-CM. D05.11- intraductal carcinoma in situ of right breast-ICD-10-CM The clip placed at time of biopsy is present in the posterior retroareolar/6:00 part of the right breast. With the patient prone, this is 9.5 cm posterior to the nipple. There is a minimal Ill-defines 5mm size area of enhancement at the level of the clip. No evidence of multicentric or multifocal abnormality. no suspicious enhancement present elsewhere in either breast. No evidence of axillary or internal mammary chain adenopathy. known biopsy proven malignancy. No evidence of multicentric or multifocal abnormality. Minimal postbiopsy changes on the right are present' reason for change: Data Entry Error	Steven Anderson (b) (4)	21 Oct 2020 13:36:47
User opened query 'PV Query: Please provide records from oncology consultation appointment, when available, with patient identifiers redacted and subject ID added to Safety_Moderna@iqvia.com or fax to 866.599.1342. Please leave query unanswered until records sent or, if unable to obtain, please state so.' (Site from Safety).	(b) (4), (b) (6)	20 Oct 2020 13:49:48
Query 'PV Query: Please provide records from oncology consultation appointment when available.' canceled (Site from Safety).		20 Oct 2020 13:49:33
User opened query 'Please update narrative' (Site from CRA).		07 Oct 2020 19:02:46
User opened query 'PV Query: Please add concomitant medication received within 30 days prior to event (or >30 days if relevant to event) to concomitant medication eCRF (including dates of administration, dose, units, frequency, route and indication). If none, please state so.' (Site from Safety).		20 Aug 2020 12:53:29

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Audit	User	Time (GMT)
User opened query 'PV Query: Please provide records from oncology consultation appointment when available.' (Site from Safety).	(b) (4), (b) (6)	20 Aug 2020 12:51:41
User opened query 'PV Query: Please provide treatment given for the event including medical intervention and/or surgical treatments. Please add any treatment medications to the concomitant medication eCRF (including dates of administration, dose, units, frequency, route and indication). If no treatment was provided, please state so.' (Site from Safety).		20 Aug 2020 12:51:34
User opened query 'PV Query: Please provide any relevant laboratory and diagnostic test results (including MRI). Please include units and reference ranges if applicable.' (Site from Safety).	(b) (4), (b) (6)	20 Aug 2020 12:51:12
User entered 'Subject COntacted for telephone visit @ 17:30. She notes she had a mamogram and biopsy last week of her right breast on 12-Aug-2020. SHe was informed that they found stage 0 breast cancer (no involvement of lymph nodes). to get an MRI next week to gather further detail on 26-Aug-2020. Subject saw an oncologist- was told radiation is a possibility. Will follow up. Records are pending.'	Steven Anderson (b) (4) (b) (4)	17 Aug 2020 23:46:23

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Form: Adverse Events (1)

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[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Amendment Manager: User entered 'I'	System	21 Aug 2020 03:13:21
Amendment Manager inserted this DataPoint.	System	21 Aug 2020 03:13:19

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Folder: Adverse Events

Form: Adverse Events (1)

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[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '1'	System	28 Jan 2021 15:54:02
Amendment Manager: User entered '0'	System	21 Aug 2020 03:13:21
Amendment Manager inserted this DataPoint.	System	21 Aug 2020 03:13:19

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Folder: Adverse Events

Form: Adverse Events (1)

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[Admitted to ICU Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Amendment Manager inserted this DataPoint.	System	21 Aug 2020 03:13:19

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Folder: Adverse Events

Form: Adverse Events (2)

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[AEID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:40:28

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Folder: Adverse Events

Form: Adverse Events (2)

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[Adverse event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:40:28
User coded data point as SOC: General disorders and administration site conditions, HLGT: Administration site reactions, HLT: Injection site reactions, PT: Injection site pain, LLT: Injection site pain - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	03 Feb 2021 15:20:25
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	03 Feb 2021 15:20:25
Data point term sent to Coder	System	03 Feb 2021 15:20:12
User entered 'INJECTION SITE PAIN (LEFT ARM)'	Melissa Fuson (b) (4) (b) (4)	03 Feb 2021 15:19:20

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:30:24

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:40:28
User entered 'Yes (Y)'	Melissa Fuson (b) (4) (b) (4)	03 Feb 2021 15:19:20

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:30:24

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:40:28
User closed query 'Per DM CLR: Note, solicited reactions are only reported as AE if it meets AE reporting criteria per protocol section 8.3.4. This AE started after Day 7 (onwards), review if this is considered as unsolicited event per protocol. If yes, update this field to No. Else, provide clarification.' (Site from DM).		19 Feb 2021 04:31:10
Query 'Per DM CLR: Note, solicited reactions are only reported as AE if it meets AE reporting criteria per protocol section 8.3.4. This AE started after Day 7 (onwards), review if this is considered as unsolicited event per protocol. If yes, update this field to No. Else, provide clarification.' answered with 'updated' (Site from DM).	Andrea Newlands (b) (4)	18 Feb 2021 13:47:45
User entered 'No (N)' reason for change: Data Entry Error	(b) (4)	18 Feb 2021 13:47:40
User opened query 'Per DM CLR: Note, solicited reactions are only reported as AE if it meets AE reporting criteria per protocol section 8.3.4. This AE started after Day 7 (onwards), review if this is considered as unsolicited event per protocol. If yes, update this field to No. Else, provide clarification.' (Site from DM).	(b) (4), (b) (6)	17 Feb 2021 15:56:27
User entered 'Yes (Y)'	Melissa Fuson (b) (4)	03 Feb 2021 15:19:20

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:30:24

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:40:28
User entered 'No (N)'	Melissa Fuson (b) (4) (b) (4)	03 Feb 2021 15:19:20

US3412184

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:30:24

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:40:28
User entered '5 Jan 2021'	Melissa Fuson (b) (4) (b) (4)	03 Feb 2021 15:19:20

US3412184

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:30:24

Start time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:40:28
User closed query 'Data is required. Please provide.' (Site from System).	System	18 Feb 2021 13:51:23
User entered '14:00' reason for change: Data Entry Error	Andrea Newlands (b) (4)	18 Feb 2021 13:51:23
Query 'Data is required. Please provide.' answered with 'time unknown' (Site from System).	Andrea Newlands (b) (4)	18 Feb 2021 13:50:52
User opened query 'Data is required. Please provide.' (Site from System).	System	18 Feb 2021 13:50:28
User closed query 'Data entered is non-conformant. Please correct.' (Site from System).	System	18 Feb 2021 13:50:28
User entered empty; reason for change Data Entry Error	Andrea Newlands (b) (4)	18 Feb 2021 13:50:28
User opened query 'Data entered is non-conformant. Please correct.' (Site from System).	System	18 Feb 2021 13:50:17
User closed query 'Data is required. Please provide.' (Site from System).	System	18 Feb 2021 13:50:17
User entered 'un:un' (non-conformant).	Andrea Newlands (b) (4)	18 Feb 2021 13:50:17
User opened query 'Data is required. Please provide.' (Site from System).	System	17 Feb 2021 23:47:55
User entered empty.	Melissa Fuson (b) (4)	03 Feb 2021 15:19:20

US3412184

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:30:24

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:40:28
User entered '5 Jan 2021 14:00'	System	18 Feb 2021 13:51:23
User entered empty.	System	18 Feb 2021 13:50:28
User entered '5 Jan 2021 UN:UN' (non-conformant).	System	18 Feb 2021 13:50:17
User entered empty.	System	03 Feb 2021 15:19:20

US3412184

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:30:24

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:40:28
User entered 'No (N)'	Melissa Fuson (b) (4) (b) (4)	03 Feb 2021 15:19:20

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:30:24

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:40:28
User entered '7 Jan 2021'	Melissa Fuson (b) (4) (b) (4)	03 Feb 2021 15:19:20

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:30:24

End time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:40:28
User closed query 'Data is required. Please provide.' (Site from System).	(b) (4)	19 Feb 2021 04:31:22
Query 'Data is required. Please provide.' answered with 'time unknown' (Site from System).	Andrea Newlands (b) (4)	18 Feb 2021 13:50:54
User opened query 'Data is required. Please provide.' (Site from System).	(b) (4)	
User entered empty.	System	17 Feb 2021 23:47:55
	Melissa Fuson (b) (4)	03 Feb 2021 15:19:20
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:30:24

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:40:28
User entered empty.	System	03 Feb 2021 15:19:20

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:30:24

[Severity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:40:28
User entered 'Grade 1/Mild (Grade 1/Mild)'	Melissa Fuson (b) (4) (b) (4)	03 Feb 2021 15:19:20

US3412184

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:30:24

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:40:28
User entered 'No (N)'	Melissa Fuson (b) (4) (b) (4)	03 Feb 2021 15:19:20

US3412184

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:30:24

[Death](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:40:28
User entered '0'	Melissa Fuson (b) (4) (b) (4)	03 Feb 2021 15:19:20

US3412184

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:30:24

[Life threatening](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:40:28
User entered '0'	Melissa Fuson (b) (4) (b) (4)	03 Feb 2021 15:19:20

US3412184

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:30:24

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:40:28
User entered '0'	Melissa Fuson (b) (4) (b) (4)	03 Feb 2021 15:19:20

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:30:24

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:40:28
User entered empty.	Melissa Fuson (b) (4) (b) (4)	03 Feb 2021 15:19:20

US3412184

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:30:24

Hospital Discharge Date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:40:28
User entered empty.	Melissa Fuson (b) (4) (b) (4)	03 Feb 2021 15:19:20

US3412184

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:30:24

[Admitted to ICU?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:40:28
User entered empty.	Melissa Fuson (b) (4) (b) (4)	03 Feb 2021 15:19:20

US3412184

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:30:24

[Number of Days in ICU](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:40:28
User entered empty.	Melissa Fuson (b) (4) (b) (4)	03 Feb 2021 15:19:20

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:30:24

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:40:28
User entered '0'	Melissa Fuson (b) (4) (b) (4)	03 Feb 2021 15:19:20

US3412184

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:30:24

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:40:28
User entered '0'	Melissa Fuson (b) (4) (b) (4)	03 Feb 2021 15:19:20

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:30:24

[Other medically important event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:40:28
User entered '0'	Melissa Fuson (b) (4) (b) (4)	03 Feb 2021 15:19:20

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:30:24

[Relationship to investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:40:28
User entered 'Related (RELATED)'	Melissa Fuson (b) (4) (b) (4)	03 Feb 2021 15:19:20

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:30:24

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:40:28
User entered 'Not Related (NOT RELATED)'	Melissa Fuson (b) (4) (b) (4)	03 Feb 2021 15:19:20

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:30:24

[Action taken with investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:40:28
User entered 'None (NONE)'	Melissa Fuson (b) (4) (b) (4)	03 Feb 2021 15:19:20

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:30:24

[None](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:40:28
User entered '1'	Melissa Fuson (b) (4) (b) (4)	03 Feb 2021 15:19:20

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:30:24

[Concomitant Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:40:28
User entered '0'	Melissa Fuson (b) (4) (b) (4)	03 Feb 2021 15:19:20

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:30:24

[Concomitant Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:40:28
User entered '0'	Melissa Fuson (b) (4) (b) (4)	03 Feb 2021 15:19:20

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:30:24

[Outcome](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:40:28
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)'	Melissa Fuson (b) (4) (b) (4)	03 Feb 2021 15:19:20

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:30:24

[If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:40:28
User entered empty.	Melissa Fuson (b) (4) (b) (4)	03 Feb 2021 15:19:20

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:30:24

[Narrative](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:40:28
User entered empty.	Melissa Fuson (b) (4) (b) (4)	03 Feb 2021 15:19:20

US3412184

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:30:24

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:40:28
User entered '0'	System	03 Feb 2021 15:19:20

US3412184

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:30:24

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:40:28
User entered 'I'	System	03 Feb 2021 15:19:20

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:30:24

[Admitted to ICU Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:40:28

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination Summary

Generated On: 09 Jun 2021 17:30:24

[Were any prior/concomitant medications and/or vaccinations taken?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 06:41:35
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:37:59
User entered 'Yes (Y)'	Mylene Asmar-Rios (b) (4)	08 Sep 2020 14:05:19

US3412184

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 17:30:24

Name of Medication

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:20:13
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 22:10:57
User coded data point as ATC: MUSCULO-SKELETAL SYSTEM, ATC: ANTIINFLAMMATORY AND ANTIRHEUMATIC PRODUCTS, ATC: ANTIINFLAMMATORY AND ANTIRHEUMATIC PRODUCTS, NON-STEROIDS, ATC: PROPIONIC ACID DERIVATIVES, PRODUCT: IBUPROFEN, PRODUCTSYNONYM: ADVIL [IBUPROFEN] - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	08 Sep 2020 14:12:51
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	08 Sep 2020 14:12:51
Data point term sent to Coder	System	08 Sep 2020 14:07:43
User entered 'ADVIL'	Mylene Asmar-Rios (b) (4)	08 Sep 2020 14:06:46

US3412184

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 17:30:24

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:20:13
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 22:10:57
User entered 'No (N)'	Mylene Asmar-Rios (b) (4)	08 Sep 2020 14:06:46

US3412184

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 17:30:24

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:20:13
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 22:10:57
User entered 'OSTEOARTHRITIS OF KNEE'	Mylene Asmar-Rios (b) (4)	08 Sep 2020 14:06:46

US3412184

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 17:30:24

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:20:13
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 22:10:57
User closed query 'Data is required. Please complete.' (Site from System).	System	15 Oct 2020 12:36:56
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	15 Oct 2020 12:36:56
User entered '200' reason for change: Data Entry Error	Melissa Fuson (b) (4) (b) (4)	15 Oct 2020 12:36:56
User opened query 'Data is required. Please complete.' (Site from System).	System	08 Sep 2020 14:06:46
User entered empty.	Mylene Asmar-Rios (b) (4)	08 Sep 2020 14:06:46

US3412184

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 17:30:24

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:20:13
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 22:10:57
User closed query 'Data is required. Please complete.' (Site from System).	System	15 Oct 2020 12:36:56
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	15 Oct 2020 12:36:56
User entered 'mg (mg)' reason for change: Data Entry Error	Melissa Fuson (b) (4) (b) (4)	15 Oct 2020 12:36:56
User opened query 'Data is required. Please complete.' (Site from System).	System	08 Sep 2020 14:06:46
User entered empty.	Mylene Asmar-Rios (b) (4)	08 Sep 2020 14:06:46

US3412184

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 17:30:24

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:20:13
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 22:10:57
User entered empty.	Mylene Asmar-Rios (b) (4)	08 Sep 2020 14:06:46

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 17:30:24

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:20:13
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 22:10:57
User entered 'as needed (PRN)'	Mylene Asmar-Rios (b) (4)	08 Sep 2020 14:06:46

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 17:30:24

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:20:13
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 22:10:57
User entered empty.	Mylene Asmar-Rios (b) (4)	08 Sep 2020 14:06:46

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 17:30:24

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:20:13
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 22:10:57
User entered 'Oral (ORAL)'	Mylene Asmar-Rios (b) (4)	08 Sep 2020 14:06:46

US3412184

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 17:30:24

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:20:13
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 22:10:57
User entered empty.	Mylene Asmar-Rios (b) (4)	08 Sep 2020 14:06:46

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 17:30:24

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:20:13
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	10 Nov 2020 22:10:57
User closed query 'Per DM CLR: Con Med start date is prior to the start date of the corresponding MH condition. Please review and reconcile Con Med and MH start dates as appropriate. ' (Site from DM).		22 Oct 2020 04:47:53
Query 'Per DM CLR: Con Med start date is prior to the start date of the corresponding MH condition. Please review and reconcile Con Med and MH start dates as appropriate. ' answered with 'verified source and updated' (Site from DM).	Melissa Fuson (b) (4) (b) (4)	15 Oct 2020 12:37:15
User entered 'UN UNK 2010' reason for change: Data Entry Error	Melissa Fuson (b) (4) (b) (4)	15 Oct 2020 12:36:56
User opened query 'Per DM CLR: Con Med start date is prior to the start date of the corresponding MH condition. Please review and reconcile Con Med and MH start dates as appropriate. ' (Site from DM).	(b) (4), (b) (6)	02 Oct 2020 07:58:06
User entered 'UN UNK 2000'	Mylene Asmar-Rios (b) (4)	08 Sep 2020 14:06:46

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 17:30:24

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:20:13
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 22:10:57
User entered '0'	Mylene Asmar-Rios (b) (4)	08 Sep 2020 14:06:46

US3412184

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 17:30:24

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:20:13
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 22:10:57
User entered 'Yes (Y)'	Mylene Asmar-Rios (b) (4)	08 Sep 2020 14:06:46

US3412184

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 17:30:24

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:20:13
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 22:10:57
User entered empty.	Mylene Asmar-Rios (b) (4)	08 Sep 2020 14:06:46

US3412184

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 17:30:24

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:20:13
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 22:10:57
User entered 'No (N)'	Mylene Asmar-Rios (b) (4)	08 Sep 2020 14:06:46

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 17:30:24

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	08 Sep 2020 14:06:46

US3412184

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 17:30:24

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	08 Sep 2020 14:06:46

US3412184

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 17:30:24

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	08 Sep 2020 14:06:46

US3412184

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 17:30:24

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:20:13
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 22:10:57
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: VITAMINS, ATC: MULTIVITAMINS, PLAIN, ATC: MULTIVITAMINS, PLAIN, PRODUCT: VITAMINS NOS, PRODUCTSYNONYM: MULTIVITAMIN [VITAMINS NOS] - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	08 Sep 2020 14:08:58
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	08 Sep 2020 14:08:58
Data point term sent to Coder	System	08 Sep 2020 14:07:46
User entered 'MULTIVITAMIN'	Mylene Asmar-Rios (b) (4)	08 Sep 2020 14:07:34

US3412184

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 17:30:24

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:20:13
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	10 Nov 2020 22:10:57
User closed query 'Per CDM: Prophylaxis is No; however, indication recorded may indicate medication was given as a prophylaxis. Please clarify.' (Site from DM).		05 Nov 2020 16:21:46
Query 'Per CDM: Prophylaxis is No; however, indication recorded may indicate medication was given as a prophylaxis. Please clarify.' answered with 'updated' (Site from DM).	Mylene Asmar-Rios (b) (4)	22 Oct 2020 21:46:25
User entered 'Yes (Y)' reason for change: Data Entry Error	Mylene Asmar-Rios (b) (4)	22 Oct 2020 21:46:16
User opened query 'Per CDM: Prophylaxis is No; however, indication recorded may indicate medication was given as a prophylaxis. Please clarify.' (Site from DM).	(b) (4), (b) (6)	22 Oct 2020 06:42:46
User entered 'No (N)'	Mylene Asmar-Rios (b) (4)	08 Sep 2020 14:07:34

US3412184

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 17:30:24

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:20:13
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 22:10:57
User entered 'GENERAL HEALTH'	Mylene Asmar-Rios (b) (4)	08 Sep 2020 14:07:34

US3412184

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 17:30:24

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:20:13
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 22:10:57
User closed query 'Data is required. Please complete.' (Site from System).	System	15 Oct 2020 12:38:29
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	15 Oct 2020 12:38:29
User entered '1' reason for change: Data Entry Error	Melissa Fuson (b) (4) (b) (4)	15 Oct 2020 12:38:29
User opened query 'Data is required. Please complete.' (Site from System).	System	08 Sep 2020 14:07:34
User entered empty.	Mylene Asmar-Rios (b) (4)	08 Sep 2020 14:07:34

US3412184

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 17:30:24

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:20:13
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 22:10:57
User closed query 'Data is required. Please complete.' (Site from System).	System	15 Oct 2020 12:38:29
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	15 Oct 2020 12:38:29
User entered 'tablet (TABLET)' reason for change: Data Entry Error	Melissa Fuson (b) (4) (b) (4)	15 Oct 2020 12:38:29
User opened query 'Data is required. Please complete.' (Site from System).	System	08 Sep 2020 14:07:34
User entered empty.	Mylene Asmar-Rios (b) (4)	08 Sep 2020 14:07:34

US3412184

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 17:30:24

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:20:13
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 22:10:57
User entered empty.	Mylene Asmar-Rios (b) (4)	08 Sep 2020 14:07:34

US3412184

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 17:30:24

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:20:13
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 22:10:57
User entered 'once daily (QD)'	Mylene Asmar-Rios (b) (4)	08 Sep 2020 14:07:34

US3412184

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 17:30:24

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:20:13
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 22:10:57
User entered empty.	Mylene Asmar-Rios (b) (4)	08 Sep 2020 14:07:34

US3412184

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 17:30:24

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:20:13
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 22:10:57
User entered 'Oral (ORAL)'	Mylene Asmar-Rios (b) (4)	08 Sep 2020 14:07:34

US3412184

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 17:30:24

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:20:13
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 22:10:57
User entered empty.	Mylene Asmar-Rios (b) (4)	08 Sep 2020 14:07:34

US3412184

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 17:30:24

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:20:13
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 22:10:57
User entered 'UN UNK 2000'	Mylene Asmar-Rios (b) (4)	08 Sep 2020 14:07:34

US3412184

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 17:30:24

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:20:13
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 22:10:57
User entered '0'	Mylene Asmar-Rios (b) (4)	08 Sep 2020 14:07:34

US3412184

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 17:30:24

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:20:13
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 22:10:57
User entered 'Yes (Y)'	Mylene Asmar-Rios (b) (4)	08 Sep 2020 14:07:34

US3412184

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 17:30:24

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:20:13
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 22:10:57
User entered empty.	Mylene Asmar-Rios (b) (4)	08 Sep 2020 14:07:34

US3412184

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 17:30:24

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:20:13
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 22:10:57
User entered 'No (N)'	Mylene Asmar-Rios (b) (4)	08 Sep 2020 14:07:34

US3412184

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 17:30:24

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	08 Sep 2020 14:07:34

US3412184

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 17:30:24

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	08 Sep 2020 14:07:34

US3412184

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 17:30:24

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	08 Sep 2020 14:07:34

US3412184

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 17:30:24

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:20:13
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 22:10:57
User coded data point as ATC: VARIOUS, ATC: GENERAL NUTRIENTS, ATC: OTHER NUTRIENTS, ATC: OTHER COMBINATIONS OF NUTRIENTS, PRODUCT: FISH OIL, PRODUCTSYNONYM: OMEGA 3 [FISH OIL] - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	08 Sep 2020 14:25:48
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	08 Sep 2020 14:25:48
Data point term sent to Coder	System	08 Sep 2020 14:08:47
User entered 'OMEGA 3 (FISH OIL)'	Mylene Asmar-Rios (b) (4)	08 Sep 2020 14:08:30

US3412184

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 17:30:24

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:20:13
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	10 Nov 2020 22:10:57
User closed query 'Per CDM: Prophylaxis is No; however, indication recorded may indicate medication was given as a prophylaxis. Please clarify.' (Site from DM).		05 Nov 2020 16:21:51
Query 'Per CDM: Prophylaxis is No; however, indication recorded may indicate medication was given as a prophylaxis. Please clarify.' answered with 'updated' (Site from DM).	Mylene Asmar-Rios (b) (4)	22 Oct 2020 21:46:48
User entered 'Yes (Y)' reason for change: Data Entry Error	Mylene Asmar-Rios (b) (4)	22 Oct 2020 21:46:40
User opened query 'Per CDM: Prophylaxis is No; however, indication recorded may indicate medication was given as a prophylaxis. Please clarify.' (Site from DM).	(b) (4), (b) (6)	22 Oct 2020 06:43:14
User entered 'No (N)'	Mylene Asmar-Rios (b) (4)	08 Sep 2020 14:08:30

US3412184

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 17:30:24

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:20:13
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 22:10:57
User entered 'GENERAL HEALTH'	Mylene Asmar-Rios (b) (4)	08 Sep 2020 14:08:30

US3412184

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 17:30:24

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:20:13
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 22:10:57
User closed query 'Data is required. Please complete.' (Site from System).	System	15 Oct 2020 12:39:11
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	15 Oct 2020 12:39:11
User entered '1000' reason for change: Data Entry Error	Melissa Fuson (b) (4) (b) (4)	15 Oct 2020 12:39:11
User opened query 'Data is required. Please complete.' (Site from System).	System	08 Sep 2020 14:08:30
User entered empty.	Mylene Asmar-Rios (b) (4)	08 Sep 2020 14:08:30

US3412184

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 17:30:24

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:20:13
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 22:10:57
User closed query 'Data is required. Please complete.' (Site from System).	System	15 Oct 2020 12:39:11
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	15 Oct 2020 12:39:11
User entered 'mg (mg)' reason for change: Data Entry Error	Melissa Fuson (b) (4) (b) (4)	15 Oct 2020 12:39:11
User opened query 'Data is required. Please complete.' (Site from System).	System	08 Sep 2020 14:08:30
User entered empty.	Mylene Asmar-Rios (b) (4)	08 Sep 2020 14:08:30

US3412184

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 17:30:24

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:20:13
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 22:10:57
User entered empty.	Mylene Asmar-Rios (b) (4)	08 Sep 2020 14:08:30

US3412184

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 17:30:24

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:20:13
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 22:10:57
User entered 'once daily (QD)'	Mylene Asmar-Rios (b) (4)	08 Sep 2020 14:08:30

US3412184

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 17:30:24

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:20:13
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 22:10:57
User entered empty.	Mylene Asmar-Rios (b) (4)	08 Sep 2020 14:08:30

US3412184

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 17:30:24

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:20:13
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 22:10:57
User entered 'Oral (ORAL)'	Mylene Asmar-Rios (b) (4)	08 Sep 2020 14:08:30

US3412184

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 17:30:24

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:20:13
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 22:10:57
User entered empty.	Mylene Asmar-Rios (b) (4)	08 Sep 2020 14:08:30

US3412184

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 17:30:24

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:20:13
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 22:10:57
User entered 'UN UNK 2000'	Mylene Asmar-Rios (b) (4)	08 Sep 2020 14:08:30

US3412184

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 17:30:24

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:20:13
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 22:10:57
User entered '0'	Mylene Asmar-Rios (b) (4)	08 Sep 2020 14:08:30

US3412184

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 17:30:24

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:20:13
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 22:10:57
User entered 'Yes (Y)'	Mylene Asmar-Rios (b) (4)	08 Sep 2020 14:08:30

US3412184

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 17:30:24

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:20:13
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 22:10:57
User entered empty.	Mylene Asmar-Rios (b) (4)	08 Sep 2020 14:08:30

US3412184

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 17:30:24

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:20:13
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 22:10:57
User entered 'No (N)'	Mylene Asmar-Rios (b) (4)	08 Sep 2020 14:08:30

US3412184

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 17:30:24

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	08 Sep 2020 14:08:30

US3412184

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 17:30:24

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	08 Sep 2020 14:08:30

US3412184

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 17:30:24

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	08 Sep 2020 14:08:30

US3412184

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 17:30:24

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:20:13
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 22:10:57
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: VITAMINS, ATC: VITAMIN A AND D, INCL. COMBINATIONS OF THE TWO, ATC: VITAMIN D AND ANALOGUES, PRODUCT: COLECALCIFEROL, PRODUCTSYNONYM: VITAMIN D3 - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	08 Sep 2020 14:10:48
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	08 Sep 2020 14:10:48
Data point term sent to Coder	System	08 Sep 2020 14:09:50
User entered 'VITAMIN D3'	Mylene Asmar-Rios (b) (4)	08 Sep 2020 14:09:06

US3412184

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 17:30:24

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:20:13
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	10 Nov 2020 22:10:57
User closed query 'Per CDM: Prophylaxis is No; however, indication recorded may indicate medication was given as a prophylaxis. Please clarify.' (Site from DM).		05 Nov 2020 16:21:57
Query 'Per CDM: Prophylaxis is No; however, indication recorded may indicate medication was given as a prophylaxis. Please clarify.' answered with 'updated' (Site from DM).	Mylene Asmar-Rios (b) (4)	22 Oct 2020 21:47:09
User entered 'Yes (Y)' reason for change: Data Entry Error	Mylene Asmar-Rios (b) (4)	22 Oct 2020 21:47:02
User opened query 'Per CDM: Prophylaxis is No; however, indication recorded may indicate medication was given as a prophylaxis. Please clarify.' (Site from DM).	(b) (4), (b) (6)	22 Oct 2020 06:43:32
User entered 'No (N)'	Mylene Asmar-Rios (b) (4)	08 Sep 2020 14:09:06

US3412184

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 17:30:24

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:20:13
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 22:10:57
User entered 'GENERAL HEALTH'	Mylene Asmar-Rios (b) (4)	08 Sep 2020 14:09:06

US3412184

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 17:30:24

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:20:13
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	10 Nov 2020 22:10:57
User closed query 'Data is required. Please complete.' (Site from System).	System	15 Oct 2020 12:39:31
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	15 Oct 2020 12:39:31
User entered '1000' reason for change: Data Entry Error	Melissa Fuson (b) (4)	15 Oct 2020 12:39:31
	(b) (4)	
User opened query 'Data is required. Please complete.' (Site from System).	System	08 Sep 2020 14:09:06
User entered empty.	Mylene Asmar-Rios	08 Sep 2020 14:09:06
	(b) (4)	

US3412184

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 17:30:24

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:20:13
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 22:10:57
User closed query 'Data is required. Please complete.' (Site from System).	System	15 Oct 2020 12:39:31
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	15 Oct 2020 12:39:31
User entered 'IU (IU)' reason for change: Data Entry Error	Melissa Fuson (b) (4) (b) (4)	15 Oct 2020 12:39:31
User opened query 'Data is required. Please complete.' (Site from System).	System	08 Sep 2020 14:09:06
User entered empty.	Mylene Asmar-Rios (b) (4)	08 Sep 2020 14:09:06

US3412184

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 17:30:24

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:20:13
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 22:10:57
User entered empty.	Mylene Asmar-Rios (b) (4)	08 Sep 2020 14:09:06

US3412184

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 17:30:24

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:20:13
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 22:10:57
User entered 'once daily (QD)'	Mylene Asmar-Rios (b) (4)	08 Sep 2020 14:09:06

US3412184

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 17:30:24

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:20:13
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 22:10:57
User entered empty.	Mylene Asmar-Rios (b) (4)	08 Sep 2020 14:09:06

US3412184

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 17:30:24

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:20:13
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 22:10:57
User entered 'Oral (ORAL)'	Mylene Asmar-Rios (b) (4)	08 Sep 2020 14:09:06

US3412184

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 17:30:24

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:20:13
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 22:10:57
User entered empty.	Mylene Asmar-Rios (b) (4)	08 Sep 2020 14:09:06

US3412184

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 17:30:24

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:20:13
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 22:10:57
User entered 'UN UNK 2000'	Mylene Asmar-Rios (b) (4)	08 Sep 2020 14:09:06

US3412184

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 17:30:24

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:20:13
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 22:10:57
User entered '0'	Mylene Asmar-Rios (b) (4)	08 Sep 2020 14:09:06

US3412184

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 17:30:24

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:20:13
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 22:10:57
User entered 'Yes (Y)'	Mylene Asmar-Rios (b) (4)	08 Sep 2020 14:09:06

US3412184

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 17:30:24

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:20:13
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 22:10:57
User entered empty.	Mylene Asmar-Rios (b) (4)	08 Sep 2020 14:09:06

US3412184

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 17:30:24

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:20:13
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 22:10:57
User entered 'No (N)'	Mylene Asmar-Rios (b) (4)	08 Sep 2020 14:09:06

US3412184

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 17:30:24

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	08 Sep 2020 14:09:06

US3412184

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 17:30:24

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	08 Sep 2020 14:09:06

US3412184

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 17:30:24

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	08 Sep 2020 14:09:06

US3412184

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 17:30:24

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:20:13
User coded data point as ATC: ANTINEOPLASTIC AND IMMUNOMODULATING AGENTS, ATC: ENDOCRINE THERAPY, ATC: HORMONE ANTAGONISTS AND RELATED AGENTS, ATC: AROMATASE INHIBITORS, PRODUCT: ANASTROZOLE - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4)	10 Feb 2021 15:21:47
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	10 Feb 2021 15:21:47
Data point term sent to Coder	System	10 Feb 2021 15:21:26
User entered 'anastrozole'	Steven Anderson (b) (4) (b) (4)	10 Feb 2021 15:21:22

US3412184

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 17:30:24

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:20:13
	(b) (4)	
User entered 'No (N)'	Steven Anderson (b) (4)	10 Feb 2021 15:21:22
	(b) (4)	

US3412184

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 17:30:24

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:20:13
	(b) (4)	
User entered 'breast cancer'	Steven Anderson (b) (4)	10 Feb 2021 15:21:22
	(b) (4)	

US3412184

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 17:30:24

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:20:13
	(b) (4)	
User entered '1'	Steven Anderson (b) (4)	10 Feb 2021 15:21:22
	(b) (4)	

US3412184

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 17:30:24

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:20:13
	(b) (4)	
User entered 'mg (mg)'	Steven Anderson (b) (4)	10 Feb 2021 15:21:22
	(b) (4)	

US3412184

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 17:30:24

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:20:13
	(b) (4)	
User entered empty.	Steven Anderson (b) (4)	10 Feb 2021 15:21:22
	(b) (4)	

US3412184

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 17:30:24

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:20:13
	(b) (4)	
User entered 'once daily (QD)'	Steven Anderson (b) (4)	10 Feb 2021 15:21:22
	(b) (4)	

US3412184

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 17:30:24

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:20:13
	(b) (4)	
User entered empty.	Steven Anderson (b) (4)	10 Feb 2021 15:21:22
	(b) (4)	

US3412184

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 17:30:24

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:20:13
	(b) (4)	
User entered 'Oral (ORAL)'	Steven Anderson (b) (4)	10 Feb 2021 15:21:22
	(b) (4)	

US3412184

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 17:30:24

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:20:13
	(b) (4)	
User entered empty.	Steven Anderson (b) (4)	10 Feb 2021 15:21:22
	(b) (4)	

US3412184

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 17:30:24

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:20:13
	(b) (4)	
User entered '03 Nov 2020'	Steven Anderson (b) (4)	10 Feb 2021 15:21:22
	(b) (4)	

US3412184

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 17:30:24

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:20:13
	(b) (4)	
User entered '0'	Steven Anderson (b) (4)	10 Feb 2021 15:21:22
	(b) (4)	

US3412184

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 17:30:24

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:20:13
	(b) (4)	
User entered 'Yes (Y)'	Steven Anderson (b) (4)	10 Feb 2021 15:21:22
	(b) (4)	

US3412184

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 17:30:24

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:20:13
	(b) (4)	
User entered empty.	Steven Anderson (b) (4)	10 Feb 2021 15:21:22
	(b) (4)	

US3412184

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 17:30:24

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:20:13
	(b) (4)	
User entered 'No (N)'	Steven Anderson (b) (4)	10 Feb 2021 15:21:22
	(b) (4)	

US3412184

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 17:30:24

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	10 Feb 2021 15:21:22

US3412184

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 17:30:24

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	10 Feb 2021 15:21:22

US3412184

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 17:30:24

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	10 Feb 2021 15:21:22

US3412184

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 17:30:24

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:20:13
User coded data point as ATC: MUSCULO-SKELETAL SYSTEM, ATC: ANTIINFLAMMATORY AND ANTIRHEUMATIC PRODUCTS, ATC: ANTIINFLAMMATORY AND ANTIRHEUMATIC PRODUCTS, NON-STEROIDS, ATC: PROPIONIC ACID DERIVATIVES, PRODUCT: IBUPROFEN - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4) (b) (4)	10 Feb 2021 15:22:47
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	10 Feb 2021 15:22:47
Data point term sent to Coder	System	10 Feb 2021 15:22:27
User entered 'ibuprofen'	Steven Anderson (b) (4) (b) (4)	10 Feb 2021 15:21:59

US3412184

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 17:30:24

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:20:13
	(b) (4)	
User entered 'No (N)'	Steven Anderson (b) (4)	10 Feb 2021 15:21:59
	(b) (4)	

US3412184

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 17:30:24

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:20:13
	(b) (4)	
User entered 'OA'	Steven Anderson (b) (4)	10 Feb 2021 15:21:59
	(b) (4)	

US3412184

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 17:30:24

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:20:13
	(b) (4)	
User entered '400'	Steven Anderson (b) (4)	10 Feb 2021 15:21:59
	(b) (4)	

US3412184

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 17:30:24

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:20:13
	(b) (4)	
User entered 'mg (mg)'	Steven Anderson (b) (4)	10 Feb 2021 15:21:59
	(b) (4)	

US3412184

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 17:30:24

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:20:13
	(b) (4)	
User entered empty.	Steven Anderson (b) (4)	10 Feb 2021 15:21:59
	(b) (4)	

US3412184

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 17:30:24

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:20:13
	(b) (4)	
User entered 'once daily (QD)'	Steven Anderson (b) (4)	10 Feb 2021 15:21:59
	(b) (4)	

US3412184

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 17:30:24

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:20:13
	(b) (4)	
User entered empty.	Steven Anderson (b) (4)	10 Feb 2021 15:21:59
	(b) (4)	

US3412184

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 17:30:24

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:20:13
	(b) (4)	
User entered 'Oral (ORAL)'	Steven Anderson (b) (4)	10 Feb 2021 15:21:59
	(b) (4)	

US3412184

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 17:30:24

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:20:13
	(b) (4)	
User entered empty.	Steven Anderson (b) (4)	10 Feb 2021 15:21:59
	(b) (4)	

US3412184

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 17:30:24

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:20:13
	(b) (4)	
User entered 'un UNK 2020'	Steven Anderson (b) (4)	10 Feb 2021 15:21:59
	(b) (4)	

US3412184

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 17:30:24

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:20:13
	(b) (4)	
User entered '0'	Steven Anderson (b) (4)	10 Feb 2021 15:21:59
	(b) (4)	

US3412184

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 17:30:24

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:20:13
	(b) (4)	
User entered 'Yes (Y)'	Steven Anderson (b) (4)	10 Feb 2021 15:21:59
	(b) (4)	

US3412184

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 17:30:24

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:20:13
	(b) (4)	
User entered empty.	Steven Anderson (b) (4)	10 Feb 2021 15:21:59
	(b) (4)	

US3412184

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 17:30:24

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:20:13
	(b) (4)	
User entered 'No (N)'	Steven Anderson (b) (4)	10 Feb 2021 15:21:59
	(b) (4)	

US3412184

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 17:30:24

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	10 Feb 2021 15:21:59

US3412184

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 17:30:24

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	10 Feb 2021 15:21:59

US3412184

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 17:30:24

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	10 Feb 2021 15:21:59

US3412184

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures Summary

Generated On: 09 Jun 2021 17:30:24

[Were any concomitant procedures performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 06:41:35
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:37:59
User entered 'Yes (Y)' reason for change: Data Entry Error	Steven Anderson (b) (4)	21 Oct 2020 19:29:36
User entered 'No (N)' reason for change: Data Entry Error	Mylene Asmar-Rios (b) (4)	08 Sep 2020 14:09:22
User entered 'Yes (Y)'	Mylene Asmar-Rios (b) (4)	08 Sep 2020 14:09:16

US3412184

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (2)

Generated On: 09 Jun 2021 17:30:24

Procedure/Surgery date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:31:16
	(b) (4)	
Signature has been broken.	Andrea Newlands (b) (4)	13 Apr 2021 15:21:07
	(b) (4)	
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:37:59
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 22:03:02
User entered '12 Aug 2020'	Steven Anderson (b) (4)	21 Oct 2020 19:35:04
	(b) (4)	

US3412184

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (2)

Generated On: 09 Jun 2021 17:30:24

[Procedure/Surgery](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:37:59
User closed query 'please confirm this was therapeutic procedure. If not please update to diagnostic and confirm ConProc not checked on AE form unless therapeutic procedure done' (Site from CRA).	(b) (4) (b) (4), (b) (6)	11 Mar 2021 01:15:05
Query 'please confirm this was therapeutic procedure. If not please update to diagnostic and confirm ConProc not checked on AE form unless therapeutic procedure done' answered with 'updated' (Site from CRA).	Andrea Newlands (b) (4) (b) (4)	18 Feb 2021 13:46:33
User opened query 'please confirm this was therapeutic procedure. If not please update to diagnostic and confirm ConProc not checked on AE form unless therapeutic procedure done' (Site from CRA).	(b) (4), (b) (6)	11 Feb 2021 19:47:02
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 22:03:02
User entered 'Mam sterotactic loc breast biopsy right'	Steven Anderson (b) (4) (b) (4)	21 Oct 2020 19:35:04

US3412184

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (2)

Generated On: 09 Jun 2021 17:30:24

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:37:59
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	11 Mar 2021 01:15:09
DataPoint Un-verified.		
	Andrea Newlands (b) (4)	18 Feb 2021 13:46:29
	(b) (4)	
User entered 'Diagnostic (DIAGNOSTIC)' reason	Andrea Newlands (b) (4)	18 Feb 2021 13:46:29
for change: Data Entry Error	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 22:03:02
User entered 'Adverse Event (AE)'	Steven Anderson (b) (4)	21 Oct 2020 19:35:04
	(b) (4)	

US3412184

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (2)

Generated On: 09 Jun 2021 17:30:24

If indication is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4) (b) (4)	16 Apr 2021 13:31:16
Signature has been broken.	Andrea Newlands (b) (4) (b) (4)	13 Apr 2021 15:21:11
User signature succeeded.	Richard Powell (b) (4) (b) (4)	12 Apr 2021 14:37:59
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 22:03:02
User entered empty.	Steven Anderson (b) (4) (b) (4)	21 Oct 2020 19:35:04

US3412184

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (3)

Generated On: 09 Jun 2021 17:30:24

Procedure/Surgery date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:35:27
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:37:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 22:03:02
User entered '16 Sep 2020'	Steven Anderson (b) (4) (b) (4)	21 Oct 2020 19:38:30

US3412184

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (3)

Generated On: 09 Jun 2021 17:30:24

[Procedure/Surgery](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:35:27
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:37:59
User closed query 'please confirm this was therapeutic procedure. If not please update to diagnostic and confirm ConProc not checked on AE form unless therapeutic procedure done' (Site from CRA).	(b) (4) (b) (4), (b) (6)	11 Mar 2021 01:15:55
Query 'please confirm this was therapeutic procedure. If not please update to diagnostic and confirm ConProc not checked on AE form unless therapeutic procedure done' answered with 'updated' (Site from CRA).	Andrea Newlands (b) (4) (b) (4)	18 Feb 2021 13:46:44
User opened query 'please confirm this was therapeutic procedure. If not please update to diagnostic and confirm ConProc not checked on AE form unless therapeutic procedure done' (Site from CRA).	(b) (4), (b) (6)	11 Feb 2021 19:47:21
DataPoint Verified.		10 Nov 2020 22:03:02
User entered 'DX Bone density Axial Skeleton'	Steven Anderson (b) (4) (b) (4)	21 Oct 2020 19:38:30

US3412184

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (3)

Generated On: 09 Jun 2021 17:30:24

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:35:27
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:37:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Mar 2021 01:16:00
DataPoint Un-verified.	Andrea Newlands (b) (4)	18 Feb 2021 13:46:41
User entered 'Diagnostic (DIAGNOSTIC)' reason for change: Data Entry Error	(b) (4) Andrea Newlands (b) (4)	18 Feb 2021 13:46:41
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 22:03:02
User entered 'Adverse Event (AE)'	Steven Anderson (b) (4)	21 Oct 2020 19:38:30

US3412184

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (3)

Generated On: 09 Jun 2021 17:30:24

If indication is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:35:27
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:37:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 22:03:02
User entered empty.	Steven Anderson (b) (4) (b) (4)	21 Oct 2020 19:38:30

US3412184

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (4)

Generated On: 09 Jun 2021 17:30:24

Procedure/Surgery date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:35:30
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:37:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 22:03:02
User entered '17 Sep 2020'	Steven Anderson (b) (4) (b) (4)	21 Oct 2020 19:39:28

US3412184

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (4)

Generated On: 09 Jun 2021 17:30:24

[Procedure/Surgery](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:35:30
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:37:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 22:03:02
User entered 'MRI Breast bilateral w wo contrast w CAD'	Steven Anderson (b) (4) (b) (4)	21 Oct 2020 19:39:28

US3412184

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (4)

Generated On: 09 Jun 2021 17:30:24

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:35:30
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:37:59
User closed query 'Per CDM: 'Indication' is 'Other' and if 'Indication' is Other, specify' is entered as 'Diagnostic procedure'. Please review predefined options available for 'Indication' and confirm or update as appropriate.' (Site from DM).	(b) (4) (b) (4), (b) (6)	07 Jan 2021 13:53:26
User closed query 'Indication is not Other, however specify has been provided. Please correct.' (Site from System).	System	06 Jan 2021 20:17:05
Query 'Per CDM: 'Indication' is 'Other' and if 'Indication' is Other, specify' is entered as 'Diagnostic procedure'. Please review predefined options available for 'Indication' and confirm or update as appropriate.' answered with 'updated to diagnostic' (Site from DM).	Melissa Fuson (b) (4) (b) (4)	06 Jan 2021 20:16:48
User opened query 'Indication is not Other, however specify has been provided. Please correct.' (Site from System).	System	06 Jan 2021 20:16:28
User entered 'Diagnostic (DIAGNOSTIC)' reason for change: Data Entry Error	Melissa Fuson (b) (4) (b) (4)	06 Jan 2021 20:16:28
User opened query 'Per CDM: 'Indication' is 'Other' and if 'Indication' is Other, specify' is entered as 'Diagnostic procedure'. Please review predefined options available for 'Indication' and confirm or update as appropriate.' (Site from DM).	(b) (4), (b) (6)	18 Dec 2020 14:08:21
Un-reviewed for Data Management.		18 Dec 2020 14:05:59
Reviewed for Data Management.		18 Dec 2020 14:05:55
DataPoint Un-verified.	Melissa Fuson (b) (4) (b) (4)	11 Dec 2020 16:41:20
User entered 'Other (OTHER)' reason for change: Data Entry Error	Melissa Fuson (b) (4) (b) (4)	11 Dec 2020 16:41:20
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 22:03:02
User entered 'Adverse Event (AE)'	Steven Anderson (b) (4) (b) (4)	21 Oct 2020 19:39:28

US3412184

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (4)

Generated On: 09 Jun 2021 17:30:24

If indication is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:35:30
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:37:59
User entered empty; reason for change Data Entry Error	Melissa Fuson (b) (4)	06 Jan 2021 20:17:05
DataPoint Un-verified.	Melissa Fuson (b) (4)	11 Dec 2020 16:41:20
User entered 'DIAGNOSTIC PROCEDURES' reason for change: Data Entry Error	Melissa Fuson (b) (4)	11 Dec 2020 16:41:20
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 22:03:02
User entered empty.	Steven Anderson (b) (4)	21 Oct 2020 19:39:28

US3412184

Folder: SAE USA-US061-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 09 Jun 2021 17:30:24

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:34:07
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Nov 2020 14:46:32
Reviewed for Safety.		18 Aug 2020 13:45:43
User entered 'USA-US061-2020-MRNA-1273-P301000002'	System	18 Aug 2020 13:40:20

US3412184

Folder: SAE USA-US061-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 09 Jun 2021 17:30:24

Serious

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:34:07
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Nov 2020 14:46:32
Reviewed for Safety.		18 Aug 2020 13:45:43
User entered 'Yes (Y)'	System	18 Aug 2020 13:40:20

US3412184

Folder: SAE USA-US061-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 09 Jun 2021 17:30:24

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:34:07
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Nov 2020 14:46:32
Reviewed for Safety.		18 Aug 2020 13:45:43
User entered 'No (N)'	System	18 Aug 2020 13:40:20

US3412184

Folder: SAE USA-US061-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 09 Jun 2021 17:30:24

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:34:07
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Nov 2020 14:46:32
Reviewed for Safety.		18 Aug 2020 13:45:43
User entered 'No (N)'	System	18 Aug 2020 13:40:20

US3412184

Folder: SAE USA-US061-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 09 Jun 2021 17:30:24

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:34:07
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 14:46:32
Reviewed for Safety.		18 Aug 2020 13:45:43
User entered 'No (N)'	System	18 Aug 2020 13:40:20

US3412184

Folder: SAE USA-US061-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 09 Jun 2021 17:30:24

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:34:07
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 14:46:32
Reviewed for Safety.		18 Aug 2020 13:45:43
User entered 'No (N)'	System	18 Aug 2020 13:40:20

US3412184

Folder: SAE USA-US061-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 09 Jun 2021 17:30:24

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:34:07
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Nov 2020 14:46:32
Reviewed for Safety.		18 Aug 2020 13:45:43
User entered 'No (N)'	System	18 Aug 2020 13:40:20

US3412184

Folder: SAE USA-US061-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 09 Jun 2021 17:30:24

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:34:07
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Nov 2020 14:46:32
Reviewed for Safety.		18 Aug 2020 13:45:43
User entered 'Yes (Y)'	System	18 Aug 2020 13:40:20

US3412184

Folder: SAE USA-US061-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 09 Jun 2021 17:30:24

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:34:07
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 14:46:32
Reviewed for Safety.		22 Oct 2020 14:00:39
User entered 'Gregory'	Steven Anderson (b) (4)	18 Aug 2020 22:35:40

US3412184

Folder: SAE USA-US061-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 09 Jun 2021 17:30:24

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:34:07
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	05 Nov 2020 14:46:32
Reviewed for Safety.		22 Oct 2020 14:00:39
User entered 'Gottschlich'	Steven Anderson (b) (4)	18 Aug 2020 22:35:40
	(b) (4)	

US3412184

Folder: SAE USA-US061-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 09 Jun 2021 17:30:24

[Site Address: Street](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:34:07
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 14:46:32
Reviewed for Safety.		22 Oct 2020 14:00:39
User entered '4260 Glendale Milford Road'	Steven Anderson (b) (4)	18 Aug 2020 22:35:40

US3412184

Folder: SAE USA-US061-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 09 Jun 2021 17:30:24

[Site Address: City](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:34:07
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Nov 2020 14:46:32
Reviewed for Safety.		22 Oct 2020 14:00:39
Amendment Manager: User entered 'Cincinnati'	System	14 Sep 2020 21:47:33
User entered empty.	Steven Anderson (b) (4) (b) (4)	18 Aug 2020 22:35:40

US3412184

Folder: SAE USA-US061-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 09 Jun 2021 17:30:24

[Site Address: State](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:34:07
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 14:46:32
Reviewed for Safety.	(b) (4)	22 Oct 2020 14:00:39
User entered empty.	Steven Anderson (b) (4)	18 Aug 2020 22:35:40
	(b) (4)	

US3412184

Folder: SAE USA-US061-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 09 Jun 2021 17:30:24

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:34:07
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 14:46:32
Reviewed for Safety.		22 Oct 2020 14:00:39
User entered '45242'	Steven Anderson (b) (4)	18 Aug 2020 22:35:40

US3412184

Folder: SAE USA-US061-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 09 Jun 2021 17:30:24

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:34:07
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Nov 2020 14:46:32
Reviewed for Safety.		22 Oct 2020 14:00:39
Amendment Manager: Data point set to conformant.	System	19 Sep 2020 04:43:12
User entered 'US' (non-conformant).	System	18 Aug 2020 13:46:01

US3412184

Folder: SAE USA-US061-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 09 Jun 2021 17:30:24

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '6'	System	18 Feb 2021 22:17:31
User entered '5'	System	29 Jan 2021 16:51:49
User entered '4'	System	25 Nov 2020 12:59:02
User entered '3'	System	11 Nov 2020 15:33:50
User entered '2'	System	22 Oct 2020 14:00:54
User entered '1'	System	18 Aug 2020 13:46:01

US3412184

Folder: SAE USA-US061-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 09 Jun 2021 17:30:24

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:34:07
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Nov 2020 14:46:32
Reviewed for Safety.		18 Aug 2020 13:45:43
User entered 'USA-US061-2020-MRNA-1273-P301000002'	System	18 Aug 2020 13:40:20

US3412184

Folder: SAE USA-US061-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 09 Jun 2021 17:30:24

Serious

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:34:07
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 14:46:32
Reviewed for Safety.		18 Aug 2020 13:45:43
User entered 'Yes (Y)'	System	18 Aug 2020 13:40:20

US3412184

Folder: SAE USA-US061-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 09 Jun 2021 17:30:24

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:34:07
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Nov 2020 14:46:32
Reviewed for Safety.		18 Aug 2020 13:45:43
User entered 'No (N)'	System	18 Aug 2020 13:40:20

US3412184

Folder: SAE USA-US061-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 09 Jun 2021 17:30:24

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:34:07
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 14:46:32
Reviewed for Safety.		18 Aug 2020 13:45:43
User entered 'No (N)'	System	18 Aug 2020 13:40:20

US3412184

Folder: SAE USA-US061-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 09 Jun 2021 17:30:24

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:34:07
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Nov 2020 14:46:32
Reviewed for Safety.		18 Aug 2020 13:45:43
User entered 'No (N)'	System	18 Aug 2020 13:40:20

US3412184

Folder: SAE USA-US061-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 09 Jun 2021 17:30:24

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:34:07
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 14:46:32
Reviewed for Safety.		18 Aug 2020 13:45:43
User entered 'No (N)'	System	18 Aug 2020 13:40:20

US3412184

Folder: SAE USA-US061-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 09 Jun 2021 17:30:24

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:34:07
DataPoint Verified.	(b) (4)	05 Nov 2020 14:46:32
Reviewed for Safety.	(b) (4), (b) (6)	18 Aug 2020 13:45:43
User entered 'No (N)'	System	18 Aug 2020 13:40:20

US3412184

Folder: SAE USA-US061-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 09 Jun 2021 17:30:24

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:34:07
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Nov 2020 14:46:32
Reviewed for Safety.		18 Aug 2020 13:45:43
User entered 'Yes (Y)'	System	18 Aug 2020 13:40:20

US3412184

Folder: SAE USA-US061-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 09 Jun 2021 17:30:24

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:34:07
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	05 Nov 2020 14:46:32
Reviewed for Safety.		22 Oct 2020 14:00:39
User entered 'Gregory'	Steven Anderson (b) (4)	18 Aug 2020 22:35:40
	(b) (4)	

US3412184

Folder: SAE USA-US061-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 09 Jun 2021 17:30:24

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:34:07
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 14:46:32
Reviewed for Safety.		22 Oct 2020 14:00:39
User entered 'Gottschlich'	Steven Anderson (b) (4)	18 Aug 2020 22:35:40

US3412184

Folder: SAE USA-US061-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 09 Jun 2021 17:30:24

[Site Address: Street](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:34:07
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Nov 2020 14:46:32
Reviewed for Safety.		22 Oct 2020 14:00:39
User entered '4260 Glendale Milford Road'	Steven Anderson (b) (4) (b) (4)	18 Aug 2020 22:35:40

US3412184

Folder: SAE USA-US061-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 09 Jun 2021 17:30:24

[Site Address: City](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:34:07
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	05 Nov 2020 14:46:32
Reviewed for Safety.		22 Oct 2020 14:00:39
Amendment Manager: User entered 'Cincinnati'	System	14 Sep 2020 21:47:33
User entered empty.	Steven Anderson (b) (4)	18 Aug 2020 22:35:40
	(b) (4)	

US3412184

Folder: SAE USA-US061-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 09 Jun 2021 17:30:24

[Site Address: State](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:34:07
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 14:46:32
Reviewed for Safety.		22 Oct 2020 14:00:39
User entered empty.	Steven Anderson (b) (4)	18 Aug 2020 22:35:40

US3412184

Folder: SAE USA-US061-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 09 Jun 2021 17:30:24

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:34:07
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	05 Nov 2020 14:46:32
Reviewed for Safety.		22 Oct 2020 14:00:39
User entered '45242'	Steven Anderson (b) (4)	18 Aug 2020 22:35:40
	(b) (4)	

US3412184

Folder: SAE USA-US061-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 09 Jun 2021 17:30:24

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:34:07
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Nov 2020 14:46:32
Reviewed for Safety.		22 Oct 2020 14:00:39
Amendment Manager: Data point set to conformant.	System	19 Sep 2020 04:43:12
User entered 'US' (non-conformant).	System	18 Aug 2020 13:46:01

US3412184

Folder: SAE USA-US061-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 09 Jun 2021 17:30:24

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '6'	System	18 Feb 2021 22:17:31
User entered '5'	System	29 Jan 2021 16:51:49
User entered '4'	System	25 Nov 2020 12:59:02
User entered '3'	System	11 Nov 2020 15:33:50
User entered '2'	System	22 Oct 2020 14:00:54
User entered '1'	System	18 Aug 2020 13:46:01

US3412184

Folder: SAE USA-US061-2020-MRNA-1273-P301000002

Form: Safety Report Form (1)

Generated On: 09 Jun 2021 17:30:24

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:34:07
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Nov 2020 14:46:32
User entered '18/Aug/2020 09:46'	System	18 Aug 2020 13:46:01

US3412184

Folder: SAE USA-US061-2020-MRNA-1273-P301000002

Form: Safety Report Form (1)

Generated On: 09 Jun 2021 17:30:24

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)	16 Apr 2021 14:34:07
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 14:46:32
Reviewed for Safety.		22 Oct 2020 14:00:39
User entered '1'		18 Aug 2020 13:46:01

US3412184

Folder: SAE USA-US061-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 09 Jun 2021 17:30:24

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:34:07
DataPoint Verified.	(b) (4)	05 Nov 2020 14:46:32
Reviewed for Safety.	(b) (4), (b) (6)	18 Aug 2020 13:45:43
User entered 'USA-US061-2020-MRNA-1273-P301000002'	System	18 Aug 2020 13:40:20

US3412184

Folder: SAE USA-US061-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 09 Jun 2021 17:30:24

Serious

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:34:07
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 14:46:32
Reviewed for Safety.		18 Aug 2020 13:45:43
User entered 'Yes (Y)'	System	18 Aug 2020 13:40:20

US3412184

Folder: SAE USA-US061-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 09 Jun 2021 17:30:24

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:34:07
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Nov 2020 14:46:32
Reviewed for Safety.		18 Aug 2020 13:45:43
User entered 'No (N)'	System	18 Aug 2020 13:40:20

US3412184

Folder: SAE USA-US061-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 09 Jun 2021 17:30:24

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:34:07
DataPoint Verified.	(b) (4)	05 Nov 2020 14:46:32
Reviewed for Safety.	(b) (4), (b) (6)	18 Aug 2020 13:45:43
User entered 'No (N)'	System	18 Aug 2020 13:40:20

US3412184

Folder: SAE USA-US061-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 09 Jun 2021 17:30:24

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:34:07
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 14:46:32
Reviewed for Safety.		18 Aug 2020 13:45:43
User entered 'No (N)'	System	18 Aug 2020 13:40:20

US3412184

Folder: SAE USA-US061-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 09 Jun 2021 17:30:24

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:34:07
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 14:46:32
Reviewed for Safety.		18 Aug 2020 13:45:43
User entered 'No (N)'	System	18 Aug 2020 13:40:20

US3412184

Folder: SAE USA-US061-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 09 Jun 2021 17:30:24

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:34:07
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 14:46:32
Reviewed for Safety.		18 Aug 2020 13:45:43
User entered 'No (N)'	System	18 Aug 2020 13:40:20

US3412184

Folder: SAE USA-US061-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 09 Jun 2021 17:30:24

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:34:07
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 14:46:32
Reviewed for Safety.		18 Aug 2020 13:45:43
User entered 'Yes (Y)'	System	18 Aug 2020 13:40:20

US3412184

Folder: SAE USA-US061-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 09 Jun 2021 17:30:24

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:34:07
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 14:46:32
Reviewed for Safety.	(b) (4)	22 Oct 2020 14:00:39
User entered 'Gregory'	Steven Anderson (b) (4)	18 Aug 2020 22:35:40
	(b) (4)	

US3412184

Folder: SAE USA-US061-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 09 Jun 2021 17:30:24

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:34:07
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	05 Nov 2020 14:46:32
Reviewed for Safety.		22 Oct 2020 14:00:39
User entered 'Gottschlich'	Steven Anderson (b) (4)	18 Aug 2020 22:35:40
	(b) (4)	

US3412184

Folder: SAE USA-US061-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 09 Jun 2021 17:30:24

[Site Address: Street](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:34:07
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 14:46:32
Reviewed for Safety.		22 Oct 2020 14:00:39
User entered '4260 Glendale Milford Road'	Steven Anderson (b) (4)	18 Aug 2020 22:35:40

US3412184

Folder: SAE USA-US061-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 09 Jun 2021 17:30:24

[Site Address: City](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:34:07
DataPoint Verified.	(b) (4)	(b) (4), (b) (6) 05 Nov 2020 14:46:32
Reviewed for Safety.		22 Oct 2020 14:00:39
Amendment Manager: User entered 'Cincinnati'	System	14 Sep 2020 21:47:33
User entered empty.	Steven Anderson (b) (4)	18 Aug 2020 22:35:40
	(b) (4)	

US3412184

Folder: SAE USA-US061-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 09 Jun 2021 17:30:24

[Site Address: State](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:34:07
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Nov 2020 14:46:32
Reviewed for Safety.		22 Oct 2020 14:00:39
User entered empty.	Steven Anderson (b) (4) (b) (4)	18 Aug 2020 22:35:40

US3412184

Folder: SAE USA-US061-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 09 Jun 2021 17:30:24

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:34:07
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Nov 2020 14:46:32
Reviewed for Safety.		22 Oct 2020 14:00:39
User entered '45242'	Steven Anderson (b) (4) (b) (4)	18 Aug 2020 22:35:40

US3412184

Folder: SAE USA-US061-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 09 Jun 2021 17:30:24

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:34:07
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Nov 2020 14:46:32
Reviewed for Safety.		22 Oct 2020 14:00:39
Amendment Manager: Data point set to conformant.	System	19 Sep 2020 04:43:12
User entered 'US' (non-conformant).	System	18 Aug 2020 13:46:01

US3412184

Folder: SAE USA-US061-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 09 Jun 2021 17:30:24

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '6'	System	18 Feb 2021 22:17:31
User entered '5'	System	29 Jan 2021 16:51:49
User entered '4'	System	25 Nov 2020 12:59:02
User entered '3'	System	11 Nov 2020 15:33:50
User entered '2'	System	22 Oct 2020 14:00:54
User entered '1'	System	18 Aug 2020 13:46:01

US3412184

Folder: SAE USA-US061-2020-MRNA-1273-P301000002

Form: Safety Report Form (2)

Generated On: 09 Jun 2021 17:30:24

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:34:07
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Nov 2020 14:46:32
User entered '22/Oct/2020 10:00'	System	22 Oct 2020 14:00:54

US3412184

Folder: SAE USA-US061-2020-MRNA-1273-P301000002

Form: Safety Report Form (2)

Generated On: 09 Jun 2021 17:30:24

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)	16 Apr 2021 14:34:07
Reviewed for Safety.	(b) (4), (b) (6)	11 Nov 2020 15:33:38
DataPoint Verified.		05 Nov 2020 14:46:32
User entered '1'		22 Oct 2020 14:00:54

US3412184

Folder: SAE USA-US061-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 09 Jun 2021 17:30:24

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:34:07
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 14:46:32
Reviewed for Safety.		18 Aug 2020 13:45:43
User entered 'USA-US061-2020-MRNA-1273-P301000002'	System	18 Aug 2020 13:40:20

US3412184

Folder: SAE USA-US061-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 09 Jun 2021 17:30:24

Serious

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:34:07
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 14:46:32
Reviewed for Safety.		18 Aug 2020 13:45:43
User entered 'Yes (Y)'	System	18 Aug 2020 13:40:20

US3412184

Folder: SAE USA-US061-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 09 Jun 2021 17:30:24

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:34:07
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Nov 2020 14:46:32
Reviewed for Safety.		18 Aug 2020 13:45:43
User entered 'No (N)'	System	18 Aug 2020 13:40:20

US3412184

Folder: SAE USA-US061-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 09 Jun 2021 17:30:24

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:34:07
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Nov 2020 14:46:32
Reviewed for Safety.		18 Aug 2020 13:45:43
User entered 'No (N)'	System	18 Aug 2020 13:40:20

US3412184

Folder: SAE USA-US061-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 09 Jun 2021 17:30:24

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:34:07
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Nov 2020 14:46:32
Reviewed for Safety.		18 Aug 2020 13:45:43
User entered 'No (N)'	System	18 Aug 2020 13:40:20

US3412184

Folder: SAE USA-US061-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 09 Jun 2021 17:30:24

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:34:07
DataPoint Verified.	(b) (4)	(b) (4), (b) (6) 05 Nov 2020 14:46:32
Reviewed for Safety.		18 Aug 2020 13:45:43
User entered 'No (N)'	System	18 Aug 2020 13:40:20

US3412184

Folder: SAE USA-US061-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 09 Jun 2021 17:30:24

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:34:07
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Nov 2020 14:46:32
Reviewed for Safety.		18 Aug 2020 13:45:43
User entered 'No (N)'	System	18 Aug 2020 13:40:20

US3412184

Folder: SAE USA-US061-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 09 Jun 2021 17:30:24

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:34:07
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 14:46:32
Reviewed for Safety.		18 Aug 2020 13:45:43
User entered 'Yes (Y)'	System	18 Aug 2020 13:40:20

US3412184

Folder: SAE USA-US061-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 09 Jun 2021 17:30:24

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:34:07
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Nov 2020 14:46:32
Reviewed for Safety.		22 Oct 2020 14:00:39
User entered 'Gregory'	Steven Anderson (b) (4) (b) (4)	18 Aug 2020 22:35:40

US3412184

Folder: SAE USA-US061-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 09 Jun 2021 17:30:24

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:34:07
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 14:46:32
Reviewed for Safety.	(b) (4)	22 Oct 2020 14:00:39
User entered 'Gottschlich'	Steven Anderson (b) (4) (b) (4)	18 Aug 2020 22:35:40

US3412184

Folder: SAE USA-US061-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 09 Jun 2021 17:30:24

[Site Address: Street](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:34:07
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Nov 2020 14:46:32
Reviewed for Safety.		22 Oct 2020 14:00:39
User entered '4260 Glendale Milford Road'	Steven Anderson (b) (4) (b) (4)	18 Aug 2020 22:35:40

US3412184

Folder: SAE USA-US061-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 09 Jun 2021 17:30:24

[Site Address: City](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:34:07
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	05 Nov 2020 14:46:32
Reviewed for Safety.		22 Oct 2020 14:00:39
Amendment Manager: User entered 'Cincinnati'	System	14 Sep 2020 21:47:33
User entered empty.	Steven Anderson (b) (4)	18 Aug 2020 22:35:40
	(b) (4)	

US3412184

Folder: SAE USA-US061-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 09 Jun 2021 17:30:24

[Site Address: State](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:34:07
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 14:46:32
Reviewed for Safety.	(b) (4)	22 Oct 2020 14:00:39
User entered empty.	Steven Anderson (b) (4)	18 Aug 2020 22:35:40

US3412184

Folder: SAE USA-US061-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 09 Jun 2021 17:30:24

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:34:07
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 14:46:32
Reviewed for Safety.	(b) (4)	22 Oct 2020 14:00:39
User entered '45242'	Steven Anderson (b) (4)	18 Aug 2020 22:35:40
	(b) (4)	

US3412184

Folder: SAE USA-US061-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 09 Jun 2021 17:30:24

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:34:07
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Nov 2020 14:46:32
Reviewed for Safety.		22 Oct 2020 14:00:39
Amendment Manager: Data point set to conformant.	System	19 Sep 2020 04:43:12
User entered 'US' (non-conformant).	System	18 Aug 2020 13:46:01

US3412184

Folder: SAE USA-US061-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 09 Jun 2021 17:30:24

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '6'	System	18 Feb 2021 22:17:31
User entered '5'	System	29 Jan 2021 16:51:49
User entered '4'	System	25 Nov 2020 12:59:02
User entered '3'	System	11 Nov 2020 15:33:50
User entered '2'	System	22 Oct 2020 14:00:54
User entered '1'	System	18 Aug 2020 13:46:01

US3412184

Folder: SAE USA-US061-2020-MRNA-1273-P301000002

Form: Safety Report Form (3)

Generated On: 09 Jun 2021 17:30:24

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:34:07
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Apr 2021 12:12:45
User entered '11/Nov/2020 15:33'	System	11 Nov 2020 15:33:50

US3412184

Folder: SAE USA-US061-2020-MRNA-1273-P301000002

Form: Safety Report Form (3)

Generated On: 09 Jun 2021 17:30:24

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)	16 Apr 2021 14:34:07
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 12:12:45
Reviewed for Safety.		25 Nov 2020 12:58:51
User entered '1'		11 Nov 2020 15:33:50

US3412184

Folder: SAE USA-US061-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 09 Jun 2021 17:30:24

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:34:07
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 14:46:32
Reviewed for Safety.		18 Aug 2020 13:45:43
User entered 'USA-US061-2020-MRNA-1273-P301000002'	System	18 Aug 2020 13:40:20

US3412184

Folder: SAE USA-US061-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 09 Jun 2021 17:30:24

Serious

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:34:07
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 14:46:32
Reviewed for Safety.		18 Aug 2020 13:45:43
User entered 'Yes (Y)'	System	18 Aug 2020 13:40:20

US3412184

Folder: SAE USA-US061-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 09 Jun 2021 17:30:24

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:34:07
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 14:46:32
Reviewed for Safety.		18 Aug 2020 13:45:43
User entered 'No (N)'	System	18 Aug 2020 13:40:20

US3412184

Folder: SAE USA-US061-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 09 Jun 2021 17:30:24

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:34:07
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Nov 2020 14:46:32
Reviewed for Safety.		18 Aug 2020 13:45:43
User entered 'No (N)'	System	18 Aug 2020 13:40:20

US3412184

Folder: SAE USA-US061-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 09 Jun 2021 17:30:24

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:34:07
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 14:46:32
Reviewed for Safety.		18 Aug 2020 13:45:43
User entered 'No (N)'	System	18 Aug 2020 13:40:20

US3412184

Folder: SAE USA-US061-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 09 Jun 2021 17:30:24

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:34:07
DataPoint Verified.	(b) (4)	05 Nov 2020 14:46:32
Reviewed for Safety.	(b) (4), (b) (6)	18 Aug 2020 13:45:43
User entered 'No (N)'	System	18 Aug 2020 13:40:20

US3412184

Folder: SAE USA-US061-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 09 Jun 2021 17:30:24

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:34:07
DataPoint Verified.	(b) (4)	05 Nov 2020 14:46:32
Reviewed for Safety.	(b) (4), (b) (6)	18 Aug 2020 13:45:43
User entered 'No (N)'	System	18 Aug 2020 13:40:20

US3412184

Folder: SAE USA-US061-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 09 Jun 2021 17:30:24

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:34:07
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Nov 2020 14:46:32
Reviewed for Safety.		18 Aug 2020 13:45:43
User entered 'Yes (Y)'	System	18 Aug 2020 13:40:20

US3412184

Folder: SAE USA-US061-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 09 Jun 2021 17:30:24

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:34:07
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	05 Nov 2020 14:46:32
Reviewed for Safety.		22 Oct 2020 14:00:39
User entered 'Gregory'	Steven Anderson (b) (4)	18 Aug 2020 22:35:40
	(b) (4)	

US3412184

Folder: SAE USA-US061-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 09 Jun 2021 17:30:24

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:34:07
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	05 Nov 2020 14:46:32
Reviewed for Safety.		22 Oct 2020 14:00:39
User entered 'Gottschlich'	Steven Anderson (b) (4)	18 Aug 2020 22:35:40
	(b) (4)	

US3412184

Folder: SAE USA-US061-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 09 Jun 2021 17:30:24

[Site Address: Street](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:34:07
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 14:46:32
Reviewed for Safety.	(b) (4)	22 Oct 2020 14:00:39
User entered '4260 Glendale Milford Road'	Steven Anderson (b) (4)	18 Aug 2020 22:35:40

US3412184

Folder: SAE USA-US061-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 09 Jun 2021 17:30:24

[Site Address: City](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:34:07
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	05 Nov 2020 14:46:32
Reviewed for Safety.		22 Oct 2020 14:00:39
Amendment Manager: User entered 'Cincinnati'	System	14 Sep 2020 21:47:33
User entered empty.	Steven Anderson (b) (4)	18 Aug 2020 22:35:40
	(b) (4)	

US3412184

Folder: SAE USA-US061-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 09 Jun 2021 17:30:24

[Site Address: State](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:34:07
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 14:46:32
Reviewed for Safety.	(b) (4)	22 Oct 2020 14:00:39
User entered empty.	Steven Anderson (b) (4)	18 Aug 2020 22:35:40
	(b) (4)	

US3412184

Folder: SAE USA-US061-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 09 Jun 2021 17:30:24

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:34:07
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Nov 2020 14:46:32
Reviewed for Safety.		22 Oct 2020 14:00:39
User entered '45242'	Steven Anderson (b) (4) (b) (4)	18 Aug 2020 22:35:40

US3412184

Folder: SAE USA-US061-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 09 Jun 2021 17:30:24

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:34:07
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Nov 2020 14:46:32
Reviewed for Safety.		22 Oct 2020 14:00:39
Amendment Manager: Data point set to conformant.	System	19 Sep 2020 04:43:12
User entered 'US' (non-conformant).	System	18 Aug 2020 13:46:01

US3412184

Folder: SAE USA-US061-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 09 Jun 2021 17:30:24

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '6'	System	18 Feb 2021 22:17:31
User entered '5'	System	29 Jan 2021 16:51:49
User entered '4'	System	25 Nov 2020 12:59:02
User entered '3'	System	11 Nov 2020 15:33:50
User entered '2'	System	22 Oct 2020 14:00:54
User entered '1'	System	18 Aug 2020 13:46:01

US3412184

Folder: SAE USA-US061-2020-MRNA-1273-P301000002

Form: Safety Report Form (4)

Generated On: 09 Jun 2021 17:30:24

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:34:07
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Apr 2021 12:12:45
User entered '25/Nov/2020 12:59'	System	25 Nov 2020 12:59:02

US3412184

Folder: SAE USA-US061-2020-MRNA-1273-P301000002

Form: Safety Report Form (4)

Generated On: 09 Jun 2021 17:30:24

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)	16 Apr 2021 14:34:07
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 12:12:45
Reviewed for Safety.		29 Jan 2021 16:51:53
User entered '1'		25 Nov 2020 12:59:02

US3412184

Folder: SAE USA-US061-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 09 Jun 2021 17:30:24

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:34:07
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 14:46:32
Reviewed for Safety.		18 Aug 2020 13:45:43
User entered 'USA-US061-2020-MRNA-1273-P301000002'	System	18 Aug 2020 13:40:20

US3412184

Folder: SAE USA-US061-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 09 Jun 2021 17:30:24

Serious

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:34:07
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 14:46:32
Reviewed for Safety.		18 Aug 2020 13:45:43
User entered 'Yes (Y)'	System	18 Aug 2020 13:40:20

US3412184

Folder: SAE USA-US061-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 09 Jun 2021 17:30:24

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:34:07
DataPoint Verified.	(b) (4)	(b) (4), (b) (6)05 Nov 2020 14:46:32
Reviewed for Safety.		18 Aug 2020 13:45:43
User entered 'No (N)'	System	18 Aug 2020 13:40:20

US3412184

Folder: SAE USA-US061-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 09 Jun 2021 17:30:24

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:34:07
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Nov 2020 14:46:32
Reviewed for Safety.		18 Aug 2020 13:45:43
User entered 'No (N)'	System	18 Aug 2020 13:40:20

US3412184

Folder: SAE USA-US061-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 09 Jun 2021 17:30:24

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:34:07
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 14:46:32
Reviewed for Safety.		18 Aug 2020 13:45:43
User entered 'No (N)'	System	18 Aug 2020 13:40:20

US3412184

Folder: SAE USA-US061-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 09 Jun 2021 17:30:24

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:34:07
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 14:46:32
Reviewed for Safety.		18 Aug 2020 13:45:43
User entered 'No (N)'	System	18 Aug 2020 13:40:20

US3412184

Folder: SAE USA-US061-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 09 Jun 2021 17:30:24

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:34:07
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 14:46:32
Reviewed for Safety.		18 Aug 2020 13:45:43
User entered 'No (N)'	System	18 Aug 2020 13:40:20

US3412184

Folder: SAE USA-US061-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 09 Jun 2021 17:30:24

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:34:07
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Nov 2020 14:46:32
Reviewed for Safety.		18 Aug 2020 13:45:43
User entered 'Yes (Y)'	System	18 Aug 2020 13:40:20

US3412184

Folder: SAE USA-US061-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 09 Jun 2021 17:30:24

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:34:07
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	05 Nov 2020 14:46:32
Reviewed for Safety.		22 Oct 2020 14:00:39
User entered 'Gregory'	Steven Anderson (b) (4)	18 Aug 2020 22:35:40
	(b) (4)	

US3412184

Folder: SAE USA-US061-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 09 Jun 2021 17:30:24

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:34:07
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Nov 2020 14:46:32
Reviewed for Safety.		22 Oct 2020 14:00:39
User entered 'Gottschlich'	Steven Anderson (b) (4) (b) (4)	18 Aug 2020 22:35:40

US3412184

Folder: SAE USA-US061-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 09 Jun 2021 17:30:24

[Site Address: Street](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:34:07
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 14:46:32
Reviewed for Safety.		22 Oct 2020 14:00:39
User entered '4260 Glendale Milford Road'	Steven Anderson (b) (4)	18 Aug 2020 22:35:40

US3412184

Folder: SAE USA-US061-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 09 Jun 2021 17:30:24

[Site Address: City](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:34:07
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	05 Nov 2020 14:46:32
Reviewed for Safety.		22 Oct 2020 14:00:39
Amendment Manager: User entered 'Cincinnati'	System	14 Sep 2020 21:47:33
User entered empty.	Steven Anderson (b) (4)	18 Aug 2020 22:35:40
	(b) (4)	

US3412184

Folder: SAE USA-US061-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 09 Jun 2021 17:30:24

[Site Address: State](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:34:07
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 14:46:32
Reviewed for Safety.		22 Oct 2020 14:00:39
User entered empty.	Steven Anderson (b) (4)	18 Aug 2020 22:35:40

US3412184

Folder: SAE USA-US061-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 09 Jun 2021 17:30:24

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:34:07
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Nov 2020 14:46:32
Reviewed for Safety.		22 Oct 2020 14:00:39
User entered '45242'	Steven Anderson (b) (4) (b) (4)	18 Aug 2020 22:35:40

US3412184

Folder: SAE USA-US061-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 09 Jun 2021 17:30:24

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:34:07
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Nov 2020 14:46:32
Reviewed for Safety.		22 Oct 2020 14:00:39
Amendment Manager: Data point set to conformant.	System	19 Sep 2020 04:43:12
User entered 'US' (non-conformant).	System	18 Aug 2020 13:46:01

US3412184

Folder: SAE USA-US061-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 09 Jun 2021 17:30:24

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '6'	System	18 Feb 2021 22:17:31
User entered '5'	System	29 Jan 2021 16:51:49
User entered '4'	System	25 Nov 2020 12:59:02
User entered '3'	System	11 Nov 2020 15:33:50
User entered '2'	System	22 Oct 2020 14:00:54
User entered '1'	System	18 Aug 2020 13:46:01

US3412184

Folder: SAE USA-US061-2020-MRNA-1273-P301000002

Form: Safety Report Form (5)

Generated On: 09 Jun 2021 17:30:24

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:34:07
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Apr 2021 12:12:45
User entered '29/Jan/2021 11:51'	System	29 Jan 2021 16:51:49

US3412184

Folder: SAE USA-US061-2020-MRNA-1273-P301000002

Form: Safety Report Form (5)

Generated On: 09 Jun 2021 17:30:24

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)	16 Apr 2021 14:34:07
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 12:12:45
Reviewed for Safety.		29 Jan 2021 16:51:53
User entered '1'		29 Jan 2021 16:51:49

US3412184

Folder: SAE USA-US061-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 09 Jun 2021 17:30:24

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:34:07
DataPoint Verified.	(b) (4)	05 Nov 2020 14:46:32
Reviewed for Safety.	(b) (4), (b) (6)	18 Aug 2020 13:45:43
User entered 'USA-US061-2020-MRNA-1273-P301000002'	System	18 Aug 2020 13:40:20

US3412184

Folder: SAE USA-US061-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 09 Jun 2021 17:30:24

Serious

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:34:07
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 14:46:32
Reviewed for Safety.		18 Aug 2020 13:45:43
User entered 'Yes (Y)'	System	18 Aug 2020 13:40:20

US3412184

Folder: SAE USA-US061-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 09 Jun 2021 17:30:24

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:34:07
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 14:46:32
Reviewed for Safety.		18 Aug 2020 13:45:43
User entered 'No (N)'	System	18 Aug 2020 13:40:20

US3412184

Folder: SAE USA-US061-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 09 Jun 2021 17:30:24

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:34:07
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 14:46:32
Reviewed for Safety.		18 Aug 2020 13:45:43
User entered 'No (N)'	System	18 Aug 2020 13:40:20

US3412184

Folder: SAE USA-US061-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 09 Jun 2021 17:30:24

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:34:07
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 14:46:32
Reviewed for Safety.		18 Aug 2020 13:45:43
User entered 'No (N)'	System	18 Aug 2020 13:40:20

US3412184

Folder: SAE USA-US061-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 09 Jun 2021 17:30:24

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:34:07
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 14:46:32
Reviewed for Safety.		18 Aug 2020 13:45:43
User entered 'No (N)'	System	18 Aug 2020 13:40:20

US3412184

Folder: SAE USA-US061-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 09 Jun 2021 17:30:24

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:34:07
DataPoint Verified.	(b) (4)	05 Nov 2020 14:46:32
Reviewed for Safety.	(b) (4), (b) (6)	18 Aug 2020 13:45:43
User entered 'No (N)'	System	18 Aug 2020 13:40:20

US3412184

Folder: SAE USA-US061-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 09 Jun 2021 17:30:24

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:34:07
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Nov 2020 14:46:32
Reviewed for Safety.		18 Aug 2020 13:45:43
User entered 'Yes (Y)'	System	18 Aug 2020 13:40:20

US3412184

Folder: SAE USA-US061-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 09 Jun 2021 17:30:24

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:34:07
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Nov 2020 14:46:32
Reviewed for Safety.		22 Oct 2020 14:00:39
User entered 'Gregory'	Steven Anderson (b) (4) (b) (4)	18 Aug 2020 22:35:40

US3412184

Folder: SAE USA-US061-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 09 Jun 2021 17:30:24

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:34:07
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Nov 2020 14:46:32
Reviewed for Safety.		22 Oct 2020 14:00:39
User entered 'Gottschlich'	Steven Anderson (b) (4) (b) (4)	18 Aug 2020 22:35:40

US3412184

Folder: SAE USA-US061-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 09 Jun 2021 17:30:24

[Site Address: Street](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:34:07
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Nov 2020 14:46:32
Reviewed for Safety.		22 Oct 2020 14:00:39
User entered '4260 Glendale Milford Road'	Steven Anderson (b) (4) (b) (4)	18 Aug 2020 22:35:40

US3412184

Folder: SAE USA-US061-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 09 Jun 2021 17:30:24

[Site Address: City](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:34:07
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Nov 2020 14:46:32
Reviewed for Safety.		22 Oct 2020 14:00:39
Amendment Manager: User entered 'Cincinnati'	System	14 Sep 2020 21:47:33
User entered empty.	Steven Anderson (b) (4) (b) (4)	18 Aug 2020 22:35:40

US3412184

Folder: SAE USA-US061-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 09 Jun 2021 17:30:24

[Site Address: State](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:34:07
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Nov 2020 14:46:32
Reviewed for Safety.		22 Oct 2020 14:00:39
User entered empty.	Steven Anderson (b) (4) (b) (4)	18 Aug 2020 22:35:40

US3412184

Folder: SAE USA-US061-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 09 Jun 2021 17:30:24

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:34:07
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 14:46:32
Reviewed for Safety.		22 Oct 2020 14:00:39
User entered '45242'	Steven Anderson (b) (4)	18 Aug 2020 22:35:40

US3412184

Folder: SAE USA-US061-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 09 Jun 2021 17:30:24

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:34:07
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 14:46:32
Reviewed for Safety.		22 Oct 2020 14:00:39
Amendment Manager: Data point set to conformant.	System	19 Sep 2020 04:43:12
User entered 'US' (non-conformant).	System	18 Aug 2020 13:46:01

US3412184

Folder: SAE USA-US061-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 09 Jun 2021 17:30:24

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '6'	System	18 Feb 2021 22:17:31
User entered '5'	System	29 Jan 2021 16:51:49
User entered '4'	System	25 Nov 2020 12:59:02
User entered '3'	System	11 Nov 2020 15:33:50
User entered '2'	System	22 Oct 2020 14:00:54
User entered '1'	System	18 Aug 2020 13:46:01

US3412184

Folder: SAE USA-US061-2020-MRNA-1273-P301000002

Form: Safety Report Form (6)

Generated On: 09 Jun 2021 17:30:24

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:34:07
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Apr 2021 12:12:45
User entered '18/Feb/2021 17:17'	System	18 Feb 2021 22:17:31

US3412184

Folder: SAE USA-US061-2020-MRNA-1273-P301000002

Form: Safety Report Form (6)

Generated On: 09 Jun 2021 17:30:24

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)	16 Apr 2021 14:34:07
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 12:12:45
User entered 'I'		18 Feb 2021 22:17:31