

US3342204 (Prod: Tekton Research- Austin)

Generated By: KC Joubran

Generated On: 11 Aug 2021 22:34:12

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US3342204

Form: Participant Creation

Data signed: (b) (4) 12 Mar 2021 23:17:35

Generated On: 11 Aug 2021 22:34:12

[Participant ID](#)

US3342204

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

US3342204

Folder: Screening

Form: Visit Date

Data signed: (b) (4) 12 Mar 2021 23:17:36

Generated On: 11 Aug 2021 22:34:12

Was this visit performed? Yes
No

Visit date (dd MMM yyyy) 08 SEP 2020

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

Folder OID SCRN

US3342204

Folder: Screening

Form: Demographics

Data signed: (b) (4) 12 Mar 2021 23:17:36

Generated On: 11 Aug 2021 22:34:12

Date of Birth (MMM yyyy)	(b) (6) 1985
Age	34
Age Units	YEARS
Age (Derived)	34
Sex	Female <input checked="" type="radio"/> Male <input type="radio"/>
Ethnicity	Hispanic or Latino <input type="radio"/> Not Hispanic or Latino <input checked="" type="radio"/> Not Reported <input type="radio"/> Unknown <input type="radio"/>
Race (Check All That Apply)	
White	True
Black	False
Asian	False
American Indian or Alaska Native	False
Native Hawaiian or other Pacific Islander	False
Other	False
If race is Other, specify	_____
Unknown	False
Not reported	False

US3342204

Folder: Screening

Form: Enrollment

Data signed: (b) (4) 12 Mar 2021 23:17:36

Generated On: 11 Aug 2021 22:34:12

Date of Informed Consent (*dd MMM yyyy*) 8 SEP 2020

Month and Year of Informed Consent (derived) SEP 2020

Year of Informed Consent (derived) 2020

Protocol Version

Amendment 1

Amendment 2

Amendment 3

Amendment 4

Amendment 5

Was participant enrolled in the study? Yes
No

If No, indicate reason for screen fail

Withdrew Consent

Inclusion/Exclusion

Cohort Full

Other

If reason for screen fail is Other, specify _____

Was this participant screened previously? Yes
No

If Yes, previous participant number _____

Enrollment Trigger 1

US3342204

Folder: Screening

Form: Inclusion/Exclusion Criteria Summary

Data signed: (b) (4) 12 Mar 2021 23:17:36

Generated On: 11 Aug 2021 22:34:12

Did the participant meet all eligibility criteria?

Yes

No

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Folder: Screening

Form: Medical History Summary

Data signed: (b) (4) 12 Mar 2021 23:17:36

Generated On: 11 Aug 2021 22:34:12

Were any significant conditions reported?

Yes

No

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Folder: Screening

Form: Medical History (1)

Data signed: (b) (4) 12 Mar 2021 23:17:36

Generated On: 11 Aug 2021 22:34:12

Condition	SEASONAL ALLERGIES
Start date (dd MMM yyyy)	UN UNK 1990
Start date completely unknown	False
Condition ongoing at study entry	Yes <input checked="" type="radio"/> No <input type="radio"/>
If No, please specify the stop date (dd MMM yyyy)	
Stop date completely unknown	False
Start Month and Year (derived)	JAN 1990
Start Year (derived)	1990
Stop Month and Year (derived)	
Stop Year (derived)	

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Folder: Screening

Form: Medical History (2)

Data signed: (b) (4) 12 Mar 2021 23:17:36

Generated On: 11 Aug 2021 22:34:12

Condition	RESTRICTIVE LUNG DISEASE DUE PECTUS EXCAVATION
Start date (dd MMM yyyy)	UN UNK 2020
Start date completely unknown	False
Condition ongoing at study entry	Yes <input checked="" type="radio"/> No <input type="radio"/>
If No, please specify the stop date (dd MMM yyyy)	_____
Stop date completely unknown	False
Start Month and Year (derived)	JAN 2020
Start Year (derived)	2020
Stop Month and Year (derived)	_____
Stop Year (derived)	_____

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Folder: Screening

Form: Medical History (3)

Data signed: (b) (4) 12 Mar 2021 23:17:36

Generated On: 11 Aug 2021 22:34:12

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

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Folder: Screening

Form: Medical History (4)

Data signed: (b) (4) 12 Mar 2021 23:17:36

Generated On: 11 Aug 2021 22:34:12

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

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Folder: Screening

Form: Medical History (5)

Data signed: (b) (4) 12 Mar 2021 23:17:36

Generated On: 11 Aug 2021 22:34:12

Condition	PECTUS EXCAVATUM
Start date (dd MMM yyyy)	(b) (6) 1985
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)	(b) (6) 1985
Start Year (derived)	1985
Stop Month and Year (derived)	_____
Stop Year (derived)	_____

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Folder: Screening

Form: Vital Signs

Data signed: (b) (4) 12 Mar 2021 23:17:36

Generated On: 11 Aug 2021 22:34:12

Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (<i>dd MMM yyyy</i>)	8 SEP 2020
Time of assessment (<i>00:00-23:59</i>)	10:32 (24 HR)
Vital Signs Date and Time (derived)	8 SEP 2020 10:32
Height (<i>xxx.x</i>)	167.5 cm
Weight (<i>xxx.x</i>)	55.1 kg
BMI (<i>xxx.x</i>)	19.63912 kg/m ²
BMI units	KG/M2
Temperature (<i>xxx.x</i>)	ND - Not Done
Route of measurement	Oral <input type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	_____
Pulse (<i>xxx</i>)	ND - Not Done
Pulse units	BPM
Respiratory Rate (<i>xxx</i>)	ND - Not Done
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (<i>xxx</i>)	ND - Not Done
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (<i>xxx</i>)	ND - Not Done
Diastolic Blood Pressure units	MMHG
Height (derived)	_____
Weight (derived)	_____

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Folder: Screening

Form: Physical Examination

Data signed: (b) (4) 12 Mar 2021 23:17:36

Generated On: 11 Aug 2021 22:34:12

Was the physical examination performed?

Yes

No

Date of examination (dd MMM yyyy)

8 SEP 2020

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

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Folder: Screening

Form: Childbearing Potential

Data signed: (b) (4) 12 Mar 2021 23:17:36

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Date of assessment (*dd MMM yyyy*) 08 SEP 2020

Is the participant of childbearing potential? Yes
No

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

If Partner medically sterile or Other, specify _____

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

Date of surgery unknown False

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

Date of last menstruation unknown False

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Folder: Screening

Form: Pregnancy Test

Data signed: (b) (4) 12 Mar 2021 23:17:36

Generated On: 11 Aug 2021 22:34:12

Was the pregnancy test performed? Yes
No

Date of test (dd MMM yyyy) 8 SEP 2020

Test performed Urine
Serum

Result Positive
Negative

Was FSH sample collected? Yes
No

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

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Folder: Screening

Form: Risk of Exposure

Data signed: (b) (4) 12 Mar 2021 23:17:36

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Occupational Risk

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

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

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

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

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

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

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

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

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

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

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

Other Yes No

Specify _____

Location and Living Circumstances Risk (check all that apply)

No Risk Identified False

Resides in Nursing Home or Assisted Living Facility False

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Folder: Screening

Form: Risk of Exposure

Data signed: (b) (4) 12 Mar 2021 23:17:36

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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	False
Specify	

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Folder: Visit 1 Day 1

Form: Visit Date

Data signed: (b) (4) 12 Mar 2021 23:17:36

Generated On: 11 Aug 2021 22:34:12

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	8 SEP 2020
Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>
Folder OID	VISIT1

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Folder: Visit 1 Day 1

Form: Randomization

Data signed: (b) (4) 12 Mar 2021 23:17:36

Generated On: 11 Aug 2021 22:34:12

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

What was the participant's randomization number? 145718

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

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

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

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

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

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

Liver Disease Yes No

Human Immunodeficiency Virus (HIV) infection Yes No

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Data signed: (b) (4) 12 Mar 2021 23:17:36

Generated On: 11 Aug 2021 22:34:12

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) 12 Mar 2021 23:17:36

Generated On: 11 Aug 2021 22:34:12

Height	ND - Not Done
Weight	ND - Not Done
Timepoint	Pre-Dose <input checked="" type="radio"/> Post-Dose <input type="radio"/>
Were vital signs assessed?	Yes <input checked="" type="radio"/> No <input type="radio"/>
Date of assessment (<i>dd MMM yyyy</i>)	8 SEP 2020
Time of assessment (<i>00:00-23:59</i>)	10:32 (24 HR)
Vital Signs Date and Time (derived)	8 SEP 2020 10:32
Temperature (<i>xxx.x</i>)	98.1 F
Route of measurement	Oral <input checked="" type="radio"/> Axillary <input type="radio"/> Other <input type="radio"/>
If Other, specify	_____
Pulse (<i>xxx</i>)	76 beats/min
Pulse units	BPM
Respiratory Rate (<i>xxx</i>)	13 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (<i>xxx</i>)	103 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (<i>xxx</i>)	73 mmHg
Diastolic Blood Pressure units	MMHG

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Data signed: (b) (4) 12 Mar 2021 23:17:36

Generated On: 11 Aug 2021 22:34:12

Height	ND - Not Done
Weight	ND - Not Done
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 (<i>dd MMM yyyy</i>)	8 SEP 2020
Time of assessment (<i>00:00-23:59</i>)	12:20 (24 HR)
Vital Signs Date and Time (derived)	8 SEP 2020 12:20
Temperature (<i>xxx.x</i>)	97.3 F
Route of measurement	Oral <input checked="" type="checkbox"/> Axillary <input type="checkbox"/> Other <input type="checkbox"/>
If Other, specify	_____
Pulse (<i>xxx</i>)	55 beats/min
Pulse units	BPM
Respiratory Rate (<i>xxx</i>)	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (<i>xxx</i>)	109 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (<i>xxx</i>)	75 mmHg
Diastolic Blood Pressure units	MMHG

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Folder: Visit 1 Day 1

Form: Physical Examination

Data signed: (b) (4) 12 Mar 2021 23:17:36

Generated On: 11 Aug 2021 22:34:12

Was the physical examination performed?

Yes

No

Date of examination (*dd MMM yyyy*) _____

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

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Folder: Visit 1 Day 1

Form: Pregnancy Test

Data signed: (b) (4) 12 Mar 2021 23:17:36

Generated On: 11 Aug 2021 22:34:12

Was the pregnancy test performed? Yes
No

Date of test (dd MMM yyyy) _____

Test performed Urine
Serum

Result Positive
Negative

Was FSH sample collected? Yes
No

Collection date _____

Collection time _____

Collection date and time (derived) _____

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Folder: Visit 1 Day 1

Form: Exposure

Data signed: (b) (4) 12 Mar 2021 23:17:36

Generated On: 11 Aug 2021 22:34:12

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) 8 SEP 2020

What was the treatment time? (00:00-23:59) 11:44 (24 HR)

Treatment Date and Time (derived) 8 SEP 2020 11:44

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) 12 Mar 2021 23:17:36

Generated On: 11 Aug 2021 22:34:12

Was the sample collected?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Collection date (<i>dd MMM yyyy</i>)	8 SEP 2020
Collection time (<i>00:00-23:59</i>)	11:12 (24 HR)
Collection date and time (derived)	8 SEP 2020 11:12

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Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab

Data signed: (b) (4) 12 Mar 2021 23:17:36

Generated On: 11 Aug 2021 22:34:12

Collection date (<i>dd MMM yyyy</i>)			8 SEP 2020
Lab Test	Was the sample collected?	Collection time (<i>00:00 - 23:59</i>)	Collection date and time (derived)
Nasopharyngeal Swab 1	Yes	11:14	8 SEP 2020 11:14
Nasopharyngeal Swab 2	No		

US3342204

Folder: Visit 1 Day 1

Form: Continuing

Data signed: (b) (4) 12 Mar 2021 23:17:36

Generated On: 11 Aug 2021 22:34:12

Is the participant continuing to the next visit?

Yes

No

Continuing Flag

1

US3342204

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 11 Aug 2021 22:34:12

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 97.3 °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 12:23

PC Open Date & Time 08 SEP 2020 12:04

PC Close Date & Time 08 SEP 2020 14:34

US3342204

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 11 Aug 2021 22:34:12

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 97.9 °F

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

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

PC Time Stamp 08 SEP 2020 20:27
PC Open Date & Time 08 SEP 2020 15:29
PC Close Date & Time 09 SEP 2020 11:59

US3342204

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 11 Aug 2021 22:34:12

TIMEPOINT

DAY 2

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

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

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

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

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

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

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

Was TEMPERATURE taken?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Please record your TEMPERATURE in °F	97.3 °F
Was any MEDICATION TAKEN today for pain or fever?	Yes <input type="radio"/>
	No <input checked="" type="radio"/>

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

PC Time Stamp	09 SEP 2020 20:50
PC Open Date & Time	09 SEP 2020 12:00
PC Close Date & Time	10 SEP 2020 11:59

US3342204

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 11 Aug 2021 22:34:12

TIMEPOINT

DAY 3

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

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

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

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

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

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

Was TEMPERATURE taken?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Please record your TEMPERATURE in °F	98.0 °F
Was any MEDICATION TAKEN today for pain or fever?	Yes <input type="radio"/>
	No <input checked="" type="radio"/>

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

PC Time Stamp	10 SEP 2020 22:39
PC Open Date & Time	10 SEP 2020 12:00
PC Close Date & Time	11 SEP 2020 11:59

US3342204

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 11 Aug 2021 22:34:12

TIMEPOINT

DAY 4

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

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

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

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

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

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

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

Was TEMPERATURE taken?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Please record your TEMPERATURE in °F	97.3 °F
Was any MEDICATION TAKEN today for pain or fever?	Yes <input type="radio"/>
	No <input checked="" type="radio"/>

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

PC Time Stamp	11 SEP 2020 22:27
PC Open Date & Time	11 SEP 2020 12:00
PC Close Date & Time	12 SEP 2020 11:59

US3342204

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 11 Aug 2021 22:34:12

TIMEPOINT

DAY 5

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

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

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

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

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

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

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

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

PC Time Stamp	13 SEP 2020 00:00
PC Open Date & Time	12 SEP 2020 12:00
PC Close Date & Time	13 SEP 2020 11:59

US3342204

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 11 Aug 2021 22:34:12

TIMEPOINT

DAY 6

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

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

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

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

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

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

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

Was TEMPERATURE taken?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Please record your TEMPERATURE in °F	97.6 °F
Was any MEDICATION TAKEN today for pain or fever?	Yes <input type="radio"/>
	No <input checked="" type="radio"/>

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

PC Time Stamp	13 SEP 2020 22:47
PC Open Date & Time	13 SEP 2020 12:00
PC Close Date & Time	14 SEP 2020 11:59

US3342204

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 11 Aug 2021 22:34:12

TIMEPOINT

DAY 7

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

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

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

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

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

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

Was TEMPERATURE taken?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Please record your TEMPERATURE in °F	97.5 °F
Was any MEDICATION TAKEN today for pain or fever?	Yes <input type="radio"/>
	No <input checked="" type="radio"/>

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

PC Time Stamp	14 SEP 2020 22:45
PC Open Date & Time	14 SEP 2020 12:00
PC Close Date & Time	15 SEP 2020 11:59

US3342204

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 11 Aug 2021 22:34:12

TIMEPOINT

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

Please record - **PAIN AT INJECTION SITE.**
Please select one response below

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

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

- Yes
- No

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

- Yes
- No

Please record - **UNDERARM GLAND SWELLING OR
TENDERNESS.**
Please select one response below

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

PC Time Stamp

08 SEP 2020 12:24

PC Open Date & Time

08 SEP 2020 12:04

PC Close Date & Time

08 SEP 2020 14:34

US3342204

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 11 Aug 2021 22:34:12

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 20:28

PC Open Date & Time

08 SEP 2020 15:29

PC Close Date & Time

09 SEP 2020 11:59

US3342204

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 11 Aug 2021 22:34:12

TIMEPOINT

DAY 2

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

Please select one response below

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

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

- Yes
- No

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

- Yes
- No

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

Please select one response below

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

PC Time Stamp	09 SEP 2020 20:51
PC Open Date & Time	09 SEP 2020 12:00
PC Close Date & Time	10 SEP 2020 11:59

US3342204

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 11 Aug 2021 22:34:12

TIMEPOINT

DAY 3

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

Please select one response below

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

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

- Yes
- No

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

- Yes
- No

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

Please select one response below

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

PC Time Stamp	10 SEP 2020 22:40
PC Open Date & Time	10 SEP 2020 12:00
PC Close Date & Time	11 SEP 2020 11:59

US3342204

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 11 Aug 2021 22:34:12

TIMEPOINT

DAY 4

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

Please select one response below

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

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

- Yes
- No

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

- Yes
- No

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

Please select one response below

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

PC Time Stamp	11 SEP 2020 22:28
PC Open Date & Time	11 SEP 2020 12:00
PC Close Date & Time	12 SEP 2020 11:59

US3342204

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 11 Aug 2021 22:34:12

TIMEPOINT

DAY 5

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

Please select one response below

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

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

- Yes
- No

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

- Yes
- No

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

Please select one response below

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

PC Time Stamp	12 SEP 2020 23:59
PC Open Date & Time	12 SEP 2020 12:00
PC Close Date & Time	13 SEP 2020 11:59

US3342204

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 11 Aug 2021 22:34:12

TIMEPOINT

DAY 6

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

Please select one response below

None

Does not interfere with activity

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

Any use of prescription pain
reliever or prevents daily activity

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

Yes

No

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

Yes

No

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

Please select one response below

None

Does not interfere with activity

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

Any use of prescription pain
reliever or prevents daily activity

PC Time Stamp

13 SEP 2020 22:46

PC Open Date & Time

13 SEP 2020 12:00

PC Close Date & Time

14 SEP 2020 11:59

US3342204

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 11 Aug 2021 22:34:12

TIMEPOINT

DAY 7

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

Please select one response below

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

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

- Yes
- No

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

- Yes
- No

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

Please select one response below

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

PC Time Stamp	14 SEP 2020 22:44
PC Open Date & Time	14 SEP 2020 12:00
PC Close Date & Time	15 SEP 2020 11:59

US3342204

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 11 Aug 2021 22:34:12

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

US3342204

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 11 Aug 2021 22:34:12

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

No

Yes

PC Time stamp	08 SEP 2020 12:25
PC Open Date & Time	08 SEP 2020 12:04
PC Close Date & Time	08 SEP 2020 14:34

US3342204

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 11 Aug 2021 22:34:12

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

US3342204

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 11 Aug 2021 22:34:12

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

No

Yes

PC Time stamp	08 SEP 2020 20:28
PC Open Date & Time	08 SEP 2020 15:29
PC Close Date & Time	09 SEP 2020 11:59

US3342204

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 11 Aug 2021 22:34:12

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

US3342204

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 11 Aug 2021 22:34:12

	Yes <input type="checkbox"/>
PC Time stamp	09 SEP 2020 20:51
PC Open Date & Time	09 SEP 2020 12:00
PC Close Date & Time	10 SEP 2020 11:59

US3342204

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 11 Aug 2021 22:34:12

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

US3342204

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 11 Aug 2021 22:34:12

	Yes <input type="checkbox"/>
PC Time stamp	10 SEP 2020 22:40
PC Open Date & Time	10 SEP 2020 12:00
PC Close Date & Time	11 SEP 2020 11:59

US3342204

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 11 Aug 2021 22:34:12

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

US3342204

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 11 Aug 2021 22:34:12

	Yes <input type="checkbox"/>
PC Time stamp	11 SEP 2020 22:28
PC Open Date & Time	11 SEP 2020 12:00
PC Close Date & Time	12 SEP 2020 11:59

US3342204

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 11 Aug 2021 22:34:12

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

US3342204

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 11 Aug 2021 22:34:12

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

US3342204

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 11 Aug 2021 22:34:12

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

US3342204

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 11 Aug 2021 22:34:12

	Yes <input type="checkbox"/>
PC Time stamp	13 SEP 2020 22:46
PC Open Date & Time	13 SEP 2020 12:00
PC Close Date & Time	14 SEP 2020 11:59

US3342204

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 11 Aug 2021 22:34:12

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

US3342204

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 11 Aug 2021 22:34:12

	Yes <input type="checkbox"/>
PC Time stamp	14 SEP 2020 22:45
PC Open Date & Time	14 SEP 2020 12:00
PC Close Date & Time	15 SEP 2020 11:59

US3342204

Folder: Safety Call Day 8 (1)

Form: Safety Call

Data signed: (b) (4) 12 Mar 2021 23:17:36

Generated On: 11 Aug 2021 22:34:12

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

US3342204

Folder: Safety Call Day 8 (1)

Form: Continuing

Data signed: (b) (4) 12 Mar 2021 23:17:36

Generated On: 11 Aug 2021 22:34:12

Is the participant continuing to the next visit?

Yes

No

Continuing Flag

1

US3342204

Folder: Safety Call Day 15 (1)

Form: Safety Call

Data signed: (b) (4) 12 Mar 2021 23:17:36

Generated On: 11 Aug 2021 22:34:12

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

US3342204

Folder: Safety Call Day 15 (1)

Form: Continuing

Data signed: (b) (4) 12 Mar 2021 23:17:36

Generated On: 11 Aug 2021 22:34:12

Is the participant continuing to the next visit?

Yes

No

Continuing Flag

1

US3342204

Folder: Safety Call Day 22 (1)

Form: Safety Call

Data signed: (b) (4) 12 Mar 2021 23:17:36

Generated On: 11 Aug 2021 22:34:12

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

US3342204

Folder: Safety Call Day 22 (1)

Form: Continuing

Data signed: (b) (4) 12 Mar 2021 23:17:36

Generated On: 11 Aug 2021 22:34:12

Is the participant continuing to the next visit?

Yes

No

Continuing Flag

1

US3342204

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Data signed: (b) (4) 12 Mar 2021 23:17:36

Generated On: 11 Aug 2021 22:34:12

Was this visit performed? Yes
No

Visit date (dd MMM yyyy) 26 OCT 2020

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

Folder OID VISIT2

US3342204

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Data signed: (b) (4) 12 Mar 2021 23:17:36

Generated On: 11 Aug 2021 22:34:12

Timepoint	Pre-Dose <input checked="" type="radio"/>
	Post-Dose <input type="radio"/>
Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (<i>dd MMM yyyy</i>)	26 OCT 2020
Time of assessment (<i>00:00-23:59</i>)	10:22 (24 HR)
Vital Signs Date and Time (derived)	26 OCT 2020 10:22
Temperature (<i>xxx.x</i>)	98.0 F
Route of measurement	Oral <input checked="" type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify _____	
Pulse (<i>xxx</i>)	69 beats/min
Pulse units	BPM
Respiratory Rate (<i>xxx</i>)	12 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (<i>xxx</i>)	97 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (<i>xxx</i>)	67 mmHg
Diastolic Blood Pressure units	MMHG

US3342204

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Data signed: (b) (4) 12 Mar 2021 23:17:36

Generated On: 11 Aug 2021 22:34:12

Timepoint	Pre-Dose <input type="radio"/>
	Post-Dose <input checked="" type="radio"/>
Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (<i>dd MMM yyyy</i>)	26 OCT 2020
Time of assessment (<i>00:00-23:59</i>)	12:02 (24 HR)
Vital Signs Date and Time (derived)	26 OCT 2020 12:02
Temperature (<i>xxx.x</i>)	97.0 F
Route of measurement	Oral <input checked="" type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify _____	
Pulse (<i>xxx</i>)	72 beats/min
Pulse units	BPM
Respiratory Rate (<i>xxx</i>)	12 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (<i>xxx</i>)	108 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (<i>xxx</i>)	63 mmHg
Diastolic Blood Pressure units	MMHG

US3342204

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Data signed: (b) (4) 12 Mar 2021 23:17:36

Generated On: 11 Aug 2021 22:34:12

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.

US3342204

Folder: Visit 2 Day 29 (1)

Form: Pregnancy Test

Data signed: (b) (4) 12 Mar 2021 23:17:36

Generated On: 11 Aug 2021 22:34:12

Was the pregnancy test performed? Yes
No

Date of test (dd MMM yyyy) 26 OCT 2020

Test performed Urine
Serum

Result Positive
Negative

Was FSH sample collected? Yes
No

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

US3342204

Folder: Visit 2 Day 29 (1)

Form: Exposure

Data signed: (b) (4) 12 Mar 2021 23:17:36

Generated On: 11 Aug 2021 22:34:12

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) 26 OCT 2020

What was the treatment time? (00:00-23:59) 11:27 (24 HR)

Treatment Date and Time (derived) 26 OCT 2020 11:27

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

US3342204

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 12 Mar 2021 23:17:36

Generated On: 11 Aug 2021 22:34:12

Was the sample collected? Yes No

Collection date (*dd MMM yyyy*) 26 OCT 2020

Collection time (*00:00-23:59*) 11:23 (24 HR)

Collection date and time (derived) 26 OCT 2020 11:23

US3342204

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab

Data signed: (b) (4) 12 Mar 2021 23:17:36

Generated On: 11 Aug 2021 22:34:12

Collection date (<i>dd MMM yyyy</i>)			26 OCT 2020
Lab Test	Was the sample collected?	Collection time (<i>00:00 - 23:59</i>)	Collection date and time (derived)
Nasopharyngeal Swab 1	Yes	11:25	26 OCT 2020 11:25
Nasopharyngeal Swab 2	No		

US3342204

Folder: Visit 2 Day 29 (1)

Form: Continuing

Data signed: (b) (4) 12 Mar 2021 23:17:36

Generated On: 11 Aug 2021 22:34:12

Is the participant continuing to the next visit?

Yes

No

Continuing Flag

1

US3342204

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 11 Aug 2021 22:34:12

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 97.0 °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 26 OCT 2020 12:03

PC Open Date & Time 26 OCT 2020 11:47

PC Close Date & Time 26 OCT 2020 14:17

US3342204

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 11 Aug 2021 22:34:12

TIMEPOINT

DAY 1, AFTER VACCINATION
(AT HOME)

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

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

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

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

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

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

Was **TEMPERATURE** taken? Yes No

Please record your **TEMPERATURE** in °F 96.9 °F

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

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

PC Time Stamp 26 OCT 2020 23:49
PC Open Date & Time 26 OCT 2020 15:12
PC Close Date & Time 27 OCT 2020 11:59

US3342204

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 11 Aug 2021 22:34:12

TIMEPOINT

DAY 2

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

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

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

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

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

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

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

Was TEMPERATURE taken?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Please record your TEMPERATURE in °F	97.3 °F
Was any MEDICATION TAKEN today for pain or fever?	Yes <input type="radio"/>
	No <input checked="" type="radio"/>

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

PC Time Stamp	27 OCT 2020 23:41
PC Open Date & Time	27 OCT 2020 12:00
PC Close Date & Time	28 OCT 2020 11:59

US3342204

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 11 Aug 2021 22:34:12

TIMEPOINT

DAY 3

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

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

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

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

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

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

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

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

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

PC Time Stamp	28 OCT 2020 21:04
PC Open Date & Time	28 OCT 2020 12:00
PC Close Date & Time	29 OCT 2020 11:59

US3342204

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 11 Aug 2021 22:34:12

TIMEPOINT

DAY 4

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

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

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

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

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

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

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

Was TEMPERATURE taken?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Please record your TEMPERATURE in °F	98.0 °F
Was any MEDICATION TAKEN today for pain or fever?	Yes <input type="radio"/>
	No <input checked="" type="radio"/>

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

PC Time Stamp	30 OCT 2020 00:00
PC Open Date & Time	29 OCT 2020 12:00
PC Close Date & Time	30 OCT 2020 11:59

US3342204

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 11 Aug 2021 22:34:12

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 98.4 °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 30 OCT 2020 23:08
PC Open Date & Time 30 OCT 2020 12:00
PC Close Date & Time 31 OCT 2020 11:59

US3342204

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 11 Aug 2021 22:34:12

TIMEPOINT

DAY 6

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

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

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

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

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

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

Was TEMPERATURE taken?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Please record your TEMPERATURE in °F	98.5 °F
Was any MEDICATION TAKEN today for pain or fever?	Yes <input type="radio"/>
	No <input checked="" type="radio"/>

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

PC Time Stamp	01 NOV 2020 07:19
PC Open Date & Time	31 OCT 2020 12:00
PC Close Date & Time	01 NOV 2020 11:59

US3342204

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 11 Aug 2021 22:34:12

TIMEPOINT

DAY 7

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

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

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

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

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

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

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

Was TEMPERATURE taken?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Please record your TEMPERATURE in °F	98.6 °F
Was any MEDICATION TAKEN today for pain or fever?	Yes <input type="radio"/>
	No <input checked="" type="radio"/>

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

PC Time Stamp	01 NOV 2020 20:02
PC Open Date & Time	01 NOV 2020 12:00
PC Close Date & Time	02 NOV 2020 11:59

US3342204

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 11 Aug 2021 22:34:12

TIMEPOINT

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

Please record - **PAIN AT INJECTION SITE.**
Please select one response below

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

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

- Yes
- No

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

- Yes
- No

Please record - **UNDERARM GLAND SWELLING OR
TENDERNESS.**
Please select one response below

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

PC Time Stamp	26 OCT 2020 12:00
PC Open Date & Time	26 OCT 2020 11:47
PC Close Date & Time	26 OCT 2020 14:17

US3342204

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 11 Aug 2021 22:34:12

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

26 OCT 2020 23:51

PC Open Date & Time

26 OCT 2020 15:12

PC Close Date & Time

27 OCT 2020 11:59

US3342204

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 11 Aug 2021 22:34:12

TIMEPOINT

DAY 2

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

Please select one response below

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

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

- Yes
- No

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

- Yes
- No

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

Please select one response below

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

PC Time Stamp	27 OCT 2020 23:40
PC Open Date & Time	27 OCT 2020 12:00
PC Close Date & Time	28 OCT 2020 11:59

US3342204

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 11 Aug 2021 22:34:12

TIMEPOINT

DAY 3

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

Please select one response below

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

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

- Yes
- No

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

- Yes
- No

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

Please select one response below

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

PC Time Stamp	28 OCT 2020 21:05
PC Open Date & Time	28 OCT 2020 12:00
PC Close Date & Time	29 OCT 2020 11:59

US3342204

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 11 Aug 2021 22:34:12

TIMEPOINT

DAY 4

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

Please select one response below

None

Does not interfere with activity

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

Any use of prescription pain
reliever or prevents daily activity

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

Yes

No

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

Yes

No

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

Please select one response below

None

Does not interfere with activity

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

Any use of prescription pain
reliever or prevents daily activity

PC Time Stamp

30 OCT 2020 00:00

PC Open Date & Time

29 OCT 2020 12:00

PC Close Date & Time

30 OCT 2020 11:59

US3342204

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 11 Aug 2021 22:34:12

TIMEPOINT

DAY 5

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

Please select one response below

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

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

- Yes
- No

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

- Yes
- No

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

Please select one response below

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

PC Time Stamp	30 OCT 2020 23:07
PC Open Date & Time	30 OCT 2020 12:00
PC Close Date & Time	31 OCT 2020 11:59

US3342204

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 11 Aug 2021 22:34:12

TIMEPOINT

DAY 6

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

Please select one response below

None

Does not interfere with activity

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

Any use of prescription pain
reliever or prevents daily activity

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

Yes

No

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

Yes

No

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

Please select one response below

None

Does not interfere with activity

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

Any use of prescription pain
reliever or prevents daily activity

PC Time Stamp

01 NOV 2020 07:17

PC Open Date & Time

31 OCT 2020 12:00

PC Close Date & Time

01 NOV 2020 11:59

US3342204

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 11 Aug 2021 22:34:12

TIMEPOINT

DAY 7

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

Please select one response below

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

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

- Yes
- No

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

- Yes
- No

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

Please select one response below

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

PC Time Stamp	01 NOV 2020 20:03
PC Open Date & Time	01 NOV 2020 12:00
PC Close Date & Time	02 NOV 2020 11:59

US3342204

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 11 Aug 2021 22:34:12

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

US3342204

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 11 Aug 2021 22:34:12

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

No

Yes

PC Time stamp	26 OCT 2020 11:59
PC Open Date & Time	26 OCT 2020 11:47
PC Close Date & Time	26 OCT 2020 14:17

US3342204

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 11 Aug 2021 22:34:12

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

US3342204

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 11 Aug 2021 22:34:12

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

No

Yes

PC Time stamp	26 OCT 2020 23:49
PC Open Date & Time	26 OCT 2020 15:12
PC Close Date & Time	27 OCT 2020 11:59

US3342204

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 11 Aug 2021 22:34:12

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

US3342204

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 11 Aug 2021 22:34:12

	Yes <input type="checkbox"/>
PC Time stamp	27 OCT 2020 23:39
PC Open Date & Time	27 OCT 2020 12:00
PC Close Date & Time	28 OCT 2020 11:59

US3342204

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 11 Aug 2021 22:34:12

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

US3342204

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 11 Aug 2021 22:34:12

	Yes <input type="checkbox"/>
PC Time stamp	28 OCT 2020 21:03
PC Open Date & Time	28 OCT 2020 12:00
PC Close Date & Time	29 OCT 2020 11:59

US3342204

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 11 Aug 2021 22:34:12

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

US3342204

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 11 Aug 2021 22:34:12

	Yes <input type="checkbox"/>
PC Time stamp	30 OCT 2020 00:00
PC Open Date & Time	29 OCT 2020 12:00
PC Close Date & Time	30 OCT 2020 11:59

US3342204

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 11 Aug 2021 22:34:12

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

US3342204

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 11 Aug 2021 22:34:12

	Yes <input type="checkbox"/>
PC Time stamp	30 OCT 2020 23:07
PC Open Date & Time	30 OCT 2020 12:00
PC Close Date & Time	31 OCT 2020 11:59

US3342204

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 11 Aug 2021 22:34:12

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

US3342204

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 11 Aug 2021 22:34:12

	Yes <input type="checkbox"/>
PC Time stamp	01 NOV 2020 07:17
PC Open Date & Time	31 OCT 2020 12:00
PC Close Date & Time	01 NOV 2020 11:59

US3342204

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 11 Aug 2021 22:34:12

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

US3342204

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 11 Aug 2021 22:34:12

	Yes <input type="checkbox"/>
PC Time stamp	01 NOV 2020 20:03
PC Open Date & Time	01 NOV 2020 12:00
PC Close Date & Time	02 NOV 2020 11:59

US3342204

Folder: Safety Call Day 36 (1)

Form: Safety Call

Data signed: (b) (4) 12 Mar 2021 23:17:36

Generated On: 11 Aug 2021 22:34:12

Was Contact Attempted? Yes
No

Date of Contact or Contact Attempt (*dd MMM yyyy*) 2 NOV 2020

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

Comments

If Contact Not Made, please provide Comments

US3342204

Folder: Safety Call Day 36 (1)

Form: Continuing

Data signed: (b) (4) 12 Mar 2021 23:17:36

Generated On: 11 Aug 2021 22:34:12

Is the participant continuing to the next visit?

Yes

No

Continuing Flag

1

US3342204

Folder: Safety Call Day 43 (1)

Form: Safety Call

Data signed: (b) (4) 12 Mar 2021 23:17:36

Generated On: 11 Aug 2021 22:34:12

Was Contact Attempted? Yes
No

Date of Contact or Contact Attempt (*dd MMM yyyy*) 9 NOV 2020

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

Comments

If Contact Not Made, please provide Comments

US3342204

Folder: Safety Call Day 43 (1)

Form: Continuing

Data signed: (b) (4) 12 Mar 2021 23:17:36

Generated On: 11 Aug 2021 22:34:12

Is the participant continuing to the next visit?

Yes

No

Continuing Flag

1

US3342204

Folder: Safety Call Day 50 (1)

Form: Safety Call

Data signed: (b) (4) 12 Mar 2021 23:17:36

Generated On: 11 Aug 2021 22:34:12

Was Contact Attempted? Yes
No

Date of Contact or Contact Attempt (*dd MMM yyyy*) 17 NOV 2020

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

Comments

If Contact Not Made, please provide Comments

US3342204

Folder: Safety Call Day 50 (1)

Form: Continuing

Data signed: (b) (4) 12 Mar 2021 23:17:36

Generated On: 11 Aug 2021 22:34:12

Is the participant continuing to the next visit?

Yes

No

Continuing Flag

1

US3342204

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Data signed: (b) (4) 12 Mar 2021 23:17:37

Generated On: 11 Aug 2021 22:34:12

Was this visit performed? Yes
No

Visit date (dd MMM yyyy) 20 NOV 2020

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

Folder OID VISIT3

US3342204

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Data signed: (b) (4) 12 Mar 2021 23:17:37

Generated On: 11 Aug 2021 22:34:12

Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (<i>dd MMM yyyy</i>)	20 NOV 2020
Time of assessment (<i>00:00-23:59</i>)	10:19 (24 HR)
Vital Signs Date and Time (derived)	20 NOV 2020 10:19
Temperature (<i>xxx.x</i>)	98.2 F
Route of measurement	Oral <input checked="" type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	_____
Pulse (<i>xxx</i>)	83 beats/min
Pulse units	BPM
Respiratory Rate (<i>xxx</i>)	12 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (<i>xxx</i>)	99 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (<i>xxx</i>)	68 mmHg
Diastolic Blood Pressure units	MMHG
Height (derived)	_____
Weight (derived)	_____

US3342204

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Data signed: (b) (4) 12 Mar 2021 23:17:37

Generated On: 11 Aug 2021 22:34:12

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.

US3342204

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 12 Mar 2021 23:17:37

Generated On: 11 Aug 2021 22:34:12

Was the sample collected? Yes No

Collection date (*dd MMM yyyy*) 20 NOV 2020

Collection time (*00:00-23:59*) 10:43 (24 HR)

Collection date and time (derived) 20 NOV 2020 10:43

US3342204

Folder: Visit 3 Day 57 (1)

Form: Continuing

Data signed: (b) (4) 12 Mar 2021 23:17:37

Generated On: 11 Aug 2021 22:34:12

Is the participant continuing to the next visit?

Yes

No

Continuing Flag

1

US3342204

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:34:12

TIMEPOINT	DAY 64
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature \geq 100.4°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"/>

US3342204

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:34:12

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

Patient Cloud Close Date & Time

12 NOV 2020 23:59

US3342204

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:34:12

TIMEPOINT	DAY 71
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input 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"/>

US3342204

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:34:12

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

Patient Cloud Close Date & Time

19 NOV 2020 23:59

US3342204

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:34:12

TIMEPOINT

DAY 75

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

No

Yes

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

No

Yes

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

Date and time of submission 20 NOV 2020 10:31:28

Patient Cloud Open Date & Time 19 NOV 2020 00:01

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

US3342204

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:34:12

TIMEPOINT	DAY 82
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	28 NOV 2020 12:34:11
Patient Cloud Open Date & Time	26 NOV 2020 00:01
Patient Cloud Close Date & Time	30 NOV 2020 23:59

US3342204

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:34:12

TIMEPOINT

DAY 89

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

No

Yes

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

No

Yes

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

Date and time of submission 05 DEC 2020 13:36:43

Patient Cloud Open Date & Time 03 DEC 2020 00:01

Patient Cloud Close Date & Time 07 DEC 2020 23:59

US3342204

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:34:12

TIMEPOINT	DAY 96
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	12 DEC 2020 12:14:38
Patient Cloud Open Date & Time	10 DEC 2020 00:01
Patient Cloud Close Date & Time	14 DEC 2020 23:59

US3342204

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:34:12

TIMEPOINT	DAY 103
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	19 DEC 2020 12:18:17
Patient Cloud Open Date & Time	17 DEC 2020 00:01
Patient Cloud Close Date & Time	21 DEC 2020 23:59

US3342204

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:34:12

TIMEPOINT	DAY 110
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	25 DEC 2020 16:03:30
Patient Cloud Open Date & Time	24 DEC 2020 00:01
Patient Cloud Close Date & Time	28 DEC 2020 23:59

US3342204

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:34:12

TIMEPOINT

DAY 117

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

No

Yes

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

No

Yes

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

Date and time of submission 02 JAN 2021 12:00:41

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

Patient Cloud Close Date & Time 04 JAN 2021 23:59

US3342204

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:34:12

TIMEPOINT	DAY 124
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	09 JAN 2021 10:29:25
Patient Cloud Open Date & Time	07 JAN 2021 00:01
Patient Cloud Close Date & Time	11 JAN 2021 23:59

US3342204

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:34:12

TIMEPOINT	DAY 131
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	16 JAN 2021 12:00:32
Patient Cloud Open Date & Time	14 JAN 2021 00:01
Patient Cloud Close Date & Time	18 JAN 2021 23:59

US3342204

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:34:12

TIMEPOINT	DAY 138
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	23 JAN 2021 12:58:47
Patient Cloud Open Date & Time	21 JAN 2021 00:01
Patient Cloud Close Date & Time	25 JAN 2021 23:59

US3342204

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:34:12

TIMEPOINT	DAY 145
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	30 JAN 2021 12:07:52
Patient Cloud Open Date & Time	28 JAN 2021 00:01
Patient Cloud Close Date & Time	01 FEB 2021 23:59

US3342204

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:34:12

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

Have 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):

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

Date and time of submission 05 FEB 2021 20:43:56

Patient Cloud Open Date & Time 04 FEB 2021 00:01

Patient Cloud Close Date & Time 08 FEB 2021 23:59

US3342204

Folder: Cosmetic Injections and Dermal Fillers

Form: Cosmetic Injection_ Dermal Filler eDiary

Generated On: 11 Aug 2021 22:34:12

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
---	--	---------------------------

US3342204

Folder: Safety Call Day 85 (1)

Form: Safety Call

Data signed: (b) (4) 12 Mar 2021 23:17:36

Generated On: 11 Aug 2021 22:34:12

Was Contact Attempted? Yes
No

Date of Contact or Contact Attempt (*dd MMM yyyy*) 18 DEC 2020

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

Comments

If Contact Not Made, please provide Comments

US3342204

Folder: Safety Call Day 85 (1)

Form: Continuing

Data signed: (b) (4) 12 Mar 2021 23:17:36

Generated On: 11 Aug 2021 22:34:12

Is the participant continuing to the next visit?

Yes

No

Continuing Flag

1

US3342204

Folder: Safety Call Day 119 (1)

Form: Safety Call

Data signed: (b) (4) 12 Mar 2021 23:17:36

Generated On: 11 Aug 2021 22:34:12

Was Contact Attempted? Yes
No

Date of Contact or Contact Attempt (*dd MMM yyyy*) 21 JAN 2021

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

Comments

If Contact Not Made, please provide Comments

US3342204

Folder: Safety Call Day 119 (1)

Form: Continuing

Data signed: (b) (4) 22 Mar 2021 13:27:29

Generated On: 11 Aug 2021 22:34:12

Is the participant continuing to the next visit?

Yes

No

Continuing Flag

US3342204

Folder: Covid-19 Assessment (1)

Form: COVID-19 Contact

Generated On: 11 Aug 2021 22:34:12

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"/>

US3342204

Folder: Covid-19 Assessment (1)

Form: Generate Next COVID-19 Assessment

Generated On: 11 Aug 2021 22:34:12

Generate Next COVID-19 Assessment

Yes

No

US3342204

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

Form: Visit Date

Data signed: (b) (4) 12 Mar 2021 23:17:35

Generated On: 11 Aug 2021 22:34:12

Was this visit performed? Yes
No

Visit date (dd MMM yyyy) 12 JAN 2021

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

Folder OID UNBLND_DECIDE

US3342204

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

Form: Unblinding

Data signed: (b) (4) 12 Mar 2021 23:17:35

Generated On: 11 Aug 2021 22:34:12

Date of updated informed consent (<i>dd MMM yyyy</i>)	12 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>)	12 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

US3342204

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

Form: Vital Signs - Dosing

Data signed: (b) (4) 12 Mar 2021 23:17:35

Generated On: 11 Aug 2021 22:34:12

Height	_____
Weight	_____
BMI (xxx.x)	_____

US3342204

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

Form: Vital Signs - Dosing (1)

Data signed: (b) (4) 12 Mar 2021 23:17:35

Generated On: 11 Aug 2021 22:34:12

Height	_____
Weight	_____
BMI (xxx.x)	_____
Timepoint	Pre-Dose <input checked="" type="radio"/> Post-Dose <input type="radio"/>
Were vital signs assessed?	Yes <input checked="" type="radio"/> No <input type="radio"/>
Date of assessment (dd MMM yyyy)	12 JAN 2021
Time of assessment (00:00-23:59)	08:41 (24 HR)
Vital Signs Date and Time (derived)	12 JAN 2021 08:41
Temperature (xxx.x)	97.8 F
Route of measurement	Oral <input checked="" type="radio"/> Axillary <input type="radio"/> Other <input type="radio"/>
If Other, specify	_____
Pulse (xxx)	86 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	14 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	104 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	72 mmHg
Diastolic Blood Pressure units	MMHG

US3342204

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

Form: Vital Signs - Dosing (2)

Data signed: (b) (4) 12 Mar 2021 23:17:35

Generated On: 11 Aug 2021 22:34:12

Height	_____
Weight	_____
BMI (xxx.x)	_____
Timepoint	Pre-Dose <input type="radio"/> Post-Dose <input checked="" type="radio"/>
Were vital signs assessed?	Yes <input checked="" type="radio"/> No <input type="radio"/>
Date of assessment (dd MMM yyyy)	12 JAN 2021
Time of assessment (00:00-23:59)	10:12 (24 HR)
Vital Signs Date and Time (derived)	12 JAN 2021 10:12
Temperature (xxx.x)	98.3 F
Route of measurement	Oral <input checked="" type="radio"/> Axillary <input type="radio"/> Other <input type="radio"/>
If Other, specify	_____
Pulse (xxx)	94 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	12 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	94 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	67 mmHg
Diastolic Blood Pressure units	MMHG

US3342204

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

Form: Physical Examination

Data signed: (b) (4) 12 Mar 2021 23:17:35

Generated On: 11 Aug 2021 22:34:12

Was the physical examination performed?

Yes

No

Date of examination (dd MMM yyyy)

12 JAN 2021

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

US3342204

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

Form: Pregnancy Test

Data signed: (b) (4) 22 Mar 2021 13:27:29

Generated On: 11 Aug 2021 22:34:12

Was the pregnancy test performed? Yes
No

Date of test (dd MMM yyyy) 12 JAN 2021

Test performed Urine
Serum

Result Positive
Negative

Was FSH sample collected? Yes
No

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

US3342204

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

Form: Exposure

Data signed: (b) (4) 12 Mar 2021 23:17:35

Generated On: 11 Aug 2021 22:34:12

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) 12 JAN 2021

What was the treatment time? (00:00-23:59) 09:35 (24 HR)

Treatment Date and Time (derived) 12 JAN 2021 09:35

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

US3342204

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

Form: Immunogenicity Assessment

Data signed: (b) (4) 12 Mar 2021 23:17:35

Generated On: 11 Aug 2021 22:34:12

Was the sample collected? Yes No

Collection date (*dd MMM yyyy*) 12 JAN 2021

Collection time (*00:00-23:59*) 09:07 (24 HR)

Collection date and time (derived) 12 JAN 2021 09:07

US3342204

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

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Data signed: (b) (4) 12 Mar 2021 23:17:35

Generated On: 11 Aug 2021 22:34:12

Was the sample collected? Yes No

Collection date (*dd MMM yyyy*) 12 JAN 2021

Collection time (*00:00 - 23:59*) 09:08

Collection Date and Time (derived) 12 JAN 2021 09:08

US3342204

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

Form: Continuing

Data signed: (b) (4) 12 Mar 2021 23:17:35

Generated On: 11 Aug 2021 22:34:12

Is the participant continuing to the next visit?

Yes

No

Continuing Flag

1

US3342204

Folder: Safety Call OL-D8 (1)

Form: Safety Call

Data signed: (b) (4) 12 Mar 2021 23:17:36

Generated On: 11 Aug 2021 22:34:12

Was Contact Attempted? Yes
No

Date of Contact or Contact Attempt (*dd MMM yyyy*) 19 JAN 2021

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

Comments

If Contact Not Made, please provide Comments

US3342204

Folder: Safety Call OL-D8 (1)

Form: Continuing

Data signed: (b) (4) 12 Mar 2021 23:17:36

Generated On: 11 Aug 2021 22:34:12

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

US3342204

Folder: OL-D29 (1)

Form: Visit Date

Generated On: 11 Aug 2021 22:34:12

Was this visit performed? Yes
No

Visit date (dd MMM yyyy) _____

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

Folder OID _____

US3342204

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:34:12

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

US3342204

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:34:12

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

US3342204

Folder: OL-D29 (1)

Form: Physical Examination

Generated On: 11 Aug 2021 22:34:12

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.

US3342204

Folder: OL-D29 (1)

Form: Pregnancy Test

Generated On: 11 Aug 2021 22:34:12

Was the pregnancy test performed? Yes
No

Date of test (*dd MMM yyyy*) _____

Test performed Urine
Serum

Result Positive
Negative

Was FSH sample collected? Yes
No

Collection date _____

Collection time _____

Collection date and time (derived) _____

US3342204

Folder: OL-D29 (1)

Form: Exposure

Generated On: 11 Aug 2021 22:34:12

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) _____

What was the treatment date? (dd MMM yyyy) _____

What was the treatment time? (00:00-23:59) _____

Treatment Date and Time (derived) _____

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

What was the frequency of the study treatment dosing? _____

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

US3342204

Folder: OL-D29 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:34:12

Is the participant continuing to the next visit?

Yes

No

Continuing Flag

US3342204

Folder: Adverse Events

Form: Adverse Events Summary

Data signed: (b) (4) 12 Mar 2021 23:17:35

Generated On: 11 Aug 2021 22:34:12

Did the participant experience any adverse events?

Yes

No

If Yes, enter details on the Adverse Events form.

US3342204

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination Summary

Data signed: (b) (4) 12 Mar 2021 23:17:35

Generated On: 11 Aug 2021 22:34:12

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

Yes

No

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

US3342204

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Data signed: (b) (4) 28 Apr 2021 16:37:51

Generated On: 11 Aug 2021 22:34:12

Name of Medication CLARITIN

Prophylaxis Yes
No

Indication SEASONAL ALLERGIES

Dose per administration 10

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

US3342204

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Data signed: (b) (4) 28 Apr 2021 16:37:51

Generated On: 11 Aug 2021 22:34:12

	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

_____ No

If not Ongoing, End date (*dd MMM yyyy*) _____

Was this medication taken for solicited event? _____ Yes

_____ No

Separate Dosage Number (derived) _____

Interval Dosage Unit Number (derived) _____

Interval Dosage Definition (derived) _____ 802

_____ 803

_____ 804

US3342204

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Data signed: (b) (4) 28 Apr 2021 16:37:51

Generated On: 11 Aug 2021 22:34:12

Name of Medication IBUPROFEN

Prophylaxis Yes
No

Indication SEASONAL ALLERGIES

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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US3342204

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Data signed: (b) (4) 28 Apr 2021 16:37:51

Generated On: 11 Aug 2021 22:34:12

	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

_____ No

If not Ongoing, End date (*dd MMM yyyy*) _____

Was this medication taken for solicited event? _____ Yes

_____ No

Separate Dosage Number (derived) _____

Interval Dosage Unit Number (derived) _____

Interval Dosage Definition (derived) _____ 802

_____ 803

_____ 804

US3342204

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Data signed: (b) (4) 28 Apr 2021 16:37:51

Generated On: 11 Aug 2021 22:34:12

Name of Medication INFLUENZA VACCINATION

Prophylaxis Yes
No

Indication INFLUENZA PROPHYLAXIS

Dose per administration 0.5

Dose unit mg
ug
mL
g
IU
tablet
capsule
puff
Other

If dose unit is Other, specify

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

If frequency is Other, specify

Route of administration Oral
Topical
Subcutaneous
Transdermal
Intraocular

US3342204

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Data signed: (b) (4) 28 Apr 2021 16:37:51

Generated On: 11 Aug 2021 22:34:12

	Intramuscular	<input checked="" type="radio"/>
	Respiratory (Inhalation)	<input type="radio"/>
	Intralesional	<input type="radio"/>
	Intraperitoneal	<input type="radio"/>
	Nasal	<input type="radio"/>
	Vaginal	<input type="radio"/>
	Rectal	<input type="radio"/>
	Intravenous	<input type="radio"/>
	Intravenous Bolus	<input type="radio"/>
	Intravenous Drip	<input type="radio"/>
	Other	<input type="radio"/>

If route of administration is Other, specify _____

Start date (*dd MMM yyyy*) 10 NOV 2020

Start date completely unknown False

Ongoing? Yes
No

If not Ongoing, End date (*dd MMM yyyy*) 10 NOV 2020

Was this medication taken for solicited event? Yes
No

Separate Dosage Number (derived) _____

Interval Dosage Unit Number (derived) _____

Interval Dosage Definition (derived) 802
803
804

US3342204

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Data signed: (b) (4) 28 Apr 2021 16:37:51

Generated On: 11 Aug 2021 22:34:12

Name of Medication MRNA-1273 VACCINE

Prophylaxis Yes
No

Indication COVID-19

Dose per administration 100

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

US3342204

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Data signed: (b) (4) 28 Apr 2021 16:37:51

Generated On: 11 Aug 2021 22:34:12

	Intramuscular	<input checked="" type="radio"/>
	Respiratory (Inhalation)	<input type="radio"/>
	Intralesional	<input type="radio"/>
	Intraperitoneal	<input type="radio"/>
	Nasal	<input type="radio"/>
	Vaginal	<input type="radio"/>
	Rectal	<input type="radio"/>
	Intravenous	<input type="radio"/>
	Intravenous Bolus	<input type="radio"/>
	Intravenous Drip	<input type="radio"/>
	Other	<input type="radio"/>

If route of administration is Other, specify _____

Start date (*dd MMM yyyy*) 09 FEB 2021

Start date completely unknown False

Ongoing? Yes
No

If not Ongoing, End date (*dd MMM yyyy*) 09 FEB 2021

Was this medication taken for solicited event? Yes
No

Separate Dosage Number (derived) _____

Interval Dosage Unit Number (derived) _____

Interval Dosage Definition (derived) 802
803
804

US3342204

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures Summary

Data signed: (b) (4) 12 Mar 2021 23:17:35

Generated On: 11 Aug 2021 22:34:12

Were any concomitant procedures performed?

Yes

No

If yes, please complete Concomitant Procedures form.

US3342204

Folder: End of Study (1)

Form: Dosing Discontinuation

Generated On: 11 Aug 2021 22:34:12

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

US3342204

Folder: End of Study (1)

Form: End of Study / Study Discontinuation

Data signed: (b) (4) 12 Mar 2021 23:17:35

Generated On: 11 Aug 2021 22:34:12

Date of study discontinuation/completion (dd MMM yyyy) 10 FEB 2021

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

SUBJECT RECEIVED SECOND DOSE OF MRNA-1273 OUTSIDE OF STUDY SITE. PD NOTED.

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

Audit

US3342204 (Prod: Tekton Research- Austin)

US3342204

Form: Participant Creation

Generated On: 11 Aug 2021 22:34:12

[Participant ID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:31:52
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 17:10:56
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:17:37
User entered 'US3342204'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	08 Sep 2020 15:49:38

US3342204

Form: Participant Creation

Generated On: 11 Aug 2021 22:34:12

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:31:52

US3342204

Folder: Screening

Form: Visit Date

Generated On: 11 Aug 2021 22:34:12

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:55:52
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:17:37
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	08 Sep 2020 17:00:55

US3342204

Folder: Screening

Form: Visit Date

Generated On: 11 Aug 2021 22:34:12

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:55:52
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:17:37
User entered '08 SEP 2020'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	08 Sep 2020 15:49:39

US3342204

Folder: Screening

Form: Visit Date

Generated On: 11 Aug 2021 22:34:12

[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 12:55:52
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:17:37
User entered 'Clinic (Clinic)'	(b) (4) (b) (4), (b) (6)	08 Sep 2020 17:00:55

US3342204

Folder: Screening

Form: Visit Date

Generated On: 11 Aug 2021 22:34:12

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:55:52
User entered 'SCRN'	System	08 Sep 2020 17:00:55

US3342204

Folder: Screening

Form: Demographics

Generated On: 11 Aug 2021 22:34:12

Date of Birth (MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:55:52
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:17:37
User entered (b) (6) 1985'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	08 Sep 2020 15:49:40

US3342204

Folder: Screening

Form: Demographics

Generated On: 11 Aug 2021 22:34:12

[Age](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:55:52
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:17:37
User entered '34'	(b) (4) (b) (4), (b) (6)	08 Sep 2020 17:01:14

US3342204

Folder: Screening

Form: Demographics

Generated On: 11 Aug 2021 22:34:12

[Age Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:55:52
User entered 'YEARS'	System	08 Sep 2020 17:01:14

US3342204

Folder: Screening

Form: Demographics

Generated On: 11 Aug 2021 22:34:12

[Age \(Derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:55:52
User entered '34'	System	08 Sep 2020 17:01:32

US3342204

Folder: Screening

Form: Demographics

Generated On: 11 Aug 2021 22:34:12

[Sex](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:55:52
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:17:37
User entered 'Female (F)'	(b) (4) (b) (4), (b) (6)	08 Sep 2020 17:01:14

US3342204

Folder: Screening

Form: Demographics

Generated On: 11 Aug 2021 22:34:12

[Ethnicity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:55:52
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:17:37
User entered 'Not Hispanic or Latino (NOT HISPANIC OR LATINO)'	(b) (4) (b) (4), (b) (6)	08 Sep 2020 17:01:14

US3342204

Folder: Screening

Form: Demographics

Generated On: 11 Aug 2021 22:34:12

White

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:55:52
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:17:37
User entered '1'	(b) (4) (b) (4), (b) (6)	08 Sep 2020 17:01:14

US3342204

Folder: Screening

Form: Demographics

Generated On: 11 Aug 2021 22:34:12

[Black](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:55:52
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:17:37
User entered '0'	(b) (4) (b) (4), (b) (6)	08 Sep 2020 17:01:14

US3342204

Folder: Screening

Form: Demographics

Generated On: 11 Aug 2021 22:34:12

[Asian](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:55:52
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:17:37
User entered '0'	(b) (4) (b) (4), (b) (6)	08 Sep 2020 17:01:14

US3342204

Folder: Screening

Form: Demographics

Generated On: 11 Aug 2021 22:34:12

[American Indian or Alaska Native](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:55:52
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:17:37
User entered '0'	(b) (4) (b) (4), (b) (6)	08 Sep 2020 17:01:14

US3342204

Folder: Screening

Form: Demographics

Generated On: 11 Aug 2021 22:34:12

[Native Hawaiian or other Pacific Islander](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:55:52
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:17:37
User entered '0'	(b) (4) (b) (4), (b) (6)	08 Sep 2020 17:01:14

US3342204

Folder: Screening

Form: Demographics

Generated On: 11 Aug 2021 22:34:12

[Other](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:55:52
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:17:37
User entered '0'	(b) (4) (b) (4), (b) (6)	08 Sep 2020 17:01:14

US3342204

Folder: Screening

Form: Demographics

Generated On: 11 Aug 2021 22:34:12

If race is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:55:52
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:17:37
User entered empty.	(b) (4) (b) (4), (b) (6)	08 Sep 2020 17:01:14

US3342204

Folder: Screening

Form: Demographics

Generated On: 11 Aug 2021 22:34:12

[Unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:55:52
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:17:37
User entered '0'	(b) (4) (b) (4), (b) (6)	08 Sep 2020 17:01:14

US3342204

Folder: Screening

Form: Demographics

Generated On: 11 Aug 2021 22:34:12

Not reported

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:55:52
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:17:37
User entered '0'	(b) (4) (b) (4), (b) (6)	08 Sep 2020 17:01:14

US3342204

Folder: Screening

Form: Enrollment

Generated On: 11 Aug 2021 22:34:12

Date of Informed Consent (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:55:52
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:17:37
User entered '8 Sep 2020'	(b) (4) (b) (4), (b) (6)	08 Sep 2020 17:01:32

US3342204

Folder: Screening

Form: Enrollment

Generated On: 11 Aug 2021 22:34:12

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:55:52
User entered 'Sep 2020'	System	08 Sep 2020 17:01:32

US3342204

Folder: Screening

Form: Enrollment

Generated On: 11 Aug 2021 22:34:12

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:55:52
User entered '2020'	System	08 Sep 2020 17:01:32

US3342204

Folder: Screening

Form: Enrollment

Generated On: 11 Aug 2021 22:34:12

[Protocol Version](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:55:52
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:17:37
User entered 'Amendment 3 (3)'	(b) (4) (b) (4), (b) (6)	08 Sep 2020 17:01:32

US3342204

Folder: Screening

Form: Enrollment

Generated On: 11 Aug 2021 22:34:12

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:55:52
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:17:37
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	08 Sep 2020 17:01:32

US3342204

Folder: Screening

Form: Enrollment

Generated On: 11 Aug 2021 22:34:12

If No, indicate reason for screen fail

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:55:52
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:17:37
User entered empty.	(b) (4) (b) (4), (b) (6)	08 Sep 2020 17:01:32

US3342204

Folder: Screening

Form: Enrollment

Generated On: 11 Aug 2021 22:34:12

If reason for screen fail is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:55:52
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:17:37
User entered empty.	(b) (4) (b) (4), (b) (6)	08 Sep 2020 17:01:32

US3342204

Folder: Screening

Form: Enrollment

Generated On: 11 Aug 2021 22:34:12

[Was this participant screened previously?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:55:52
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:17:37
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	08 Sep 2020 17:01:32

US3342204

Folder: Screening

Form: Enrollment

Generated On: 11 Aug 2021 22:34:12

[If Yes, previous participant number](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:55:52
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:17:37
User entered empty.	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	08 Sep 2020 15:49:39

US3342204

Folder: Screening

Form: Enrollment

Generated On: 11 Aug 2021 22:34:12

[Enrollment Trigger](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:55:52
User entered '1'	System	08 Sep 2020 17:01:40

US3342204

Folder: Screening

Form: Inclusion/Exclusion Criteria Summary

Generated On: 11 Aug 2021 22:34:12

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:55:52
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:17:37
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	08 Sep 2020 17:01:40

US3342204

Folder: Screening

Form: Medical History Summary

Generated On: 11 Aug 2021 22:34:12

[Were any significant conditions reported?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:55:52
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:17:37
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	08 Sep 2020 17:01:49

US3342204

Folder: Screening

Form: Medical History (1)

Generated On: 11 Aug 2021 22:34:12

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:55:52
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:17:37
User coded data point as SOC: Immune system disorders, HLGT: Allergic conditions, HLT: Atopic disorders, PT: Seasonal allergy, LLT: Seasonal allergy - version MedDRA\\23.0.	Coder Import (b) (4)	08 Sep 2020 18:14:50
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	08 Sep 2020 18:14:50
Data point term sent to Coder	System	08 Sep 2020 18:14:07
User entered 'Seasonal Allergies'	(b) (4), (b) (6)	08 Sep 2020 18:13:53

US3342204

Folder: Screening

Form: Medical History (1)

Generated On: 11 Aug 2021 22:34:12

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:55:52
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:17:37
User entered 'UN UNK 1990'	(b) (4) (b) (4), (b) (6)	08 Sep 2020 18:13:53

US3342204

Folder: Screening

Form: Medical History (1)

Generated On: 11 Aug 2021 22:34:12

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:55:52
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:17:37
User entered '0'	(b) (4) (b) (4), (b) (6)	08 Sep 2020 18:13:53

US3342204

Folder: Screening

Form: Medical History (1)

Generated On: 11 Aug 2021 22:34:12

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:55:52
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:17:37
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	08 Sep 2020 18:13:53

US3342204

Folder: Screening

Form: Medical History (1)

Generated On: 11 Aug 2021 22:34:12

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:55:52
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:17:37
User entered empty.	(b) (4) (b) (4), (b) (6)	08 Sep 2020 18:13:53

US3342204

Folder: Screening

Form: Medical History (1)

Generated On: 11 Aug 2021 22:34:12

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:55:52
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:17:37
User entered '0'	(b) (4) (b) (4), (b) (6)	08 Sep 2020 18:13:53

US3342204

Folder: Screening

Form: Medical History (1)

Generated On: 11 Aug 2021 22:34:12

Start Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:55:52
User entered 'Jan 1990'	System	08 Sep 2020 18:13:53

US3342204

Folder: Screening

Form: Medical History (1)

Generated On: 11 Aug 2021 22:34:12

Start Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:55:52
User entered '1990'	System	08 Sep 2020 18:13:53

US3342204

Folder: Screening

Form: Medical History (1)

Generated On: 11 Aug 2021 22:34:12

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:55:52
User entered empty.	System	08 Sep 2020 18:13:53

US3342204

Folder: Screening

Form: Medical History (1)

Generated On: 11 Aug 2021 22:34:12

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:55:52
User entered empty.	System	08 Sep 2020 18:13:53

US3342204

Folder: Screening

Form: Medical History (2)

Generated On: 11 Aug 2021 22:34:12

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:55:52
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:17:37
User coded data point as SOC: Respiratory, thoracic and mediastinal disorders, HLG: Lower respiratory tract disorders (excl obstruction and infection), HLT: Parenchymal lung disorders NEC, PT: Restrictive pulmonary disease, LLT: Restrictive pulmonary disease - version MedDRA\23.0.	Coder Import (b) (4)	18 Nov 2020 12:05:05
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\23.0.	Coder Import (b) (4)	18 Nov 2020 12:05:05
Data point term sent to Coder	System	08 Sep 2020 18:15:09
User entered 'Restrictive Lung Disease Due Pectus Excavation'	(b) (4), (b) (6)	08 Sep 2020 18:15:03

US3342204

Folder: Screening

Form: Medical History (2)

Generated On: 11 Aug 2021 22:34:12

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:55:52
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:17:37
User entered 'UN UNK 2020'	(b) (4) (b) (4), (b) (6)	08 Sep 2020 18:15:03

US3342204

Folder: Screening

Form: Medical History (2)

Generated On: 11 Aug 2021 22:34:12

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:55:52
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:17:37
User entered '0'	(b) (4) (b) (4), (b) (6)	08 Sep 2020 18:15:03

US3342204

Folder: Screening

Form: Medical History (2)

Generated On: 11 Aug 2021 22:34:12

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:55:52
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:17:37
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	08 Sep 2020 18:15:03

US3342204

Folder: Screening

Form: Medical History (2)

Generated On: 11 Aug 2021 22:34:12

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:55:52
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:17:37
User entered empty.	(b) (4) (b) (4), (b) (6)	08 Sep 2020 18:15:03

US3342204

Folder: Screening

Form: Medical History (2)

Generated On: 11 Aug 2021 22:34:12

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:55:52
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:17:37
User entered '0'	(b) (4) (b) (4), (b) (6)	08 Sep 2020 18:15:03

US3342204

Folder: Screening

Form: Medical History (2)

Generated On: 11 Aug 2021 22:34:12

Start Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:55:52
User entered 'Jan 2020'	System	08 Sep 2020 18:15:03

US3342204

Folder: Screening

Form: Medical History (2)

Generated On: 11 Aug 2021 22:34:12

Start Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:55:52
User entered '2020'	System	08 Sep 2020 18:15:03

US3342204

Folder: Screening

Form: Medical History (2)

Generated On: 11 Aug 2021 22:34:12

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:55:52
User entered empty.	System	08 Sep 2020 18:15:03

US3342204

Folder: Screening

Form: Medical History (2)

Generated On: 11 Aug 2021 22:34:12

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:55:52
User entered empty.	System	08 Sep 2020 18:15:03

US3342204

Folder: Screening

Form: Medical History (3)

Generated On: 11 Aug 2021 22:34:12

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:55:52
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:17:37
User coded data point as SOC: Skin and subcutaneous tissue disorders, HLGT: Skin appendage conditions, HLT: Acnes, PT: Acne, LLT: Acne - version MedDRA\\23.0.	Coder Import (b) (4)	08 Sep 2020 18:16:56
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	08 Sep 2020 18:16:56
Data point term sent to Coder	System	08 Sep 2020 18:16:12
User entered 'Acne'	(b) (4), (b) (6)	08 Sep 2020 18:15:25

US3342204

Folder: Screening

Form: Medical History (3)

Generated On: 11 Aug 2021 22:34:12

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:55:52
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:17:37
User entered 'UN UNK 2000' reason for change: Data Entry Error	(b) (4) (b) (4), (b) (6)	08 Sep 2020 18:16:59
User entered 'UN UNK 2020'	(b) (4), (b) (6)	08 Sep 2020 18:15:25

US3342204

Folder: Screening

Form: Medical History (3)

Generated On: 11 Aug 2021 22:34:12

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:55:52
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:17:37
User entered '0'	(b) (4) (b) (4), (b) (6)	08 Sep 2020 18:15:25

US3342204

Folder: Screening

Form: Medical History (3)

Generated On: 11 Aug 2021 22:34:12

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:55:52
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:17:37
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	08 Sep 2020 18:15:25

US3342204

Folder: Screening

Form: Medical History (3)

Generated On: 11 Aug 2021 22:34:12

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:55:52
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:17:37
User entered empty.	(b) (4) (b) (4), (b) (6)	08 Sep 2020 18:15:25

US3342204

Folder: Screening

Form: Medical History (3)

Generated On: 11 Aug 2021 22:34:12

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:55:52
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:17:37
User entered '0'	(b) (4) (b) (4), (b) (6)	08 Sep 2020 18:15:25

US3342204

Folder: Screening

Form: Medical History (3)

Generated On: 11 Aug 2021 22:34:12

Start Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:55:52
User entered 'Jan 2000'	System	08 Sep 2020 18:16:59
User entered 'Jan 2020'	System	08 Sep 2020 18:15:25

US3342204

Folder: Screening

Form: Medical History (3)

Generated On: 11 Aug 2021 22:34:12

Start Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:55:52
User entered '2000'	System	08 Sep 2020 18:16:59
User entered '2020'	System	08 Sep 2020 18:15:25

US3342204

Folder: Screening

Form: Medical History (3)

Generated On: 11 Aug 2021 22:34:12

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:55:52
User entered empty.	System	08 Sep 2020 18:15:25

US3342204

Folder: Screening

Form: Medical History (3)

Generated On: 11 Aug 2021 22:34:12

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:55:52
User entered empty.	System	08 Sep 2020 18:15:25

US3342204

Folder: Screening

Form: Medical History (4)

Generated On: 11 Aug 2021 22:34:12

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:55:52
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:17:37
User coded data point as SOC: Nervous system disorders, HLGT: Headaches, HLT: Headaches NEC, PT: Headache, LLT: Headache - version MedDRA\\23.0.	Coder Import (b) (4)	08 Sep 2020 18:16:57
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	08 Sep 2020 18:16:57
Data point term sent to Coder	System	08 Sep 2020 18:16:12
User entered 'Headaches'	(b) (4), (b) (6)	08 Sep 2020 18:15:47

US3342204

Folder: Screening

Form: Medical History (4)

Generated On: 11 Aug 2021 22:34:12

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:55:52
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:17:37
User entered 'UN UNK 2000'	(b) (4) (b) (4), (b) (6)	08 Sep 2020 18:15:47

US3342204

Folder: Screening

Form: Medical History (4)

Generated On: 11 Aug 2021 22:34:12

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:55:52
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:17:37
User entered '0'	(b) (4) (b) (4), (b) (6)	08 Sep 2020 18:15:47

US3342204

Folder: Screening

Form: Medical History (4)

Generated On: 11 Aug 2021 22:34:12

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:55:52
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:17:37
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	08 Sep 2020 18:15:47

US3342204

Folder: Screening

Form: Medical History (4)

Generated On: 11 Aug 2021 22:34:12

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:55:52
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:17:37
User entered empty.	(b) (4) (b) (4), (b) (6)	08 Sep 2020 18:15:47

US3342204

Folder: Screening

Form: Medical History (4)

Generated On: 11 Aug 2021 22:34:12

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:55:52
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:17:37
User entered '0'	(b) (4) (b) (4), (b) (6)	08 Sep 2020 18:15:47

US3342204

Folder: Screening

Form: Medical History (4)

Generated On: 11 Aug 2021 22:34:12

Start Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:55:52
User entered 'Jan 2000'	System	08 Sep 2020 18:15:47

US3342204

Folder: Screening

Form: Medical History (4)

Generated On: 11 Aug 2021 22:34:12

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:55:52
User entered '2000'	System	08 Sep 2020 18:15:47

US3342204

Folder: Screening

Form: Medical History (4)

Generated On: 11 Aug 2021 22:34:12

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:55:52
User entered empty.	System	08 Sep 2020 18:15:47

US3342204

Folder: Screening

Form: Medical History (4)

Generated On: 11 Aug 2021 22:34:12

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:55:52
User entered empty.	System	08 Sep 2020 18:15:47

US3342204

Folder: Screening

Form: Medical History (5)

Generated On: 11 Aug 2021 22:34:12

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:55:52
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:17:37
User coded data point as SOC: Congenital, familial and genetic disorders, HLGT: Musculoskeletal and connective tissue disorders congenital, HLT: Musculoskeletal and connective tissue disorders of trunk congenital (excl spine), PT: Pectus excavatum, LLT: Pectus excavatum - version MedDRA\\23.0.	Coder Import (b) (4)	08 Sep 2020 18:18:45
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	08 Sep 2020 18:18:45
Data point term sent to Coder	System	08 Sep 2020 18:17:14
User entered 'Pectus Excavatum'	(b) (4), (b) (6)	08 Sep 2020 18:16:31

US3342204

Folder: Screening

Form: Medical History (5)

Generated On: 11 Aug 2021 22:34:12

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:55:52
User signature succeeded.	Paul Pickrell (b) (4) (b) (4)	12 Mar 2021 23:17:37
User closed query 'Start date is missing and Start date is completely unknown has not been checked. Please correct.' (Site from System).	System	09 Sep 2020 20:13:00
User entered (b) (6) 1985' reason for change: Data Entry Error	John Luna (b) (4)	09 Sep 2020 20:13:00
User opened query 'Start date is missing and Start date is completely unknown has not been checked. Please correct.' (Site from System).	System	08 Sep 2020 18:16:31
User entered empty.	(b) (4), (b) (6)	08 Sep 2020 18:16:31

US3342204

Folder: Screening

Form: Medical History (5)

Generated On: 11 Aug 2021 22:34:12

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:55:52
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:17:37
User entered '0'	(b) (4) (b) (4), (b) (6)	08 Sep 2020 18:16:31

US3342204

Folder: Screening

Form: Medical History (5)

Generated On: 11 Aug 2021 22:34:12

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:55:52
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:17:37
User closed query 'Data is required. Please complete.' (Site from System).	(b) (4) (b) (4), (b) (6)	11 Sep 2020 09:44:59
User entered 'Yes (Y)' reason for change: Data Entry Error	John Luna (b) (4)	09 Sep 2020 20:13:00
Query 'Data is required. Please complete.' answered with 'data corrected' (Site from System).	John Luna (b) (4)	09 Sep 2020 20:12:44
User opened query 'Data is required. Please complete.' (Site from System).	System	08 Sep 2020 18:16:31
User entered empty.	(b) (4), (b) (6)	08 Sep 2020 18:16:31

US3342204

Folder: Screening

Form: Medical History (5)

Generated On: 11 Aug 2021 22:34:12

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:55:52
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:17:37
User entered empty.	(b) (4) (b) (4), (b) (6)	08 Sep 2020 18:16:31

US3342204

Folder: Screening

Form: Medical History (5)

Generated On: 11 Aug 2021 22:34:12

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:55:52
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:17:37
User entered '0'	(b) (4) (b) (4), (b) (6)	08 Sep 2020 18:16:31

US3342204

Folder: Screening

Form: Medical History (5)

Generated On: 11 Aug 2021 22:34:12

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:55:52
User entered (b) (6) 1985'	System	09 Sep 2020 20:13:00
User entered empty.	System	08 Sep 2020 18:16:31

US3342204

Folder: Screening

Form: Medical History (5)

Generated On: 11 Aug 2021 22:34:12

Start Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:55:52
User entered '1985'	System	09 Sep 2020 20:13:00
User entered empty.	System	08 Sep 2020 18:16:31

US3342204

Folder: Screening

Form: Medical History (5)

Generated On: 11 Aug 2021 22:34:12

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:55:52
User entered empty.	System	08 Sep 2020 18:16:31

US3342204

Folder: Screening

Form: Medical History (5)

Generated On: 11 Aug 2021 22:34:12

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:55:52
User entered empty.	System	08 Sep 2020 18:16:31

US3342204

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 22:34:12

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:55:52
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:17:37
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	08 Sep 2020 17:03:33

US3342204

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 22:34:12

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:55:52
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:17:37
User entered '8 Sep 2020'	(b) (4) (b) (4), (b) (6)	08 Sep 2020 17:03:33

US3342204

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 22:34:12

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:55:52
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:17:37
User entered '10:32'	(b) (4) (b) (4), (b) (6)	08 Sep 2020 17:03:33

US3342204

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 22:34:12

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:55:52
User entered '8 Sep 2020 10:32'	System	08 Sep 2020 17:03:33

US3342204

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 22:34:12

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:55:52
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:17:37
User entered '167.5' cm	(b) (4) (b) (4), (b) (6)	08 Sep 2020 17:03:33
DataPoint set to visible.	System	08 Sep 2020 17:01:40

US3342204

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 22:34:12

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:55:52
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:17:37
User entered '55.1' kg	(b) (4) (b) (4), (b) (6)	08 Sep 2020 17:03:33
DataPoint set to visible.	System	08 Sep 2020 17:01:40

US3342204

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 22:34:12

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:55:52
User entered '19.63912'	System	08 Sep 2020 17:03:33
DataPoint set to visible.	System	08 Sep 2020 17:01:40

US3342204

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 22:34:12

[BMI units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:55:52
User entered 'kg/m2'	System	08 Sep 2020 17:03:33
DataPoint set to visible.	System	08 Sep 2020 17:01:40

US3342204

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 22:34:12

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:55:52
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:17:37
User entered missing code ND - Not Done.	(b) (4) (b) (4), (b) (6)	08 Sep 2020 17:03:33

US3342204

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 22:34:12

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:55:52
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:17:37
User entered empty.	(b) (4) (b) (4), (b) (6)	08 Sep 2020 17:03:33

US3342204

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 22:34:12

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:55:52
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:17:37
User entered empty.	(b) (4) (b) (4), (b) (6)	08 Sep 2020 17:03:33

US3342204

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 22:34:12

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:55:52
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:17:37
User entered missing code ND - Not Done.	(b) (4) (b) (4), (b) (6)	08 Sep 2020 17:03:33

US3342204

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 22:34:12

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:55:52
User entered 'bpm'	System	08 Sep 2020 17:03:33

US3342204

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 22:34:12

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:55:52
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:17:37
User entered missing code ND - Not Done.	(b) (4) (b) (4), (b) (6)	08 Sep 2020 17:03:33

US3342204

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 22:34:12

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:55:52
User entered 'breaths/min'	System	08 Sep 2020 17:03:33

US3342204

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 22:34:12

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:55:52
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:17:37
User entered missing code ND - Not Done.	(b) (4) (b) (4), (b) (6)	08 Sep 2020 17:03:33

US3342204

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 22:34:12

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:55:52
User entered 'mmHg'	System	08 Sep 2020 17:03:33

US3342204

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 22:34:12

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:55:52
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:17:37
User entered missing code ND - Not Done.	(b) (4) (b) (4), (b) (6)	08 Sep 2020 17:03:33

US3342204

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 22:34:12

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:55:52
User entered 'mmHg'	System	08 Sep 2020 17:03:33

US3342204

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 22:34:12

[Height \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:55:52

US3342204

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 22:34:12

[Weight \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:55:52

US3342204

Folder: Screening

Form: Physical Examination

Generated On: 11 Aug 2021 22:34:12

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:55:52
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:17:37
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	08 Sep 2020 17:03:41

US3342204

Folder: Screening

Form: Physical Examination

Generated On: 11 Aug 2021 22:34:12

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:55:52
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:17:37
User entered '8 Sep 2020'	(b) (4) (b) (4), (b) (6)	08 Sep 2020 17:03:41

US3342204

Folder: Screening

Form: Childbearing Potential

Generated On: 11 Aug 2021 22:34:12

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:55:52
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:17:37
User entered '08 Sep 2020' reason for change: Data Entry Error	(b) (4)	17 Nov 2020 15:40:15
User entered '8 Sep 2020'	Morgan Schulle (b) (4)	08 Sep 2020 18:18:05
	(b) (4)	
	(b) (4), (b) (6)	

US3342204

Folder: Screening

Form: Childbearing Potential

Generated On: 11 Aug 2021 22:34:12

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:55:52
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:17:37
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	08 Sep 2020 18:18:05

US3342204

Folder: Screening

Form: Childbearing Potential

Generated On: 11 Aug 2021 22:34:12

If No, what is the reason?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:55:52
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:17:37
User entered empty.	(b) (4) (b) (4), (b) (6)	08 Sep 2020 18:18:05

US3342204

Folder: Screening

Form: Childbearing Potential

Generated On: 11 Aug 2021 22:34:12

If Partner medically sterile or Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:55:52
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:17:37
User entered empty.	(b) (4) (b) (4), (b) (6)	08 Sep 2020 18:18:05

US3342204

Folder: Screening

Form: Childbearing Potential

Generated On: 11 Aug 2021 22:34:12

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:55:52
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:17:37
User entered empty.	(b) (4) (b) (4), (b) (6)	08 Sep 2020 18:18:05

US3342204

Folder: Screening

Form: Childbearing Potential

Generated On: 11 Aug 2021 22:34:12

Date of surgery unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:55:52
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:17:37
User entered '0'	(b) (4) (b) (4), (b) (6)	08 Sep 2020 18:18:05

US3342204

Folder: Screening

Form: Childbearing Potential

Generated On: 11 Aug 2021 22:34:12

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:55:52
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:17:37
User entered empty.	(b) (4) (b) (4), (b) (6)	08 Sep 2020 18:18:05

US3342204

Folder: Screening

Form: Childbearing Potential

Generated On: 11 Aug 2021 22:34:12

Date of last menstruation unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:55:52
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:17:37
User entered '0'	(b) (4) (b) (4), (b) (6)	08 Sep 2020 18:18:05

US3342204

Folder: Screening

Form: Pregnancy Test

Generated On: 11 Aug 2021 22:34:12

[Was the pregnancy test performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:55:52
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:17:37
User entered 'Yes (Y)'	(b) (4) Morgan Schulle (b) (4)	09 Sep 2020 14:11:47

US3342204

Folder: Screening

Form: Pregnancy Test

Generated On: 11 Aug 2021 22:34:12

Date of test (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:55:52
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:17:37
User entered '8 Sep 2020'	(b) (4) Morgan Schulle (b) (4)	09 Sep 2020 14:11:47

US3342204

Folder: Screening

Form: Pregnancy Test

Generated On: 11 Aug 2021 22:34:12

[Test performed](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:55:52
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:17:37
User entered 'Urine (URINE)'	(b) (4) Morgan Schulle (b) (4)	09 Sep 2020 14:11:47

US3342204

Folder: Screening

Form: Pregnancy Test

Generated On: 11 Aug 2021 22:34:12

[Result](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:55:52
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:17:37
User entered 'Negative (NEGATIVE)'	(b) (4) Morgan Schulle (b) (4)	09 Sep 2020 14:11:47

US3342204

Folder: Screening

Form: Pregnancy Test

Generated On: 11 Aug 2021 22:34:12

Was FSH sample collected?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:55:52
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:17:37
User entered 'No (N)'	(b) (4) Morgan Schulle (b) (4)	09 Sep 2020 14:11:47

US3342204

Folder: Screening

Form: Pregnancy Test

Generated On: 11 Aug 2021 22:34:12

[Collection date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:55:52
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:17:37
User entered empty; reason for change Data Entry Error	(b) (4)	
	Morgan Schulle (b) (4)	09 Sep 2020 16:16:59
User entered '8 Sep 2020'	(b) (4)	
	Morgan Schulle (b) (4)	09 Sep 2020 14:11:47
	(b) (4)	

US3342204

Folder: Screening

Form: Pregnancy Test

Generated On: 11 Aug 2021 22:34:12

[Collection time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:55:52
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:17:37
User entered empty; reason for change Data Entry Error	(b) (4)	
	Morgan Schulle (b) (4)	09 Sep 2020 16:16:59
User entered '10:37'	(b) (4)	
	Morgan Schulle (b) (4)	09 Sep 2020 14:11:47
	(b) (4)	

US3342204

Folder: Screening

Form: Pregnancy Test

Generated On: 11 Aug 2021 22:34:12

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:55:52
User entered empty.	System	09 Sep 2020 16:16:59
User entered '8 Sep 2020 10:37'	System	09 Sep 2020 14:11:47

US3342204

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 22:34:12

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 12:55:52
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:17:37
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	08 Sep 2020 17:04:37

US3342204

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 22:34:12

[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 12:55:52
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:17:37
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	08 Sep 2020 17:04:37

US3342204

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 22:34:12

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 12:55:52
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:17:37
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	08 Sep 2020 17:04:37

US3342204

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 22:34:12

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 12:55:52
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:17:37
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	08 Sep 2020 17:04:37

US3342204

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 22:34:12

[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 12:55:52
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:17:37
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	08 Sep 2020 17:04:37

US3342204

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 22:34:12

[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 12:55:52
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:17:37
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	08 Sep 2020 17:04:37

US3342204

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 22:34:12

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 12:55:52
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:17:37
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	08 Sep 2020 17:04:37

US3342204

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 22:34:12

[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 12:55:52
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:17:37
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	08 Sep 2020 17:04:37

US3342204

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 22:34:12

[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 12:55:52
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:17:37
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	08 Sep 2020 17:04:37

US3342204

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 22:34:12

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 12:55:52
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:17:37
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	08 Sep 2020 17:04:37

US3342204

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 22:34:12

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 12:55:52
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:17:37
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	08 Sep 2020 17:04:37

US3342204

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 22:34:12

[Other](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:55:52
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:17:37
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	08 Sep 2020 17:04:37

US3342204

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 22:34:12

[Specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:55:52
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:17:37
User entered empty.	(b) (4) (b) (4), (b) (6)	08 Sep 2020 17:04:37

US3342204

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 22:34:12

No Risk Identified

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:55:52
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:17:37
User entered '0'	(b) (4) (b) (4), (b) (6)	08 Sep 2020 17:04:37

US3342204

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 22:34:12

[Resides in Nursing Home or Assisted Living Facility](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:55:52
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:17:37
User entered '0'	(b) (4) (b) (4), (b) (6)	08 Sep 2020 17:04:37

US3342204

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 22:34:12

[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 12:55:52
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:17:37
User entered '0'	(b) (4) (b) (4), (b) (6)	08 Sep 2020 17:04:37

US3342204

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 22:34:12

[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 12:55:52
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:17:37
User entered '0'	(b) (4) (b) (4), (b) (6)	08 Sep 2020 17:04:37

US3342204

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 22:34:12

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 12:55:52
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:17:37
User entered '0'	(b) (4) (b) (4), (b) (6)	08 Sep 2020 17:04:37

US3342204

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 22:34:12

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:55:52
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:17:37
User entered '1'	(b) (4) (b) (4), (b) (6)	08 Sep 2020 17:04:37

US3342204

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 22:34:12

[Other](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:55:52
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:17:37
User entered '0'	(b) (4) (b) (4), (b) (6)	08 Sep 2020 17:04:37

US3342204

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 22:34:12

[Specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:55:52
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:17:37
User entered empty.	(b) (4) (b) (4), (b) (6)	08 Sep 2020 17:04:37

US3342204

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 11 Aug 2021 22:34:12

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:55:52
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:17:37
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	08 Sep 2020 17:04:52

US3342204

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 11 Aug 2021 22:34:12

Visit date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:55:52
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:17:37
User entered '8 Sep 2020'	(b) (4) (b) (4), (b) (6)	08 Sep 2020 17:04:52

US3342204

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 11 Aug 2021 22:34:12

[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 12:55:52
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:17:37
User entered 'Clinic (Clinic)'	(b) (4) (b) (4), (b) (6)	08 Sep 2020 17:04:52

US3342204

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 11 Aug 2021 22:34:12

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:55:52
User entered 'VISIT1'	System	08 Sep 2020 17:04:52

US3342204

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 11 Aug 2021 22:34:12

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:55:52
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:17:37
User entered '08 SEP 2020'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	08 Sep 2020 16:09:45

US3342204

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 11 Aug 2021 22:34:12

[What was the participant's randomization number?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:55:52
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:17:37
User entered '145718'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	08 Sep 2020 16:09:45

US3342204

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 11 Aug 2021 22:34:12

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:55:52
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:17:37
User entered '>=18 and <65 years and at risk (2)'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	08 Sep 2020 16:09:45

US3342204

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 11 Aug 2021 22:34:12

Chronic lung disease (eg, emphysema and chronic bronchitis, idiopathic pulmonary fibrosis and cystic fibrosis, or moderate to severe asthma)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:55:52
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:17:37
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	08 Sep 2020 17:05:22

US3342204

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 11 Aug 2021 22:34:12

Significant cardiac disease (eg, heart failure, coronary artery disease, congenital heart disease, cardiomyopathies, and pulmonary hypertension)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:55:52
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:17:37
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	08 Sep 2020 17:05:22

US3342204

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 11 Aug 2021 22:34:12

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:55:52
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:17:37
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	08 Sep 2020 17:05:22

US3342204

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 11 Aug 2021 22:34:12

Diabetes (Type I, Type 2, or gestational)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:55:52
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:17:37
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	08 Sep 2020 17:05:22

US3342204

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 11 Aug 2021 22:34:12

[Liver Disease](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:55:52
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:17:37
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	08 Sep 2020 17:05:22

US3342204

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 11 Aug 2021 22:34:12

Human Immunodeficiency Virus (HIV) infection

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:55:52
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:17:37
User closed query 'Per CDM: This field requires a Yes or No response. Please complete.' (Site from DM).	(b) (4) (b) (4), (b) (6)	04 Dec 2020 15:16:25
Query 'Per CDM: This field requires a Yes or No response. Please complete.' answered with 'Answered' (Site from DM).	Olivia Hapanowicz (b) (4)	03 Dec 2020 23:27:56
User entered 'No (N)'	Olivia Hapanowicz (b) (4)	03 Dec 2020 23:27:51
User opened query 'Per CDM: This field requires a Yes or No response. Please complete.' (Site from DM).	(b) (4) (b) (4), (b) (6)	02 Dec 2020 21:59:40
Amendment Manager: DataPoint set to visible.	System	19 Sep 2020 05:38:36
Amendment Manager inserted this DataPoint.	System	19 Sep 2020 05:38:34

US3342204

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 11 Aug 2021 22:34:12

[Height](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:55:52
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:17:37
User entered missing code ND - Not Done.	(b) (4) (b) (4), (b) (6)	08 Sep 2020 17:06:34

US3342204

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 11 Aug 2021 22:34:12

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:55:52
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:17:37
User entered missing code ND - Not Done.	(b) (4) (b) (4), (b) (6)	08 Sep 2020 17:06:34

US3342204

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 11 Aug 2021 22:34:12

[Height](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:55:52
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:17:37
User entered missing code ND - Not Done.	(b) (4) (b) (4), (b) (6)	08 Sep 2020 17:06:34

US3342204

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 11 Aug 2021 22:34:12

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:55:52
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:17:37
User entered missing code ND - Not Done.	(b) (4) (b) (4), (b) (6)	08 Sep 2020 17:06:34

US3342204

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:34:12

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:55:52
User accepted default value 'Pre-Dose (PREDOSE)'	(b) (4), (b) (6)	08 Sep 2020 17:06:34

US3342204

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:34:12

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:55:52
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:17:37
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	08 Sep 2020 17:06:34

US3342204

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:34:12

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:55:52
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:17:37
User entered '8 Sep 2020'	(b) (4) (b) (4), (b) (6)	08 Sep 2020 17:06:34

US3342204

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:34:12

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:55:52
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:17:37
User entered '10:32'	(b) (4) (b) (4), (b) (6)	08 Sep 2020 17:06:34

US3342204

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:34:12

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:55:52
User entered '8 Sep 2020 10:32'	System	08 Sep 2020 17:06:34

US3342204

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:34:12

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:55:52
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:17:37
User closed query 'Data entered is non-conformant. Please correct.' (Site from System).	(b) (4)	09 Sep 2020 20:14:21
User entered '98.1' F reason for change: Data Entry Error	John Luna (b) (4)	09 Sep 2020 20:14:21
User opened query 'Data entered is non-conformant. Please correct.' (Site from System).	System	08 Sep 2020 17:06:34
User entered '98.1' (non-conformant).	(b) (4), (b) (6)	08 Sep 2020 17:06:34

US3342204

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:34:12

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:55:52
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:17:37
User entered 'Oral (Oral)'	(b) (4) (b) (4), (b) (6)	08 Sep 2020 17:06:34

US3342204

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:34:12

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:55:52
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:17:37
User entered empty.	(b) (4) (b) (4), (b) (6)	08 Sep 2020 17:06:34

US3342204

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:34:12

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:55:52
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:17:37
User entered '76'	(b) (4) (b) (4), (b) (6)	08 Sep 2020 17:06:34

US3342204

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:34:12

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:55:52
User entered 'bpm'	System	08 Sep 2020 17:06:34

US3342204

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:34:12

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:55:52
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:17:37
User entered '13'	(b) (4) (b) (4), (b) (6)	08 Sep 2020 17:06:34

US3342204

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:34:12

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:55:52
User entered 'breaths/min'	System	08 Sep 2020 17:06:34

US3342204

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:34:12

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:55:52
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:17:37
User entered '103'	(b) (4) (b) (4), (b) (6)	08 Sep 2020 17:06:34

US3342204

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:34:12

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:55:52
User entered 'mmHg'	System	08 Sep 2020 17:06:34

US3342204

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:34:12

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:55:52
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:17:37
User entered '73'	(b) (4) (b) (4), (b) (6)	08 Sep 2020 17:06:34

US3342204

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:34:12

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:55:52
User entered 'mmHg'	System	08 Sep 2020 17:06:34

US3342204

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 11 Aug 2021 22:34:12

[Height](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:55:52
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:17:37
User entered missing code ND - Not Done.	(b) (4) (b) (4), (b) (6)	08 Sep 2020 17:06:34

US3342204

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 11 Aug 2021 22:34:12

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:55:52
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:17:37
User entered missing code ND - Not Done.	(b) (4) (b) (4), (b) (6)	08 Sep 2020 17:06:34

US3342204

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:34:12

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:55:52
User accepted default value 'Post-Dose (POSTDOSE)'	(b) (4), (b) (6)	08 Sep 2020 17:06:34

US3342204

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:34:12

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:55:52
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:17:37
User closed query 'Data is required. Please complete.' (Site from System).	(b) (4) (b) (4), (b) (6)	14 Sep 2020 10:15:25
User entered 'Yes (Y)' reason for change: Data Entry Error	John Luna (b) (4)	09 Sep 2020 20:16:17
Query 'Data is required. Please complete.' answered with 'data corrected' (Site from System).	John Luna (b) (4)	09 Sep 2020 20:14:38
User opened query 'Data is required. Please complete.' (Site from System).	System	08 Sep 2020 17:06:34
User entered empty.	(b) (4), (b) (6)	08 Sep 2020 17:06:34

US3342204

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:34:12

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:55:52
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:17:37
User entered '8 Sep 2020' reason for change: Data Entry Error	(b) (4)	
User entered empty.	John Luna (b) (4)	09 Sep 2020 20:16:17
	(b) (4), (b) (6)	08 Sep 2020 17:06:34

US3342204

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:34:12

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:55:52
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:17:37
User entered '12:20' reason for change: Data Entry Error	(b) (4)	
	John Luna (b) (4)	09 Sep 2020 20:16:17
User entered empty.	(b) (4), (b) (6)	08 Sep 2020 17:06:34

US3342204

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:34:12

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:55:52
User entered '8 Sep 2020 12:20'	System	09 Sep 2020 20:16:17
User entered empty.	System	08 Sep 2020 17:06:34

US3342204

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:34:12

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:55:52
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:17:37
User entered '97.3' F reason for change: Data Entry Error	(b) (4)	
User entered empty.	John Luna (b) (4)	09 Sep 2020 20:16:17
	(b) (4), (b) (6)	08 Sep 2020 17:06:34

US3342204

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:34:12

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:55:52
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:17:37
User entered 'Oral (Oral)' reason for change: Data Entry Error	(b) (4)	
User entered empty.	John Luna (b) (4)	09 Sep 2020 20:16:17
	(b) (4), (b) (6)	08 Sep 2020 17:06:34

US3342204

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:34:12

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:55:52
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:17:37
User entered empty.	(b) (4) (b) (4), (b) (6)	08 Sep 2020 17:06:34

US3342204

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:34:12

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:55:52
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:17:37
User entered '55' reason for change: Data Entry Error	(b) (4)	
User entered empty.	John Luna (b) (4)	09 Sep 2020 20:16:17
	(b) (4), (b) (6)	08 Sep 2020 17:06:34

US3342204

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:34:12

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:55:52
User entered 'bpm'	System	09 Sep 2020 20:16:17
User entered empty.	System	08 Sep 2020 17:06:34

US3342204

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:34:12

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:55:52
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:17:37
User entered '16' reason for change: Data Entry Error	(b) (4)	
User entered empty.	John Luna (b) (4)	09 Sep 2020 20:16:17
	(b) (4), (b) (6)	08 Sep 2020 17:06:34

US3342204

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:34:12

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:55:52
User entered 'breaths/min'	System	09 Sep 2020 20:16:17
User entered empty.	System	08 Sep 2020 17:06:34

US3342204

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:34:12

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:55:52
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:17:37
User entered '109' reason for change: Data Entry Error	(b) (4)	
User entered empty.	John Luna (b) (4)	09 Sep 2020 20:16:17
	(b) (4), (b) (6)	08 Sep 2020 17:06:34

US3342204

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:34:12

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:55:52
User entered 'mmHg'	System	09 Sep 2020 20:16:17
User entered empty.	System	08 Sep 2020 17:06:34

US3342204

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:34:12

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:55:52
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:17:37
User entered '75' reason for change: Data Entry Error	(b) (4)	
User entered empty.	John Luna (b) (4)	09 Sep 2020 20:16:17
	(b) (4), (b) (6)	08 Sep 2020 17:06:34

US3342204

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:34:12

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:55:52
User entered 'mmHg'	System	09 Sep 2020 20:16:17
User entered empty.	System	08 Sep 2020 17:06:34

US3342204

Folder: Visit 1 Day 1

Form: Physical Examination

Generated On: 11 Aug 2021 22:34:12

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:55:52
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:17:37
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	08 Sep 2020 17:06:39

US3342204

Folder: Visit 1 Day 1

Form: Physical Examination

Generated On: 11 Aug 2021 22:34:12

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:55:52
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:17:37
User entered empty.	(b) (4) (b) (4), (b) (6)	08 Sep 2020 17:06:39

US3342204

Folder: Visit 1 Day 1

Form: Pregnancy Test

Generated On: 11 Aug 2021 22:34:12

[Was the pregnancy test performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:55:52
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:17:37
User closed query 'Per CDM: Thank you. Per version 1.0 of the CCGs data was entered correctly, however; to eliminate duplicate data the newest version 2.0 of the CCGs will have updated data entry guidelines. Per Sponsor, If Screening and Visit 1 Day 1 are done on the same day, please enter Pregnancy Test (if applicable) at Screening, and select No at Visit 1 Day 1 Pregnancy Test. Thank you.' (Site from DM).	(b) (4), (b) (6)	09 Nov 2020 16:48:23
Query 'Per CDM: Thank you. Per version 1.0 of the CCGs data was entered correctly, however; to eliminate duplicate data the newest version 2.0 of the CCGs will have updated data entry guidelines. Per Sponsor, If Screening and Visit 1 Day 1 are done on the same day, please enter Pregnancy Test (if applicable) at Screening, and select No at Visit 1 Day 1 Pregnancy Test. Thank you.' answered with 'Pregnancy test listed only for screening visit ' (Site from DM).	(b) (4), (b) (6)	05 Nov 2020 22:51:16
User entered 'No (N)' reason for change: Data Entry Error	(b) (4), (b) (6)	05 Nov 2020 22:51:09
User opened query 'Per CDM: Thank you. Per version 1.0 of the CCGs data was entered correctly, however; to eliminate duplicate data the newest version 2.0 of the CCGs will have updated data entry guidelines. Per Sponsor, If Screening and Visit 1 Day 1 are done on the same day, please enter Pregnancy Test (if applicable) at Screening, and select No at Visit 1 Day 1 Pregnancy Test. Thank you.' (Site from DM).	(b) (4), (b) (6)	25 Sep 2020 19:00:02
User closed query 'Per CDM: Thank you for your answer. However, please be aware that Screening and Visit 1 Day 1 "Dates" are the same which means that Visit 1 Day 1 "Pregnancy Test" form is duplicate of the pregnancy test performed at screening visit. Kindly consider only keeping one record (at screening) and updating this assessment as "No". Thank you!' (Site from DM).	(b) (4), (b) (6)	25 Sep 2020 18:59:23

US3342204

Folder: Visit 1 Day 1

Form: Pregnancy Test

Generated On: 11 Aug 2021 22:34:12

[Was the pregnancy test performed?](#)

Audit	User	Time (GMT)
Query ' Per CDM: Thank you for your answer. However, please be aware that Screening and Visit 1 Day 1 "Dates" are the same which means that Visit 1 Day 1 "Pregnancy Test" form is duplicate of the pregnancy test performed at screening visit. Kindly consider only keeping one record (at screening) and updating this assessment as "No". Thank you!' answered with 'Per CRF guidelines, both screening and baseline pregnancy test CRFs are to be completed if dosed same day as screening' (Site from DM).	Eileen Euperio (b) (4) (b) (4)	25 Sep 2020 14:50:28
User opened query ' Per CDM: Thank you for your answer. However, please be aware that Screening and Visit 1 Day 1 "Dates" are the same which means that Visit 1 Day 1 "Pregnancy Test" form is duplicate of the pregnancy test performed at screening visit. Kindly consider only keeping one record (at screening) and updating this assessment as "No". Thank you!' (Site from DM).	(b) (4), (b) (6)	21 Sep 2020 07:30:45
User closed query 'Per CDM: Thank you for your answer. However, please be aware that Screening and Visit 1 Day 1 "Dates" are the same which means that Visit 1 Day 1 "Pregnancy Test" form is duplicate of the pregnancy test performed at screening visit. Kindly consider only keeping one record (at screening) and updating this assessment as "No". Thank you!' (Site from DM).	(b) (4), (b) (6)	21 Sep 2020 07:30:45

US3342204

Folder: Visit 1 Day 1

Form: Pregnancy Test

Generated On: 11 Aug 2021 22:34:12

[Was the pregnancy test performed?](#)

Audit	User	Time (GMT)
Query 'Per CDM: Thank you for your answer. However, please be aware that Screening and Visit 1 Day 1 "Dates" are the same which means that Visit 1 Day 1 "Pregnancy Test" form is duplicate of the pregnancy test performed at screening visit. Kindly consider only keeping one record (at screening) and updating this assessment as "No". Thank you!' answered with 'Understood. Screening date and Visit1 dates are the same due to the visit being a combination Screening/Visit1 Day1 in clinic visit. Per the current eCRF Completion Guidelines, pages 15 and 16, under "DATA REQUIREMENTS", the information required to be input is listed as "Pregnancy Test (if applicable)" in the Screening Visit folder and again information is required to be input listed as "Pregnancy Test (if applicable)" in the Visit 1 Day 1 folder.' (Site from DM).	Darrell O'Brien (b) (4) (b) (4)	18 Sep 2020 17:48:44
User opened query 'Per CDM: Thank you for your answer. However, please be aware that Screening and Visit 1 Day 1 "Dates" are the same which means that Visit 1 Day 1 "Pregnancy Test" form is duplicate of the pregnancy test performed at screening visit. Kindly consider only keeping one record (at screening) and updating this assessment as "No". Thank you!' (Site from DM).	(b) (4), (b) (6)	18 Sep 2020 06:41:56
User closed query 'Per CDM: This data seems to be a duplicate of the pregnancy test performed at screening visit. Kindly consider only keeping one record (at screening) and updating this assessment as "No" and keeping the eCRF blank at Visit 1 Day 1.' (Site from DM).	(b) (4), (b) (6)	18 Sep 2020 06:41:56

US3342204

Folder: Visit 1 Day 1

Form: Pregnancy Test

Generated On: 11 Aug 2021 22:34:12

[Was the pregnancy test performed?](#)

Audit	User	Time (GMT)
Query 'Per CDM: This data seems to be a duplicate of the pregnancy test performed at screening visit. Kindly consider only keeping one record (at screening) and updating this assessment as "No" and keeping the eCRF blank at Visit 1 Day 1.' answered with 'Understood. However, per the current eCRF Completion Guidelines, pages 15 and 16, under "DATA REQUIREMENTS", the information required to be input is listed as "Pregnancy Test (if applicable)" in the Screening Visit folder and again information is required to be input listed as "Pregnancy Test (if applicable)" in the Visit 1 Day 1 folder.' (Site from DM).	Darrell O'Brien (b) (4) (b) (4)	17 Sep 2020 22:35:52
User opened query 'Per CDM: This data seems to be a duplicate of the pregnancy test performed at screening visit. Kindly consider only keeping one record (at screening) and updating this assessment as "No" and keeping the eCRF blank at Visit 1 Day 1.' (Site from DM).	(b) (4), (b) (6)	16 Sep 2020 11:08:11
User entered 'Yes (Y)'	(b) (4), (b) (6)	08 Sep 2020 18:18:43

US3342204

Folder: Visit 1 Day 1

Form: Pregnancy Test

Generated On: 11 Aug 2021 22:34:12

Date of test (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:55:52
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:17:37
User entered empty; reason for change Data Entry Error	(b) (4) (b) (4), (b) (6)	05 Nov 2020 22:51:09
User entered '8 Sep 2020'	(b) (4), (b) (6)	08 Sep 2020 18:18:43

US3342204

Folder: Visit 1 Day 1

Form: Pregnancy Test

Generated On: 11 Aug 2021 22:34:12

[Test performed](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:55:52
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:17:37
User entered empty; reason for change Data Entry Error	(b) (4) (b) (4), (b) (6)	05 Nov 2020 22:51:09
User entered 'Urine (URINE)'	(b) (4), (b) (6)	08 Sep 2020 18:18:43

US3342204

Folder: Visit 1 Day 1

Form: Pregnancy Test

Generated On: 11 Aug 2021 22:34:12

[Result](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:55:52
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:17:37
User entered empty; reason for change Data Entry Error	(b) (4) (b) (4), (b) (6)	05 Nov 2020 22:51:09
User closed query 'Data is required. Please provide.' (Site from System).	System	09 Sep 2020 14:11:04
User entered 'Negative (NEGATIVE)' reason for change: Data Entry Error	Morgan Schulle (b) (4) (b) (4)	09 Sep 2020 14:11:04
User opened query 'Data is required. Please provide.' (Site from System).	System	08 Sep 2020 18:18:43
User entered empty.	(b) (4), (b) (6)	08 Sep 2020 18:18:43

US3342204

Folder: Visit 1 Day 1

Form: Pregnancy Test

Generated On: 11 Aug 2021 22:34:12

Was FSH sample collected?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:55:52
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:17:37
User entered empty; reason for change Data Entry Error	(b) (4) (b) (4), (b) (6)	05 Nov 2020 22:51:09
User entered 'No (N)' reason for change: Data Entry Error	Morgan Schulle (b) (4)	09 Sep 2020 14:11:04
User entered empty.	(b) (4) (b) (4), (b) (6)	08 Sep 2020 18:18:43

US3342204

Folder: Visit 1 Day 1

Form: Pregnancy Test

Generated On: 11 Aug 2021 22:34:12

[Collection date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:55:52
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:17:37
User entered empty; reason for change Data Entry Error	(b) (4)	09 Sep 2020 16:16:34
User entered '8 Sep 2020'	Morgan Schulle (b) (4)	08 Sep 2020 18:18:43
	(b) (4), (b) (6)	

US3342204

Folder: Visit 1 Day 1

Form: Pregnancy Test

Generated On: 11 Aug 2021 22:34:12

[Collection time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:55:52
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:17:37
User entered empty; reason for change Data Entry Error	(b) (4) Morgan Schulle (b) (4)	09 Sep 2020 16:16:34
User entered '10:37' reason for change: Data Entry Error	Morgan Schulle (b) (4)	09 Sep 2020 14:11:04
User entered empty.	(b) (4) (b) (4), (b) (6)	08 Sep 2020 18:18:43

US3342204

Folder: Visit 1 Day 1

Form: Pregnancy Test

Generated On: 11 Aug 2021 22:34:12

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:55:52
User entered empty.	System	09 Sep 2020 16:16:34
User entered '8 Sep 2020 10:37'	System	09 Sep 2020 14:11:04
User entered empty.	System	08 Sep 2020 18:18:43

US3342204

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 11 Aug 2021 22:34:12

[Was study treatment given?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:55:52
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:17:37
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	08 Sep 2020 17:07:02

US3342204

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 11 Aug 2021 22:34:12

If No, reason not given

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:55:52
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:17:37
User entered empty.	(b) (4) (b) (4), (b) (6)	08 Sep 2020 17:07:02

US3342204

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 11 Aug 2021 22:34:12

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:55:52
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:17:37
User entered empty.	(b) (4) (b) (4), (b) (6)	08 Sep 2020 17:07:02

US3342204

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 11 Aug 2021 22:34:12

[What was the study treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:55:52
User entered 'MRNA-1273 OR PLACEBO'	System	08 Sep 2020 17:07:02

US3342204

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 11 Aug 2021 22:34:12

What was the treatment date? (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:55:52
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:17:37
User entered '8 Sep 2020'	(b) (4) (b) (4), (b) (6)	08 Sep 2020 17:07:02

US3342204

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 11 Aug 2021 22:34:12

[What was the treatment time? \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:55:52
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:17:37
User entered '11:44'	(b) (4) (b) (4), (b) (6)	08 Sep 2020 17:07:02

US3342204

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 11 Aug 2021 22:34:12

[Treatment Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:55:52
User entered '8 Sep 2020 11:44'	System	08 Sep 2020 17:07:02

US3342204

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 11 Aug 2021 22:34:12

[Which arm was used to give treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:55:52
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:17:37
User entered 'Left Arm (LEFT ARM)'	(b) (4) (b) (4), (b) (6)	08 Sep 2020 17:07:02

US3342204

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 11 Aug 2021 22:34:12

[What was the frequency of the study treatment dosing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:55:52
User entered 'ONCE'	System	08 Sep 2020 17:07:02

US3342204

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 11 Aug 2021 22:34:12

What was the route of administration for the study treatment?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:55:52
User entered 'INTRAMUSCULAR'	System	08 Sep 2020 17:07:02

US3342204

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 22:34:12

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:55:52
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:17:37
User entered 'Yes (Y)'	(b) (4) Morgan Schulle (b) (4)	09 Sep 2020 14:10:35

US3342204

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 22:34:12

Collection date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:55:52
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:17:37
User entered '8 Sep 2020'	(b) (4) Morgan Schulle (b) (4)	09 Sep 2020 14:10:35

US3342204

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 22:34:12

Collection time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:55:52
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:17:37
User entered '11:12'	(b) (4) Morgan Schulle (b) (4)	09 Sep 2020 14:10:35

US3342204

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 22:34:12

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:55:52
User entered '8 Sep 2020 11:12'	System	09 Sep 2020 14:10:35

US3342204

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab

Generated On: 11 Aug 2021 22:34:12

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:55:52
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:17:37
User entered '8 Sep 2020'	(b) (4) Morgan Schulle (b) (4)	09 Sep 2020 14:10:18

US3342204

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 11 Aug 2021 22:34:12

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:55:52
User accepted default value 'Nasopharyngeal Swab 1 (NASAL1)'	Morgan Schulle (b) (4) (b) (4)	09 Sep 2020 14:10:18

US3342204

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 11 Aug 2021 22:34:12

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:55:52
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:17:37
User entered 'Yes (Y)'	(b) (4) Morgan Schulle (b) (4)	09 Sep 2020 14:10:18

US3342204

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 11 Aug 2021 22:34:12

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:55:52
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:17:37
User entered '11:14'	Morgan Schulle (b) (4)	09 Sep 2020 14:10:18

US3342204

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 11 Aug 2021 22:34:12

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:55:52
User entered '8 Sep 2020 11:14'	System	09 Sep 2020 14:10:18

US3342204

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 11 Aug 2021 22:34:12

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:55:52
User accepted default value 'Nasopharyngeal Swab 2 (NASAL2)'	Morgan Schulle (b) (4) (b) (4)	09 Sep 2020 14:10:18

US3342204

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 11 Aug 2021 22:34:12

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:55:52
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:17:37
User entered 'No (N)'	(b) (4) Morgan Schulle (b) (4)	09 Sep 2020 14:10:18

US3342204

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 11 Aug 2021 22:34:12

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:55:52
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:17:37
User entered empty.	(b) (4) Morgan Schulle (b) (4)	09 Sep 2020 14:10:18

US3342204

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 11 Aug 2021 22:34:12

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:55:52
User entered empty.	System	09 Sep 2020 14:10:18

US3342204

Folder: Visit 1 Day 1

Form: Continuing

Generated On: 11 Aug 2021 22:34:12

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:55:52
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:17:37
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	08 Sep 2020 18:18:59

US3342204

Folder: Visit 1 Day 1

Form: Continuing

Generated On: 11 Aug 2021 22:34:12

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:55:52
User entered '1'	System	08 Sep 2020 18:18:59

US3342204

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 11 Aug 2021 22:34:12

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:12:42
Data entry locked.	System	08 Sep 2020 17:07:02
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	08 Sep 2020 17:07:02

US3342204

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 11 Aug 2021 22:34:12

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:12:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7A504897-431F-4E74-9F03-DAC668AE5D1E)', Time: '2020-09-08T12:23:08', User OID: 'PatientReportedOutcome (US3342204)', ODM File OID: 'c9d59fba-0939-4f50-a580-e46d74d6946a' User entered 'Yes (Y)'	System	08 Sep 2020 17:23:41
	System	08 Sep 2020 17:23:41

US3342204

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 11 Aug 2021 22:34:12

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:12:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7A504897-431F-4E74-9F03-DAC668AE5D1E)', Time: '2020-09-08T12:23:17', User OID: 'PatientReportedOutcome (US3342204)', ODM File OID: 'c9d59fba-0939-4f50-a580-e46d74d6946a' User entered '97.3'	System	08 Sep 2020 17:23:41
	System	08 Sep 2020 17:23:41

US3342204

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 11 Aug 2021 22:34:12

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:12:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7A504897-431F-4E74-9F03-DAC668AE5D1E)', Time: '2020-09-08T12:23:23', User OID: 'PatientReportedOutcome (US3342204)', ODM File OID: 'c9d59fba-0939-4f50-a580-e46d74d6946a' User entered 'No (N)'	System	08 Sep 2020 17:23:41
	System	08 Sep 2020 17:23:41

US3342204

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 11 Aug 2021 22:34:12

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:12:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7A504897-431F-4E74-9F03-DAC668AE5D1E)', Time: '2020-09-08T12:23:35', User OID: 'PatientReportedOutcome (US3342204)', ODM File OID: 'c9d59fba-0939-4f50-a580-e46d74d6946a' User entered '08 Sep 2020 12:23'	System	08 Sep 2020 17:23:41
	System	08 Sep 2020 17:23:41

US3342204

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 11 Aug 2021 22:34:12

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:12:42
User entered '08 Sep 2020 12:04'	System	08 Sep 2020 17:07:02

US3342204

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 11 Aug 2021 22:34:12

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:12:42
User entered '08 Sep 2020 14:34'	System	08 Sep 2020 17:07:02

US3342204

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 11 Aug 2021 22:34:12

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:12:42
Data entry locked.	System	08 Sep 2020 17:07:02
User entered 'Day 1, after vaccination (at home)'	System	08 Sep 2020 17:07:02

US3342204

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 11 Aug 2021 22:34:12

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:12:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7A504897-431F-4E74-9F03-DAC668AE5D1E)', Time: '2020-09-08T20:27:06', User OID: 'PatientReportedOutcome (US3342204)', ODM File OID: 'cfe93c03-7b87-4657-a2d5-ba9f6cd8e6ad' User entered 'Yes (Y)'	System	09 Sep 2020 01:27:23
	System	09 Sep 2020 01:27:23

US3342204

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 11 Aug 2021 22:34:12

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:12:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7A504897-431F-4E74-9F03-DAC668AE5D1E)', Time: '2020-09-08T20:27:12', User OID: 'PatientReportedOutcome (US3342204)', ODM File OID: 'cfe93c03-7b87-4657-a2d5-ba9f6cd8e6ad' User entered '97.9'	System	09 Sep 2020 01:27:23
	System	09 Sep 2020 01:27:23

US3342204

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 11 Aug 2021 22:34:12

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:12:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7A504897-431F-4E74-9F03-DAC668AE5D1E)', Time: '2020-09-08T20:27:15', User OID: 'PatientReportedOutcome (US3342204)', ODM File OID: 'cfe93c03-7b87-4657-a2d5-ba9f6cd8e6ad' User entered 'No (N)'	System	09 Sep 2020 01:27:23
	System	09 Sep 2020 01:27:23

US3342204

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 11 Aug 2021 22:34:12

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:12:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7A504897-431F-4E74-9F03-DAC668AE5D1E)', Time: '2020-09-08T20:27:21', User OID: 'PatientReportedOutcome (US3342204)', ODM File OID: 'cfe93c03-7b87-4657-a2d5-ba9f6cd8e6ad' User entered '08 Sep 2020 20:27'	System	09 Sep 2020 01:27:23
	System	09 Sep 2020 01:27:23

US3342204

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 11 Aug 2021 22:34:12

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:12:42
User entered '08 Sep 2020 15:29'	System	08 Sep 2020 17:07:02

US3342204

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 11 Aug 2021 22:34:12

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:12:42
User entered '09 Sep 2020 11:59'	System	08 Sep 2020 17:07:02

US3342204

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 11 Aug 2021 22:34:12

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:12:42
Data entry locked.	System	08 Sep 2020 17:07:02
User entered 'Day 2'	System	08 Sep 2020 17:07:02

US3342204

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 11 Aug 2021 22:34:12

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:12:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7A504897-431F-4E74-9F03-DAC668AE5D1E)', Time: '2020-09-09T20:50:08', User OID: 'PatientReportedOutcome (US3342204)', ODM File OID: 'c562e808-4c3b-4279-8b57-6f6ccdc907df' User entered 'Yes (Y)'	System	10 Sep 2020 01:50:29
	System	10 Sep 2020 01:50:29

US3342204

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 11 Aug 2021 22:34:12

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:12:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7A504897-431F-4E74-9F03-DAC668AE5D1E)', Time: '2020-09-09T20:50:13', User OID: 'PatientReportedOutcome (US3342204)', ODM File OID: 'c562e808-4c3b-4279-8b57-6f6ccdc907df' User entered '97.3'	System	10 Sep 2020 01:50:29
	System	10 Sep 2020 01:50:29

US3342204

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 11 Aug 2021 22:34:12

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:12:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7A504897-431F-4E74-9F03-DAC668AE5D1E)', Time: '2020-09-09T20:50:20', User OID: 'PatientReportedOutcome (US3342204)', ODM File OID: 'c562e808-4c3b-4279-8b57-6f6ccdc907df' User entered 'No (N)'	System	10 Sep 2020 01:50:29
	System	10 Sep 2020 01:50:29

US3342204

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 11 Aug 2021 22:34:12

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:12:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7A504897-431F-4E74-9F03-DAC668AE5D1E)', Time: '2020-09-09T20:50:25', User OID: 'PatientReportedOutcome (US3342204)', ODM File OID: 'c562e808-4c3b-4279-8b57-6f6ccdc907df' User entered '09 Sep 2020 20:50'	System	10 Sep 2020 01:50:29
	System	10 Sep 2020 01:50:29

US3342204

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 11 Aug 2021 22:34:12

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:12:42
User entered '09 Sep 2020 12:00'	System	08 Sep 2020 17:07:02

US3342204

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 11 Aug 2021 22:34:12

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:12:42
User entered '10 Sep 2020 11:59'	System	08 Sep 2020 17:07:02

US3342204

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 11 Aug 2021 22:34:12

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:12:42
Data entry locked.	System	08 Sep 2020 17:07:02
User entered 'Day 3'	System	08 Sep 2020 17:07:02

US3342204

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 11 Aug 2021 22:34:12

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:12:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7A504897-431F-4E74-9F03-DAC668AE5D1E)', Time: '2020-09-10T22:39:45', User OID: 'PatientReportedOutcome (US3342204)', ODM File OID: 'c024836b-be4e-4133-96eb-aa00480e7f96' User entered 'Yes (Y)'	System	11 Sep 2020 03:39:58
	System	11 Sep 2020 03:39:58

US3342204

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 11 Aug 2021 22:34:12

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:12:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7A504897-431F-4E74-9F03-DAC668AE5D1E)', Time: '2020-09-10T22:39:49', User OID: 'PatientReportedOutcome (US3342204)', ODM File OID: 'c024836b-be4e-4133-96eb-aa00480e7f96' User entered '98.0'	System	11 Sep 2020 03:39:58
	System	11 Sep 2020 03:39:58

US3342204

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 11 Aug 2021 22:34:12

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:12:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7A504897-431F-4E74-9F03-DAC668AE5D1E)', Time: '2020-09-10T22:39:51', User OID: 'PatientReportedOutcome (US3342204)', ODM File OID: 'c024836b-be4e-4133-96eb-aa00480e7f96'	System	11 Sep 2020 03:39:58
User entered 'No (N)'	System	11 Sep 2020 03:39:58

US3342204

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 11 Aug 2021 22:34:12

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:12:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7A504897-431F-4E74-9F03-DAC668AE5D1E)', Time: '2020-09-10T22:39:57', User OID: 'PatientReportedOutcome (US3342204)', ODM File OID: 'c024836b-be4e-4133-96eb-aa00480e7f96' User entered '10 Sep 2020 22:39'	System	11 Sep 2020 03:39:58
	System	11 Sep 2020 03:39:58

US3342204

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 11 Aug 2021 22:34:12

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:12:42
User entered '10 Sep 2020 12:00'	System	08 Sep 2020 17:07:02

US3342204

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 11 Aug 2021 22:34:12

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:12:42
User entered '11 Sep 2020 11:59'	System	08 Sep 2020 17:07:02

US3342204

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 11 Aug 2021 22:34:12

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:12:42
Data entry locked.	System	08 Sep 2020 17:07:02
User entered 'Day 4'	System	08 Sep 2020 17:07:02

US3342204

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 11 Aug 2021 22:34:12

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:12:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7A504897-431F-4E74-9F03-DAC668AE5D1E)', Time: '2020-09-11T22:27:10', User OID: 'PatientReportedOutcome (US3342204)', ODM File OID: '6d92b5b4-2868-4480-9082-15381382e047' User entered 'Yes (Y)'	System	12 Sep 2020 03:28:01
	System	12 Sep 2020 03:28:01

US3342204

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 11 Aug 2021 22:34:12

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:12:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7A504897-431F-4E74-9F03-DAC668AE5D1E)', Time: '2020-09-11T22:27:47', User OID: 'PatientReportedOutcome (US3342204)', ODM File OID: '6d92b5b4-2868-4480-9082-15381382e047' User entered '97.3'	System	12 Sep 2020 03:28:01
	System	12 Sep 2020 03:28:01

US3342204

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 11 Aug 2021 22:34:12

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:12:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7A504897-431F-4E74-9F03-DAC668AE5D1E)', Time: '2020-09-11T22:27:51', User OID: 'PatientReportedOutcome (US3342204)', ODM File OID: '6d92b5b4-2868-4480-9082-15381382e047'	System	12 Sep 2020 03:28:01
User entered 'No (N)'	System	12 Sep 2020 03:28:01

US3342204

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 11 Aug 2021 22:34:12

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:12:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7A504897-431F-4E74-9F03-DAC668AE5D1E)', Time: '2020-09-11T22:27:57', User OID: 'PatientReportedOutcome (US3342204)', ODM File OID: '6d92b5b4-2868-4480-9082-15381382e047'	System	12 Sep 2020 03:28:01
User entered '11 Sep 2020 22:27'	System	12 Sep 2020 03:28:01

US3342204

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 11 Aug 2021 22:34:12

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:12:42
User entered '11 Sep 2020 12:00'	System	08 Sep 2020 17:07:02

US3342204

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 11 Aug 2021 22:34:12

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:12:42
User entered '12 Sep 2020 11:59'	System	08 Sep 2020 17:07:02

US3342204

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 11 Aug 2021 22:34:12

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:12:42
Data entry locked.	System	08 Sep 2020 17:07:02
User entered 'Day 5'	System	08 Sep 2020 17:07:02

US3342204

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 11 Aug 2021 22:34:12

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:12:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7A504897-431F-4E74-9F03-DAC668AE5D1E)', Time: '2020-09-13T00:00:26', User OID: 'PatientReportedOutcome (US3342204)', ODM File OID: 'ce032ed9-ec9c-453c-a9d9-fe682043d854' User entered 'Yes (Y)'	System	13 Sep 2020 05:00:46
	System	13 Sep 2020 05:00:46

US3342204

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 11 Aug 2021 22:34:12

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:12:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7A504897-431F-4E74-9F03-DAC668AE5D1E)', Time: '2020-09-13T00:00:32', User OID: 'PatientReportedOutcome (US3342204)', ODM File OID: 'ce032ed9-ec9c-453c-a9d9-fe682043d854'	System	13 Sep 2020 05:00:46
User entered '96.6'	System	13 Sep 2020 05:00:46

US3342204

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 11 Aug 2021 22:34:12

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:12:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7A504897-431F-4E74-9F03-DAC668AE5D1E)', Time: '2020-09-13T00:00:36', User OID: 'PatientReportedOutcome (US3342204)', ODM File OID: 'ce032ed9-ec9c-453c-a9d9-fe682043d854'	System	13 Sep 2020 05:00:46
User entered 'No (N)'	System	13 Sep 2020 05:00:46

US3342204

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 11 Aug 2021 22:34:12

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:12:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7A504897-431F-4E74-9F03-DAC668AE5D1E)', Time: '2020-09-13T00:00:42', User OID: 'PatientReportedOutcome (US3342204)', ODM File OID: 'ce032ed9-ec9c-453c-a9d9-fe682043d854' User entered '13 Sep 2020 00:00'	System	13 Sep 2020 05:00:46
	System	13 Sep 2020 05:00:46

US3342204

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 11 Aug 2021 22:34:12

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:12:42
User entered '12 Sep 2020 12:00'	System	08 Sep 2020 17:07:02

US3342204

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 11 Aug 2021 22:34:12

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:12:42
User entered '13 Sep 2020 11:59'	System	08 Sep 2020 17:07:02

US3342204

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 11 Aug 2021 22:34:12

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:12:42
Data entry locked.	System	08 Sep 2020 17:07:02
User entered 'Day 6'	System	08 Sep 2020 17:07:02

US3342204

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 11 Aug 2021 22:34:12

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:12:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7A504897-431F-4E74-9F03-DAC668AE5D1E)', Time: '2020-09-13T22:46:49', User OID: 'PatientReportedOutcome (US3342204)', ODM File OID: 'ddfaf4a2-4f27-4354-8849-0621b78fef44' User entered 'Yes (Y)'	System	14 Sep 2020 03:47:10
	System	14 Sep 2020 03:47:10

US3342204

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 11 Aug 2021 22:34:12

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:12:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7A504897-431F-4E74-9F03-DAC668AE5D1E)', Time: '2020-09-13T22:46:55', User OID: 'PatientReportedOutcome (US3342204)', ODM File OID: 'ddfaf4a2-4f27-4354-8849-0621b78fef44' User entered '97.6'	System	14 Sep 2020 03:47:10
	System	14 Sep 2020 03:47:10

US3342204

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 11 Aug 2021 22:34:12

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:12:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7A504897-431F-4E74-9F03-DAC668AE5D1E)', Time: '2020-09-13T22:46:58', User OID: 'PatientReportedOutcome (US3342204)', ODM File OID: 'ddfaf4a2-4f27-4354-8849-0621b78fef44'	System	14 Sep 2020 03:47:10
User entered 'No (N)'	System	14 Sep 2020 03:47:10

US3342204

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 11 Aug 2021 22:34:12

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:12:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7A504897-431F-4E74-9F03-DAC668AE5D1E)', Time: '2020-09-13T22:47:06', User OID: 'PatientReportedOutcome (US3342204)', ODM File OID: 'ddfaf4a2-4f27-4354-8849-0621b78fef44' User entered '13 Sep 2020 22:47'	System	14 Sep 2020 03:47:10
	System	14 Sep 2020 03:47:10

US3342204

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 11 Aug 2021 22:34:12

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:12:42
User entered '13 Sep 2020 12:00'	System	08 Sep 2020 17:07:02

US3342204

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 11 Aug 2021 22:34:12

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:12:42
User entered '14 Sep 2020 11:59'	System	08 Sep 2020 17:07:02

US3342204

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 11 Aug 2021 22:34:12

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:12:42
Data entry locked.	System	08 Sep 2020 17:07:02
User entered 'Day 7'	System	08 Sep 2020 17:07:02

US3342204

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 11 Aug 2021 22:34:12

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:12:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7A504897-431F-4E74-9F03-DAC668AE5D1E)', Time: '2020-09-14T22:45:13', User OID: 'PatientReportedOutcome (US3342204)', ODM File OID: '3fd15377-2e59-42de-93f0-b355a4b20b0e' User entered 'Yes (Y)'	System	15 Sep 2020 03:45:28
	System	15 Sep 2020 03:45:28

US3342204

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 11 Aug 2021 22:34:12

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:12:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7A504897-431F-4E74-9F03-DAC668AE5D1E)', Time: '2020-09-14T22:45:17', User OID: 'PatientReportedOutcome (US3342204)', ODM File OID: '3fd15377-2e59-42de-93f0-b355a4b20b0e' User entered '97.5'	System	15 Sep 2020 03:45:28
	System	15 Sep 2020 03:45:28

US3342204

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 11 Aug 2021 22:34:12

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:12:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7A504897-431F-4E74-9F03-DAC668AE5D1E)', Time: '2020-09-14T22:45:22', User OID: 'PatientReportedOutcome (US3342204)', ODM File OID: '3fd15377-2e59-42de-93f0-b355a4b20b0e' User entered 'No (N)'	System	15 Sep 2020 03:45:28
	System	15 Sep 2020 03:45:28

US3342204

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 11 Aug 2021 22:34:12

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:12:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7A504897-431F-4E74-9F03-DAC668AE5D1E)', Time: '2020-09-14T22:45:25', User OID: 'PatientReportedOutcome (US3342204)', ODM File OID: '3fd15377-2e59-42de-93f0-b355a4b20b0e' User entered '14 Sep 2020 22:45'	System	15 Sep 2020 03:45:28
	System	15 Sep 2020 03:45:28

US3342204

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 11 Aug 2021 22:34:12

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:12:42
User entered '14 Sep 2020 12:00'	System	08 Sep 2020 17:07:02

US3342204

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 11 Aug 2021 22:34:12

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:12:42
User entered '15 Sep 2020 11:59'	System	08 Sep 2020 17:07:02

US3342204

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 11 Aug 2021 22:34:12

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:12:42
Data entry locked.	System	08 Sep 2020 17:07:02
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	08 Sep 2020 17:07:02

US3342204

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 11 Aug 2021 22:34:12

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:12:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7A504897-431F-4E74-9F03-DAC668AE5D1E)', Time: '2020-09-08T12:23:44', User OID: 'PatientReportedOutcome (US3342204)', ODM File OID: '567aa29f-7121-4bcd-897f-92a5c66cae4b' User entered 'None (1)'	System	08 Sep 2020 17:24:36
	System	08 Sep 2020 17:24:36

US3342204

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 11 Aug 2021 22:34:12

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:12:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7A504897-431F-4E74-9F03-DAC668AE5D1E)', Time: '2020-09-08T12:24:06', User OID: 'PatientReportedOutcome (US3342204)', ODM File OID: '567aa29f-7121-4bcd-897f-92a5c66cae4b' User entered 'No (N)'	System	08 Sep 2020 17:24:36
	System	08 Sep 2020 17:24:36

US3342204

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 11 Aug 2021 22:34:12

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:12:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7A504897-431F-4E74-9F03-DAC668AE5D1E)', Time: '2020-09-08T12:24:11', User OID: 'PatientReportedOutcome (US3342204)', ODM File OID: '567aa29f-7121-4bcd-897f-92a5c66cae4b' User entered 'No (N)'	System	08 Sep 2020 17:24:36
	System	08 Sep 2020 17:24:36

US3342204

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 11 Aug 2021 22:34:12

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:12:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7A504897-431F-4E74-9F03-DAC668AE5D1E)', Time: '2020-09-08T12:24:26', User OID: 'PatientReportedOutcome (US3342204)', ODM File OID: '567aa29f-7121-4bcd-897f-92a5c66cae4b' User entered 'None (1)'	System	08 Sep 2020 17:24:36
	System	08 Sep 2020 17:24:36

US3342204

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 11 Aug 2021 22:34:12

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:12:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7A504897-431F-4E74-9F03-DAC668AE5D1E)', Time: '2020-09-08T12:24:31', User OID: 'PatientReportedOutcome (US3342204)', ODM File OID: '567aa29f-7121-4bcd-897f-92a5c66cae4b' User entered '08 Sep 2020 12:24'	System	08 Sep 2020 17:24:36
	System	08 Sep 2020 17:24:36

US3342204

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 11 Aug 2021 22:34:12

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:12:42
User entered '08 Sep 2020 12:04'	System	08 Sep 2020 17:07:02

US3342204

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 11 Aug 2021 22:34:12

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:12:42
User entered '08 Sep 2020 14:34'	System	08 Sep 2020 17:07:02

US3342204

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 11 Aug 2021 22:34:12

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:12:42
Data entry locked.	System	08 Sep 2020 17:07:02
User entered 'Day 1, after vaccination (at home)'	System	08 Sep 2020 17:07:02

US3342204

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 11 Aug 2021 22:34:12

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:12:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7A504897-431F-4E74-9F03-DAC668AE5D1E)', Time: '2020-09-08T20:27:33', User OID: 'PatientReportedOutcome (US3342204)', ODM File OID: '063f3066-a854-41dc-a6ea-341062319b1e'	System	09 Sep 2020 01:28:05
User entered 'None (1)'	System	09 Sep 2020 01:28:05

US3342204

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 11 Aug 2021 22:34:12

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:12:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7A504897-431F-4E74-9F03-DAC668AE5D1E)', Time: '2020-09-08T20:27:36', User OID: 'PatientReportedOutcome (US3342204)', ODM File OID: '063f3066-a854-41dc-a6ea-341062319b1e' User entered 'No (N)'	System	09 Sep 2020 01:28:05
	System	09 Sep 2020 01:28:05

US3342204

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 11 Aug 2021 22:34:12

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:12:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7A504897-431F-4E74-9F03-DAC668AE5D1E)', Time: '2020-09-08T20:27:44', User OID: 'PatientReportedOutcome (US3342204)', ODM File OID: '063f3066-a854-41dc-a6ea-341062319b1e' User entered 'No (N)'	System	09 Sep 2020 01:28:05
	System	09 Sep 2020 01:28:05

US3342204

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 11 Aug 2021 22:34:12

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:12:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7A504897-431F-4E74-9F03-DAC668AE5D1E)', Time: '2020-09-08T20:27:58', User OID: 'PatientReportedOutcome (US3342204)', ODM File OID: '063f3066-a854-41dc-a6ea-341062319b1e'	System	09 Sep 2020 01:28:05
User entered 'None (1)'	System	09 Sep 2020 01:28:05

US3342204

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 11 Aug 2021 22:34:12

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:12:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7A504897-431F-4E74-9F03-DAC668AE5D1E)', Time: '2020-09-08T20:28:03', User OID: 'PatientReportedOutcome (US3342204)', ODM File OID: '063f3066-a854-41dc-a6ea-341062319b1e' User entered '08 Sep 2020 20:28'	System	09 Sep 2020 01:28:05
	System	09 Sep 2020 01:28:05

US3342204

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 11 Aug 2021 22:34:12

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:12:42
User entered '08 Sep 2020 15:29'	System	08 Sep 2020 17:07:02

US3342204

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 11 Aug 2021 22:34:12

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:12:42
User entered '09 Sep 2020 11:59'	System	08 Sep 2020 17:07:02

US3342204

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 11 Aug 2021 22:34:12

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:12:42
Data entry locked.	System	08 Sep 2020 17:07:02
User entered 'Day 2'	System	08 Sep 2020 17:07:02

US3342204

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 11 Aug 2021 22:34:12

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:12:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7A504897-431F-4E74-9F03-DAC668AE5D1E)', Time: '2020-09-09T20:50:40', User OID: 'PatientReportedOutcome (US3342204)', ODM File OID: '4587d6db-dd34-4764-a0bb-87a4c58a5c4c' User entered 'None (1)'	System	10 Sep 2020 01:51:07
	System	10 Sep 2020 01:51:07

US3342204

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 11 Aug 2021 22:34:12

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:12:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7A504897-431F-4E74-9F03-DAC668AE5D1E)', Time: '2020-09-09T20:50:43', User OID: 'PatientReportedOutcome (US3342204)', ODM File OID: '4587d6db-dd34-4764-a0bb-87a4c58a5c4c' User entered 'No (N)'	System	10 Sep 2020 01:51:07
	System	10 Sep 2020 01:51:07

US3342204

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 11 Aug 2021 22:34:12

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:12:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7A504897-431F-4E74-9F03-DAC668AE5D1E)', Time: '2020-09-09T20:50:46', User OID: 'PatientReportedOutcome (US3342204)', ODM File OID: '4587d6db-dd34-4764-a0bb-87a4c58a5c4c' User entered 'No (N)'	System	10 Sep 2020 01:51:07
	System	10 Sep 2020 01:51:07

US3342204

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 11 Aug 2021 22:34:12

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:12:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7A504897-431F-4E74-9F03-DAC668AE5D1E)', Time: '2020-09-09T20:51:00', User OID: 'PatientReportedOutcome (US3342204)', ODM File OID: '4587d6db-dd34-4764-a0bb-87a4c58a5c4c'	System	10 Sep 2020 01:51:07
User entered 'None (1)'	System	10 Sep 2020 01:51:07

US3342204

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 11 Aug 2021 22:34:12

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:12:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7A504897-431F-4E74-9F03-DAC668AE5D1E)', Time: '2020-09-09T20:51:03', User OID: 'PatientReportedOutcome (US3342204)', ODM File OID: '4587d6db-dd34-4764-a0bb-87a4c58a5c4c' User entered '09 Sep 2020 20:51'	System	10 Sep 2020 01:51:07
	System	10 Sep 2020 01:51:07

US3342204

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 11 Aug 2021 22:34:12

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:12:42
User entered '09 Sep 2020 12:00'	System	08 Sep 2020 17:07:02

US3342204

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 11 Aug 2021 22:34:12

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:12:42
User entered '10 Sep 2020 11:59'	System	08 Sep 2020 17:07:02

US3342204

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 11 Aug 2021 22:34:12

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:12:42
Data entry locked.	System	08 Sep 2020 17:07:02
User entered 'Day 3'	System	08 Sep 2020 17:07:02

US3342204

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 11 Aug 2021 22:34:12

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:12:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7A504897-431F-4E74-9F03-DAC668AE5D1E)', Time: '2020-09-10T22:40:02', User OID: 'PatientReportedOutcome (US3342204)', ODM File OID: 'd5d10e91-40ad-40b0-b9c9-3676f8c2aeec'	System	11 Sep 2020 03:40:28
User entered 'None (1)'	System	11 Sep 2020 03:40:28

US3342204

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 11 Aug 2021 22:34:12

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:12:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7A504897-431F-4E74-9F03-DAC668AE5D1E)', Time: '2020-09-10T22:40:05', User OID: 'PatientReportedOutcome (US3342204)', ODM File OID: 'd5d10e91-40ad-40b0-b9c9-3676f8c2aeec' User entered 'No (N)'	System	11 Sep 2020 03:40:28
	System	11 Sep 2020 03:40:28

US3342204

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 11 Aug 2021 22:34:12

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:12:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7A504897-431F-4E74-9F03-DAC668AE5D1E)', Time: '2020-09-10T22:40:08', User OID: 'PatientReportedOutcome (US3342204)', ODM File OID: 'd5d10e91-40ad-40b0-b9c9-3676f8c2aeec' User entered 'No (N)'	System	11 Sep 2020 03:40:28
	System	11 Sep 2020 03:40:28

US3342204

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 11 Aug 2021 22:34:12

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:12:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7A504897-431F-4E74-9F03-DAC668AE5D1E)', Time: '2020-09-10T22:40:21', User OID: 'PatientReportedOutcome (US3342204)', ODM File OID: 'd5d10e91-40ad-40b0-b9c9-3676f8c2aeec'	System	11 Sep 2020 03:40:28
User entered 'None (1)'	System	11 Sep 2020 03:40:28

US3342204

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 11 Aug 2021 22:34:12

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:12:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7A504897-431F-4E74-9F03-DAC668AE5D1E)', Time: '2020-09-10T22:40:25', User OID: 'PatientReportedOutcome (US3342204)', ODM File OID: 'd5d10e91-40ad-40b0-b9c9-3676f8c2aeec' User entered '10 Sep 2020 22:40'	System	11 Sep 2020 03:40:28
	System	11 Sep 2020 03:40:28

US3342204

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 11 Aug 2021 22:34:12

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:12:42
User entered '10 Sep 2020 12:00'	System	08 Sep 2020 17:07:02

US3342204

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 11 Aug 2021 22:34:12

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:12:42
User entered '11 Sep 2020 11:59'	System	08 Sep 2020 17:07:02

US3342204

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 11 Aug 2021 22:34:12

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:12:42
Data entry locked.	System	08 Sep 2020 17:07:02
User entered 'Day 4'	System	08 Sep 2020 17:07:02

US3342204

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 11 Aug 2021 22:34:12

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:12:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7A504897-431F-4E74-9F03-DAC668AE5D1E)', Time: '2020-09-11T22:28:01', User OID: 'PatientReportedOutcome (US3342204)', ODM File OID: '60f0de2e-a2ef-4a62-ac92-8adb99f854ce'	System	12 Sep 2020 03:28:27
User entered 'None (1)'	System	12 Sep 2020 03:28:27

US3342204

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 11 Aug 2021 22:34:12

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:12:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7A504897-431F-4E74-9F03-DAC668AE5D1E)', Time: '2020-09-11T22:28:03', User OID: 'PatientReportedOutcome (US3342204)', ODM File OID: '60f0de2e-a2ef-4a62-ac92-8adb99f854ce' User entered 'No (N)'	System	12 Sep 2020 03:28:27
	System	12 Sep 2020 03:28:27

US3342204

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 11 Aug 2021 22:34:12

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:12:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7A504897-431F-4E74-9F03-DAC668AE5D1E)', Time: '2020-09-11T22:28:06', User OID: 'PatientReportedOutcome (US3342204)', ODM File OID: '60f0de2e-a2ef-4a62-ac92-8adb99f854ce' User entered 'No (N)'	System	12 Sep 2020 03:28:27
	System	12 Sep 2020 03:28:27

US3342204

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 11 Aug 2021 22:34:12

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:12:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7A504897-431F-4E74-9F03-DAC668AE5D1E)', Time: '2020-09-11T22:28:21', User OID: 'PatientReportedOutcome (US3342204)', ODM File OID: '60f0de2e-a2ef-4a62-ac92-8adb99f854ce' User entered 'None (1)'	System	12 Sep 2020 03:28:27
	System	12 Sep 2020 03:28:27

US3342204

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 11 Aug 2021 22:34:12

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:12:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7A504897-431F-4E74-9F03-DAC668AE5D1E)', Time: '2020-09-11T22:28:24', User OID: 'PatientReportedOutcome (US3342204)', ODM File OID: '60f0de2e-a2ef-4a62-ac92-8adb99f854ce' User entered '11 Sep 2020 22:28'	System	12 Sep 2020 03:28:27
	System	12 Sep 2020 03:28:27

US3342204

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 11 Aug 2021 22:34:12

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:12:42
User entered '11 Sep 2020 12:00'	System	08 Sep 2020 17:07:02

US3342204

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 11 Aug 2021 22:34:12

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:12:42
User entered '12 Sep 2020 11:59'	System	08 Sep 2020 17:07:02

US3342204

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 11 Aug 2021 22:34:12

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:12:42
Data entry locked.	System	08 Sep 2020 17:07:02
User entered 'Day 5'	System	08 Sep 2020 17:07:02

US3342204

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 11 Aug 2021 22:34:12

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:12:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7A504897-431F-4E74-9F03-DAC668AE5D1E)', Time: '2020-09-12T23:59:31', User OID: 'PatientReportedOutcome (US3342204)', ODM File OID: 'ffa107ea-67f7-4f59-a3b5-d2358a96fd22'	System	13 Sep 2020 04:59:54
User entered 'None (1)'	System	13 Sep 2020 04:59:54

US3342204

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 11 Aug 2021 22:34:12

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:12:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7A504897-431F-4E74-9F03-DAC668AE5D1E)', Time: '2020-09-12T23:59:36', User OID: 'PatientReportedOutcome (US3342204)', ODM File OID: 'ffa107ea-67f7-4f59-a3b5-d2358a96fd22'	System	13 Sep 2020 04:59:54
User entered 'No (N)'	System	13 Sep 2020 04:59:54

US3342204

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 11 Aug 2021 22:34:12

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:12:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7A504897-431F-4E74-9F03-DAC668AE5D1E)', Time: '2020-09-12T23:59:41', User OID: 'PatientReportedOutcome (US3342204)', ODM File OID: 'ffa107ea-67f7-4f59-a3b5-d2358a96fd22'	System	13 Sep 2020 04:59:54
User entered 'No (N)'	System	13 Sep 2020 04:59:54

US3342204

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 11 Aug 2021 22:34:12

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:12:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7A504897-431F-4E74-9F03-DAC668AE5D1E)', Time: '2020-09-12T23:59:46', User OID: 'PatientReportedOutcome (US3342204)', ODM File OID: 'ffa107ea-67f7-4f59-a3b5-d2358a96fd22'	System	13 Sep 2020 04:59:54
User entered 'None (1)'	System	13 Sep 2020 04:59:54

US3342204

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 11 Aug 2021 22:34:12

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:12:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7A504897-431F-4E74-9F03-DAC668AE5D1E)', Time: '2020-09-12T23:59:49', User OID: 'PatientReportedOutcome (US3342204)', ODM File OID: 'ffa107ea-67f7-4f59-a3b5-d2358a96fd22'	System	13 Sep 2020 04:59:54
User entered '12 Sep 2020 23:59'	System	13 Sep 2020 04:59:54

US3342204

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 11 Aug 2021 22:34:12

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:12:42
User entered '12 Sep 2020 12:00'	System	08 Sep 2020 17:07:02

US3342204

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 11 Aug 2021 22:34:12

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:12:42
User entered '13 Sep 2020 11:59'	System	08 Sep 2020 17:07:02

US3342204

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 11 Aug 2021 22:34:12

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:12:42
Data entry locked.	System	08 Sep 2020 17:07:02
User entered 'Day 6'	System	08 Sep 2020 17:07:02

US3342204

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 11 Aug 2021 22:34:12

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:12:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7A504897-431F-4E74-9F03-DAC668AE5D1E)', Time: '2020-09-13T22:45:56', User OID: 'PatientReportedOutcome (US3342204)', ODM File OID: '115152ea-9e03-47e4-801f-cf1ea775f10d'	System	14 Sep 2020 03:46:20
User entered 'None (1)'	System	14 Sep 2020 03:46:20

US3342204

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 11 Aug 2021 22:34:12

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:12:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7A504897-431F-4E74-9F03-DAC668AE5D1E)', Time: '2020-09-13T22:46:02', User OID: 'PatientReportedOutcome (US3342204)', ODM File OID: '115152ea-9e03-47e4-801f-cf1ea775f10d'	System	14 Sep 2020 03:46:20
User entered 'No (N)'	System	14 Sep 2020 03:46:20

US3342204

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 11 Aug 2021 22:34:12

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:12:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7A504897-431F-4E74-9F03-DAC668AE5D1E)', Time: '2020-09-13T22:46:05', User OID: 'PatientReportedOutcome (US3342204)', ODM File OID: '115152ea-9e03-47e4-801f-cf1ea775f10d'	System	14 Sep 2020 03:46:20
User entered 'No (N)'	System	14 Sep 2020 03:46:20

US3342204

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 11 Aug 2021 22:34:12

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:12:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7A504897-431F-4E74-9F03-DAC668AE5D1E)', Time: '2020-09-13T22:46:15', User OID: 'PatientReportedOutcome (US3342204)', ODM File OID: '115152ea-9e03-47e4-801f-cf1ea775f10d'	System	14 Sep 2020 03:46:20
User entered 'None (1)'	System	14 Sep 2020 03:46:20

US3342204

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 11 Aug 2021 22:34:12

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:12:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7A504897-431F-4E74-9F03-DAC668AE5D1E)', Time: '2020-09-13T22:46:19', User OID: 'PatientReportedOutcome (US3342204)', ODM File OID: '115152ea-9e03-47e4-801f-cf1ea775f10d' User entered '13 Sep 2020 22:46'	System	14 Sep 2020 03:46:20
	System	14 Sep 2020 03:46:20

US3342204

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 11 Aug 2021 22:34:12

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:12:42
User entered '13 Sep 2020 12:00'	System	08 Sep 2020 17:07:02

US3342204

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 11 Aug 2021 22:34:12

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:12:42
User entered '14 Sep 2020 11:59'	System	08 Sep 2020 17:07:02

US3342204

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 11 Aug 2021 22:34:12

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:12:42
Data entry locked.	System	08 Sep 2020 17:07:02
User entered 'Day 7'	System	08 Sep 2020 17:07:02

US3342204

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 11 Aug 2021 22:34:12

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:12:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7A504897-431F-4E74-9F03-DAC668AE5D1E)', Time: '2020-09-14T22:44:17', User OID: 'PatientReportedOutcome (US3342204)', ODM File OID: '8f8392c3-a2d0-42b2-877f-542129323b58'	System	15 Sep 2020 03:44:37
User entered 'None (1)'	System	15 Sep 2020 03:44:37

US3342204

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 11 Aug 2021 22:34:12

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:12:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7A504897-431F-4E74-9F03-DAC668AE5D1E)', Time: '2020-09-14T22:44:20', User OID: 'PatientReportedOutcome (US3342204)', ODM File OID: '8f8392c3-a2d0-42b2-877f-542129323b58'	System	15 Sep 2020 03:44:37
User entered 'No (N)'	System	15 Sep 2020 03:44:37

US3342204

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 11 Aug 2021 22:34:12

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:12:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7A504897-431F-4E74-9F03-DAC668AE5D1E)', Time: '2020-09-14T22:44:22', User OID: 'PatientReportedOutcome (US3342204)', ODM File OID: '8f8392c3-a2d0-42b2-877f-542129323b58' User entered 'No (N)'	System	15 Sep 2020 03:44:37
	System	15 Sep 2020 03:44:37

US3342204

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 11 Aug 2021 22:34:12

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:12:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7A504897-431F-4E74-9F03-DAC668AE5D1E)', Time: '2020-09-14T22:44:32', User OID: 'PatientReportedOutcome (US3342204)', ODM File OID: '8f8392c3-a2d0-42b2-877f-542129323b58'	System	15 Sep 2020 03:44:37
User entered 'None (1)'	System	15 Sep 2020 03:44:37

US3342204

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 11 Aug 2021 22:34:12

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:12:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7A504897-431F-4E74-9F03-DAC668AE5D1E)', Time: '2020-09-14T22:44:35', User OID: 'PatientReportedOutcome (US3342204)', ODM File OID: '8f8392c3-a2d0-42b2-877f-542129323b58' User entered '14 Sep 2020 22:44'	System	15 Sep 2020 03:44:37
	System	15 Sep 2020 03:44:37

US3342204

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 11 Aug 2021 22:34:12

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:12:42
User entered '14 Sep 2020 12:00'	System	08 Sep 2020 17:07:02

US3342204

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 11 Aug 2021 22:34:12

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:12:42
User entered '15 Sep 2020 11:59'	System	08 Sep 2020 17:07:02

US3342204

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 11 Aug 2021 22:34:12

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:12:42
Data entry locked.	System	08 Sep 2020 17:07:02
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	08 Sep 2020 17:07:02

US3342204

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 11 Aug 2021 22:34:12

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:12:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7A504897-431F-4E74-9F03-DAC668AE5D1E)', Time: '2020-09-08T12:24:38', User OID: 'PatientReportedOutcome (US3342204)', ODM File OID: '82008983-d76e-4ec2-933d-05f5944d91bb' User entered 'None (0)'	System	08 Sep 2020 17:25:07
	System	08 Sep 2020 17:25:07

US3342204

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 11 Aug 2021 22:34:12

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:12:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7A504897-431F-4E74-9F03-DAC668AE5D1E)', Time: '2020-09-08T12:24:40', User OID: 'PatientReportedOutcome (US3342204)', ODM File OID: '82008983-d76e-4ec2-933d-05f5944d91bb' User entered 'None (0)'	System	08 Sep 2020 17:25:07
	System	08 Sep 2020 17:25:07

US3342204

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 11 Aug 2021 22:34:12

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:12:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7A504897-431F-4E74-9F03-DAC668AE5D1E)', Time: '2020-09-08T12:24:42', User OID: 'PatientReportedOutcome (US3342204)', ODM File OID: '82008983-d76e-4ec2-933d-05f5944d91bb' User entered 'None (0)'	System	08 Sep 2020 17:25:07
	System	08 Sep 2020 17:25:07

US3342204

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 11 Aug 2021 22:34:12

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:12:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7A504897-431F-4E74-9F03-DAC668AE5D1E)', Time: '2020-09-08T12:24:44', User OID: 'PatientReportedOutcome (US3342204)', ODM File OID: '82008983-d76e-4ec2-933d-05f5944d91bb' User entered 'None (0)'	System	08 Sep 2020 17:25:07
	System	08 Sep 2020 17:25:07

US3342204

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 11 Aug 2021 22:34:12

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:12:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7A504897-431F-4E74-9F03-DAC668AE5D1E)', Time: '2020-09-08T12:24:46', User OID: 'PatientReportedOutcome (US3342204)', ODM File OID: '82008983-d76e-4ec2-933d-05f5944d91bb' User entered 'None (0)'	System	08 Sep 2020 17:25:07
	System	08 Sep 2020 17:25:07

US3342204

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 11 Aug 2021 22:34:12

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:12:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7A504897-431F-4E74-9F03-DAC668AE5D1E)', Time: '2020-09-08T12:24:48', User OID: 'PatientReportedOutcome (US3342204)', ODM File OID: '82008983-d76e-4ec2-933d-05f5944d91bb' User entered 'None (0)'	System	08 Sep 2020 17:25:07
	System	08 Sep 2020 17:25:07

US3342204

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 11 Aug 2021 22:34:12

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:12:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7A504897-431F-4E74-9F03-DAC668AE5D1E)', Time: '2020-09-08T12:24:57', User OID: 'PatientReportedOutcome (US3342204)', ODM File OID: '82008983-d76e-4ec2-933d-05f5944d91bb' User entered 'No (N)'	System	08 Sep 2020 17:25:07
	System	08 Sep 2020 17:25:07

US3342204

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 11 Aug 2021 22:34:12

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:12:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7A504897-431F-4E74-9F03-DAC668AE5D1E)', Time: '2020-09-08T12:25:02', User OID: 'PatientReportedOutcome (US3342204)', ODM File OID: '82008983-d76e-4ec2-933d-05f5944d91bb' User entered '08 Sep 2020 12:25'	System	08 Sep 2020 17:25:07
	System	08 Sep 2020 17:25:07

US3342204

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 11 Aug 2021 22:34:12

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:12:42
User entered '08 Sep 2020 12:04'	System	08 Sep 2020 17:07:02

US3342204

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 11 Aug 2021 22:34:12

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:12:42
User entered '08 Sep 2020 14:34'	System	08 Sep 2020 17:07:02

US3342204

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 11 Aug 2021 22:34:12

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:12:42
Data entry locked.	System	08 Sep 2020 17:07:02
User entered 'Day 1, after vaccination (at home)'	System	08 Sep 2020 17:07:02

US3342204

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 11 Aug 2021 22:34:12

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:12:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7A504897-431F-4E74-9F03-DAC668AE5D1E)', Time: '2020-09-08T20:28:10', User OID: 'PatientReportedOutcome (US3342204)', ODM File OID: '6c700365-4dbf-4fbd-a60d-1f05001e291c' User entered 'None (0)'	System	09 Sep 2020 01:28:38
	System	09 Sep 2020 01:28:38

US3342204

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 11 Aug 2021 22:34:12

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:12:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7A504897-431F-4E74-9F03-DAC668AE5D1E)', Time: '2020-09-08T20:28:12', User OID: 'PatientReportedOutcome (US3342204)', ODM File OID: '6c700365-4dbf-4fbd-a60d-1f05001e291c' User entered 'None (0)'	System	09 Sep 2020 01:28:38
	System	09 Sep 2020 01:28:38

US3342204

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 11 Aug 2021 22:34:12

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:12:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7A504897-431F-4E74-9F03-DAC668AE5D1E)', Time: '2020-09-08T20:28:14', User OID: 'PatientReportedOutcome (US3342204)', ODM File OID: '6c700365-4dbf-4fbd-a60d-1f05001e291c' User entered 'None (0)'	System	09 Sep 2020 01:28:38
	System	09 Sep 2020 01:28:38

US3342204

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 11 Aug 2021 22:34:12

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:12:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7A504897-431F-4E74-9F03-DAC668AE5D1E)', Time: '2020-09-08T20:28:16', User OID: 'PatientReportedOutcome (US3342204)', ODM File OID: '6c700365-4dbf-4fbd-a60d-1f05001e291c' User entered 'None (0)'	System	09 Sep 2020 01:28:38
	System	09 Sep 2020 01:28:38

US3342204

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 11 Aug 2021 22:34:12

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:12:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7A504897-431F-4E74-9F03-DAC668AE5D1E)', Time: '2020-09-08T20:28:20', User OID: 'PatientReportedOutcome (US3342204)', ODM File OID: '6c700365-4dbf-4fbd-a60d-1f05001e291c' User entered 'None (0)'	System	09 Sep 2020 01:28:38
	System	09 Sep 2020 01:28:38

US3342204

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 11 Aug 2021 22:34:12

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:12:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7A504897-431F-4E74-9F03-DAC668AE5D1E)', Time: '2020-09-08T20:28:22', User OID: 'PatientReportedOutcome (US3342204)', ODM File OID: '6c700365-4dbf-4fbd-a60d-1f05001e291c' User entered 'None (0)'	System	09 Sep 2020 01:28:38
	System	09 Sep 2020 01:28:38

US3342204

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 11 Aug 2021 22:34:12

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:12:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7A504897-431F-4E74-9F03-DAC668AE5D1E)', Time: '2020-09-08T20:28:29', User OID: 'PatientReportedOutcome (US3342204)', ODM File OID: '6c700365-4dbf-4fbd-a60d-1f05001e291c' User entered 'No (N)'	System	09 Sep 2020 01:28:38
	System	09 Sep 2020 01:28:38

US3342204

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 11 Aug 2021 22:34:12

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:12:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7A504897-431F-4E74-9F03-DAC668AE5D1E)', Time: '2020-09-08T20:28:34', User OID: 'PatientReportedOutcome (US3342204)', ODM File OID: '6c700365-4dbf-4fbd-a60d-1f05001e291c' User entered '08 Sep 2020 20:28'	System	09 Sep 2020 01:28:38
	System	09 Sep 2020 01:28:38

US3342204

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 11 Aug 2021 22:34:12

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:12:42
User entered '08 Sep 2020 15:29'	System	08 Sep 2020 17:07:02

US3342204

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 11 Aug 2021 22:34:12

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:12:42
User entered '09 Sep 2020 11:59'	System	08 Sep 2020 17:07:02

US3342204

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 11 Aug 2021 22:34:12

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:12:42
Data entry locked.	System	08 Sep 2020 17:07:02
User entered 'Day 2'	System	08 Sep 2020 17:07:02

US3342204

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 11 Aug 2021 22:34:12

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:12:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7A504897-431F-4E74-9F03-DAC668AE5D1E)', Time: '2020-09-09T20:51:07', User OID: 'PatientReportedOutcome (US3342204)', ODM File OID: '9fc77b95-f2f6-4a13-90e5-319709891660' User entered 'None (0)'	System	10 Sep 2020 01:51:24
	System	10 Sep 2020 01:51:24

US3342204

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 11 Aug 2021 22:34:12

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:12:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7A504897-431F-4E74-9F03-DAC668AE5D1E)', Time: '2020-09-09T20:51:09', User OID: 'PatientReportedOutcome (US3342204)', ODM File OID: '9fc77b95-f2f6-4a13-90e5-319709891660' User entered 'None (0)'	System	10 Sep 2020 01:51:24
	System	10 Sep 2020 01:51:24

US3342204

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 11 Aug 2021 22:34:12

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:12:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7A504897-431F-4E74-9F03-DAC668AE5D1E)', Time: '2020-09-09T20:51:11', User OID: 'PatientReportedOutcome (US3342204)', ODM File OID: '9fc77b95-f2f6-4a13-90e5-319709891660' User entered 'None (0)'	System	10 Sep 2020 01:51:24
	System	10 Sep 2020 01:51:24

US3342204

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 11 Aug 2021 22:34:12

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:12:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7A504897-431F-4E74-9F03-DAC668AE5D1E)', Time: '2020-09-09T20:51:12', User OID: 'PatientReportedOutcome (US3342204)', ODM File OID: '9fc77b95-f2f6-4a13-90e5-319709891660' User entered 'None (0)'	System	10 Sep 2020 01:51:24
	System	10 Sep 2020 01:51:24

US3342204

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 11 Aug 2021 22:34:12

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:12:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7A504897-431F-4E74-9F03-DAC668AE5D1E)', Time: '2020-09-09T20:51:14', User OID: 'PatientReportedOutcome (US3342204)', ODM File OID: '9fc77b95-f2f6-4a13-90e5-319709891660' User entered 'None (0)'	System	10 Sep 2020 01:51:24
	System	10 Sep 2020 01:51:24

US3342204

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 11 Aug 2021 22:34:12

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:12:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7A504897-431F-4E74-9F03-DAC668AE5D1E)', Time: '2020-09-09T20:51:16', User OID: 'PatientReportedOutcome (US3342204)', ODM File OID: '9fc77b95-f2f6-4a13-90e5-319709891660' User entered 'None (0)'	System	10 Sep 2020 01:51:24
	System	10 Sep 2020 01:51:24

US3342204

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 11 Aug 2021 22:34:12

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:12:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7A504897-431F-4E74-9F03-DAC668AE5D1E)', Time: '2020-09-09T20:51:19', User OID: 'PatientReportedOutcome (US3342204)', ODM File OID: '9fc77b95-f2f6-4a13-90e5-319709891660'	System	10 Sep 2020 01:51:24
User entered 'No (N)'	System	10 Sep 2020 01:51:24

US3342204

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 11 Aug 2021 22:34:12

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:12:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7A504897-431F-4E74-9F03-DAC668AE5D1E)', Time: '2020-09-09T20:51:21', User OID: 'PatientReportedOutcome (US3342204)', ODM File OID: '9fc77b95-f2f6-4a13-90e5-319709891660' User entered '09 Sep 2020 20:51'	System	10 Sep 2020 01:51:24
	System	10 Sep 2020 01:51:24

US3342204

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 11 Aug 2021 22:34:12

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:12:42
User entered '09 Sep 2020 12:00'	System	08 Sep 2020 17:07:02

US3342204

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 11 Aug 2021 22:34:12

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:12:42
User entered '10 Sep 2020 11:59'	System	08 Sep 2020 17:07:02

US3342204

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 11 Aug 2021 22:34:12

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:12:42
Data entry locked.	System	08 Sep 2020 17:07:02
User entered 'Day 3'	System	08 Sep 2020 17:07:02

US3342204

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 11 Aug 2021 22:34:12

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:12:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7A504897-431F-4E74-9F03-DAC668AE5D1E)', Time: '2020-09-10T22:40:31', User OID: 'PatientReportedOutcome (US3342204)', ODM File OID: 'f7b0e7e2-e731-4c86-b6c6-3b88c59271a3' User entered 'None (0)'	System	11 Sep 2020 03:40:51
	System	11 Sep 2020 03:40:51

US3342204

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 11 Aug 2021 22:34:12

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:12:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7A504897-431F-4E74-9F03-DAC668AE5D1E)', Time: '2020-09-10T22:40:36', User OID: 'PatientReportedOutcome (US3342204)', ODM File OID: 'f7b0e7e2-e731-4c86-b6c6-3b88c59271a3' User entered 'None (0)'	System	11 Sep 2020 03:40:51
	System	11 Sep 2020 03:40:51

US3342204

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 11 Aug 2021 22:34:12

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:12:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7A504897-431F-4E74-9F03-DAC668AE5D1E)', Time: '2020-09-10T22:40:38', User OID: 'PatientReportedOutcome (US3342204)', ODM File OID: 'f7b0e7e2-e731-4c86-b6c6-3b88c59271a3' User entered 'None (0)'	System	11 Sep 2020 03:40:51
	System	11 Sep 2020 03:40:51

US3342204

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 11 Aug 2021 22:34:12

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:12:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7A504897-431F-4E74-9F03-DAC668AE5D1E)', Time: '2020-09-10T22:40:40', User OID: 'PatientReportedOutcome (US3342204)', ODM File OID: 'f7b0e7e2-e731-4c86-b6c6-3b88c59271a3' User entered 'None (0)'	System	11 Sep 2020 03:40:51
	System	11 Sep 2020 03:40:51

US3342204

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 11 Aug 2021 22:34:12

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:12:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7A504897-431F-4E74-9F03-DAC668AE5D1E)', Time: '2020-09-10T22:40:42', User OID: 'PatientReportedOutcome (US3342204)', ODM File OID: 'f7b0e7e2-e731-4c86-b6c6-3b88c59271a3' User entered 'None (0)'	System	11 Sep 2020 03:40:51
	System	11 Sep 2020 03:40:51

US3342204

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 11 Aug 2021 22:34:12

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:12:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7A504897-431F-4E74-9F03-DAC668AE5D1E)', Time: '2020-09-10T22:40:44', User OID: 'PatientReportedOutcome (US3342204)', ODM File OID: 'f7b0e7e2-e731-4c86-b6c6-3b88c59271a3' User entered 'None (0)'	System	11 Sep 2020 03:40:51
	System	11 Sep 2020 03:40:51

US3342204

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 11 Aug 2021 22:34:12

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:12:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7A504897-431F-4E74-9F03-DAC668AE5D1E)', Time: '2020-09-10T22:40:47', User OID: 'PatientReportedOutcome (US3342204)', ODM File OID: 'f7b0e7e2-e731-4c86-b6c6-3b88c59271a3' User entered 'No (N)'	System	11 Sep 2020 03:40:51
	System	11 Sep 2020 03:40:51

US3342204

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 11 Aug 2021 22:34:12

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:12:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7A504897-431F-4E74-9F03-DAC668AE5D1E)', Time: '2020-09-10T22:40:50', User OID: 'PatientReportedOutcome (US3342204)', ODM File OID: 'f7b0e7e2-e731-4c86-b6c6-3b88c59271a3' User entered '10 Sep 2020 22:40'	System	11 Sep 2020 03:40:51
	System	11 Sep 2020 03:40:51

US3342204

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 11 Aug 2021 22:34:12

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:12:42
User entered '10 Sep 2020 12:00'	System	08 Sep 2020 17:07:02

US3342204

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 11 Aug 2021 22:34:12

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:12:42
User entered '11 Sep 2020 11:59'	System	08 Sep 2020 17:07:02

US3342204

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 11 Aug 2021 22:34:12

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:12:42
Data entry locked.	System	08 Sep 2020 17:07:02
User entered 'Day 4'	System	08 Sep 2020 17:07:02

US3342204

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 11 Aug 2021 22:34:12

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:12:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7A504897-431F-4E74-9F03-DAC668AE5D1E)', Time: '2020-09-11T22:28:27', User OID: 'PatientReportedOutcome (US3342204)', ODM File OID: '8e38da9e-fe66-4e99-8a68-3ff403f3a3a4' User entered 'None (0)'	System	12 Sep 2020 03:28:48
	System	12 Sep 2020 03:28:48

US3342204

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 11 Aug 2021 22:34:12

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:12:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7A504897-431F-4E74-9F03-DAC668AE5D1E)', Time: '2020-09-11T22:28:31', User OID: 'PatientReportedOutcome (US3342204)', ODM File OID: '8e38da9e-fe66-4e99-8a68-3ff403f3a3a4' User entered 'None (0)'	System	12 Sep 2020 03:28:48
	System	12 Sep 2020 03:28:48

US3342204

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 11 Aug 2021 22:34:12

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:12:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7A504897-431F-4E74-9F03-DAC668AE5D1E)', Time: '2020-09-11T22:28:32', User OID: 'PatientReportedOutcome (US3342204)', ODM File OID: '8e38da9e-fe66-4e99-8a68-3ff403f3a3a4' User entered 'None (0)'	System	12 Sep 2020 03:28:48
	System	12 Sep 2020 03:28:48

US3342204

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 11 Aug 2021 22:34:12

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:12:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7A504897-431F-4E74-9F03-DAC668AE5D1E)', Time: '2020-09-11T22:28:34', User OID: 'PatientReportedOutcome (US3342204)', ODM File OID: '8e38da9e-fe66-4e99-8a68-3ff403f3a3a4' User entered 'None (0)'	System	12 Sep 2020 03:28:48
	System	12 Sep 2020 03:28:48

US3342204

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 11 Aug 2021 22:34:12

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:12:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7A504897-431F-4E74-9F03-DAC668AE5D1E)', Time: '2020-09-11T22:28:37', User OID: 'PatientReportedOutcome (US3342204)', ODM File OID: '8e38da9e-fe66-4e99-8a68-3ff403f3a3a4'	System	12 Sep 2020 03:28:48
User entered 'None (0)'	System	12 Sep 2020 03:28:48

US3342204

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 11 Aug 2021 22:34:12

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:12:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7A504897-431F-4E74-9F03-DAC668AE5D1E)', Time: '2020-09-11T22:28:39', User OID: 'PatientReportedOutcome (US3342204)', ODM File OID: '8e38da9e-fe66-4e99-8a68-3ff403f3a3a4' User entered 'None (0)'	System	12 Sep 2020 03:28:48
	System	12 Sep 2020 03:28:48

US3342204

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 11 Aug 2021 22:34:12

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:12:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7A504897-431F-4E74-9F03-DAC668AE5D1E)', Time: '2020-09-11T22:28:42', User OID: 'PatientReportedOutcome (US3342204)', ODM File OID: '8e38da9e-fe66-4e99-8a68-3ff403f3a3a4' User entered 'No (N)'	System	12 Sep 2020 03:28:48
	System	12 Sep 2020 03:28:48

US3342204

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 11 Aug 2021 22:34:12

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:12:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7A504897-431F-4E74-9F03-DAC668AE5D1E)', Time: '2020-09-11T22:28:46', User OID: 'PatientReportedOutcome (US3342204)', ODM File OID: '8e38da9e-fe66-4e99-8a68-3ff403f3a3a4' User entered '11 Sep 2020 22:28'	System	12 Sep 2020 03:28:48
	System	12 Sep 2020 03:28:48

US3342204

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 11 Aug 2021 22:34:12

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:12:42
User entered '11 Sep 2020 12:00'	System	08 Sep 2020 17:07:02

US3342204

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 11 Aug 2021 22:34:12

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:12:42
User entered '12 Sep 2020 11:59'	System	08 Sep 2020 17:07:02

US3342204

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 11 Aug 2021 22:34:12

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:12:42
Data entry locked.	System	08 Sep 2020 17:07:02
User entered 'Day 5'	System	08 Sep 2020 17:07:02

US3342204

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 11 Aug 2021 22:34:12

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:12:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7A504897-431F-4E74-9F03-DAC668AE5D1E)', Time: '2020-09-12T23:59:54', User OID: 'PatientReportedOutcome (US3342204)', ODM File OID: '73ba6947-a3c8-492e-a275-eee01744cd04' User entered 'None (0)'	System	13 Sep 2020 05:00:24
	System	13 Sep 2020 05:00:24

US3342204

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 11 Aug 2021 22:34:12

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:12:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7A504897-431F-4E74-9F03-DAC668AE5D1E)', Time: '2020-09-12T23:59:56', User OID: 'PatientReportedOutcome (US3342204)', ODM File OID: '73ba6947-a3c8-492e-a275-eee01744cd04' User entered 'None (0)'	System	13 Sep 2020 05:00:24
	System	13 Sep 2020 05:00:24

US3342204

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 11 Aug 2021 22:34:12

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:12:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7A504897-431F-4E74-9F03-DAC668AE5D1E)', Time: '2020-09-12T23:59:58', User OID: 'PatientReportedOutcome (US3342204)', ODM File OID: '73ba6947-a3c8-492e-a275-eee01744cd04' User entered 'None (0)'	System	13 Sep 2020 05:00:24
	System	13 Sep 2020 05:00:24

US3342204

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 11 Aug 2021 22:34:12

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:12:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7A504897-431F-4E74-9F03-DAC668AE5D1E)', Time: '2020-09-13T00:00:00', User OID: 'PatientReportedOutcome (US3342204)', ODM File OID: '73ba6947-a3c8-492e-a275-eee01744cd04' User entered 'None (0)'	System	13 Sep 2020 05:00:24
	System	13 Sep 2020 05:00:24

US3342204

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 11 Aug 2021 22:34:12

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:12:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7A504897-431F-4E74-9F03-DAC668AE5D1E)', Time: '2020-09-13T00:00:04', User OID: 'PatientReportedOutcome (US3342204)', ODM File OID: '73ba6947-a3c8-492e-a275-eee01744cd04' User entered 'None (0)'	System	13 Sep 2020 05:00:24
	System	13 Sep 2020 05:00:24

US3342204

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 11 Aug 2021 22:34:12

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:12:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7A504897-431F-4E74-9F03-DAC668AE5D1E)', Time: '2020-09-13T00:00:12', User OID: 'PatientReportedOutcome (US3342204)', ODM File OID: '73ba6947-a3c8-492e-a275-eee01744cd04' User entered 'None (0)'	System	13 Sep 2020 05:00:24
	System	13 Sep 2020 05:00:24

US3342204

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 11 Aug 2021 22:34:12

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:12:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7A504897-431F-4E74-9F03-DAC668AE5D1E)', Time: '2020-09-13T00:00:17', User OID: 'PatientReportedOutcome (US3342204)', ODM File OID: '73ba6947-a3c8-492e-a275-eee01744cd04' User entered 'No (N)'	System	13 Sep 2020 05:00:24
	System	13 Sep 2020 05:00:24

US3342204

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 11 Aug 2021 22:34:12

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:12:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7A504897-431F-4E74-9F03-DAC668AE5D1E)', Time: '2020-09-13T00:00:20', User OID: 'PatientReportedOutcome (US3342204)', ODM File OID: '73ba6947-a3c8-492e-a275-eee01744cd04' User entered '13 Sep 2020 00:00'	System	13 Sep 2020 05:00:24
	System	13 Sep 2020 05:00:24

US3342204

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 11 Aug 2021 22:34:12

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:12:42
User entered '12 Sep 2020 12:00'	System	08 Sep 2020 17:07:02

US3342204

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 11 Aug 2021 22:34:12

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:12:42
User entered '13 Sep 2020 11:59'	System	08 Sep 2020 17:07:02

US3342204

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 11 Aug 2021 22:34:12

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:12:42
Data entry locked.	System	08 Sep 2020 17:07:02
User entered 'Day 6'	System	08 Sep 2020 17:07:02

US3342204

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 11 Aug 2021 22:34:12

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:12:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7A504897-431F-4E74-9F03-DAC668AE5D1E)', Time: '2020-09-13T22:46:24', User OID: 'PatientReportedOutcome (US3342204)', ODM File OID: '040eb58f-7a3e-46cd-ba5f-b8a538367b42' User entered 'None (0)'	System	14 Sep 2020 03:46:47
	System	14 Sep 2020 03:46:47

US3342204

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 11 Aug 2021 22:34:12

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:12:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7A504897-431F-4E74-9F03-DAC668AE5D1E)', Time: '2020-09-13T22:46:26', User OID: 'PatientReportedOutcome (US3342204)', ODM File OID: '040eb58f-7a3e-46cd-ba5f-b8a538367b42' User entered 'None (0)'	System	14 Sep 2020 03:46:47
	System	14 Sep 2020 03:46:47

US3342204

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 11 Aug 2021 22:34:12

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:12:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7A504897-431F-4E74-9F03-DAC668AE5D1E)', Time: '2020-09-13T22:46:28', User OID: 'PatientReportedOutcome (US3342204)', ODM File OID: '040eb58f-7a3e-46cd-ba5f-b8a538367b42' User entered 'None (0)'	System	14 Sep 2020 03:46:47
	System	14 Sep 2020 03:46:47

US3342204

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 11 Aug 2021 22:34:12

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:12:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7A504897-431F-4E74-9F03-DAC668AE5D1E)', Time: '2020-09-13T22:46:30', User OID: 'PatientReportedOutcome (US3342204)', ODM File OID: '040eb58f-7a3e-46cd-ba5f-b8a538367b42' User entered 'None (0)'	System	14 Sep 2020 03:46:47
	System	14 Sep 2020 03:46:47

US3342204

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 11 Aug 2021 22:34:12

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:12:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7A504897-431F-4E74-9F03-DAC668AE5D1E)', Time: '2020-09-13T22:46:33', User OID: 'PatientReportedOutcome (US3342204)', ODM File OID: '040eb58f-7a3e-46cd-ba5f-b8a538367b42' User entered 'None (0)'	System	14 Sep 2020 03:46:47
	System	14 Sep 2020 03:46:47

US3342204

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 11 Aug 2021 22:34:12

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:12:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7A504897-431F-4E74-9F03-DAC668AE5D1E)', Time: '2020-09-13T22:46:35', User OID: 'PatientReportedOutcome (US3342204)', ODM File OID: '040eb58f-7a3e-46cd-ba5f-b8a538367b42'	System	14 Sep 2020 03:46:47
User entered 'None (0)'	System	14 Sep 2020 03:46:47

US3342204

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 11 Aug 2021 22:34:12

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:12:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7A504897-431F-4E74-9F03-DAC668AE5D1E)', Time: '2020-09-13T22:46:38', User OID: 'PatientReportedOutcome (US3342204)', ODM File OID: '040eb58f-7a3e-46cd-ba5f-b8a538367b42'	System	14 Sep 2020 03:46:47
User entered 'No (N)'	System	14 Sep 2020 03:46:47

US3342204

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 11 Aug 2021 22:34:12

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:12:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7A504897-431F-4E74-9F03-DAC668AE5D1E)', Time: '2020-09-13T22:46:43', User OID: 'PatientReportedOutcome (US3342204)', ODM File OID: '040eb58f-7a3e-46cd-ba5f-b8a538367b42' User entered '13 Sep 2020 22:46'	System	14 Sep 2020 03:46:47
	System	14 Sep 2020 03:46:47

US3342204

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 11 Aug 2021 22:34:12

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:12:42
User entered '13 Sep 2020 12:00'	System	08 Sep 2020 17:07:02

US3342204

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 11 Aug 2021 22:34:12

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:12:42
User entered '14 Sep 2020 11:59'	System	08 Sep 2020 17:07:02

US3342204

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 11 Aug 2021 22:34:12

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:12:42
Data entry locked.	System	08 Sep 2020 17:07:02
User entered 'Day 7'	System	08 Sep 2020 17:07:02

US3342204

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 11 Aug 2021 22:34:12

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:12:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7A504897-431F-4E74-9F03-DAC668AE5D1E)', Time: '2020-09-14T22:44:47', User OID: 'PatientReportedOutcome (US3342204)', ODM File OID: '10347df6-dd58-443c-9533-d43040420260' User entered 'None (0)'	System	15 Sep 2020 03:45:11
	System	15 Sep 2020 03:45:11

US3342204

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 11 Aug 2021 22:34:12

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:12:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7A504897-431F-4E74-9F03-DAC668AE5D1E)', Time: '2020-09-14T22:44:52', User OID: 'PatientReportedOutcome (US3342204)', ODM File OID: '10347df6-dd58-443c-9533-d43040420260' User entered 'None (0)'	System	15 Sep 2020 03:45:11
	System	15 Sep 2020 03:45:11

US3342204

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 11 Aug 2021 22:34:12

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:12:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7A504897-431F-4E74-9F03-DAC668AE5D1E)', Time: '2020-09-14T22:44:54', User OID: 'PatientReportedOutcome (US3342204)', ODM File OID: '10347df6-dd58-443c-9533-d43040420260' User entered 'None (0)'	System	15 Sep 2020 03:45:11
	System	15 Sep 2020 03:45:11

US3342204

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 11 Aug 2021 22:34:12

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:12:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7A504897-431F-4E74-9F03-DAC668AE5D1E)', Time: '2020-09-14T22:44:55', User OID: 'PatientReportedOutcome (US3342204)', ODM File OID: '10347df6-dd58-443c-9533-d43040420260' User entered 'None (0)'	System	15 Sep 2020 03:45:11
	System	15 Sep 2020 03:45:11

US3342204

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 11 Aug 2021 22:34:12

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:12:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7A504897-431F-4E74-9F03-DAC668AE5D1E)', Time: '2020-09-14T22:44:57', User OID: 'PatientReportedOutcome (US3342204)', ODM File OID: '10347df6-dd58-443c-9533-d43040420260' User entered 'None (0)'	System	15 Sep 2020 03:45:11
	System	15 Sep 2020 03:45:11

US3342204

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 11 Aug 2021 22:34:12

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:12:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7A504897-431F-4E74-9F03-DAC668AE5D1E)', Time: '2020-09-14T22:44:59', User OID: 'PatientReportedOutcome (US3342204)', ODM File OID: '10347df6-dd58-443c-9533-d43040420260' User entered 'None (0)'	System	15 Sep 2020 03:45:11
	System	15 Sep 2020 03:45:11

US3342204

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 11 Aug 2021 22:34:12

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:12:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7A504897-431F-4E74-9F03-DAC668AE5D1E)', Time: '2020-09-14T22:45:05', User OID: 'PatientReportedOutcome (US3342204)', ODM File OID: '10347df6-dd58-443c-9533-d43040420260' User entered 'No (N)'	System	15 Sep 2020 03:45:11
	System	15 Sep 2020 03:45:11

US3342204

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 11 Aug 2021 22:34:12

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:12:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7A504897-431F-4E74-9F03-DAC668AE5D1E)', Time: '2020-09-14T22:45:07', User OID: 'PatientReportedOutcome (US3342204)', ODM File OID: '10347df6-dd58-443c-9533-d43040420260'	System	15 Sep 2020 03:45:11
User entered '14 Sep 2020 22:45'	System	15 Sep 2020 03:45:11

US3342204

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 11 Aug 2021 22:34:12

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:12:42
User entered '14 Sep 2020 12:00'	System	08 Sep 2020 17:07:02

US3342204

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 11 Aug 2021 22:34:12

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:12:42
User entered '15 Sep 2020 11:59'	System	08 Sep 2020 17:07:02

US3342204

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:34:12

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:55:52
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:17:37
User entered 'Yes (Y)'	Ethan Shotton (b) (4)	15 Sep 2020 20:45:12

US3342204

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:34:12

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:55:52
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:17:37
User entered '15 Sep 2020'	Ethan Shotton (b) (4)	15 Sep 2020 20:45:12

US3342204

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:34:12

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:55:52
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:17:37
User entered 'Contact Made (CONTACT MADE)'	Ethan Shotton (b) (4)	15 Sep 2020 20:45:12

US3342204

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:34:12

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:55:52
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:17:37
User entered empty.	Ethan Shotton (b) (4)	15 Sep 2020 20:45:12

US3342204

Folder: Safety Call Day 8 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:34:12

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:55:52
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:17:37
User entered 'Yes (Y)'	Ethan Shotton (b) (4)	15 Sep 2020 20:45:16

US3342204

Folder: Safety Call Day 8 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:34:12

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:55:52
User entered '1'	System	15 Sep 2020 20:45:16

US3342204

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:34:12

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:55:52
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:17:37
User entered 'Yes (Y)'	Ethan Shotton (b) (4)	22 Sep 2020 16:54:11

US3342204

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:34:12

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:55:52
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:17:37
User entered '22 Sep 2020'	Ethan Shotton (b) (4)	22 Sep 2020 16:54:11

US3342204

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:34:12

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:55:52
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:17:37
User entered 'Contact Made (CONTACT MADE)'	Ethan Shotton (b) (4)	22 Sep 2020 16:54:11

US3342204

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:34:12

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:55:52
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:17:37
User entered empty.	Ethan Shotton (b) (4)	22 Sep 2020 16:54:11

US3342204

Folder: Safety Call Day 15 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:34:12

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:55:52
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:17:37
User entered 'Yes (Y)'	Ethan Shotton (b) (4)	22 Sep 2020 16:54:16

US3342204

Folder: Safety Call Day 15 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:34:12

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:55:52
User entered '1'	System	22 Sep 2020 16:54:16

US3342204

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:34:12

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:55:52
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:17:37
User entered 'Yes (Y)'	Ethan Shotton (b) (4)	29 Sep 2020 18:43:55

US3342204

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:34:12

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:55:52
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:17:37
User entered '29 Sep 2020'	(b) (4) Ethan Shotton (b) (4)	29 Sep 2020 18:43:55

US3342204

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:34:12

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:55:52
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:17:37
User entered 'Contact Made (CONTACT MADE)'	Ethan Shotton (b) (4)	29 Sep 2020 18:43:55

US3342204

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:34:12

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:55:52
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:17:37
User entered empty.	Ethan Shotton (b) (4)	29 Sep 2020 18:43:55

US3342204

Folder: Safety Call Day 22 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:34:12

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:55:52
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:17:37
User entered 'Yes (Y)'	Ethan Shotton (b) (4)	29 Sep 2020 18:44:25

US3342204

Folder: Safety Call Day 22 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:34:12

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:55:52
User entered '1'	System	29 Sep 2020 18:44:25

US3342204

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 11 Aug 2021 22:34:12

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 13:03:22
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:17:37
User entered 'Yes (Y)'	(b) (4) Andrew Bell (b) (4)	26 Oct 2020 16:05:33

US3342204

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 11 Aug 2021 22:34:12

Visit date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 13:03:22
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:17:37
User closed query 'Visit 2 Date is < 25 days or > 35 days after Visit 1 vaccination. Please reconcile or confirm dates.' (Site from System).	(b) (4) (b) (4), (b) (6)	27 Oct 2020 14:38:18
Query 'Visit 2 Date is < 25 days or > 35 days after Visit 1 vaccination. Please reconcile or confirm dates.' answered with 'Second visit confirmed as outside of window due to sponsor supply issue.' (Site from System).	Andrew Bell (b) (4) (b) (4)	26 Oct 2020 16:06:00
User opened query 'Visit 2 Date is < 25 days or > 35 days after Visit 1 vaccination. Please reconcile or confirm dates.' (Site from System).	System	26 Oct 2020 16:05:33
User entered '26 Oct 2020'	Andrew Bell (b) (4) (b) (4)	26 Oct 2020 16:05:33

US3342204

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 11 Aug 2021 22:34:12

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 13:03:22
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:17:37
User entered 'Clinic (Clinic)'	Andrew Bell (b) (4)	26 Oct 2020 16:05:33

US3342204

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 11 Aug 2021 22:34:12

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 13:03:22
User entered 'VISIT2'	System	26 Oct 2020 16:05:33

US3342204

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:34:12

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 13:03:22
User accepted default value 'Pre-Dose (PREDOSE)'	Andrew Bell (b) (4) (b) (4)	26 Oct 2020 16:06:47

US3342204

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:34:12

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 13:03:22
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:17:37
User entered 'Yes (Y)'	(b) (4) Andrew Bell (b) (4)	26 Oct 2020 16:06:47

US3342204

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:34:12

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 13:03:22
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:17:37
User entered '26 Oct 2020'	(b) (4) Andrew Bell (b) (4)	26 Oct 2020 16:06:47

US3342204

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:34:12

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 13:03:22
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:17:37
User entered '10:22'	(b) (4) Andrew Bell (b) (4)	26 Oct 2020 16:06:47

US3342204

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:34:12

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 13:03:22
User entered '26 Oct 2020 10:22'	System	26 Oct 2020 16:06:47

US3342204

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:34:12

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 13:03:22
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:17:37
User entered '98.0' F	(b) (4) Andrew Bell (b) (4)	26 Oct 2020 16:06:47

US3342204

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:34:12

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 13:03:22
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:17:37
User entered 'Oral (Oral)'	(b) (4) Andrew Bell (b) (4)	26 Oct 2020 16:06:47

US3342204

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:34:12

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 13:03:22
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:17:37
User entered empty.	(b) (4) Andrew Bell (b) (4)	26 Oct 2020 16:06:47

US3342204

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:34:12

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 13:03:22
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:17:37
User entered '69'	(b) (4) Andrew Bell (b) (4)	26 Oct 2020 16:06:47

US3342204

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:34:12

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 13:03:22
User entered 'bpm'	System	26 Oct 2020 16:06:47

US3342204

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:34:12

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 13:03:22
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:17:37
User entered '12'	(b) (4) Andrew Bell (b) (4)	26 Oct 2020 16:06:47

US3342204

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:34:12

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 13:03:22
User entered 'breaths/min'	System	26 Oct 2020 16:06:47

US3342204

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:34:12

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 13:03:22
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:17:37
User entered '97'	(b) (4) Andrew Bell (b) (4)	26 Oct 2020 16:06:47

US3342204

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:34:12

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 13:03:22
User entered 'mmHg'	System	26 Oct 2020 16:06:47

US3342204

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:34:12

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 13:03:22
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:17:37
User entered '67'	(b) (4) Andrew Bell (b) (4)	26 Oct 2020 16:06:47

US3342204

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:34:12

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 13:03:22
User entered 'mmHg'	System	26 Oct 2020 16:06:47

US3342204

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:34:12

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 13:03:22
User accepted default value 'Post-Dose (POSTDOSE)'	Andrew Bell (b) (4) (b) (4)	26 Oct 2020 16:06:47

US3342204

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:34:12

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 13:03:22
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:17:37
User closed query 'Data is required. Please complete.' (Site from System).	(b) (4)	26 Oct 2020 17:08:19
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	26 Oct 2020 17:08:19
User entered 'Yes (Y)' reason for change: Data Entry Error	Morgan Schulle (b) (4)	26 Oct 2020 17:08:19
User opened query 'Data is required. Please complete.' (Site from System).	(b) (4)	26 Oct 2020 16:06:47
User entered empty.	System	26 Oct 2020 16:06:47
	Andrew Bell (b) (4)	26 Oct 2020 16:06:47
	(b) (4)	

US3342204

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:34:12

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 13:03:22
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:17:37
User entered '26 Oct 2020' reason for change: Data Entry Error	(b) (4)	
	Morgan Schulle (b) (4)	26 Oct 2020 17:08:19
User entered empty.	(b) (4)	
	Andrew Bell (b) (4)	26 Oct 2020 16:06:47
	(b) (4)	

US3342204

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:34:12

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 13:03:22
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:17:37
User entered '12:02' reason for change: Data Entry Error	(b) (4)	26 Oct 2020 17:08:19
User entered empty.	Morgan Schulle (b) (4)	26 Oct 2020 16:06:47
	(b) (4)	

US3342204

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:34:12

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 13:03:22
User entered '26 Oct 2020 12:02'	System	26 Oct 2020 17:08:19
User entered empty.	System	26 Oct 2020 16:06:47

US3342204

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:34:12

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 13:03:22
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:17:37
User entered '97.0' F reason for change: Data Entry Error	(b) (4)	26 Oct 2020 17:08:19
User entered empty.	Morgan Schulle (b) (4)	26 Oct 2020 16:06:47
	(b) (4)	

US3342204

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:34:12

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 13:03:22
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:17:37
User entered 'Oral (Oral)' reason for change: Data Entry Error	(b) (4)	
	Morgan Schulle (b) (4)	26 Oct 2020 17:08:19
User entered empty.	(b) (4)	
	Andrew Bell (b) (4)	26 Oct 2020 16:06:47
	(b) (4)	

US3342204

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:34:12

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 13:03:22
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:17:37
User entered empty.	(b) (4) Andrew Bell (b) (4)	26 Oct 2020 16:06:47

US3342204

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:34:12

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 13:03:22
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:17:37
User entered '72' reason for change: Data Entry Error	(b) (4)	
	Morgan Schulle (b) (4)	26 Oct 2020 17:08:19
User entered empty.	(b) (4)	
	Andrew Bell (b) (4)	26 Oct 2020 16:06:47
	(b) (4)	

US3342204

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:34:12

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 13:03:22
User entered 'bpm'	System	26 Oct 2020 17:08:19
User entered empty.	System	26 Oct 2020 16:06:47

US3342204

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:34:12

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 13:03:22
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:17:37
User entered '12' reason for change: Data Entry Error	(b) (4)	
	Morgan Schulle (b) (4)	26 Oct 2020 17:08:19
User entered empty.	(b) (4)	
	Andrew Bell (b) (4)	26 Oct 2020 16:06:47
	(b) (4)	

US3342204

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:34:12

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 13:03:22
User entered 'breaths/min'	System	26 Oct 2020 17:08:19
User entered empty.	System	26 Oct 2020 16:06:47

US3342204

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:34:12

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 13:03:22
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:17:37
User entered '108' reason for change: Data Entry Error	(b) (4)	
	Morgan Schulle (b) (4)	26 Oct 2020 17:08:19
User entered empty.	(b) (4)	
	Andrew Bell (b) (4)	26 Oct 2020 16:06:47
	(b) (4)	

US3342204

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:34:12

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 13:03:22
User entered 'mmHg'	System	26 Oct 2020 17:08:19
User entered empty.	System	26 Oct 2020 16:06:47

US3342204

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:34:12

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 13:03:22
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:17:37
User entered '63' reason for change: Data Entry Error	(b) (4)	26 Oct 2020 17:08:19
User entered empty.	Morgan Schulle (b) (4)	26 Oct 2020 17:08:19
	(b) (4)	
	Andrew Bell (b) (4)	26 Oct 2020 16:06:47
	(b) (4)	

US3342204

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:34:12

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 13:03:22
User entered 'mmHg'	System	26 Oct 2020 17:08:19
User entered empty.	System	26 Oct 2020 16:06:47

US3342204

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Generated On: 11 Aug 2021 22:34:12

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 13:03:22
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:17:37
User entered 'No (N)'	(b) (4) Andrew Bell (b) (4)	26 Oct 2020 16:06:58

US3342204

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Generated On: 11 Aug 2021 22:34:12

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 13:03:22
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:17:37
User entered empty.	(b) (4) Andrew Bell (b) (4)	26 Oct 2020 16:06:58

US3342204

Folder: Visit 2 Day 29 (1)

Form: Pregnancy Test

Generated On: 11 Aug 2021 22:34:12

[Was the pregnancy test performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 13:03:22
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:17:37
User entered 'Yes (Y)'	(b) (4) Andrew Bell (b) (4)	26 Oct 2020 16:07:10

US3342204

Folder: Visit 2 Day 29 (1)

Form: Pregnancy Test

Generated On: 11 Aug 2021 22:34:12

Date of test (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 13:03:22
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:17:37
User entered '26 Oct 2020'	(b) (4) Andrew Bell (b) (4)	26 Oct 2020 16:07:10

US3342204

Folder: Visit 2 Day 29 (1)

Form: Pregnancy Test

Generated On: 11 Aug 2021 22:34:12

[Test performed](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 13:03:22
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:17:37
User entered 'Urine (URINE)'	(b) (4) Andrew Bell (b) (4)	26 Oct 2020 16:07:10

US3342204

Folder: Visit 2 Day 29 (1)

Form: Pregnancy Test

Generated On: 11 Aug 2021 22:34:12

[Result](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 13:03:22
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:17:37
User entered 'Negative (NEGATIVE)'	(b) (4) Andrew Bell (b) (4)	26 Oct 2020 16:07:10

US3342204

Folder: Visit 2 Day 29 (1)

Form: Pregnancy Test

Generated On: 11 Aug 2021 22:34:12

Was FSH sample collected?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 13:03:22
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:17:37
User entered 'No (N)'	(b) (4) Andrew Bell (b) (4)	26 Oct 2020 16:07:10

US3342204

Folder: Visit 2 Day 29 (1)

Form: Pregnancy Test

Generated On: 11 Aug 2021 22:34:12

[Collection date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 13:03:22
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:17:37
User entered empty.	(b) (4) Andrew Bell (b) (4)	26 Oct 2020 16:07:10

US3342204

Folder: Visit 2 Day 29 (1)

Form: Pregnancy Test

Generated On: 11 Aug 2021 22:34:12

[Collection time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 13:03:22
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:17:37
User entered empty.	(b) (4) Andrew Bell (b) (4)	26 Oct 2020 16:07:10

US3342204

Folder: Visit 2 Day 29 (1)

Form: Pregnancy Test

Generated On: 11 Aug 2021 22:34:12

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 13:03:22
User entered empty.	System	26 Oct 2020 16:07:10

US3342204

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 11 Aug 2021 22:34:12

[Was study treatment given?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 13:03:22
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:17:37
User entered 'Yes (Y)'	(b) (4) Morgan Schulle (b) (4)	26 Oct 2020 16:37:26

US3342204

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 11 Aug 2021 22:34:12

[If No, reason not given](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 13:03:22
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:17:37
User entered empty.	(b) (4) Morgan Schulle (b) (4)	26 Oct 2020 16:37:26

US3342204

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 11 Aug 2021 22:34:12

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 Apr 2021 13:03:22
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:17:37
User entered empty.	Morgan Schulle (b) (4)	26 Oct 2020 16:37:26

US3342204

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 11 Aug 2021 22:34:12

[What was the study treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 13:03:22
User entered 'MRNA-1273 OR PLACEBO'	System	26 Oct 2020 16:37:26

US3342204

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 11 Aug 2021 22:34:12

What was the treatment date? (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 13:03:22
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:17:37
User entered '26 Oct 2020'	(b) (4) Morgan Schulle (b) (4)	26 Oct 2020 16:37:26

US3342204

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 11 Aug 2021 22:34:12

[What was the treatment time? \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 13:03:22
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:17:37
User entered '11:27'	(b) (4) Morgan Schulle (b) (4)	26 Oct 2020 16:37:26

US3342204

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 11 Aug 2021 22:34:12

[Treatment Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 13:03:22
User entered '26 Oct 2020 11:27'	System	26 Oct 2020 16:37:26

US3342204

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 11 Aug 2021 22:34:12

Which arm was used to give treatment?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 13:03:22
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:17:37
User entered 'Left Arm (LEFT ARM)'	(b) (4) Morgan Schulle (b) (4)	26 Oct 2020 16:37:26

US3342204

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 11 Aug 2021 22:34:12

[What was the frequency of the study treatment dosing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 13:03:22
User entered 'ONCE'	System	26 Oct 2020 16:37:26

US3342204

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 11 Aug 2021 22:34:12

What was the route of administration for the study treatment?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 13:03:22
User entered 'INTRAMUSCULAR'	System	26 Oct 2020 16:37:26

US3342204

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 22:34:12

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 13:03:22
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:17:37
User entered 'Yes (Y)'	Morgan Schulle (b) (4)	28 Oct 2020 19:23:37

US3342204

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 22:34:12

Collection date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 13:03:22
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:17:37
User closed query 'Per GCL Lab recon: Immunogenicity- Sample collection date for Visit 2 Day 29 is recorded as 26-OCT-2020. However, collection date is missing in GCL. Please confirm if 26-OCT-2020 is correct date to update in GCL records.' (Site from DM).	(b) (4) (b) (4), (b) (6)	30 Nov 2020 08:43:17
Query 'Per GCL Lab recon: Immunogenicity- Sample collection date for Visit 2 Day 29 is recorded as 26-OCT-2020. However, collection date is missing in GCL. Please confirm if 26-OCT-2020 is correct date to update in GCL records.' answered with 'Visit 2 Day 29 collection date confirmed as 26-OCT-2020.' (Site from DM).	Andrew Bell (b) (4) (b) (4)	12 Nov 2020 15:39:12
User opened query 'Per GCL Lab recon: Immunogenicity- Sample collection date for Visit 2 Day 29 is recorded as 26-OCT-2020. However, collection date is missing in GCL. Please confirm if 26-OCT-2020 is correct date to update in GCL records.' (Site from DM).	(b) (4), (b) (6)	10 Nov 2020 09:52:19
User entered '26 Oct 2020'	Morgan Schulle (b) (4) (b) (4)	28 Oct 2020 19:23:37

US3342204

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 22:34:12

Collection time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 13:03:22
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:17:37
User entered '11:23'	(b) (4) Morgan Schulle (b) (4)	28 Oct 2020 19:23:37

US3342204

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 22:34:12

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 13:03:22
User entered '26 Oct 2020 11:23'	System	28 Oct 2020 19:23:37

US3342204

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab

Generated On: 11 Aug 2021 22:34:12

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 13:03:22
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:17:37
User entered '26 Oct 2020'	(b) (4) Morgan Schulle (b) (4)	28 Oct 2020 19:23:24

US3342204

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 11 Aug 2021 22:34:12

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 13:03:22
User accepted default value 'Nasopharyngeal Swab 1 (NASAL1)'	Morgan Schulle (b) (4) (b) (4)	28 Oct 2020 19:23:24

US3342204

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 11 Aug 2021 22:34:12

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 13:03:22
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:17:37
User entered 'Yes (Y)'	(b) (4) Morgan Schulle (b) (4)	28 Oct 2020 19:23:24

US3342204

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 11 Aug 2021 22:34:12

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 13:03:22
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:17:37
User entered '11:25'	(b) (4) Morgan Schulle (b) (4)	28 Oct 2020 19:23:24

US3342204

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 11 Aug 2021 22:34:12

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 13:03:22
User entered '26 Oct 2020 11:25'	System	28 Oct 2020 19:23:24

US3342204

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 11 Aug 2021 22:34:12

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 13:03:22
User accepted default value 'Nasopharyngeal Swab 2 (NASAL2)'	Morgan Schulle (b) (4) (b) (4)	28 Oct 2020 19:23:24

US3342204

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 11 Aug 2021 22:34:12

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 13:03:22
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:17:37
User entered 'No (N)'	(b) (4) Morgan Schulle (b) (4)	28 Oct 2020 19:23:24

US3342204

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 11 Aug 2021 22:34:12

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 13:03:22
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:17:37
User entered empty.	(b) (4) Morgan Schulle (b) (4)	28 Oct 2020 19:23:24

US3342204

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 11 Aug 2021 22:34:12

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 13:03:22
User entered empty.	System	28 Oct 2020 19:23:24

US3342204

Folder: Visit 2 Day 29 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:34:12

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 13:03:22
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:17:37
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	26 Oct 2020 16:34:59

US3342204

Folder: Visit 2 Day 29 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:34:12

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 13:03:22
User entered '1'	System	26 Oct 2020 16:34:59

US3342204

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 11 Aug 2021 22:34:12

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:12:42
Data entry locked.	System	26 Oct 2020 16:37:26
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	26 Oct 2020 16:37:26

US3342204

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 11 Aug 2021 22:34:12

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:12:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7A504897-431F-4E74-9F03-DAC668AE5D1E)', Time: '2020-10-26T12:03:09', User OID: 'PatientReportedOutcome (US3342204)', ODM File OID: '7fa06664-bbe5-461d-8048-bee161d361fa' User entered 'Yes (Y)'	System	26 Oct 2020 17:04:19
	System	26 Oct 2020 17:04:19

US3342204

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 11 Aug 2021 22:34:12

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:12:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7A504897-431F-4E74-9F03-DAC668AE5D1E)', Time: '2020-10-26T12:03:15', User OID: 'PatientReportedOutcome (US3342204)', ODM File OID: '7fa06664-bbe5-461d-8048-bee161d361fa' User entered '97.0'	System	26 Oct 2020 17:04:19
	System	26 Oct 2020 17:04:19

US3342204

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 11 Aug 2021 22:34:12

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:12:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7A504897-431F-4E74-9F03-DAC668AE5D1E)', Time: '2020-10-26T12:03:18', User OID: 'PatientReportedOutcome (US3342204)', ODM File OID: '7fa06664-bbe5-461d-8048-bee161d361fa' User entered 'No (N)'	System	26 Oct 2020 17:04:19
	System	26 Oct 2020 17:04:19

US3342204

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 11 Aug 2021 22:34:12

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:12:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7A504897-431F-4E74-9F03-DAC668AE5D1E)', Time: '2020-10-26T12:03:23', User OID: 'PatientReportedOutcome (US3342204)', ODM File OID: '7fa06664-bbe5-461d-8048-bee161d361fa' User entered '26 Oct 2020 12:03'	System	26 Oct 2020 17:04:19
	System	26 Oct 2020 17:04:19

US3342204

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 11 Aug 2021 22:34:12

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:12:42
User entered '26 Oct 2020 11:47'	System	26 Oct 2020 16:37:26

US3342204

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 11 Aug 2021 22:34:12

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:12:42
User entered '26 Oct 2020 14:17'	System	26 Oct 2020 16:37:26

US3342204

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 11 Aug 2021 22:34:12

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:12:42
Data entry locked.	System	26 Oct 2020 16:37:26
User entered 'Day 1, after vaccination (at home)'	System	26 Oct 2020 16:37:26

US3342204

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 11 Aug 2021 22:34:12

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:12:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7A504897-431F-4E74-9F03-DAC668AE5D1E)', Time: '2020-10-26T23:49:45', User OID: 'PatientReportedOutcome (US3342204)', ODM File OID: 'f5dc7eb9-ead0-48ab-9e17-7d775c784cb4' User entered 'Yes (Y)'	System	27 Oct 2020 04:50:01
	System	27 Oct 2020 04:50:01

US3342204

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 11 Aug 2021 22:34:12

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:12:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7A504897-431F-4E74-9F03-DAC668AE5D1E)', Time: '2020-10-26T23:49:53', User OID: 'PatientReportedOutcome (US3342204)', ODM File OID: 'f5dc7eb9-ead0-48ab-9e17-7d775c784cb4' User entered '96.9'	System	27 Oct 2020 04:50:01
	System	27 Oct 2020 04:50:01

US3342204

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 11 Aug 2021 22:34:12

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:12:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7A504897-431F-4E74-9F03-DAC668AE5D1E)', Time: '2020-10-26T23:49:56', User OID: 'PatientReportedOutcome (US3342204)', ODM File OID: 'f5dc7eb9-ead0-48ab-9e17-7d775c784cb4' User entered 'No (N)'	System	27 Oct 2020 04:50:01
	System	27 Oct 2020 04:50:01

US3342204

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 11 Aug 2021 22:34:12

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:12:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7A504897-431F-4E74-9F03-DAC668AE5D1E)', Time: '2020-10-26T23:49:59', User OID: 'PatientReportedOutcome (US3342204)', ODM File OID: 'f5dc7eb9-ead0-48ab-9e17-7d775c784cb4' User entered '26 Oct 2020 23:49'	System	27 Oct 2020 04:50:01
	System	27 Oct 2020 04:50:01

US3342204

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 11 Aug 2021 22:34:12

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:12:42
User entered '26 Oct 2020 15:12'	System	26 Oct 2020 16:37:26

US3342204

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 11 Aug 2021 22:34:12

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:12:42
User entered '27 Oct 2020 11:59'	System	26 Oct 2020 16:37:26

US3342204

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 11 Aug 2021 22:34:12

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:12:42
Data entry locked.	System	26 Oct 2020 16:37:26
User entered 'Day 2'	System	26 Oct 2020 16:37:26

US3342204

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 11 Aug 2021 22:34:12

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:12:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7A504897-431F-4E74-9F03-DAC668AE5D1E)', Time: '2020-10-27T23:41:48', User OID: 'PatientReportedOutcome (US3342204)', ODM File OID: '7e5ac799-619d-48ee-bcd4-70253bed7e28' User entered 'Yes (Y)'	System	28 Oct 2020 04:42:03
	System	28 Oct 2020 04:42:03

US3342204

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 11 Aug 2021 22:34:12

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:12:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7A504897-431F-4E74-9F03-DAC668AE5D1E)', Time: '2020-10-27T23:41:52', User OID: 'PatientReportedOutcome (US3342204)', ODM File OID: '7e5ac799-619d-48ee-bcd4-70253bed7e28' User entered '97.3'	System	28 Oct 2020 04:42:03
	System	28 Oct 2020 04:42:03

US3342204

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 11 Aug 2021 22:34:12

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:12:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7A504897-431F-4E74-9F03-DAC668AE5D1E)', Time: '2020-10-27T23:41:56', User OID: 'PatientReportedOutcome (US3342204)', ODM File OID: '7e5ac799-619d-48ee-bcd4-70253bed7e28' User entered 'No (N)'	System	28 Oct 2020 04:42:03
	System	28 Oct 2020 04:42:03

US3342204

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 11 Aug 2021 22:34:12

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:12:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7A504897-431F-4E74-9F03-DAC668AE5D1E)', Time: '2020-10-27T23:41:59', User OID: 'PatientReportedOutcome (US3342204)', ODM File OID: '7e5ac799-619d-48ee-bcd4-70253bed7e28' User entered '27 Oct 2020 23:41'	System	28 Oct 2020 04:42:03
	System	28 Oct 2020 04:42:03

US3342204

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 11 Aug 2021 22:34:12

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:12:42
User entered '27 Oct 2020 12:00'	System	26 Oct 2020 16:37:26

US3342204

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 11 Aug 2021 22:34:12

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:12:42
User entered '28 Oct 2020 11:59'	System	26 Oct 2020 16:37:26

US3342204

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 11 Aug 2021 22:34:12

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:12:42
Data entry locked.	System	26 Oct 2020 16:37:26
User entered 'Day 3'	System	26 Oct 2020 16:37:26

US3342204

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 11 Aug 2021 22:34:12

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:12:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7A504897-431F-4E74-9F03-DAC668AE5D1E)', Time: '2020-10-28T21:03:58', User OID: 'PatientReportedOutcome (US3342204)', ODM File OID: 'b7eca131-c41f-4684-a7e0-31b8f9572e88'	System	29 Oct 2020 02:04:26
User entered 'Yes (Y)'	System	29 Oct 2020 02:04:26

US3342204

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 11 Aug 2021 22:34:12

Please record your **TEMPERATURE in °F**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:12:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7A504897-431F-4E74-9F03-DAC668AE5D1E)', Time: '2020-10-28T21:04:04', User OID: 'PatientReportedOutcome (US3342204)', ODM File OID: 'b7eca131-c41f-4684-a7e0-31b8f9572e88' User entered '97.9'	System	29 Oct 2020 02:04:26
	System	29 Oct 2020 02:04:26

US3342204

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 11 Aug 2021 22:34:12

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:12:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7A504897-431F-4E74-9F03-DAC668AE5D1E)', Time: '2020-10-28T21:04:08', User OID: 'PatientReportedOutcome (US3342204)', ODM File OID: 'b7eca131-c41f-4684-a7e0-31b8f9572e88'	System	29 Oct 2020 02:04:26
User entered 'No (N)'	System	29 Oct 2020 02:04:26

US3342204

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 11 Aug 2021 22:34:12

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:12:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7A504897-431F-4E74-9F03-DAC668AE5D1E)', Time: '2020-10-28T21:04:20', User OID: 'PatientReportedOutcome (US3342204)', ODM File OID: 'b7eca131-c41f-4684-a7e0-31b8f9572e88' User entered '28 Oct 2020 21:04'	System	29 Oct 2020 02:04:26
	System	29 Oct 2020 02:04:26

US3342204

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 11 Aug 2021 22:34:12

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:12:42
User entered '28 Oct 2020 12:00'	System	26 Oct 2020 16:37:26

US3342204

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 11 Aug 2021 22:34:12

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:12:42
User entered '29 Oct 2020 11:59'	System	26 Oct 2020 16:37:26

US3342204

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 11 Aug 2021 22:34:12

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:12:42
Data entry locked.	System	26 Oct 2020 16:37:26
User entered 'Day 4'	System	26 Oct 2020 16:37:26

US3342204

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 11 Aug 2021 22:34:12

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:12:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7A504897-431F-4E74-9F03-DAC668AE5D1E)', Time: '2020-10-30T00:00:37', User OID: 'PatientReportedOutcome (US3342204)', ODM File OID: '54dc3f80-7468-40a1-8df0-8ac114bbadcb' User entered 'Yes (Y)'	System	30 Oct 2020 05:00:53
	System	30 Oct 2020 05:00:53

US3342204

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 11 Aug 2021 22:34:12

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:12:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7A504897-431F-4E74-9F03-DAC668AE5D1E)', Time: '2020-10-30T00:00:45', User OID: 'PatientReportedOutcome (US3342204)', ODM File OID: '54dc3f80-7468-40a1-8df0-8ac114bbadcb' User entered '98.0'	System	30 Oct 2020 05:00:53
	System	30 Oct 2020 05:00:53

US3342204

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 11 Aug 2021 22:34:12

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:12:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7A504897-431F-4E74-9F03-DAC668AE5D1E)', Time: '2020-10-30T00:00:48', User OID: 'PatientReportedOutcome (US3342204)', ODM File OID: '54dc3f80-7468-40a1-8df0-8ac114bbadcb' User entered 'No (N)'	System	30 Oct 2020 05:00:53
	System	30 Oct 2020 05:00:53

US3342204

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 11 Aug 2021 22:34:12

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:12:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7A504897-431F-4E74-9F03-DAC668AE5D1E)', Time: '2020-10-30T00:00:50', User OID: 'PatientReportedOutcome (US3342204)', ODM File OID: '54dc3f80-7468-40a1-8df0-8ac114bbadcb' User entered '30 Oct 2020 00:00'	System	30 Oct 2020 05:00:53
	System	30 Oct 2020 05:00:53

US3342204

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 11 Aug 2021 22:34:12

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:12:42
User entered '29 Oct 2020 12:00'	System	26 Oct 2020 16:37:26

US3342204

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 11 Aug 2021 22:34:12

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:12:42
User entered '30 Oct 2020 11:59'	System	26 Oct 2020 16:37:26

US3342204

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 11 Aug 2021 22:34:12

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:12:42
Data entry locked.	System	26 Oct 2020 16:37:26
User entered 'Day 5'	System	26 Oct 2020 16:37:26

US3342204

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 11 Aug 2021 22:34:12

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:12:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7A504897-431F-4E74-9F03-DAC668AE5D1E)', Time: '2020-10-30T23:07:49', User OID: 'PatientReportedOutcome (US3342204)', ODM File OID: 'ebc25dfe-4c12-4d2c-937e-933cbbd00bc8' User entered 'Yes (Y)'	System	31 Oct 2020 04:08:57
	System	31 Oct 2020 04:08:57

US3342204

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 11 Aug 2021 22:34:12

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:12:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7A504897-431F-4E74-9F03-DAC668AE5D1E)', Time: '2020-10-30T23:08:41', User OID: 'PatientReportedOutcome (US3342204)', ODM File OID: 'ebc25dfe-4c12-4d2c-937e-933cbbd00bc8' User entered '98.4'	System	31 Oct 2020 04:08:57
	System	31 Oct 2020 04:08:57

US3342204

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 11 Aug 2021 22:34:12

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:12:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7A504897-431F-4E74-9F03-DAC668AE5D1E)', Time: '2020-10-30T23:08:50', User OID: 'PatientReportedOutcome (US3342204)', ODM File OID: 'ebc25dfe-4c12-4d2c-937e-933cbbd00bc8' User entered 'No (N)'	System	31 Oct 2020 04:08:57
	System	31 Oct 2020 04:08:57

US3342204

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 11 Aug 2021 22:34:12

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:12:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7A504897-431F-4E74-9F03-DAC668AE5D1E)', Time: '2020-10-30T23:08:55', User OID: 'PatientReportedOutcome (US3342204)', ODM File OID: 'ebc25dfe-4c12-4d2c-937e-933cbbd00bc8' User entered '30 Oct 2020 23:08'	System	31 Oct 2020 04:08:57
	System	31 Oct 2020 04:08:57

US3342204

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 11 Aug 2021 22:34:12

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:12:42
User entered '30 Oct 2020 12:00'	System	26 Oct 2020 16:37:26

US3342204

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 11 Aug 2021 22:34:12

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:12:42
User entered '31 Oct 2020 11:59'	System	26 Oct 2020 16:37:26

US3342204

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 11 Aug 2021 22:34:12

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:12:42
Data entry locked.	System	26 Oct 2020 16:37:26
User entered 'Day 6'	System	26 Oct 2020 16:37:26

US3342204

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 11 Aug 2021 22:34:12

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:12:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7A504897-431F-4E74-9F03-DAC668AE5D1E)', Time: '2020-11-01T07:19:09', User OID: 'PatientReportedOutcome (US3342204)', ODM File OID: 'ab4f2a1c-a99a-4917-a423-08ac082b1a8d' User entered 'Yes (Y)'	System	01 Nov 2020 13:19:20
	System	01 Nov 2020 13:19:20

US3342204

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 11 Aug 2021 22:34:12

Please record your **TEMPERATURE in °F**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:12:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7A504897-431F-4E74-9F03-DAC668AE5D1E)', Time: '2020-11-01T07:19:12', User OID: 'PatientReportedOutcome (US3342204)', ODM File OID: 'ab4f2a1c-a99a-4917-a423-08ac082b1a8d' User entered '98.5'	System	01 Nov 2020 13:19:20
	System	01 Nov 2020 13:19:20

US3342204

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 11 Aug 2021 22:34:12

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:12:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7A504897-431F-4E74-9F03-DAC668AE5D1E)', Time: '2020-11-01T07:19:16', User OID: 'PatientReportedOutcome (US3342204)', ODM File OID: 'ab4f2a1c-a99a-4917-a423-08ac082b1a8d' User entered 'No (N)'	System	01 Nov 2020 13:19:20
	System	01 Nov 2020 13:19:20

US3342204

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 11 Aug 2021 22:34:12

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:12:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7A504897-431F-4E74-9F03-DAC668AE5D1E)', Time: '2020-11-01T07:19:18', User OID: 'PatientReportedOutcome (US3342204)', ODM File OID: 'ab4f2a1c-a99a-4917-a423-08ac082b1a8d' User entered '01 Nov 2020 07:19'	System	01 Nov 2020 13:19:20
	System	01 Nov 2020 13:19:20

US3342204

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 11 Aug 2021 22:34:12

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:12:42
User entered '31 Oct 2020 12:00'	System	26 Oct 2020 16:37:26

US3342204

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 11 Aug 2021 22:34:12

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:12:42
User entered '01 Nov 2020 11:59'	System	26 Oct 2020 16:37:26

US3342204

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 11 Aug 2021 22:34:12

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:12:42
Data entry locked.	System	26 Oct 2020 16:37:26
User entered 'Day 7'	System	26 Oct 2020 16:37:26

US3342204

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 11 Aug 2021 22:34:12

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:12:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7A504897-431F-4E74-9F03-DAC668AE5D1E)', Time: '2020-11-01T20:02:50', User OID: 'PatientReportedOutcome (US3342204)', ODM File OID: '8e820c66-cc47-48d8-b519-5ebf60e0f336'	System	02 Nov 2020 02:02:59
User entered 'Yes (Y)'	System	02 Nov 2020 02:02:59

US3342204

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 11 Aug 2021 22:34:12

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:12:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7A504897-431F-4E74-9F03-DAC668AE5D1E)', Time: '2020-11-01T20:02:54', User OID: 'PatientReportedOutcome (US3342204)', ODM File OID: '8e820c66-cc47-48d8-b519-5ebf60e0f336' User entered '98.6'	System	02 Nov 2020 02:02:59
	System	02 Nov 2020 02:02:59

US3342204

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 11 Aug 2021 22:34:12

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:12:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7A504897-431F-4E74-9F03-DAC668AE5D1E)', Time: '2020-11-01T20:02:56', User OID: 'PatientReportedOutcome (US3342204)', ODM File OID: '8e820c66-cc47-48d8-b519-5ebf60e0f336'	System	02 Nov 2020 02:02:59
User entered 'No (N)'	System	02 Nov 2020 02:02:59

US3342204

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 11 Aug 2021 22:34:12

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:12:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7A504897-431F-4E74-9F03-DAC668AE5D1E)', Time: '2020-11-01T20:02:58', User OID: 'PatientReportedOutcome (US3342204)', ODM File OID: '8e820c66-cc47-48d8-b519-5ebf60e0f336' User entered '01 Nov 2020 20:02'	System	02 Nov 2020 02:02:59
	System	02 Nov 2020 02:02:59

US3342204

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 11 Aug 2021 22:34:12

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:12:42
User entered '01 Nov 2020 12:00'	System	26 Oct 2020 16:37:26

US3342204

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 11 Aug 2021 22:34:12

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:12:42
User entered '02 Nov 2020 11:59'	System	26 Oct 2020 16:37:26

US3342204

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 11 Aug 2021 22:34:12

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:12:42
Data entry locked.	System	26 Oct 2020 16:37:26
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	26 Oct 2020 16:37:26

US3342204

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 11 Aug 2021 22:34:12

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:12:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7A504897-431F-4E74-9F03-DAC668AE5D1E)', Time: '2020-10-26T11:59:14', User OID: 'PatientReportedOutcome (US3342204)', ODM File OID: '2874ddb7-0c97-42f2-bf97-564b34f79f62'	System	26 Oct 2020 17:00:41
User entered 'None (1)'	System	26 Oct 2020 17:00:41

US3342204

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 11 Aug 2021 22:34:12

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:12:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7A504897-431F-4E74-9F03-DAC668AE5D1E)', Time: '2020-10-26T11:59:35', User OID: 'PatientReportedOutcome (US3342204)', ODM File OID: '2874ddb7-0c97-42f2-bf97-564b34f79f62' User entered 'No (N)'	System	26 Oct 2020 17:00:41
	System	26 Oct 2020 17:00:41

US3342204

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 11 Aug 2021 22:34:12

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:12:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7A504897-431F-4E74-9F03-DAC668AE5D1E)', Time: '2020-10-26T11:59:58', User OID: 'PatientReportedOutcome (US3342204)', ODM File OID: '2874ddb7-0c97-42f2-bf97-564b34f79f62' User entered 'No (N)'	System	26 Oct 2020 17:00:41
	System	26 Oct 2020 17:00:41

US3342204

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 11 Aug 2021 22:34:12

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:12:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7A504897-431F-4E74-9F03-DAC668AE5D1E)', Time: '2020-10-26T12:00:10', User OID: 'PatientReportedOutcome (US3342204)', ODM File OID: '2874ddb7-0c97-42f2-bf97-564b34f79f62'	System	26 Oct 2020 17:00:41
User entered 'None (1)'	System	26 Oct 2020 17:00:41

US3342204

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 11 Aug 2021 22:34:12

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:12:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7A504897-431F-4E74-9F03-DAC668AE5D1E)', Time: '2020-10-26T12:00:14', User OID: 'PatientReportedOutcome (US3342204)', ODM File OID: '2874ddb7-0c97-42f2-bf97-564b34f79f62' User entered '26 Oct 2020 12:00'	System	26 Oct 2020 17:00:41
	System	26 Oct 2020 17:00:41

US3342204

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 11 Aug 2021 22:34:12

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:12:42
User entered '26 Oct 2020 11:47'	System	26 Oct 2020 16:37:26

US3342204

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 11 Aug 2021 22:34:12

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:12:42
User entered '26 Oct 2020 14:17'	System	26 Oct 2020 16:37:26

US3342204

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 11 Aug 2021 22:34:12

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:12:42
Data entry locked.	System	26 Oct 2020 16:37:26
User entered 'Day 1, after vaccination (at home)'	System	26 Oct 2020 16:37:26

US3342204

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 11 Aug 2021 22:34:12

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:12:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7A504897-431F-4E74-9F03-DAC668AE5D1E)', Time: '2020-10-26T23:50:16', User OID: 'PatientReportedOutcome (US3342204)', ODM File OID: 'ebb0df2d-3ce7-4004-9083-ef7d1d50204a' User entered 'None (1)'	System	27 Oct 2020 04:51:37
	System	27 Oct 2020 04:51:37

US3342204

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 11 Aug 2021 22:34:12

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:12:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7A504897-431F-4E74-9F03-DAC668AE5D1E)', Time: '2020-10-26T23:50:19', User OID: 'PatientReportedOutcome (US3342204)', ODM File OID: 'ebb0df2d-3ce7-4004-9083-ef7d1d50204a' User entered 'No (N)'	System	27 Oct 2020 04:51:37
	System	27 Oct 2020 04:51:37

US3342204

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 11 Aug 2021 22:34:12

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:12:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7A504897-431F-4E74-9F03-DAC668AE5D1E)', Time: '2020-10-26T23:50:22', User OID: 'PatientReportedOutcome (US3342204)', ODM File OID: 'ebb0df2d-3ce7-4004-9083-ef7d1d50204a' User entered 'No (N)'	System	27 Oct 2020 04:51:37
	System	27 Oct 2020 04:51:37

US3342204

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 11 Aug 2021 22:34:12

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:12:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7A504897-431F-4E74-9F03-DAC668AE5D1E)', Time: '2020-10-26T23:51:25', User OID: 'PatientReportedOutcome (US3342204)', ODM File OID: 'ebb0df2d-3ce7-4004-9083-ef7d1d50204a'	System	27 Oct 2020 04:51:37
User entered 'Does not interfere with activity (2)'	System	27 Oct 2020 04:51:37

US3342204

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 11 Aug 2021 22:34:12

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:12:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7A504897-431F-4E74-9F03-DAC668AE5D1E)', Time: '2020-10-26T23:51:33', User OID: 'PatientReportedOutcome (US3342204)', ODM File OID: 'ebb0df2d-3ce7-4004-9083-ef7d1d50204a' User entered '26 Oct 2020 23:51'	System	27 Oct 2020 04:51:37
	System	27 Oct 2020 04:51:37

US3342204

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 11 Aug 2021 22:34:12

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:12:42
User entered '26 Oct 2020 15:12'	System	26 Oct 2020 16:37:26

US3342204

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 11 Aug 2021 22:34:12

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:12:42
User entered '27 Oct 2020 11:59'	System	26 Oct 2020 16:37:26

US3342204

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 11 Aug 2021 22:34:12

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:12:42
Data entry locked.	System	26 Oct 2020 16:37:26
User entered 'Day 2'	System	26 Oct 2020 16:37:26

US3342204

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 11 Aug 2021 22:34:12

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:12:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7A504897-431F-4E74-9F03-DAC668AE5D1E)', Time: '2020-10-27T23:39:54', User OID: 'PatientReportedOutcome (US3342204)', ODM File OID: '056cacd1-c617-48d8-a25d-253718664af2'	System	28 Oct 2020 04:40:13
User entered 'None (1)'	System	28 Oct 2020 04:40:13

US3342204

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 11 Aug 2021 22:34:12

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:12:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7A504897-431F-4E74-9F03-DAC668AE5D1E)', Time: '2020-10-27T23:39:56', User OID: 'PatientReportedOutcome (US3342204)', ODM File OID: '056cacd1-c617-48d8-a25d-253718664af2'	System	28 Oct 2020 04:40:13
User entered 'No (N)'	System	28 Oct 2020 04:40:13

US3342204

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 11 Aug 2021 22:34:12

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:12:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7A504897-431F-4E74-9F03-DAC668AE5D1E)', Time: '2020-10-27T23:40:01', User OID: 'PatientReportedOutcome (US3342204)', ODM File OID: '056cacd1-c617-48d8-a25d-253718664af2' User entered 'No (N)'	System	28 Oct 2020 04:40:13
	System	28 Oct 2020 04:40:13

US3342204

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 11 Aug 2021 22:34:12

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:12:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7A504897-431F-4E74-9F03-DAC668AE5D1E)', Time: '2020-10-27T23:40:05', User OID: 'PatientReportedOutcome (US3342204)', ODM File OID: '056cacd1-c617-48d8-a25d-253718664af2'	System	28 Oct 2020 04:40:13
User entered 'Does not interfere with activity (2)'	System	28 Oct 2020 04:40:13

US3342204

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 11 Aug 2021 22:34:12

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:12:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7A504897-431F-4E74-9F03-DAC668AE5D1E)', Time: '2020-10-27T23:40:08', User OID: 'PatientReportedOutcome (US3342204)', ODM File OID: '056cacd1-c617-48d8-a25d-253718664af2' User entered '27 Oct 2020 23:40'	System	28 Oct 2020 04:40:13
	System	28 Oct 2020 04:40:13

US3342204

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 11 Aug 2021 22:34:12

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:12:42
User entered '27 Oct 2020 12:00'	System	26 Oct 2020 16:37:26

US3342204

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 11 Aug 2021 22:34:12

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:12:42
User entered '28 Oct 2020 11:59'	System	26 Oct 2020 16:37:26

US3342204

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 11 Aug 2021 22:34:12

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:12:42
Data entry locked.	System	26 Oct 2020 16:37:26
User entered 'Day 3'	System	26 Oct 2020 16:37:26

US3342204

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 11 Aug 2021 22:34:12

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:12:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7A504897-431F-4E74-9F03-DAC668AE5D1E)', Time: '2020-10-28T21:04:48', User OID: 'PatientReportedOutcome (US3342204)', ODM File OID: 'da8788bb-ad31-47a1-b7a4-19d6347d0d09'	System	29 Oct 2020 02:05:26
User entered 'None (1)'	System	29 Oct 2020 02:05:26

US3342204

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 11 Aug 2021 22:34:12

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:12:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7A504897-431F-4E74-9F03-DAC668AE5D1E)', Time: '2020-10-28T21:04:51', User OID: 'PatientReportedOutcome (US3342204)', ODM File OID: 'da8788bb-ad31-47a1-b7a4-19d6347d0d09'	System	29 Oct 2020 02:05:26
User entered 'No (N)'	System	29 Oct 2020 02:05:26

US3342204

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 11 Aug 2021 22:34:12

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:12:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7A504897-431F-4E74-9F03-DAC668AE5D1E)', Time: '2020-10-28T21:04:55', User OID: 'PatientReportedOutcome (US3342204)', ODM File OID: 'da8788bb-ad31-47a1-b7a4-19d6347d0d09'	System	29 Oct 2020 02:05:26
User entered 'No (N)'	System	29 Oct 2020 02:05:26

US3342204

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 11 Aug 2021 22:34:12

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:12:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7A504897-431F-4E74-9F03-DAC668AE5D1E)', Time: '2020-10-28T21:05:20', User OID: 'PatientReportedOutcome (US3342204)', ODM File OID: 'da8788bb-ad31-47a1-b7a4-19d6347d0d09'	System	29 Oct 2020 02:05:26
User entered 'None (1)'	System	29 Oct 2020 02:05:26

US3342204

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 11 Aug 2021 22:34:12

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:12:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7A504897-431F-4E74-9F03-DAC668AE5D1E)', Time: '2020-10-28T21:05:23', User OID: 'PatientReportedOutcome (US3342204)', ODM File OID: 'da8788bb-ad31-47a1-b7a4-19d6347d0d09' User entered '28 Oct 2020 21:05'	System	29 Oct 2020 02:05:26
	System	29 Oct 2020 02:05:26

US3342204

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 11 Aug 2021 22:34:12

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:12:42
User entered '28 Oct 2020 12:00'	System	26 Oct 2020 16:37:26

US3342204

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 11 Aug 2021 22:34:12

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:12:42
User entered '29 Oct 2020 11:59'	System	26 Oct 2020 16:37:26

US3342204

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 11 Aug 2021 22:34:12

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:12:42
Data entry locked.	System	26 Oct 2020 16:37:26
User entered 'Day 4'	System	26 Oct 2020 16:37:26

US3342204

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 11 Aug 2021 22:34:12

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:12:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7A504897-431F-4E74-9F03-DAC668AE5D1E)', Time: '2020-10-30T00:00:12', User OID: 'PatientReportedOutcome (US3342204)', ODM File OID: 'c5fe079e-2a01-49fb-a7a1-d8b3620bf2d8'	System	30 Oct 2020 05:00:37
User entered 'None (1)'	System	30 Oct 2020 05:00:37

US3342204

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 11 Aug 2021 22:34:12

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:12:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7A504897-431F-4E74-9F03-DAC668AE5D1E)', Time: '2020-10-30T00:00:14', User OID: 'PatientReportedOutcome (US3342204)', ODM File OID: 'c5fe079e-2a01-49fb-a7a1-d8b3620bf2d8'	System	30 Oct 2020 05:00:37
User entered 'No (N)'	System	30 Oct 2020 05:00:37

US3342204

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 11 Aug 2021 22:34:12

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:12:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7A504897-431F-4E74-9F03-DAC668AE5D1E)', Time: '2020-10-30T00:00:20', User OID: 'PatientReportedOutcome (US3342204)', ODM File OID: 'c5fe079e-2a01-49fb-a7a1-d8b3620bf2d8' User entered 'No (N)'	System	30 Oct 2020 05:00:37
	System	30 Oct 2020 05:00:37

US3342204

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 11 Aug 2021 22:34:12

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:12:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7A504897-431F-4E74-9F03-DAC668AE5D1E)', Time: '2020-10-30T00:00:24', User OID: 'PatientReportedOutcome (US3342204)', ODM File OID: 'c5fe079e-2a01-49fb-a7a1-d8b3620bf2d8'	System	30 Oct 2020 05:00:37
User entered 'None (1)'	System	30 Oct 2020 05:00:37

US3342204

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 11 Aug 2021 22:34:12

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:12:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7A504897-431F-4E74-9F03-DAC668AE5D1E)', Time: '2020-10-30T00:00:31', User OID: 'PatientReportedOutcome (US3342204)', ODM File OID: 'c5fe079e-2a01-49fb-a7a1-d8b3620bf2d8' User entered '30 Oct 2020 00:00'	System	30 Oct 2020 05:00:37
	System	30 Oct 2020 05:00:37

US3342204

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 11 Aug 2021 22:34:12

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:12:42
User entered '29 Oct 2020 12:00'	System	26 Oct 2020 16:37:26

US3342204

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 11 Aug 2021 22:34:12

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:12:42
User entered '30 Oct 2020 11:59'	System	26 Oct 2020 16:37:26

US3342204

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 11 Aug 2021 22:34:12

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:12:42
Data entry locked.	System	26 Oct 2020 16:37:26
User entered 'Day 5'	System	26 Oct 2020 16:37:26

US3342204

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 11 Aug 2021 22:34:12

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:12:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7A504897-431F-4E74-9F03-DAC668AE5D1E)', Time: '2020-10-30T23:07:07', User OID: 'PatientReportedOutcome (US3342204)', ODM File OID: 'a323cda8-1d04-485e-af76-96e38c69a903'	System	31 Oct 2020 04:07:27
User entered 'None (1)'	System	31 Oct 2020 04:07:27

US3342204

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 11 Aug 2021 22:34:12

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:12:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7A504897-431F-4E74-9F03-DAC668AE5D1E)', Time: '2020-10-30T23:07:09', User OID: 'PatientReportedOutcome (US3342204)', ODM File OID: 'a323cda8-1d04-485e-af76-96e38c69a903' User entered 'No (N)'	System	31 Oct 2020 04:07:27
	System	31 Oct 2020 04:07:27

US3342204

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 11 Aug 2021 22:34:12

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:12:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7A504897-431F-4E74-9F03-DAC668AE5D1E)', Time: '2020-10-30T23:07:11', User OID: 'PatientReportedOutcome (US3342204)', ODM File OID: 'a323cda8-1d04-485e-af76-96e38c69a903' User entered 'No (N)'	System	31 Oct 2020 04:07:27
	System	31 Oct 2020 04:07:27

US3342204

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 11 Aug 2021 22:34:12

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:12:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7A504897-431F-4E74-9F03-DAC668AE5D1E)', Time: '2020-10-30T23:07:23', User OID: 'PatientReportedOutcome (US3342204)', ODM File OID: 'a323cda8-1d04-485e-af76-96e38c69a903'	System	31 Oct 2020 04:07:27
User entered 'None (1)'	System	31 Oct 2020 04:07:27

US3342204

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 11 Aug 2021 22:34:12

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:12:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7A504897-431F-4E74-9F03-DAC668AE5D1E)', Time: '2020-10-30T23:07:25', User OID: 'PatientReportedOutcome (US3342204)', ODM File OID: 'a323cda8-1d04-485e-af76-96e38c69a903' User entered '30 Oct 2020 23:07'	System	31 Oct 2020 04:07:27
	System	31 Oct 2020 04:07:27

US3342204

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 11 Aug 2021 22:34:12

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:12:42
User entered '30 Oct 2020 12:00'	System	26 Oct 2020 16:37:26

US3342204

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 11 Aug 2021 22:34:12

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:12:42
User entered '31 Oct 2020 11:59'	System	26 Oct 2020 16:37:26

US3342204

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 11 Aug 2021 22:34:12

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:12:42
Data entry locked.	System	26 Oct 2020 16:37:26
User entered 'Day 6'	System	26 Oct 2020 16:37:26

US3342204

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 11 Aug 2021 22:34:12

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:12:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7A504897-431F-4E74-9F03-DAC668AE5D1E)', Time: '2020-11-01T07:17:32', User OID: 'PatientReportedOutcome (US3342204)', ODM File OID: 'c65c2f17-1078-4b8f-a133-a1a299cc460c'	System	01 Nov 2020 13:17:43
User entered 'None (1)'	System	01 Nov 2020 13:17:43

US3342204

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 11 Aug 2021 22:34:12

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:12:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7A504897-431F-4E74-9F03-DAC668AE5D1E)', Time: '2020-11-01T07:17:34', User OID: 'PatientReportedOutcome (US3342204)', ODM File OID: 'c65c2f17-1078-4b8f-a133-a1a299cc460c' User entered 'No (N)'	System	01 Nov 2020 13:17:43
	System	01 Nov 2020 13:17:43

US3342204

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 11 Aug 2021 22:34:12

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:12:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7A504897-431F-4E74-9F03-DAC668AE5D1E)', Time: '2020-11-01T07:17:36', User OID: 'PatientReportedOutcome (US3342204)', ODM File OID: 'c65c2f17-1078-4b8f-a133-a1a299cc460c' User entered 'No (N)'	System	01 Nov 2020 13:17:43
	System	01 Nov 2020 13:17:43

US3342204

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 11 Aug 2021 22:34:12

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:12:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7A504897-431F-4E74-9F03-DAC668AE5D1E)', Time: '2020-11-01T07:17:38', User OID: 'PatientReportedOutcome (US3342204)', ODM File OID: 'c65c2f17-1078-4b8f-a133-a1a299cc460c' User entered 'None (1)'	System	01 Nov 2020 13:17:43
	System	01 Nov 2020 13:17:43

US3342204

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 11 Aug 2021 22:34:12

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:12:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7A504897-431F-4E74-9F03-DAC668AE5D1E)', Time: '2020-11-01T07:17:41', User OID: 'PatientReportedOutcome (US3342204)', ODM File OID: 'c65c2f17-1078-4b8f-a133-a1a299cc460c' User entered '01 Nov 2020 07:17'	System	01 Nov 2020 13:17:43
	System	01 Nov 2020 13:17:43

US3342204

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 11 Aug 2021 22:34:12

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:12:42
User entered '31 Oct 2020 12:00'	System	26 Oct 2020 16:37:26

US3342204

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 11 Aug 2021 22:34:12

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:12:42
User entered '01 Nov 2020 11:59'	System	26 Oct 2020 16:37:26

US3342204

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 11 Aug 2021 22:34:12

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:12:42
Data entry locked.	System	26 Oct 2020 16:37:26
User entered 'Day 7'	System	26 Oct 2020 16:37:26

US3342204

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 11 Aug 2021 22:34:12

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:12:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7A504897-431F-4E74-9F03-DAC668AE5D1E)', Time: '2020-11-01T20:03:15', User OID: 'PatientReportedOutcome (US3342204)', ODM File OID: '3fce0b7f-16c8-4a1a-b2f8-a8f116694f9c' User entered 'None (1)'	System	02 Nov 2020 02:03:26
	System	02 Nov 2020 02:03:26

US3342204

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 11 Aug 2021 22:34:12

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:12:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7A504897-431F-4E74-9F03-DAC668AE5D1E)', Time: '2020-11-01T20:03:17', User OID: 'PatientReportedOutcome (US3342204)', ODM File OID: '3fce0b7f-16c8-4a1a-b2f8-a8f116694f9c' User entered 'No (N)'	System	02 Nov 2020 02:03:26
	System	02 Nov 2020 02:03:26

US3342204

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 11 Aug 2021 22:34:12

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:12:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7A504897-431F-4E74-9F03-DAC668AE5D1E)', Time: '2020-11-01T20:03:19', User OID: 'PatientReportedOutcome (US3342204)', ODM File OID: '3fce0b7f-16c8-4a1a-b2f8-a8f116694f9c' User entered 'No (N)'	System	02 Nov 2020 02:03:26
	System	02 Nov 2020 02:03:26

US3342204

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 11 Aug 2021 22:34:12

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:12:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7A504897-431F-4E74-9F03-DAC668AE5D1E)', Time: '2020-11-01T20:03:21', User OID: 'PatientReportedOutcome (US3342204)', ODM File OID: '3fce0b7f-16c8-4a1a-b2f8-a8f116694f9c'	System	02 Nov 2020 02:03:26
User entered 'None (1)'	System	02 Nov 2020 02:03:26

US3342204

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 11 Aug 2021 22:34:12

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:12:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7A504897-431F-4E74-9F03-DAC668AE5D1E)', Time: '2020-11-01T20:03:24', User OID: 'PatientReportedOutcome (US3342204)', ODM File OID: '3fce0b7f-16c8-4a1a-b2f8-a8f116694f9c' User entered '01 Nov 2020 20:03'	System	02 Nov 2020 02:03:26
	System	02 Nov 2020 02:03:26

US3342204

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 11 Aug 2021 22:34:12

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:12:42
User entered '01 Nov 2020 12:00'	System	26 Oct 2020 16:37:26

US3342204

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 11 Aug 2021 22:34:12

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:12:42
User entered '02 Nov 2020 11:59'	System	26 Oct 2020 16:37:26

US3342204

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 11 Aug 2021 22:34:12

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:12:42
Data entry locked.	System	26 Oct 2020 16:37:26
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	26 Oct 2020 16:37:26

US3342204

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 11 Aug 2021 22:34:12

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:12:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7A504897-431F-4E74-9F03-DAC668AE5D1E)', Time: '2020-10-26T11:58:49', User OID: 'PatientReportedOutcome (US3342204)', ODM File OID: 'c32e09a3-dd4a-4d03-9c6d-68d7424ddd57' User entered 'None (0)'	System	26 Oct 2020 16:59:06
	System	26 Oct 2020 16:59:06

US3342204

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 11 Aug 2021 22:34:12

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:12:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7A504897-431F-4E74-9F03-DAC668AE5D1E)', Time: '2020-10-26T11:58:51', User OID: 'PatientReportedOutcome (US3342204)', ODM File OID: 'c32e09a3-dd4a-4d03-9c6d-68d7424ddd57' User entered 'None (0)'	System	26 Oct 2020 16:59:06
	System	26 Oct 2020 16:59:06

US3342204

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 11 Aug 2021 22:34:12

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:12:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7A504897-431F-4E74-9F03-DAC668AE5D1E)', Time: '2020-10-26T11:58:53', User OID: 'PatientReportedOutcome (US3342204)', ODM File OID: 'c32e09a3-dd4a-4d03-9c6d-68d7424ddd57'	System	26 Oct 2020 16:59:06
User entered 'None (0)'	System	26 Oct 2020 16:59:06

US3342204

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 11 Aug 2021 22:34:12

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:12:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7A504897-431F-4E74-9F03-DAC668AE5D1E)', Time: '2020-10-26T11:58:54', User OID: 'PatientReportedOutcome (US3342204)', ODM File OID: 'c32e09a3-dd4a-4d03-9c6d-68d7424ddd57' User entered 'None (0)'	System	26 Oct 2020 16:59:06
	System	26 Oct 2020 16:59:06

US3342204

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 11 Aug 2021 22:34:12

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:12:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7A504897-431F-4E74-9F03-DAC668AE5D1E)', Time: '2020-10-26T11:58:56', User OID: 'PatientReportedOutcome (US3342204)', ODM File OID: 'c32e09a3-dd4a-4d03-9c6d-68d7424ddd57'	System	26 Oct 2020 16:59:06
User entered 'None (0)'	System	26 Oct 2020 16:59:06

US3342204

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 11 Aug 2021 22:34:12

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:12:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7A504897-431F-4E74-9F03-DAC668AE5D1E)', Time: '2020-10-26T11:58:58', User OID: 'PatientReportedOutcome (US3342204)', ODM File OID: 'c32e09a3-dd4a-4d03-9c6d-68d7424ddd57' User entered 'None (0)'	System	26 Oct 2020 16:59:06
	System	26 Oct 2020 16:59:06

US3342204

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 11 Aug 2021 22:34:12

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:12:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7A504897-431F-4E74-9F03-DAC668AE5D1E)', Time: '2020-10-26T11:59:00', User OID: 'PatientReportedOutcome (US3342204)', ODM File OID: 'c32e09a3-dd4a-4d03-9c6d-68d7424ddd57' User entered 'No (N)'	System	26 Oct 2020 16:59:06
	System	26 Oct 2020 16:59:06

US3342204

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 11 Aug 2021 22:34:12

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:12:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7A504897-431F-4E74-9F03-DAC668AE5D1E)', Time: '2020-10-26T11:59:03', User OID: 'PatientReportedOutcome (US3342204)', ODM File OID: 'c32e09a3-dd4a-4d03-9c6d-68d7424ddd57' User entered '26 Oct 2020 11:59'	System	26 Oct 2020 16:59:06
	System	26 Oct 2020 16:59:06

US3342204

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 11 Aug 2021 22:34:12

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:12:42
User entered '26 Oct 2020 11:47'	System	26 Oct 2020 16:37:26

US3342204

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 11 Aug 2021 22:34:12

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:12:42
User entered '26 Oct 2020 14:17'	System	26 Oct 2020 16:37:26

US3342204

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 11 Aug 2021 22:34:12

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:12:42
Data entry locked.	System	26 Oct 2020 16:37:26
User entered 'Day 1, after vaccination (at home)'	System	26 Oct 2020 16:37:26

US3342204

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 11 Aug 2021 22:34:12

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:12:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7A504897-431F-4E74-9F03-DAC668AE5D1E)', Time: '2020-10-26T23:49:03', User OID: 'PatientReportedOutcome (US3342204)', ODM File OID: '47b90952-1fa9-46e3-8d82-e4c807ac65c8' User entered 'None (0)'	System	27 Oct 2020 04:49:27
	System	27 Oct 2020 04:49:27

US3342204

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 11 Aug 2021 22:34:12

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:12:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7A504897-431F-4E74-9F03-DAC668AE5D1E)', Time: '2020-10-26T23:49:06', User OID: 'PatientReportedOutcome (US3342204)', ODM File OID: '47b90952-1fa9-46e3-8d82-e4c807ac65c8' User entered 'None (0)'	System	27 Oct 2020 04:49:27
	System	27 Oct 2020 04:49:27

US3342204

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 11 Aug 2021 22:34:12

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:12:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7A504897-431F-4E74-9F03-DAC668AE5D1E)', Time: '2020-10-26T23:49:08', User OID: 'PatientReportedOutcome (US3342204)', ODM File OID: '47b90952-1fa9-46e3-8d82-e4c807ac65c8' User entered 'None (0)'	System	27 Oct 2020 04:49:27
	System	27 Oct 2020 04:49:27

US3342204

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 11 Aug 2021 22:34:12

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:12:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7A504897-431F-4E74-9F03-DAC668AE5D1E)', Time: '2020-10-26T23:49:12', User OID: 'PatientReportedOutcome (US3342204)', ODM File OID: '47b90952-1fa9-46e3-8d82-e4c807ac65c8' User entered 'None (0)'	System	27 Oct 2020 04:49:27
	System	27 Oct 2020 04:49:27

US3342204

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 11 Aug 2021 22:34:12

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:12:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7A504897-431F-4E74-9F03-DAC668AE5D1E)', Time: '2020-10-26T23:49:15', User OID: 'PatientReportedOutcome (US3342204)', ODM File OID: '47b90952-1fa9-46e3-8d82-e4c807ac65c8' User entered 'None (0)'	System	27 Oct 2020 04:49:27
	System	27 Oct 2020 04:49:27

US3342204

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 11 Aug 2021 22:34:12

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:12:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7A504897-431F-4E74-9F03-DAC668AE5D1E)', Time: '2020-10-26T23:49:18', User OID: 'PatientReportedOutcome (US3342204)', ODM File OID: '47b90952-1fa9-46e3-8d82-e4c807ac65c8' User entered 'None (0)'	System	27 Oct 2020 04:49:27
	System	27 Oct 2020 04:49:27

US3342204

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 11 Aug 2021 22:34:12

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:12:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7A504897-431F-4E74-9F03-DAC668AE5D1E)', Time: '2020-10-26T23:49:21', User OID: 'PatientReportedOutcome (US3342204)', ODM File OID: '47b90952-1fa9-46e3-8d82-e4c807ac65c8' User entered 'No (N)'	System	27 Oct 2020 04:49:27
	System	27 Oct 2020 04:49:27

US3342204

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 11 Aug 2021 22:34:12

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:12:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7A504897-431F-4E74-9F03-DAC668AE5D1E)', Time: '2020-10-26T23:49:25', User OID: 'PatientReportedOutcome (US3342204)', ODM File OID: '47b90952-1fa9-46e3-8d82-e4c807ac65c8' User entered '26 Oct 2020 23:49'	System	27 Oct 2020 04:49:27
	System	27 Oct 2020 04:49:27

US3342204

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 11 Aug 2021 22:34:12

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:12:42
User entered '26 Oct 2020 15:12'	System	26 Oct 2020 16:37:26

US3342204

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 11 Aug 2021 22:34:12

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:12:42
User entered '27 Oct 2020 11:59'	System	26 Oct 2020 16:37:26

US3342204

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 11 Aug 2021 22:34:12

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:12:42
Data entry locked.	System	26 Oct 2020 16:37:26
User entered 'Day 2'	System	26 Oct 2020 16:37:26

US3342204

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 11 Aug 2021 22:34:12

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:12:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7A504897-431F-4E74-9F03-DAC668AE5D1E)', Time: '2020-10-27T23:38:58', User OID: 'PatientReportedOutcome (US3342204)', ODM File OID: '094eb8a1-0cd6-4823-b5cd-185bc1d56cdf' User entered 'None (0)'	System	28 Oct 2020 04:39:17
	System	28 Oct 2020 04:39:17

US3342204

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 11 Aug 2021 22:34:12

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:12:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7A504897-431F-4E74-9F03-DAC668AE5D1E)', Time: '2020-10-27T23:39:00', User OID: 'PatientReportedOutcome (US3342204)', ODM File OID: '094eb8a1-0cd6-4823-b5cd-185bc1d56cdf' User entered 'None (0)'	System	28 Oct 2020 04:39:17
	System	28 Oct 2020 04:39:17

US3342204

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 11 Aug 2021 22:34:12

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:12:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7A504897-431F-4E74-9F03-DAC668AE5D1E)', Time: '2020-10-27T23:39:02', User OID: 'PatientReportedOutcome (US3342204)', ODM File OID: '094eb8a1-0cd6-4823-b5cd-185bc1d56cdf' User entered 'None (0)'	System	28 Oct 2020 04:39:17
	System	28 Oct 2020 04:39:17

US3342204

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 11 Aug 2021 22:34:12

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:12:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7A504897-431F-4E74-9F03-DAC668AE5D1E)', Time: '2020-10-27T23:39:06', User OID: 'PatientReportedOutcome (US3342204)', ODM File OID: '094eb8a1-0cd6-4823-b5cd-185bc1d56cdf' User entered 'None (0)'	System	28 Oct 2020 04:39:17
	System	28 Oct 2020 04:39:17

US3342204

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 11 Aug 2021 22:34:12

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:12:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7A504897-431F-4E74-9F03-DAC668AE5D1E)', Time: '2020-10-27T23:39:08', User OID: 'PatientReportedOutcome (US3342204)', ODM File OID: '094eb8a1-0cd6-4823-b5cd-185bc1d56cdf' User entered 'None (0)'	System	28 Oct 2020 04:39:17
	System	28 Oct 2020 04:39:17

US3342204

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 11 Aug 2021 22:34:12

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:12:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7A504897-431F-4E74-9F03-DAC668AE5D1E)', Time: '2020-10-27T23:39:10', User OID: 'PatientReportedOutcome (US3342204)', ODM File OID: '094eb8a1-0cd6-4823-b5cd-185bc1d56cdf' User entered 'None (0)'	System	28 Oct 2020 04:39:17
	System	28 Oct 2020 04:39:17

US3342204

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 11 Aug 2021 22:34:12

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:12:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7A504897-431F-4E74-9F03-DAC668AE5D1E)', Time: '2020-10-27T23:39:13', User OID: 'PatientReportedOutcome (US3342204)', ODM File OID: '094eb8a1-0cd6-4823-b5cd-185bc1d56cdf' User entered 'No (N)'	System	28 Oct 2020 04:39:17
	System	28 Oct 2020 04:39:17

US3342204

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 11 Aug 2021 22:34:12

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:12:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7A504897-431F-4E74-9F03-DAC668AE5D1E)', Time: '2020-10-27T23:39:15', User OID: 'PatientReportedOutcome (US3342204)', ODM File OID: '094eb8a1-0cd6-4823-b5cd-185bc1d56cdf' User entered '27 Oct 2020 23:39'	System	28 Oct 2020 04:39:17
	System	28 Oct 2020 04:39:17

US3342204

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 11 Aug 2021 22:34:12

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:12:42
User entered '27 Oct 2020 12:00'	System	26 Oct 2020 16:37:26

US3342204

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 11 Aug 2021 22:34:12

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:12:42
User entered '28 Oct 2020 11:59'	System	26 Oct 2020 16:37:26

US3342204

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 11 Aug 2021 22:34:12

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:12:42
Data entry locked.	System	26 Oct 2020 16:37:26
User entered 'Day 3'	System	26 Oct 2020 16:37:26

US3342204

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 11 Aug 2021 22:34:12

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:12:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7A504897-431F-4E74-9F03-DAC668AE5D1E)', Time: '2020-10-28T21:03:21', User OID: 'PatientReportedOutcome (US3342204)', ODM File OID: '3962cf47-b49c-47ca-90fd-eb54afd7921a' User entered 'None (0)'	System	29 Oct 2020 02:03:47
	System	29 Oct 2020 02:03:47

US3342204

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 11 Aug 2021 22:34:12

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:12:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7A504897-431F-4E74-9F03-DAC668AE5D1E)', Time: '2020-10-28T21:03:23', User OID: 'PatientReportedOutcome (US3342204)', ODM File OID: '3962cf47-b49c-47ca-90fd-eb54afd7921a' User entered 'None (0)'	System	29 Oct 2020 02:03:47
	System	29 Oct 2020 02:03:47

US3342204

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 11 Aug 2021 22:34:12

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:12:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7A504897-431F-4E74-9F03-DAC668AE5D1E)', Time: '2020-10-28T21:03:25', User OID: 'PatientReportedOutcome (US3342204)', ODM File OID: '3962cf47-b49c-47ca-90fd-eb54afd7921a' User entered 'None (0)'	System	29 Oct 2020 02:03:47
	System	29 Oct 2020 02:03:47

US3342204

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 11 Aug 2021 22:34:12

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:12:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7A504897-431F-4E74-9F03-DAC668AE5D1E)', Time: '2020-10-28T21:03:27', User OID: 'PatientReportedOutcome (US3342204)', ODM File OID: '3962cf47-b49c-47ca-90fd-eb54afd7921a' User entered 'None (0)'	System	29 Oct 2020 02:03:47
	System	29 Oct 2020 02:03:47

US3342204

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 11 Aug 2021 22:34:12

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:12:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7A504897-431F-4E74-9F03-DAC668AE5D1E)', Time: '2020-10-28T21:03:29', User OID: 'PatientReportedOutcome (US3342204)', ODM File OID: '3962cf47-b49c-47ca-90fd-eb54afd7921a' User entered 'None (0)'	System	29 Oct 2020 02:03:47
	System	29 Oct 2020 02:03:47

US3342204

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 11 Aug 2021 22:34:12

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:12:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7A504897-431F-4E74-9F03-DAC668AE5D1E)', Time: '2020-10-28T21:03:32', User OID: 'PatientReportedOutcome (US3342204)', ODM File OID: '3962cf47-b49c-47ca-90fd-eb54afd7921a' User entered 'None (0)'	System	29 Oct 2020 02:03:47
	System	29 Oct 2020 02:03:47

US3342204

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 11 Aug 2021 22:34:12

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:12:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7A504897-431F-4E74-9F03-DAC668AE5D1E)', Time: '2020-10-28T21:03:43', User OID: 'PatientReportedOutcome (US3342204)', ODM File OID: '3962cf47-b49c-47ca-90fd-eb54afd7921a' User entered 'No (N)'	System	29 Oct 2020 02:03:47
	System	29 Oct 2020 02:03:47

US3342204

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 11 Aug 2021 22:34:12

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:12:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7A504897-431F-4E74-9F03-DAC668AE5D1E)', Time: '2020-10-28T21:03:46', User OID: 'PatientReportedOutcome (US3342204)', ODM File OID: '3962cf47-b49c-47ca-90fd-eb54afd7921a' User entered '28 Oct 2020 21:03'	System	29 Oct 2020 02:03:47
	System	29 Oct 2020 02:03:47

US3342204

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 11 Aug 2021 22:34:12

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:12:42
User entered '28 Oct 2020 12:00'	System	26 Oct 2020 16:37:26

US3342204

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 11 Aug 2021 22:34:12

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:12:42
User entered '29 Oct 2020 11:59'	System	26 Oct 2020 16:37:26

US3342204

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 11 Aug 2021 22:34:12

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:12:42
Data entry locked.	System	26 Oct 2020 16:37:26
User entered 'Day 4'	System	26 Oct 2020 16:37:26

US3342204

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 11 Aug 2021 22:34:12

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:12:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7A504897-431F-4E74-9F03-DAC668AE5D1E)', Time: '2020-10-29T23:59:49', User OID: 'PatientReportedOutcome (US3342204)', ODM File OID: '215382c0-e577-4252-8253-b2e6de56a066' User entered 'None (0)'	System	30 Oct 2020 05:00:12
	System	30 Oct 2020 05:00:12

US3342204

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 11 Aug 2021 22:34:12

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:12:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7A504897-431F-4E74-9F03-DAC668AE5D1E)', Time: '2020-10-29T23:59:51', User OID: 'PatientReportedOutcome (US3342204)', ODM File OID: '215382c0-e577-4252-8253-b2e6de56a066' User entered 'None (0)'	System	30 Oct 2020 05:00:12
	System	30 Oct 2020 05:00:12

US3342204

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 11 Aug 2021 22:34:12

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:12:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7A504897-431F-4E74-9F03-DAC668AE5D1E)', Time: '2020-10-29T23:59:54', User OID: 'PatientReportedOutcome (US3342204)', ODM File OID: '215382c0-e577-4252-8253-b2e6de56a066' User entered 'None (0)'	System	30 Oct 2020 05:00:12
	System	30 Oct 2020 05:00:12

US3342204

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 11 Aug 2021 22:34:12

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:12:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7A504897-431F-4E74-9F03-DAC668AE5D1E)', Time: '2020-10-29T23:59:57', User OID: 'PatientReportedOutcome (US3342204)', ODM File OID: '215382c0-e577-4252-8253-b2e6de56a066' User entered 'None (0)'	System	30 Oct 2020 05:00:12
	System	30 Oct 2020 05:00:12

US3342204

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 11 Aug 2021 22:34:12

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:12:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7A504897-431F-4E74-9F03-DAC668AE5D1E)', Time: '2020-10-29T23:59:59', User OID: 'PatientReportedOutcome (US3342204)', ODM File OID: '215382c0-e577-4252-8253-b2e6de56a066' User entered 'None (0)'	System	30 Oct 2020 05:00:12
	System	30 Oct 2020 05:00:12

US3342204

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 11 Aug 2021 22:34:12

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:12:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7A504897-431F-4E74-9F03-DAC668AE5D1E)', Time: '2020-10-30T00:00:02', User OID: 'PatientReportedOutcome (US3342204)', ODM File OID: '215382c0-e577-4252-8253-b2e6de56a066' User entered 'None (0)'	System	30 Oct 2020 05:00:12
	System	30 Oct 2020 05:00:12

US3342204

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 11 Aug 2021 22:34:12

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:12:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7A504897-431F-4E74-9F03-DAC668AE5D1E)', Time: '2020-10-30T00:00:05', User OID: 'PatientReportedOutcome (US3342204)', ODM File OID: '215382c0-e577-4252-8253-b2e6de56a066' User entered 'No (N)'	System	30 Oct 2020 05:00:12
	System	30 Oct 2020 05:00:12

US3342204

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 11 Aug 2021 22:34:12

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:12:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7A504897-431F-4E74-9F03-DAC668AE5D1E)', Time: '2020-10-30T00:00:07', User OID: 'PatientReportedOutcome (US3342204)', ODM File OID: '215382c0-e577-4252-8253-b2e6de56a066' User entered '30 Oct 2020 00:00'	System	30 Oct 2020 05:00:12
	System	30 Oct 2020 05:00:12

US3342204

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 11 Aug 2021 22:34:12

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:12:42
User entered '29 Oct 2020 12:00'	System	26 Oct 2020 16:37:26

US3342204

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 11 Aug 2021 22:34:12

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:12:42
User entered '30 Oct 2020 11:59'	System	26 Oct 2020 16:37:26

US3342204

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 11 Aug 2021 22:34:12

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:12:42
Data entry locked.	System	26 Oct 2020 16:37:26
User entered 'Day 5'	System	26 Oct 2020 16:37:26

US3342204

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 11 Aug 2021 22:34:12

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:12:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7A504897-431F-4E74-9F03-DAC668AE5D1E)', Time: '2020-10-30T23:06:44', User OID: 'PatientReportedOutcome (US3342204)', ODM File OID: '6f3ab6a5-fe42-4c5e-a394-03b5e9c38a05' User entered 'None (0)'	System	31 Oct 2020 04:07:09
	System	31 Oct 2020 04:07:09

US3342204

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 11 Aug 2021 22:34:12

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:12:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7A504897-431F-4E74-9F03-DAC668AE5D1E)', Time: '2020-10-30T23:06:46', User OID: 'PatientReportedOutcome (US3342204)', ODM File OID: '6f3ab6a5-fe42-4c5e-a394-03b5e9c38a05' User entered 'None (0)'	System	31 Oct 2020 04:07:09
	System	31 Oct 2020 04:07:09

US3342204

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 11 Aug 2021 22:34:12

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:12:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7A504897-431F-4E74-9F03-DAC668AE5D1E)', Time: '2020-10-30T23:06:48', User OID: 'PatientReportedOutcome (US3342204)', ODM File OID: '6f3ab6a5-fe42-4c5e-a394-03b5e9c38a05' User entered 'None (0)'	System	31 Oct 2020 04:07:09
	System	31 Oct 2020 04:07:09

US3342204

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 11 Aug 2021 22:34:12

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:12:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7A504897-431F-4E74-9F03-DAC668AE5D1E)', Time: '2020-10-30T23:06:50', User OID: 'PatientReportedOutcome (US3342204)', ODM File OID: '6f3ab6a5-fe42-4c5e-a394-03b5e9c38a05' User entered 'None (0)'	System	31 Oct 2020 04:07:09
	System	31 Oct 2020 04:07:09

US3342204

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 11 Aug 2021 22:34:12

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:12:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7A504897-431F-4E74-9F03-DAC668AE5D1E)', Time: '2020-10-30T23:06:51', User OID: 'PatientReportedOutcome (US3342204)', ODM File OID: '6f3ab6a5-fe42-4c5e-a394-03b5e9c38a05' User entered 'None (0)'	System	31 Oct 2020 04:07:09
	System	31 Oct 2020 04:07:09

US3342204

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 11 Aug 2021 22:34:12

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:12:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7A504897-431F-4E74-9F03-DAC668AE5D1E)', Time: '2020-10-30T23:06:53', User OID: 'PatientReportedOutcome (US3342204)', ODM File OID: '6f3ab6a5-fe42-4c5e-a394-03b5e9c38a05' User entered 'None (0)'	System	31 Oct 2020 04:07:09
	System	31 Oct 2020 04:07:09

US3342204

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 11 Aug 2021 22:34:12

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:12:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7A504897-431F-4E74-9F03-DAC668AE5D1E)', Time: '2020-10-30T23:07:00', User OID: 'PatientReportedOutcome (US3342204)', ODM File OID: '6f3ab6a5-fe42-4c5e-a394-03b5e9c38a05'	System	31 Oct 2020 04:07:09
User entered 'No (N)'	System	31 Oct 2020 04:07:09

US3342204

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 11 Aug 2021 22:34:12

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:12:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7A504897-431F-4E74-9F03-DAC668AE5D1E)', Time: '2020-10-30T23:07:03', User OID: 'PatientReportedOutcome (US3342204)', ODM File OID: '6f3ab6a5-fe42-4c5e-a394-03b5e9c38a05' User entered '30 Oct 2020 23:07'	System	31 Oct 2020 04:07:09
	System	31 Oct 2020 04:07:09

US3342204

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 11 Aug 2021 22:34:12

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:12:42
User entered '30 Oct 2020 12:00'	System	26 Oct 2020 16:37:26

US3342204

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 11 Aug 2021 22:34:12

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:12:42
User entered '31 Oct 2020 11:59'	System	26 Oct 2020 16:37:26

US3342204

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 11 Aug 2021 22:34:12

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:12:42
Data entry locked.	System	26 Oct 2020 16:37:26
User entered 'Day 6'	System	26 Oct 2020 16:37:26

US3342204

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 11 Aug 2021 22:34:12

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:12:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7A504897-431F-4E74-9F03-DAC668AE5D1E)', Time: '2020-11-01T07:17:12', User OID: 'PatientReportedOutcome (US3342204)', ODM File OID: '5ba206ad-b14e-4794-aa10-f870645f3a15' User entered 'None (0)'	System	01 Nov 2020 13:17:29
	System	01 Nov 2020 13:17:29

US3342204

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 11 Aug 2021 22:34:12

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:12:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7A504897-431F-4E74-9F03-DAC668AE5D1E)', Time: '2020-11-01T07:17:14', User OID: 'PatientReportedOutcome (US3342204)', ODM File OID: '5ba206ad-b14e-4794-aa10-f870645f3a15' User entered 'None (0)'	System	01 Nov 2020 13:17:29
	System	01 Nov 2020 13:17:29

US3342204

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 11 Aug 2021 22:34:12

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:12:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7A504897-431F-4E74-9F03-DAC668AE5D1E)', Time: '2020-11-01T07:17:16', User OID: 'PatientReportedOutcome (US3342204)', ODM File OID: '5ba206ad-b14e-4794-aa10-f870645f3a15' User entered 'None (0)'	System	01 Nov 2020 13:17:29
	System	01 Nov 2020 13:17:29

US3342204

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 11 Aug 2021 22:34:12

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:12:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7A504897-431F-4E74-9F03-DAC668AE5D1E)', Time: '2020-11-01T07:17:18', User OID: 'PatientReportedOutcome (US3342204)', ODM File OID: '5ba206ad-b14e-4794-aa10-f870645f3a15' User entered 'None (0)'	System	01 Nov 2020 13:17:29
	System	01 Nov 2020 13:17:29

US3342204

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 11 Aug 2021 22:34:12

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:12:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7A504897-431F-4E74-9F03-DAC668AE5D1E)', Time: '2020-11-01T07:17:19', User OID: 'PatientReportedOutcome (US3342204)', ODM File OID: '5ba206ad-b14e-4794-aa10-f870645f3a15' User entered 'None (0)'	System	01 Nov 2020 13:17:29
	System	01 Nov 2020 13:17:29

US3342204

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 11 Aug 2021 22:34:12

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:12:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7A504897-431F-4E74-9F03-DAC668AE5D1E)', Time: '2020-11-01T07:17:21', User OID: 'PatientReportedOutcome (US3342204)', ODM File OID: '5ba206ad-b14e-4794-aa10-f870645f3a15' User entered 'None (0)'	System	01 Nov 2020 13:17:29
	System	01 Nov 2020 13:17:29

US3342204

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 11 Aug 2021 22:34:12

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:12:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7A504897-431F-4E74-9F03-DAC668AE5D1E)', Time: '2020-11-01T07:17:24', User OID: 'PatientReportedOutcome (US3342204)', ODM File OID: '5ba206ad-b14e-4794-aa10-f870645f3a15' User entered 'No (N)'	System	01 Nov 2020 13:17:29
	System	01 Nov 2020 13:17:29

US3342204

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 11 Aug 2021 22:34:12

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:12:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7A504897-431F-4E74-9F03-DAC668AE5D1E)', Time: '2020-11-01T07:17:27', User OID: 'PatientReportedOutcome (US3342204)', ODM File OID: '5ba206ad-b14e-4794-aa10-f870645f3a15' User entered '01 Nov 2020 07:17'	System	01 Nov 2020 13:17:29
	System	01 Nov 2020 13:17:29

US3342204

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 11 Aug 2021 22:34:12

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:12:42
User entered '31 Oct 2020 12:00'	System	26 Oct 2020 16:37:26

US3342204

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 11 Aug 2021 22:34:12

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:12:42
User entered '01 Nov 2020 11:59'	System	26 Oct 2020 16:37:26

US3342204

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 11 Aug 2021 22:34:12

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:12:42
Data entry locked.	System	26 Oct 2020 16:37:26
User entered 'Day 7'	System	26 Oct 2020 16:37:26

US3342204

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 11 Aug 2021 22:34:12

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:12:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7A504897-431F-4E74-9F03-DAC668AE5D1E)', Time: '2020-11-01T20:03:01', User OID: 'PatientReportedOutcome (US3342204)', ODM File OID: '2ffa9b11-1a12-4cf6-918e-360daa129bf9' User entered 'None (0)'	System	02 Nov 2020 02:03:14
	System	02 Nov 2020 02:03:14

US3342204

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 11 Aug 2021 22:34:12

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:12:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7A504897-431F-4E74-9F03-DAC668AE5D1E)', Time: '2020-11-01T20:03:02', User OID: 'PatientReportedOutcome (US3342204)', ODM File OID: '2ffa9b11-1a12-4cf6-918e-360daa129bf9' User entered 'None (0)'	System	02 Nov 2020 02:03:14
	System	02 Nov 2020 02:03:14

US3342204

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 11 Aug 2021 22:34:12

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:12:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7A504897-431F-4E74-9F03-DAC668AE5D1E)', Time: '2020-11-01T20:03:04', User OID: 'PatientReportedOutcome (US3342204)', ODM File OID: '2ffa9b11-1a12-4cf6-918e-360daa129bf9' User entered 'None (0)'	System	02 Nov 2020 02:03:14
	System	02 Nov 2020 02:03:14

US3342204

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 11 Aug 2021 22:34:12

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:12:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7A504897-431F-4E74-9F03-DAC668AE5D1E)', Time: '2020-11-01T20:03:05', User OID: 'PatientReportedOutcome (US3342204)', ODM File OID: '2ffa9b11-1a12-4cf6-918e-360daa129bf9' User entered 'None (0)'	System	02 Nov 2020 02:03:14
	System	02 Nov 2020 02:03:14

US3342204

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 11 Aug 2021 22:34:12

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:12:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7A504897-431F-4E74-9F03-DAC668AE5D1E)', Time: '2020-11-01T20:03:06', User OID: 'PatientReportedOutcome (US3342204)', ODM File OID: '2ffa9b11-1a12-4cf6-918e-360daa129bf9' User entered 'None (0)'	System	02 Nov 2020 02:03:14
	System	02 Nov 2020 02:03:14

US3342204

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 11 Aug 2021 22:34:12

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:12:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7A504897-431F-4E74-9F03-DAC668AE5D1E)', Time: '2020-11-01T20:03:08', User OID: 'PatientReportedOutcome (US3342204)', ODM File OID: '2ffa9b11-1a12-4cf6-918e-360daa129bf9' User entered 'None (0)'	System	02 Nov 2020 02:03:14
	System	02 Nov 2020 02:03:14

US3342204

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 11 Aug 2021 22:34:12

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:12:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7A504897-431F-4E74-9F03-DAC668AE5D1E)', Time: '2020-11-01T20:03:10', User OID: 'PatientReportedOutcome (US3342204)', ODM File OID: '2ffa9b11-1a12-4cf6-918e-360daa129bf9' User entered 'No (N)'	System	02 Nov 2020 02:03:14
	System	02 Nov 2020 02:03:14

US3342204

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 11 Aug 2021 22:34:12

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:12:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7A504897-431F-4E74-9F03-DAC668AE5D1E)', Time: '2020-11-01T20:03:12', User OID: 'PatientReportedOutcome (US3342204)', ODM File OID: '2ffa9b11-1a12-4cf6-918e-360daa129bf9' User entered '01 Nov 2020 20:03'	System	02 Nov 2020 02:03:14
	System	02 Nov 2020 02:03:14

US3342204

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 11 Aug 2021 22:34:12

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:12:42
User entered '01 Nov 2020 12:00'	System	26 Oct 2020 16:37:26

US3342204

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 11 Aug 2021 22:34:12

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:12:42
User entered '02 Nov 2020 11:59'	System	26 Oct 2020 16:37:26

US3342204

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:34:12

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 13:03:22
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:17:37
User entered 'Yes (Y)'	Ethan Shotton (b) (4)	02 Nov 2020 20:01:44

US3342204

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:34:12

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 13:03:22
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:17:37
User entered '2 Nov 2020'	Ethan Shotton (b) (4)	02 Nov 2020 20:01:44

US3342204

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:34:12

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 13:03:22
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:17:37
User entered 'Contact Made (CONTACT MADE)'	Ethan Shotton (b) (4)	02 Nov 2020 20:01:44

US3342204

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:34:12

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 13:03:22
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:17:37
User entered empty.	Ethan Shotton (b) (4)	02 Nov 2020 20:01:44

US3342204

Folder: Safety Call Day 36 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:34:12

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 13:03:22
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:17:37
User entered 'Yes (Y)'	Ethan Shotton (b) (4)	02 Nov 2020 20:01:48

US3342204

Folder: Safety Call Day 36 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:34:12

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 13:03:22
User entered '1'	System	02 Nov 2020 20:01:48

US3342204

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:34:12

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 13:03:22
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:17:37
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	09 Nov 2020 15:06:47

US3342204

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:34:12

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 13:03:22
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:17:37
User entered '9 Nov 2020'	(b) (4) (b) (4), (b) (6)	09 Nov 2020 15:06:47

US3342204

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:34:12

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 13:03:22
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:17:37
User entered 'Contact Made (CONTACT MADE)'	(b) (4) (b) (4), (b) (6)	09 Nov 2020 15:06:47

US3342204

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:34:12

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 13:03:22
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:17:37
User entered empty.	(b) (4) (b) (4), (b) (6)	09 Nov 2020 15:06:47

US3342204

Folder: Safety Call Day 43 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:34:12

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 13:03:22
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:17:37
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	09 Nov 2020 15:06:52

US3342204

Folder: Safety Call Day 43 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:34:12

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 13:03:22
User entered '1'	System	09 Nov 2020 15:06:52

US3342204

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:34:12

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 13:03:22
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:17:37
User entered 'Yes (Y)'	(b) (4) Morgan Schulle (b) (4)	17 Nov 2020 17:40:35

US3342204

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:34:12

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 13:03:22
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:17:37
User entered '17 Nov 2020'	(b) (4) Morgan Schulle (b) (4)	17 Nov 2020 17:40:35

US3342204

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:34:12

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 13:03:22
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:17:37
User entered 'Contact Made (CONTACT MADE)'	(b) (4) Morgan Schulle (b) (4)	17 Nov 2020 17:40:35

US3342204

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:34:12

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 13:03:22
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:17:37
User entered empty.	(b) (4) Morgan Schulle (b) (4)	17 Nov 2020 17:40:35

US3342204

Folder: Safety Call Day 50 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:34:12

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 13:03:22
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:17:37
User entered 'Yes (Y)'	Morgan Schulle (b) (4)	17 Nov 2020 17:40:45

US3342204

Folder: Safety Call Day 50 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:34:12

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 13:03:22
User entered '1'	System	17 Nov 2020 17:40:45

US3342204

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 11 Aug 2021 22:34:12

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 13:03:22
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:17:37
User entered 'Yes (Y)'	(b) (4) Darrell O'Brien (b) (4)	20 Nov 2020 17:11:45

US3342204

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 11 Aug 2021 22:34:12

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 13:03:22
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:17:37
User entered '20 Nov 2020'	(b) (4) Darrell O'Brien (b) (4)	20 Nov 2020 17:11:45

US3342204

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 11 Aug 2021 22:34:12

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 13:03:22
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:17:37
User entered 'Clinic (Clinic)'	(b) (4) Darrell O'Brien (b) (4)	20 Nov 2020 17:11:45

US3342204

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 11 Aug 2021 22:34:12

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 13:03:22
User entered 'VISIT3'	System	20 Nov 2020 17:11:45

US3342204

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:34:12

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 13:03:22
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:17:37
User entered 'Yes (Y)'	(b) (4) Darrell O'Brien (b) (4)	20 Nov 2020 17:13:05

US3342204

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:34:12

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 13:03:22
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:17:37
User entered '20 Nov 2020'	(b) (4) Darrell O'Brien (b) (4)	20 Nov 2020 17:13:05

US3342204

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:34:12

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 13:03:22
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:17:37
User entered '10:19'	(b) (4) Darrell O'Brien (b) (4)	20 Nov 2020 17:13:05

US3342204

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:34:12

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 13:03:22
User entered '20 Nov 2020 10:19'	System	20 Nov 2020 17:13:05

US3342204

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:34:12

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 13:03:22
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:17:37
User entered '98.2' F	(b) (4) Darrell O'Brien (b) (4)	20 Nov 2020 17:13:05

US3342204

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:34:12

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 13:03:22
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:17:37
User entered 'Oral (Oral)'	(b) (4) Darrell O'Brien (b) (4)	20 Nov 2020 17:13:05

US3342204

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:34:12

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 13:03:22
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:17:37
User entered empty.	(b) (4) Darrell O'Brien (b) (4)	20 Nov 2020 17:13:05

US3342204

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:34:12

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 13:03:22
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:17:37
User entered '83'	(b) (4) Darrell O'Brien (b) (4)	20 Nov 2020 17:13:05

US3342204

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:34:12

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 13:03:22
User entered 'bpm'	System	20 Nov 2020 17:13:05

US3342204

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:34:12

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 13:03:22
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:17:37
User entered '12'	(b) (4) Darrell O'Brien (b) (4)	20 Nov 2020 17:13:05

US3342204

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:34:12

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 13:03:22
User entered 'breaths/min'	System	20 Nov 2020 17:13:05

US3342204

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:34:12

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 13:03:22
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:17:37
User entered '99'	(b) (4) Darrell O'Brien (b) (4)	20 Nov 2020 17:13:05

US3342204

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:34:12

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 13:03:22
User entered 'mmHg'	System	20 Nov 2020 17:13:05

US3342204

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:34:12

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 13:03:22
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:17:37
User entered '68'	(b) (4) Darrell O'Brien (b) (4)	20 Nov 2020 17:13:05

US3342204

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:34:12

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 13:03:22
User entered 'mmHg'	System	20 Nov 2020 17:13:05

US3342204

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:34:12

[Height \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 13:03:22

US3342204

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:34:12

[Weight \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 13:03:22

US3342204

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Generated On: 11 Aug 2021 22:34:12

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 13:03:22
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:17:37
User entered 'No (N)'	(b) (4) Darrell O'Brien (b) (4)	20 Nov 2020 17:13:17

US3342204

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Generated On: 11 Aug 2021 22:34:12

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 13:03:22
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:17:37
User entered empty.	(b) (4) Darrell O'Brien (b) (4)	20 Nov 2020 17:13:17

US3342204

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 22:34:12

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 13:03:22
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:17:37
User entered 'Yes (Y)'	(b) (4) Eileen Euperio (b) (4)	23 Nov 2020 16:04:13

US3342204

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 22:34:12

Collection date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 13:03:22
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:17:37
User entered '20 Nov 2020'	(b) (4) Eileen Euperio (b) (4)	23 Nov 2020 16:04:13

US3342204

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 22:34:12

Collection time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 13:03:22
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:17:37
User entered '10:43'	(b) (4) Eileen Euperio (b) (4)	23 Nov 2020 16:04:13

US3342204

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 22:34:12

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 13:03:22
User entered '20 Nov 2020 10:43'	System	23 Nov 2020 16:04:13

US3342204

Folder: Visit 3 Day 57 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:34:12

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 13:03:22
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:17:37
User entered 'Yes (Y)'	(b) (4) Darrell O'Brien (b) (4)	20 Nov 2020 16:43:41

US3342204

Folder: Visit 3 Day 57 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:34:12

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 13:03:22
User entered '1'	System	20 Nov 2020 16:43:41

US3342204

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:34:12

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:31:52
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 06:06:44
Data entry locked.	System	08 Sep 2020 17:07:02
User entered 'Day 64'	System	08 Sep 2020 17:07:02

US3342204

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:34:12

[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)	28 Apr 2021 15:31:52
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 06:06:44

US3342204

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:34:12

Have you been exposed to someone with 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)	28 Apr 2021 15:31:52
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 06:06:44

US3342204

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:34:12

Please 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)	28 Apr 2021 15:31:52
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 06:06:44

US3342204

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:34:12

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)	28 Apr 2021 15:31:52
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 06:06:44

US3342204

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:34:12

Fever (Temperature \geq 100.4°F/38°C)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:31:52
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 06:06:44

US3342204

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:34:12

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:31:52
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 06:06:44

US3342204

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:34:12

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:31:52
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 06:06:44

US3342204

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:34:12

[Shortness of breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:31:52
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 06:06:44

US3342204

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:34:12

[Difficulty breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:31:52
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 06:06:44

US3342204

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:34:12

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:31:52
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 06:06:44

US3342204

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:34:12

[Muscle aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:31:52
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 06:06:44

US3342204

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:34:12

[Body aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:31:52
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 06:06:44

US3342204

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:34:12

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:31:52
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 06:06:44

US3342204

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:34:12

[New loss of taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:31:52
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 06:06:44

US3342204

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:34:12

[New loss of smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:31:52
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 06:06:44

US3342204

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:34:12

[Sore throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:31:52
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 06:06:44

US3342204

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:34:12

[Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:31:52
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 06:06:44

US3342204

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:34:12

[Runny nose](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:31:52
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 06:06:44

US3342204

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:34:12

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:31:52
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 06:06:44

US3342204

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:34:12

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:31:52
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 06:06:44

US3342204

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:34:12

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:31:52
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 06:06:44

US3342204

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:34:12

Please 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)	28 Apr 2021 15:31:52
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 06:06:44

US3342204

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:34:12

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)	28 Apr 2021 15:31:52
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 06:06:44

US3342204

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:34:12

Please 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)	28 Apr 2021 15:31:52
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 06:06:44

US3342204

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:34:12

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:31:52
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 06:06:44

US3342204

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:34:12

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:31:52
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 06:06:44
Data entry locked.	System	08 Sep 2020 17:07:02
User entered '08 Nov 2020 00:01'	System	08 Sep 2020 17:07:02

US3342204

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:34:12

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:31:52
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 06:06:44
Data entry locked.	System	08 Sep 2020 17:07:02
User entered '12 Nov 2020 23:59'	System	08 Sep 2020 17:07:02

US3342204

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:34:12

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:31:52
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 06:06:44
Data entry locked.	System	08 Sep 2020 17:07:02
User entered 'Day 71'	System	08 Sep 2020 17:07:02

US3342204

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:34:12

[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)	28 Apr 2021 15:31:52
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 06:06:44

US3342204

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:34:12

Have you been exposed to someone with 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)	28 Apr 2021 15:31:52
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 06:06:44

US3342204

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:34:12

Please 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)	28 Apr 2021 15:31:52
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 06:06:44

US3342204

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:34:12

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)	28 Apr 2021 15:31:52
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 06:06:44

US3342204

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:34:12

Fever (Temperature \geq 100.4°F/38°C)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:31:52
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 06:06:44

US3342204

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:34:12

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:31:52
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 06:06:44

US3342204

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:34:12

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:31:52
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 06:06:44

US3342204

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:34:12

[Shortness of breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:31:52
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 06:06:44

US3342204

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:34:12

[Difficulty breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:31:52
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 06:06:44

US3342204

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:34:12

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:31:52
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 06:06:44

US3342204

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:34:12

[Muscle aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:31:52
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 06:06:44

US3342204

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:34:12

[Body aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:31:52
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 06:06:44

US3342204

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:34:12

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:31:52
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 06:06:44

US3342204

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:34:12

[New loss of taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:31:52
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 06:06:44

US3342204

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:34:12

[New loss of smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:31:52
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 06:06:44

US3342204

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:34:12

[Sore throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:31:52
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 06:06:44

US3342204

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:34:12

[Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:31:52
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 06:06:44

US3342204

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:34:12

[Runny nose](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:31:52
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 06:06:44

US3342204

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:34:12

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:31:52
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 06:06:44

US3342204

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:34:12

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:31:52
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 06:06:44

US3342204

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:34:12

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:31:52
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 06:06:44

US3342204

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:34:12

Please 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)	28 Apr 2021 15:31:52
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 06:06:44

US3342204

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:34:12

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)	28 Apr 2021 15:31:52
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 06:06:44

US3342204

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:34:12

Please 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)	28 Apr 2021 15:31:52
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 06:06:44

US3342204

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:34:12

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:31:52
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 06:06:44

US3342204

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:34:12

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:31:52
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 06:06:44
Data entry locked.	System	08 Sep 2020 17:07:02
User entered '15 Nov 2020 00:01'	System	08 Sep 2020 17:07:02

US3342204

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:34:12

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:31:52
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 06:06:44
Data entry locked.	System	08 Sep 2020 17:07:02
User entered '19 Nov 2020 23:59'	System	08 Sep 2020 17:07:02

US3342204

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:34:12

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:31:52
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:06:44
Amendment Manager: User entered 'Day 75'	System	20 Nov 2020 06:06:44

US3342204

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:34:12

[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)	28 Apr 2021 15:31:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7A504897-431F-4E74-9F03-DAC668AE5D1E)', Time: '2020-11-20T10:31:06', User OID: 'PatientReportedOutcome (US3342204)', ODM File OID: '52566f05-29c2-4e1d-b253-8fd73ee36efd'	System	20 Nov 2020 16:31:33
User entered 'No (N)'	System	20 Nov 2020 16:31:33

US3342204

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:34:12

Have you been exposed to someone with 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)	28 Apr 2021 15:31:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7A504897-431F-4E74-9F03-DAC668AE5D1E)', Time: '2020-11-20T10:31:13', User OID: 'PatientReportedOutcome (US3342204)', ODM File OID: '52566f05-29c2-4e1d-b253-8fd73ee36efd'	System	20 Nov 2020 16:31:33
User entered 'No (N)'	System	20 Nov 2020 16:31:33

US3342204

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:34:12

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:31:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7A504897-431F-4E74-9F03-DAC668AE5D1E)', Time: '2020-11-20T10:31:28', User OID: 'PatientReportedOutcome (US3342204)', ODM File OID: '52566f05-29c2-4e1d-b253-8fd73ee36efd' User entered '20 Nov 2020 10:31:28'	System	20 Nov 2020 16:31:33
	System	20 Nov 2020 16:31:33

US3342204

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:34:12

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:31:52
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:06:44
Amendment Manager: User entered '19 Nov 2020 00:01'	System	20 Nov 2020 06:06:44

US3342204

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:34:12

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:31:52
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:06:44
Amendment Manager: User entered '23 Nov 2020 23:59'	System	20 Nov 2020 06:06:44

US3342204

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:34:12

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:31:52
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:06:44
Amendment Manager: User entered 'Day 82'	System	20 Nov 2020 06:06:44

US3342204

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:34:12

[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)	28 Apr 2021 15:31:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7A504897-431F-4E74-9F03-DAC668AE5D1E)', Time: '2020-11-28T12:34:02', User OID: 'PatientReportedOutcome (US3342204)', ODM File OID: '74af8522-291d-48f8-9cc3-9d2f477ec098'	System	28 Nov 2020 18:34:15
User entered 'No (N)'	System	28 Nov 2020 18:34:15

US3342204

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:34:12

Have you been exposed to someone with 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)	28 Apr 2021 15:31:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7A504897-431F-4E74-9F03-DAC668AE5D1E)', Time: '2020-11-28T12:34:07', User OID: 'PatientReportedOutcome (US3342204)', ODM File OID: '74af8522-291d-48f8-9cc3-9d2f477ec098'	System	28 Nov 2020 18:34:15
User entered 'No (N)'	System	28 Nov 2020 18:34:15

US3342204

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:34:12

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:31:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7A504897-431F-4E74-9F03-DAC668AE5D1E)', Time: '2020-11-28T12:34:11', User OID: 'PatientReportedOutcome (US3342204)', ODM File OID: '74af8522-291d-48f8-9cc3-9d2f477ec098' User entered '28 Nov 2020 12:34:11'	System	28 Nov 2020 18:34:15
	System	28 Nov 2020 18:34:15

US3342204

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:34:12

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:31:52
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:06:44
Amendment Manager: User entered '26 Nov 2020 00:01'	System	20 Nov 2020 06:06:44

US3342204

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:34:12

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:31:52
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:06:44
Amendment Manager: User entered '30 Nov 2020 23:59'	System	20 Nov 2020 06:06:44

US3342204

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:34:12

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:31:52
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:06:44
Amendment Manager: User entered 'Day 89'	System	20 Nov 2020 06:06:44

US3342204

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:34:12

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)	28 Apr 2021 15:31:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7A504897-431F-4E74-9F03-DAC668AE5D1E)', Time: '2020-12-05T13:36:35', User OID: 'PatientReportedOutcome (US3342204)', ODM File OID: '81ff5703-6490-4c57-8248-b9fc2dec24e1'	System	05 Dec 2020 19:36:45
User entered 'No (N)'	System	05 Dec 2020 19:36:45

US3342204

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:34:12

Have you been exposed to someone with 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)	28 Apr 2021 15:31:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7A504897-431F-4E74-9F03-DAC668AE5D1E)', Time: '2020-12-05T13:36:40', User OID: 'PatientReportedOutcome (US3342204)', ODM File OID: '81ff5703-6490-4c57-8248-b9fc2dec24e1'	System	05 Dec 2020 19:36:45
User entered 'No (N)'	System	05 Dec 2020 19:36:45

US3342204

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:34:12

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:31:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7A504897-431F-4E74-9F03-DAC668AE5D1E)', Time: '2020-12-05T13:36:43', User OID: 'PatientReportedOutcome (US3342204)', ODM File OID: '81ff5703-6490-4c57-8248-b9fc2dec24e1' User entered '05 Dec 2020 13:36:43'	System	05 Dec 2020 19:36:45
	System	05 Dec 2020 19:36:45

US3342204

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:34:12

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:31:52
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:06:44
Amendment Manager: User entered '03 Dec 2020 00:01'	System	20 Nov 2020 06:06:44

US3342204

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:34:12

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:31:52
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:06:44
Amendment Manager: User entered '07 Dec 2020 23:59'	System	20 Nov 2020 06:06:44

US3342204

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:34:12

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:31:52
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:06:44
Amendment Manager: User entered 'Day 96'	System	20 Nov 2020 06:06:44

US3342204

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:34:12

[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)	28 Apr 2021 15:31:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7A504897-431F-4E74-9F03-DAC668AE5D1E)', Time: '2020-12-12T12:14:28', User OID: 'PatientReportedOutcome (US3342204)', ODM File OID: '0fb2e9a2-2876-4f1d-821d-765a34de3be0'	System	12 Dec 2020 18:14:40
User entered 'No (N)'	System	12 Dec 2020 18:14:40

US3342204

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:34:12

Have you been exposed to someone with 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)	28 Apr 2021 15:31:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7A504897-431F-4E74-9F03-DAC668AE5D1E)', Time: '2020-12-12T12:14:34', User OID: 'PatientReportedOutcome (US3342204)', ODM File OID: '0fb2e9a2-2876-4f1d-821d-765a34de3be0'	System	12 Dec 2020 18:14:40
User entered 'No (N)'	System	12 Dec 2020 18:14:40

US3342204

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:34:12

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:31:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7A504897-431F-4E74-9F03-DAC668AE5D1E)', Time: '2020-12-12T12:14:38', User OID: 'PatientReportedOutcome (US3342204)', ODM File OID: '0fb2e9a2-2876-4f1d-821d-765a34de3be0' User entered '12 Dec 2020 12:14:38'	System	12 Dec 2020 18:14:40
	System	12 Dec 2020 18:14:40

US3342204

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:34:12

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:31:52
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:06:44
Amendment Manager: User entered '10 Dec 2020 00:01'	System	20 Nov 2020 06:06:44

US3342204

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:34:12

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:31:52
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:06:44
Amendment Manager: User entered '14 Dec 2020 23:59'	System	20 Nov 2020 06:06:44

US3342204

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:34:12

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:31:52
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:06:44
Amendment Manager: User entered 'Day 103'	System	20 Nov 2020 06:06:44

US3342204

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:34:12

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)	28 Apr 2021 15:31:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7A504897-431F-4E74-9F03-DAC668AE5D1E)', Time: '2020-12-19T12:18:03', User OID: 'PatientReportedOutcome (US3342204)', ODM File OID: '761ce316-6aab-48e0-b3c1-81f78ca7b14a'	System	19 Dec 2020 18:18:19
User entered 'No (N)'	System	19 Dec 2020 18:18:19

US3342204

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:34:12

Have you been exposed to someone with 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)	28 Apr 2021 15:31:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7A504897-431F-4E74-9F03-DAC668AE5D1E)', Time: '2020-12-19T12:18:11', User OID: 'PatientReportedOutcome (US3342204)', ODM File OID: '761ce316-6aab-48e0-b3c1-81f78ca7b14a'	System	19 Dec 2020 18:18:19
User entered 'No (N)'	System	19 Dec 2020 18:18:19

US3342204

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:34:12

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:31:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7A504897-431F-4E74-9F03-DAC668AE5D1E)', Time: '2020-12-19T12:18:17', User OID: 'PatientReportedOutcome (US3342204)', ODM File OID: '761ce316-6aab-48e0-b3c1-81f78ca7b14a' User entered '19 Dec 2020 12:18:17'	System	19 Dec 2020 18:18:19
	System	19 Dec 2020 18:18:19

US3342204

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:34:12

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:31:52
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:06:44
Amendment Manager: User entered '17 Dec 2020 00:01'	System	20 Nov 2020 06:06:44

US3342204

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:34:12

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:31:52
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:06:44
Amendment Manager: User entered '21 Dec 2020 23:59'	System	20 Nov 2020 06:06:44

US3342204

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:34:12

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:31:52
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:06:44
Amendment Manager: User entered 'Day 110'	System	20 Nov 2020 06:06:44

US3342204

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:34:12

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)	28 Apr 2021 15:31:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7A504897-431F-4E74-9F03-DAC668AE5D1E)', Time: '2020-12-25T16:03:25', User OID: 'PatientReportedOutcome (US3342204)', ODM File OID: 'c634522d-bbb8-4de8-aff7-89241ad63e19'	System	25 Dec 2020 22:03:35
User entered 'No (N)'	System	25 Dec 2020 22:03:35

US3342204

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:34:12

Have you been exposed to someone with 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)	28 Apr 2021 15:31:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7A504897-431F-4E74-9F03-DAC668AE5D1E)', Time: '2020-12-25T16:03:27', User OID: 'PatientReportedOutcome (US3342204)', ODM File OID: 'c634522d-bbb8-4de8-aff7-89241ad63e19'	System	25 Dec 2020 22:03:35
User entered 'No (N)'	System	25 Dec 2020 22:03:35

US3342204

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:34:12

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:31:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7A504897-431F-4E74-9F03-DAC668AE5D1E)', Time: '2020-12-25T16:03:30', User OID: 'PatientReportedOutcome (US3342204)', ODM File OID: 'c634522d-bbb8-4de8-aff7-89241ad63e19' User entered '25 Dec 2020 16:03:30'	System	25 Dec 2020 22:03:35
	System	25 Dec 2020 22:03:35

US3342204

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:34:12

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:31:52
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:06:44
Amendment Manager: User entered '24 Dec 2020 00:01'	System	20 Nov 2020 06:06:44

US3342204

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:34:12

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:31:52
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:06:44
Amendment Manager: User entered '28 Dec 2020 23:59'	System	20 Nov 2020 06:06:44

US3342204

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:34:12

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:31:52
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:06:44
Amendment Manager: User entered 'Day 117'	System	20 Nov 2020 06:06:44

US3342204

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:34:12

[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)	28 Apr 2021 15:31:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7A504897-431F-4E74-9F03-DAC668AE5D1E)', Time: '2021-01-02T12:00:36', User OID: 'PatientReportedOutcome (US3342204)', ODM File OID: '91e19d74-291f-4eb3-8128-06f7d3d63175'	System	02 Jan 2021 18:00:46
User entered 'No (N)'	System	02 Jan 2021 18:00:46

US3342204

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:34:12

Have you been exposed to someone with 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)	28 Apr 2021 15:31:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7A504897-431F-4E74-9F03-DAC668AE5D1E)', Time: '2021-01-02T12:00:38', User OID: 'PatientReportedOutcome (US3342204)', ODM File OID: '91e19d74-291f-4eb3-8128-06f7d3d63175'	System	02 Jan 2021 18:00:46
User entered 'No (N)'	System	02 Jan 2021 18:00:46

US3342204

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:34:12

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:31:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7A504897-431F-4E74-9F03-DAC668AE5D1E)', Time: '2021-01-02T12:00:41', User OID: 'PatientReportedOutcome (US3342204)', ODM File OID: '91e19d74-291f-4eb3-8128-06f7d3d63175' User entered '02 Jan 2021 12:00:41'	System	02 Jan 2021 18:00:46
	System	02 Jan 2021 18:00:46

US3342204

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:34:12

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:31:52
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:06:44
Amendment Manager: User entered '31 Dec 2020 00:01'	System	20 Nov 2020 06:06:44

US3342204

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:34:12

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:31:52
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:06:44
Amendment Manager: User entered '04 Jan 2021 23:59'	System	20 Nov 2020 06:06:44

US3342204

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:34:12

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:31:52
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:06:44
Amendment Manager: User entered 'Day 124'	System	20 Nov 2020 06:06:44

US3342204

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:34:12

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)	28 Apr 2021 15:31:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7A504897-431F-4E74-9F03-DAC668AE5D1E)', Time: '2021-01-09T10:29:20', User OID: 'PatientReportedOutcome (US3342204)', ODM File OID: '33012fbf-faeb-4b2b-8c0e-4ea9a8f0dfaf'	System	09 Jan 2021 16:29:28
User entered 'No (N)'	System	09 Jan 2021 16:29:28

US3342204

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:34:12

Have you been exposed to someone with 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)	28 Apr 2021 15:31:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7A504897-431F-4E74-9F03-DAC668AE5D1E)', Time: '2021-01-09T10:29:21', User OID: 'PatientReportedOutcome (US3342204)', ODM File OID: '33012fbf-faeb-4b2b-8c0e-4ea9a8f0dfaf'	System	09 Jan 2021 16:29:28
User entered 'No (N)'	System	09 Jan 2021 16:29:28

US3342204

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:34:12

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:31:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7A504897-431F-4E74-9F03-DAC668AE5D1E)', Time: '2021-01-09T10:29:25', User OID: 'PatientReportedOutcome (US3342204)', ODM File OID: '33012fbf-faeb-4b2b-8c0e-4ea9a8f0dfaf' User entered '09 Jan 2021 10:29:25'	System	09 Jan 2021 16:29:28
	System	09 Jan 2021 16:29:28

US3342204

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:34:12

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:31:52
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:06:44
Amendment Manager: User entered '07 Jan 2021 00:01'	System	20 Nov 2020 06:06:44

US3342204

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:34:12

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:31:52
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:06:44
Amendment Manager: User entered '11 Jan 2021 23:59'	System	20 Nov 2020 06:06:44

US3342204

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:34:12

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:31:52
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:06:44
Amendment Manager: User entered 'Day 131'	System	20 Nov 2020 06:06:44

US3342204

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:34:12

[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)	28 Apr 2021 15:31:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7A504897-431F-4E74-9F03-DAC668AE5D1E)', Time: '2021-01-16T12:00:26', User OID: 'PatientReportedOutcome (US3342204)', ODM File OID: '7a6747fb-e3ec-4fba-af7b-07f393311a23'	System	16 Jan 2021 18:00:48
User entered 'No (N)'	System	16 Jan 2021 18:00:48

US3342204

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:34:12

Have you been exposed to someone with 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)	28 Apr 2021 15:31:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7A504897-431F-4E74-9F03-DAC668AE5D1E)', Time: '2021-01-16T12:00:29', User OID: 'PatientReportedOutcome (US3342204)', ODM File OID: '7a6747fb-e3ec-4fba-af7b-07f393311a23'	System	16 Jan 2021 18:00:48
User entered 'No (N)'	System	16 Jan 2021 18:00:48

US3342204

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:34:12

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:31:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7A504897-431F-4E74-9F03-DAC668AE5D1E)', Time: '2021-01-16T12:00:32', User OID: 'PatientReportedOutcome (US3342204)', ODM File OID: '7a6747fb-e3ec-4fba-af7b-07f393311a23' User entered '16 Jan 2021 12:00:32'	System	16 Jan 2021 18:00:48
	System	16 Jan 2021 18:00:48

US3342204

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:34:12

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:31:52
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:06:44
Amendment Manager: User entered '14 Jan 2021 00:01'	System	20 Nov 2020 06:06:44

US3342204

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:34:12

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:31:52
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:06:44
Amendment Manager: User entered '18 Jan 2021 23:59'	System	20 Nov 2020 06:06:44

US3342204

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:34:12

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:31:52
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:06:44
Amendment Manager: User entered 'Day 138'	System	20 Nov 2020 06:06:44

US3342204

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:34:12

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)	28 Apr 2021 15:31:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7A504897-431F-4E74-9F03-DAC668AE5D1E)', Time: '2021-01-23T12:58:42', User OID: 'PatientReportedOutcome (US3342204)', ODM File OID: '8f5ef2e9-b4fb-4590-933f-787ac641a9b1'	System	23 Jan 2021 18:58:49
User entered 'No (N)'	System	23 Jan 2021 18:58:49

US3342204

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:34:12

Have you been exposed to someone with 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)	28 Apr 2021 15:31:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7A504897-431F-4E74-9F03-DAC668AE5D1E)', Time: '2021-01-23T12:58:44', User OID: 'PatientReportedOutcome (US3342204)', ODM File OID: '8f5ef2e9-b4fb-4590-933f-787ac641a9b1'	System	23 Jan 2021 18:58:49
User entered 'No (N)'	System	23 Jan 2021 18:58:49

US3342204

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:34:12

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:31:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7A504897-431F-4E74-9F03-DAC668AE5D1E)', Time: '2021-01-23T12:58:47', User OID: 'PatientReportedOutcome (US3342204)', ODM File OID: '8f5ef2e9-b4fb-4590-933f-787ac641a9b1' User entered '23 Jan 2021 12:58:47'	System	23 Jan 2021 18:58:49
	System	23 Jan 2021 18:58:49

US3342204

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:34:12

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:31:52
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:06:44
Amendment Manager: User entered '21 Jan 2021 00:01'	System	20 Nov 2020 06:06:44

US3342204

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:34:12

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:31:52
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:06:44
Amendment Manager: User entered '25 Jan 2021 23:59'	System	20 Nov 2020 06:06:44

US3342204

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:34:12

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:31:52
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:06:44
Amendment Manager: User entered 'Day 145'	System	20 Nov 2020 06:06:44

US3342204

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:34:12

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)	28 Apr 2021 15:31:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7A504897-431F-4E74-9F03-DAC668AE5D1E)', Time: '2021-01-30T12:07:46', User OID: 'PatientReportedOutcome (US3342204)', ODM File OID: '88e3fe97-96ce-478a-b909-d637b4fcbe7c'	System	30 Jan 2021 18:07:55
User entered 'No (N)'	System	30 Jan 2021 18:07:55

US3342204

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:34:12

Have you been exposed to someone with 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)	28 Apr 2021 15:31:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7A504897-431F-4E74-9F03-DAC668AE5D1E)', Time: '2021-01-30T12:07:48', User OID: 'PatientReportedOutcome (US3342204)', ODM File OID: '88e3fe97-96ce-478a-b909-d637b4fcbe7c'	System	30 Jan 2021 18:07:55
User entered 'No (N)'	System	30 Jan 2021 18:07:55

US3342204

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:34:12

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:31:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7A504897-431F-4E74-9F03-DAC668AE5D1E)', Time: '2021-01-30T12:07:52', User OID: 'PatientReportedOutcome (US3342204)', ODM File OID: '88e3fe97-96ce-478a-b909-d637b4fcbe7c' User entered '30 Jan 2021 12:07:52'	System	30 Jan 2021 18:07:55
	System	30 Jan 2021 18:07:55

US3342204

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:34:12

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:31:52
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:06:44
Amendment Manager: User entered '28 Jan 2021 00:01'	System	20 Nov 2020 06:06:44

US3342204

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:34:12

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:31:52
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:06:44
Amendment Manager: User entered '01 Feb 2021 23:59'	System	20 Nov 2020 06:06:44

US3342204

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:34:12

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:31:52
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:06:44
Amendment Manager: User entered 'Day 152'	System	20 Nov 2020 06:06:44

US3342204

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:34:12

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)	28 Apr 2021 15:31:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7A504897-431F-4E74-9F03-DAC668AE5D1E)', Time: '2021-02-05T20:43:07', User OID: 'PatientReportedOutcome (US3342204)', ODM File OID: '63f3cf33-c70a-4d5e-94fa-6dfcab315b39'	System	06 Feb 2021 02:43:58
User entered 'Yes (Y)'	System	06 Feb 2021 02:43:58

US3342204

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:34:12

Have you been exposed to someone with 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)	28 Apr 2021 15:31:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7A504897-431F-4E74-9F03-DAC668AE5D1E)', Time: '2021-02-05T20:43:13', User OID: 'PatientReportedOutcome (US3342204)', ODM File OID: '63f3cf33-c70a-4d5e-94fa-6dfcab315b39'	System	06 Feb 2021 02:43:58
User entered 'No (N)'	System	06 Feb 2021 02:43:58

US3342204

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:34:12

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)	28 Apr 2021 15:31:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7A504897-431F-4E74-9F03-DAC668AE5D1E)', Time: '2021-02-05T20:43:18', User OID: 'PatientReportedOutcome (US3342204)', ODM File OID: '63f3cf33-c70a-4d5e-94fa-6dfcab315b39'	System	06 Feb 2021 02:43:58
User entered 'No (N)'	System	06 Feb 2021 02:43:58

US3342204

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:34:12

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)	28 Apr 2021 15:31:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7A504897-431F-4E74-9F03-DAC668AE5D1E)', Time: '2021-02-05T20:43:26', User OID: 'PatientReportedOutcome (US3342204)', ODM File OID: '63f3cf33-c70a-4d5e-94fa-6dfcab315b39'	System	06 Feb 2021 02:43:58
User entered 'No (N)'	System	06 Feb 2021 02:43:58

US3342204

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:34:12

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:31:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7A504897-431F-4E74-9F03-DAC668AE5D1E)', Time: '2021-02-05T20:43:56', User OID: 'PatientReportedOutcome (US3342204)', ODM File OID: '63f3cf33-c70a-4d5e-94fa-6dfcab315b39' User entered '05 Feb 2021 20:43:56'	System	06 Feb 2021 02:43:58
	System	06 Feb 2021 02:43:58

US3342204

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:34:12

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:31:52
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:06:44
Amendment Manager: User entered '04 Feb 2021 00:01'	System	20 Nov 2020 06:06:44

US3342204

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:34:12

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:31:52
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:06:44
Amendment Manager: User entered '08 Feb 2021 23:59'	System	20 Nov 2020 06:06:44

US3342204

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:34:12

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 13:03:22
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:17:37
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	18 Dec 2020 19:40:11

US3342204

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:34:12

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 13:03:22
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:17:37
User entered '18 Dec 2020'	(b) (4) (b) (4), (b) (6)	18 Dec 2020 19:40:11

US3342204

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:34:12

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 13:03:22
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:17:37
User entered 'Contact Made (CONTACT MADE)'	(b) (4) (b) (4), (b) (6)	18 Dec 2020 19:40:11

US3342204

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:34:12

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 13:03:22
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:17:37
User entered empty.	(b) (4) (b) (4), (b) (6)	18 Dec 2020 19:40:11

US3342204

Folder: Safety Call Day 85 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:34:12

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 13:03:22
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:17:37
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	18 Dec 2020 19:40:16

US3342204

Folder: Safety Call Day 85 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:34:12

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 13:03:22
User entered '1'	System	18 Dec 2020 19:40:16

US3342204

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:34:12

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:31:52
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:17:37
User entered 'Yes (Y)'	Ethan Shotton (b) (4)	21 Jan 2021 19:54:01

US3342204

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:34:12

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:31:52
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:17:37
User entered '21 Jan 2021'	Ethan Shotton (b) (4)	21 Jan 2021 19:54:01

US3342204

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:34:12

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:31:52
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:17:37
User entered 'Contact Made (CONTACT MADE)'	Ethan Shotton (b) (4)	21 Jan 2021 19:54:01

US3342204

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:34:12

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:31:52
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:17:37
User entered empty.	Ethan Shotton (b) (4)	21 Jan 2021 19:54:01

US3342204

Folder: Safety Call Day 119 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:34:12

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:31:52
User signature succeeded.	Paul Pickrell (b) (4)	22 Mar 2021 13:27:29
Signature has been broken.	(b) (4) Ethan Shotton (b) (4)	17 Mar 2021 21:19:58
User entered 'No (N)' reason for change: Data Entry Error	(b) (4) Ethan Shotton (b) (4)	17 Mar 2021 21:19:58
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:17:37
User entered 'Yes (Y)'	(b) (4) Ethan Shotton (b) (4)	21 Jan 2021 19:54:05

US3342204

Folder: Safety Call Day 119 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:34:12

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:31:52
User entered empty.	System	17 Mar 2021 21:19:58
User entered '1'	System	21 Jan 2021 19:54:05

US3342204

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

Form: Visit Date

Generated On: 11 Aug 2021 22:34:12

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:31:52
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:17:37
User entered 'Yes (Y)'	(b) (4) Eileen Euperio (b) (4)	12 Jan 2021 17:31:52

US3342204

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

Form: Visit Date

Generated On: 11 Aug 2021 22:34:12

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:31:52
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:17:37
User entered '12 Jan 2021'	Eileen Euperio (b) (4)	12 Jan 2021 17:31:52

US3342204

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

Form: Visit Date

Generated On: 11 Aug 2021 22:34:12

[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 15:31:52
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:17:37
User entered 'Clinic (Clinic)'	Eileen Euperio (b) (4)	12 Jan 2021 17:31:52

US3342204

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

Form: Visit Date

Generated On: 11 Aug 2021 22:34:12

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:31:52
User entered 'UNBLND_DECIDE'	System	12 Jan 2021 17:31:52

US3342204

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

Form: Unblinding

Generated On: 11 Aug 2021 22:34:12

Date of updated informed consent (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:31:52
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:17:37
User entered '12 Jan 2021'	(b) (4) Eileen Euperio (b) (4)	12 Jan 2021 17:32:20

US3342204

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

Form: Unblinding

Generated On: 11 Aug 2021 22:34:12

[N/A - Subject Unblinded under Amendment 5 and Discontinued from Study](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:31:52
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:17:37
User entered '0'	(b) (4) Ethan Shotton (b) (4)	09 Mar 2021 13:46:09
Amendment Manager inserted this DataPoint.	(b) (4) System	06 Mar 2021 18:49:56

US3342204

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

Form: Unblinding

Generated On: 11 Aug 2021 22:34:12

[Was the participant unblinded?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:31:52
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:17:37
User entered 'Yes (Y)'	(b) (4) Eileen Euperio (b) (4)	12 Jan 2021 17:32:20

US3342204

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

Form: Unblinding

Generated On: 11 Aug 2021 22:34:12

[Under what version of the Protocol was the Participant unblinded?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:31:52
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:17:37
User entered 'Amendment 6 or later (Amendment 6 or later)'	(b) (4)	09 Mar 2021 13:46:09
Amendment Manager inserted this DataPoint.	Ethan Shotton (b) (4)	06 Mar 2021 18:49:56
	System	

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

Form: Unblinding

Generated On: 11 Aug 2021 22:34:12

Date of unblinding (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:31:52
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:17:37
User entered '12 Jan 2021'	(b) (4) Eileen Euperio (b) (4)	12 Jan 2021 17:32:20

US3342204

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

Form: Unblinding

Generated On: 11 Aug 2021 22:34:12

[Participant randomization assignment](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:31:52
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:17:37
User entered 'Placebo (Placebo)'	Eileen Euperio (b) (4)	12 Jan 2021 17:32:20

US3342204

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

Form: Unblinding

Generated On: 11 Aug 2021 22:34:12

[Actual Dose 1](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:31:52
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:17:37
Amendment Manager: User entered 'Placebo (Placebo)'	(b) (4) System	20 Jan 2021 14:23:09
User entered 'Placebo (Placebo)'	Eileen Euperio (b) (4) (b) (4)	12 Jan 2021 17:32:20

US3342204

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

Form: Unblinding

Generated On: 11 Aug 2021 22:34:12

[Actual Dose 2](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:31:52
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:17:37
Amendment Manager: User entered 'Placebo (Placebo)'	(b) (4) System	20 Jan 2021 14:23:09
User entered 'Placebo (Placebo)'	Eileen Euperio (b) (4) (b) (4)	12 Jan 2021 17:32:20

US3342204

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

Form: Unblinding

Generated On: 11 Aug 2021 22:34:12

[Will participant receive mRNA-1273?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:31:52
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:17:37
User entered 'Yes (Y)'	(b) (4) Eileen Euperio (b) (4)	12 Jan 2021 17:32:20

US3342204

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

Form: Unblinding

Generated On: 11 Aug 2021 22:34:12

[Placebo Only Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:31:52
User entered '1'	System	12 Jan 2021 17:32:20

US3342204

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

Form: Unblinding

Generated On: 11 Aug 2021 22:34:12

[Continuing with mRNA-1273](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:31:52
User entered '1'	System	12 Jan 2021 17:32:20

US3342204

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

Form: Vital Signs - Dosing

Generated On: 11 Aug 2021 22:34:12

[Height](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:31:52
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:17:37
User entered empty.	(b) (4) Eileen Euperio (b) (4)	12 Jan 2021 17:34:15

US3342204

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

Form: Vital Signs - Dosing

Generated On: 11 Aug 2021 22:34:12

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:31:52
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:17:37
User entered empty.	(b) (4) Eileen Euperio (b) (4)	12 Jan 2021 17:34:15

US3342204

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

Form: Vital Signs - Dosing

Generated On: 11 Aug 2021 22:34:12

BMI (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:31:52
User entered empty.	System	12 Jan 2021 17:34:15
DataPoint set to visible.	System	12 Jan 2021 17:32:20

US3342204

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

Form: Vital Signs - Dosing

Generated On: 11 Aug 2021 22:34:12

[Height](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:31:52
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:17:37
User entered empty.	(b) (4) Eileen Euperio (b) (4)	12 Jan 2021 17:34:15

US3342204

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

Form: Vital Signs - Dosing

Generated On: 11 Aug 2021 22:34:12

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:31:52
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:17:37
User entered empty.	(b) (4) Eileen Euperio (b) (4)	12 Jan 2021 17:34:15

US3342204

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

Form: Vital Signs - Dosing

Generated On: 11 Aug 2021 22:34:12

BMI (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:31:52
User entered empty.	System	12 Jan 2021 17:34:15
DataPoint set to visible.	System	12 Jan 2021 17:32:20

US3342204

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

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:34:12

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:31:52
User accepted default value 'Pre-Dose (PREDOSE)'	Eileen Euperio (b) (4) (b) (4)	12 Jan 2021 17:34:15

US3342204

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

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:34:12

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:31:52
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:17:37
User entered 'Yes (Y)'	(b) (4) Eileen Euperio (b) (4)	12 Jan 2021 17:34:15

US3342204

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

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:34:12

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:31:52
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:17:37
User entered '12 Jan 2021'	(b) (4) Eileen Euperio (b) (4)	12 Jan 2021 17:34:15

US3342204

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

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:34:12

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:31:52
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:17:37
User entered '08:41'	Eileen Euperio (b) (4)	12 Jan 2021 17:34:15

US3342204

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

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:34:12

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:31:52
User entered '12 Jan 2021 08:41'	System	12 Jan 2021 17:34:15

US3342204

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

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:34:12

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:31:52
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:17:37
User entered '97.8' F	Eileen Euperio (b) (4)	12 Jan 2021 17:34:15

US3342204

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

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:34:12

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:31:52
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:17:37
User entered 'Oral (Oral)'	(b) (4) Eileen Euperio (b) (4)	12 Jan 2021 17:34:15

US3342204

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

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:34:12

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:31:52
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:17:37
User entered empty.	(b) (4) Eileen Euperio (b) (4)	12 Jan 2021 17:34:15

US3342204

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

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:34:12

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:31:52
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:17:37
User entered '86'	(b) (4) Eileen Euperio (b) (4)	12 Jan 2021 17:34:15

US3342204

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

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:34:12

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:31:52
User entered 'bpm'	System	12 Jan 2021 17:34:15

US3342204

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

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:34:12

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:31:52
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:17:37
User entered '14'	Eileen Euperio (b) (4)	12 Jan 2021 17:34:15

US3342204

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

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:34:12

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:31:52
User entered 'breaths/min'	System	12 Jan 2021 17:34:15

US3342204

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

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:34:12

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:31:52
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:17:37
User entered '104'	Eileen Euperio (b) (4)	12 Jan 2021 17:34:15

US3342204

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

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:34:12

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:31:52
User entered 'mmHg'	System	12 Jan 2021 17:34:15

US3342204

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

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:34:12

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:31:52
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:17:37
User entered '72'	Eileen Euperio (b) (4)	12 Jan 2021 17:34:15

US3342204

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

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:34:12

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:31:52
User entered 'mmHg'	System	12 Jan 2021 17:34:15

US3342204

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

Form: Vital Signs - Dosing

Generated On: 11 Aug 2021 22:34:12

[Height](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:31:52
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:17:37
User entered empty.	(b) (4) Eileen Euperio (b) (4)	12 Jan 2021 17:34:15

US3342204

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

Form: Vital Signs - Dosing

Generated On: 11 Aug 2021 22:34:12

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:31:52
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:17:37
User entered empty.	(b) (4) Eileen Euperio (b) (4)	12 Jan 2021 17:34:15

US3342204

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

Form: Vital Signs - Dosing

Generated On: 11 Aug 2021 22:34:12

BMI (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:31:52
User entered empty.	System	12 Jan 2021 17:34:15
DataPoint set to visible.	System	12 Jan 2021 17:32:20

US3342204

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

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:34:12

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:31:52
User accepted default value 'Post-Dose (POSTDOSE)'	Eileen Euperio (b) (4) (b) (4)	12 Jan 2021 17:34:15

US3342204

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

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:34:12

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:31:52
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:17:37
User entered 'Yes (Y)'	(b) (4) Eileen Euperio (b) (4)	12 Jan 2021 17:34:15

US3342204

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

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:34:12

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:31:52
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:17:37
User entered '12 Jan 2021'	(b) (4) Eileen Euperio (b) (4)	12 Jan 2021 17:34:15

US3342204

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

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:34:12

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:31:52
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:17:37
User entered '10:12'	Eileen Euperio (b) (4)	12 Jan 2021 17:34:15

US3342204

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

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:34:12

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:31:52
User entered '12 Jan 2021 10:12'	System	12 Jan 2021 17:34:15

US3342204

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

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:34:12

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:31:52
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:17:37
User entered '98.3' F	(b) (4) Eileen Euperio (b) (4)	12 Jan 2021 17:34:15

US3342204

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

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:34:12

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:31:52
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:17:37
User entered 'Oral (Oral)'	(b) (4) Eileen Euperio (b) (4)	12 Jan 2021 17:34:15

US3342204

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

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:34:12

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:31:52
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:17:37
User entered empty.	(b) (4) Eileen Euperio (b) (4)	12 Jan 2021 17:34:15

US3342204

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

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:34:12

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:31:52
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:17:37
User entered '94'	(b) (4) Eileen Euperio (b) (4)	12 Jan 2021 17:34:15

US3342204

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

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:34:12

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:31:52
User entered 'bpm'	System	12 Jan 2021 17:34:15

US3342204

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

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:34:12

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:31:52
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:17:37
User entered '12'	Eileen Euperio (b) (4)	12 Jan 2021 17:34:15

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

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:34:12

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:31:52
User entered 'breaths/min'	System	12 Jan 2021 17:34:15

US3342204

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

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:34:12

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:31:52
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:17:37
User entered '94'	Eileen Euperio (b) (4)	12 Jan 2021 17:34:15

US3342204

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

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:34:12

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:31:52
User entered 'mmHg'	System	12 Jan 2021 17:34:15

US3342204

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

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:34:12

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:31:52
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:17:37
User entered '67'	Eileen Euperio (b) (4)	12 Jan 2021 17:34:15

US3342204

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

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:34:12

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:31:52
User entered 'mmHg'	System	12 Jan 2021 17:34:15

US3342204

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

Form: Physical Examination

Generated On: 11 Aug 2021 22:34:12

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:31:52
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:17:37
User entered 'Yes (Y)'	Eileen Euperio (b) (4)	12 Jan 2021 17:34:34

US3342204

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

Form: Physical Examination

Generated On: 11 Aug 2021 22:34:12

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:31:52
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:17:37
User entered '12 Jan 2021'	(b) (4) Eileen Euperio (b) (4)	12 Jan 2021 17:34:34

US3342204

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

Form: Pregnancy Test

Generated On: 11 Aug 2021 22:34:12

[Was the pregnancy test performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:31:52
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:17:37
User entered 'Yes (Y)'	(b) (4) Eileen Euperio (b) (4)	12 Jan 2021 17:35:07

US3342204

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

Form: Pregnancy Test

Generated On: 11 Aug 2021 22:34:12

Date of test (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:31:52
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:17:37
User entered '12 Jan 2021'	(b) (4) Eileen Euperio (b) (4)	12 Jan 2021 17:35:07

US3342204

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

Form: Pregnancy Test

Generated On: 11 Aug 2021 22:34:12

[Test performed](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:31:52
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:17:37
User entered 'Urine (URINE)'	Eileen Euperio (b) (4)	12 Jan 2021 17:35:07

US3342204

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

Form: Pregnancy Test

Generated On: 11 Aug 2021 22:34:12

[Result](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:31:52
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:17:37
User entered 'Negative (NEGATIVE)'	(b) (4) Eileen Euperio (b) (4)	12 Jan 2021 17:35:07

US3342204

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

Form: Pregnancy Test

Generated On: 11 Aug 2021 22:34:12

Was FSH sample collected?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:31:52
User closed query 'Per CDM: "Was FSH sample collected?" is answered as NO, however date and time are collected. If date and time belongs to FSH then please consider changing answer from No to Yes. If date and time belongs to Pregnancy test, then please remove date and time. Thank you! ' (Site from DM).	(b) (4), (b) (6)	22 Mar 2021 12:52:28
Query 'Per CDM: "Was FSH sample collected?" is answered as NO, however date and time are collected. If date and time belongs to FSH then please consider changing answer from No to Yes. If date and time belongs to Pregnancy test, then please remove date and time. Thank you! ' answered with 'corrected' (Site from DM).	Olivia Hapanowicz (b) (4) (b) (4)	19 Mar 2021 13:12:14
User opened query 'Per CDM: "Was FSH sample collected?" is answered as NO, however date and time are collected. If date and time belongs to FSH then please consider changing answer from No to Yes. If date and time belongs to Pregnancy test, then please remove date and time. Thank you! ' (Site from DM).	(b) (4), (b) (6)	19 Mar 2021 13:08:28
User signature succeeded.	Paul Pickrell (b) (4) (b) (4)	12 Mar 2021 23:17:37
User entered 'No (N)'	Eileen Euperio (b) (4) (b) (4)	12 Jan 2021 17:35:07

US3342204

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

Form: Pregnancy Test

Generated On: 11 Aug 2021 22:34:12

[Collection date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:31:52
User signature succeeded.	Paul Pickrell (b) (4)	22 Mar 2021 13:27:29
Signature has been broken.	(b) (4) Olivia Hapanowicz (b) (4)	19 Mar 2021 13:12:08
User entered empty; reason for change Data Entry Error	(b) (4) Olivia Hapanowicz (b) (4)	19 Mar 2021 13:12:08
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:17:37
User entered '12 Jan 2021'	(b) (4) Eileen Euperio (b) (4)	12 Jan 2021 17:35:07

US3342204

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

Form: Pregnancy Test

Generated On: 11 Aug 2021 22:34:12

[Collection time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:31:52
User signature succeeded.	Paul Pickrell (b) (4)	22 Mar 2021 13:27:29
Signature has been broken.	(b) (4) Olivia Hapanowicz (b) (4)	19 Mar 2021 13:12:08
User entered empty; reason for change Data Entry Error	(b) (4) Olivia Hapanowicz (b) (4)	19 Mar 2021 13:12:08
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:17:37
User entered '08:44'	(b) (4) Eileen Euperio (b) (4)	12 Jan 2021 17:35:07

US3342204

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

Form: Pregnancy Test

Generated On: 11 Aug 2021 22:34:12

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:31:52
User entered empty.	System	19 Mar 2021 13:12:08
User entered '12 Jan 2021 08:44'	System	12 Jan 2021 17:35:07

US3342204

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

Form: Exposure

Generated On: 11 Aug 2021 22:34:12

[Was study treatment given?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:31:52
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:17:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Mar 2021 20:28:28
User entered 'Yes (Y)'	Eileen Euperio (b) (4) (b) (4)	12 Jan 2021 17:35:39

US3342204

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

Form: Exposure

Generated On: 11 Aug 2021 22:34:12

[If No, reason not given](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:31:52
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:17:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Mar 2021 20:28:28
User entered empty.	Eileen Euperio (b) (4) (b) (4)	12 Jan 2021 17:35:39

US3342204

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

Form: Exposure

Generated On: 11 Aug 2021 22:34:12

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:31:52
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:17:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Mar 2021 20:28:28
User entered empty.	Eileen Euperio (b) (4) (b) (4)	12 Jan 2021 17:35:39

US3342204

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

Form: Exposure

Generated On: 11 Aug 2021 22:34:12

[What was the study treatment? \(Unblinded\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:31:52
User entered 'mRNA-1273'	System	12 Jan 2021 17:35:39
DataPoint set to visible.	System	12 Jan 2021 17:32:20

US3342204

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

Form: Exposure

Generated On: 11 Aug 2021 22:34:12

[What was the treatment date? \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:31:52
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:17:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Mar 2021 20:28:28
User entered '12 Jan 2021'	Eileen Euperio (b) (4) (b) (4)	12 Jan 2021 17:35:39

US3342204

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

Form: Exposure

Generated On: 11 Aug 2021 22:34:12

[What was the treatment time? \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:31:52
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:17:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Mar 2021 20:28:28
User entered '09:35'	Eileen Euperio (b) (4) (b) (4)	12 Jan 2021 17:35:39

US3342204

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

Form: Exposure

Generated On: 11 Aug 2021 22:34:12

[Treatment Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:31:52
User entered '12 Jan 2021 09:35'	System	12 Jan 2021 17:35:39

US3342204

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

Form: Exposure

Generated On: 11 Aug 2021 22:34:12

[Which arm was used to give treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:31:52
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:17:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Mar 2021 20:28:28
User entered 'Left Arm (LEFT ARM)'	Eileen Euperio (b) (4) (b) (4)	12 Jan 2021 17:35:39

US3342204

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

Form: Exposure

Generated On: 11 Aug 2021 22:34:12

[What was the frequency of the study treatment dosing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:31:52
DataPoint Verified.	(b) (4), (b) (6)	03 Mar 2021 20:28:28
User entered 'ONCE'	System	12 Jan 2021 17:35:39

US3342204

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

Form: Exposure

Generated On: 11 Aug 2021 22:34:12

What was the route of administration for the study treatment?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:31:52
User entered 'INTRAMUSCULAR'	System	12 Jan 2021 17:35:39

US3342204

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

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 22:34:12

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:31:52
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:17:37
User entered 'Yes (Y)'	(b) (4) Eileen Euperio (b) (4)	13 Jan 2021 20:56:03

US3342204

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

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 22:34:12

Collection date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:31:52
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:17:37
User closed query 'Per GCL Lab Reconciliation: Antibody-mediated Immunogenicity: Per GCL, no immunogenicity sample was received for the Participant Decision Visit/ OL-D1 on 12Jan2021. Please provide accession number and tracking or clarify. Thank you.' (Site from DM).	(b) (4) (b) (4), (b) (6)	19 Feb 2021 18:33:38
Query 'Per GCL Lab Reconciliation: Antibody-mediated Immunogenicity: Per GCL, no immunogenicity sample was received for the Participant Decision Visit/ OL-D1 on 12Jan2021. Please provide accession number and tracking or clarify. Thank you.' answered with 'sample was received, req number 1F606964435' (Site from DM).	Olivia Hapanowicz (b) (4) (b) (4)	05 Feb 2021 22:21:26
User opened query 'Per GCL Lab Reconciliation: Antibody-mediated Immunogenicity: Per GCL, no immunogenicity sample was received for the Participant Decision Visit/ OL-D1 on 12Jan2021. Please provide accession number and tracking or clarify. Thank you.' (Site from DM).	(b) (4), (b) (6)	04 Feb 2021 18:32:05
User entered '12 Jan 2021'	Eileen Euperio (b) (4) (b) (4)	13 Jan 2021 20:56:03

US3342204

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

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 22:34:12

Collection time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:31:52
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:17:37
User entered '09:07'	(b) (4) Eileen Euperio (b) (4)	13 Jan 2021 20:56:03

US3342204

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

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 22:34:12

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:31:52
User entered '12 Jan 2021 09:07'	System	13 Jan 2021 20:56:03

US3342204

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

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 11 Aug 2021 22:34:12

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:31:52
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:17:37
User entered 'Yes (Y)'	Eileen Euperio (b) (4)	13 Jan 2021 20:56:11

US3342204

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

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 11 Aug 2021 22:34:12

Collection date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:31:52
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:17:37
User closed query 'Per GCL Lab Reconciliation: Swab: Sample dated "11-JAN-2021" is recorded under Covid-19 Assessment visit in EDC; however, in PPD portal, it is recorded as "12-JAN-2021" for Illness visit Day 1. Kindly review the collection date and update as appropriate, else clarify.' (Site from DM).	(b) (4) (b) (4), (b) (6)	11 Feb 2021 11:52:01
Query 'Per GCL Lab Reconciliation: Swab: Sample dated "11-JAN-2021" is recorded under Covid-19 Assessment visit in EDC; however, in PPD portal, it is recorded as "12-JAN-2021" for Illness visit Day 1. Kindly review the collection date and update as appropriate, else clarify.' answered with 'should be 12jan' (Site from DM).	Eileen Euperio (b) (4) (b) (4)	09 Feb 2021 16:34:08
User entered '12 Jan 2021' reason for change: Data Entry Error	Eileen Euperio (b) (4) (b) (4)	09 Feb 2021 16:34:00
User opened query 'Per GCL Lab Reconciliation: Swab: Sample dated "11-JAN-2021" is recorded under Covid-19 Assessment visit in EDC; however, in PPD portal, it is recorded as "12-JAN-2021" for Illness visit Day 1. Kindly review the collection date and update as appropriate, else clarify.' (Site from DM).	(b) (4), (b) (6)	03 Feb 2021 08:34:31
User entered '11 Jan 2021'	Eileen Euperio (b) (4) (b) (4)	13 Jan 2021 20:56:11

US3342204

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

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 11 Aug 2021 22:34:12

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:31:52
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:17:37
User entered '09:08'	Eileen Euperio (b) (4)	13 Jan 2021 20:56:11

US3342204

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

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 11 Aug 2021 22:34:12

[Collection Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:31:52
User entered '12 Jan 2021 09:08'	System	09 Feb 2021 16:34:00
User entered '11 Jan 2021 09:08'	System	13 Jan 2021 20:56:11

US3342204

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

Form: Continuing

Generated On: 11 Aug 2021 22:34:12

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:31:52
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:17:37
User entered 'Yes (Y)'	(b) (4) Eileen Euperio (b) (4)	12 Jan 2021 17:36:01

US3342204

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

Form: Continuing

Generated On: 11 Aug 2021 22:34:12

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:31:52
User entered '1'	System	12 Jan 2021 17:36:01

US3342204

Folder: Safety Call OL-D8 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:34:12

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:31:52
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:17:37
User entered 'Yes (Y)'	Ethan Shotton (b) (4)	19 Jan 2021 16:51:37

US3342204

Folder: Safety Call OL-D8 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:34:12

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:31:52
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:17:37
User entered '19 Jan 2021'	Ethan Shotton (b) (4)	19 Jan 2021 16:51:37

US3342204

Folder: Safety Call OL-D8 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:34:12

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:31:52
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:17:37
User entered 'Contact Made (CONTACT MADE)'	Ethan Shotton (b) (4)	19 Jan 2021 16:51:37

US3342204

Folder: Safety Call OL-D8 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:34:12

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:31:52
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:17:37
User entered empty.	Ethan Shotton (b) (4)	19 Jan 2021 16:51:37

US3342204

Folder: Safety Call OL-D8 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:34:12

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:31:52
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:17:37
User entered 'Yes (Y)'	Ethan Shotton (b) (4)	19 Jan 2021 16:51:41

US3342204

Folder: Safety Call OL-D8 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:34:12

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:31:52
User entered '1'	System	19 Jan 2021 16:51:41

US3342204

Folder: Safety Call OL-D8 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:34:12

[OLD29 Placebo Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:31:52
User entered '1'	System	19 Jan 2021 16:51:41
DataPoint set to visible.	System	19 Jan 2021 16:51:41

US3342204

Folder: OL-D29 (1)

Form: Exposure

Generated On: 11 Aug 2021 22:34:12

[What was the study treatment? \(Unblinded\)](#)

Audit	User	Time (GMT)
DataPoint set to visible.	System	19 Jan 2021 16:51:41

US3342204

Folder: Adverse Events

Form: Adverse Events Summary

Generated On: 11 Aug 2021 22:34:12

[Did the participant experience any adverse events?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:31:52
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:17:37
User entered 'No (N)'	Ethan Shotton (b) (4)	04 Mar 2021 00:11:46

US3342204

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination Summary

Generated On: 11 Aug 2021 22:34:12

[Were any prior/concomitant medications and/or vaccinations taken?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:31:52
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:17:37
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	08 Sep 2020 18:19:09

US3342204

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 11 Aug 2021 22:34:12

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:31:52
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:17:37
User coded data point as ATC: RESPIRATORY SYSTEM, ATC: ANTIHISTAMINES FOR SYSTEMIC USE, ATC: ANTIHISTAMINES FOR SYSTEMIC USE, ATC: OTHER ANTIHISTAMINES FOR SYSTEMIC USE, PRODUCT: LORATADINE, PRODUCTSYNONYM: CLARITIN [LORATADINE] - version WHODrug-Global-B3\202003.	Coder Import (b) (4)	08 Sep 2020 18:22:47
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\202003.	Coder Import (b) (4)	08 Sep 2020 18:22:47
Data point term sent to Coder User entered 'Claritin'	System (b) (4), (b) (6)	08 Sep 2020 18:21:20 08 Sep 2020 18:20:49

US3342204

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 11 Aug 2021 22:34:12

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:31:52
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:17:37
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	08 Sep 2020 18:20:49

US3342204

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 11 Aug 2021 22:34:12

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:31:52
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:17:37
User entered 'Seasonal Allergies'	(b) (4) (b) (4), (b) (6)	08 Sep 2020 18:20:49

US3342204

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 11 Aug 2021 22:34:12

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:31:52
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:17:37
User entered '10'	(b) (4) (b) (4), (b) (6)	08 Sep 2020 18:20:49

US3342204

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 11 Aug 2021 22:34:12

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:31:52
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:17:37
User entered 'mg (mg)'	(b) (4) (b) (4), (b) (6)	08 Sep 2020 18:20:49

US3342204

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 11 Aug 2021 22:34:12

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:31:52
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:17:37
User entered empty.	(b) (4) (b) (4), (b) (6)	08 Sep 2020 18:20:49

US3342204

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 11 Aug 2021 22:34:12

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:31:52
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:17:37
User entered 'as needed (PRN)'	(b) (4) (b) (4), (b) (6)	08 Sep 2020 18:20:49

US3342204

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 11 Aug 2021 22:34:12

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:31:52
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:17:37
User entered empty.	(b) (4) (b) (4), (b) (6)	08 Sep 2020 18:20:49

US3342204

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 11 Aug 2021 22:34:12

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:31:52
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:17:37
User entered 'Oral (ORAL)'	(b) (4) (b) (4), (b) (6)	08 Sep 2020 18:20:49

US3342204

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 11 Aug 2021 22:34:12

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:31:52
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:17:37
User entered empty.	(b) (4) (b) (4), (b) (6)	08 Sep 2020 18:20:49

US3342204

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 11 Aug 2021 22:34:12

Start date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:31:52
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:17:37
User entered 'UN UNK 2000'	(b) (4) (b) (4), (b) (6)	08 Sep 2020 18:20:49

US3342204

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 11 Aug 2021 22:34:12

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:31:52
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:17:37
User entered '0'	(b) (4) (b) (4), (b) (6)	08 Sep 2020 18:20:49

US3342204

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 11 Aug 2021 22:34:12

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:31:52
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:17:37
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	08 Sep 2020 18:20:49

US3342204

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 11 Aug 2021 22:34:12

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:31:52
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:17:37
User entered empty.	(b) (4) (b) (4), (b) (6)	08 Sep 2020 18:20:49

US3342204

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 11 Aug 2021 22:34:12

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:31:52
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:17:37
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	08 Sep 2020 18:20:49

US3342204

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 11 Aug 2021 22:34:12

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:31:52
User entered empty.	System	08 Sep 2020 18:20:49

US3342204

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 11 Aug 2021 22:34:12

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:31:52
User entered empty.	System	08 Sep 2020 18:20:49

US3342204

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 11 Aug 2021 22:34:12

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:31:52
User entered empty.	System	08 Sep 2020 18:20:49

US3342204

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 11 Aug 2021 22:34:12

Name of Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:31:52
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:17:37
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.	Coder Import (b) (4)	31 Dec 2020 20:51:22
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\202003.	Coder Import (b) (4)	31 Dec 2020 20:51:22
User coded data point as ATC: RESPIRATORY SYSTEM, ATC: THROAT PREPARATIONS, ATC: THROAT PREPARATIONS, ATC: OTHER THROAT PREPARATIONS, PRODUCT: IBUPROFEN - version WHODrug-Global-B3\202003.	Coder Import (b) (4)	08 Sep 2020 18:23:49
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\202003.	Coder Import (b) (4)	08 Sep 2020 18:23:49
Data point term sent to Coder User entered 'ibuprofen'	System (b) (4), (b) (6)	08 Sep 2020 18:22:23 08 Sep 2020 18:21:50

US3342204

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 11 Aug 2021 22:34:12

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:31:52
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:17:37
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	08 Sep 2020 18:21:50

US3342204

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 11 Aug 2021 22:34:12

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:31:52
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:17:37
User entered 'Seasonal Allergies'	(b) (4) (b) (4), (b) (6)	08 Sep 2020 18:21:50

US3342204

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 11 Aug 2021 22:34:12

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:31:52
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:17:37
User entered '400'	(b) (4) (b) (4), (b) (6)	08 Sep 2020 18:21:50

US3342204

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 11 Aug 2021 22:34:12

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:31:52
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:17:37
User entered 'mg (mg)'	(b) (4) (b) (4), (b) (6)	08 Sep 2020 18:21:50

US3342204

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 11 Aug 2021 22:34:12

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:31:52
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:17:37
User entered empty.	(b) (4) (b) (4), (b) (6)	08 Sep 2020 18:21:50

US3342204

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 11 Aug 2021 22:34:12

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:31:52
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:17:37
User entered 'as needed (PRN)'	(b) (4) (b) (4), (b) (6)	08 Sep 2020 18:21:50

US3342204

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 11 Aug 2021 22:34:12

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:31:52
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:17:37
User entered empty.	(b) (4) (b) (4), (b) (6)	08 Sep 2020 18:21:50

US3342204

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 11 Aug 2021 22:34:12

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:31:52
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:17:37
User entered 'Oral (ORAL)'	(b) (4) (b) (4), (b) (6)	08 Sep 2020 18:21:50

US3342204

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 11 Aug 2021 22:34:12

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:31:52
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:17:37
User entered empty.	(b) (4) (b) (4), (b) (6)	08 Sep 2020 18:21:50

US3342204

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 11 Aug 2021 22:34:12

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:31:52
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:17:37
User entered 'UN UNK 2000'	(b) (4) (b) (4), (b) (6)	08 Sep 2020 18:21:50

US3342204

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 11 Aug 2021 22:34:12

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:31:52
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:17:37
User entered '0'	(b) (4) (b) (4), (b) (6)	08 Sep 2020 18:21:50

US3342204

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 11 Aug 2021 22:34:12

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:31:52
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:17:37
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	08 Sep 2020 18:21:50

US3342204

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 11 Aug 2021 22:34:12

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:31:52
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:17:37
User entered empty.	(b) (4) (b) (4), (b) (6)	08 Sep 2020 18:21:50

US3342204

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 11 Aug 2021 22:34:12

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:31:52
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:17:37
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	08 Sep 2020 18:21:50

US3342204

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 11 Aug 2021 22:34:12

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:31:52
User entered empty.	System	08 Sep 2020 18:21:50

US3342204

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 11 Aug 2021 22:34:12

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:31:52
User entered empty.	System	08 Sep 2020 18:21:50

US3342204

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 11 Aug 2021 22:34:12

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:31:52
User entered empty.	System	08 Sep 2020 18:21:50

US3342204

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 11 Aug 2021 22:34:12

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:31:52
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:17:37
User coded data point as ATC: ANTIINFECTIVES FOR SYSTEMIC USE, ATC: VACCINES, ATC: VIRAL VACCINES, ATC: INFLUENZA VACCINES, PRODUCT: INFLUENZA VACCINE - version WHODrug-Global-B3\202003.	Coder Import (b) (4)	17 Nov 2020 17:43:48
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\202003.	Coder Import (b) (4)	17 Nov 2020 17:43:48
Data point term sent to Coder	System	17 Nov 2020 17:42:47
User entered 'INFLUENZA VACCINATION'	Morgan Schulle (b) (4)	17 Nov 2020 17:41:58

US3342204

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 11 Aug 2021 22:34:12

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:31:52
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:17:37
User entered 'Yes (Y)'	Morgan Schulle (b) (4)	17 Nov 2020 17:41:58

US3342204

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 11 Aug 2021 22:34:12

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:31:52
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:17:37
User entered 'INFLUENZA PROPHYLAXIS'	Morgan Schulle (b) (4)	17 Nov 2020 17:41:58

US3342204

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 11 Aug 2021 22:34:12

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:31:52
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:17:37
User entered '0.5'	Morgan Schulle (b) (4)	17 Nov 2020 17:41:58

US3342204

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 11 Aug 2021 22:34:12

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:31:52
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:17:37
User entered 'mL (mL)'	Morgan Schulle (b) (4)	17 Nov 2020 17:41:58

US3342204

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 11 Aug 2021 22:34:12

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:31:52
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:17:37
User entered empty.	(b) (4) Morgan Schulle (b) (4)	17 Nov 2020 17:41:58

US3342204

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 11 Aug 2021 22:34:12

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:31:52
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:17:37
User entered 'once (ONCE)'	Morgan Schulle (b) (4)	17 Nov 2020 17:41:58

US3342204

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 11 Aug 2021 22:34:12

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:31:52
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:17:37
User entered empty.	(b) (4) Morgan Schulle (b) (4)	17 Nov 2020 17:41:58

US3342204

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 11 Aug 2021 22:34:12

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:31:52
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:17:37
User entered 'Intramuscular (INTRAMUSCULAR)'	(b) (4) Morgan Schulle (b) (4)	17 Nov 2020 17:41:58

US3342204

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 11 Aug 2021 22:34:12

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:31:52
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:17:37
User entered empty.	Morgan Schulle (b) (4)	17 Nov 2020 17:41:58

US3342204

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 11 Aug 2021 22:34:12

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:31:52
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:17:37
User entered '10 Nov 2020'	Morgan Schulle (b) (4)	17 Nov 2020 17:41:58

US3342204

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 11 Aug 2021 22:34:12

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:31:52
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:17:37
User entered '0'	Morgan Schulle (b) (4)	17 Nov 2020 17:41:58

US3342204

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 11 Aug 2021 22:34:12

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:31:52
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:17:37
User entered 'No (N)'	Morgan Schulle (b) (4)	17 Nov 2020 17:41:58

US3342204

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 11 Aug 2021 22:34:12

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:31:52
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:17:37
User entered '10 Nov 2020'	Morgan Schulle (b) (4)	17 Nov 2020 17:41:58

US3342204

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 11 Aug 2021 22:34:12

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:31:52
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:17:37
User entered 'No (N)'	Morgan Schulle (b) (4)	17 Nov 2020 17:41:58

US3342204

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 11 Aug 2021 22:34:12

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:31:52
User entered empty.	System	17 Nov 2020 17:41:58

US3342204

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 11 Aug 2021 22:34:12

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:31:52
User entered empty.	System	17 Nov 2020 17:41:58

US3342204

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 11 Aug 2021 22:34:12

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:31:52
User entered empty.	System	17 Nov 2020 17:41:58

US3342204

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 11 Aug 2021 22:34:12

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:31:52
User coded data point as ATC: ANTIINFECTIVES FOR SYSTEMIC USE, ATC: VACCINES, ATC: VIRAL VACCINES, ATC: OTHER VIRAL VACCINES, PRODUCT: OTHER VIRAL VACCINES - version WHODrug-Global-B3\202003.	Coder Import (b) (4) (b) (4)	22 Apr 2021 13:15:55
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\202003.	Coder Import (b) (4) (b) (4)	22 Apr 2021 13:15:55
Data point term sent to Coder Coding entries removed.	System Olivia Hapanowicz (b) (4)	22 Apr 2021 13:15:25 22 Apr 2021 13:15:02
User signature succeeded.	(b) (4) Paul Pickrell (b) (4)	12 Apr 2021 15:51:51
User coded data point as ATC: ANTIINFECTIVES FOR SYSTEMIC USE, ATC: VACCINES, ATC: VIRAL VACCINES, ATC: OTHER VIRAL VACCINES, PRODUCT: OTHER VIRAL VACCINES - version WHODrug-Global-B3\202003.	Coder Import (b) (4) (b) (4)	07 Apr 2021 21:53:38
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\202003.	Coder Import (b) (4) (b) (4)	07 Apr 2021 21:53:38
Data point term sent to Coder Coding entries removed.	System Ethan Shotton (b) (4)	07 Apr 2021 21:52:48 07 Apr 2021 21:52:03
Coding entries removed.	(b) (4) Ethan Shotton (b) (4)	07 Apr 2021 21:52:03
Signature has been broken.	(b) (4) Ethan Shotton (b) (4)	07 Apr 2021 21:52:03
User entered 'MRNA-1273 Vaccine' reason for change: Data Entry Error	Ethan Shotton (b) (4) (b) (4)	07 Apr 2021 21:52:03
User signature succeeded.	Paul Pickrell (b) (4) (b) (4)	12 Mar 2021 23:17:37
User coded data point as ATC: ANTIINFECTIVES FOR SYSTEMIC USE, ATC: VACCINES, ATC: VIRAL VACCINES, ATC: OTHER VIRAL VACCINES, PRODUCT: OTHER VIRAL VACCINES - version WHODrug-Global-B3\202003.	Coder Import (b) (4) (b) (4)	09 Feb 2021 23:47:38

US3342204

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 11 Aug 2021 22:34:12

[Name of Medication](#)

Audit	User	Time (GMT)
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003. Data point term sent to Coder User entered 'mRNA-1273'	Coder Import (b) (4) (b) (4) System Ethan Shotton (b) (4) (b) (4)	09 Feb 2021 23:47:38 09 Feb 2021 23:47:12 09 Feb 2021 23:46:45

US3342204

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 11 Aug 2021 22:34:12

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:31:52
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:17:37
User closed query 'Per CDM: Per CCGs, prophylaxis applies to any medication used for prevention. Please confirm prophylaxis is "Yes". Thank you' (Site from DM).	(b) (4) (b) (4), (b) (6)	12 Mar 2021 10:11:09
Query 'Per CDM: Per CCGs, prophylaxis applies to any medication used for prevention. Please confirm prophylaxis is "Yes". Thank you' answered with 'corrected' (Site from DM).	Olivia Hapanowicz (b) (4) (b) (4)	11 Mar 2021 18:54:18
User entered 'Yes (Y)' reason for change: Data Entry Error	Olivia Hapanowicz (b) (4) (b) (4)	11 Mar 2021 18:54:09
User opened query 'Per CDM: Per CCGs, prophylaxis applies to any medication used for prevention. Please confirm prophylaxis is "Yes". Thank you' (Site from DM).	(b) (4), (b) (6)	17 Feb 2021 16:35:58
User entered 'No (N)'	Ethan Shotton (b) (4) (b) (4)	09 Feb 2021 23:46:45

US3342204

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 11 Aug 2021 22:34:12

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Pickrell (b) (4)	28 Apr 2021 16:37:51
Data hard locked.	(b) (4) (b) (4), (b) (6)	28 Apr 2021 15:31:52
User closed query 'Per CDM: The medication recorded is a COVID 19 vaccine. Please agree to update the indication to 'COVID 19'.' (Site from DM).	(b) (4), (b) (6)	22 Apr 2021 17:36:03
Query 'Per CDM: The medication recorded is a COVID 19 vaccine. Please agree to update the indication to 'COVID 19'.' answered with 'updated' (Site from DM).	Olivia Hapanowicz (b) (4) (b) (4)	22 Apr 2021 13:15:39
Signature has been broken.	Olivia Hapanowicz (b) (4) (b) (4)	22 Apr 2021 13:15:02
User entered 'COVID-19' reason for change: Data Entry Error	Olivia Hapanowicz (b) (4) (b) (4)	22 Apr 2021 13:15:02
User opened query 'Per CDM: The medication recorded is a COVID 19 vaccine. Please agree to update the indication to 'COVID 19'.' (Site from DM).	(b) (4), (b) (6)	21 Apr 2021 18:03:00
User signature succeeded.	Paul Pickrell (b) (4) (b) (4)	12 Apr 2021 15:51:51
Signature has been broken.	Ethan Shotton (b) (4) (b) (4)	07 Apr 2021 21:52:03
User entered 'COVID-19 Prophylaxis' reason for change: Data Entry Error	Ethan Shotton (b) (4) (b) (4)	07 Apr 2021 21:52:03
User signature succeeded.	Paul Pickrell (b) (4) (b) (4)	12 Mar 2021 23:17:37
User entered 'Wellness'	Ethan Shotton (b) (4) (b) (4)	09 Feb 2021 23:46:45

US3342204

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 11 Aug 2021 22:34:12

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:31:52
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:17:37
User entered '100'	Ethan Shotton (b) (4)	09 Feb 2021 23:46:45

US3342204

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 11 Aug 2021 22:34:12

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:31:52
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:17:37
User entered 'ug (ug)'	Ethan Shotton (b) (4)	09 Feb 2021 23:46:45

US3342204

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 11 Aug 2021 22:34:12

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:31:52
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:17:37
User entered empty.	Ethan Shotton (b) (4)	09 Feb 2021 23:46:45

US3342204

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 11 Aug 2021 22:34:12

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:31:52
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:17:37
User entered 'once (ONCE)'	Ethan Shotton (b) (4)	09 Feb 2021 23:46:45

US3342204

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 11 Aug 2021 22:34:12

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:31:52
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:17:37
User entered empty.	Ethan Shotton (b) (4)	09 Feb 2021 23:46:45

US3342204

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 11 Aug 2021 22:34:12

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:31:52
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:17:37
User closed query 'Data is required. Please complete.' (Site from System).	(b) (4)	09 Feb 2021 23:46:52
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	09 Feb 2021 23:46:52
User entered 'Intramuscular (INTRAMUSCULAR)' reason for change: Data Entry Error	Ethan Shotton (b) (4)	09 Feb 2021 23:46:52
User opened query 'Data is required. Please complete.' (Site from System).	(b) (4)	09 Feb 2021 23:46:45
User entered empty.	System	09 Feb 2021 23:46:45
	Ethan Shotton (b) (4)	09 Feb 2021 23:46:45
	(b) (4)	

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 11 Aug 2021 22:34:12

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:31:52
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:17:37
User entered empty.	Ethan Shotton (b) (4)	09 Feb 2021 23:46:45

US3342204

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 11 Aug 2021 22:34:12

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:31:52
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:17:37
User entered '09 Feb 2021'	Ethan Shotton (b) (4)	09 Feb 2021 23:46:45

US3342204

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 11 Aug 2021 22:34:12

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:31:52
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:17:37
User entered '0'	Ethan Shotton (b) (4)	09 Feb 2021 23:46:45

US3342204

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 11 Aug 2021 22:34:12

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:31:52
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:17:37
User entered 'No (N)'	Ethan Shotton (b) (4)	09 Feb 2021 23:46:45

US3342204

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 11 Aug 2021 22:34:12

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:31:52
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:17:37
User entered '09 Feb 2021'	Ethan Shotton (b) (4)	09 Feb 2021 23:46:45

US3342204

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 11 Aug 2021 22:34:12

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:31:52
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:17:37
User entered 'No (N)'	Ethan Shotton (b) (4)	09 Feb 2021 23:46:45

US3342204

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 11 Aug 2021 22:34:12

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:31:52
User entered empty.	System	09 Feb 2021 23:46:45

US3342204

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 11 Aug 2021 22:34:12

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:31:52
User entered empty.	System	09 Feb 2021 23:46:45

US3342204

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 11 Aug 2021 22:34:12

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:31:52
User entered empty.	System	09 Feb 2021 23:46:45

US3342204

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures Summary

Generated On: 11 Aug 2021 22:34:12

[Were any concomitant procedures performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:31:52
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:17:37
User entered 'No (N)'	Ethan Shotton (b) (4)	04 Mar 2021 23:14:13

US3342204

Folder: End of Study (1)

Form: End of Study / Study Discontinuation

Generated On: 11 Aug 2021 22:34:12

Date of study discontinuation/completion (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 12:39:04
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:17:37
User entered '10 Feb 2021'	Ethan Shotton (b) (4)	10 Feb 2021 19:18:32

US3342204

Folder: End of Study (1)

Form: End of Study / Study Discontinuation

Generated On: 11 Aug 2021 22:34:12

[Reason for discontinuation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 12:39:04
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:17:37
User entered 'Protocol deviation (specify) (PROTOCOL DEVIATION)'	Ethan Shotton (b) (4)	10 Feb 2021 19:18:32

US3342204

Folder: End of Study (1)

Form: End of Study / Study Discontinuation

Generated On: 11 Aug 2021 22:34:12

If reason is AE, SAE, Physician Decision, Withdrawal of consent by participant, Protocol deviation, or Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 12:39:04
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:17:37
User entered 'Subject received second dose of mRNA-1273 outside of study site. PD noted.'	Ethan Shotton (b) (4)	10 Feb 2021 19:18:32

US3342204

Folder: End of Study (1)

Form: End of Study / Study Discontinuation

Generated On: 11 Aug 2021 22:34:12

If reason for discontinuation is Death, main cause of death

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 12:39:04
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:17:37
User entered empty.	Ethan Shotton (b) (4)	10 Feb 2021 19:18:32

US3342204

Folder: End of Study (1)

Form: End of Study / Study Discontinuation

Generated On: 11 Aug 2021 22:34:12

If main cause of death is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 12:39:04
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:17:37
User entered empty.	Ethan Shotton (b) (4)	10 Feb 2021 19:18:32

US3342204

Folder: End of Study (1)

Form: End of Study / Study Discontinuation

Generated On: 11 Aug 2021 22:34:12

Date of death (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 12:39:04
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:17:37
User entered empty.	Ethan Shotton (b) (4)	10 Feb 2021 19:18:32

US3342204

Folder: End of Study (1)

Form: End of Study / Study Discontinuation

Generated On: 11 Aug 2021 22:34:12

[Was autopsy performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 12:39:04
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:17:37
User entered empty.	Ethan Shotton (b) (4)	10 Feb 2021 19:18:32