

US3432334 (Prod: Brigham and Womens Hospital)

Generated By: KC Joubran

Generated On: 11 Aug 2021 22:41:12

All time stamps listed in this document are displayed in GMT

US3432334

Form: Participant Creation

Data signed: (b) (4) 19 Feb 2021 02:29:37

Generated On: 11 Aug 2021 22:41:12

Participant ID

US3432334

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

US3432334

Folder: Screening

Form: Visit Date

Data signed: (b) (4) 19 Feb 2021 02:30:00

Generated On: 11 Aug 2021 22:41:12

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	28 AUG 2020
Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>
Folder OID	SCRN

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Folder: Screening

Form: Demographics

Data signed: (b) (4) 19 Feb 2021 02:29:39

Generated On: 11 Aug 2021 22:41:12

Date of Birth (MMM yyyy)	(b) (6) 1991
Age	29
Age Units	YEARS
Age (Derived)	29
Sex	Female <input type="radio"/> Male <input checked="" type="radio"/>
Ethnicity	Hispanic or Latino <input type="radio"/> Not Hispanic or Latino <input checked="" type="radio"/> Not Reported <input type="radio"/> Unknown <input type="radio"/>
Race (Check All That Apply)	
White	True
Black	False
Asian	False
American Indian or Alaska Native	False
Native Hawaiian or other Pacific Islander	False
Other	False
If race is Other, specify _____	
Unknown	False
Not reported	False

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Folder: Screening

Form: Enrollment

Data signed: (b) (4) 19 Feb 2021 02:29:39

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Date of Informed Consent (<i>dd MMM yyyy</i>)	28 AUG 2020
Month and Year of Informed Consent (derived)	AUG 2020
Year of Informed Consent (derived)	2020
Protocol Version	Amendment 1 <input type="radio"/> Amendment 2 <input type="radio"/> Amendment 3 <input checked="" type="radio"/> Amendment 4 <input type="radio"/> Amendment 5 <input type="radio"/>
Was participant enrolled in the study?	Yes <input checked="" type="radio"/> No <input type="radio"/>
If No, indicate reason for screen fail	Withdrew Consent <input type="radio"/> Inclusion/Exclusion <input type="radio"/> Cohort Full <input type="radio"/> Other <input type="radio"/>
If reason for screen fail is Other, specify	
Was this participant screened previously?	Yes <input type="radio"/> No <input checked="" type="radio"/>
If Yes, previous participant number	
Enrollment Trigger	1

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Folder: Screening

Form: Inclusion/Exclusion Criteria Summary

Data signed: (b) (4) 19 Feb 2021 02:29:39

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Did the participant meet all eligibility criteria?

Yes ☒

No ☐

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Folder: Screening

Form: Medical History Summary

Data signed: (b) (4) 19 Feb 2021 02:29:39

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Were any significant conditions reported?

Yes ☒

No ☐

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Folder: Screening

Form: Medical History (1)

Data signed: (b) (4) 19 Feb 2021 02:29:39

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Condition	MILD ASTHMA
Start date (dd MMM yyyy)	UN UNK 2018
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 2018
Start Year (derived)	2018
Stop Month and Year (derived)	
Stop Year (derived)	

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Folder: Screening

Form: Vital Signs

Data signed: (b) (4) 19 Feb 2021 02:30:00

Generated On: 11 Aug 2021 22:41:12

Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (<i>dd MMM yyyy</i>)	28 AUG 2020
Time of assessment (<i>00:00-23:59</i>)	09:37 (24 HR)
Vital Signs Date and Time (derived)	28 AUG 2020 09:37
Height (<i>xxx.x</i>)	170.5 cm
Weight (<i>xxx.x</i>)	72.5 kg
BMI (<i>xxx.x</i>)	24.93959 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) 19 Feb 2021 02:29:39

Generated On: 11 Aug 2021 22:41:12

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

28 AUG 2020

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

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Folder: Screening

Form: Risk of Exposure

Data signed: (b) (4) 19 Feb 2021 02:29:39

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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) 19 Feb 2021 02:29:39

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

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Folder: Visit 1 Day 1

Form: Visit Date

Data signed: (b) (4) 19 Feb 2021 02:30:00

Generated On: 11 Aug 2021 22:41:12

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

Visit date (dd MMM yyyy)	28 AUG 2020
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Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>

Folder OID	VISIT1
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US3432334

Folder: Visit 1 Day 1

Form: Randomization

Data signed: (b) (4) 19 Feb 2021 02:30:00

Generated On: 11 Aug 2021 22:41:12

What was the date of randomization? (dd MMM yyyy) 28 AUG 2020

What was the participant's randomization number? 109372

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) 19 Feb 2021 02:30:00

Generated On: 11 Aug 2021 22:41:12

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) 19 Feb 2021 02:30:00

Generated On: 11 Aug 2021 22:41:12

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 (dd MMM yyyy)	28 AUG 2020
Time of assessment (00:00-23:59)	9:37 (24 HR)
Vital Signs Date and Time (derived)	28 AUG 2020 9:37
Temperature (xxx.x)	36.6 C
Route of measurement	Oral <input checked="" type="radio"/> Axillary <input type="radio"/> Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	48 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	141 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	80 mmHg
Diastolic Blood Pressure units	MMHG

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Data signed: (b) (4) 19 Feb 2021 02:30:00

Generated On: 11 Aug 2021 22:41:12

Height	ND - Not Done
Weight	ND - Not Done
Timepoint	Pre-Dose <input type="radio"/> Post-Dose <input checked="" type="radio"/>
Were vital signs assessed?	Yes <input checked="" type="radio"/> No <input type="radio"/>
Date of assessment (dd MMM yyyy)	28 AUG 2020
Time of assessment (00:00-23:59)	11:19 (24 HR)
Vital Signs Date and Time (derived)	28 AUG 2020 11:19
Temperature (xxx.x)	36.7 C
Route of measurement	Oral <input checked="" type="radio"/> Axillary <input type="radio"/> Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	53 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	122 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	87 mmHg
Diastolic Blood Pressure units	MMHG

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Folder: Visit 1 Day 1

Form: Physical Examination

Data signed: (b) (4) 19 Feb 2021 02:30:00

Generated On: 11 Aug 2021 22:41:12

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: Exposure

Data signed: (b) (4) 19 Feb 2021 02:30:00

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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) 28 AUG 2020

What was the treatment time? (00:00-23:59) 10:41 (24 HR)

Treatment Date and Time (derived) 28 AUG 2020 10:41

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) 19 Feb 2021 02:30:00

Generated On: 11 Aug 2021 22:41:12

Was the sample collected?

Yes ☒

No ☐

Collection date (dd MMM yyyy)

28 AUG 2020

Collection time (00:00-23:59)

9:45 (24 HR)

Collection date and time (derived)

28 AUG 2020 9:45

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Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab

Data signed: (b) (4) 19 Feb 2021 02:30:00

Generated On: 11 Aug 2021 22:41:12

Collection date (dd MMM yyyy)			28 AUG 2020
Lab Test	Was the sample collected?	Collection time (00:00 - 23:59)	Collection date and time (derived)
Nasopharyngeal Swab 1	Yes	9:56	28 AUG 2020 9:56
Nasopharyngeal Swab 2	No		

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Folder: Visit 1 Day 1

Form: Continuing

Data signed: (b) (4) 19 Feb 2021 02:30:00

Generated On: 11 Aug 2021 22:41:12

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

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Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 11 Aug 2021 22:41:12

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

98.0 °F

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

Yes ☐

No ☒

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

PC Time Stamp

28 AUG 2020 11:23

PC Open Date & Time

28 AUG 2020 11:01

PC Close Date & Time

28 AUG 2020 13:31

US3432334

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 11 Aug 2021 22:41:12

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

97.7 °F

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

Yes ☐
No ☒

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

PC Time Stamp	29 AUG 2020 10:09
PC Open Date & Time	28 AUG 2020 14:26
PC Close Date & Time	29 AUG 2020 11:59

US3432334

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 11 Aug 2021 22:41:12

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 ☐

No ☐

Please record your **TEMPERATURE** in °F

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

Yes ☐

No ☐

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

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

To **PREVENT** pain or fever from occurring

PC Time Stamp

PC Open Date & Time

29 AUG 2020 12:00

PC Close Date & Time

30 AUG 2020 11:59

US3432334

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 11 Aug 2021 22:41:12

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 ☒

No ☐

Please record your **TEMPERATURE** in °F

96.0 °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

30 AUG 2020 17:49

PC Open Date & Time

30 AUG 2020 12:00

PC Close Date & Time

31 AUG 2020 11:59

US3432334

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 11 Aug 2021 22:41:12

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 ☒

No ☐

Please record your **TEMPERATURE** in °F

96.1 °F

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

Yes ☐

No ☒

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

PC Time Stamp

31 AUG 2020 18:36

PC Open Date & Time

31 AUG 2020 12:00

PC Close Date & Time

01 SEP 2020 11:59

US3432334

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 11 Aug 2021 22:41:12

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

96.4 °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

01 SEP 2020 18:15

PC Open Date & Time

01 SEP 2020 12:00

PC Close Date & Time

02 SEP 2020 11:59

US3432334

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 11 Aug 2021 22:41:12

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 ☒

No ☐

Please record your **TEMPERATURE** in °F

94.7 °F

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

Yes ☐

No ☒

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

PC Time Stamp

02 SEP 2020 18:06

PC Open Date & Time

02 SEP 2020 12:00

PC Close Date & Time

03 SEP 2020 11:59

US3432334

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 11 Aug 2021 22:41:12

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 ☒

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

03 SEP 2020 17:12

PC Open Date & Time

03 SEP 2020 12:00

PC Close Date & Time

04 SEP 2020 11:59

US3432334

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 11 Aug 2021 22:41:12

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

28 AUG 2020 11:24

PC Open Date & Time

28 AUG 2020 11:01

PC Close Date & Time

28 AUG 2020 13:31

US3432334

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 11 Aug 2021 22:41:12

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

29 AUG 2020 10:10

PC Open Date & Time

28 AUG 2020 14:26

PC Close Date & Time

29 AUG 2020 11:59

US3432334

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 11 Aug 2021 22:41:12

TIMEPOINT

DAY 2

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

None ☐

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☐

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

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

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

Yes ☐

No ☐

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

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

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

None ☐

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

PC Open Date & Time

29 AUG 2020 12:00

PC Close Date & Time

30 AUG 2020 11:59

US3432334

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 11 Aug 2021 22:41:12

TIMEPOINT

DAY 3

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

30 AUG 2020 17:49

PC Open Date & Time

30 AUG 2020 12:00

PC Close Date & Time

31 AUG 2020 11:59

US3432334

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 11 Aug 2021 22:41:12

TIMEPOINT

DAY 4

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

31 AUG 2020 18:37

PC Open Date & Time

31 AUG 2020 12:00

PC Close Date & Time

01 SEP 2020 11:59

US3432334

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 11 Aug 2021 22:41:12

TIMEPOINT

DAY 5

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

01 SEP 2020 18:15

PC Open Date & Time

01 SEP 2020 12:00

PC Close Date & Time

02 SEP 2020 11:59

US3432334

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 11 Aug 2021 22:41:12

TIMEPOINT

DAY 6

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

02 SEP 2020 18:06

PC Open Date & Time

02 SEP 2020 12:00

PC Close Date & Time

03 SEP 2020 11:59

US3432334

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 11 Aug 2021 22:41:12

TIMEPOINT

DAY 7

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

03 SEP 2020 17:11

PC Open Date & Time

03 SEP 2020 12:00

PC Close Date & Time

04 SEP 2020 11:59

US3432334

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 11 Aug 2021 22:41:12

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 ☐

US3432334

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 11 Aug 2021 22:41:12

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

No ☒

Yes ☐

PC Time stamp	28 AUG 2020 11:24
PC Open Date & Time	28 AUG 2020 11:01
PC Close Date & Time	28 AUG 2020 13:31

US3432334

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 11 Aug 2021 22:41:12

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 ☐

US3432334

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 11 Aug 2021 22:41:12

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

No ☒

Yes ☐

PC Time stamp	29 AUG 2020 10:10
PC Open Date & Time	28 AUG 2020 14:26
PC Close Date & Time	29 AUG 2020 11:59

US3432334

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 11 Aug 2021 22:41:12

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 ☐

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Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 11 Aug 2021 22:41:12

Yes ☐

PC Time stamp

PC Open Date & Time

29 AUG 2020 12:00

PC Close Date & Time

30 AUG 2020 11:59

US3432334

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 11 Aug 2021 22:41:12

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 ☒

US3432334

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 11 Aug 2021 22:41:12

Yes <input type="checkbox"/>	
PC Time stamp	30 AUG 2020 17:49
PC Open Date & Time	30 AUG 2020 12:00
PC Close Date & Time	31 AUG 2020 11:59

US3432334

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 11 Aug 2021 22:41:12

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 ☒

US3432334

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 11 Aug 2021 22:41:12

		Yes <input type="checkbox"/>
PC Time stamp	31 AUG 2020 18:38	
PC Open Date & Time	31 AUG 2020 12:00	
PC Close Date & Time	01 SEP 2020 11:59	

US3432334

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 11 Aug 2021 22:41:12

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 ☒

US3432334

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 11 Aug 2021 22:41:12

Yes <input type="checkbox"/>	
PC Time stamp	01 SEP 2020 18:15
PC Open Date & Time	01 SEP 2020 12:00
PC Close Date & Time	02 SEP 2020 11:59

US3432334

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 11 Aug 2021 22:41:12

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 ☒

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EAB) (1725)

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Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 11 Aug 2021 22:41:12

Yes <input type="checkbox"/>	
PC Time stamp	02 SEP 2020 18:07
PC Open Date & Time	02 SEP 2020 12:00
PC Close Date & Time	03 SEP 2020 11:59

US3432334

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 11 Aug 2021 22:41:12

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 ☒

US3432334

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 11 Aug 2021 22:41:12

Yes <input type="checkbox"/>	
PC Time stamp	03 SEP 2020 17:11
PC Open Date & Time	03 SEP 2020 12:00
PC Close Date & Time	04 SEP 2020 11:59

US3432334

Folder: Safety Call Day 8 (1)

Form: Safety Call

Data signed: (b) (4) 19 Feb 2021 02:29:39

Generated On: 11 Aug 2021 22:41:12

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

4 SEP 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3432334

Folder: Safety Call Day 8 (1)

Form: Continuing

Data signed: (b) (4) 19 Feb 2021 02:29:39

Generated On: 11 Aug 2021 22:41:12

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3432334

Folder: Safety Call Day 15 (1)

Form: Safety Call

Data signed: (b) (4) 19 Feb 2021 02:29:39

Generated On: 11 Aug 2021 22:41:12

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

11 SEP 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3432334

Folder: Safety Call Day 15 (1)

Form: Continuing

Data signed: (b) (4) 19 Feb 2021 02:29:39

Generated On: 11 Aug 2021 22:41:12

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3432334

Folder: Safety Call Day 22 (1)

Form: Safety Call

Data signed: (b) (4) 19 Feb 2021 02:29:39

Generated On: 11 Aug 2021 22:41:12

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

18 SEP 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3432334

Folder: Safety Call Day 22 (1)

Form: Continuing

Data signed: (b) (4) 19 Feb 2021 02:29:39

Generated On: 11 Aug 2021 22:41:12

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3432334

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Data signed: (b) (4) 19 Feb 2021 02:30:01

Generated On: 11 Aug 2021 22:41:12

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

Visit date (dd MMM yyyy)	28 SEP 2020
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Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>

Folder OID	VISIT2
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US3432334

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Data signed: (b) (4) 19 Feb 2021 02:30:01

Generated On: 11 Aug 2021 22:41:12

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 (dd MMM yyyy)	28 SEP 2020
Time of assessment (00:00-23:59)	14:28 (24 HR)
Vital Signs Date and Time (derived)	28 SEP 2020 14:28
Temperature (xxx.x)	97.7 F
Route of measurement	Oral <input type="radio"/>
	Axillary <input type="radio"/>
	Other <input checked="" type="radio"/>
If Other, specify	INFRARED
Pulse (xxx)	60 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	12 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	120 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	66 mmHg
Diastolic Blood Pressure units	MMHG

US3432334

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Data signed: (b) (4) 19 Feb 2021 02:30:01

Generated On: 11 Aug 2021 22:41:12

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

US3432334

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Data signed: (b) (4) 19 Feb 2021 02:30:01

Generated On: 11 Aug 2021 22:41:12

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

28 SEP 2020

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

US3432334

Folder: Visit 2 Day 29 (1)

Form: Exposure

Data signed: (b) (4) 19 Feb 2021 02:30:01

Generated On: 11 Aug 2021 22:41:12

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?

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?

US3432334

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 19 Feb 2021 02:30:01

Generated On: 11 Aug 2021 22:41:12

Was the sample collected?

Yes ☒

No ☐

Collection date (dd MMM yyyy)

28 SEP 2020

Collection time (00:00-23:59)

14:40 (24 HR)

Collection date and time (derived)

28 SEP 2020 14:40

US3432334

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab

Data signed: (b) (4) 19 Feb 2021 02:30:01

Generated On: 11 Aug 2021 22:41:12

Collection date (dd MMM yyyy)

Lab Test	Was the sample collected?	Collection time (00:00 - 23:59)	Collection date and time (derived)
Nasopharyngeal Swab 1	No		
Nasopharyngeal Swab 2	No		

US3432334

Folder: Visit 2 Day 29 (1)

Form: Continuing

Data signed: (b) (4) 19 Feb 2021 02:30:01

Generated On: 11 Aug 2021 22:41:12

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3432334

Folder: Safety Call Day 36 (1)

Form: Safety Call

Data signed: (b) (4) 19 Feb 2021 02:29:39

Generated On: 11 Aug 2021 22:41:12

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

5 OCT 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3432334

Folder: Safety Call Day 36 (1)

Form: Continuing

Data signed: (b) (4) 19 Feb 2021 02:29:39

Generated On: 11 Aug 2021 22:41:12

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3432334

Folder: Safety Call Day 43 (1)

Form: Safety Call

Data signed: (b) (4) 19 Feb 2021 02:29:39

Generated On: 11 Aug 2021 22:41:12

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

12 OCT 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3432334

Folder: Safety Call Day 43 (1)

Form: Continuing

Data signed: (b) (4) 19 Feb 2021 02:29:39

Generated On: 11 Aug 2021 22:41:12

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3432334

Folder: Safety Call Day 50 (1)

Form: Safety Call

Data signed: (b) (4) 19 Feb 2021 02:29:39

Generated On: 11 Aug 2021 22:41:12

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

19 OCT 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3432334

Folder: Safety Call Day 50 (1)

Form: Continuing

Data signed: (b) (4) 19 Feb 2021 02:29:39

Generated On: 11 Aug 2021 22:41:12

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3432334

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Data signed: (b) (4) 19 Feb 2021 02:30:01

Generated On: 11 Aug 2021 22:41:12

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	28 OCT 2020
Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>
Folder OID	VISIT3

US3432334

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Data signed: (b) (4) 19 Feb 2021 02:30:01

Generated On: 11 Aug 2021 22:41:12

Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (dd MMM yyyy)	28 OCT 2020
Time of assessment (00:00-23:59)	11:25 (24 HR)
Vital Signs Date and Time (derived)	28 OCT 2020 11:25
Temperature (xxx.x)	97.3 F
Route of measurement	Oral <input checked="" type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	65 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	121 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	75 mmHg
Diastolic Blood Pressure units	MMHG
Height (derived)	
Weight (derived)	

US3432334

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Data signed: (b) (4) 19 Feb 2021 02:30:01

Generated On: 11 Aug 2021 22:41:12

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.

US3432334

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 19 Feb 2021 02:30:01

Generated On: 11 Aug 2021 22:41:12

Was the sample collected?

Yes ☒

No ☐

Collection date (dd MMM yyyy)

28 OCT 2020

Collection time (00:00-23:59)

11:32 (24 HR)

Collection date and time (derived)

28 OCT 2020 11:32

US3432334

Folder: Visit 3 Day 57 (1)

Form: Continuing

Data signed: (b) (4) 19 Feb 2021 02:30:01

Generated On: 11 Aug 2021 22:41:12

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3432334

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:41:12

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 checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input checked="" type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input checked="" type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	31 OCT 2020 12:36:56
Patient Cloud Open Date & Time	28 OCT 2020 00:01
Patient Cloud Close Date & Time	01 NOV 2020 23:59

US3432334

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:41:12

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 ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

06 NOV 2020 12:00:56

Patient Cloud Open Date & Time

04 NOV 2020 00:01

Patient Cloud Close Date & Time

08 NOV 2020 23:59

US3432334

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:41:12

TIMEPOINT

DAY 78

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

11 NOV 2020 05:44:51

Patient Cloud Open Date & Time

11 NOV 2020 00:01

Patient Cloud Close Date & Time

15 NOV 2020 23:59

US3432334

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:41:12

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

22 NOV 2020 14:45:36

Patient Cloud Open Date & Time

22 NOV 2020 00:01

Patient Cloud Close Date & Time

26 NOV 2020 23:59

US3432334

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:41:12

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	29 NOV 2020 11:51:23
Patient Cloud Open Date & Time	29 NOV 2020 00:01
Patient Cloud Close Date & Time	03 DEC 2020 23:59

US3432334

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:41:12

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 ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

07 DEC 2020 06:40:21

Patient Cloud Open Date & Time

06 DEC 2020 00:01

Patient Cloud Close Date & Time

10 DEC 2020 23:59

US3432334

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:41:12

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	17 DEC 2020 11:59:18
Patient Cloud Open Date & Time	13 DEC 2020 00:01
Patient Cloud Close Date & Time	17 DEC 2020 23:59

US3432334

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:41:12

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

23 DEC 2020 12:42:27

Patient Cloud Open Date & Time

20 DEC 2020 00:01

Patient Cloud Close Date & Time

24 DEC 2020 23:59

US3432334

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:41:12

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	29 DEC 2020 16:19:28
Patient Cloud Open Date & Time	27 DEC 2020 00:01
Patient Cloud Close Date & Time	31 DEC 2020 23:59

US3432334

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:41:12

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	07 JAN 2021 12:07:36
Patient Cloud Open Date & Time	03 JAN 2021 00:01
Patient Cloud Close Date & Time	07 JAN 2021 23:59

US3432334

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:41:12

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 ☒

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

12 JAN 2021 12:00:20

Patient Cloud Open Date & Time

10 JAN 2021 00:01

Patient Cloud Close Date & Time

14 JAN 2021 23:59

US3432334

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:41:12

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 ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

19 JAN 2021 12:04:47

Patient Cloud Open Date & Time

17 JAN 2021 00:01

Patient Cloud Close Date & Time

21 JAN 2021 23:59

US3432334

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:41:12

TIMEPOINT

DAY 159

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

31 JAN 2021 07:05:45

Patient Cloud Open Date & Time

31 JAN 2021 00:01

Patient Cloud Close Date & Time

04 FEB 2021 23:59

US3432334

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:41:12

TIMEPOINT

DAY 166

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

08 FEB 2021 19:13:13

Patient Cloud Open Date & Time

07 FEB 2021 00:01

Patient Cloud Close Date & Time

11 FEB 2021 23:59

US3432334

Folder: Cosmetic Injections and Dermal Fillers

Form: Cosmetic Injection_ Dermal Filler eDiary

Generated On: 11 Aug 2021 22:41:12

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
No		27 FEB 2021 20:37:33

US3432334

Folder: Safety Call Day 85 (1)

Form: Safety Call

Data signed: (b) (4) 19 Feb 2021 02:29:39

Generated On: 11 Aug 2021 22:41:12

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

23 NOV 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3432334

Folder: Safety Call Day 85 (1)

Form: Continuing

Data signed: (b) (4) 19 Feb 2021 02:29:39

Generated On: 11 Aug 2021 22:41:12

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3432334

Folder: Safety Call Day 119 (1)

Form: Safety Call

Data signed: (b) (4) 19 Feb 2021 02:29:39

Generated On: 11 Aug 2021 22:41:12

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

24 DEC 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3432334

Folder: Safety Call Day 119 (1)

Form: Continuing

Data signed: (b) (4) 19 Feb 2021 02:29:39

Generated On: 11 Aug 2021 22:41:12

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3432334

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:41:12

Was Contact Attempted? Yes ☐
No ☐

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Please select one status for the follow-up contact

Contact Made ☐

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3432334

Folder: Safety Call Day 149 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:41:12

Is the participant continuing to the next visit?

Yes ☐

No ☐

Continuing Flag

US3432334

Folder: Covid-19 Assessment (1)

Form: COVID-19 Contact

Generated On: 11 Aug 2021 22:41:12

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"/>

US3432334

Folder: Covid-19 Assessment (1)

Form: Generate Next COVID-19 Assessment

Generated On: 11 Aug 2021 22:41:12

Generate Next COVID-19 Assessment

Yes ☐

No ☐

US3432334

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

Form: Visit Date

Data signed: (b) (4) 04 Apr 2021 20:51:13

Generated On: 11 Aug 2021 22:41:12

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 UNBLND_DECIDE

US3432334

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

Form: Unblinding

Data signed: (b) (4) 25 Apr 2021 11:14:34

Generated On: 11 Aug 2021 22:41:12

Date of updated informed consent (<i>dd MMM yyyy</i>)	
N/A - Subject Unblinded under Amendment 5 and Discontinued from Study	True
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 checked="" type="radio"/> Amendment 6 or later <input type="radio"/>
Date of unblinding (<i>dd MMM yyyy</i>)	29 DEC 2020
Participant randomization assignment	mRNA-1273 <input checked="" type="radio"/> Placebo <input type="radio"/>
Actual Dose 1	mRNA-1273 <input checked="" type="radio"/> Placebo <input type="radio"/> Not Administered <input type="radio"/>
Actual Dose 2	mRNA-1273 <input type="radio"/> Placebo <input type="radio"/> Not Administered <input checked="" type="radio"/>
Will participant receive mRNA-1273?	Yes <input type="radio"/> No <input checked="" type="radio"/>
Placebo Only Flag	
Continuing with mRNA-1273	

US3432334

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

Form: Immunogenicity Assessment

Data signed: (b) (4) 04 Apr 2021 20:51:13

Generated On: 11 Aug 2021 22:41:12

Was the sample collected?

Yes ☐

No ☒

Collection date (dd MMM yyyy)

Collection time (00:00-23:59)

Collection date and time (derived)

US3432334

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

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Data signed: (b) (4) 04 Apr 2021 20:51:13

Generated On: 11 Aug 2021 22:41:12

Was the sample collected?

Yes ☐

No ☒

Collection date (dd MMM yyyy)

Collection time (00:00 - 23:59)

Collection Date and Time (derived)

US3432334

Folder: Adverse Events

Form: Adverse Events Summary

Data signed: (b) (4) 19 Feb 2021 02:29:39

Generated On: 11 Aug 2021 22:41:12

Did the participant experience any adverse events?

Yes ☒

No ☐

If Yes, enter details on the Adverse Events form.

US3432334

Folder: Adverse Events

Form: Adverse Events (1)

Data signed: (b) (4) 19 Feb 2021 02:29:39

Generated On: 11 Aug 2021 22:41:12

AEID

Adverse event

SARS-COV-2 INFECTION
(ASYMPTOMATIC)

Was this a medically-attended AE?

Yes ☒

No ☐

Was this a Solicited Adverse Reaction?

Yes ☐

No ☒

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

Yes ☐

No ☒

Start date (dd MMM yyyy)

16 SEP 2020

Start time (00:00-23:59)

AE start date and time (derived)

Ongoing?

Yes ☐

No ☒

If not Ongoing, end date (dd MMM yyyy)

26 SEP 2020

End time (00:00-23:59)

AE End Date and Time (derived)

Severity

Grade 1/Mild ☒

Grade 2/Moderate ☐

Grade 3/Severe ☐

Grade 4 ☐

Is the adverse event serious?

Yes ☐

No ☒

AE is serious due To (check all that apply)

Death

False

Life threatening

False

Requires inpatient or prolongation of existing Hospitalization

False

Hospital Admission Date (dd MMM yyyy)

Hospital Discharge Date (dd MMM yyyy)

Admitted to ICU?

Yes ☐

No ☐

Unknown ☐

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EAB) (1725)

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Folder: Adverse Events

Form: Adverse Events (1)

Data signed: (b) (4) 19 Feb 2021 02:29:39

Generated On: 11 Aug 2021 22:41:12

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

US3432334

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination Summary

Data signed: (b) (4) 19 Feb 2021 02:29:39

Generated On: 11 Aug 2021 22:41:12

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

Yes ☒

No ☐

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

US3432334

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Data signed: (b) (4) 19 Feb 2021 02:29:39

Generated On: 11 Aug 2021 22:41:12

Name of Medication ALBUTEROL

Prophylaxis Yes ☐
No ☒

Indication ASTHMA

Dose per administration 2

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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US3432334

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Data signed: (b) (4) 19 Feb 2021 02:29:39

Generated On: 11 Aug 2021 22:41:12

	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input checked="" type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	UN UNK 2018	
Start date completely unknown	False	
Ongoing?	Yes	<input checked="" type="checkbox"/>
	No	<input type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived) _____		
Interval Dosage Unit Number (derived) _____		
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input type="checkbox"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Data signed: (b) (4) 19 Feb 2021 02:29:39

Generated On: 11 Aug 2021 22:41:12

Name of Medication FLU VACCINE

Prophylaxis Yes ☒
No ☐

Indication FLU 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 ☐

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EAB) (1725)

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Data signed: (b) (4) 19 Feb 2021 02:29:39

Generated On: 11 Aug 2021 22:41:12

	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)	05 OCT 2020	
Start date completely unknown	False	
Ongoing?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
If not Ongoing, End date (dd MMM yyyy)		5 OCT 2020
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived) _____		
Interval Dosage Unit Number (derived) _____		
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input type="radio"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Data signed: (b) (4) 19 Feb 2021 02:29:39

Generated On: 11 Aug 2021 22:41:12

Name of Medication HEPATITIS B VACCINE

Prophylaxis Yes ☒
No ☐

Indication HEPATITIS B PROPHYLAXIS

Dose per administration 1

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

If dose unit is Other, specify INJECTION

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

If frequency is Other, specify

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

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EAB) (1725)

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Data signed: (b) (4) 19 Feb 2021 02:29:39

Generated On: 11 Aug 2021 22:41:12

	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)		05 OCT 2020
Start date completely unknown		False
Ongoing?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
If not Ongoing, End date (dd MMM yyyy)		5 OCT 2020
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived) _____		
Interval Dosage Unit Number (derived) _____		
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input type="radio"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Data signed: (b) (4) 19 Feb 2021 02:29:39

Generated On: 11 Aug 2021 22:41:12

Name of Medication PFIZER COVID-19 VACCINE

Prophylaxis Yes ☒
No ☐

Indication COVID-19 PROPHYLAXIS

Dose per administration 1

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

If dose unit is Other, specify INJECTION

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

If frequency is Other, specify

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

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EAB) (1725)

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Data signed: (b) (4) 19 Feb 2021 02:29:39

Generated On: 11 Aug 2021 22:41:12

	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)		17 DEC 2020
Start date completely unknown		False
Ongoing?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
If not Ongoing, End date (dd MMM yyyy)		17 DEC 2020
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived) _____		
Interval Dosage Unit Number (derived) _____		
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input type="radio"/>

US3432334

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures Summary

Data signed: (b) (4) 04 Apr 2021 20:51:13

Generated On: 11 Aug 2021 22:41:12

Were any concomitant procedures performed?

Yes ☐

No ☒

If yes, please complete Concomitant Procedures form.

US3432334

Folder: End of Study (1)

Form: Dosing Discontinuation

Data signed: (b) (4) 19 Feb 2021 02:29:39

Generated On: 11 Aug 2021 22:41:12

Date of dosing discontinuation (dd MMM yyyy) 26 SEP 2020

Primary reason for dosing discontinuation

AE (specify)	<input type="checkbox"/>
SAE (specify)	<input type="checkbox"/>
Death	<input type="checkbox"/>
Lost To Follow-up	<input type="checkbox"/>
Physician decision (specify)	<input type="checkbox"/>
Pregnancy	<input type="checkbox"/>
Protocol deviation (specify)	<input type="checkbox"/>
Study Terminated By Sponsor	<input type="checkbox"/>
Withdrawal of consent by participant (specify)	<input type="checkbox"/>
Due to SARS-COV-2	<input checked="" type="checkbox"/>
Other	<input type="checkbox"/>

If reason is AE, SAE, Physician Decision, Withdrawal of consent by participant, Protocol deviation, or Other, specify

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Folder: End of Study (1)

Form: End of Study / Study Discontinuation

Data signed: (b) (4) 04 Apr 2021 20:51:13

Generated On: 11 Aug 2021 22:41:12

Date of study discontinuation/completion (dd MMM yyyy) 29 DEC 2020

Reason for discontinuation

AE (specify)	<input type="checkbox"/>
SAE (specify)	<input type="checkbox"/>
Complete	<input type="checkbox"/>
Death	<input type="checkbox"/>
Lost To Follow-up	<input type="checkbox"/>
Physician decision (specify)	<input type="checkbox"/>
Pregnancy	<input type="checkbox"/>
Protocol deviation (specify)	<input checked="" type="checkbox"/>
Study Terminated By Sponsor	<input type="checkbox"/>
Withdrawal of consent by participant (specify)	<input type="checkbox"/>
Other	<input type="checkbox"/>

If reason is AE, SAE, Physician Decision, Withdrawal of consent by participant, Protocol deviation, or Other, specify RECEIVED EUA VACCINE OUTSIDE STUDY

If reason for discontinuation is Death, main cause of death

Adverse event	<input type="checkbox"/>
Unknown	<input type="checkbox"/>
Other	<input type="checkbox"/>

If main cause of death is Other, specify

Date of death (dd MMM yyyy)

Was autopsy performed?

Yes	<input type="checkbox"/>
No	<input type="checkbox"/>
Unknown	<input type="checkbox"/>

Audit

US3432334 (Prod: Brigham and Womens Hospital)

US3432334

Form: Participant Creation

Generated On: 11 Aug 2021 22:41:12

[Participant ID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:43:11
DataPoint Verified.	(b) (4), (b) (6)	30 Mar 2021 16:39:33
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:29:40
User entered 'US3432334'	RWS_ENDPOINT ENDPOINT (b) (4)	28 Aug 2020 13:34:46

US3432334

Form: Participant Creation

Generated On: 11 Aug 2021 22:41:12

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:43:11

US3432334

Folder: Screening

Form: Visit Date

Generated On: 11 Aug 2021 22:41:12

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:15:38
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:30:01
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 20:57:10
User entered 'Yes (Y)'	Phoebe Cunningham (b) (4)	28 Aug 2020 14:22:46

US3432334

Folder: Screening

Form: Visit Date

Generated On: 11 Aug 2021 22:41:12

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:15:38
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:30:01
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 20:57:10
User entered '28 AUG 2020'	RWS_ENDPOINT ENDPOINT (b) (4)	28 Aug 2020 13:34:47

US3432334

Folder: Screening

Form: Visit Date

Generated On: 11 Aug 2021 22:41:12

[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 07:15:38
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:30:01
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 20:57:10
User entered 'Clinic (Clinic)'	Phoebe Cunningham (b) (4)	28 Aug 2020 14:22:46

US3432334

Folder: Screening

Form: Visit Date

Generated On: 11 Aug 2021 22:41:12

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:15:38
User entered 'SCRN'	System	28 Aug 2020 14:22:46

US3432334

Folder: Screening

Form: Demographics

Generated On: 11 Aug 2021 22:41:12

Date of Birth (MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:15:38
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:29:40
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 21:00:23
User entered (b) (6) 1991'	RWS_ENDPOINT ENDPOINT (b) (4)	28 Aug 2020 13:34:48

US3432334

Folder: Screening

Form: Demographics

Generated On: 11 Aug 2021 22:41:12

[Age](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:15:38
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:29:40
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 21:00:23
User entered '29'	Phoebe Cunningham (b) (4)	28 Aug 2020 15:46:27

US3432334

Folder: Screening

Form: Demographics

Generated On: 11 Aug 2021 22:41:12

[Age Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:15:38
User entered 'YEARS'	System	28 Aug 2020 15:46:27

US3432334

Folder: Screening

Form: Demographics

Generated On: 11 Aug 2021 22:41:12

[Age \(Derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:15:38
User entered '29'	System	28 Aug 2020 14:23:01

US3432334

Folder: Screening

Form: Demographics

Generated On: 11 Aug 2021 22:41:12

Sex

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:15:38
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:29:40
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 21:00:23
User entered 'Male (M)'	Phoebe Cunningham (b) (4)	28 Aug 2020 15:46:27

US3432334

Folder: Screening

Form: Demographics

Generated On: 11 Aug 2021 22:41:12

[Ethnicity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:15:38
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:29:40
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 21:00:23
User entered 'Not Hispanic or Latino (NOT HISPANIC OR LATINO)'	Phoebe Cunningham (b) (4)	28 Aug 2020 15:46:27

US3432334

Folder: Screening

Form: Demographics

Generated On: 11 Aug 2021 22:41:12

White

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:15:38
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:29:40
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 21:00:23
User entered 'I'	Phoebe Cunningham (b) (4)	28 Aug 2020 15:46:27

US3432334

Folder: Screening

Form: Demographics

Generated On: 11 Aug 2021 22:41:12

[Black](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:15:38
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:29:40
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 21:00:23
User entered '0'	Phoebe Cunningham (b) (4)	28 Aug 2020 15:46:27

US3432334

Folder: Screening

Form: Demographics

Generated On: 11 Aug 2021 22:41:12

[Asian](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:15:38
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:29:40
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 21:00:23
User entered '0'	Phoebe Cunningham (b) (4)	28 Aug 2020 15:46:27

US3432334

Folder: Screening

Form: Demographics

Generated On: 11 Aug 2021 22:41:12

[American Indian or Alaska Native](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:15:38
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:29:40
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 21:00:23
User entered '0'	Phoebe Cunningham (b) (4)	28 Aug 2020 15:46:27

US3432334

Folder: Screening

Form: Demographics

Generated On: 11 Aug 2021 22:41:12

[Native Hawaiian or other Pacific Islander](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:15:38
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:29:40
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 21:00:23
User entered '0'	Phoebe Cunningham (b) (4)	28 Aug 2020 15:46:27

US3432334

Folder: Screening

Form: Demographics

Generated On: 11 Aug 2021 22:41:12

[Other](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:15:38
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:29:40
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 21:00:23
User entered '0'	Phoebe Cunningham (b) (4)	28 Aug 2020 15:46:27

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Folder: Screening

Form: Demographics

Generated On: 11 Aug 2021 22:41:12

If race is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:15:38
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:29:40
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 21:00:23
User entered empty.	Phoebe Cunningham (b) (4)	28 Aug 2020 15:46:27

US3432334

Folder: Screening

Form: Demographics

Generated On: 11 Aug 2021 22:41:12

Unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:15:38
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:29:40
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 21:00:23
User entered '0'	Phoebe Cunningham (b) (4)	28 Aug 2020 15:46:27

US3432334

Folder: Screening

Form: Demographics

Generated On: 11 Aug 2021 22:41:12

Not reported

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:15:38
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:29:40
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 21:00:23
User entered '0'	Phoebe Cunningham (b) (4)	28 Aug 2020 15:46:27

US3432334

Folder: Screening

Form: Enrollment

Generated On: 11 Aug 2021 22:41:12

Date of Informed Consent (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:15:38
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:29:40
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 21:00:47
User entered '28 Aug 2020'	Phoebe Cunningham (b) (4)	28 Aug 2020 14:23:01

US3432334

Folder: Screening

Form: Enrollment

Generated On: 11 Aug 2021 22:41:12

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:15:38
User entered 'Aug 2020'	System	28 Aug 2020 14:23:01

US3432334

Folder: Screening

Form: Enrollment

Generated On: 11 Aug 2021 22:41:12

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:15:38
User entered '2020'	System	28 Aug 2020 14:23:01

US3432334

Folder: Screening

Form: Enrollment

Generated On: 11 Aug 2021 22:41:12

[Protocol Version](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:15:38
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:29:40
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 21:00:47
User closed query 'Data is required. Please complete.' (Site from System).	System	31 Aug 2020 19:18:28
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	31 Aug 2020 19:18:28
User entered 'Amendment 3 (3)' reason for change: Data Entry Error	Monica Feeley (b) (4)	31 Aug 2020 19:18:28
User opened query 'Data is required. Please complete.' (Site from System).	System	28 Aug 2020 14:23:01
User entered empty.	Phoebe Cunningham (b) (4)	28 Aug 2020 14:23:01

US3432334

Folder: Screening

Form: Enrollment

Generated On: 11 Aug 2021 22:41:12

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:15:38
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:29:40
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 21:00:47
User entered 'Yes (Y)'	Phoebe Cunningham (b) (4)	28 Aug 2020 14:23:01

US3432334

Folder: Screening

Form: Enrollment

Generated On: 11 Aug 2021 22:41:12

If No, indicate reason for screen fail

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:15:38
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:29:40
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 21:00:47
User entered empty.	Phoebe Cunningham (b) (4)	28 Aug 2020 14:23:01

US3432334

Folder: Screening

Form: Enrollment

Generated On: 11 Aug 2021 22:41:12

If reason for screen fail is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:15:38
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:29:40
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 21:00:47
User entered empty.	Phoebe Cunningham (b) (4)	28 Aug 2020 14:23:01

US3432334

Folder: Screening

Form: Enrollment

Generated On: 11 Aug 2021 22:41:12

[Was this participant screened previously?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:15:38
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:29:40
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 21:00:47
User entered 'No (N)'	Phoebe Cunningham (b) (4)	28 Aug 2020 14:23:01

US3432334

Folder: Screening

Form: Enrollment

Generated On: 11 Aug 2021 22:41:12

[If Yes, previous participant number](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:15:38
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:29:40
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 21:00:47
User entered empty.	RWS_ENDPOINT ENDPOINT (b) (4)	28 Aug 2020 13:34:47

US3432334

Folder: Screening

Form: Enrollment

Generated On: 11 Aug 2021 22:41:12

[Enrollment Trigger](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:15:38
User entered 'I'	System	28 Aug 2020 14:23:08

US3432334

Folder: Screening

Form: Inclusion/Exclusion Criteria Summary

Generated On: 11 Aug 2021 22:41:12

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:15:38
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:29:40
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 21:01:07
User entered 'Yes (Y)'	Phoebe Cunningham (b) (4)	28 Aug 2020 14:23:08

US3432334

Folder: Screening

Form: Medical History Summary

Generated On: 11 Aug 2021 22:41:12

[Were any significant conditions reported?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:15:38
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:29:40
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 21:01:09
User entered 'Yes (Y)'	Phoebe Cunningham (b) (4)	28 Aug 2020 15:47:03

US3432334

Folder: Screening

Form: Medical History (1)

Generated On: 11 Aug 2021 22:41:12

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:15:38
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:29:40
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 21:03:07
User coded data point as SOC: Respiratory, thoracic and mediastinal disorders, HLG: Bronchial disorders (excl neoplasms), HLT: Bronchospasm and obstruction, PT: Asthma, LLT: Asthma - version MedDRA\\23.0.	Coder Import (b) (4)	28 Aug 2020 15:48:47
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	28 Aug 2020 15:48:47
Data point term sent to Coder	System	28 Aug 2020 15:48:08
User entered 'Mild asthma'	Phoebe Cunningham (b) (4)	28 Aug 2020 15:47:38

US3432334

Folder: Screening

Form: Medical History (1)

Generated On: 11 Aug 2021 22:41:12

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:15:38
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:29:40
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 21:03:07
User entered 'un UNK 2018'	Phoebe Cunningham (b) (4)	28 Aug 2020 15:47:38

US3432334

Folder: Screening

Form: Medical History (1)

Generated On: 11 Aug 2021 22:41:12

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:15:38
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:29:40
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 21:03:07
User entered '0'	Phoebe Cunningham (b) (4)	28 Aug 2020 15:47:38

US3432334

Folder: Screening

Form: Medical History (1)

Generated On: 11 Aug 2021 22:41:12

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:15:38
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:29:40
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 21:03:07
User entered 'Yes (Y)'	Phoebe Cunningham (b) (4)	28 Aug 2020 15:47:38

US3432334

Folder: Screening

Form: Medical History (1)

Generated On: 11 Aug 2021 22:41:12

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:15:38
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:29:40
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 21:03:07
User entered empty.	Phoebe Cunningham (b) (4)	28 Aug 2020 15:47:38

US3432334

Folder: Screening

Form: Medical History (1)

Generated On: 11 Aug 2021 22:41:12

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:15:38
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:29:40
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 21:03:07
User entered '0'	Phoebe Cunningham (b) (4)	28 Aug 2020 15:47:38

US3432334

Folder: Screening

Form: Medical History (1)

Generated On: 11 Aug 2021 22:41:12

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:15:38
User entered 'Jan 2018'	System	28 Aug 2020 15:47:38

US3432334

Folder: Screening

Form: Medical History (1)

Generated On: 11 Aug 2021 22:41:12

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:15:38
User entered '2018'	System	28 Aug 2020 15:47:38

US3432334

Folder: Screening

Form: Medical History (1)

Generated On: 11 Aug 2021 22:41:12

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:15:38
User entered empty.	System	28 Aug 2020 15:47:38

US3432334

Folder: Screening

Form: Medical History (1)

Generated On: 11 Aug 2021 22:41:12

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:15:38
User entered empty.	System	28 Aug 2020 15:47:38

US3432334

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 22:41:12

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:15:38
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:30:01
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 21:03:33
User entered 'Yes (Y)'	Phoebe Cunningham (b) (4)	28 Aug 2020 15:48:53

US3432334

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 22:41:12

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:15:38
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:30:01
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 21:03:33
User entered '28 Aug 2020'	Phoebe Cunningham (b) (4)	28 Aug 2020 15:48:53

US3432334

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 22:41:12

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:15:38
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:30:01
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 21:03:33
User entered '09:37' reason for change: Data Entry Error	Julia Klopfer (b) (4)	19 Oct 2020 23:21:30
User entered '9:37'	Phoebe Cunningham (b) (4)	28 Aug 2020 15:48:53

US3432334

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 22:41:12

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:15:38
User entered '28 Aug 2020 09:37'	System	19 Oct 2020 23:21:30
User entered '28 Aug 2020 9:37'	System	28 Aug 2020 15:48:53

US3432334

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 22:41:12

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:15:38
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:30:01
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 21:03:33
User entered '170.5' cm	Phoebe Cunningham (b) (4)	28 Aug 2020 15:48:53
DataPoint set to visible.	System	28 Aug 2020 14:23:08

US3432334

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 22:41:12

Weight (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:15:38
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:30:01
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 21:03:33
User entered '72.5' kg	Phoebe Cunningham (b) (4)	28 Aug 2020 15:48:53
DataPoint set to visible.	System	28 Aug 2020 14:23:08

US3432334

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 22:41:12

BMI (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:15:38
User entered '24.93959'	System	28 Aug 2020 15:48:53
DataPoint set to visible.	System	28 Aug 2020 14:23:08

US3432334

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 22:41:12

[BMI units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:15:38
User entered 'kg/m2'	System	28 Aug 2020 15:48:53
DataPoint set to visible.	System	28 Aug 2020 14:23:08

US3432334

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 22:41:12

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:15:38
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:30:01
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 21:03:33
User entered missing code ND - Not Done.	Phoebe Cunningham (b) (4)	28 Aug 2020 15:48:53

US3432334

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 22:41:12

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:15:38
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:30:01
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 21:03:33
User entered empty.	Phoebe Cunningham (b) (4)	28 Aug 2020 15:48:53

US3432334

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 22:41:12

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:15:38
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:30:01
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 21:03:33
User entered empty.	Phoebe Cunningham (b) (4)	28 Aug 2020 15:48:53

US3432334

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 22:41:12

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:15:38
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:30:01
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 21:03:33
User entered missing code ND - Not Done.	Phoebe Cunningham (b) (4)	28 Aug 2020 15:48:53

US3432334

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 22:41:12

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:15:38
User entered 'bpm'	System	28 Aug 2020 15:48:53

US3432334

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 22:41:12

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:15:38
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:30:01
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 21:03:33
User entered missing code ND - Not Done.	Phoebe Cunningham (b) (4)	28 Aug 2020 15:48:53

US3432334

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 22:41:12

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:15:38
User entered 'breaths/min'	System	28 Aug 2020 15:48:53

US3432334

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 22:41:12

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:15:38
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:30:01
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 21:03:33
User entered missing code ND - Not Done.	Phoebe Cunningham (b) (4)	28 Aug 2020 15:48:53

US3432334

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 22:41:12

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:15:38
User entered 'mmHg'	System	28 Aug 2020 15:48:53

US3432334

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 22:41:12

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:15:38
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:30:01
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 21:03:33
User entered missing code ND - Not Done.	Phoebe Cunningham (b) (4)	28 Aug 2020 15:48:53

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Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 22:41:12

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:15:38
User entered 'mmHg'	System	28 Aug 2020 15:48:53

US3432334

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 22:41:12

[Height \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:15:38

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Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 22:41:12

Weight (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:15:38

US3432334

Folder: Screening

Form: Physical Examination

Generated On: 11 Aug 2021 22:41:12

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:15:38
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:29:40
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 21:03:36
User entered 'Yes (Y)'	Phoebe Cunningham (b) (4)	28 Aug 2020 14:23:27

US3432334

Folder: Screening

Form: Physical Examination

Generated On: 11 Aug 2021 22:41:12

Date of examination (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:15:38
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:29:40
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 21:03:36
User entered '28 Aug 2020'	Phoebe Cunningham (b) (4)	28 Aug 2020 14:23:27

US3432334

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 22:41:12

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 07:15:38
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:29:40
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 21:00:42
User entered 'Yes (Y)'	Phoebe Cunningham (b) (4)	28 Aug 2020 15:49:51

US3432334

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 22:41:12

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 07:15:38
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:29:40
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 21:00:42
User entered 'No (N)'	Phoebe Cunningham (b) (4)	28 Aug 2020 15:49:51

US3432334

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 22:41:12

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 07:15:38
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:29:40
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 21:00:42
User entered 'No (N)'	Phoebe Cunningham (b) (4)	28 Aug 2020 15:49:51

US3432334

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 22:41:12

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 07:15:38
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:29:40
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 21:00:42
User entered 'No (N)'	Phoebe Cunningham (b) (4)	28 Aug 2020 15:49:51

US3432334

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 22:41:12

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 07:15:38
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:29:40
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 21:00:42
User entered 'No (N)'	Phoebe Cunningham (b) (4)	28 Aug 2020 15:49:51

US3432334

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 22:41:12

[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 07:15:38
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:29:40
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 21:00:42
User entered 'No (N)'	Phoebe Cunningham (b) (4)	28 Aug 2020 15:49:51

US3432334

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 22:41:12

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 07:15:38
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:29:40
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 21:00:42
User entered 'No (N)'	Phoebe Cunningham (b) (4)	28 Aug 2020 15:49:51

US3432334

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 22:41:12

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 07:15:38
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:29:40
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 21:00:42
User entered 'No (N)'	Phoebe Cunningham (b) (4)	28 Aug 2020 15:49:51

US3432334

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 22:41:12

[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 07:15:38
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:29:40
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 21:00:42
User entered 'No (N)'	Phoebe Cunningham (b) (4)	28 Aug 2020 15:49:51

US3432334

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 22:41:12

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 07:15:38
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:29:40
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 21:00:42
User entered 'No (N)'	Phoebe Cunningham (b) (4)	28 Aug 2020 15:49:51

US3432334

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 22:41:12

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 07:15:38
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:29:40
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 21:00:42
User entered 'No (N)'	Phoebe Cunningham (b) (4)	28 Aug 2020 15:49:51

US3432334

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 22:41:12

Other

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:15:38
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:29:40
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 21:00:42
User entered 'No (N)'	Phoebe Cunningham (b) (4)	28 Aug 2020 15:49:51

US3432334

Folder: Screening

Form: Risk of Exposure

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[Specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:15:38
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:29:40
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 21:00:42
User entered empty.	Phoebe Cunningham (b) (4)	28 Aug 2020 15:49:51

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Folder: Screening

Form: Risk of Exposure

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No Risk Identified

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:15:38
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:29:40
User entered '0'	Phoebe Cunningham (b) (4)	28 Aug 2020 15:49:51

US3432334

Folder: Screening

Form: Risk of Exposure

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Resides in Nursing Home or Assisted Living Facility

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:15:38
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:29:40
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 21:00:42
User entered '0'	Phoebe Cunningham (b) (4)	28 Aug 2020 15:49:51

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Folder: Screening

Form: Risk of Exposure

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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 07:15:38
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:29:40
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 21:00:42
User entered '0'	Phoebe Cunningham (b) (4)	28 Aug 2020 15:49:51

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Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 22:41:12

[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 07:15:38
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:29:40
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 21:00:42
User entered 'I'	Phoebe Cunningham (b) (4)	28 Aug 2020 15:49:51

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Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 22:41:12

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 07:15:38
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:29:40
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 21:00:42
User entered '0'	Phoebe Cunningham (b) (4)	28 Aug 2020 15:49:51

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Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 22:41:12

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:15:38
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:29:40
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 21:00:42
User entered '0'	Phoebe Cunningham (b) (4)	28 Aug 2020 15:49:51

US3432334

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 22:41:12

[Other](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:15:38
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:29:40
User entered '0'	Phoebe Cunningham (b) (4)	28 Aug 2020 15:49:51

US3432334

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 22:41:12

[Specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:15:38
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:29:40
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 21:00:42
User entered empty.	Phoebe Cunningham (b) (4)	28 Aug 2020 15:49:51

US3432334

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 11 Aug 2021 22:41:12

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:15:38
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:30:01
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 21:03:48
User entered 'Yes (Y)'	Phoebe Cunningham (b) (4)	28 Aug 2020 14:23:18

US3432334

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 11 Aug 2021 22:41:12

Visit date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:15:38
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:30:01
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 21:03:48
User entered '28 Aug 2020'	Phoebe Cunningham (b) (4)	28 Aug 2020 14:23:18

US3432334

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 11 Aug 2021 22:41:12

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 07:15:38
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:30:01
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 21:03:48
User entered 'Clinic (Clinic)'	Phoebe Cunningham (b) (4)	28 Aug 2020 14:23:18

US3432334

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 11 Aug 2021 22:41:12

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:15:38
User entered 'VISIT1'	System	28 Aug 2020 14:23:18

US3432334

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 11 Aug 2021 22:41:12

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:15:38
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:30:01
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 21:03:58
User entered '28 AUG 2020'	RWS_ENDPOINT ENDPOINT (b) (4)	28 Aug 2020 13:49:43

US3432334

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 11 Aug 2021 22:41:12

What was the participant's randomization number?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:15:38
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:30:01
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 21:03:58
User entered '109372'	RWS_ENDPOINT ENDPOINT (b) (4)	28 Aug 2020 13:49:43

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Folder: Visit 1 Day 1

Form: Randomization

Generated On: 11 Aug 2021 22:41:12

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:15:38
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:30:01
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 21:03:58
User entered '>=18 and <65 years and not at risk (1)'	RWS_ENDPOINT ENDPOINT (b) (4)	28 Aug 2020 13:49:43

US3432334

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 11 Aug 2021 22:41:12

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 07:15:38
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:30:01
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 21:03:58
User entered 'No (N)'	Phoebe Cunningham (b) (4)	28 Aug 2020 15:50:31

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Folder: Visit 1 Day 1

Form: Randomization

Generated On: 11 Aug 2021 22:41:12

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 07:15:38
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:30:01
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 21:03:58
User entered 'No (N)'	Phoebe Cunningham (b) (4)	28 Aug 2020 15:50:31

US3432334

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 11 Aug 2021 22:41:12

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:15:38
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:30:01
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 21:03:58
User entered 'No (N)'	Phoebe Cunningham (b) (4)	28 Aug 2020 15:50:31

US3432334

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 11 Aug 2021 22:41:12

Diabetes (Type I, Type 2, or gestational)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:15:38
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:30:01
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 21:03:58
User entered 'No (N)'	Phoebe Cunningham (b) (4)	28 Aug 2020 15:50:31

US3432334

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 11 Aug 2021 22:41:12

[Liver Disease](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:15:38
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:30:01
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 21:03:58
User entered 'No (N)'	Phoebe Cunningham (b) (4)	28 Aug 2020 15:50:31

US3432334

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 11 Aug 2021 22:41:12

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:15:38
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:30:01
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 21:03:58
User entered 'No (N)'	Julia Klopfer (b) (4)	19 Oct 2020 23:22:38
Amendment Manager: DataPoint set to visible.	System	19 Sep 2020 08:23:58
Amendment Manager inserted this DataPoint.	System	19 Sep 2020 08:23:57

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 11 Aug 2021 22:41:12

[Height](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:15:38
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:30:01
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 21:05:20
User entered missing code ND - Not Done.	Phoebe Cunningham (b) (4)	28 Aug 2020 15:52:49

US3432334

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 11 Aug 2021 22:41:12

Weight

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:15:38
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:30:01
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 21:05:20
User entered missing code ND - Not Done.	Phoebe Cunningham (b) (4)	28 Aug 2020 15:52:49

US3432334

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 11 Aug 2021 22:41:12

[Height](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:15:38
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:30:01
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 21:05:20
User entered missing code ND - Not Done.	Phoebe Cunningham (b) (4)	28 Aug 2020 15:52:49

US3432334

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 11 Aug 2021 22:41:12

Weight

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:15:38
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:30:01
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 21:05:20
User entered missing code ND - Not Done.	Phoebe Cunningham (b) (4)	28 Aug 2020 15:52:49

US3432334

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:41:12

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:15:38
User accepted default value 'Pre-Dose (PREDOSE)'	Phoebe Cunningham (b) (4)	28 Aug 2020 15:52:49

US3432334

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:41:12

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:15:38
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:30:01
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 21:05:20
User entered 'Yes (Y)'	Phoebe Cunningham (b) (4)	28 Aug 2020 15:52:49

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:41:12

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:15:38
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:30:01
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 21:05:20
User entered '28 Aug 2020'	Phoebe Cunningham (b) (4)	28 Aug 2020 15:52:49

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:41:12

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:15:38
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:30:01
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 21:05:20
User entered '9:37'	Phoebe Cunningham (b) (4)	28 Aug 2020 15:52:49

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:41:12

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:15:38
User entered '28 Aug 2020 9:37'	System	28 Aug 2020 15:52:49

US3432334

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:41:12

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:15:38
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:30:01
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 21:05:20
User entered '36.6' C	Phoebe Cunningham (b) (4)	28 Aug 2020 15:52:49

US3432334

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:41:12

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:15:38
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:30:01
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 21:05:20
User entered 'Oral (Oral)'	Phoebe Cunningham (b) (4)	28 Aug 2020 15:52:49

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:41:12

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:15:38
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:30:01
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 21:05:20
User entered empty.	Phoebe Cunningham (b) (4)	28 Aug 2020 15:52:49

US3432334

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:41:12

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:15:38
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:30:01
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 21:05:20
User entered '48'	Phoebe Cunningham (b) (4)	28 Aug 2020 15:52:49

US3432334

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:41:12

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:15:38
User entered 'bpm'	System	28 Aug 2020 15:52:49

US3432334

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:41:12

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:15:38
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:30:01
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 21:05:20
User entered '16'	Phoebe Cunningham (b) (4)	28 Aug 2020 15:52:49

US3432334

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:41:12

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:15:38
User entered 'breaths/min'	System	28 Aug 2020 15:52:49

US3432334

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:41:12

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:15:38
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:30:01
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 21:05:20
User entered '141'	Phoebe Cunningham (b) (4)	28 Aug 2020 15:52:49

US3432334

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:41:12

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:15:38
User entered 'mmHg'	System	28 Aug 2020 15:52:49

US3432334

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:41:12

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:15:38
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:30:01
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 21:05:20
User entered '80'	Phoebe Cunningham (b) (4)	28 Aug 2020 15:52:49

US3432334

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:41:12

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:15:38
User entered 'mmHg'	System	28 Aug 2020 15:52:49

US3432334

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 11 Aug 2021 22:41:12

[Height](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:15:38
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:30:01
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 21:05:20
User entered missing code ND - Not Done.	Phoebe Cunningham (b) (4)	28 Aug 2020 15:52:49

US3432334

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 11 Aug 2021 22:41:12

Weight

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:15:38
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:30:01
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 21:05:20
User entered missing code ND - Not Done.	Phoebe Cunningham (b) (4)	28 Aug 2020 15:52:49

US3432334

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:41:12

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:15:38
User accepted default value 'Post-Dose (POSTDOSE)'	Phoebe Cunningham (b) (4)	28 Aug 2020 15:52:49

US3432334

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:41:12

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:15:38
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:30:01
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 21:05:20
User entered 'Yes (Y)'	Phoebe Cunningham (b) (4)	28 Aug 2020 15:52:49

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:41:12

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:15:38
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:30:01
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 21:05:20
User entered '28 Aug 2020'	Phoebe Cunningham (b) (4)	28 Aug 2020 15:52:49

US3432334

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:41:12

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:15:38
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:30:01
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 21:05:20
User entered '11:19'	Phoebe Cunningham (b) (4)	28 Aug 2020 15:52:49

US3432334

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:41:12

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:15:38
User entered '28 Aug 2020 11:19'	System	28 Aug 2020 15:52:49

US3432334

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:41:12

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:15:38
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:30:01
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 21:05:20
User entered '36.7' C	Phoebe Cunningham (b) (4)	28 Aug 2020 15:52:49

US3432334

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:41:12

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:15:38
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:30:01
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 21:05:20
User entered 'Oral (Oral)'	Phoebe Cunningham (b) (4)	28 Aug 2020 15:52:49

US3432334

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:41:12

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:15:38
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:30:01
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 21:05:20
User entered empty.	Phoebe Cunningham (b) (4)	28 Aug 2020 15:52:49

US3432334

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:41:12

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:15:38
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:30:01
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 21:05:20
User entered '53'	Phoebe Cunningham (b) (4)	28 Aug 2020 15:52:49

US3432334

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:41:12

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:15:38
User entered 'bpm'	System	28 Aug 2020 15:52:49

US3432334

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:41:12

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:15:38
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:30:01
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 21:05:20
User entered '16'	Phoebe Cunningham (b) (4)	28 Aug 2020 15:52:49

US3432334

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:41:12

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:15:38
User entered 'breaths/min'	System	28 Aug 2020 15:52:49

US3432334

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:41:12

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:15:38
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:30:01
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 21:05:20
User entered '122'	Phoebe Cunningham (b) (4)	28 Aug 2020 15:52:49

US3432334

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:41:12

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:15:38
User entered 'mmHg'	System	28 Aug 2020 15:52:49

US3432334

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:41:12

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:15:38
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:30:01
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 21:05:20
User entered '87'	Phoebe Cunningham (b) (4)	28 Aug 2020 15:52:49

US3432334

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:41:12

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:15:38
User entered 'mmHg'	System	28 Aug 2020 15:52:49

US3432334

Folder: Visit 1 Day 1

Form: Physical Examination

Generated On: 11 Aug 2021 22:41:12

Was the physical examination performed?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:15:38
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:30:01
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 21:05:23
User closed query 'Was the physical examination performed is No, however Date of examination is provided. Please correct.' (Site from System).	System	14 Sep 2020 12:14:37
User opened query 'Was the physical examination performed is No, however Date of examination is provided. Please correct.' (Site from System).	System	28 Aug 2020 14:23:33
User entered 'No (N)'	Phoebe Cunningham (b) (4)	28 Aug 2020 14:23:33

US3432334

Folder: Visit 1 Day 1

Form: Physical Examination

Generated On: 11 Aug 2021 22:41:12

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:15:38
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:30:01
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 21:05:23
User entered empty; reason for change Per Query Resolution	Jessica Cauley (b) (4)	14 Sep 2020 12:14:37
User entered '28 Aug 2020'	Phoebe Cunningham (b) (4)	28 Aug 2020 14:23:33

US3432334

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 11 Aug 2021 22:41:12

[Was study treatment given?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:15:38
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:30:01
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 21:05:38
User entered 'Yes (Y)'	Phoebe Cunningham (b) (4)	28 Aug 2020 15:13:20

US3432334

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 11 Aug 2021 22:41:12

If No, reason not given

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:15:38
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:30:01
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 21:05:38
User entered empty.	Phoebe Cunningham (b) (4)	28 Aug 2020 15:13:20

US3432334

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 11 Aug 2021 22:41:12

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 07:15:38
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:30:01
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 21:05:38
User entered empty.	Phoebe Cunningham (b) (4)	28 Aug 2020 15:13:20

US3432334

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 11 Aug 2021 22:41:12

[What was the study treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:15:38
User entered 'MRNA-1273 OR PLACEBO'	System	28 Aug 2020 15:13:20

US3432334

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 11 Aug 2021 22:41:12

What was the treatment date? (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:15:38
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:30:01
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 21:05:38
User entered '28 Aug 2020'	Phoebe Cunningham (b) (4)	28 Aug 2020 15:13:20

US3432334

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 11 Aug 2021 22:41:12

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:15:38
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:30:01
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 21:05:38
User entered '10:41'	Phoebe Cunningham (b) (4)	28 Aug 2020 15:13:20

US3432334

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 11 Aug 2021 22:41:12

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:15:38
User entered '28 Aug 2020 10:41'	System	28 Aug 2020 15:13:20

US3432334

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 11 Aug 2021 22:41:12

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:15:38
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:30:01
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 21:05:38
User entered 'Left Arm (LEFT ARM)'	Phoebe Cunningham (b) (4)	28 Aug 2020 15:13:20

US3432334

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 11 Aug 2021 22:41:12

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:15:38
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 21:05:38
User entered 'ONCE'	System	28 Aug 2020 15:13:20

US3432334

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 11 Aug 2021 22:41:12

What was the route of administration for the study treatment?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:15:38
User entered 'INTRAMUSCULAR'	System	28 Aug 2020 15:13:20

US3432334

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 22:41:12

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:15:38
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:30:01
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 21:05:55
User entered 'Yes (Y)'	Phoebe Cunningham (b) (4)	28 Aug 2020 18:57:58

US3432334

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 22:41:12

Collection date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:15:38
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:30:01
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 21:05:55
User entered '28 Aug 2020'	Phoebe Cunningham (b) (4)	28 Aug 2020 18:57:58

US3432334

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 22:41:12

Collection time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:15:38
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:30:01
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 21:05:55
User entered '9:45'	Phoebe Cunningham (b) (4)	28 Aug 2020 18:57:58

US3432334

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 22:41:12

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:15:38
User entered '28 Aug 2020 9:45'	System	28 Aug 2020 18:57:58

US3432334

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab

Generated On: 11 Aug 2021 22:41:12

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:15:38
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:30:01
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 21:05:59
User entered '28 Aug 2020'	Phoebe Cunningham (b) (4)	28 Aug 2020 18:58:13

US3432334

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 11 Aug 2021 22:41:12

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:15:38
User accepted default value 'Nasopharyngeal Swab 1 (NASAL1)'	Phoebe Cunningham (b) (4)	28 Aug 2020 18:58:13

US3432334

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 11 Aug 2021 22:41:12

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:15:38
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:30:01
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 21:05:59
User entered 'Yes (Y)'	Phoebe Cunningham (b) (4)	28 Aug 2020 18:58:13

US3432334

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 11 Aug 2021 22:41:12

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:15:38
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:30:01
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 21:05:59
User entered '9:56'	Phoebe Cunningham (b) (4)	28 Aug 2020 18:58:13

US3432334

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 11 Aug 2021 22:41:12

Collection date and time (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:15:38
User entered '28 Aug 2020 9:56'	System	28 Aug 2020 18:58:13

US3432334

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 11 Aug 2021 22:41:12

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:15:38
User accepted default value 'Nasopharyngeal Swab 2 (NASAL2)'	Phoebe Cunningham (b) (4)	28 Aug 2020 18:58:13

US3432334

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 11 Aug 2021 22:41:12

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:15:38
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:30:01
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 21:05:59
User entered 'No (N)'	Phoebe Cunningham (b) (4)	28 Aug 2020 18:58:13

US3432334

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 11 Aug 2021 22:41:12

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:15:38
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:30:01
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 21:05:59
User entered empty.	Phoebe Cunningham (b) (4)	28 Aug 2020 18:58:13

US3432334

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 11 Aug 2021 22:41:12

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:15:38
User entered empty.	System	28 Aug 2020 18:58:13

US3432334

Folder: Visit 1 Day 1

Form: Continuing

Generated On: 11 Aug 2021 22:41:12

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:15:38
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:30:01
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 21:06:01
User entered 'Yes (Y)'	Phoebe Cunningham (b) (4)	28 Aug 2020 15:52:55

US3432334

Folder: Visit 1 Day 1

Form: Continuing

Generated On: 11 Aug 2021 22:41:12

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:15:38
User entered 'I'	System	28 Aug 2020 15:52:55

US3432334

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 11 Aug 2021 22:41:12

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:04:43
Data entry locked.	System	28 Aug 2020 15:13:20
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	28 Aug 2020 15:13:20

US3432334

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 11 Aug 2021 22:41:12

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:04:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C38FDA40-A52C-492B-ACED-AF41296DC535)', Time: '2020-08-28T11:23:36', User OID: 'PatientReportedOutcome (US3432334)', ODM File OID: 'ff52a4b2-6fa3-4f62-baff-ebe91e24c1ef'	System	28 Aug 2020 15:23:50
User entered 'Yes (Y)'	System	28 Aug 2020 15:23:50

US3432334

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 11 Aug 2021 22:41:12

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:04:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C38FDA40-A52C-492B-ACED-AF41296DC535)', Time: '2020-08-28T11:23:39', User OID: 'PatientReportedOutcome (US3432334)', ODM File OID: 'ff52a4b2-6fa3-4f62-baff-ebe91e24c1ef' User entered '98.0'	System	28 Aug 2020 15:23:50
	System	28 Aug 2020 15:23:50

US3432334

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 11 Aug 2021 22:41:12

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:04:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C38FDA40-A52C-492B-ACED-AF41296DC535)', Time: '2020-08-28T11:23:44', User OID: 'PatientReportedOutcome (US3432334)', ODM File OID: 'ff52a4b2-6fa3-4f62-baff-ebe91e24c1ef'	System	28 Aug 2020 15:23:50
User entered 'No (N)'	System	28 Aug 2020 15:23:50

US3432334

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 11 Aug 2021 22:41:12

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:04:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C38FDA40-A52C-492B-ACED-AF41296DC535)', Time: '2020-08-28T11:23:48', User OID: 'PatientReportedOutcome (US3432334)', ODM File OID: 'ff52a4b2-6fa3-4f62-baff-ebe91e24c1ef' User entered '28 Aug 2020 11:23'	System	28 Aug 2020 15:23:50
	System	28 Aug 2020 15:23:50

US3432334

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 11 Aug 2021 22:41:12

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:04:43
User entered '28 Aug 2020 11:01'	System	28 Aug 2020 15:13:20

US3432334

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 11 Aug 2021 22:41:12

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:04:43
User entered '28 Aug 2020 13:31'	System	28 Aug 2020 15:13:20

US3432334

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 11 Aug 2021 22:41:12

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:04:43
Data entry locked.	System	28 Aug 2020 15:13:20
User entered 'Day 1, after vaccination (at home)'	System	28 Aug 2020 15:13:20

US3432334

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 11 Aug 2021 22:41:12

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:04:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C38FDA40-A52C-492B-ACED-AF41296DC535)', Time: '2020-08-29T08:39:34', User OID: 'PatientReportedOutcome (US3432334)', ODM File OID: '19b3f324-f6bf-40a3-b968-bd926d4dcdd5'	System	29 Aug 2020 14:09:33
User entered 'Yes (Y)'	System	29 Aug 2020 14:09:33

US3432334

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 11 Aug 2021 22:41:12

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:04:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C38FDA40-A52C-492B-ACED-AF41296DC535)', Time: '2020-08-29T10:09:24', User OID: 'PatientReportedOutcome (US3432334)', ODM File OID: '19b3f324-f6bf-40a3-b968-bd926d4dcdd5' User entered '97.7'	System	29 Aug 2020 14:09:33
	System	29 Aug 2020 14:09:33

US3432334

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 11 Aug 2021 22:41:12

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:04:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C38FDA40-A52C-492B-ACED-AF41296DC535)', Time: '2020-08-29T10:09:27', User OID: 'PatientReportedOutcome (US3432334)', ODM File OID: '19b3f324-f6bf-40a3-b968-bd926d4dcdd5'	System	29 Aug 2020 14:09:33
User entered 'No (N)'	System	29 Aug 2020 14:09:33

US3432334

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 11 Aug 2021 22:41:12

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:04:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C38FDA40-A52C-492B-ACED-AF41296DC535)', Time: '2020-08-29T10:09:31', User OID: 'PatientReportedOutcome (US3432334)', ODM File OID: '19b3f324-f6bf-40a3-b968-bd926d4dcdd5' User entered '29 Aug 2020 10:09'	System	29 Aug 2020 14:09:33
	System	29 Aug 2020 14:09:33

US3432334

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 11 Aug 2021 22:41:12

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:04:43
User entered '28 Aug 2020 14:26'	System	28 Aug 2020 15:13:20

US3432334

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 11 Aug 2021 22:41:12

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:04:43
User entered '29 Aug 2020 11:59'	System	28 Aug 2020 15:13:20

US3432334

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 11 Aug 2021 22:41:12

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:04:43
Data entry locked.	System	28 Aug 2020 15:13:20
User entered 'Day 2'	System	28 Aug 2020 15:13:20

US3432334

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 11 Aug 2021 22:41:12

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:04:43

US3432334

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 11 Aug 2021 22:41:12

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:04:43

US3432334

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 11 Aug 2021 22:41:12

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:04:43

US3432334

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 11 Aug 2021 22:41:12

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:04:43

US3432334

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 11 Aug 2021 22:41:12

To **PREVENT** pain or fever from occurring

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:04:43

US3432334

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 11 Aug 2021 22:41:12

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:04:43

US3432334

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 11 Aug 2021 22:41:12

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:04:43
User entered '29 Aug 2020 12:00'	System	28 Aug 2020 15:13:20

US3432334

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 11 Aug 2021 22:41:12

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:04:43
User entered '30 Aug 2020 11:59'	System	28 Aug 2020 15:13:20

US3432334

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 11 Aug 2021 22:41:12

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:04:43
Data entry locked.	System	28 Aug 2020 15:13:20
User entered 'Day 3'	System	28 Aug 2020 15:13:20

US3432334

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 11 Aug 2021 22:41:12

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:04:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C38FDA40-A52C-492B-ACED-AF41296DC535)', Time: '2020-08-30T17:48:50', User OID: 'PatientReportedOutcome (US3432334)', ODM File OID: '90f7d1ba-690a-408b-9db4-b3125314a8ed' User entered 'Yes (Y)'	System	30 Aug 2020 21:49:02
	System	30 Aug 2020 21:49:02

US3432334

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 11 Aug 2021 22:41:12

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:04:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C38FDA40-A52C-492B-ACED-AF41296DC535)', Time: '2020-08-30T17:48:56', User OID: 'PatientReportedOutcome (US3432334)', ODM File OID: '90f7d1ba-690a-408b-9db4-b3125314a8ed' User entered '96.0'	System	30 Aug 2020 21:49:02
	System	30 Aug 2020 21:49:02

US3432334

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 11 Aug 2021 22:41:12

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:04:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C38FDA40-A52C-492B-ACED-AF41296DC535)', Time: '2020-08-30T17:48:58', User OID: 'PatientReportedOutcome (US3432334)', ODM File OID: '90f7d1ba-690a-408b-9db4-b3125314a8ed'	System	30 Aug 2020 21:49:02
User entered 'No (N)'	System	30 Aug 2020 21:49:02

US3432334

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 11 Aug 2021 22:41:12

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:04:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C38FDA40-A52C-492B-ACED-AF41296DC535)', Time: '2020-08-30T17:49:01', User OID: 'PatientReportedOutcome (US3432334)', ODM File OID: '90f7d1ba-690a-408b-9db4-b3125314a8ed' User entered '30 Aug 2020 17:49'	System	30 Aug 2020 21:49:02
	System	30 Aug 2020 21:49:02

US3432334

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 11 Aug 2021 22:41:12

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:04:43
User entered '30 Aug 2020 12:00'	System	28 Aug 2020 15:13:20

US3432334

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 11 Aug 2021 22:41:12

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:04:43
User entered '31 Aug 2020 11:59'	System	28 Aug 2020 15:13:20

US3432334

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 11 Aug 2021 22:41:12

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:04:43
Data entry locked.	System	28 Aug 2020 15:13:20
User entered 'Day 4'	System	28 Aug 2020 15:13:20

US3432334

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 11 Aug 2021 22:41:12

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:04:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C38FDA40-A52C-492B-ACED-AF41296DC535)', Time: '2020-08-31T18:36:13', User OID: 'PatientReportedOutcome (US3432334)', ODM File OID: 'd190ae70-5e3e-4b2c-ba9c-8324b27344af' User entered 'Yes (Y)'	System	31 Aug 2020 22:36:25
	System	31 Aug 2020 22:36:25

US3432334

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 11 Aug 2021 22:41:12

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:04:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C38FDA40-A52C-492B-ACED-AF41296DC535)', Time: '2020-08-31T18:36:17', User OID: 'PatientReportedOutcome (US3432334)', ODM File OID: 'd190ae70-5e3e-4b2c-ba9c-8324b27344af' User entered '96.1'	System	31 Aug 2020 22:36:25
	System	31 Aug 2020 22:36:25

US3432334

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 11 Aug 2021 22:41:12

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:04:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C38FDA40-A52C-492B-ACED-AF41296DC535)', Time: '2020-08-31T18:36:19', User OID: 'PatientReportedOutcome (US3432334)', ODM File OID: 'd190ae70-5e3e-4b2c-ba9c-8324b27344af' User entered 'No (N)'	System	31 Aug 2020 22:36:25
	System	31 Aug 2020 22:36:25

US3432334

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 11 Aug 2021 22:41:12

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:04:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C38FDA40-A52C-492B-ACED-AF41296DC535)', Time: '2020-08-31T18:36:22', User OID: 'PatientReportedOutcome (US3432334)', ODM File OID: 'd190ae70-5e3e-4b2c-ba9c-8324b27344af' User entered '31 Aug 2020 18:36'	System	31 Aug 2020 22:36:25
	System	31 Aug 2020 22:36:25

US3432334

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 11 Aug 2021 22:41:12

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:04:43
User entered '31 Aug 2020 12:00'	System	28 Aug 2020 15:13:20

US3432334

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 11 Aug 2021 22:41:12

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:04:43
User entered '01 Sep 2020 11:59'	System	28 Aug 2020 15:13:20

US3432334

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 11 Aug 2021 22:41:12

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:04:43
Data entry locked.	System	28 Aug 2020 15:13:20
User entered 'Day 5'	System	28 Aug 2020 15:13:20

US3432334

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 11 Aug 2021 22:41:12

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:04:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C38FDA40-A52C-492B-ACED-AF41296DC535)', Time: '2020-09-01T18:15:42', User OID: 'PatientReportedOutcome (US3432334)', ODM File OID: 'f9823d05-4bb0-460a-886f-f1f7d2d0d2ee' User entered 'Yes (Y)'	System	01 Sep 2020 22:15:52
	System	01 Sep 2020 22:15:52

US3432334

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 11 Aug 2021 22:41:12

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:04:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C38FDA40-A52C-492B-ACED-AF41296DC535)', Time: '2020-09-01T18:15:46', User OID: 'PatientReportedOutcome (US3432334)', ODM File OID: 'f9823d05-4bb0-460a-886f-f1f7d2d0d2ee' User entered '96.4'	System	01 Sep 2020 22:15:52
	System	01 Sep 2020 22:15:52

US3432334

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 11 Aug 2021 22:41:12

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:04:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C38FDA40-A52C-492B-ACED-AF41296DC535)', Time: '2020-09-01T18:15:48', User OID: 'PatientReportedOutcome (US3432334)', ODM File OID: 'f9823d05-4bb0-460a-886f-f1f7d2d0d2ee'	System	01 Sep 2020 22:15:52
User entered 'No (N)'	System	01 Sep 2020 22:15:52

US3432334

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 11 Aug 2021 22:41:12

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:04:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C38FDA40-A52C-492B-ACED-AF41296DC535)', Time: '2020-09-01T18:15:50', User OID: 'PatientReportedOutcome (US3432334)', ODM File OID: 'f9823d05-4bb0-460a-886f-f1f7d2d0d2ee'	System	01 Sep 2020 22:15:52
User entered '01 Sep 2020 18:15'	System	01 Sep 2020 22:15:52

US3432334

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 11 Aug 2021 22:41:12

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:04:43
User entered '01 Sep 2020 12:00'	System	28 Aug 2020 15:13:20

US3432334

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 11 Aug 2021 22:41:12

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:04:43
User entered '02 Sep 2020 11:59'	System	28 Aug 2020 15:13:20

US3432334

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 11 Aug 2021 22:41:12

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:04:43
Data entry locked.	System	28 Aug 2020 15:13:20
User entered 'Day 6'	System	28 Aug 2020 15:13:20

US3432334

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 11 Aug 2021 22:41:12

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:04:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C38FDA40-A52C-492B-ACED-AF41296DC535)', Time: '2020-09-02T18:02:08', User OID: 'PatientReportedOutcome (US3432334)', ODM File OID: '07fefb70-405b-4634-8682-ee99565df9c5'	System	02 Sep 2020 22:06:52
User entered 'Yes (Y)'	System	02 Sep 2020 22:06:52

US3432334

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 11 Aug 2021 22:41:12

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:04:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C38FDA40-A52C-492B-ACED-AF41296DC535)', Time: '2020-09-02T18:06:46', User OID: 'PatientReportedOutcome (US3432334)', ODM File OID: '07fefb70-405b-4634-8682-ee99565df9c5' User entered '94.7'	System	02 Sep 2020 22:06:52
	System	02 Sep 2020 22:06:52

US3432334

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 11 Aug 2021 22:41:12

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:04:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C38FDA40-A52C-492B-ACED-AF41296DC535)', Time: '2020-09-02T18:06:48', User OID: 'PatientReportedOutcome (US3432334)', ODM File OID: '07fefb70-405b-4634-8682-ee99565df9c5'	System	02 Sep 2020 22:06:52
User entered 'No (N)'	System	02 Sep 2020 22:06:52

US3432334

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 11 Aug 2021 22:41:12

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:04:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C38FDA40-A52C-492B-ACED-AF41296DC535)', Time: '2020-09-02T18:06:50', User OID: 'PatientReportedOutcome (US3432334)', ODM File OID: '07fefb70-405b-4634-8682-ee99565df9c5' User entered '02 Sep 2020 18:06'	System	02 Sep 2020 22:06:52
	System	02 Sep 2020 22:06:52

US3432334

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 11 Aug 2021 22:41:12

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:04:43
User entered '02 Sep 2020 12:00'	System	28 Aug 2020 15:13:20

US3432334

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 11 Aug 2021 22:41:12

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:04:43
User entered '03 Sep 2020 11:59'	System	28 Aug 2020 15:13:20

US3432334

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 11 Aug 2021 22:41:12

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:04:43
Data entry locked.	System	28 Aug 2020 15:13:20
User entered 'Day 7'	System	28 Aug 2020 15:13:20

US3432334

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 11 Aug 2021 22:41:12

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:04:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C38FDA40-A52C-492B-ACED-AF41296DC535)', Time: '2020-09-03T17:11:33', User OID: 'PatientReportedOutcome (US3432334)', ODM File OID: '9c8af5a2-966a-4640-ac36-fa8242e968c9' User entered 'Yes (Y)'	System	03 Sep 2020 21:12:09
	System	03 Sep 2020 21:12:09

US3432334

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 11 Aug 2021 22:41:12

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:04:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C38FDA40-A52C-492B-ACED-AF41296DC535)', Time: '2020-09-03T17:12:02', User OID: 'PatientReportedOutcome (US3432334)', ODM File OID: '9c8af5a2-966a-4640-ac36-fa8242e968c9' User entered '96.9'	System	03 Sep 2020 21:12:09
	System	03 Sep 2020 21:12:09

US3432334

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 11 Aug 2021 22:41:12

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:04:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C38FDA40-A52C-492B-ACED-AF41296DC535)', Time: '2020-09-03T17:12:04', User OID: 'PatientReportedOutcome (US3432334)', ODM File OID: '9c8af5a2-966a-4640-ac36-fa8242e968c9' User entered 'No (N)'	System	03 Sep 2020 21:12:09
	System	03 Sep 2020 21:12:09

US3432334

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 11 Aug 2021 22:41:12

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:04:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C38FDA40-A52C-492B-ACED-AF41296DC535)', Time: '2020-09-03T17:12:07', User OID: 'PatientReportedOutcome (US3432334)', ODM File OID: '9c8af5a2-966a-4640-ac36-fa8242e968c9' User entered '03 Sep 2020 17:12'	System	03 Sep 2020 21:12:09
	System	03 Sep 2020 21:12:09

US3432334

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 11 Aug 2021 22:41:12

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:04:43
User entered '03 Sep 2020 12:00'	System	28 Aug 2020 15:13:20

US3432334

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 11 Aug 2021 22:41:12

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:04:43
User entered '04 Sep 2020 11:59'	System	28 Aug 2020 15:13:20

US3432334

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 11 Aug 2021 22:41:12

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:04:43
Data entry locked.	System	28 Aug 2020 15:13:20
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	28 Aug 2020 15:13:20

US3432334

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 11 Aug 2021 22:41:12

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 21:04:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C38FDA40-A52C-492B-ACED-AF41296DC535)', Time: '2020-08-28T11:23:55', User OID: 'PatientReportedOutcome (US3432334)', ODM File OID: '73c1ce4e-7e99-4a21-8333-828d58bc2660'	System	28 Aug 2020 15:24:14
User entered 'None (1)'	System	28 Aug 2020 15:24:14

US3432334

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 11 Aug 2021 22:41:12

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:04:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C38FDA40-A52C-492B-ACED-AF41296DC535)', Time: '2020-08-28T11:24:01', User OID: 'PatientReportedOutcome (US3432334)', ODM File OID: '73c1ce4e-7e99-4a21-8333-828d58bc2660' User entered 'No (N)'	System	28 Aug 2020 15:24:14
	System	28 Aug 2020 15:24:14

US3432334

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 11 Aug 2021 22:41:12

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:04:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C38FDA40-A52C-492B-ACED-AF41296DC535)', Time: '2020-08-28T11:24:04', User OID: 'PatientReportedOutcome (US3432334)', ODM File OID: '73c1ce4e-7e99-4a21-8333-828d58bc2660'	System	28 Aug 2020 15:24:14
User entered 'No (N)'	System	28 Aug 2020 15:24:14

US3432334

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 11 Aug 2021 22:41:12

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 21:04:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C38FDA40-A52C-492B-ACED-AF41296DC535)', Time: '2020-08-28T11:24:08', User OID: 'PatientReportedOutcome (US3432334)', ODM File OID: '73c1ce4e-7e99-4a21-8333-828d58bc2660'	System	28 Aug 2020 15:24:14
User entered 'None (1)'	System	28 Aug 2020 15:24:14

US3432334

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 11 Aug 2021 22:41:12

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:04:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C38FDA40-A52C-492B-ACED-AF41296DC535)', Time: '2020-08-28T11:24:11', User OID: 'PatientReportedOutcome (US3432334)', ODM File OID: '73c1ce4e-7e99-4a21-8333-828d58bc2660' User entered '28 Aug 2020 11:24'	System	28 Aug 2020 15:24:14
	System	28 Aug 2020 15:24:14

US3432334

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 11 Aug 2021 22:41:12

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:04:43
User entered '28 Aug 2020 11:01'	System	28 Aug 2020 15:13:20

US3432334

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 11 Aug 2021 22:41:12

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:04:43
User entered '28 Aug 2020 13:31'	System	28 Aug 2020 15:13:20

US3432334

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 11 Aug 2021 22:41:12

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:04:43
Data entry locked.	System	28 Aug 2020 15:13:20
User entered 'Day 1, after vaccination (at home)'	System	28 Aug 2020 15:13:20

US3432334

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 11 Aug 2021 22:41:12

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 21:04:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C38FDA40-A52C-492B-ACED-AF41296DC535)', Time: '2020-08-29T10:09:47', User OID: 'PatientReportedOutcome (US3432334)', ODM File OID: '65fdc107-aa93-4686-a2c7-0aa013845bbf'	System	29 Aug 2020 14:10:05
User entered 'Does not interfere with activity (2)'	System	29 Aug 2020 14:10:05

US3432334

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 11 Aug 2021 22:41:12

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:04:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C38FDA40-A52C-492B-ACED-AF41296DC535)', Time: '2020-08-29T10:09:51', User OID: 'PatientReportedOutcome (US3432334)', ODM File OID: '65fdc107-aa93-4686-a2c7-0aa013845bbf' User entered 'No (N)'	System	29 Aug 2020 14:10:05
	System	29 Aug 2020 14:10:05

US3432334

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 11 Aug 2021 22:41:12

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:04:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C38FDA40-A52C-492B-ACED-AF41296DC535)', Time: '2020-08-29T10:09:57', User OID: 'PatientReportedOutcome (US3432334)', ODM File OID: '65fdc107-aa93-4686-a2c7-0aa013845bbf'	System	29 Aug 2020 14:10:05
User entered 'No (N)'	System	29 Aug 2020 14:10:05

US3432334

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 11 Aug 2021 22:41:12

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 21:04:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C38FDA40-A52C-492B-ACED-AF41296DC535)', Time: '2020-08-29T10:10:00', User OID: 'PatientReportedOutcome (US3432334)', ODM File OID: '65fdc107-aa93-4686-a2c7-0aa013845bbf'	System	29 Aug 2020 14:10:05
User entered 'None (1)'	System	29 Aug 2020 14:10:05

US3432334

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 11 Aug 2021 22:41:12

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:04:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C38FDA40-A52C-492B-ACED-AF41296DC535)', Time: '2020-08-29T10:10:03', User OID: 'PatientReportedOutcome (US3432334)', ODM File OID: '65fdc107-aa93-4686-a2c7-0aa013845bbf' User entered '29 Aug 2020 10:10'	System	29 Aug 2020 14:10:05
	System	29 Aug 2020 14:10:05

US3432334

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 11 Aug 2021 22:41:12

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:04:43
User entered '28 Aug 2020 14:26'	System	28 Aug 2020 15:13:20

US3432334

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 11 Aug 2021 22:41:12

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:04:43
User entered '29 Aug 2020 11:59'	System	28 Aug 2020 15:13:20

US3432334

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 11 Aug 2021 22:41:12

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:04:43
Data entry locked.	System	28 Aug 2020 15:13:20
User entered 'Day 2'	System	28 Aug 2020 15:13:20

US3432334

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 11 Aug 2021 22:41:12

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 21:04:43

US3432334

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 11 Aug 2021 22:41:12

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:04:43

US3432334

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 11 Aug 2021 22:41:12

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

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:04:43

US3432334

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 11 Aug 2021 22:41:12

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:04:43

US3432334

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 11 Aug 2021 22:41:12

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

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:04:43

US3432334

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 11 Aug 2021 22:41:12

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 21:04:43

US3432334

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 11 Aug 2021 22:41:12

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:04:43

US3432334

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 11 Aug 2021 22:41:12

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:04:43
User entered '29 Aug 2020 12:00'	System	28 Aug 2020 15:13:20

US3432334

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 11 Aug 2021 22:41:12

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:04:43
User entered '30 Aug 2020 11:59'	System	28 Aug 2020 15:13:20

US3432334

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 11 Aug 2021 22:41:12

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:04:43
Data entry locked.	System	28 Aug 2020 15:13:20
User entered 'Day 3'	System	28 Aug 2020 15:13:20

US3432334

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 11 Aug 2021 22:41:12

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 21:04:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C38FDA40-A52C-492B-ACED-AF41296DC535)', Time: '2020-08-30T17:49:06', User OID: 'PatientReportedOutcome (US3432334)', ODM File OID: 'c28e2278-5fdc-40ac-aa4f-dc432fce8af9'	System	30 Aug 2020 21:49:24
User entered 'None (1)'	System	30 Aug 2020 21:49:24

US3432334

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 11 Aug 2021 22:41:12

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:04:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C38FDA40-A52C-492B-ACED-AF41296DC535)', Time: '2020-08-30T17:49:09', User OID: 'PatientReportedOutcome (US3432334)', ODM File OID: 'c28e2278-5fdc-40ac-aa4f-dc432fce8af9'	System	30 Aug 2020 21:49:24
User entered 'No (N)'	System	30 Aug 2020 21:49:24

US3432334

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 11 Aug 2021 22:41:12

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:04:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C38FDA40-A52C-492B-ACED-AF41296DC535)', Time: '2020-08-30T17:49:15', User OID: 'PatientReportedOutcome (US3432334)', ODM File OID: 'c28e2278-5fdc-40ac-aa4f-dc432fce8af9'	System	30 Aug 2020 21:49:24
User entered 'No (N)'	System	30 Aug 2020 21:49:24

US3432334

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 11 Aug 2021 22:41:12

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 21:04:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C38FDA40-A52C-492B-ACED-AF41296DC535)', Time: '2020-08-30T17:49:17', User OID: 'PatientReportedOutcome (US3432334)', ODM File OID: 'c28e2278-5fdc-40ac-aa4f-dc432fce8af9'	System	30 Aug 2020 21:49:24
User entered 'None (1)'	System	30 Aug 2020 21:49:24

US3432334

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 11 Aug 2021 22:41:12

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:04:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C38FDA40-A52C-492B-ACED-AF41296DC535)', Time: '2020-08-30T17:49:19', User OID: 'PatientReportedOutcome (US3432334)', ODM File OID: 'c28e2278-5fdc-40ac-aa4f-dc432fce8af9'	System	30 Aug 2020 21:49:24
User entered '30 Aug 2020 17:49'	System	30 Aug 2020 21:49:24

US3432334

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 11 Aug 2021 22:41:12

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:04:43
User entered '30 Aug 2020 12:00'	System	28 Aug 2020 15:13:20

US3432334

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 11 Aug 2021 22:41:12

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:04:43
User entered '31 Aug 2020 11:59'	System	28 Aug 2020 15:13:20

US3432334

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 11 Aug 2021 22:41:12

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:04:43
Data entry locked.	System	28 Aug 2020 15:13:20
User entered 'Day 4'	System	28 Aug 2020 15:13:20

US3432334

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 11 Aug 2021 22:41:12

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 21:04:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C38FDA40-A52C-492B-ACED-AF41296DC535)', Time: '2020-08-31T18:36:30', User OID: 'PatientReportedOutcome (US3432334)', ODM File OID: '4049a8a4-f9a5-4185-9dd1-3775b8d2dba4'	System	31 Aug 2020 22:37:50
User entered 'None (1)'	System	31 Aug 2020 22:37:50

US3432334

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 11 Aug 2021 22:41:12

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:04:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C38FDA40-A52C-492B-ACED-AF41296DC535)', Time: '2020-08-31T18:37:12', User OID: 'PatientReportedOutcome (US3432334)', ODM File OID: '4049a8a4-f9a5-4185-9dd1-3775b8d2dba4' User entered 'No (N)'	System	31 Aug 2020 22:37:50
	System	31 Aug 2020 22:37:50

US3432334

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 11 Aug 2021 22:41:12

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:04:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C38FDA40-A52C-492B-ACED-AF41296DC535)', Time: '2020-08-31T18:37:34', User OID: 'PatientReportedOutcome (US3432334)', ODM File OID: '4049a8a4-f9a5-4185-9dd1-3775b8d2dba4' User entered 'No (N)'	System	31 Aug 2020 22:37:50
	System	31 Aug 2020 22:37:50

US3432334

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 11 Aug 2021 22:41:12

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 21:04:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C38FDA40-A52C-492B-ACED-AF41296DC535)', Time: '2020-08-31T18:37:36', User OID: 'PatientReportedOutcome (US3432334)', ODM File OID: '4049a8a4-f9a5-4185-9dd1-3775b8d2dba4'	System	31 Aug 2020 22:37:50
User entered 'None (1)'	System	31 Aug 2020 22:37:50

US3432334

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 11 Aug 2021 22:41:12

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:04:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C38FDA40-A52C-492B-ACED-AF41296DC535)', Time: '2020-08-31T18:37:45', User OID: 'PatientReportedOutcome (US3432334)', ODM File OID: '4049a8a4-f9a5-4185-9dd1-3775b8d2dba4' User entered '31 Aug 2020 18:37'	System	31 Aug 2020 22:37:50
	System	31 Aug 2020 22:37:50

US3432334

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 11 Aug 2021 22:41:12

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:04:43
User entered '31 Aug 2020 12:00'	System	28 Aug 2020 15:13:20

US3432334

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 11 Aug 2021 22:41:12

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:04:43
User entered '01 Sep 2020 11:59'	System	28 Aug 2020 15:13:20

US3432334

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 11 Aug 2021 22:41:12

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:04:43
Data entry locked.	System	28 Aug 2020 15:13:20
User entered 'Day 5'	System	28 Aug 2020 15:13:20

US3432334

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 11 Aug 2021 22:41:12

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 21:04:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C38FDA40-A52C-492B-ACED-AF41296DC535)', Time: '2020-09-01T18:15:16', User OID: 'PatientReportedOutcome (US3432334)', ODM File OID: '4a34c94a-1085-4c6e-ba7c-0ec10bac909a'	System	01 Sep 2020 22:15:26
User entered 'None (1)'	System	01 Sep 2020 22:15:26

US3432334

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 11 Aug 2021 22:41:12

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:04:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C38FDA40-A52C-492B-ACED-AF41296DC535)', Time: '2020-09-01T18:15:17', User OID: 'PatientReportedOutcome (US3432334)', ODM File OID: '4a34c94a-1085-4c6e-ba7c-0ec10bac909a' User entered 'No (N)'	System	01 Sep 2020 22:15:26
	System	01 Sep 2020 22:15:26

US3432334

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 11 Aug 2021 22:41:12

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:04:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C38FDA40-A52C-492B-ACED-AF41296DC535)', Time: '2020-09-01T18:15:19', User OID: 'PatientReportedOutcome (US3432334)', ODM File OID: '4a34c94a-1085-4c6e-ba7c-0ec10bac909a' User entered 'No (N)'	System	01 Sep 2020 22:15:26
	System	01 Sep 2020 22:15:26

US3432334

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 11 Aug 2021 22:41:12

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 21:04:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C38FDA40-A52C-492B-ACED-AF41296DC535)', Time: '2020-09-01T18:15:21', User OID: 'PatientReportedOutcome (US3432334)', ODM File OID: '4a34c94a-1085-4c6e-ba7c-0ec10bac909a'	System	01 Sep 2020 22:15:26
User entered 'None (1)'	System	01 Sep 2020 22:15:26

US3432334

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 11 Aug 2021 22:41:12

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:04:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C38FDA40-A52C-492B-ACED-AF41296DC535)', Time: '2020-09-01T18:15:22', User OID: 'PatientReportedOutcome (US3432334)', ODM File OID: '4a34c94a-1085-4c6e-ba7c-0ec10bac909a' User entered '01 Sep 2020 18:15'	System	01 Sep 2020 22:15:26
	System	01 Sep 2020 22:15:26

US3432334

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 11 Aug 2021 22:41:12

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:04:43
User entered '01 Sep 2020 12:00'	System	28 Aug 2020 15:13:20

US3432334

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 11 Aug 2021 22:41:12

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:04:43
User entered '02 Sep 2020 11:59'	System	28 Aug 2020 15:13:20

US3432334

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 11 Aug 2021 22:41:12

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:04:43
Data entry locked.	System	28 Aug 2020 15:13:20
User entered 'Day 6'	System	28 Aug 2020 15:13:20

US3432334

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 11 Aug 2021 22:41:12

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 21:04:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C38FDA40-A52C-492B-ACED-AF41296DC535)', Time: '2020-09-02T18:06:53', User OID: 'PatientReportedOutcome (US3432334)', ODM File OID: '9e5afb97-b25c-43c1-9203-a88d38b458ec'	System	02 Sep 2020 22:07:04
User entered 'None (1)'	System	02 Sep 2020 22:07:04

US3432334

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 11 Aug 2021 22:41:12

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:04:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C38FDA40-A52C-492B-ACED-AF41296DC535)', Time: '2020-09-02T18:06:55', User OID: 'PatientReportedOutcome (US3432334)', ODM File OID: '9e5afb97-b25c-43c1-9203-a88d38b458ec' User entered 'No (N)'	System	02 Sep 2020 22:07:04
	System	02 Sep 2020 22:07:04

US3432334

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 11 Aug 2021 22:41:12

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:04:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C38FDA40-A52C-492B-ACED-AF41296DC535)', Time: '2020-09-02T18:06:56', User OID: 'PatientReportedOutcome (US3432334)', ODM File OID: '9e5afb97-b25c-43c1-9203-a88d38b458ec' User entered 'No (N)'	System	02 Sep 2020 22:07:04
	System	02 Sep 2020 22:07:04

US3432334

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 11 Aug 2021 22:41:12

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 21:04:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C38FDA40-A52C-492B-ACED-AF41296DC535)', Time: '2020-09-02T18:06:58', User OID: 'PatientReportedOutcome (US3432334)', ODM File OID: '9e5afb97-b25c-43c1-9203-a88d38b458ec'	System	02 Sep 2020 22:07:04
User entered 'None (1)'	System	02 Sep 2020 22:07:04

US3432334

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 11 Aug 2021 22:41:12

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:04:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C38FDA40-A52C-492B-ACED-AF41296DC535)', Time: '2020-09-02T18:06:59', User OID: 'PatientReportedOutcome (US3432334)', ODM File OID: '9e5afb97-b25c-43c1-9203-a88d38b458ec' User entered '02 Sep 2020 18:06'	System	02 Sep 2020 22:07:04
	System	02 Sep 2020 22:07:04

US3432334

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 11 Aug 2021 22:41:12

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:04:43
User entered '02 Sep 2020 12:00'	System	28 Aug 2020 15:13:20

US3432334

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 11 Aug 2021 22:41:12

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:04:43
User entered '03 Sep 2020 11:59'	System	28 Aug 2020 15:13:20

US3432334

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 11 Aug 2021 22:41:12

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:04:43
Data entry locked.	System	28 Aug 2020 15:13:20
User entered 'Day 7'	System	28 Aug 2020 15:13:20

US3432334

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 11 Aug 2021 22:41:12

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 21:04:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C38FDA40-A52C-492B-ACED-AF41296DC535)', Time: '2020-09-03T17:11:19', User OID: 'PatientReportedOutcome (US3432334)', ODM File OID: 'de63bf0e-c69e-453b-bf3c-869543f50e64'	System	03 Sep 2020 21:11:32
User entered 'None (1)'	System	03 Sep 2020 21:11:32

US3432334

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 11 Aug 2021 22:41:12

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:04:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C38FDA40-A52C-492B-ACED-AF41296DC535)', Time: '2020-09-03T17:11:22', User OID: 'PatientReportedOutcome (US3432334)', ODM File OID: 'de63bf0e-c69e-453b-bf3c-869543f50e64'	System	03 Sep 2020 21:11:32
User entered 'No (N)'	System	03 Sep 2020 21:11:32

US3432334

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 11 Aug 2021 22:41:12

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:04:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C38FDA40-A52C-492B-ACED-AF41296DC535)', Time: '2020-09-03T17:11:24', User OID: 'PatientReportedOutcome (US3432334)', ODM File OID: 'de63bf0e-c69e-453b-bf3c-869543f50e64'	System	03 Sep 2020 21:11:32
User entered 'No (N)'	System	03 Sep 2020 21:11:32

US3432334

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 11 Aug 2021 22:41:12

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 21:04:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C38FDA40-A52C-492B-ACED-AF41296DC535)', Time: '2020-09-03T17:11:25', User OID: 'PatientReportedOutcome (US3432334)', ODM File OID: 'de63bf0e-c69e-453b-bf3c-869543f50e64'	System	03 Sep 2020 21:11:32
User entered 'None (1)'	System	03 Sep 2020 21:11:32

US3432334

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 11 Aug 2021 22:41:12

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:04:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C38FDA40-A52C-492B-ACED-AF41296DC535)', Time: '2020-09-03T17:11:28', User OID: 'PatientReportedOutcome (US3432334)', ODM File OID: 'de63bf0e-c69e-453b-bf3c-869543f50e64'	System	03 Sep 2020 21:11:32
User entered '03 Sep 2020 17:11'	System	03 Sep 2020 21:11:32

US3432334

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 11 Aug 2021 22:41:12

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:04:43
User entered '03 Sep 2020 12:00'	System	28 Aug 2020 15:13:20

US3432334

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 11 Aug 2021 22:41:12

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:04:43
User entered '04 Sep 2020 11:59'	System	28 Aug 2020 15:13:20

US3432334

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 11 Aug 2021 22:41:12

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:04:43
Data entry locked.	System	28 Aug 2020 15:13:20
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	28 Aug 2020 15:13:20

US3432334

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 11 Aug 2021 22:41:12

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:04:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C38FDA40-A52C-492B-ACED-AF41296DC535)', Time: '2020-08-28T11:24:17', User OID: 'PatientReportedOutcome (US3432334)', ODM File OID: 'f9ae7b2c-1b28-4f59-bc04-1be2c29ab24d' User entered 'None (0)'	System	28 Aug 2020 15:24:34
	System	28 Aug 2020 15:24:34

US3432334

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 11 Aug 2021 22:41:12

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:04:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C38FDA40-A52C-492B-ACED-AF41296DC535)', Time: '2020-08-28T11:24:18', User OID: 'PatientReportedOutcome (US3432334)', ODM File OID: 'f9ae7b2c-1b28-4f59-bc04-1be2c29ab24d' User entered 'None (0)'	System	28 Aug 2020 15:24:34
	System	28 Aug 2020 15:24:34

US3432334

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 11 Aug 2021 22:41:12

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:04:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C38FDA40-A52C-492B-ACED-AF41296DC535)', Time: '2020-08-28T11:24:20', User OID: 'PatientReportedOutcome (US3432334)', ODM File OID: 'f9ae7b2c-1b28-4f59-bc04-1be2c29ab24d' User entered 'None (0)'	System	28 Aug 2020 15:24:34
	System	28 Aug 2020 15:24:34

US3432334

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 11 Aug 2021 22:41:12

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:04:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C38FDA40-A52C-492B-ACED-AF41296DC535)', Time: '2020-08-28T11:24:22', User OID: 'PatientReportedOutcome (US3432334)', ODM File OID: 'f9ae7b2c-1b28-4f59-bc04-1be2c29ab24d' User entered 'None (0)'	System	28 Aug 2020 15:24:34
	System	28 Aug 2020 15:24:34

US3432334

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 11 Aug 2021 22:41:12

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:04:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C38FDA40-A52C-492B-ACED-AF41296DC535)', Time: '2020-08-28T11:24:24', User OID: 'PatientReportedOutcome (US3432334)', ODM File OID: 'f9ae7b2c-1b28-4f59-bc04-1be2c29ab24d' User entered 'None (0)'	System	28 Aug 2020 15:24:34
	System	28 Aug 2020 15:24:34

US3432334

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 11 Aug 2021 22:41:12

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:04:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C38FDA40-A52C-492B-ACED-AF41296DC535)', Time: '2020-08-28T11:24:25', User OID: 'PatientReportedOutcome (US3432334)', ODM File OID: 'f9ae7b2c-1b28-4f59-bc04-1be2c29ab24d' User entered 'None (0)'	System	28 Aug 2020 15:24:34
	System	28 Aug 2020 15:24:34

US3432334

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 11 Aug 2021 22:41:12

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 21:04:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C38FDA40-A52C-492B-ACED-AF41296DC535)', Time: '2020-08-28T11:24:29', User OID: 'PatientReportedOutcome (US3432334)', ODM File OID: 'f9ae7b2c-1b28-4f59-bc04-1be2c29ab24d' User entered 'No (N)'	System	28 Aug 2020 15:24:34
	System	28 Aug 2020 15:24:34

US3432334

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 11 Aug 2021 22:41:12

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:04:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C38FDA40-A52C-492B-ACED-AF41296DC535)', Time: '2020-08-28T11:24:30', User OID: 'PatientReportedOutcome (US3432334)', ODM File OID: 'f9ae7b2c-1b28-4f59-bc04-1be2c29ab24d' User entered '28 Aug 2020 11:24'	System	28 Aug 2020 15:24:34
	System	28 Aug 2020 15:24:34

US3432334

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 11 Aug 2021 22:41:12

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:04:43
User entered '28 Aug 2020 11:01'	System	28 Aug 2020 15:13:20

US3432334

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 11 Aug 2021 22:41:12

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:04:43
User entered '28 Aug 2020 13:31'	System	28 Aug 2020 15:13:20

US3432334

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 11 Aug 2021 22:41:12

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:04:43
Data entry locked.	System	28 Aug 2020 15:13:20
User entered 'Day 1, after vaccination (at home)'	System	28 Aug 2020 15:13:20

US3432334

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 11 Aug 2021 22:41:12

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:04:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C38FDA40-A52C-492B-ACED-AF41296DC535)', Time: '2020-08-29T10:10:09', User OID: 'PatientReportedOutcome (US3432334)', ODM File OID: '804f15da-ba1c-4238-8f8e-a3b823e8edb6' User entered 'None (0)'	System	29 Aug 2020 14:10:29
	System	29 Aug 2020 14:10:29

US3432334

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 11 Aug 2021 22:41:12

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:04:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C38FDA40-A52C-492B-ACED-AF41296DC535)', Time: '2020-08-29T10:10:12', User OID: 'PatientReportedOutcome (US3432334)', ODM File OID: '804f15da-ba1c-4238-8f8e-a3b823e8edb6' User entered 'None (0)'	System	29 Aug 2020 14:10:29
	System	29 Aug 2020 14:10:29

US3432334

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 11 Aug 2021 22:41:12

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:04:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C38FDA40-A52C-492B-ACED-AF41296DC535)', Time: '2020-08-29T10:10:14', User OID: 'PatientReportedOutcome (US3432334)', ODM File OID: '804f15da-ba1c-4238-8f8e-a3b823e8edb6' User entered 'None (0)'	System	29 Aug 2020 14:10:29
	System	29 Aug 2020 14:10:29

US3432334

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 11 Aug 2021 22:41:12

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:04:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C38FDA40-A52C-492B-ACED-AF41296DC535)', Time: '2020-08-29T10:10:16', User OID: 'PatientReportedOutcome (US3432334)', ODM File OID: '804f15da-ba1c-4238-8f8e-a3b823e8edb6' User entered 'None (0)'	System	29 Aug 2020 14:10:29
	System	29 Aug 2020 14:10:29

US3432334

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 11 Aug 2021 22:41:12

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:04:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C38FDA40-A52C-492B-ACED-AF41296DC535)', Time: '2020-08-29T10:10:17', User OID: 'PatientReportedOutcome (US3432334)', ODM File OID: '804f15da-ba1c-4238-8f8e-a3b823e8edb6' User entered 'None (0)'	System	29 Aug 2020 14:10:29
	System	29 Aug 2020 14:10:29

US3432334

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 11 Aug 2021 22:41:12

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:04:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C38FDA40-A52C-492B-ACED-AF41296DC535)', Time: '2020-08-29T10:10:19', User OID: 'PatientReportedOutcome (US3432334)', ODM File OID: '804f15da-ba1c-4238-8f8e-a3b823e8edb6' User entered 'None (0)'	System	29 Aug 2020 14:10:29
	System	29 Aug 2020 14:10:29

US3432334

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 11 Aug 2021 22:41:12

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 21:04:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C38FDA40-A52C-492B-ACED-AF41296DC535)', Time: '2020-08-29T10:10:23', User OID: 'PatientReportedOutcome (US3432334)', ODM File OID: '804f15da-ba1c-4238-8f8e-a3b823e8edb6'	System	29 Aug 2020 14:10:29
User entered 'No (N)'	System	29 Aug 2020 14:10:29

US3432334

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 11 Aug 2021 22:41:12

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:04:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C38FDA40-A52C-492B-ACED-AF41296DC535)', Time: '2020-08-29T10:10:25', User OID: 'PatientReportedOutcome (US3432334)', ODM File OID: '804f15da-ba1c-4238-8f8e-a3b823e8edb6' User entered '29 Aug 2020 10:10'	System	29 Aug 2020 14:10:29
	System	29 Aug 2020 14:10:29

US3432334

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 11 Aug 2021 22:41:12

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:04:43
User entered '28 Aug 2020 14:26'	System	28 Aug 2020 15:13:20

US3432334

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 11 Aug 2021 22:41:12

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:04:43
User entered '29 Aug 2020 11:59'	System	28 Aug 2020 15:13:20

US3432334

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 11 Aug 2021 22:41:12

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:04:43
Data entry locked.	System	28 Aug 2020 15:13:20
User entered 'Day 2'	System	28 Aug 2020 15:13:20

US3432334

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 11 Aug 2021 22:41:12

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:04:43

US3432334

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 11 Aug 2021 22:41:12

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:04:43

US3432334

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 11 Aug 2021 22:41:12

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:04:43

US3432334

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 11 Aug 2021 22:41:12

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:04:43

US3432334

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 11 Aug 2021 22:41:12

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:04:43

US3432334

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 11 Aug 2021 22:41:12

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:04:43

US3432334

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 11 Aug 2021 22:41:12

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 21:04:43

US3432334

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 11 Aug 2021 22:41:12

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:04:43

US3432334

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 11 Aug 2021 22:41:12

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:04:43
User entered '29 Aug 2020 12:00'	System	28 Aug 2020 15:13:20

US3432334

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 11 Aug 2021 22:41:12

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:04:43
User entered '30 Aug 2020 11:59'	System	28 Aug 2020 15:13:20

US3432334

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 11 Aug 2021 22:41:12

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:04:43
Data entry locked.	System	28 Aug 2020 15:13:20
User entered 'Day 3'	System	28 Aug 2020 15:13:20

US3432334

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 11 Aug 2021 22:41:12

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:04:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C38FDA40-A52C-492B-ACED-AF41296DC535)', Time: '2020-08-30T17:49:23', User OID: 'PatientReportedOutcome (US3432334)', ODM File OID: 'a902c62d-abca-4f69-9d9a-bbd5bee84377' User entered 'None (0)'	System	30 Aug 2020 21:49:40
	System	30 Aug 2020 21:49:40

US3432334

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 11 Aug 2021 22:41:12

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:04:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C38FDA40-A52C-492B-ACED-AF41296DC535)', Time: '2020-08-30T17:49:24', User OID: 'PatientReportedOutcome (US3432334)', ODM File OID: 'a902c62d-abca-4f69-9d9a-bbd5bee84377' User entered 'None (0)'	System	30 Aug 2020 21:49:40
	System	30 Aug 2020 21:49:40

US3432334

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 11 Aug 2021 22:41:12

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:04:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C38FDA40-A52C-492B-ACED-AF41296DC535)', Time: '2020-08-30T17:49:27', User OID: 'PatientReportedOutcome (US3432334)', ODM File OID: 'a902c62d-abca-4f69-9d9a-bbd5bee84377' User entered 'None (0)'	System	30 Aug 2020 21:49:40
	System	30 Aug 2020 21:49:40

US3432334

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 11 Aug 2021 22:41:12

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:04:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C38FDA40-A52C-492B-ACED-AF41296DC535)', Time: '2020-08-30T17:49:28', User OID: 'PatientReportedOutcome (US3432334)', ODM File OID: 'a902c62d-abca-4f69-9d9a-bbd5bee84377' User entered 'None (0)'	System	30 Aug 2020 21:49:40
	System	30 Aug 2020 21:49:40

US3432334

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 11 Aug 2021 22:41:12

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:04:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C38FDA40-A52C-492B-ACED-AF41296DC535)', Time: '2020-08-30T17:49:29', User OID: 'PatientReportedOutcome (US3432334)', ODM File OID: 'a902c62d-abca-4f69-9d9a-bbd5bee84377' User entered 'None (0)'	System	30 Aug 2020 21:49:40
	System	30 Aug 2020 21:49:40

US3432334

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 11 Aug 2021 22:41:12

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:04:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C38FDA40-A52C-492B-ACED-AF41296DC535)', Time: '2020-08-30T17:49:30', User OID: 'PatientReportedOutcome (US3432334)', ODM File OID: 'a902c62d-abca-4f69-9d9a-bbd5bee84377' User entered 'None (0)'	System	30 Aug 2020 21:49:40
	System	30 Aug 2020 21:49:40

US3432334

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 11 Aug 2021 22:41:12

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 21:04:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C38FDA40-A52C-492B-ACED-AF41296DC535)', Time: '2020-08-30T17:49:34', User OID: 'PatientReportedOutcome (US3432334)', ODM File OID: 'a902c62d-abca-4f69-9d9a-bbd5bee84377'	System	30 Aug 2020 21:49:40
User entered 'No (N)'	System	30 Aug 2020 21:49:40

US3432334

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 11 Aug 2021 22:41:12

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:04:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C38FDA40-A52C-492B-ACED-AF41296DC535)', Time: '2020-08-30T17:49:36', User OID: 'PatientReportedOutcome (US3432334)', ODM File OID: 'a902c62d-abca-4f69-9d9a-bbd5bee84377' User entered '30 Aug 2020 17:49'	System	30 Aug 2020 21:49:40
	System	30 Aug 2020 21:49:40

US3432334

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 11 Aug 2021 22:41:12

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:04:43
User entered '30 Aug 2020 12:00'	System	28 Aug 2020 15:13:20

US3432334

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 11 Aug 2021 22:41:12

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:04:43
User entered '31 Aug 2020 11:59'	System	28 Aug 2020 15:13:20

US3432334

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 11 Aug 2021 22:41:12

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:04:43
Data entry locked.	System	28 Aug 2020 15:13:20
User entered 'Day 4'	System	28 Aug 2020 15:13:20

US3432334

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 11 Aug 2021 22:41:12

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:04:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C38FDA40-A52C-492B-ACED-AF41296DC535)', Time: '2020-08-31T18:37:54', User OID: 'PatientReportedOutcome (US3432334)', ODM File OID: 'cff938c6-a791-4f79-bc43-f2d386f9f75d'	System	31 Aug 2020 22:38:18
User entered 'No interference with activity (1)'	System	31 Aug 2020 22:38:18

US3432334

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 11 Aug 2021 22:41:12

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:04:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C38FDA40-A52C-492B-ACED-AF41296DC535)', Time: '2020-08-31T18:38:01', User OID: 'PatientReportedOutcome (US3432334)', ODM File OID: 'cff938c6-a791-4f79-bc43-f2d386f9f75d'	System	31 Aug 2020 22:38:18
User entered 'None (0)'	System	31 Aug 2020 22:38:18

US3432334

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 11 Aug 2021 22:41:12

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:04:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C38FDA40-A52C-492B-ACED-AF41296DC535)', Time: '2020-08-31T18:38:02', User OID: 'PatientReportedOutcome (US3432334)', ODM File OID: 'cff938c6-a791-4f79-bc43-f2d386f9f75d'	System	31 Aug 2020 22:38:18
User entered 'None (0)'	System	31 Aug 2020 22:38:18

US3432334

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 11 Aug 2021 22:41:12

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:04:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C38FDA40-A52C-492B-ACED-AF41296DC535)', Time: '2020-08-31T18:38:03', User OID: 'PatientReportedOutcome (US3432334)', ODM File OID: 'cff938c6-a791-4f79-bc43-f2d386f9f75d' User entered 'None (0)'	System	31 Aug 2020 22:38:18
	System	31 Aug 2020 22:38:18

US3432334

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 11 Aug 2021 22:41:12

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:04:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C38FDA40-A52C-492B-ACED-AF41296DC535)', Time: '2020-08-31T18:38:05', User OID: 'PatientReportedOutcome (US3432334)', ODM File OID: 'cff938c6-a791-4f79-bc43-f2d386f9f75d'	System	31 Aug 2020 22:38:18
User entered 'None (0)'	System	31 Aug 2020 22:38:18

US3432334

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 11 Aug 2021 22:41:12

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:04:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C38FDA40-A52C-492B-ACED-AF41296DC535)', Time: '2020-08-31T18:38:06', User OID: 'PatientReportedOutcome (US3432334)', ODM File OID: 'cff938c6-a791-4f79-bc43-f2d386f9f75d'	System	31 Aug 2020 22:38:18
User entered 'None (0)'	System	31 Aug 2020 22:38:18

US3432334

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 11 Aug 2021 22:41:12

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 21:04:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C38FDA40-A52C-492B-ACED-AF41296DC535)', Time: '2020-08-31T18:38:08', User OID: 'PatientReportedOutcome (US3432334)', ODM File OID: 'cff938c6-a791-4f79-bc43-f2d386f9f75d'	System	31 Aug 2020 22:38:18
User entered 'No (N)'	System	31 Aug 2020 22:38:18

US3432334

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 11 Aug 2021 22:41:12

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:04:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C38FDA40-A52C-492B-ACED-AF41296DC535)', Time: '2020-08-31T18:38:10', User OID: 'PatientReportedOutcome (US3432334)', ODM File OID: 'cff938c6-a791-4f79-bc43-f2d386f9f75d'	System	31 Aug 2020 22:38:18
User entered '31 Aug 2020 18:38'	System	31 Aug 2020 22:38:18

US3432334

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 11 Aug 2021 22:41:12

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:04:43
User entered '31 Aug 2020 12:00'	System	28 Aug 2020 15:13:20

US3432334

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 11 Aug 2021 22:41:12

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:04:43
User entered '01 Sep 2020 11:59'	System	28 Aug 2020 15:13:20

US3432334

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 11 Aug 2021 22:41:12

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:04:43
Data entry locked.	System	28 Aug 2020 15:13:20
User entered 'Day 5'	System	28 Aug 2020 15:13:20

US3432334

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 11 Aug 2021 22:41:12

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:04:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C38FDA40-A52C-492B-ACED-AF41296DC535)', Time: '2020-09-01T18:15:25', User OID: 'PatientReportedOutcome (US3432334)', ODM File OID: '6ece0dfa-943e-4603-9ad3-77d8c240505c' User entered 'None (0)'	System	01 Sep 2020 22:15:40
	System	01 Sep 2020 22:15:40

US3432334

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 11 Aug 2021 22:41:12

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:04:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C38FDA40-A52C-492B-ACED-AF41296DC535)', Time: '2020-09-01T18:15:28', User OID: 'PatientReportedOutcome (US3432334)', ODM File OID: '6ece0dfa-943e-4603-9ad3-77d8c240505c' User entered 'None (0)'	System	01 Sep 2020 22:15:40
	System	01 Sep 2020 22:15:40

US3432334

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 11 Aug 2021 22:41:12

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:04:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C38FDA40-A52C-492B-ACED-AF41296DC535)', Time: '2020-09-01T18:15:29', User OID: 'PatientReportedOutcome (US3432334)', ODM File OID: '6ece0dfa-943e-4603-9ad3-77d8c240505c' User entered 'None (0)'	System	01 Sep 2020 22:15:40
	System	01 Sep 2020 22:15:40

US3432334

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 11 Aug 2021 22:41:12

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:04:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C38FDA40-A52C-492B-ACED-AF41296DC535)', Time: '2020-09-01T18:15:30', User OID: 'PatientReportedOutcome (US3432334)', ODM File OID: '6ece0dfa-943e-4603-9ad3-77d8c240505c' User entered 'None (0)'	System	01 Sep 2020 22:15:40
	System	01 Sep 2020 22:15:40

US3432334

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 11 Aug 2021 22:41:12

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:04:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C38FDA40-A52C-492B-ACED-AF41296DC535)', Time: '2020-09-01T18:15:31', User OID: 'PatientReportedOutcome (US3432334)', ODM File OID: '6ece0dfa-943e-4603-9ad3-77d8c240505c' User entered 'None (0)'	System	01 Sep 2020 22:15:40
	System	01 Sep 2020 22:15:40

US3432334

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 11 Aug 2021 22:41:12

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:04:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C38FDA40-A52C-492B-ACED-AF41296DC535)', Time: '2020-09-01T18:15:33', User OID: 'PatientReportedOutcome (US3432334)', ODM File OID: '6ece0dfa-943e-4603-9ad3-77d8c240505c' User entered 'None (0)'	System	01 Sep 2020 22:15:40
	System	01 Sep 2020 22:15:40

US3432334

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 11 Aug 2021 22:41:12

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 21:04:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C38FDA40-A52C-492B-ACED-AF41296DC535)', Time: '2020-09-01T18:15:34', User OID: 'PatientReportedOutcome (US3432334)', ODM File OID: '6ece0dfa-943e-4603-9ad3-77d8c240505c' User entered 'No (N)'	System	01 Sep 2020 22:15:40
	System	01 Sep 2020 22:15:40

US3432334

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 11 Aug 2021 22:41:12

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:04:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C38FDA40-A52C-492B-ACED-AF41296DC535)', Time: '2020-09-01T18:15:36', User OID: 'PatientReportedOutcome (US3432334)', ODM File OID: '6ece0dfa-943e-4603-9ad3-77d8c240505c' User entered '01 Sep 2020 18:15'	System	01 Sep 2020 22:15:40
	System	01 Sep 2020 22:15:40

US3432334

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 11 Aug 2021 22:41:12

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:04:43
User entered '01 Sep 2020 12:00'	System	28 Aug 2020 15:13:20

US3432334

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 11 Aug 2021 22:41:12

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:04:43
User entered '02 Sep 2020 11:59'	System	28 Aug 2020 15:13:20

US3432334

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 11 Aug 2021 22:41:12

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:04:43
Data entry locked.	System	28 Aug 2020 15:13:20
User entered 'Day 6'	System	28 Aug 2020 15:13:20

US3432334

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 11 Aug 2021 22:41:12

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:04:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C38FDA40-A52C-492B-ACED-AF41296DC535)', Time: '2020-09-02T18:07:02', User OID: 'PatientReportedOutcome (US3432334)', ODM File OID: '1bceef0d-5c6d-4503-bb91-569403eeaa9d' User entered 'None (0)'	System	02 Sep 2020 22:07:16
	System	02 Sep 2020 22:07:16

US3432334

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 11 Aug 2021 22:41:12

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:04:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C38FDA40-A52C-492B-ACED-AF41296DC535)', Time: '2020-09-02T18:07:03', User OID: 'PatientReportedOutcome (US3432334)', ODM File OID: '1bceef0d-5c6d-4503-bb91-569403eeaa9d' User entered 'None (0)'	System	02 Sep 2020 22:07:16
	System	02 Sep 2020 22:07:16

US3432334

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 11 Aug 2021 22:41:12

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:04:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C38FDA40-A52C-492B-ACED-AF41296DC535)', Time: '2020-09-02T18:07:05', User OID: 'PatientReportedOutcome (US3432334)', ODM File OID: '1bceef0d-5c6d-4503-bb91-569403eeaa9d' User entered 'None (0)'	System	02 Sep 2020 22:07:16
	System	02 Sep 2020 22:07:16

US3432334

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 11 Aug 2021 22:41:12

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:04:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C38FDA40-A52C-492B-ACED-AF41296DC535)', Time: '2020-09-02T18:07:06', User OID: 'PatientReportedOutcome (US3432334)', ODM File OID: '1bceef0d-5c6d-4503-bb91-569403eeaa9d' User entered 'None (0)'	System	02 Sep 2020 22:07:16
	System	02 Sep 2020 22:07:16

US3432334

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 11 Aug 2021 22:41:12

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:04:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C38FDA40-A52C-492B-ACED-AF41296DC535)', Time: '2020-09-02T18:07:07', User OID: 'PatientReportedOutcome (US3432334)', ODM File OID: '1bceef0d-5c6d-4503-bb91-569403eeaa9d' User entered 'None (0)'	System	02 Sep 2020 22:07:16
	System	02 Sep 2020 22:07:16

US3432334

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 11 Aug 2021 22:41:12

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:04:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C38FDA40-A52C-492B-ACED-AF41296DC535)', Time: '2020-09-02T18:07:08', User OID: 'PatientReportedOutcome (US3432334)', ODM File OID: '1bceef0d-5c6d-4503-bb91-569403eeaa9d' User entered 'None (0)'	System	02 Sep 2020 22:07:16
	System	02 Sep 2020 22:07:16

US3432334

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 11 Aug 2021 22:41:12

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 21:04:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C38FDA40-A52C-492B-ACED-AF41296DC535)', Time: '2020-09-02T18:07:11', User OID: 'PatientReportedOutcome (US3432334)', ODM File OID: '1bceef0d-5c6d-4503-bb91-569403eeaa9d' User entered 'No (N)'	System	02 Sep 2020 22:07:16
	System	02 Sep 2020 22:07:16

US3432334

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 11 Aug 2021 22:41:12

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:04:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C38FDA40-A52C-492B-ACED-AF41296DC535)', Time: '2020-09-02T18:07:13', User OID: 'PatientReportedOutcome (US3432334)', ODM File OID: '1bceef0d-5c6d-4503-bb91-569403eeaa9d' User entered '02 Sep 2020 18:07'	System	02 Sep 2020 22:07:16
	System	02 Sep 2020 22:07:16

US3432334

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 11 Aug 2021 22:41:12

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:04:43
User entered '02 Sep 2020 12:00'	System	28 Aug 2020 15:13:20

US3432334

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 11 Aug 2021 22:41:12

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:04:43
User entered '03 Sep 2020 11:59'	System	28 Aug 2020 15:13:20

US3432334

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 11 Aug 2021 22:41:12

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:04:43
Data entry locked.	System	28 Aug 2020 15:13:20
User entered 'Day 7'	System	28 Aug 2020 15:13:20

US3432334

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 11 Aug 2021 22:41:12

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:04:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C38FDA40-A52C-492B-ACED-AF41296DC535)', Time: '2020-09-03T17:11:03', User OID: 'PatientReportedOutcome (US3432334)', ODM File OID: '7440fb8f-cb59-4ea6-82e6-7f96d77ddb78' User entered 'None (0)'	System	03 Sep 2020 21:11:17
	System	03 Sep 2020 21:11:17

US3432334

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 11 Aug 2021 22:41:12

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:04:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C38FDA40-A52C-492B-ACED-AF41296DC535)', Time: '2020-09-03T17:11:05', User OID: 'PatientReportedOutcome (US3432334)', ODM File OID: '7440fb8f-cb59-4ea6-82e6-7f96d77ddb78' User entered 'None (0)'	System	03 Sep 2020 21:11:17
	System	03 Sep 2020 21:11:17

US3432334

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 11 Aug 2021 22:41:12

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:04:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C38FDA40-A52C-492B-ACED-AF41296DC535)', Time: '2020-09-03T17:11:06', User OID: 'PatientReportedOutcome (US3432334)', ODM File OID: '7440fb8f-cb59-4ea6-82e6-7f96d77ddb78' User entered 'None (0)'	System	03 Sep 2020 21:11:17
	System	03 Sep 2020 21:11:17

US3432334

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 11 Aug 2021 22:41:12

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:04:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C38FDA40-A52C-492B-ACED-AF41296DC535)', Time: '2020-09-03T17:11:09', User OID: 'PatientReportedOutcome (US3432334)', ODM File OID: '7440fb8f-cb59-4ea6-82e6-7f96d77ddb78' User entered 'None (0)'	System	03 Sep 2020 21:11:17
	System	03 Sep 2020 21:11:17

US3432334

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 11 Aug 2021 22:41:12

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:04:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C38FDA40-A52C-492B-ACED-AF41296DC535)', Time: '2020-09-03T17:11:10', User OID: 'PatientReportedOutcome (US3432334)', ODM File OID: '7440fb8f-cb59-4ea6-82e6-7f96d77ddb78' User entered 'None (0)'	System	03 Sep 2020 21:11:17
	System	03 Sep 2020 21:11:17

US3432334

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 11 Aug 2021 22:41:12

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:04:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C38FDA40-A52C-492B-ACED-AF41296DC535)', Time: '2020-09-03T17:11:11', User OID: 'PatientReportedOutcome (US3432334)', ODM File OID: '7440fb8f-cb59-4ea6-82e6-7f96d77ddb78' User entered 'None (0)'	System	03 Sep 2020 21:11:17
	System	03 Sep 2020 21:11:17

US3432334

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 11 Aug 2021 22:41:12

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 21:04:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C38FDA40-A52C-492B-ACED-AF41296DC535)', Time: '2020-09-03T17:11:14', User OID: 'PatientReportedOutcome (US3432334)', ODM File OID: '7440fb8f-cb59-4ea6-82e6-7f96d77ddb78' User entered 'No (N)'	System	03 Sep 2020 21:11:17
	System	03 Sep 2020 21:11:17

US3432334

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 11 Aug 2021 22:41:12

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:04:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C38FDA40-A52C-492B-ACED-AF41296DC535)', Time: '2020-09-03T17:11:15', User OID: 'PatientReportedOutcome (US3432334)', ODM File OID: '7440fb8f-cb59-4ea6-82e6-7f96d77ddb78' User entered '03 Sep 2020 17:11'	System	03 Sep 2020 21:11:17
	System	03 Sep 2020 21:11:17

US3432334

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 11 Aug 2021 22:41:12

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:04:43
User entered '03 Sep 2020 12:00'	System	28 Aug 2020 15:13:20

US3432334

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 11 Aug 2021 22:41:12

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:04:43
User entered '04 Sep 2020 11:59'	System	28 Aug 2020 15:13:20

US3432334

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:41:12

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:15:38
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:29:40
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 21:06:36
User entered 'Yes (Y)'	Phoebe Cunningham (b) (4)	04 Sep 2020 23:36:41

US3432334

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:41:12

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:15:38
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:29:40
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 21:06:36
User entered '4 Sep 2020'	Phoebe Cunningham (b) (4)	04 Sep 2020 23:36:41

US3432334

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:41:12

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:15:38
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:29:40
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 21:06:36
User entered 'Contact Made (CONTACT MADE)'	Phoebe Cunningham (b) (4)	04 Sep 2020 23:36:41

US3432334

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:41:12

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:15:38
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:29:40
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 21:06:36
User entered empty.	Phoebe Cunningham (b) (4)	04 Sep 2020 23:36:41

US3432334

Folder: Safety Call Day 8 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:41:12

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:15:38
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:29:40
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 21:06:39
User entered 'Yes (Y)'	(b) (4), (b) (6)	11 Sep 2020 17:00:42

US3432334

Folder: Safety Call Day 8 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:41:12

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:15:38
User entered 'I'	System	11 Sep 2020 17:00:42

US3432334

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:41:12

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:15:38
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:29:40
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 21:06:42
User entered 'Yes (Y)'	(b) (4), (b) (6)	11 Sep 2020 17:01:51

US3432334

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:41:12

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:15:38
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:29:40
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 21:06:42
User entered '11 Sep 2020'	(b) (4), (b) (6)	11 Sep 2020 17:01:51

US3432334

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:41:12

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:15:38
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:29:40
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 21:06:42
User entered 'Contact Made (CONTACT MADE)'	(b) (4), (b) (6)	11 Sep 2020 17:01:51

US3432334

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:41:12

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:15:38
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:29:40
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 21:06:42
User entered empty.	(b) (4), (b) (6)	11 Sep 2020 17:01:51

US3432334

Folder: Safety Call Day 15 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:41:12

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:15:38
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:29:40
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 21:06:45
User entered 'Yes (Y)'	(b) (4), (b) (6)	11 Sep 2020 17:01:56

US3432334

Folder: Safety Call Day 15 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:41:12

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:15:38
User entered 'I'	System	11 Sep 2020 17:01:56

US3432334

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:41:12

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:15:38
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:29:40
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 21:06:49
User entered 'Yes (Y)'	Phoebe Cunningham (b) (4)	21 Sep 2020 16:07:58

US3432334

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:41:12

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:15:38
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:29:40
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 21:06:49
User entered '18 Sep 2020'	Phoebe Cunningham (b) (4)	21 Sep 2020 16:07:58

US3432334

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:41:12

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:15:38
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:29:40
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 21:06:49
User entered 'Contact Made (CONTACT MADE)'	Phoebe Cunningham (b) (4)	21 Sep 2020 16:07:58

US3432334

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:41:12

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:15:38
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:29:40
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 21:06:49
User entered empty.	Phoebe Cunningham (b) (4)	21 Sep 2020 16:07:58

US3432334

Folder: Safety Call Day 22 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:41:12

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:15:38
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:29:40
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 21:07:25
User entered 'Yes (Y)'	Natalie Izaguirre (b) (4)	29 Sep 2020 00:05:08

US3432334

Folder: Safety Call Day 22 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:41:12

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:15:38
User entered 'I'	System	29 Sep 2020 00:05:08

US3432334

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 11 Aug 2021 22:41:12

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:59:50
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:30:01
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 21:10:09
User entered 'Yes (Y)'	Natalie Izaguirre (b) (4)	29 Sep 2020 00:07:32

US3432334

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 11 Aug 2021 22:41:12

Visit date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:59:50
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:30:01
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 21:10:09
User entered '28 Sep 2020'	Natalie Izaguirre (b) (4)	29 Sep 2020 00:07:32

US3432334

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 11 Aug 2021 22:41:12

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 08:59:50
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:30:01
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 21:10:09
User entered 'Clinic (Clinic)'	Natalie Izaguirre (b) (4)	29 Sep 2020 00:07:32

US3432334

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 11 Aug 2021 22:41:12

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:59:50
User entered 'VISIT2'	System	29 Sep 2020 00:07:32

US3432334

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:41:12

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:59:50
User accepted default value 'Pre-Dose (PREDOSE)'	Natalie Izaguirre (b) (4) (b) (4)	29 Sep 2020 00:08:23

US3432334

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:41:12

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:59:50
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:30:01
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 21:10:51
User entered 'Yes (Y)'	Natalie Izaguirre (b) (4)	29 Sep 2020 00:08:23

US3432334

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:41:12

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:59:50
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:30:01
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 21:10:51
User entered '28 Sep 2020'	Natalie Izaguirre (b) (4)	29 Sep 2020 00:08:23

US3432334

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:41:12

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:59:50
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:30:01
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 21:10:51
User entered '14:28'	Natalie Izaguirre (b) (4)	29 Sep 2020 00:08:23

US3432334

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:41:12

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:59:50
User entered '28 Sep 2020 14:28'	System	29 Sep 2020 00:08:23

US3432334

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:41:12

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:59:50
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:30:01
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 21:10:51
User entered '97.7' F	Natalie Izaguirre (b) (4)	29 Sep 2020 00:08:23

US3432334

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:41:12

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:59:50
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:30:01
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 21:10:51
User entered 'Other (Other)'	Natalie Izaguirre (b) (4)	29 Sep 2020 00:08:23

US3432334

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:41:12

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:59:50
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:30:01
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 21:10:51
User entered 'infrared'	Natalie Izaguirre (b) (4)	29 Sep 2020 00:08:23

US3432334

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:41:12

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:59:50
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:30:01
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 21:10:51
User entered '60'	Natalie Izaguirre (b) (4)	29 Sep 2020 00:08:23

US3432334

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:41:12

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:59:50
User entered 'bpm'	System	29 Sep 2020 00:08:23

US3432334

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:41:12

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:59:50
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:30:01
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 21:10:51
User entered '12'	Natalie Izaguirre (b) (4)	29 Sep 2020 00:08:23

US3432334

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:41:12

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:59:50
User entered 'breaths/min'	System	29 Sep 2020 00:08:23

US3432334

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:41:12

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:59:50
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:30:01
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 21:10:51
User entered '120'	Natalie Izaguirre (b) (4)	29 Sep 2020 00:08:23

US3432334

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:41:12

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:59:50
User entered 'mmHg'	System	29 Sep 2020 00:08:23

US3432334

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:41:12

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:59:50
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:30:01
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 21:10:51
User entered '66'	Natalie Izaguirre (b) (4)	29 Sep 2020 00:08:23

US3432334

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:41:12

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:59:50
User entered 'mmHg'	System	29 Sep 2020 00:08:23

US3432334

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:41:12

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:59:50
User accepted default value 'Post-Dose (POSTDOSE)'	Natalie Izaguirre (b) (4) (b) (4)	29 Sep 2020 00:08:23

US3432334

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:41:12

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:59:50
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:30:01
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 21:10:51
User entered 'No (N)'	Natalie Izaguirre (b) (4)	29 Sep 2020 00:08:23

US3432334

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:41:12

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:59:50
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:30:01
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 21:10:51
User entered empty.	Natalie Izaguirre (b) (4)	29 Sep 2020 00:08:23

US3432334

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:41:12

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:59:50
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:30:01
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 21:10:51
User entered empty.	Natalie Izaguirre (b) (4)	29 Sep 2020 00:08:23

US3432334

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:41:12

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:59:50
User entered empty.	System	29 Sep 2020 00:08:23

US3432334

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:41:12

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:59:50
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:30:01
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 21:10:51
User entered empty.	Natalie Izaguirre (b) (4)	29 Sep 2020 00:08:23

US3432334

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:41:12

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:59:50
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:30:01
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 21:10:51
User entered empty.	Natalie Izaguirre (b) (4)	29 Sep 2020 00:08:23

US3432334

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:41:12

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:59:50
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:30:01
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 21:10:51
User entered empty.	Natalie Izaguirre (b) (4)	29 Sep 2020 00:08:23

US3432334

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:41:12

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:59:50
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:30:01
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 21:10:51
User entered empty.	Natalie Izaguirre (b) (4)	29 Sep 2020 00:08:23

US3432334

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:41:12

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:59:50
User entered empty.	System	29 Sep 2020 00:08:23

US3432334

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:41:12

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:59:50
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:30:01
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 21:10:51
User entered empty.	Natalie Izaguirre (b) (4)	29 Sep 2020 00:08:23

US3432334

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:41:12

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:59:50
User entered empty.	System	29 Sep 2020 00:08:23

US3432334

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:41:12

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:59:50
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:30:01
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 21:10:51
User entered empty.	Natalie Izaguirre (b) (4)	29 Sep 2020 00:08:23

US3432334

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:41:12

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:59:50
User entered empty.	System	29 Sep 2020 00:08:23

US3432334

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:41:12

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:59:50
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:30:01
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 21:10:51
User entered empty.	Natalie Izaguirre (b) (4)	29 Sep 2020 00:08:23

US3432334

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:41:12

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:59:50
User entered empty.	System	29 Sep 2020 00:08:23

US3432334

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Generated On: 11 Aug 2021 22:41:12

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:59:50
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:30:01
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 21:10:54
User entered 'Yes (Y)'	Natalie Izaguirre (b) (4)	29 Sep 2020 00:08:39

US3432334

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Generated On: 11 Aug 2021 22:41:12

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:59:50
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:30:01
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 21:10:54
User entered '28 Sep 2020'	Natalie Izaguirre (b) (4)	29 Sep 2020 00:08:39

US3432334

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 11 Aug 2021 22:41:12

[Was study treatment given?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:59:50
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:30:01
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 21:02:48
User entered 'No (N)'	Natalie Izaguirre (b) (4)	29 Sep 2020 00:09:24

US3432334

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 11 Aug 2021 22:41:12

[If No, reason not given](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:59:50
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:30:01
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 21:02:48
User entered 'Physician withheld dose due to Adverse Event (PHYSICIAN AE)'	Natalie Izaguirre (b) (4)	29 Sep 2020 00:09:24

US3432334

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 11 Aug 2021 22:41:12

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 08:59:50
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:30:01
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 21:02:48
User entered empty.	Natalie Izaguirre (b) (4)	29 Sep 2020 00:09:24

US3432334

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 11 Aug 2021 22:41:12

[What was the study treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:59:50
User entered empty.	System	29 Sep 2020 00:09:24

US3432334

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 11 Aug 2021 22:41:12

What was the treatment date? (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:59:50
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:30:01
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 21:02:48
User entered empty.	Natalie Izaguirre (b) (4)	29 Sep 2020 00:09:24

US3432334

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 11 Aug 2021 22:41:12

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:59:50
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:30:01
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 21:02:48
User entered empty.	Natalie Izaguirre (b) (4)	29 Sep 2020 00:09:24

US3432334

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 11 Aug 2021 22:41:12

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:59:50
User entered empty.	System	29 Sep 2020 00:09:24

US3432334

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 11 Aug 2021 22:41:12

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:59:50
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:30:01
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 21:02:48
User entered empty.	Natalie Izaguirre (b) (4)	29 Sep 2020 00:09:24

US3432334

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 11 Aug 2021 22:41:12

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:59:50
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 21:02:48
User entered empty.	System	29 Sep 2020 00:09:24

US3432334

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 11 Aug 2021 22:41:12

What was the route of administration for the study treatment?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:59:50
User entered empty.	System	29 Sep 2020 00:09:24

US3432334

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 22:41:12

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:59:50
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:30:01
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 21:11:04
User entered 'Yes (Y)'	Natalie Izaguirre (b) (4)	29 Sep 2020 00:09:42

US3432334

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 22:41:12

Collection date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:59:50
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:30:01
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 21:11:04
User entered '28 Sep 2020'	Natalie Izaguirre (b) (4)	29 Sep 2020 00:09:42

US3432334

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 22:41:12

Collection time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:59:50
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:30:01
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 21:11:04
User entered '14:40'	Natalie Izaguirre (b) (4)	29 Sep 2020 00:09:42

US3432334

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 22:41:12

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:59:50
User entered '28 Sep 2020 14:40'	System	29 Sep 2020 00:09:42

US3432334

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab

Generated On: 11 Aug 2021 22:41:12

Collection date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:59:47
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:30:01
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 21:11:10
User closed query 'Samples were not collected, however Collection Date is provided. Please correct.' (Site from System).	System	29 Sep 2020 00:10:18
Query 'Samples were not collected, however Collection Date is provided. Please correct.' answered by data change (Site from System).	System	29 Sep 2020 00:10:18
User entered empty; reason for change Data Entry Error	Natalie Izaguirre (b) (4)	29 Sep 2020 00:10:18
User opened query 'Samples were not collected, however Collection Date is provided. Please correct.' (Site from System).	System	29 Sep 2020 00:09:58
User entered '28 Sep 2020'	Natalie Izaguirre (b) (4)	29 Sep 2020 00:09:58

US3432334

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 11 Aug 2021 22:41:12

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:59:47
User accepted default value 'Nasopharyngeal Swab 1 (NASAL1)'	Natalie Izaguirre (b) (4)	29 Sep 2020 00:09:58

US3432334

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 11 Aug 2021 22:41:12

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:59:47
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:30:01
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 21:11:10
User entered 'No (N)'	Natalie Izaguirre (b) (4)	29 Sep 2020 00:09:58

US3432334

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 11 Aug 2021 22:41:12

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:59:47
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:30:01
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 21:11:10
User entered empty.	Natalie Izaguirre (b) (4)	29 Sep 2020 00:09:58

US3432334

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 11 Aug 2021 22:41:12

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:59:47
User entered empty.	System	29 Sep 2020 00:09:58

US3432334

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 11 Aug 2021 22:41:12

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:59:47
User accepted default value 'Nasopharyngeal Swab 2 (NASAL2)'	Natalie Izaguirre (b) (4)	29 Sep 2020 00:09:58

US3432334

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 11 Aug 2021 22:41:12

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:59:47
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:30:01
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 21:11:10
User entered 'No (N)'	Natalie Izaguirre (b) (4)	29 Sep 2020 00:09:58

US3432334

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 11 Aug 2021 22:41:12

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:59:47
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:30:01
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 21:11:10
User entered empty.	Natalie Izaguirre (b) (4)	29 Sep 2020 00:09:58

US3432334

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 11 Aug 2021 22:41:12

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:59:47
User entered empty.	System	29 Sep 2020 00:09:58

US3432334

Folder: Visit 2 Day 29 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:41:12

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:59:47
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:30:01
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 21:11:13
User entered 'Yes (Y)'	Natalie Izaguirre (b) (4)	29 Sep 2020 00:10:27

US3432334

Folder: Visit 2 Day 29 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:41:12

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:59:47
User entered '1'	System	29 Sep 2020 00:10:27

US3432334

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:41:12

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:59:47
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:29:40
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 21:11:29
User entered 'Yes (Y)'	(b) (4), (b) (6)	05 Oct 2020 16:43:42

US3432334

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:41:12

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:59:47
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:29:40
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 21:11:29
User entered '5 Oct 2020'	(b) (4), (b) (6)	05 Oct 2020 16:43:42

US3432334

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:41:12

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:59:47
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:29:40
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 21:11:29
User entered 'Contact Made (CONTACT MADE)'	(b) (4), (b) (6)	05 Oct 2020 16:43:42

US3432334

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:41:12

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:59:47
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:29:40
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 21:11:29
User entered empty.	(b) (4), (b) (6)	05 Oct 2020 16:43:42

US3432334

Folder: Safety Call Day 36 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:41:12

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:59:47
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:29:40
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 21:11:31
User entered 'Yes (Y)'	Phoebe Cunningham (b) (4)	12 Oct 2020 16:23:57

US3432334

Folder: Safety Call Day 36 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:41:12

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:59:47
User entered 'I'	System	12 Oct 2020 16:23:57

US3432334

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:41:12

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:59:47
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:29:40
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 21:11:34
User entered 'Yes (Y)'	Xhoi Mitre (b) (4)	12 Oct 2020 18:54:32

US3432334

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:41:12

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:59:47
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:29:40
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 21:11:34
User entered '12 Oct 2020'	Xhoi Mitre (b) (4)	12 Oct 2020 18:54:32

US3432334

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:41:12

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:59:47
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:29:40
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 21:11:34
User entered 'Contact Made (CONTACT MADE)'	Xhoi Mitre (b) (4)	12 Oct 2020 18:54:32

US3432334

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:41:12

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:59:47
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:29:40
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 21:11:34
User entered empty.	Xhoi Mitre (b) (4)	12 Oct 2020 18:54:32

US3432334

Folder: Safety Call Day 43 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:41:12

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:59:47
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:29:40
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 21:11:36
User entered 'Yes (Y)'	Kathleen Garvey (b) (4)	19 Oct 2020 15:12:47

US3432334

Folder: Safety Call Day 43 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:41:12

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:59:47
User entered 'I'	System	19 Oct 2020 15:12:47

US3432334

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:41:12

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:59:47
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:29:40
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 21:11:40
User entered 'Yes (Y)'	(b) (4), (b) (6)	19 Oct 2020 16:20:38

US3432334

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:41:12

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:59:47
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:29:40
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 21:11:40
User entered '19 Oct 2020'	(b) (4), (b) (6)	19 Oct 2020 16:20:38

US3432334

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:41:12

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:59:47
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:29:40
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 21:11:40
User entered 'Contact Made (CONTACT MADE)'	(b) (4), (b) (6)	19 Oct 2020 16:20:38

US3432334

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:41:12

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:59:47
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:29:40
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 21:11:40
User entered empty.	(b) (4), (b) (6)	19 Oct 2020 16:20:38

US3432334

Folder: Safety Call Day 50 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:41:12

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:59:47
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:29:40
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 21:11:42
User entered 'Yes (Y)'	(b) (4), (b) (6)	19 Oct 2020 16:21:29

US3432334

Folder: Safety Call Day 50 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:41:12

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:59:47
User entered 'I'	System	19 Oct 2020 16:21:29

US3432334

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 11 Aug 2021 22:41:12

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:59:50
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:30:01
DataPoint Verified.	(b) (4), (b) (6)	20 Jan 2021 18:38:20
User entered 'Yes (Y)'	(b) (4), (b) (6)	28 Oct 2020 15:45:54

US3432334

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 11 Aug 2021 22:41:12

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:59:50
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:30:01
DataPoint Verified.	(b) (4), (b) (6)	20 Jan 2021 18:38:20
User entered '28 Oct 2020'	(b) (4), (b) (6)	28 Oct 2020 15:45:54

US3432334

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 11 Aug 2021 22:41:12

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 08:59:50
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:30:01
DataPoint Verified.	(b) (4), (b) (6)	20 Jan 2021 18:38:20
User entered 'Clinic (Clinic)'	(b) (4), (b) (6)	28 Oct 2020 15:45:54

US3432334

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 11 Aug 2021 22:41:12

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:59:50
User entered 'VISIT3'	System	28 Oct 2020 15:45:54

US3432334

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:41:12

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:59:50
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:30:01
DataPoint Verified.	(b) (4), (b) (6)	20 Jan 2021 18:38:32
User entered 'Yes (Y)'	(b) (4), (b) (6)	28 Oct 2020 15:55:15

US3432334

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:41:12

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:59:50
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:30:01
DataPoint Verified.	(b) (4), (b) (6)	20 Jan 2021 18:38:32
User entered '28 Oct 2020'	(b) (4), (b) (6)	28 Oct 2020 15:55:15

US3432334

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:41:12

[Time of assessment \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:59:50
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:30:01
DataPoint Verified.	(b) (4), (b) (6)	20 Jan 2021 18:38:32
User entered '11:25'	(b) (4), (b) (6)	28 Oct 2020 15:55:15

US3432334

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:41:12

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:59:50
User entered '28 Oct 2020 11:25'	System	28 Oct 2020 15:55:15

US3432334

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:41:12

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:59:50
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:30:01
DataPoint Verified.	(b) (4), (b) (6)	20 Jan 2021 18:38:32
User entered '97.3' F	(b) (4), (b) (6)	28 Oct 2020 15:55:15

US3432334

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:41:12

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:59:50
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:30:01
DataPoint Verified.	(b) (4), (b) (6)	20 Jan 2021 18:38:32
User entered 'Oral (Oral)'	(b) (4), (b) (6)	28 Oct 2020 15:55:15

US3432334

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:41:12

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:59:50
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:30:01
DataPoint Verified.	(b) (4), (b) (6)	20 Jan 2021 18:38:32
User entered empty.	(b) (4), (b) (6)	28 Oct 2020 15:55:15

US3432334

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:41:12

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:59:50
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:30:01
DataPoint Verified.	(b) (4), (b) (6)	20 Jan 2021 18:38:32
User closed query 'Pulse reported is out of range < 45 or > 130 per protocol considered grade 3. Please indicate if CS/NCS and report as AE, if appropriate.' (Site from System).	System	28 Oct 2020 15:55:44
Query 'Pulse reported is out of range < 45 or > 130 per protocol considered grade 3. Please indicate if CS/NCS and report as AE, if appropriate.' answered by data change (Site from System).	System	28 Oct 2020 15:55:44
User entered '65' reason for change: Data Entry Error	(b) (4), (b) (6)	28 Oct 2020 15:55:44
User opened query 'Pulse reported is out of range < 45 or > 130 per protocol considered grade 3. Please indicate if CS/NCS and report as AE, if appropriate.' (Site from System).	System	28 Oct 2020 15:55:15
User entered '16'	(b) (4), (b) (6)	28 Oct 2020 15:55:15

US3432334

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:41:12

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:59:50
User entered 'bpm'	System	28 Oct 2020 15:55:15

US3432334

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:41:12

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:59:50
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:30:01
DataPoint Verified.	(b) (4), (b) (6)	20 Jan 2021 18:38:32
User entered '16'	(b) (4), (b) (6)	28 Oct 2020 15:55:15

US3432334

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:41:12

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:59:50
User entered 'breaths/min'	System	28 Oct 2020 15:55:15

US3432334

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:41:12

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:59:50
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:30:01
DataPoint Verified.	(b) (4), (b) (6)	20 Jan 2021 18:38:32
User entered '121'	(b) (4), (b) (6)	28 Oct 2020 15:55:15

US3432334

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:41:12

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:59:50
User entered 'mmHg'	System	28 Oct 2020 15:55:15

US3432334

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:41:12

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:59:50
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:30:01
DataPoint Verified.	(b) (4), (b) (6)	20 Jan 2021 18:38:32
User entered '75'	(b) (4), (b) (6)	28 Oct 2020 15:55:15

US3432334

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:41:12

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:59:50
User entered 'mmHg'	System	28 Oct 2020 15:55:15

US3432334

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:41:12

[Height \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:59:50

US3432334

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:41:12

Weight (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:59:50

US3432334

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Generated On: 11 Aug 2021 22:41:12

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:59:50
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:30:01
DataPoint Verified.	(b) (4), (b) (6)	20 Jan 2021 18:39:30
User entered 'No (N)'	(b) (4), (b) (6)	28 Oct 2020 15:55:52

US3432334

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Generated On: 11 Aug 2021 22:41:12

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:59:50
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:30:01
DataPoint Verified.	(b) (4), (b) (6)	20 Jan 2021 18:39:30
User entered empty.	(b) (4), (b) (6)	28 Oct 2020 15:55:52

US3432334

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 22:41:12

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:59:50
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:30:01
DataPoint Verified.	(b) (4), (b) (6)	20 Jan 2021 18:38:55
User closed query 'Per IMMUNO Lab Recon: it appears a sample was collected on 28Oct2020; however, it has not been received by GCL. Please clarify and, if shipped, please provide tracking detail.' (Site from DM).	(b) (4), (b) (6)	25 Nov 2020 15:23:48
Query 'Per IMMUNO Lab Recon: it appears a sample was collected on 28Oct2020; however, it has not been received by GCL. Please clarify and, if shipped, please provide tracking detail.' answered with 'PPD reports receiving this.' (Site from DM).	Jun Bai Park Chang (b) (4)	10 Nov 2020 16:30:03
User opened query 'Per IMMUNO Lab Recon: it appears a sample was collected on 28Oct2020; however, it has not been received by GCL. Please clarify and, if shipped, please provide tracking detail.' (Site from DM).	(b) (4), (b) (6)	05 Nov 2020 19:02:53
User entered 'Yes (Y)'	(b) (4), (b) (6)	28 Oct 2020 15:56:27

US3432334

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 22:41:12

Collection date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:59:50
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:30:01
DataPoint Verified.	(b) (4), (b) (6)	20 Jan 2021 18:38:55
User entered '28 Oct 2020'	(b) (4), (b) (6)	28 Oct 2020 15:56:27

US3432334

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 22:41:12

Collection time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:59:50
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:30:01
DataPoint Verified.	(b) (4), (b) (6)	20 Jan 2021 18:38:55
User entered '11:32'	(b) (4), (b) (6)	28 Oct 2020 15:56:27

US3432334

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 22:41:12

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:59:50
User entered '28 Oct 2020 11:32'	System	28 Oct 2020 15:56:27

US3432334

Folder: Visit 3 Day 57 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:41:12

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:59:50
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:30:01
DataPoint Verified.	(b) (4), (b) (6)	20 Jan 2021 18:39:36
User entered 'Yes (Y)'	(b) (4), (b) (6)	28 Oct 2020 15:56:34

US3432334

Folder: Visit 3 Day 57 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:41:12

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:59:50
User entered 'I'	System	28 Oct 2020 15:56:34

US3432334

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:41:12

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:04:43
Data entry locked.	System	28 Aug 2020 15:13:20
User entered 'Day 64'	System	28 Aug 2020 15:13:20

US3432334

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:41:12

[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)	25 Feb 2021 21:04:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C38FDA40-A52C-492B-ACED-AF41296DC535)', Time: '2020-10-31T12:36:31', User OID: 'PatientReportedOutcome (US3432334)', ODM File OID: 'e9ab420c-5b59-4cc7-a879-96b6e705fe9f' User entered 'No (N)'	System	31 Oct 2020 16:37:04
	System	31 Oct 2020 16:37:04

US3432334

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:41:12

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)	25 Feb 2021 21:04:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C38FDA40-A52C-492B-ACED-AF41296DC535)', Time: '2020-10-31T12:36:50', User OID: 'PatientReportedOutcome (US3432334)', ODM File OID: 'e9ab420c-5b59-4cc7-a879-96b6e705fe9f' User entered 'Yes (Y)'	System	31 Oct 2020 16:37:04
	System	31 Oct 2020 16:37:04

US3432334

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:41:12

[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)	25 Feb 2021 21:04:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C38FDA40-A52C-492B-ACED-AF41296DC535)', Time: '2020-10-31T12:36:52', User OID: 'PatientReportedOutcome (US3432334)', ODM File OID: 'e9ab420c-5b59-4cc7-a879-96b6e705fe9f'	System	31 Oct 2020 16:37:04
User entered 'I confirm I have read this message and will call the study clinic immediately (9)'	System	31 Oct 2020 16:37:04

US3432334

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:41:12

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:04:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C38FDA40-A52C-492B-ACED-AF41296DC535)', Time: '2020-10-31T12:36:56', User OID: 'PatientReportedOutcome (US3432334)', ODM File OID: 'e9ab420c-5b59-4cc7-a879-96b6e705fe9f' User entered '31 Oct 2020 12:36:56'	System	31 Oct 2020 16:37:04
	System	31 Oct 2020 16:37:04

US3432334

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:41:12

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:04:43
Data entry locked.	System	28 Aug 2020 15:13:20
User entered '28 Oct 2020 00:01'	System	28 Aug 2020 15:13:20

US3432334

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:41:12

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:04:43
Data entry locked.	System	28 Aug 2020 15:13:20
User entered '01 Nov 2020 23:59'	System	28 Aug 2020 15:13:20

US3432334

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:41:12

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:04:43
Data entry locked.	System	28 Aug 2020 15:13:20
User entered 'Day 71'	System	28 Aug 2020 15:13:20

US3432334

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:41:12

[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)	25 Feb 2021 21:04:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C38FDA40-A52C-492B-ACED-AF41296DC535)', Time: '2020-11-06T12:00:50', User OID: 'PatientReportedOutcome (US3432334)', ODM File OID: '2b8a3086-efe5-438f-9c3b-183c8bc2b258'	System	08 Nov 2020 20:30:36
User entered 'No (N)'	System	08 Nov 2020 20:30:36

US3432334

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:41:12

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)	25 Feb 2021 21:04:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C38FDA40-A52C-492B-ACED-AF41296DC535)', Time: '2020-11-06T12:00:53', User OID: 'PatientReportedOutcome (US3432334)', ODM File OID: '2b8a3086-efe5-438f-9c3b-183c8bc2b258'	System	08 Nov 2020 20:30:36
User entered 'No (N)'	System	08 Nov 2020 20:30:36

US3432334

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:41:12

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:04:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C38FDA40-A52C-492B-ACED-AF41296DC535)', Time: '2020-11-06T12:00:56', User OID: 'PatientReportedOutcome (US3432334)', ODM File OID: '2b8a3086-efe5-438f-9c3b-183c8bc2b258' User entered '06 Nov 2020 12:00:56'	System	08 Nov 2020 20:30:36
	System	08 Nov 2020 20:30:36

US3432334

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:41:12

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:04:43
Data entry locked.	System	28 Aug 2020 15:13:20
User entered '04 Nov 2020 00:01'	System	28 Aug 2020 15:13:20

US3432334

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:41:12

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:04:43
Data entry locked.	System	28 Aug 2020 15:13:20
User entered '08 Nov 2020 23:59'	System	28 Aug 2020 15:13:20

US3432334

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:41:12

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:04:43
Data entry locked.	System	28 Aug 2020 15:13:20
User entered 'Day 78'	System	28 Aug 2020 15:13:20

US3432334

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:41:12

[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)	25 Feb 2021 21:04:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C38FDA40-A52C-492B-ACED-AF41296DC535)', Time: '2020-11-11T05:44:47', User OID: 'PatientReportedOutcome (US3432334)', ODM File OID: 'bdbdc9b2-d2d1-4956-b2fc-c2d013b3bf53'	System	11 Nov 2020 10:44:53
User entered 'No (N)'	System	11 Nov 2020 10:44:53

US3432334

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:41:12

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)	25 Feb 2021 21:04:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C38FDA40-A52C-492B-ACED-AF41296DC535)', Time: '2020-11-11T05:44:49', User OID: 'PatientReportedOutcome (US3432334)', ODM File OID: 'bdbdc9b2-d2d1-4956-b2fc-c2d013b3bf53'	System	11 Nov 2020 10:44:53
User entered 'No (N)'	System	11 Nov 2020 10:44:53

US3432334

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:41:12

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:04:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C38FDA40-A52C-492B-ACED-AF41296DC535)', Time: '2020-11-11T05:44:51', User OID: 'PatientReportedOutcome (US3432334)', ODM File OID: 'bdbdc9b2-d2d1-4956-b2fc-c2d013b3bf53' User entered '11 Nov 2020 05:44:51'	System	11 Nov 2020 10:44:53
	System	11 Nov 2020 10:44:53

US3432334

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:41:12

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:04:43
Data entry locked.	System	28 Aug 2020 15:13:20
User entered '11 Nov 2020 00:01'	System	28 Aug 2020 15:13:20

US3432334

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:41:12

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:04:43
Data entry locked.	System	28 Aug 2020 15:13:20
User entered '15 Nov 2020 23:59'	System	28 Aug 2020 15:13:20

US3432334

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:41:12

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:43:11
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:39:09
Amendment Manager: User entered 'Day 89'	System	19 Nov 2020 19:39:09

US3432334

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:41:12

[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)	02 May 2021 16:43:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C38FDA40-A52C-492B-ACED-AF41296DC535)', Time: '2020-11-22T14:45:20', User OID: 'PatientReportedOutcome (US3432334)', ODM File OID: '54a83663-b0cf-4bbc-867a-b515f2165252' User entered 'No (N)'	System	22 Nov 2020 19:45:39
	System	22 Nov 2020 19:45:39

US3432334

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:41:12

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)	02 May 2021 16:43:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C38FDA40-A52C-492B-ACED-AF41296DC535)', Time: '2020-11-22T14:45:33', User OID: 'PatientReportedOutcome (US3432334)', ODM File OID: '54a83663-b0cf-4bbc-867a-b515f2165252'	System	22 Nov 2020 19:45:39
User entered 'No (N)'	System	22 Nov 2020 19:45:39

US3432334

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:41:12

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:43:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C38FDA40-A52C-492B-ACED-AF41296DC535)', Time: '2020-11-22T14:45:36', User OID: 'PatientReportedOutcome (US3432334)', ODM File OID: '54a83663-b0cf-4bbc-867a-b515f2165252'	System	22 Nov 2020 19:45:39
User entered '22 Nov 2020 14:45:36'	System	22 Nov 2020 19:45:39

US3432334

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:41:12

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:43:11
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:39:09
Amendment Manager: User entered '22 Nov 2020 00:01'	System	19 Nov 2020 19:39:09

US3432334

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:41:12

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:43:11
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:39:09
Amendment Manager: User entered '26 Nov 2020 23:59'	System	19 Nov 2020 19:39:09

US3432334

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:41:12

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:43:11
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:39:09
Amendment Manager: User entered 'Day 96'	System	19 Nov 2020 19:39:09

US3432334

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:41:12

[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)	02 May 2021 16:43:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C38FDA40-A52C-492B-ACED-AF41296DC535)', Time: '2020-11-29T11:51:18', User OID: 'PatientReportedOutcome (US3432334)', ODM File OID: 'c4ec0d6a-3e3b-4790-bcad-78d089993b90' User entered 'No (N)'	System	29 Nov 2020 16:51:25
	System	29 Nov 2020 16:51:25

US3432334

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:41:12

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)	02 May 2021 16:43:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C38FDA40-A52C-492B-ACED-AF41296DC535)', Time: '2020-11-29T11:51:21', User OID: 'PatientReportedOutcome (US3432334)', ODM File OID: 'c4ec0d6a-3e3b-4790-bcad-78d089993b90'	System	29 Nov 2020 16:51:25
User entered 'No (N)'	System	29 Nov 2020 16:51:25

US3432334

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:41:12

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:43:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C38FDA40-A52C-492B-ACED-AF41296DC535)', Time: '2020-11-29T11:51:23', User OID: 'PatientReportedOutcome (US3432334)', ODM File OID: 'c4ec0d6a-3e3b-4790-bcad-78d089993b90'	System	29 Nov 2020 16:51:25
User entered '29 Nov 2020 11:51:23'	System	29 Nov 2020 16:51:25

US3432334

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:41:12

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:43:11
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:39:09
Amendment Manager: User entered '29 Nov 2020 00:01'	System	19 Nov 2020 19:39:09

US3432334

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:41:12

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:43:11
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:39:09
Amendment Manager: User entered '03 Dec 2020 23:59'	System	19 Nov 2020 19:39:09

US3432334

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:41:12

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:43:11
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:39:09
Amendment Manager: User entered 'Day 103'	System	19 Nov 2020 19:39:09

US3432334

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:41:12

[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)	02 May 2021 16:43:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C38FDA40-A52C-492B-ACED-AF41296DC535)', Time: '2020-12-07T06:40:14', User OID: 'PatientReportedOutcome (US3432334)', ODM File OID: '49db58b8-02b8-4111-92c7-780de0e5c701'	System	07 Dec 2020 12:40:24
User entered 'No (N)'	System	07 Dec 2020 12:40:24

US3432334

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:41:12

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)	02 May 2021 16:43:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C38FDA40-A52C-492B-ACED-AF41296DC535)', Time: '2020-12-07T06:40:18', User OID: 'PatientReportedOutcome (US3432334)', ODM File OID: '49db58b8-02b8-4111-92c7-780de0e5c701'	System	07 Dec 2020 12:40:24
User entered 'No (N)'	System	07 Dec 2020 12:40:24

US3432334

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:41:12

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:43:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C38FDA40-A52C-492B-ACED-AF41296DC535)', Time: '2020-12-07T06:40:21', User OID: 'PatientReportedOutcome (US3432334)', ODM File OID: '49db58b8-02b8-4111-92c7-780de0e5c701' User entered '07 Dec 2020 06:40:21'	System	07 Dec 2020 12:40:24
	System	07 Dec 2020 12:40:24

US3432334

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:41:12

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:43:11
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:39:09
Amendment Manager: User entered '06 Dec 2020 00:01'	System	19 Nov 2020 19:39:09

US3432334

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:41:12

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:43:11
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:39:09
Amendment Manager: User entered '10 Dec 2020 23:59'	System	19 Nov 2020 19:39:09

US3432334

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:41:12

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:43:11
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:39:09
Amendment Manager: User entered 'Day 110'	System	19 Nov 2020 19:39:09

US3432334

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:41:12

[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)	02 May 2021 16:43:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C38FDA40-A52C-492B-ACED-AF41296DC535)', Time: '2020-12-17T11:59:12', User OID: 'PatientReportedOutcome (US3432334)', ODM File OID: 'e05a841a-5168-4299-8e3c-96ccddadca56'	System	17 Dec 2020 16:59:20
User entered 'No (N)'	System	17 Dec 2020 16:59:20

US3432334

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:41:12

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)	02 May 2021 16:43:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C38FDA40-A52C-492B-ACED-AF41296DC535)', Time: '2020-12-17T11:59:15', User OID: 'PatientReportedOutcome (US3432334)', ODM File OID: 'e05a841a-5168-4299-8e3c-96ccddadca56'	System	17 Dec 2020 16:59:20
User entered 'No (N)'	System	17 Dec 2020 16:59:20

US3432334

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:41:12

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:43:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C38FDA40-A52C-492B-ACED-AF41296DC535)', Time: '2020-12-17T11:59:18', User OID: 'PatientReportedOutcome (US3432334)', ODM File OID: 'e05a841a-5168-4299-8e3c-96ccddadca56' User entered '17 Dec 2020 11:59:18'	System	17 Dec 2020 16:59:20
	System	17 Dec 2020 16:59:20

US3432334

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:41:12

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:43:11
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:39:09
Amendment Manager: User entered '13 Dec 2020 00:01'	System	19 Nov 2020 19:39:09

US3432334

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:41:12

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:43:11
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:39:09
Amendment Manager: User entered '17 Dec 2020 23:59'	System	19 Nov 2020 19:39:09

US3432334

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:41:12

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:43:11
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:39:09
Amendment Manager: User entered 'Day 117'	System	19 Nov 2020 19:39:09

US3432334

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:41:12

[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)	02 May 2021 16:43:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C38FDA40-A52C-492B-ACED-AF41296DC535)', Time: '2020-12-23T12:42:20', User OID: 'PatientReportedOutcome (US3432334)', ODM File OID: '01f4d47b-fe3a-4108-aa18-b0940b499c8e' User entered 'No (N)'	System	23 Dec 2020 17:42:30
	System	23 Dec 2020 17:42:30

US3432334

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:41:12

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)	02 May 2021 16:43:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C38FDA40-A52C-492B-ACED-AF41296DC535)', Time: '2020-12-23T12:42:25', User OID: 'PatientReportedOutcome (US3432334)', ODM File OID: '01f4d47b-fe3a-4108-aa18-b0940b499c8e' User entered 'No (N)'	System	23 Dec 2020 17:42:30
	System	23 Dec 2020 17:42:30

US3432334

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:41:12

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:43:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C38FDA40-A52C-492B-ACED-AF41296DC535)', Time: '2020-12-23T12:42:27', User OID: 'PatientReportedOutcome (US3432334)', ODM File OID: '01f4d47b-fe3a-4108-aa18-b0940b499c8e' User entered '23 Dec 2020 12:42:27'	System	23 Dec 2020 17:42:30
	System	23 Dec 2020 17:42:30

US3432334

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:41:12

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:43:11
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:39:09
Amendment Manager: User entered '20 Dec 2020 00:01'	System	19 Nov 2020 19:39:09

US3432334

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:41:12

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:43:11
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:39:09
Amendment Manager: User entered '24 Dec 2020 23:59'	System	19 Nov 2020 19:39:09

US3432334

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:41:12

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:43:11
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:39:09
Amendment Manager: User entered 'Day 124'	System	19 Nov 2020 19:39:09

US3432334

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:41:12

[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)	02 May 2021 16:43:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C38FDA40-A52C-492B-ACED-AF41296DC535)', Time: '2020-12-29T16:19:20', User OID: 'PatientReportedOutcome (US3432334)', ODM File OID: '9165f2ba-8d7a-4a90-b6ee-d77f9869e61d' User entered 'No (N)'	System	29 Dec 2020 21:19:31
	System	29 Dec 2020 21:19:31

US3432334

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:41:12

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)	02 May 2021 16:43:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C38FDA40-A52C-492B-ACED-AF41296DC535)', Time: '2020-12-29T16:19:23', User OID: 'PatientReportedOutcome (US3432334)', ODM File OID: '9165f2ba-8d7a-4a90-b6ee-d77f9869e61d'	System	29 Dec 2020 21:19:31
User entered 'No (N)'	System	29 Dec 2020 21:19:31

US3432334

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:41:12

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:43:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C38FDA40-A52C-492B-ACED-AF41296DC535)', Time: '2020-12-29T16:19:28', User OID: 'PatientReportedOutcome (US3432334)', ODM File OID: '9165f2ba-8d7a-4a90-b6ee-d77f9869e61d' User entered '29 Dec 2020 16:19:28'	System	29 Dec 2020 21:19:31
	System	29 Dec 2020 21:19:31

US3432334

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:41:12

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:43:11
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:39:09
Amendment Manager: User entered '27 Dec 2020 00:01'	System	19 Nov 2020 19:39:09

US3432334

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:41:12

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:43:11
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:39:09
Amendment Manager: User entered '31 Dec 2020 23:59'	System	19 Nov 2020 19:39:09

US3432334

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:41:12

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:43:11
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:39:09
Amendment Manager: User entered 'Day 131'	System	19 Nov 2020 19:39:09

US3432334

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:41:12

[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)	02 May 2021 16:43:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C38FDA40-A52C-492B-ACED-AF41296DC535)', Time: '2021-01-07T12:07:33', User OID: 'PatientReportedOutcome (US3432334)', ODM File OID: '880ea7d2-f703-4fad-84d7-929c3040212a' User entered 'No (N)'	System	07 Jan 2021 18:07:41
	System	07 Jan 2021 18:07:41

US3432334

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:41:12

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)	02 May 2021 16:43:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C38FDA40-A52C-492B-ACED-AF41296DC535)', Time: '2021-01-07T12:07:34', User OID: 'PatientReportedOutcome (US3432334)', ODM File OID: '880ea7d2-f703-4fad-84d7-929c3040212a' User entered 'No (N)'	System	07 Jan 2021 18:07:41
	System	07 Jan 2021 18:07:41

US3432334

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:41:12

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:43:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C38FDA40-A52C-492B-ACED-AF41296DC535)', Time: '2021-01-07T12:07:36', User OID: 'PatientReportedOutcome (US3432334)', ODM File OID: '880ea7d2-f703-4fad-84d7-929c3040212a' User entered '07 Jan 2021 12:07:36'	System	07 Jan 2021 18:07:41
	System	07 Jan 2021 18:07:41

US3432334

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:41:12

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:43:11
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:39:09
Amendment Manager: User entered '03 Jan 2021 00:01'	System	19 Nov 2020 19:39:09

US3432334

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:41:12

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:43:11
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:39:09
Amendment Manager: User entered '07 Jan 2021 23:59'	System	19 Nov 2020 19:39:09

US3432334

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:41:12

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:43:11
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:39:09
Amendment Manager: User entered 'Day 138'	System	19 Nov 2020 19:39:09

US3432334

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:41:12

[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)	02 May 2021 16:43:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C38FDA40-A52C-492B-ACED-AF41296DC535)', Time: '2021-01-12T12:00:17', User OID: 'PatientReportedOutcome (US3432334)', ODM File OID: 'e0004b65-7174-45e8-ab2a-ffc23bb7e183'	System	12 Jan 2021 18:00:42
User entered 'No (N)'	System	12 Jan 2021 18:00:42

US3432334

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:41:12

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)	02 May 2021 16:43:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C38FDA40-A52C-492B-ACED-AF41296DC535)', Time: '2021-01-12T12:00:18', User OID: 'PatientReportedOutcome (US3432334)', ODM File OID: 'e0004b65-7174-45e8-ab2a-ffc23bb7e183'	System	12 Jan 2021 18:00:42
User entered 'No (N)'	System	12 Jan 2021 18:00:42

US3432334

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:41:12

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:43:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C38FDA40-A52C-492B-ACED-AF41296DC535)', Time: '2021-01-12T12:00:20', User OID: 'PatientReportedOutcome (US3432334)', ODM File OID: 'e0004b65-7174-45e8-ab2a-ffc23bb7e183' User entered '12 Jan 2021 12:00:20'	System	12 Jan 2021 18:00:42
	System	12 Jan 2021 18:00:42

US3432334

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:41:12

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:43:11
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:39:09
Amendment Manager: User entered '10 Jan 2021 00:01'	System	19 Nov 2020 19:39:09

US3432334

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:41:12

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:43:11
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:39:09
Amendment Manager: User entered '14 Jan 2021 23:59'	System	19 Nov 2020 19:39:09

US3432334

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:41:12

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:43:11
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:39:09
Amendment Manager: User entered 'Day 145'	System	19 Nov 2020 19:39:09

US3432334

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:41:12

[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)	02 May 2021 16:43:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C38FDA40-A52C-492B-ACED-AF41296DC535)', Time: '2021-01-19T12:04:43', User OID: 'PatientReportedOutcome (US3432334)', ODM File OID: 'f812d263-4ac6-46a4-bb2e-47b734790492' User entered 'No (N)'	System	19 Jan 2021 17:05:30
	System	19 Jan 2021 17:05:30

US3432334

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:41:12

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)	02 May 2021 16:43:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C38FDA40-A52C-492B-ACED-AF41296DC535)', Time: '2021-01-19T12:04:45', User OID: 'PatientReportedOutcome (US3432334)', ODM File OID: 'f812d263-4ac6-46a4-bb2e-47b734790492'	System	19 Jan 2021 17:05:30
User entered 'No (N)'	System	19 Jan 2021 17:05:30

US3432334

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:41:12

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:43:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C38FDA40-A52C-492B-ACED-AF41296DC535)', Time: '2021-01-19T12:04:47', User OID: 'PatientReportedOutcome (US3432334)', ODM File OID: 'f812d263-4ac6-46a4-bb2e-47b734790492' User entered '19 Jan 2021 12:04:47'	System	19 Jan 2021 17:05:30
	System	19 Jan 2021 17:05:30

US3432334

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:41:12

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:43:11
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:39:09
Amendment Manager: User entered '17 Jan 2021 00:01'	System	19 Nov 2020 19:39:09

US3432334

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:41:12

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:43:11
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:39:09
Amendment Manager: User entered '21 Jan 2021 23:59'	System	19 Nov 2020 19:39:09

US3432334

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:41:12

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:43:11
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:39:09
Amendment Manager: User entered 'Day 159'	System	19 Nov 2020 19:39:09

US3432334

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:41:12

[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)	02 May 2021 16:43:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C38FDA40-A52C-492B-ACED-AF41296DC535)', Time: '2021-01-31T07:05:40', User OID: 'PatientReportedOutcome (US3432334)', ODM File OID: '071509d4-0f3a-4ad7-8ba2-f09bd3af49c5' User entered 'No (N)'	System	31 Jan 2021 12:05:47
	System	31 Jan 2021 12:05:47

US3432334

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:41:12

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)	02 May 2021 16:43:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C38FDA40-A52C-492B-ACED-AF41296DC535)', Time: '2021-01-31T07:05:42', User OID: 'PatientReportedOutcome (US3432334)', ODM File OID: '071509d4-0f3a-4ad7-8ba2-f09bd3af49c5'	System	31 Jan 2021 12:05:47
User entered 'No (N)'	System	31 Jan 2021 12:05:47

US3432334

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:41:12

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:43:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C38FDA40-A52C-492B-ACED-AF41296DC535)', Time: '2021-01-31T07:05:45', User OID: 'PatientReportedOutcome (US3432334)', ODM File OID: '071509d4-0f3a-4ad7-8ba2-f09bd3af49c5' User entered '31 Jan 2021 07:05:45'	System	31 Jan 2021 12:05:47
	System	31 Jan 2021 12:05:47

US3432334

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:41:12

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:43:11
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:39:09
Amendment Manager: User entered '31 Jan 2021 00:01'	System	19 Nov 2020 19:39:09

US3432334

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:41:12

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:43:11
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:39:09
Amendment Manager: User entered '04 Feb 2021 23:59'	System	19 Nov 2020 19:39:09

US3432334

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:41:12

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:43:11
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:39:09
Amendment Manager: User entered 'Day 166'	System	19 Nov 2020 19:39:09

US3432334

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:41:12

[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)	02 May 2021 16:43:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C38FDA40-A52C-492B-ACED-AF41296DC535)', Time: '2021-02-08T19:13:10', User OID: 'PatientReportedOutcome (US3432334)', ODM File OID: '015850db-f752-45f3-abd7-578bd7f06373' User entered 'No (N)'	System	09 Feb 2021 00:13:57
	System	09 Feb 2021 00:13:57

US3432334

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:41:12

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)	02 May 2021 16:43:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C38FDA40-A52C-492B-ACED-AF41296DC535)', Time: '2021-02-08T19:13:11', User OID: 'PatientReportedOutcome (US3432334)', ODM File OID: '015850db-f752-45f3-abd7-578bd7f06373'	System	09 Feb 2021 00:13:57
User entered 'No (N)'	System	09 Feb 2021 00:13:57

US3432334

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:41:12

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:43:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C38FDA40-A52C-492B-ACED-AF41296DC535)', Time: '2021-02-08T19:13:13', User OID: 'PatientReportedOutcome (US3432334)', ODM File OID: '015850db-f752-45f3-abd7-578bd7f06373' User entered '08 Feb 2021 19:13:13'	System	09 Feb 2021 00:13:57
	System	09 Feb 2021 00:13:57

US3432334

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:41:12

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:43:11
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:39:09
Amendment Manager: User entered '07 Feb 2021 00:01'	System	19 Nov 2020 19:39:09

US3432334

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:41:12

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:43:11
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:39:09
Amendment Manager: User entered '11 Feb 2021 23:59'	System	19 Nov 2020 19:39:09

US3432334

Folder: Cosmetic Injections and Dermal Fillers

Form: Cosmetic Injection_ Dermal Filler eDiary (1)

Generated On: 11 Aug 2021 22:41:12

Have you ever received facial cosmetic injections, such as Juvederm, Voluma, Radiesse, Restylane, Botox or other?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 15:44:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C38FDA40-A52C-492B-ACED-AF41296DC535)', Time: '2021-02-27T15:37:30-05:00', User OID: 'PatientReportedOutcome (US3432334)', ODM File OID: '9a48f3d4-c999-4f5e-8278-1f615584628a'	System	27 Feb 2021 20:37:40
User entered 'No (N)'	System	27 Feb 2021 20:37:40

US3432334

Folder: Cosmetic Injections and Dermal Fillers

Form: Cosmetic Injection_ Dermal Filler eDiary (1)

Generated On: 11 Aug 2021 22:41:12

[Date & Time of Submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 15:44:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C38FDA40-A52C-492B-ACED-AF41296DC535)', Time: '2021-02-27T15:37:33-05:00', User OID: 'PatientReportedOutcome (US3432334)', ODM File OID: '9a48f3d4-c999-4f5e-8278-1f615584628a' User entered '27 Feb 2021 20:37:33'	System	27 Feb 2021 20:37:40
	System	27 Feb 2021 20:37:40

US3432334

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:41:12

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:59:47
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:29:40
DataPoint Verified.	(b) (4), (b) (6)	20 Jan 2021 18:52:01
User entered 'Yes (Y)'	Kathleen Garvey (b) (4)	23 Nov 2020 17:34:33

US3432334

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:41:12

Date of Contact or Contact Attempt (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:59:47
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:29:40
DataPoint Verified.	(b) (4), (b) (6)	20 Jan 2021 18:52:01
User entered '23 Nov 2020'	Kathleen Garvey (b) (4)	23 Nov 2020 17:34:33

US3432334

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:41:12

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:59:47
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:29:40
DataPoint Verified.	(b) (4), (b) (6)	20 Jan 2021 18:52:01
User entered 'Contact Made (CONTACT MADE)'	Kathleen Garvey (b) (4)	23 Nov 2020 17:34:33

US3432334

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:41:12

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:59:47
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:29:40
DataPoint Verified.	(b) (4), (b) (6)	20 Jan 2021 18:52:01
User entered empty.	Kathleen Garvey (b) (4)	23 Nov 2020 17:34:33

US3432334

Folder: Safety Call Day 85 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:41:12

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:59:47
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:29:40
DataPoint Verified.	(b) (4), (b) (6)	20 Jan 2021 18:52:19
User entered 'Yes (Y)'	Kathleen Garvey (b) (4)	23 Nov 2020 17:35:08

US3432334

Folder: Safety Call Day 85 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:41:12

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:59:47
User entered 'I'	System	23 Nov 2020 17:35:08

US3432334

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:41:12

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 18:53:36
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:29:40
DataPoint Verified.	(b) (4), (b) (6)	20 Jan 2021 18:52:57
User entered 'Yes (Y)'	(b) (4), (b) (6)	24 Dec 2020 17:21:05

US3432334

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:41:12

Date of Contact or Contact Attempt (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 18:53:36
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:29:40
DataPoint Verified.	(b) (4), (b) (6)	20 Jan 2021 18:52:57
User entered '24 Dec 2020'	(b) (4), (b) (6)	24 Dec 2020 17:21:05

US3432334

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:41:12

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 18:53:36
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:29:40
DataPoint Verified.	(b) (4), (b) (6)	20 Jan 2021 18:52:57
User entered 'Contact Made (CONTACT MADE)'	(b) (4), (b) (6)	24 Dec 2020 17:21:05

US3432334

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:41:12

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 18:53:36
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:29:40
DataPoint Verified.	(b) (4), (b) (6)	20 Jan 2021 18:52:57
User entered empty.	(b) (4), (b) (6)	24 Dec 2020 17:21:05

US3432334

Folder: Safety Call Day 119 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:41:12

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 18:53:36
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:29:40
DataPoint Verified.	(b) (4), (b) (6)	20 Jan 2021 18:53:01
User entered 'Yes (Y)'	(b) (4), (b) (6)	24 Dec 2020 17:21:11

US3432334

Folder: Safety Call Day 119 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:41:12

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 18:53:36
User entered 'I'	System	24 Dec 2020 17:21:11

US3432334

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

Form: Visit Date

Generated On: 11 Aug 2021 22:41:12

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:43:11
DataPoint Verified.	(b) (4), (b) (6)	11 Apr 2021 03:55:33
User signature succeeded.	Lindsey Baden (b) (4)	04 Apr 2021 20:51:13
User entered 'No (N)'	Bruce Bausk (b) (4)	31 Mar 2021 22:13:04
	(b) (4)	

US3432334

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

Form: Visit Date

Generated On: 11 Aug 2021 22:41:12

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:43:11
DataPoint Verified.	(b) (4), (b) (6)	11 Apr 2021 03:55:33
User signature succeeded.	Lindsey Baden (b) (4)	04 Apr 2021 20:51:13
User entered empty.	Bruce Bausk (b) (4)	31 Mar 2021 22:13:04
	(b) (4)	

US3432334

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

Form: Visit Date

Generated On: 11 Aug 2021 22:41:12

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:43:11
DataPoint Verified.	(b) (4), (b) (6)	11 Apr 2021 03:55:33
User signature succeeded.	Lindsey Baden (b) (4)	04 Apr 2021 20:51:13
User entered empty.	Bruce Bausk (b) (4)	31 Mar 2021 22:13:04
	(b) (4)	

US3432334

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

Form: Visit Date

Generated On: 11 Aug 2021 22:41:12

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:43:11
User entered 'UNBLND_DECIDE'	System	31 Mar 2021 22:13:04

US3432334

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

Form: Unblinding

Generated On: 11 Aug 2021 22:41:12

Date of updated informed consent (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:43:11
DataPoint Verified.	(b) (4), (b) (6)	11 Apr 2021 03:55:28
User signature succeeded.	Lindsey Baden (b) (4)	04 Apr 2021 20:51:13
User entered empty.	Bruce Bausk (b) (4)	31 Mar 2021 22:12:56

US3432334

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

Form: Unblinding

Generated On: 11 Aug 2021 22:41:12

[N/A - Subject Unblinded under Amendment 5 and Discontinued from Study](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:43:11
DataPoint Verified.	(b) (4), (b) (6)	11 Apr 2021 03:55:28
User signature succeeded.	Lindsey Baden (b) (4)	04 Apr 2021 20:51:13
User entered 'I'	Bruce Bausk (b) (4)	31 Mar 2021 22:12:56
	(b) (4)	

US3432334

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

Form: Unblinding

Generated On: 11 Aug 2021 22:41:12

[Was the participant unblinded?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:43:11
DataPoint Verified.	(b) (4), (b) (6)	11 Apr 2021 03:55:28
User signature succeeded.	Lindsey Baden (b) (4)	04 Apr 2021 20:51:13
User entered 'Yes (Y)'	Bruce Bausk (b) (4)	31 Mar 2021 22:12:56
	(b) (4)	

US3432334

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

Form: Unblinding

Generated On: 11 Aug 2021 22:41:12

[Under what version of the Protocol was the Participant unblinded?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:43:11
User signature succeeded.	Lindsey Baden (b) (4)	25 Apr 2021 11:14:34
User closed query 'Per sponsor review, per IRT system use and date, this subject was unblinded when the site was approved for A6. Subject was unblinded under A6, please review and update field.' (Site from DM).	(b) (4), (b) (6)	16 Apr 2021 11:54:53
DataPoint Verified.	(b) (4), (b) (6)	11 Apr 2021 03:55:28
Query 'Per sponsor review, per IRT system use and date, this subject was unblinded when the site was approved for A6. Subject was unblinded under A6, please review and update field.' answered with 'subject was unblinded under A5- site had not received approval by the time this subject was unblinded' (Site from DM).	Julia Klopfer (b) (4)	08 Apr 2021 14:10:12
User entered 'Amendment 5 (Amendment 5)' reason for change: Data Entry Error	Julia Klopfer (b) (4)	08 Apr 2021 12:44:32
Signature has been broken.	Julia Klopfer (b) (4)	08 Apr 2021 12:44:18
User entered 'Amendment 6 or later (Amendment 6 or later)' reason for change: Data Entry Error	Julia Klopfer (b) (4)	08 Apr 2021 12:44:18
User opened query 'Per sponsor review, per IRT system use and date, this subject was unblinded when the site was approved for A6. Subject was unblinded under A6, please review and update field.' (Site from DM).	(b) (4), (b) (6)	08 Apr 2021 12:34:31
User signature succeeded.	Lindsey Baden (b) (4)	04 Apr 2021 20:51:13
User entered 'Amendment 5 (Amendment 5)'	Bruce Bausk (b) (4)	31 Mar 2021 22:12:56

US3432334

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

Form: Unblinding

Generated On: 11 Aug 2021 22:41:12

Date of unblinding (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:43:11
DataPoint Verified.	(b) (4), (b) (6)	11 Apr 2021 03:55:28
User signature succeeded.	Lindsey Baden (b) (4)	04 Apr 2021 20:51:13
User entered '29 Dec 2020'	Bruce Bausk (b) (4)	31 Mar 2021 22:12:56

US3432334

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

Form: Unblinding

Generated On: 11 Aug 2021 22:41:12

[Participant randomization assignment](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:43:11
DataPoint Verified.	(b) (4), (b) (6)	11 Apr 2021 03:55:28
User signature succeeded.	Lindsey Baden (b) (4)	04 Apr 2021 20:51:13
User entered 'mRNA-1273 (mRNA-1273)'	Bruce Bausk (b) (4)	31 Mar 2021 22:12:56

US3432334

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

Form: Unblinding

Generated On: 11 Aug 2021 22:41:12

[Actual Dose 1](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:43:11
DataPoint Verified.	(b) (4), (b) (6)	11 Apr 2021 03:55:28
User signature succeeded.	Lindsey Baden (b) (4)	04 Apr 2021 20:51:13
User entered 'mRNA-1273 (mRNA-1273)'	Bruce Bausk (b) (4)	31 Mar 2021 22:12:56

US3432334

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

Form: Unblinding

Generated On: 11 Aug 2021 22:41:12

[Actual Dose 2](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:43:11
DataPoint Verified.	(b) (4), (b) (6)	11 Apr 2021 03:55:28
User signature succeeded.	Lindsey Baden (b) (4)	04 Apr 2021 20:51:13
User entered 'Not Administered (NA)'	Bruce Bausk (b) (4)	31 Mar 2021 22:12:56
	(b) (4)	

US3432334

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

Form: Unblinding

Generated On: 11 Aug 2021 22:41:12

[Will participant receive mRNA-1273?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:43:11
DataPoint Verified.	(b) (4), (b) (6)	11 Apr 2021 03:55:28
User signature succeeded.	Lindsey Baden (b) (4)	04 Apr 2021 20:51:13
User entered 'No (N)'	Bruce Bausk (b) (4)	31 Mar 2021 22:12:56
	(b) (4)	

US3432334

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

Form: Unblinding

Generated On: 11 Aug 2021 22:41:12

[Placebo Only Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:43:11
User entered empty.	System	31 Mar 2021 22:12:56

US3432334

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

Form: Unblinding

Generated On: 11 Aug 2021 22:41:12

[Continuing with mRNA-1273](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:43:11
User entered empty.	System	31 Mar 2021 22:12:56

US3432334

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

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 22:41:12

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:43:11
DataPoint Verified.	(b) (4), (b) (6)	11 Apr 2021 03:55:35
User signature succeeded.	Lindsey Baden (b) (4)	04 Apr 2021 20:51:13
User entered 'No (N)'	Bruce Bausk (b) (4)	31 Mar 2021 22:13:27

US3432334

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

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 22:41:12

Collection date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:43:11
DataPoint Verified.	(b) (4), (b) (6)	11 Apr 2021 03:55:35
User signature succeeded.	Lindsey Baden (b) (4)	04 Apr 2021 20:51:13
User entered empty.	Bruce Bausk (b) (4)	31 Mar 2021 22:13:27

US3432334

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

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 22:41:12

[Collection time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:43:11
DataPoint Verified.	(b) (4), (b) (6)	11 Apr 2021 03:55:35
User signature succeeded.	Lindsey Baden (b) (4)	04 Apr 2021 20:51:13
User entered empty.	Bruce Bausk (b) (4)	31 Mar 2021 22:13:27
	(b) (4)	

US3432334

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

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 22:41:12

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:43:11
User entered empty.	System	31 Mar 2021 22:13:27

US3432334

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

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 11 Aug 2021 22:41:12

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:43:11
DataPoint Verified.	(b) (4), (b) (6)	11 Apr 2021 03:55:38
User signature succeeded.	Lindsey Baden (b) (4)	04 Apr 2021 20:51:13
User entered 'No (N)'	Bruce Bausk (b) (4)	31 Mar 2021 22:13:31

US3432334

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

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 11 Aug 2021 22:41:12

Collection date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:43:11
DataPoint Verified.	(b) (4), (b) (6)	11 Apr 2021 03:55:38
User signature succeeded.	Lindsey Baden (b) (4)	04 Apr 2021 20:51:13
User entered empty.	Bruce Bausk (b) (4)	31 Mar 2021 22:13:31

US3432334

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

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 11 Aug 2021 22:41:12

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:43:11
DataPoint Verified.	(b) (4), (b) (6)	11 Apr 2021 03:55:38
User signature succeeded.	Lindsey Baden (b) (4)	04 Apr 2021 20:51:13
User entered empty.	Bruce Bausk (b) (4)	31 Mar 2021 22:13:31
	(b) (4)	

US3432334

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

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 11 Aug 2021 22:41:12

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:43:11
User entered empty.	System	31 Mar 2021 22:13:31

US3432334

Folder: Adverse Events

Form: Adverse Events Summary

Generated On: 11 Aug 2021 22:41:12

[Did the participant experience any adverse events?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:43:11
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:29:40
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 21:07:38
User entered 'Yes (Y)'	Monica Feeley (b) (4)	18 Sep 2020 19:27:45
	(b) (4)	

US3432334

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:41:12

[AEID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:43:11

US3432334

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:41:12

[Adverse event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:43:11
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:29:40
User coded data point as SOC: Infections and infestations, HLGT: Viral infectious disorders, HLT: Coronavirus infections, PT: Asymptomatic COVID-19, LLT: Asymptomatic SARS-CoV-2 infection - version MedDRA\\23.0.	Coder Import (b) (4)	23 Nov 2020 20:37:08
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4)	23 Nov 2020 20:37:08
Data point term sent to Coder	System	23 Nov 2020 15:08:53
Query 'For consistency, please update to Covid 19 Infection.' canceled (Site from System).	Coder Import (b) (4)	23 Nov 2020 15:08:51
User opened query 'For consistency, please update to Covid 19 Infection.' (Site from System).	Coder Import (b) (4)	07 Nov 2020 19:36:26
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 21:08:54
User coded data point as SOC: Infections and infestations, HLGT: Viral infectious disorders, HLT: Coronavirus infections, PT: Asymptomatic COVID-19, LLT: Asymptomatic SARS-CoV-2 infection - version MedDRA\\23.0.	Coder Import (b) (4)	19 Sep 2020 06:22:47
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4)	19 Sep 2020 06:22:47
Data point term sent to Coder	System	18 Sep 2020 19:31:28
User entered 'SARS-CoV-2 Infection (Asymptomatic)'	Monica Feeley (b) (4)	18 Sep 2020 19:31:10

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:41:12

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:43:11
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:29:40
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 21:08:54
User entered 'Yes (Y)'	Monica Feeley (b) (4)	18 Sep 2020 19:31:10
	(b) (4)	

US3432334

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:41:12

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:43:11
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:29:40
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 21:08:54
User entered 'No (N)'	Monica Feeley (b) (4)	18 Sep 2020 19:31:10
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:41:12

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:43:11
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:29:40
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 21:08:54
User entered 'No (N)'	Monica Feeley (b) (4)	18 Sep 2020 19:31:10
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:41:12

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:43:11
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:29:40
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 21:08:54
User entered '16 Sep 2020'	Monica Feeley (b) (4)	18 Sep 2020 19:31:10
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:41:12

Start time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:43:11
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:29:40
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 21:08:54
User entered empty.	Monica Feeley (b) (4)	18 Sep 2020 19:31:10
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:41:12

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:43:11
User entered empty.	System	18 Sep 2020 19:31:10

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:41:12

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:43:11
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:29:40
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 21:08:54
User entered 'No (N)' reason for change: Data Entry Error	Natalie Izaguirre (b) (4)	29 Sep 2020 00:06:41
	(b) (4)	
User entered 'Yes (Y)'	Monica Feeley (b) (4)	18 Sep 2020 19:31:10
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:41:12

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:43:11
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:29:40
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 21:08:54
User entered '26 Sep 2020' reason for change: Data Entry Error	Natalie Izaguirre (b) (4)	29 Sep 2020 00:06:41
	(b) (4)	
User entered empty.	Monica Feeley (b) (4)	18 Sep 2020 19:31:10
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:41:12

End time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:43:11
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:29:40
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 21:08:54
User entered empty.	Monica Feeley (b) (4)	18 Sep 2020 19:31:10
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:41:12

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:43:11
User entered empty.	System	18 Sep 2020 19:31:10

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:41:12

[Severity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:43:11
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:29:40
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 21:08:54
User entered 'Grade 1/Mild (Grade 1/Mild)'	Monica Feeley (b) (4)	18 Sep 2020 19:31:10
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:41:12

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:43:11
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:29:40
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 21:08:54
User entered 'No (N)'	Monica Feeley (b) (4)	18 Sep 2020 19:31:10
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:41:12

[Death](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:43:11
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:29:40
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 21:08:54
User entered '0'	Monica Feeley (b) (4)	18 Sep 2020 19:31:10
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:41:12

[Life threatening](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:43:11
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:29:40
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 21:08:54
User entered '0'	Monica Feeley (b) (4)	18 Sep 2020 19:31:10
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:41:12

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:43:11
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:29:40
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 21:08:54
User entered '0'	Monica Feeley (b) (4)	18 Sep 2020 19:31:10
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:41:12

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:43:11
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:29:40
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 21:08:54
User entered empty.	Monica Feeley (b) (4)	18 Sep 2020 19:31:10
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:41:12

Hospital Discharge Date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:43:11
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:29:40
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 21:08:54
User entered empty.	Monica Feeley (b) (4)	18 Sep 2020 19:31:10
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:41:12

[Admitted to ICU?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:43:11
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:29:40
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 21:08:54
User entered empty.	Monica Feeley (b) (4)	18 Sep 2020 19:31:10
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:41:12

[Number of Days in ICU](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:43:11
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:29:40
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 21:08:54
User entered empty.	Monica Feeley (b) (4)	18 Sep 2020 19:31:10
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:41:12

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:43:11
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:29:40
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 21:08:54
User entered '0'	Monica Feeley (b) (4)	18 Sep 2020 19:31:10
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:41:12

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:43:11
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:29:40
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 21:08:54
User entered '0'	Monica Feeley (b) (4)	18 Sep 2020 19:31:10
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:41:12

[Other medically important event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:43:11
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:29:40
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 21:08:54
User entered '0'	Monica Feeley (b) (4)	18 Sep 2020 19:31:10
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:41:12

[Relationship to investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:43:11
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:29:40
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 21:08:54
Query 'Action taken with investigational product is recorded as Withdrawn; however Relationship is not recorded as Related. Please review and reconcile.' canceled (Site from System).	(b) (4), (b) (6)	25 Sep 2020 13:26:29
User closed query 'Data is required. Please complete.' (Site from System).	(b) (4), (b) (6)	21 Sep 2020 13:12:03
User opened query 'Action taken with investigational product is recorded as Withdrawn; however Relationship is not recorded as Related. Please review and reconcile.' (Site from System).	System	18 Sep 2020 19:31:41
User entered 'Not Related (NOT RELATED)' reason for change: Data Entry Error	Monica Feeley (b) (4)	18 Sep 2020 19:31:41
	(b) (4)	
Query 'Data is required. Please complete.' answered with 'updated' (Site from System).	Monica Feeley (b) (4)	18 Sep 2020 19:31:35
	(b) (4)	
User opened query 'Data is required. Please complete.' (Site from System).	System	18 Sep 2020 19:31:29
User closed query 'Action taken with investigational product is recorded as Withdrawn; however Relationship is not recorded as Related. Please review and reconcile.' (Site from System).	System	18 Sep 2020 19:31:29
User entered empty; reason for change Data Entry Error	Monica Feeley (b) (4)	18 Sep 2020 19:31:29
	(b) (4)	
User opened query 'Action taken with investigational product is recorded as Withdrawn; however Relationship is not recorded as Related. Please review and reconcile.' (Site from System).	System	18 Sep 2020 19:31:19
User closed query 'Action taken with investigational product is recorded as Withdrawn; however Relationship is not recorded as Related. Please review and reconcile.' (Site from System).	System	18 Sep 2020 19:31:19
User entered 'Not Applicable (NOT APPLICABLE)' reason for change: Data Entry Error	Monica Feeley (b) (4)	18 Sep 2020 19:31:19
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:41:12

[Relationship to investigational product](#)

Audit	User	Time (GMT)
User opened query 'Action taken with investigational System product is recorded as Withdrawn; however Relationship is not recorded as Related. Please review and reconcile.' (Site from System). User entered 'Not Related (NOT RELATED)'	Monica Feeley (b) (4)	18 Sep 2020 19:31:10

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:41:12

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:43:11
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:29:40
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 21:08:54
User entered 'Not Related (NOT RELATED)'	Monica Feeley (b) (4)	18 Sep 2020 19:31:10
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:41:12

Action taken with investigational product

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:43:11
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:29:40
User closed query 'Action Taken with Investigational Product is Withdrawn, however Primary reason for Dosing Discontinuation is NOT AE (specify) or SAE (specify). Please review and reconcile.' (Site from System).	(b) (4), (b) (6)	04 Dec 2020 06:33:35
Query 'Action Taken with Investigational Product is Withdrawn, however Primary reason for Dosing Discontinuation is NOT AE (specify) or SAE (specify). Please review and reconcile.' answered with 'reason for withdrawal is AE. Updated' (Site from System).	Julia Klopfer (b) (4)	24 Nov 2020 23:20:12
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 21:08:54
User opened query 'Action Taken with Investigational Product is Withdrawn, however Primary reason for Dosing Discontinuation is NOT AE (specify) or SAE (specify). Please review and reconcile.' (Site from System).	System	22 Oct 2020 19:20:55
User entered 'Investigational Product Withdrawn (WITHDRAWN)'	Monica Feeley (b) (4)	18 Sep 2020 19:31:10
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:41:12

None

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:43:11
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:29:40
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 21:08:54
User entered 'I'	Monica Feeley (b) (4)	18 Sep 2020 19:31:10
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:41:12

[Concomitant Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:43:11
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:29:40
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 21:08:54
User entered '0'	Monica Feeley (b) (4)	18 Sep 2020 19:31:10
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:41:12

[Concomitant Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:43:11
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:29:40
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 21:08:54
User entered '0'	Monica Feeley (b) (4)	18 Sep 2020 19:31:10
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:41:12

[Outcome](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:43:11
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:29:40
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 21:08:54
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)' reason for change:	Natalie Izaguirre (b) (4)	29 Sep 2020 00:06:41
Data Entry Error	(b) (4)	
User closed query 'Data is required. Please complete.' (Site from System).	System	18 Sep 2020 19:32:10
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	18 Sep 2020 19:32:10
User entered 'Recovering/Resolving (RECOVERING/RESOLVING)' reason for change:	Monica Feeley (b) (4)	18 Sep 2020 19:32:10
Data Entry Error	(b) (4)	
User opened query 'Data is required. Please complete.' (Site from System).	System	18 Sep 2020 19:31:10
User entered empty.	Monica Feeley (b) (4)	18 Sep 2020 19:31:10
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:41:12

If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:43:11
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:29:40
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 21:08:54
User entered empty.	Monica Feeley (b) (4)	18 Sep 2020 19:31:10
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:41:12

[Narrative](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:43:11
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:29:40
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 21:08:54
User entered empty.	Monica Feeley (b) (4)	18 Sep 2020 19:31:10
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:41:12

Serious Adverse Event Derived (CSA Programming Field Only)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:43:11
User entered '0'	System	18 Sep 2020 19:31:10

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:41:12

Medically Attended AE Derived (CSA Programming Field Only)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:43:11
User entered '1'	System	18 Sep 2020 19:31:10

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:41:12

[Admitted to ICU Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:43:11

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination Summary

Generated On: 11 Aug 2021 22:41:12

[Were any prior/concomitant medications and/or vaccinations taken?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:43:11
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:29:40
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 21:08:58
User entered 'Yes (Y)'	Phoebe Cunningham	28 Aug 2020 15:53:18
	(b) (4)	

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 11 Aug 2021 22:41:12

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:43:11
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:29:40
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 21:09:49
User coded data point as ATC: RESPIRATORY SYSTEM, ATC: DRUGS FOR OBSTRUCTIVE AIRWAY DISEASES, ATC: ADRENERGICS, INHALANTS, ATC: SELECTIVE BETA-2-ADRENORECEPTOR AGONISTS, PRODUCT: SALBUTAMOL, PRODUCTSYNONYM: ALBUTEROL [SALBUTAMOL] - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	28 Aug 2020 15:54:39
	(b) (4)	
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	28 Aug 2020 15:54:39
	(b) (4)	
Data point term sent to Coder	System	28 Aug 2020 15:54:24
User entered 'Albuterol'	Phoebe Cunningham	28 Aug 2020 15:54:12
	(b) (4)	

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 11 Aug 2021 22:41:12

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:43:11
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:29:40
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 21:09:49
User entered 'No (N)'	Phoebe Cunningham	28 Aug 2020 15:54:12
	(b) (4)	

US3432334

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 11 Aug 2021 22:41:12

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:43:11
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:29:40
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 21:09:49
User entered 'Asthma'	Phoebe Cunningham	28 Aug 2020 15:54:12
	(b) (4)	

US3432334

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 11 Aug 2021 22:41:12

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:43:11
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:29:40
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 21:09:49
User entered '2'	Phoebe Cunningham	28 Aug 2020 15:54:12
	(b) (4)	

US3432334

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 11 Aug 2021 22:41:12

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:43:11
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:29:40
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 21:09:49
User entered 'puff (PUFF)'	Phoebe Cunningham	28 Aug 2020 15:54:12
	(b) (4)	

US3432334

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 11 Aug 2021 22:41:12

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:43:11
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:29:40
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 21:09:49
User entered empty.	Phoebe Cunningham	28 Aug 2020 15:54:12
	(b) (4)	

US3432334

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 11 Aug 2021 22:41:12

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:43:11
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:29:40
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 21:09:49
User entered 'as needed (PRN)'	Phoebe Cunningham	28 Aug 2020 15:54:12
	(b) (4)	

US3432334

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 11 Aug 2021 22:41:12

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:43:11
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:29:40
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 21:09:49
User entered empty.	Phoebe Cunningham	28 Aug 2020 15:54:12
	(b) (4)	

US3432334

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 11 Aug 2021 22:41:12

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:43:11
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:29:40
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 21:09:49
User entered 'Respiratory (Inhalation) (RESPIRATORY (INHALATION))'	Phoebe Cunningham (b) (4)	28 Aug 2020 15:54:12

US3432334

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 11 Aug 2021 22:41:12

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:43:11
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:29:40
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 21:09:49
User entered empty.	Phoebe Cunningham	28 Aug 2020 15:54:12
	(b) (4)	

US3432334

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 11 Aug 2021 22:41:12

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:43:11
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:29:40
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 21:09:49
User entered 'un UNK 2018'	Phoebe Cunningham	28 Aug 2020 15:54:12
	(b) (4)	

US3432334

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 11 Aug 2021 22:41:12

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:43:11
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:29:40
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 21:09:49
User entered '0'	Phoebe Cunningham	28 Aug 2020 15:54:12
	(b) (4)	

US3432334

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 11 Aug 2021 22:41:12

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:43:11
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:29:40
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 21:09:49
User entered 'Yes (Y)'	Phoebe Cunningham	28 Aug 2020 15:54:12
	(b) (4)	

US3432334

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 11 Aug 2021 22:41:12

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:43:11
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:29:40
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 21:09:49
User entered empty.	Phoebe Cunningham	28 Aug 2020 15:54:12
	(b) (4)	

US3432334

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 11 Aug 2021 22:41:12

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:43:11
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:29:40
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 21:09:49
User entered 'No (N)'	Phoebe Cunningham	28 Aug 2020 15:54:12
	(b) (4)	

US3432334

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 11 Aug 2021 22:41:12

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:43:11
User entered empty.	System	28 Aug 2020 15:54:12

US3432334

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 11 Aug 2021 22:41:12

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:43:11
User entered empty.	System	28 Aug 2020 15:54:12

US3432334

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 11 Aug 2021 22:41:12

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:43:11
User entered empty.	System	28 Aug 2020 15:54:12

US3432334

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 11 Aug 2021 22:41:12

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 07:34:32
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:29:40
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 21:09:49
User coded data point as ATC: ANTIINFECTIVES FOR SYSTEMIC USE, ATC: VACCINES, ATC: VIRAL VACCINES, ATC: INFLUENZA VACCINES, PRODUCT: INFLUENZA VACCINE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	17 Oct 2020 20:26:30
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	17 Oct 2020 20:26:30
Data point term sent to Coder	System	17 Oct 2020 20:25:57
User entered 'Flu Vaccine'	Xhoi Mitre (b) (4)	17 Oct 2020 20:25:01

US3432334

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 11 Aug 2021 22:41:12

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 07:34:32
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:29:40
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 21:09:49
User entered 'Yes (Y)'	Xhoi Mitre (b) (4)	17 Oct 2020 20:25:01

US3432334

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 11 Aug 2021 22:41:12

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 07:34:32
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:29:40
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 21:09:49
User entered 'Flu prophylaxis'	Xhoi Mitre (b) (4)	17 Oct 2020 20:25:01

US3432334

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 11 Aug 2021 22:41:12

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 07:34:32
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:29:40
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 21:09:49
User entered '0.5'	Xhoi Mitre (b) (4)	17 Oct 2020 20:25:01

US3432334

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 11 Aug 2021 22:41:12

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 07:34:32
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:29:40
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 21:09:49
User entered 'mL (mL)'	Xhoi Mitre (b) (4)	17 Oct 2020 20:25:01

US3432334

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 11 Aug 2021 22:41:12

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 07:34:32
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:29:40
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 21:09:49
User entered empty.	Xhoi Mitre (b) (4)	17 Oct 2020 20:25:01

US3432334

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 11 Aug 2021 22:41:12

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 07:34:32
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:29:40
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 21:09:49
User entered 'once (ONCE)'	Xhoi Mitre (b) (4)	17 Oct 2020 20:25:01

US3432334

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 11 Aug 2021 22:41:12

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 07:34:32
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:29:40
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 21:09:49
User entered empty.	Xhoi Mitre (b) (4)	17 Oct 2020 20:25:01

US3432334

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 11 Aug 2021 22:41:12

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 07:34:32
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:29:40
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 21:09:49
User entered 'Intramuscular (INTRAMUSCULAR)'	Xhoi Mitre (b) (4)	17 Oct 2020 20:25:01

US3432334

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 11 Aug 2021 22:41:12

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 07:34:32
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:29:40
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 21:09:49
User entered empty.	Xhoi Mitre (b) (4)	17 Oct 2020 20:25:01

US3432334

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 11 Aug 2021 22:41:12

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 07:34:32
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:29:40
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 21:09:49
User entered '05 Oct 2020'	Xhoi Mitre (b) (4)	17 Oct 2020 20:25:01

US3432334

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 11 Aug 2021 22:41:12

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 07:34:32
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:29:40
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 21:09:49
User entered '0'	Xhoi Mitre (b) (4)	17 Oct 2020 20:25:01

US3432334

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 11 Aug 2021 22:41:12

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 07:34:32
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:29:40
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 21:09:49
User entered 'No (N)'	Xhoi Mitre (b) (4)	17 Oct 2020 20:25:01

US3432334

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 11 Aug 2021 22:41:12

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 07:34:32
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:29:40
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 21:09:49
User entered '5 Oct 2020'	Xhoi Mitre (b) (4)	17 Oct 2020 20:25:01

US3432334

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 11 Aug 2021 22:41:12

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 07:34:32
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:29:40
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 21:09:49
User entered 'No (N)'	Xhoi Mitre (b) (4)	17 Oct 2020 20:25:01

US3432334

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 11 Aug 2021 22:41:12

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 07:34:32
User entered empty.	System	17 Oct 2020 20:25:01

US3432334

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 11 Aug 2021 22:41:12

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 07:34:32
User entered empty.	System	17 Oct 2020 20:25:01

US3432334

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 11 Aug 2021 22:41:12

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 07:34:32
User entered empty.	System	17 Oct 2020 20:25:01

US3432334

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 11 Aug 2021 22:41:12

Name of Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 07:34:38
User coded data point as ATC: ANTIINFECTIVES FOR SYSTEMIC USE, ATC: VACCINES, ATC: VIRAL VACCINES, ATC: HEPATITIS VACCINES, PRODUCT: HEPATITIS B VACCINE, PRODUCTSYNONYM: HEPATITIS B [HEPATITIS B VACCINE] - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	20 Apr 2021 23:33:44
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	20 Apr 2021 23:33:44
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:29:40
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 21:09:49
User coded data point as ATC: ANTIINFECTIVES FOR SYSTEMIC USE, ATC: VACCINES, ATC: VIRAL VACCINES, ATC: HEPATITIS VACCINES, PRODUCT: HEPATITIS B VACCINE, PRODUCTSYNONYM: HEPATITIS B [HEPATITIS B VACCINE] - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	02 Nov 2020 13:56:25
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	02 Nov 2020 13:56:25
User coded data point as ATC: ANTIINFECTIVES FOR SYSTEMIC USE, ATC: VACCINES, ATC: VIRAL VACCINES, ATC: HEPATITIS VACCINES, PRODUCT: HEPATITIS B VACCINE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	18 Oct 2020 02:28:32
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	18 Oct 2020 02:28:32
Data point term sent to Coder	System	17 Oct 2020 20:26:57
User entered 'hepatitis B vaccine'	Xhoi Mitre (b) (4) (b) (4)	17 Oct 2020 20:26:23

US3432334

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 11 Aug 2021 22:41:12

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 07:34:38
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:29:40
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 21:09:49
User entered 'Yes (Y)'	Xhoi Mitre (b) (4)	17 Oct 2020 20:26:23

US3432334

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 11 Aug 2021 22:41:12

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 07:34:38
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:29:40
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 21:09:49
User entered 'hepatitis B prophylaxis'	Xhoi Mitre (b) (4)	17 Oct 2020 20:26:23

US3432334

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 11 Aug 2021 22:41:12

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 07:34:38
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:29:40
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 21:09:49
User entered '1' reason for change: Data Entry Error	Julia Klopfer (b) (4)	19 Oct 2020 23:35:07
User entered 'UNK'	Xhoi Mitre (b) (4)	17 Oct 2020 20:26:23

US3432334

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 11 Aug 2021 22:41:12

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 07:34:38
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:29:40
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 21:09:49
User entered 'Other (OTHER)'	Xhoi Mitre (b) (4)	17 Oct 2020 20:26:23

US3432334

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 11 Aug 2021 22:41:12

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 07:34:38
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:29:40
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 21:09:49
User entered 'Injection' reason for change: Data Entry Error	Julia Klopfer (b) (4)	19 Oct 2020 23:35:07
User entered 'UNK'	Xhoi Mitre (b) (4)	17 Oct 2020 20:26:23

US3432334

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 11 Aug 2021 22:41:12

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 07:34:38
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:29:40
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 21:09:49
User entered 'once (ONCE)'	Xhoi Mitre (b) (4)	17 Oct 2020 20:26:23

US3432334

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 11 Aug 2021 22:41:12

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 07:34:38
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:29:40
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 21:09:49
User entered empty.	Xhoi Mitre (b) (4)	17 Oct 2020 20:26:23

US3432334

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 11 Aug 2021 22:41:12

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 07:34:38
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:29:40
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 21:09:49
User entered 'Intramuscular (INTRAMUSCULAR)'	Xhoi Mitre (b) (4)	17 Oct 2020 20:26:23

US3432334

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 11 Aug 2021 22:41:12

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 07:34:38
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:29:40
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 21:09:49
User entered empty.	Xhoi Mitre (b) (4)	17 Oct 2020 20:26:23

US3432334

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 11 Aug 2021 22:41:12

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 07:34:38
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:29:40
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 21:09:49
User entered '05 Oct 2020'	Xhoi Mitre (b) (4)	17 Oct 2020 20:26:23

US3432334

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 11 Aug 2021 22:41:12

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 07:34:38
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:29:40
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 21:09:49
User entered '0'	Xhoi Mitre (b) (4)	17 Oct 2020 20:26:23

US3432334

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 11 Aug 2021 22:41:12

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 07:34:38
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:29:40
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 21:09:49
User entered 'No (N)'	Xhoi Mitre (b) (4)	17 Oct 2020 20:26:23

US3432334

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 11 Aug 2021 22:41:12

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 07:34:38
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:29:40
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 21:09:49
User entered '5 Oct 2020'	Xhoi Mitre (b) (4)	17 Oct 2020 20:26:23

US3432334

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 11 Aug 2021 22:41:12

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 07:34:38
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:29:40
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 21:09:49
User entered 'No (N)'	Xhoi Mitre (b) (4)	17 Oct 2020 20:26:23

US3432334

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 11 Aug 2021 22:41:12

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 07:34:38
User entered empty.	System	17 Oct 2020 20:26:23

US3432334

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 11 Aug 2021 22:41:12

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 07:34:38
User entered empty.	System	17 Oct 2020 20:26:23

US3432334

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 11 Aug 2021 22:41:12

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 07:34:38
User entered empty.	System	17 Oct 2020 20:26:23

US3432334

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 11 Aug 2021 22:41:12

Name of Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 11:38:11
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:29:40
User closed query 'Per MM: Please confirm this event does not meet exclusion criteria # 4 (Prior administration of an investigational coronavirus (SARS-CoV, MERS-CoV) vaccine or current/planned simultaneous participation in another interventional study to prevent or treat COVID-19).' (Site from DM).	(b) (4), (b) (6)	03 Feb 2021 15:45:08
User closed query 'Per MM, please review and confirm if the subject meets the criteria to continue with the original study SoEs per protocol 4.1.2. If no, please ensure a protocol deviation is captured (as appropriate).' (Site from DM).	(b) (4), (b) (6)	03 Feb 2021 15:45:06
Query 'Per MM: Please confirm this event does not meet exclusion criteria # 4 (Prior administration of an investigational coronavirus (SARS-CoV, MERS-CoV) vaccine or current/planned simultaneous participation in another interventional study to prevent or treat COVID-19).' answered with 'deviation captured' (Site from DM).	Monica Feeley (b) (4)	02 Feb 2021 14:36:14
Query 'Per MM, please review and confirm if the subject meets the criteria to continue with the original study SoEs per protocol 4.1.2. If no, please ensure a protocol deviation is captured (as appropriate).' answered with 'deviation captured' (Site from DM).	Monica Feeley (b) (4)	02 Feb 2021 14:36:09
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)	01 Feb 2021 20:18:30
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	01 Feb 2021 20:18:30

US3432334

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 11 Aug 2021 22:41:12

[Name of Medication](#)

Audit	User	Time (GMT)
User opened query 'Per MM: Please confirm this event does not meet exclusion criteria # 4 (Prior administration of an investigational coronavirus (SARS-CoV, MERS-CoV) vaccine or current/planned simultaneous participation in another interventional study to prevent or treat COVID-19).' (Site from DM).	(b) (4), (b) (6)	01 Feb 2021 14:21:03
User opened query 'Per MM, please review and confirm if the subject meets the criteria to continue with the original study SoEs per protocol 4.1.2. If no, please ensure a protocol deviation is captured (as appropriate).' (Site from DM).	(b) (4), (b) (6)	01 Feb 2021 14:20:57
DataPoint Verified.	(b) (4), (b) (6)	20 Jan 2021 18:58:43
User coded data point as ATC: ANTIINFECTIVES FOR SYSTEMIC USE, ATC: VACCINES, ATC: VIRAL VACCINES, PRODUCT: VIRAL VACCINES - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	29 Dec 2020 22:01:36
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	29 Dec 2020 22:01:36
Data point term sent to Coder	System	29 Dec 2020 21:54:08
User entered 'Pfizer COVID-19 Vaccine'	Jun Bai Park Chang (b) (4)	29 Dec 2020 21:53:32

US3432334

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 11 Aug 2021 22:41:12

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 11:38:11
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:29:40
DataPoint Verified.	(b) (4), (b) (6)	20 Jan 2021 18:58:43
User entered 'Yes (Y)'	Jun Bai Park Chang (b) (4)	29 Dec 2020 21:53:32

US3432334

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 11 Aug 2021 22:41:12

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 11:38:11
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:29:40
DataPoint Verified.	(b) (4), (b) (6)	20 Jan 2021 18:58:43
User entered 'COVID-19 Prophylaxis'	Jun Bai Park Chang (b) (4)	29 Dec 2020 21:53:32

US3432334

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 11 Aug 2021 22:41:12

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 11:38:11
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:29:40
DataPoint Verified.	(b) (4), (b) (6)	20 Jan 2021 18:58:43
User entered 'I'	Jun Bai Park Chang	29 Dec 2020 21:53:32
	(b) (4)	

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 11 Aug 2021 22:41:12

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 11:38:11
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:29:40
DataPoint Verified.	(b) (4), (b) (6)	20 Jan 2021 18:58:43
User entered 'Other (OTHER)'	Jun Bai Park Chang	29 Dec 2020 21:53:32
	(b) (4)	

US3432334

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 11 Aug 2021 22:41:12

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 11:38:11
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:29:40
DataPoint Verified.	(b) (4), (b) (6)	20 Jan 2021 18:58:43
User entered 'injection'	Jun Bai Park Chang	29 Dec 2020 21:53:32
	(b) (4)	

US3432334

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 11 Aug 2021 22:41:12

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 11:38:11
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:29:40
DataPoint Verified.	(b) (4), (b) (6)	20 Jan 2021 18:58:43
User entered 'once (ONCE)'	Jun Bai Park Chang	29 Dec 2020 21:53:32
	(b) (4)	

US3432334

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 11 Aug 2021 22:41:12

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 11:38:11
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:29:40
DataPoint Verified.	(b) (4), (b) (6)	20 Jan 2021 18:58:43
User entered empty.	Jun Bai Park Chang	29 Dec 2020 21:53:32
	(b) (4)	

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 11 Aug 2021 22:41:12

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 11:38:11
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:29:40
DataPoint Verified.	(b) (4), (b) (6)	20 Jan 2021 18:58:43
User entered 'Intramuscular (INTRAMUSCULAR)'	Jun Bai Park Chang (b) (4)	29 Dec 2020 21:53:32

US3432334

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 11 Aug 2021 22:41:12

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 11:38:11
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:29:40
DataPoint Verified.	(b) (4), (b) (6)	20 Jan 2021 18:58:43
User entered empty.	Jun Bai Park Chang	29 Dec 2020 21:53:32
	(b) (4)	

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 11 Aug 2021 22:41:12

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 11:38:11
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:29:40
DataPoint Verified.	(b) (4), (b) (6)	20 Jan 2021 18:58:43
User entered '17 Dec 2020'	Jun Bai Park Chang	29 Dec 2020 21:53:32
	(b) (4)	

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 11 Aug 2021 22:41:12

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 11:38:11
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:29:40
DataPoint Verified.	(b) (4), (b) (6)	20 Jan 2021 18:58:43
User entered '0'	Jun Bai Park Chang	29 Dec 2020 21:53:32
	(b) (4)	

US3432334

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 11 Aug 2021 22:41:12

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 11:38:11
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:29:40
DataPoint Verified.	(b) (4), (b) (6)	20 Jan 2021 18:58:43
User entered 'No (N)'	Jun Bai Park Chang	29 Dec 2020 21:53:32
	(b) (4)	

US3432334

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 11 Aug 2021 22:41:12

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 11:38:11
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:29:40
DataPoint Verified.	(b) (4), (b) (6)	20 Jan 2021 18:58:43
User entered '17 Dec 2020'	Jun Bai Park Chang	29 Dec 2020 21:53:32
	(b) (4)	

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 11 Aug 2021 22:41:12

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 11:38:11
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:29:40
DataPoint Verified.	(b) (4), (b) (6)	20 Jan 2021 18:58:43
User entered 'No (N)'	Jun Bai Park Chang	29 Dec 2020 21:53:32
	(b) (4)	

US3432334

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 11 Aug 2021 22:41:12

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 11:38:11
User entered empty.	System	29 Dec 2020 21:53:32

US3432334

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 11 Aug 2021 22:41:12

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 11:38:11
User entered empty.	System	29 Dec 2020 21:53:32

US3432334

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 11 Aug 2021 22:41:12

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 11:38:11
User entered empty.	System	29 Dec 2020 21:53:32

US3432334

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures Summary

Generated On: 11 Aug 2021 22:41:12

[Were any concomitant procedures performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:43:11
User signature succeeded.	Lindsey Baden (b) (4)	04 Apr 2021 20:51:13
DataPoint Verified.	(b) (4), (b) (6)	30 Mar 2021 16:39:52
User entered 'No (N)'	Monica Feeley (b) (4)	24 Mar 2021 21:54:17
	(b) (4)	

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Folder: End of Study (1)

Form: Dosing Discontinuation

Generated On: 11 Aug 2021 22:41:12

Date of dosing discontinuation (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:00:58
DataPoint Verified.	(b) (4), (b) (6)	30 Mar 2021 16:43:31
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:29:40
User entered '26 Sep 2020'	Monica Feeley (b) (4)	22 Oct 2020 19:20:55

US3432334

Folder: End of Study (1)

Form: Dosing Discontinuation

Generated On: 11 Aug 2021 22:41:12

[Primary reason for dosing discontinuation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:00:58
DataPoint Verified.	(b) (4), (b) (6)	30 Mar 2021 16:43:31
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:29:40
User entered 'Due to SARS-COV-2 (COVID)'	Monica Feeley (b) (4)	22 Oct 2020 19:20:55

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Folder: End of Study (1)

Form: Dosing Discontinuation

Generated On: 11 Aug 2021 22:41:12

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 15:00:58
DataPoint Verified.	(b) (4), (b) (6)	30 Mar 2021 16:43:31
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:29:40
User entered empty.	Monica Feeley (b) (4)	22 Oct 2020 19:20:55

US3432334

Folder: End of Study (1)

Form: End of Study / Study Discontinuation

Generated On: 11 Aug 2021 22:41:12

Date of study discontinuation/completion (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:00:58
DataPoint Verified.	(b) (4), (b) (6)	30 Mar 2021 16:43:25
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:29:40
User entered '29 Dec 2020'	Monica Feeley (b) (4)	09 Feb 2021 17:23:48

US3432334

Folder: End of Study (1)

Form: End of Study / Study Discontinuation

Generated On: 11 Aug 2021 22:41:12

[Reason for discontinuation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:00:58
User signature succeeded.	Lindsey Baden (b) (4)	04 Apr 2021 20:51:13
DataPoint Verified.	(b) (4), (b) (6)	30 Mar 2021 16:43:25
User closed query 'Per CDM: Per Sponsor Review, if subject received EUA vaccine outside of study, discontinuation reason is to be recorded as Protocol Deviation. Please review and update as appropriate. ' (Site from DM).	(b) (4), (b) (6)	23 Mar 2021 09:16:50
Query 'Per CDM: Per Sponsor Review, if subject received EUA vaccine outside of study, discontinuation reason is to be recorded as Protocol Deviation. Please review and update as appropriate. ' answered with 'Updated.' (Site from DM).	Tenaizus Woods (b) (4)	22 Mar 2021 16:52:29
Signature has been broken.	Tenaizus Woods (b) (4)	22 Mar 2021 16:51:53
User entered 'Protocol deviation (specify) (PROTOCOL DEVIATION)' reason for change: Data Entry Error	Tenaizus Woods (b) (4)	22 Mar 2021 16:51:53
User opened query 'Per CDM: Per Sponsor Review, if subject received EUA vaccine outside of study, discontinuation reason is to be recorded as Protocol Deviation. Please review and update as appropriate. ' (Site from DM).	(b) (4), (b) (6)	22 Mar 2021 14:30:24
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:29:40
User entered 'Other (OTHER)'	Monica Feeley (b) (4)	09 Feb 2021 17:23:48

US3432334

Folder: End of Study (1)

Form: End of Study / Study Discontinuation

Generated On: 11 Aug 2021 22:41:12

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 15:00:58
DataPoint Verified.	(b) (4), (b) (6)	30 Mar 2021 16:43:25
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:29:40
User entered 'RECEIVED EUA VACCINE OUTSIDE STUDY'	Monica Feeley (b) (4)	09 Feb 2021 17:23:48

US3432334

Folder: End of Study (1)

Form: End of Study / Study Discontinuation

Generated On: 11 Aug 2021 22:41:12

If reason for discontinuation is Death, main cause of death

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:00:58
DataPoint Verified.	(b) (4), (b) (6)	30 Mar 2021 16:43:25
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:29:40
User entered empty.	Monica Feeley (b) (4)	09 Feb 2021 17:23:48

US3432334

Folder: End of Study (1)

Form: End of Study / Study Discontinuation

Generated On: 11 Aug 2021 22:41:12

If main cause of death is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:00:58
DataPoint Verified.	(b) (4), (b) (6)	30 Mar 2021 16:43:25
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:29:40
User entered empty.	Monica Feeley (b) (4)	09 Feb 2021 17:23:48

US3432334

Folder: End of Study (1)

Form: End of Study / Study Discontinuation

Generated On: 11 Aug 2021 22:41:12

Date of death (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:00:58
DataPoint Verified.	(b) (4), (b) (6)	30 Mar 2021 16:43:25
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:29:40
User entered empty.	Monica Feeley (b) (4)	09 Feb 2021 17:23:48

US3432334

Folder: End of Study (1)

Form: End of Study / Study Discontinuation

Generated On: 11 Aug 2021 22:41:12

[Was autopsy performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:00:58
DataPoint Verified.	(b) (4), (b) (6)	30 Mar 2021 16:43:25
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:29:40
User entered empty.	Monica Feeley (b) (4)	09 Feb 2021 17:23:48