US3342142 (Prod: Tekton Research- Austin)

Generated By: KC Joubran

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US3342142
Form: Participant Creation
Data signed: (b) (4) **12 Mar 2021 23:16:42**
Generated On: 11 Aug 2021 22:33:31

Participant ID	US3342142

mRNA-1273-P301 Completion Guidelines

FDA-CBER-2022-1614-2808629

US3342142
Folder: Screening
Form: Visit Date
Data signed: (b) (4) **12 Mar 2021 23:16:48**
Generated On: 11 Aug 2021 22:33:31

Was this visit performed?	Yes ■ No ☐
Visit date (dd MMM yyyy)	24 AUG 2020
Was visit performed at the participant's home or at the clinic?	Home ☐ Clinic ■
Folder OID	SCRN

FDA-CBER-2022-1614-2808630

US3342142
Folder: Screening
Form: Demographics
Data signed: (b) (4) **12 Mar 2021 23:16:48**
Generated On: 11 Aug 2021 22:33:31

Date of Birth (MMM yyyy)	(b) (6) 1983
Age	37
Age Units	YEARS
Age (Derived)	37
Sex	Female ■ Male ☐
Ethnicity	Hispanic or Latino ☐ Not Hispanic or Latino ■ Not Reported ☐ Unknown ☐
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

FDA-CBER-2022-1614-2808631

US3342142
Folder: Screening
Form: Enrollment
Data signed: (b) (4) **12 Mar 2021 23:16:48**
Generated On: 11 Aug 2021 22:33:31

Date of Informed Consent *(dd MMM yyyy)*	24 AUG 2020
Month and Year of Informed Consent (derived)	AUG 2020
Year of Informed Consent (derived)	2020
Protocol Version	Amendment 1 ☐ Amendment 2 ■ Amendment 3 ☐ Amendment 4 ☐ Amendment 5 ☐
Was participant enrolled in the study?	Yes ■ No ☐
If No, indicate reason for screen fail	Withdrew Consent ☐ Inclusion/Exclusion ☐ Cohort Full ☐ Other ☐
If reason for screen fail is Other, specify	
Was this participant screened previously?	Yes ☐ No ■
If Yes, previous participant number	
Enrollment Trigger	1

FDA-CBER-2022-1614-2808632

US3342142
Folder: Screening
Form: Inclusion/Exclusion Criteria Summary
Data signed: (b) (4) **12 Mar 2021 23:16:48**
Generated On: 11 Aug 2021 22:33:31

Did the participant meet all eligibility criteria?	Yes ■ No ☐

US3342142
Folder: Screening
Form: Medical History Summary
Data signed: (b) (4) **12 Mar 2021 23:16:48**
Generated On: 11 Aug 2021 22:33:31

Were any significant conditions reported?	Yes ■ No ☐

FDA-CBER-2022-1614-2808634

US3342142
Folder: Screening
Form: Medical History (1)
Data signed: (b) (4) **12 Mar 2021 23:16:48**
Generated On: 11 Aug 2021 22:33:31

Condition	SUPRAVENTRICULAR TACHYCARDIA
Start date (dd MMM yyyy)	UN UNK 2014
Start date completely unknown	False
Condition ongoing at study entry	Yes ☑ No ☐
If No, please specify the stop date (dd MMM yyyy)	
Stop date completely unknown	False
Start Month and Year (derived)	JAN 2014
Start Year (derived)	2014
Stop Month and Year (derived)	
Stop Year (derived)	

FDA-CBER-2022-1614-2808635

US3342142
Folder: Screening
Form: Medical History (2)
Data signed: (b) (4) **12 Mar 2021 23:16:48**
Generated On: 11 Aug 2021 22:33:31

Condition	HERPES SIMPLEX VIRUS I (GENITAL)
Start date (dd MMM yyyy)	UN UNK 2003
Start date completely unknown	False
Condition ongoing at study entry	Yes ■ No ☐
If No, please specify the stop date (dd MMM yyyy)	
Stop date completely unknown	False
Start Month and Year (derived)	JAN 2003
Start Year (derived)	2003
Stop Month and Year (derived)	
Stop Year (derived)	

FDA-CBER-2022-1614-2808636

US3342142
Folder: Screening
Form: Medical History (3)
Data signed: (b) (4) **12 Mar 2021 23:16:48**
Generated On: 11 Aug 2021 22:33:31

Condition	VENTRICULAR SEPTAL DEFECT
Start date (dd MMM yyyy)	(b) (6) 1983
Start date completely unknown	False
Condition ongoing at study entry	Yes ☐ No ■
If No, please specify the stop date (dd MMM yyyy)	UN UNK 1985
Stop date completely unknown	False
Start Month and Year (derived)	(b) (6) 1983
Start Year (derived)	1983
Stop Month and Year (derived)	JAN 1985
Stop Year (derived)	1985

FDA-CBER-2022-1614-2808637

US3342142
Folder: Screening
Form: Medical History (4)
Data signed: (b) (4) **12 Mar 2021 23:16:48**
Generated On: 11 Aug 2021 22:33:31

Condition	SEASONAL ALLERGIES
Start date (dd MMM yyyy)	UN UNK 2015
Start date completely unknown	False
Condition ongoing at study entry	Yes ☒ No ☐
If No, please specify the stop date (dd MMM yyyy)	
Stop date completely unknown	False
Start Month and Year (derived)	JAN 2015
Start Year (derived)	2015
Stop Month and Year (derived)	
Stop Year (derived)	

FDA-CBER-2022-1614-2808638

US3342142
Folder: Screening
Form: Vital Signs
Data signed: (b) (4) **12 Mar 2021 23:16:48**
Generated On: 11 Aug 2021 22:33:31

Were vital signs assessed?	Yes ☑ No ☐
Date of assessment *(dd MMM yyyy)*	24 AUG 2020
Time of assessment *(00:00-23:59)*	11:20 (24 HR)
Vital Signs Date and Time (derived)	24 AUG 2020 11:20
Height *(xxx.x)*	167.0 cm
Weight *(xxx.x)*	81.2 kg
BMI *(xxx.x)*	29.11542 kg/m^2
BMI units	KG/M2
Temperature *(xxx.x)*	ND - Not Done
Route of measurement	Oral ☐ Axillary ☐ Other ☐
If Other, specify	
Pulse *(xxx)*	ND - Not Done
Pulse units	BPM
Respiratory Rate *(xxx)*	ND - Not Done
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure *(xxx)*	ND - Not Done
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure *(xxx)*	ND - Not Done
Diastolic Blood Pressure units	MMHG
Height (derived)	
Weight (derived)	

FDA-CBER-2022-1614-2808639

US3342142
Folder: Screening
Form: Physical Examination
Data signed: (b) (4) **12 Mar 2021 23:16:48**
Generated On: 11 Aug 2021 22:33:31

Was the physical examination performed?	Yes ☑ No ☐
Date of examination *(dd MMM yyyy)*	24 AUG 2020

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

FDA-CBER-2022-1614-2808640

US3342142
Folder: Screening
Form: Childbearing Potential
Data signed: (b) (4) **12 Mar 2021 23:16:48**
Generated On: 11 Aug 2021 22:33:31

Date of assessment *(dd MMM yyyy)*	24 AUG 2020
Is the participant of childbearing potential?	Yes ■ No ☐
If No, what is the reason?	Surgically sterile ☐ Post-menopausal ☐ Partner medically sterile ☐ Not reached age of Menarche ☐ Other ☐
If Partner medically sterile or Other, specify	
If Surgically sterile, date of surgery *(dd MMM yyyy)*	
Date of surgery unknown	False
If Post-menopausal, date of last menstruation *(dd MMM yyyy)*	
Date of last menstruation unknown	False

FDA-CBER-2022-1614-2808641

US3342142
Folder: Screening
Form: Pregnancy Test
Data signed: (b) (4) **12 Mar 2021 23:16:48**
Generated On: 11 Aug 2021 22:33:31

Was the pregnancy test performed?	Yes ■ No ☐
Date of test *(dd MMM yyyy)*	24 AUG 2020
Test performed	Urine ■ Serum ☐
Result	Positive ☐ Negative ■
Was FSH sample collected?	Yes ☐ No ■
Collection date	
Collection time	
Collection date and time (derived)	

FDA-CBER-2022-1614-2808642

US3342142
Folder: Screening
Form: Risk of Exposure
Data signed: (b) (4) **12 Mar 2021 23:16:48**
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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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Resides in Multi-family dwelling (e.g., cohabitation in dwelling with > 5 people, includes grandparents living with children < 18yrs)	False
Resides in high density housing (e.g., high rise apartments with shared entrances or elevators)	False
Resides in low density, multi-family setting without (e.g., apartments complex without shared entrances or elevators, duplexes)	False
Resides in a single family home (i.e., detached housing)	True
Other	False
Specify	

FDA-CBER-2022-1614-2808644

US3342142
Folder: Visit 1 Day 1
Form: Visit Date
Data signed: (b) (4) **12 Mar 2021 23:16:48**
Generated On: 11 Aug 2021 22:33:31

Was this visit performed?	Yes ☑ No ☐
Visit date (dd MMM yyyy)	24 AUG 2020
Was visit performed at the participant's home or at the clinic?	Home ☐ Clinic ☑
Folder OID	VISIT1

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US3342142
Folder: Visit 1 Day 1
Form: Randomization
Data signed: (b) (4) **22 Mar 2021 13:27:19**
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What was the date of randomization? *(dd MMM yyyy)*	24 AUG 2020
What was the participant's randomization number?	106903
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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US3342142
Folder: Visit 1 Day 1
Form: Vital Signs - Dosing
Data signed: (b) (4) **12 Mar 2021 23:16:48**
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Height	ND - Not Done
Weight	ND - Not Done

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US3342142
Folder: Visit 1 Day 1
Form: Vital Signs - Dosing (1)
Data signed: (b) (4) **12 Mar 2021 23:16:48**
Generated On: 11 Aug 2021 22:33:31

Height	ND - Not Done
Weight	ND - Not Done
Timepoint	Pre-Dose ■ Post-Dose ☐
Were vital signs assessed?	Yes ■ No ☐
Date of assessment *(dd MMM yyyy)*	24 AUG 2020
Time of assessment *(00:00-23:59)*	11:20 (24 HR)
Vital Signs Date and Time (derived)	24 AUG 2020 11:20
Temperature *(xxx.x)*	97.5 F
Route of measurement	Oral ■ Axillary ☐ Other ☐
If Other, specify	
Pulse *(xxx)*	68 beats/min
Pulse units	BPM
Respiratory Rate *(xxx)*	18 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure *(xxx)*	112 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure *(xxx)*	74 mmHg
Diastolic Blood Pressure units	MMHG

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US3342142
Folder: Visit 1 Day 1
Form: Vital Signs - Dosing (2)
Data signed: (b) (4) **12 Mar 2021 23:16:48**
Generated On: 11 Aug 2021 22:33:31

Height	ND - Not Done
Weight	ND - Not Done
Timepoint	Pre-Dose ☐ Post-Dose ■
Were vital signs assessed?	Yes ■ No ☐
Date of assessment *(dd MMM yyyy)*	24 AUG 2020
Time of assessment *(00:00-23:59)*	12:49 (24 HR)
Vital Signs Date and Time (derived)	24 AUG 2020 12:49
Temperature *(xxx.x)*	97.7 F
Route of measurement	Oral ■ Axillary ☐ Other ☐
If Other, specify	
Pulse *(xxx)*	77 beats/min
Pulse units	BPM
Respiratory Rate *(xxx)*	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure *(xxx)*	127 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure *(xxx)*	82 mmHg
Diastolic Blood Pressure units	MMHG

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US3342142
Folder: Visit 1 Day 1
Form: Physical Examination
Data signed: (b) (4) **12 Mar 2021 23:16:48**
Generated On: 11 Aug 2021 22:33:31

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.

FDA-CBER-2022-1614-2808650

US3342142
Folder: Visit 1 Day 1
Form: Pregnancy Test
Data signed: (b) (4) **12 Mar 2021 23:16:48**
Generated On: 11 Aug 2021 22:33:31

Was the pregnancy test performed?	Yes ☐ No ■
Date of test *(dd MMM yyyy)*	
Test performed	Urine ☐ Serum ☐
Result	Positive ☐ Negative ☐
Was FSH sample collected?	Yes ☐ No ☐
Collection date	
Collection time	
Collection date and time (derived)	

FDA-CBER-2022-1614-2808651

US3342142
Folder: Visit 1 Day 1
Form: Exposure
Data signed: (b) (4) **12 Mar 2021 23:16:48**
Generated On: 11 Aug 2021 22:33:31

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)*	24 AUG 2020
What was the treatment time? *(00:00-23:59)*	12:19 (24 HR)
Treatment Date and Time (derived)	24 AUG 2020 12:19
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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US3342142
Folder: Visit 1 Day 1
Form: Immunogenicity Assessment
Data signed: (b) (4) **12 Mar 2021 23:16:48**
Generated On: 11 Aug 2021 22:33:31

Was the sample collected?	Yes ☑ No ☐
Collection date *(dd MMM yyyy)*	24 AUG 2020
Collection time *(00:00-23:59)*	11:48 (24 HR)
Collection date and time (derived)	24 AUG 2020 11:48

FDA-CBER-2022-1614-2808653

US3342142
Folder: Visit 1 Day 1
Form: Central Laboratory - Nasopharyngeal Swab
Data signed: (b) (4) **12 Mar 2021 23:16:48**
Generated On: 11 Aug 2021 22:33:31

Collection date *(dd MMM yyyy)*			24 AUG 2020
Lab Test	Was the sample collected?	Collection time *(00:00 - 23:59)*	Collection date and time (derived)
Nasopharyngeal Swab 1	Yes	11:50	24 AUG 2020 11:50
Nasopharyngeal Swab 2	No		

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US3342142
Folder: Visit 1 Day 1
Form: Continuing
Data signed: (b) (4) **12 Mar 2021 23:16:48**
Generated On: 11 Aug 2021 22:33:31

Is the participant continuing to the next visit?	Yes ☑ No ☐
Continuing Flag	1

FDA-CBER-2022-1614-2808655

US3342142
Folder: Diary Dose 1 (1)
Form: Temperature_Day(1/1)
Generated On: 11 Aug 2021 22:33:31

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?	Yes ■ No ☐
Please record your **TEMPERATURE in °F**	97.7 °F
Was any **MEDICATION TAKEN today for pain or fever**?	Yes ☐ No ■
Please confirm reason for pain or fever medication (may select more than one):	
PC Time Stamp	24 AUG 2020 12:53
PC Open Date & Time	24 AUG 2020 12:39
PC Close Date & Time	24 AUG 2020 15:09

FDA-CBER-2022-1614-2808656

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**	
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	24 AUG 2020 16:04
PC Close Date & Time	25 AUG 2020 11:59

US3342142
Folder: Diary Dose 1 (1)
Form: Temperature_Day(2)
Generated On: 11 Aug 2021 22:33:31

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**	99.1 °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	25 AUG 2020 20:16
PC Open Date & Time	25 AUG 2020 12:00
PC Close Date & Time	26 AUG 2020 11:59

US3342142
Folder: Diary Dose 1 (1)
Form: Temperature_Day(3)
Generated On: 11 Aug 2021 22:33:31

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**	99.1 °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	26 AUG 2020 20:20
PC Open Date & Time	26 AUG 2020 12:00
PC Close Date & Time	27 AUG 2020 11:59

US3342142
Folder: Diary Dose 1 (1)
Form: Temperature_Day(4)
Generated On: 11 Aug 2021 22:33:31

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**	98.7 °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	27 AUG 2020 23:31
PC Open Date & Time	27 AUG 2020 12:00
PC Close Date & Time	28 AUG 2020 11:59

US3342142
Folder: Diary Dose 1 (1)
Form: Temperature_Day(5)
Generated On: 11 Aug 2021 22:33:31

TIMEPOINT	DAY 5

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

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

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

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

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

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

Was **TEMPERATURE** taken?	Yes ●
	No ○
Please record your **TEMPERATURE in °F**	98.7 °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 07:24
PC Open Date & Time	28 AUG 2020 12:00
PC Close Date & Time	29 AUG 2020 11:59

FDA-CBER-2022-1614-2808661

US3342142
Folder: Diary Dose 1 (1)
Form: Temperature_Day(6)
Generated On: 11 Aug 2021 22:33:31

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**	98.5 °F
Was any **MEDICATION TAKEN today for pain or fever**?	Yes ○
	No ●
Please confirm reason for pain or fever medication (may select more than one):	
PC Time Stamp	29 AUG 2020 20:01
PC Open Date & Time	29 AUG 2020 12:00
PC Close Date & Time	30 AUG 2020 11:59

US3342142
Folder: Diary Dose 1 (1)
Form: Temperature_Day(7)
Generated On: 11 Aug 2021 22:33:31

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**	98.7 °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	31 AUG 2020 00:04
PC Open Date & Time	30 AUG 2020 12:00
PC Close Date & Time	31 AUG 2020 11:59

FDA-CBER-2022-1614-2808663

US3342142
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(1/1)
Generated On: 11 Aug 2021 22:33:31

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	24 AUG 2020 12:54
PC Open Date & Time	24 AUG 2020 12:39
PC Close Date & Time	24 AUG 2020 15:09

FDA-CBER-2022-1614-2808664

US3342142
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(1/2)
Generated On: 11 Aug 2021 22:33:31

TIMEPOINT	DAY 1, AFTER VACCINATION (AT HOME)
Please record - **PAIN AT INJECTION SITE.** Please select one response below	None ☐ Does not interfere with activity ☐ Repeated use of over-the-counter pain reliever > 24 hours or interferes with activity ☐ Any use of prescription pain reliever or prevents daily activity ☐
Is there any **REDNESS AT INJECTION SITE**?	Yes ☐ No ☐
Please record - **REDNESS AT INJECTION SITE (in mm)** Measure the largest size across any injection site redness with the ruler provided.	
Is there any **SWELLING/HARDNESS AT INJECTION SITE**?	Yes ☐ No ☐
Please record - **SWELLING/HARDNESS AT INJECTION SITE (in mm)** Measure the largest size across any injection site swelling/hardness with the ruler provided.	
Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.** Please select one response below	None ☐ Does not interfere with activity ☐ Repeated use of over-the-counter pain reliever > 24 hours or interferes with some activity ☐ Any use of prescription pain reliever or prevents daily activity ☐
PC Time Stamp	
PC Open Date & Time	24 AUG 2020 16:04
PC Close Date & Time	25 AUG 2020 11:59

FDA-CBER-2022-1614-2808665

US3342142
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(2)
Generated On: 11 Aug 2021 22:33:31

TIMEPOINT	DAY 2
Please record - **PAIN AT INJECTION SITE.** Please select one response below	None ☐ Does not interfere with activity ■ Repeated use of over-the-counter pain reliever > 24 hours or interferes with activity ☐ Any use of prescription pain reliever or prevents daily activity ☐
Is there any **REDNESS AT INJECTION SITE**?	Yes ☐ No ■
Is there any **SWELLING/HARDNESS AT INJECTION SITE**?	Yes ☐ No ■
Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.** Please select one response below	None ■ Does not interfere with activity ☐ Repeated use of over-the-counter pain reliever > 24 hours or interferes with some activity ☐ Any use of prescription pain reliever or prevents daily activity ☐
PC Time Stamp	25 AUG 2020 20:17
PC Open Date & Time	25 AUG 2020 12:00
PC Close Date & Time	26 AUG 2020 11:59

US3342142
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(3)
Generated On: 11 Aug 2021 22:33:31

TIMEPOINT	DAY 3
Please record - **PAIN AT INJECTION SITE.** Please select one response below	None ■ Does not interfere with activity ☐ Repeated use of over-the-counter pain reliever > 24 hours or interferes with activity ☐ Any use of prescription pain reliever or prevents daily activity ☐
Is there any **REDNESS AT INJECTION SITE**?	Yes ☐ No ■
Is there any **SWELLING/HARDNESS AT INJECTION SITE**?	Yes ☐ No ■
Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.** Please select one response below	None ■ Does not interfere with activity ☐ Repeated use of over-the-counter pain reliever > 24 hours or interferes with some activity ☐ Any use of prescription pain reliever or prevents daily activity ☐
PC Time Stamp	26 AUG 2020 20:21
PC Open Date & Time	26 AUG 2020 12:00
PC Close Date & Time	27 AUG 2020 11:59

US3342142
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(4)
Generated On: 11 Aug 2021 22:33:31

TIMEPOINT	DAY 4
Please record - **PAIN AT INJECTION SITE.** Please select one response below	None ■ Does not interfere with activity ☐ Repeated use of over-the-counter pain reliever > 24 hours or interferes with activity ☐ Any use of prescription pain reliever or prevents daily activity ☐
Is there any **REDNESS AT INJECTION SITE**?	Yes ☐ No ■
Is there any **SWELLING/HARDNESS AT INJECTION SITE**?	Yes ☐ No ■
Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.** Please select one response below	None ■ Does not interfere with activity ☐ Repeated use of over-the-counter pain reliever > 24 hours or interferes with some activity ☐ Any use of prescription pain reliever or prevents daily activity ☐
PC Time Stamp	27 AUG 2020 23:31
PC Open Date & Time	27 AUG 2020 12:00
PC Close Date & Time	28 AUG 2020 11:59

FDA-CBER-2022-1614-2808668

US3342142
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(5)
Generated On: 11 Aug 2021 22:33:31

TIMEPOINT	DAY 5
Please record - **PAIN AT INJECTION SITE.** Please select one response below	None ■ Does not interfere with activity ☐ Repeated use of over-the-counter pain reliever > 24 hours or interferes with activity ☐ Any use of prescription pain reliever or prevents daily activity ☐
Is there any **REDNESS AT INJECTION SITE**?	Yes ☐ No ■
Is there any **SWELLING/HARDNESS AT INJECTION SITE**?	Yes ☐ No ■
Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.** Please select one response below	None ■ Does not interfere with activity ☐ Repeated use of over-the-counter pain reliever > 24 hours or interferes with some activity ☐ Any use of prescription pain reliever or prevents daily activity ☐
PC Time Stamp	29 AUG 2020 07:24
PC Open Date & Time	28 AUG 2020 12:00
PC Close Date & Time	29 AUG 2020 11:59

US3342142
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(6)
Generated On: 11 Aug 2021 22:33:31

TIMEPOINT	DAY 6
Please record - **PAIN AT INJECTION SITE.** Please select one response below	None ■ Does not interfere with activity ☐ Repeated use of over-the-counter pain reliever > 24 hours or interferes with activity ☐ Any use of prescription pain reliever or prevents daily activity ☐
Is there any **REDNESS AT INJECTION SITE**?	Yes ☐ No ■
Is there any **SWELLING/HARDNESS AT INJECTION SITE**?	Yes ☐ No ■
Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.** Please select one response below	None ■ Does not interfere with activity ☐ Repeated use of over-the-counter pain reliever > 24 hours or interferes with some activity ☐ Any use of prescription pain reliever or prevents daily activity ☐
PC Time Stamp	29 AUG 2020 20:01
PC Open Date & Time	29 AUG 2020 12:00
PC Close Date & Time	30 AUG 2020 11:59

US3342142
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(7)
Generated On: 11 Aug 2021 22:33:31

TIMEPOINT	DAY 7
Please record - **PAIN AT INJECTION SITE.** Please select one response below	None ■ Does not interfere with activity ☐ Repeated use of over-the-counter pain reliever > 24 hours or interferes with activity ☐ Any use of prescription pain reliever or prevents daily activity ☐
Is there any **REDNESS AT INJECTION SITE**?	Yes ☐ No ■
Is there any **SWELLING/HARDNESS AT INJECTION SITE**?	Yes ☐ No ■
Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.** Please select one response below	None ■ Does not interfere with activity ☐ Repeated use of over-the-counter pain reliever > 24 hours or interferes with some activity ☐ Any use of prescription pain reliever or prevents daily activity ☐
PC Time Stamp	31 AUG 2020 00:04
PC Open Date & Time	30 AUG 2020 12:00
PC Close Date & Time	31 AUG 2020 11:59

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 ☐

FDA-CBER-2022-1614-2808672

US3342142
Folder: Diary Dose 1 (1)
Form: General_Day(1/1)
Generated On: 11 Aug 2021 22:33:31

Did you receive any **MEDICAL ATTENTION (doctor visit, other)** for any illness or symptoms?	No ■ Yes ☐
PC Time stamp	24 AUG 2020 12:54
PC Open Date & Time	24 AUG 2020 12:39
PC Close Date & Time	24 AUG 2020 15:09

FDA-CBER-2022-1614-2808673

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 ☐

FDA-CBER-2022-1614-2808674

US3342142
Folder: Diary Dose 1 (1)
Form: General_Day(1/2)
Generated On: 11 Aug 2021 22:33:31

Did you receive any **MEDICAL ATTENTION (doctor visit, other)** for any illness or symptoms?	No ☐ Yes ☐
PC Time stamp	
PC Open Date & Time	24 AUG 2020 16:04
PC Close Date & Time	25 AUG 2020 11:59

FDA-CBER-2022-1614-2808675

US3342142
Folder: Diary Dose 1 (1)
Form: General_Day(2)
Generated On: 11 Aug 2021 22:33:31

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 ■

FDA-CBER-2022-1614-2808676

US3342142
Folder: Diary Dose 1 (1)
Form: General_Day(2)
Generated On: 11 Aug 2021 22:33:31

	Yes ☐
PC Time stamp	25 AUG 2020 20:18
PC Open Date & Time	25 AUG 2020 12:00
PC Close Date & Time	26 AUG 2020 11:59

FDA-CBER-2022-1614-2808677

US3342142
Folder: Diary Dose 1 (1)
Form: General_Day(3)
Generated On: 11 Aug 2021 22:33:31

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 ■

FDA-CBER-2022-1614-2808678

US3342142
Folder: Diary Dose 1 (1)
Form: General_Day(3)
Generated On: 11 Aug 2021 22:33:31

	Yes ☐
PC Time stamp	26 AUG 2020 20:21
PC Open Date & Time	26 AUG 2020 12:00
PC Close Date & Time	27 AUG 2020 11:59

FDA-CBER-2022-1614-2808679

US3342142
Folder: Diary Dose 1 (1)
Form: General_Day(4)
Generated On: 11 Aug 2021 22:33:31

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 ■

FDA-CBER-2022-1614-2808680

US3342142
Folder: Diary Dose 1 (1)
Form: General_Day(4)
Generated On: 11 Aug 2021 22:33:31

	Yes ☐
PC Time stamp	27 AUG 2020 23:32
PC Open Date & Time	27 AUG 2020 12:00
PC Close Date & Time	28 AUG 2020 11:59

FDA-CBER-2022-1614-2808681

US3342142
Folder: Diary Dose 1 (1)
Form: General_Day(5)
Generated On: 11 Aug 2021 22:33:31

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 ■

FDA-CBER-2022-1614-2808682

US3342142
Folder: Diary Dose 1 (1)
Form: General_Day(5)
Generated On: 11 Aug 2021 22:33:31

	Yes ☐
PC Time stamp	29 AUG 2020 07:24
PC Open Date & Time	28 AUG 2020 12:00
PC Close Date & Time	29 AUG 2020 11:59

FDA-CBER-2022-1614-2808683

US3342142
Folder: Diary Dose 1 (1)
Form: General_Day(6)
Generated On: 11 Aug 2021 22:33:31

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 ■

FDA-CBER-2022-1614-2808684

US3342142
Folder: Diary Dose 1 (1)
Form: General_Day(6)
Generated On: 11 Aug 2021 22:33:31

	Yes ☐
PC Time stamp	29 AUG 2020 20:01
PC Open Date & Time	29 AUG 2020 12:00
PC Close Date & Time	30 AUG 2020 11:59

FDA-CBER-2022-1614-2808685

US3342142
Folder: Diary Dose 1 (1)
Form: General_Day(7)
Generated On: 11 Aug 2021 22:33:31

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 ■

FDA-CBER-2022-1614-2808686

US3342142
Folder: Diary Dose 1 (1)
Form: General_Day(7)
Generated On: 11 Aug 2021 22:33:31

	Yes ☐
PC Time stamp	31 AUG 2020 00:04
PC Open Date & Time	30 AUG 2020 12:00
PC Close Date & Time	31 AUG 2020 11:59

FDA-CBER-2022-1614-2808687

US3342142
Folder: Safety Call Day 8 (1)
Form: Safety Call
Data signed: (b) (4) **12 Mar 2021 23:16:48**
Generated On: 11 Aug 2021 22:33:31

Was Contact Attempted?	Yes ■ No ☐
Date of Contact or Contact Attempt *(dd MMM yyyy)*	31 AUG 2020
Please select one status for the follow-up contact	Contact Made ■ Contact Not Made ☐
Comments *If Contact Not Made, please provide Comments*	

FDA-CBER-2022-1614-2808688

US3342142
Folder: Safety Call Day 8 (1)
Form: Continuing
Data signed: (b) (4) **12 Mar 2021 23:16:48**
Generated On: 11 Aug 2021 22:33:31

Is the participant continuing to the next visit?	Yes ☑ No ☐
Continuing Flag	1

FDA-CBER-2022-1614-2808689

US3342142
Folder: Safety Call Day 15 (1)
Form: Safety Call
Data signed: (b) (4) **12 Mar 2021 23:16:48**
Generated On: 11 Aug 2021 22:33:31

Was Contact Attempted?	Yes ■ No ☐
Date of Contact or Contact Attempt *(dd MMM yyyy)*	8 SEP 2020
Please select one status for the follow-up contact	Contact Made ■ Contact Not Made ☐
Comments *If Contact Not Made, please provide Comments*	

FDA-CBER-2022-1614-2808690

US3342142
Folder: Safety Call Day 15 (1)
Form: Continuing
Data signed: (b) (4) **12 Mar 2021 23:16:48**
Generated On: 11 Aug 2021 22:33:31

Is the participant continuing to the next visit?	Yes ■ No ☐
Continuing Flag	1

FDA-CBER-2022-1614-2808691

US3342142
Folder: Safety Call Day 22 (1)
Form: Safety Call
Data signed: (b) (4) **12 Mar 2021 23:16:48**
Generated On: 11 Aug 2021 22:33:31

Was Contact Attempted?	Yes ■ No ☐
Date of Contact or Contact Attempt *(dd MMM yyyy)*	14 SEP 2020
Please select one status for the follow-up contact	Contact Made ■ Contact Not Made ☐
Comments	
If Contact Not Made, please provide Comments	

FDA-CBER-2022-1614-2808692

US3342142
Folder: Safety Call Day 22 (1)
Form: Continuing
Data signed: (b) (4) **12 Mar 2021 23:16:48**
Generated On: 11 Aug 2021 22:33:31

Is the participant continuing to the next visit?	Yes ☑ No ☐
Continuing Flag	1

FDA-CBER-2022-1614-2808693

US3342142
Folder: Visit 2 Day 29 (1)
Form: Visit Date
Data signed: (b) (4) **12 Mar 2021 23:16:48**
Generated On: 11 Aug 2021 22:33:31

Was this visit performed?	Yes ☑ No ☐
Visit date (dd MMM yyyy)	21 SEP 2020
Was visit performed at the participant's home or at the clinic?	Home ☐ Clinic ☑
Folder OID	VISIT2

FDA-CBER-2022-1614-2808694

US3342142
Folder: Visit 2 Day 29 (1)
Form: Vital Signs - Dosing (1)
Data signed: (b) (4) **12 Mar 2021 23:16:48**
Generated On: 11 Aug 2021 22:33:31

Timepoint	Pre-Dose ■ Post-Dose ☐
Were vital signs assessed?	Yes ■ No ☐
Date of assessment *(dd MMM yyyy)*	21 SEP 2020
Time of assessment *(00:00-23:59)*	13:12 (24 HR)
Vital Signs Date and Time (derived)	21 SEP 2020 13:12
Temperature *(xxx.x)*	98.7 F
Route of measurement	Oral ■ Axillary ☐ Other ☐
If Other, specify	
Pulse *(xxx)*	77 beats/min
Pulse units	BPM
Respiratory Rate *(xxx)*	12 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure *(xxx)*	132 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure *(xxx)*	81 mmHg
Diastolic Blood Pressure units	MMHG

FDA-CBER-2022-1614-2808695

US3342142
Folder: Visit 2 Day 29 (1)
Form: Vital Signs - Dosing (2)
Data signed: (b) (4) **12 Mar 2021 23:16:48**
Generated On: 11 Aug 2021 22:33:31

Timepoint	Pre-Dose ☐ Post-Dose ■
Were vital signs assessed?	Yes ■ No ☐
Date of assessment *(dd MMM yyyy)*	21 SEP 2020
Time of assessment *(00:00-23:59)*	14:22 (24 HR)
Vital Signs Date and Time (derived)	21 SEP 2020 14:22
Temperature *(xxx.x)*	98.8 F
Route of measurement	Oral ■ Axillary ☐ Other ☐
If Other, specify	
Pulse *(xxx)*	66 beats/min
Pulse units	BPM
Respiratory Rate *(xxx)*	12 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure *(xxx)*	116 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure *(xxx)*	76 mmHg
Diastolic Blood Pressure units	MMHG

FDA-CBER-2022-1614-2808696

US3342142
Folder: Visit 2 Day 29 (1)
Form: Physical Examination
Data signed: (b) (4) **12 Mar 2021 23:16:48**
Generated On: 11 Aug 2021 22:33:31

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.

FDA-CBER-2022-1614-2808697

US3342142
Folder: Visit 2 Day 29 (1)
Form: Pregnancy Test
Data signed: (b) (4) **12 Mar 2021 23:16:48**
Generated On: 11 Aug 2021 22:33:31

Was the pregnancy test performed?	Yes ■ No ☐
Date of test *(dd MMM yyyy)*	21 SEP 2020
Test performed	Urine ■ Serum ☐
Result	Positive ☐ Negative ■
Was FSH sample collected?	Yes ☐ No ■
Collection date	
Collection time	
Collection date and time (derived)	

FDA-CBER-2022-1614-2808698

US3342142
Folder: Visit 2 Day 29 (1)
Form: Exposure
Data signed: (b) (4) **12 Mar 2021 23:16:48**
Generated On: 11 Aug 2021 22:33:31

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)*	21 SEP 2020
What was the treatment time? *(00:00-23:59)*	13:51 (24 HR)
Treatment Date and Time (derived)	21 SEP 2020 13:51
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

FDA-CBER-2022-1614-2808699

US3342142
Folder: Visit 2 Day 29 (1)
Form: Immunogenicity Assessment
Data signed: (b) (4) **12 Mar 2021 23:16:48**
Generated On: 11 Aug 2021 22:33:31

Was the sample collected?	Yes ☑ No ☐
Collection date *(dd MMM yyyy)*	21 SEP 2020
Collection time *(00:00-23:59)*	13:35 (24 HR)
Collection date and time (derived)	21 SEP 2020 13:35

FDA-CBER-2022-1614-2808700

US3342142
Folder: Visit 2 Day 29 (1)
Form: Central Laboratory - Nasopharyngeal Swab
Data signed: (b) (4) **12 Mar 2021 23:16:48**
Generated On: 11 Aug 2021 22:33:31

Collection date *(dd MMM yyyy)*			21 SEP 2020
Lab Test	Was the sample collected?	Collection time *(00:00 - 23:59)*	Collection date and time (derived)
Nasopharyngeal Swab 1	Yes	13:37	21 SEP 2020 13:37
Nasopharyngeal Swab 2	No		

FDA-CBER-2022-1614-2808701

US3342142
Folder: Visit 2 Day 29 (1)
Form: Continuing
Data signed: (b) (4) **12 Mar 2021 23:16:48**
Generated On: 11 Aug 2021 22:33:31

Is the participant continuing to the next visit?	Yes ☑ No ☐
Continuing Flag	1

FDA-CBER-2022-1614-2808702

US3342142
Folder: Diary Dose 2 (1)
Form: Temperature_Day(1/1)
Generated On: 11 Aug 2021 22:33:31

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**	98.8 °F
Was any **MEDICATION TAKEN today for pain or fever**?	Yes ☐ No ■
Please confirm reason for pain or fever medication (may select more than one):	
PC Time Stamp	21 SEP 2020 14:30
PC Open Date & Time	21 SEP 2020 14:11
PC Close Date & Time	21 SEP 2020 16:41

FDA-CBER-2022-1614-2808703

US3342142
Folder: Diary Dose 2 (1)
Form: Temperature_Day(1/2)
Generated On: 11 Aug 2021 22:33:31

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**	97.2 °F
Was any **MEDICATION TAKEN today for pain or fever**?	Yes ☐ No ■
Please confirm reason for pain or fever medication (may select more than one):	
PC Time Stamp	21 SEP 2020 21:37
PC Open Date & Time	21 SEP 2020 17:36
PC Close Date & Time	22 SEP 2020 11:59

FDA-CBER-2022-1614-2808704

US3342142
Folder: Diary Dose 2 (1)
Form: Temperature_Day(2)
Generated On: 11 Aug 2021 22:33:31

TIMEPOINT	DAY 2

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

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

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

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

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

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

Was **TEMPERATURE** taken?	Yes ■ No ☐
Please record your **TEMPERATURE in °F**	98.0 °F
Was any **MEDICATION TAKEN today for pain or fever**?	Yes ☐ No ■
Please confirm reason for pain or fever medication (may select more than one):	
PC Time Stamp	22 SEP 2020 21:14
PC Open Date & Time	22 SEP 2020 12:00
PC Close Date & Time	23 SEP 2020 11:59

US3342142
Folder: Diary Dose 2 (1)
Form: Temperature_Day(3)
Generated On: 11 Aug 2021 22:33:31

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**	98.8 °F
Was any **MEDICATION TAKEN today for pain or fever**?	Yes ○
	No ●
Please confirm reason for pain or fever medication (may select more than one):	
PC Time Stamp	23 SEP 2020 21:41
PC Open Date & Time	23 SEP 2020 12:00
PC Close Date & Time	24 SEP 2020 11:59

US3342142
Folder: Diary Dose 2 (1)
Form: Temperature_Day(4)
Generated On: 11 Aug 2021 22:33:31

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**	98.8 °F
Was any **MEDICATION TAKEN today for pain or fever**?	Yes ■ No ☐
Please confirm reason for pain or fever medication (may select more than one):	
To **TREAT** pain or fever that has already occurred	True
To **PREVENT** pain or fever from occurring	False
PC Time Stamp	25 SEP 2020 01:53
PC Open Date & Time	24 SEP 2020 12:00
PC Close Date & Time	25 SEP 2020 11:59

FDA-CBER-2022-1614-2808707

US3342142
Folder: Diary Dose 2 (1)
Form: Temperature_Day(5)
Generated On: 11 Aug 2021 22:33:31

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**	99.2 °F
Was any **MEDICATION TAKEN today for pain or fever**?	Yes ■ No ☐
Please confirm reason for pain or fever medication (may select more than one):	
To **TREAT** pain or fever that has already occurred	True
To **PREVENT** pain or fever from occurring	False
PC Time Stamp	25 SEP 2020 23:15
PC Open Date & Time	25 SEP 2020 12:00
PC Close Date & Time	26 SEP 2020 11:59

FDA-CBER-2022-1614-2808708

US3342142
Folder: Diary Dose 2 (1)
Form: Temperature_Day(6)
Generated On: 11 Aug 2021 22:33:31

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**	98.8 °F
Was any **MEDICATION TAKEN today for pain or fever**?	Yes ○
	No ●
Please confirm reason for pain or fever medication (may select more than one):	
PC Time Stamp	27 SEP 2020 05:59
PC Open Date & Time	26 SEP 2020 12:00
PC Close Date & Time	27 SEP 2020 11:59

US3342142
Folder: Diary Dose 2 (1)
Form: Temperature_Day(7)
Generated On: 11 Aug 2021 22:33:31

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**	98.7 °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	28 SEP 2020 00:24
PC Open Date & Time	27 SEP 2020 12:00
PC Close Date & Time	28 SEP 2020 11:59

FDA-CBER-2022-1614-2808710

US3342142
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(1/1)
Generated On: 11 Aug 2021 22:33:31

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	21 SEP 2020 14:30
PC Open Date & Time	21 SEP 2020 14:11
PC Close Date & Time	21 SEP 2020 16:41

US3342142
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(1/2)
Generated On: 11 Aug 2021 22:33:31

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	21 SEP 2020 21:37
PC Open Date & Time	21 SEP 2020 17:36
PC Close Date & Time	22 SEP 2020 11:59

FDA-CBER-2022-1614-2808712

US3342142
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(2)
Generated On: 11 Aug 2021 22:33:31

TIMEPOINT	DAY 2
Please record - **PAIN AT INJECTION SITE.** Please select one response below	None ■ Does not interfere with activity ☐ Repeated use of over-the-counter pain reliever > 24 hours or interferes with activity ☐ Any use of prescription pain reliever or prevents daily activity ☐
Is there any **REDNESS AT INJECTION SITE**?	Yes ☐ No ■
Is there any **SWELLING/HARDNESS AT INJECTION SITE**?	Yes ☐ No ■
Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.** Please select one response below	None ■ Does not interfere with activity ☐ Repeated use of over-the-counter pain reliever > 24 hours or interferes with some activity ☐ Any use of prescription pain reliever or prevents daily activity ☐
PC Time Stamp	22 SEP 2020 21:15
PC Open Date & Time	22 SEP 2020 12:00
PC Close Date & Time	23 SEP 2020 11:59

US3342142
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(3)
Generated On: 11 Aug 2021 22:33:31

TIMEPOINT	DAY 3
Please record - **PAIN AT INJECTION SITE.** Please select one response below	None ■ Does not interfere with activity ☐ Repeated use of over-the-counter pain reliever > 24 hours or interferes with activity ☐ Any use of prescription pain reliever or prevents daily activity ☐
Is there any **REDNESS AT INJECTION SITE**?	Yes ☐ No ■
Is there any **SWELLING/HARDNESS AT INJECTION SITE**?	Yes ☐ No ■
Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.** Please select one response below	None ■ Does not interfere with activity ☐ Repeated use of over-the-counter pain reliever > 24 hours or interferes with some activity ☐ Any use of prescription pain reliever or prevents daily activity ☐
PC Time Stamp	23 SEP 2020 21:42
PC Open Date & Time	23 SEP 2020 12:00
PC Close Date & Time	24 SEP 2020 11:59

US3342142
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(4)
Generated On: 11 Aug 2021 22:33:31

TIMEPOINT	DAY 4
Please record - **PAIN AT INJECTION SITE.** Please select one response below	None ■ Does not interfere with activity ☐ Repeated use of over-the-counter pain reliever > 24 hours or interferes with activity ☐ Any use of prescription pain reliever or prevents daily activity ☐
Is there any **REDNESS AT INJECTION SITE**?	Yes ☐ No ■
Is there any **SWELLING/HARDNESS AT INJECTION SITE**?	Yes ☐ No ■
Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.** Please select one response below	None ■ Does not interfere with activity ☐ Repeated use of over-the-counter pain reliever > 24 hours or interferes with some activity ☐ Any use of prescription pain reliever or prevents daily activity ☐
PC Time Stamp	25 SEP 2020 01:53
PC Open Date & Time	24 SEP 2020 12:00
PC Close Date & Time	25 SEP 2020 11:59

US3342142
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(5)
Generated On: 11 Aug 2021 22:33:31

TIMEPOINT	DAY 5
Please record - **PAIN AT INJECTION SITE.** Please select one response below	None ■ Does not interfere with activity ☐ Repeated use of over-the-counter pain reliever > 24 hours or interferes with activity ☐ Any use of prescription pain reliever or prevents daily activity ☐
Is there any **REDNESS AT INJECTION SITE**?	Yes ☐ No ■
Is there any **SWELLING/HARDNESS AT INJECTION SITE**?	Yes ☐ No ■
Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.** Please select one response below	None ■ Does not interfere with activity ☐ Repeated use of over-the-counter pain reliever > 24 hours or interferes with some activity ☐ Any use of prescription pain reliever or prevents daily activity ☐
PC Time Stamp	25 SEP 2020 23:15
PC Open Date & Time	25 SEP 2020 12:00
PC Close Date & Time	26 SEP 2020 11:59

US3342142
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(6)
Generated On: 11 Aug 2021 22:33:31

TIMEPOINT	DAY 6
Please record - **PAIN AT INJECTION SITE.** Please select one response below	None ■ Does not interfere with activity ☐ Repeated use of over-the-counter pain reliever > 24 hours or interferes with activity ☐ Any use of prescription pain reliever or prevents daily activity ☐
Is there any **REDNESS AT INJECTION SITE**?	Yes ☐ No ■
Is there any **SWELLING/HARDNESS AT INJECTION SITE**?	Yes ☐ No ■
Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.** Please select one response below	None ■ Does not interfere with activity ☐ Repeated use of over-the-counter pain reliever > 24 hours or interferes with some activity ☐ Any use of prescription pain reliever or prevents daily activity ☐
PC Time Stamp	27 SEP 2020 05:59
PC Open Date & Time	26 SEP 2020 12:00
PC Close Date & Time	27 SEP 2020 11:59

US3342142
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(7)
Generated On: 11 Aug 2021 22:33:31

TIMEPOINT	DAY 7
Please record - **PAIN AT INJECTION SITE.** Please select one response below	None ● Does not interfere with activity ☐ Repeated use of over-the-counter pain reliever > 24 hours or interferes with activity ☐ Any use of prescription pain reliever or prevents daily activity ☐
Is there any **REDNESS AT INJECTION SITE**?	Yes ☐ No ●
Is there any **SWELLING/HARDNESS AT INJECTION SITE**?	Yes ☐ No ●
Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.** Please select one response below	None ● Does not interfere with activity ☐ Repeated use of over-the-counter pain reliever > 24 hours or interferes with some activity ☐ Any use of prescription pain reliever or prevents daily activity ☐
PC Time Stamp	28 SEP 2020 00:24
PC Open Date & Time	27 SEP 2020 12:00
PC Close Date & Time	28 SEP 2020 11:59

FDA-CBER-2022-1614-2808718

US3342142
Folder: Diary Dose 2 (1)
Form: General_Day(1/1)
Generated On: 11 Aug 2021 22:33:31

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 ☐

FDA-CBER-2022-1614-2808719

US3342142
Folder: Diary Dose 2 (1)
Form: General_Day(1/1)
Generated On: 11 Aug 2021 22:33:31

Did you receive any **MEDICAL ATTENTION (doctor visit, other)** for any illness or symptoms?	No ■ Yes ☐
PC Time stamp	21 SEP 2020 14:31
PC Open Date & Time	21 SEP 2020 14:11
PC Close Date & Time	21 SEP 2020 16:41

FDA-CBER-2022-1614-2808720

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

US3342142
Folder: Diary Dose 2 (1)
Form: General_Day(1/2)
Generated On: 11 Aug 2021 22:33:31

Did you receive any **MEDICAL ATTENTION (doctor visit, other)** for any illness or symptoms?	No ■ Yes ☐
PC Time stamp	21 SEP 2020 21:37
PC Open Date & Time	21 SEP 2020 17:36
PC Close Date & Time	22 SEP 2020 11:59

FDA-CBER-2022-1614-2808722

US3342142
Folder: Diary Dose 2 (1)
Form: General_Day(2)
Generated On: 11 Aug 2021 22:33:31

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 ■

FDA-CBER-2022-1614-2808723

US3342142
Folder: Diary Dose 2 (1)
Form: General_Day(2)
Generated On: 11 Aug 2021 22:33:31

	Yes ☐
PC Time stamp	22 SEP 2020 21:15
PC Open Date & Time	22 SEP 2020 12:00
PC Close Date & Time	23 SEP 2020 11:59

FDA-CBER-2022-1614-2808724

US3342142
Folder: Diary Dose 2 (1)
Form: General_Day(3)
Generated On: 11 Aug 2021 22:33:31

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 ■

FDA-CBER-2022-1614-2808725

US3342142
Folder: Diary Dose 2 (1)
Form: General_Day(3)
Generated On: 11 Aug 2021 22:33:31

	Yes ☐
PC Time stamp	23 SEP 2020 21:42
PC Open Date & Time	23 SEP 2020 12:00
PC Close Date & Time	24 SEP 2020 11:59

FDA-CBER-2022-1614-2808726

US3342142
Folder: Diary Dose 2 (1)
Form: General_Day(4)
Generated On: 11 Aug 2021 22:33:31

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 ■

FDA-CBER-2022-1614-2808727

US3342142
Folder: Diary Dose 2 (1)
Form: General_Day(4)
Generated On: 11 Aug 2021 22:33:31

	Yes ☐
PC Time stamp	25 SEP 2020 01:53
PC Open Date & Time	24 SEP 2020 12:00
PC Close Date & Time	25 SEP 2020 11:59

FDA-CBER-2022-1614-2808728

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 ■

FDA-CBER-2022-1614-2808729

US3342142
Folder: Diary Dose 2 (1)
Form: General_Day(5)
Generated On: 11 Aug 2021 22:33:31

	Yes ☐
PC Time stamp	25 SEP 2020 23:16
PC Open Date & Time	25 SEP 2020 12:00
PC Close Date & Time	26 SEP 2020 11:59

FDA-CBER-2022-1614-2808730

US3342142
Folder: Diary Dose 2 (1)
Form: General_Day(6)
Generated On: 11 Aug 2021 22:33:31

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 ■

FDA-CBER-2022-1614-2808731

US3342142
Folder: Diary Dose 2 (1)
Form: General_Day(6)
Generated On: 11 Aug 2021 22:33:31

	Yes ☐
PC Time stamp	27 SEP 2020 05:59
PC Open Date & Time	26 SEP 2020 12:00
PC Close Date & Time	27 SEP 2020 11:59

FDA-CBER-2022-1614-2808732

US3342142
Folder: Diary Dose 2 (1)
Form: General_Day(7)
Generated On: 11 Aug 2021 22:33:31

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 ☐

FDA-CBER-2022-1614-2808733

US3342142
Folder: Diary Dose 2 (1)
Form: General_Day(7)
Generated On: 11 Aug 2021 22:33:31

	Yes
PC Time stamp	28 SEP 2020 00:24
PC Open Date & Time	27 SEP 2020 12:00
PC Close Date & Time	28 SEP 2020 11:59

FDA-CBER-2022-1614-2808734

US3342142
Folder: Safety Call Day 36 (1)
Form: Safety Call
Data signed: (b) (4) **12 Mar 2021 23:16:48**
Generated On: 11 Aug 2021 22:33:31

Was Contact Attempted?	Yes ■ No ☐
Date of Contact or Contact Attempt *(dd MMM yyyy)*	28 SEP 2020
Please select one status for the follow-up contact	Contact Made ■ Contact Not Made ☐
Comments *If Contact Not Made, please provide Comments*	

FDA-CBER-2022-1614-2808735

US3342142
Folder: Safety Call Day 36 (1)
Form: Continuing
Data signed: (b) (4) **12 Mar 2021 23:16:48**
Generated On: 11 Aug 2021 22:33:31

Is the participant continuing to the next visit?	Yes ☑ No ☐
Continuing Flag	1

FDA-CBER-2022-1614-2808736

US3342142
Folder: Safety Call Day 43 (1)
Form: Safety Call
Data signed: (b) (4) **12 Mar 2021 23:16:48**
Generated On: 11 Aug 2021 22:33:31

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*	

FDA-CBER-2022-1614-2808737

US3342142
Folder: Safety Call Day 43 (1)
Form: Continuing
Data signed: (b) (4) **12 Mar 2021 23:16:48**
Generated On: 11 Aug 2021 22:33:31

Is the participant continuing to the next visit?	Yes ■ No ☐
Continuing Flag	1

FDA-CBER-2022-1614-2808738

US3342142
Folder: Safety Call Day 50 (1)
Form: Safety Call
Data signed: (b) (4) **12 Mar 2021 23:16:48**
Generated On: 11 Aug 2021 22:33:31

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	

FDA-CBER-2022-1614-2808739

US3342142
Folder: Safety Call Day 50 (1)
Form: Continuing
Data signed: (b) (4) **12 Mar 2021 23:16:48**
Generated On: 11 Aug 2021 22:33:31

Is the participant continuing to the next visit?	Yes ☑ No ☐
Continuing Flag	1

FDA-CBER-2022-1614-2808740

US3342142
Folder: Visit 3 Day 57 (1)
Form: Visit Date
Data signed: (b) (4) **12 Mar 2021 23:16:48**
Generated On: 11 Aug 2021 22:33:31

Was this visit performed?	Yes ☑ No ☐
Visit date (dd MMM yyyy)	22 OCT 2020
Was visit performed at the participant's home or at the clinic?	Home ☐ Clinic ☑
Folder OID	VISIT3

FDA-CBER-2022-1614-2808741

US3342142
Folder: Visit 3 Day 57 (1)
Form: Vital Signs
Data signed: (b) (4) **12 Mar 2021 23:16:48**
Generated On: 11 Aug 2021 22:33:31

Were vital signs assessed?	Yes ■ No ☐
Date of assessment *(dd MMM yyyy)*	22 OCT 2020
Time of assessment *(00:00-23:59)*	13:00 (24 HR)
Vital Signs Date and Time (derived)	22 OCT 2020 13:00
Temperature *(xxx.x)*	98.1 F
Route of measurement	Oral ■ Axillary ☐ Other ☐
If Other, specify	
Pulse *(xxx)*	70 beats/min
Pulse units	BPM
Respiratory Rate *(xxx)*	14 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure *(xxx)*	119 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure *(xxx)*	78 mmHg
Diastolic Blood Pressure units	MMHG
Height (derived)	
Weight (derived)	

FDA-CBER-2022-1614-2808742

US3342142
Folder: Visit 3 Day 57 (1)
Form: Physical Examination
Data signed: (b) (4) **12 Mar 2021 23:16:48**
Generated On: 11 Aug 2021 22:33:31

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.

FDA-CBER-2022-1614-2808743

US3342142
Folder: Visit 3 Day 57 (1)
Form: Immunogenicity Assessment
Data signed: (b) (4) **12 Mar 2021 23:16:48**
Generated On: 11 Aug 2021 22:33:31

Was the sample collected?	Yes ☑ No ☐
Collection date *(dd MMM yyyy)*	22 OCT 2020
Collection time *(00:00-23:59)*	13:20 (24 HR)
Collection date and time (derived)	22 OCT 2020 13:20

FDA-CBER-2022-1614-2808744

US3342142
Folder: Visit 3 Day 57 (1)
Form: Continuing
Data signed: (b) (4) **12 Mar 2021 23:16:48**
Generated On: 11 Aug 2021 22:33:31

Is the participant continuing to the next visit?	Yes ■ No ☐
Continuing Flag	1

FDA-CBER-2022-1614-2808745

US3342142
Folder: Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 22:33:31

TIMEPOINT	DAY 64
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ■ Yes ☐
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ■ Yes ☐
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	28 OCT 2020 11:59:21
Patient Cloud Open Date & Time	24 OCT 2020 00:01
Patient Cloud Close Date & Time	28 OCT 2020 23:59

FDA-CBER-2022-1614-2808746

US3342142
Folder: Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 22:33:31

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	31 OCT 2020 05:40:24
Patient Cloud Open Date & Time	31 OCT 2020 00:01
Patient Cloud Close Date & Time	04 NOV 2020 23:59

US3342142
Folder: Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 22:33:31

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 contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ■
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No ■ Yes ☐
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No ■ Yes ☐
Date and time of submission	09 NOV 2020 06:01:02
Patient Cloud Open Date & Time	07 NOV 2020 00:01
Patient Cloud Close Date & Time	11 NOV 2020 23:59

FDA-CBER-2022-1614-2808748

US3342142
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 22:33:31

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	21 NOV 2020 09:59:57
Patient Cloud Open Date & Time	18 NOV 2020 00:01
Patient Cloud Close Date & Time	22 NOV 2020 23:59

FDA-CBER-2022-1614-2808749

US3342142
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 22:33:31

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 ■ Yes ☐
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ■ Yes ☐
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	25 NOV 2020 08:57:50
Patient Cloud Open Date & Time	25 NOV 2020 00:01
Patient Cloud Close Date & Time	29 NOV 2020 23:59

US3342142
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 22:33:31

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	02 DEC 2020 10:36:56
Patient Cloud Open Date & Time	02 DEC 2020 00:01
Patient Cloud Close Date & Time	06 DEC 2020 23:59

FDA-CBER-2022-1614-2808751

US3342142
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 22:33:31

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 ■ 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	09 DEC 2020 05:40:25
Patient Cloud Open Date & Time	09 DEC 2020 00:01
Patient Cloud Close Date & Time	13 DEC 2020 23:59

FDA-CBER-2022-1614-2808752

US3342142
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 22:33:31

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	16 DEC 2020 10:00:31
Patient Cloud Open Date & Time	16 DEC 2020 00:01
Patient Cloud Close Date & Time	20 DEC 2020 23:59

FDA-CBER-2022-1614-2808753

US3342142
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 22:33:31

TIMEPOINT	DAY 124
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ■ Yes ☐
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ■ Yes ☐
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	23 DEC 2020 05:30:28
Patient Cloud Open Date & Time	23 DEC 2020 00:01
Patient Cloud Close Date & Time	27 DEC 2020 23:59

FDA-CBER-2022-1614-2808754

US3342142
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 22:33:31

TIMEPOINT	DAY 131
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ■ Yes ☐
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ■ Yes ☐
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	30 DEC 2020 16:15:19
Patient Cloud Open Date & Time	30 DEC 2020 00:01
Patient Cloud Close Date & Time	03 JAN 2021 23:59

FDA-CBER-2022-1614-2808755

US3342142
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 22:33:31

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	06 JAN 2021 05:26:25
Patient Cloud Open Date & Time	06 JAN 2021 00:01
Patient Cloud Close Date & Time	10 JAN 2021 23:59

FDA-CBER-2022-1614-2808756

US3342142
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 22:33:31

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	15 JAN 2021 12:00:37
Patient Cloud Open Date & Time	13 JAN 2021 00:01
Patient Cloud Close Date & Time	17 JAN 2021 23:59

FDA-CBER-2022-1614-2808757

US3342142
Folder: Cosmetic Injections and Dermal Fillers
Form: Cosmetic Injection_ Dermal Filler eDiary
Generated On: 11 Aug 2021 22:33:31

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

US3342142
Folder: Safety Call Day 85 (1)
Form: Safety Call
Data signed: (b) (4) **12 Mar 2021 23:16:48**
Generated On: 11 Aug 2021 22:33:31

Was Contact Attempted?	Yes ■ No ☐
Date of Contact or Contact Attempt *(dd MMM yyyy)*	13 NOV 2020
Please select one status for the follow-up contact	Contact Made ■ Contact Not Made ☐
Comments	
If Contact Not Made, please provide Comments	

FDA-CBER-2022-1614-2808759

US3342142
Folder: Safety Call Day 85 (1)
Form: Continuing
Data signed: (b) (4) **12 Mar 2021 23:16:48**
Generated On: 11 Aug 2021 22:33:31

Is the participant continuing to the next visit?	Yes ■ No ☐
Continuing Flag	1

FDA-CBER-2022-1614-2808760

US3342142
Folder: Safety Call Day 119 (1)
Form: Safety Call
Data signed: (b) (4) **12 Mar 2021 23:16:48**
Generated On: 11 Aug 2021 22:33:31

Was Contact Attempted?	Yes ■ No ☐
Date of Contact or Contact Attempt *(dd MMM yyyy)*	18 DEC 2020
Please select one status for the follow-up contact	Contact Made ■ Contact Not Made ☐
Comments *If Contact Not Made, please provide Comments*	

FDA-CBER-2022-1614-2808761

US3342142
Folder: Safety Call Day 119 (1)
Form: Continuing
Data signed: (b) (4) **22 Mar 2021 13:27:19**
Generated On: 11 Aug 2021 22:33:31

Is the participant continuing to the next visit?	Yes ☐ No ■
Continuing Flag	

FDA-CBER-2022-1614-2808762

US3342142
Folder: Covid-19 Assessment (1)
Form: COVID-19 Contact
Generated On: 11 Aug 2021 22:33:31

Date of Contact	
Time of Contact	
Date and Time of Contact (derived)	
Type of Contact	Clinic Visit - Scheduled ☐
	Clinical Visit - Unscheduled ☐
	Safety Call ☐
	Convalescent Tele-visit ☐
Has the subject reported symptoms of SARS-COV-2?	Yes ☐
	No ☐

FDA-CBER-2022-1614-2808763

Generate Next COVID-19 Assessment	Yes ☐ No ☐

US3342142
Folder: Participant Decision Visit / OL-D1 (1)
Form: Unblinding
Data signed: (b) (4) **12 Apr 2021 15:32:31**
Generated On: 11 Aug 2021 22:33:31

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

US3342142
Folder: Adverse Events
Form: Adverse Events Summary
Data signed: (b) (4) **12 Mar 2021 23:16:42**
Generated On: 11 Aug 2021 22:33:31

Did the participant experience any adverse events?	Yes ☐ No ■

If Yes, enter details on the Adverse Events form.

FDA-CBER-2022-1614-2808766

US3342142
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination Summary
Data signed: (b) (4) **12 Mar 2021 23:16:47**
Generated On: 11 Aug 2021 22:33:31

Were any prior/concomitant medications and/or vaccinations taken?	Yes ■ No ☐

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

FDA-CBER-2022-1614-2808767

Name of Medication	ZYRTEC
Prophylaxis	Yes ☐ No ■
Indication	SEASONAL ALLERGIES
Dose per administration	10
Dose unit	mg ■ ug ☐ mL ☐ g ☐ IU ☐ tablet ☐ capsule ☐ puff ☐ Other ☐
If dose unit is Other, specify	
Frequency	once daily ■ twice daily ☐ three times daily ☐ four times daily ☐ every other day ☐ every week ☐ every month ☐ as needed ☐ once ☐ unknown ☐ other ☐
If frequency is Other, specify	
Route of administration	Oral ■ Topical ☐ Subcutaneous ☐ Transdermal ☐ Intraocular ☐

FDA-CBER-2022-1614-2808768

	Intramuscular ☐
	Respiratory (Inhalation) ☐
	Intralesional ☐
	Intraperiteoneal ☐
	Nasal ☐
	Vaginal ☐
	Rectal ☐
	Intravenous ☐
	Intravenous Bolus ☐
	Intravenous Drip ☐
	Other ☐
If route of administration is Other, specify	
Start date *(dd MMM yyyy)*	UN UNK 2016
Start date completely unknown	False
Ongoing?	Yes ■ No ☐
If not Ongoing, End date *(dd MMM yyyy)*	
Was this medication taken for solicited event?	Yes ☐ No ■
Separate Dosage Number (derived)	1
Interval Dosage Unit Number (derived)	1
Interval Dosage Definition (derived)	802 ☐ 803 ☐ 804 ■

US3342142
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (2)
Data signed: (b) (4) **22 Mar 2021 13:27:19**
Generated On: 11 Aug 2021 22:33:31

Name of Medication	IBUPROFEN (MOTRIN)
Prophylaxis	Yes ☐ No ■
Indication	HEADACHE
Dose per administration	200
Dose unit	mg ■ ug ☐ mL ☐ g ☐ IU ☐ tablet ☐ capsule ☐ puff ☐ Other ☐
If dose unit is Other, specify	
Frequency	once daily ■ twice daily ☐ three times daily ☐ four times daily ☐ every other day ☐ every week ☐ every month ☐ as needed ☐ once ☐ unknown ☐ other ☐
If frequency is Other, specify	
Route of administration	Oral ■ Topical ☐ Subcutaneous ☐ Transdermal ☐ Intraocular ☐

FDA-CBER-2022-1614-2808770

	Intramuscular ☐
	Respiratory (Inhalation) ☐
	Intralesional ☐
	Intraperiteoneal ☐
	Nasal ☐
	Vaginal ☐
	Rectal ☐
	Intravenous ☐
	Intravenous Bolus ☐
	Intravenous Drip ☐
	Other ☐
If route of administration is Other, specify	
Start date *(dd MMM yyyy)*	24 SEP 2020
Start date completely unknown	False
Ongoing?	Yes ☐
	No ■
If not Ongoing, End date *(dd MMM yyyy)*	25 SEP 2020
Was this medication taken for solicited event?	Yes ■
	No ☐
Separate Dosage Number (derived)	1
Interval Dosage Unit Number (derived)	1
Interval Dosage Definition (derived)	802 ☐
	803 ☐
	804 ■

US3342142
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (3)
Data signed: (b) (4) **22 Mar 2021 13:27:19**
Generated On: 11 Aug 2021 22:33:31

Name of Medication	BNT162B2 VACCINE
Prophylaxis	Yes ■ No ☐
Indication	COVID-19 PROPHYLAXIS
Dose per administration	30
Dose unit	mg ☐ ug ■ mL ☐ g ☐ IU ☐ tablet ☐ capsule ☐ puff ☐ Other ☐
If dose unit is Other, specify	
Frequency	once daily ☐ twice daily ☐ three times daily ☐ four times daily ☐ every other day ☐ every week ☐ every month ☐ as needed ☐ once ■ unknown ☐ other ☐
If frequency is Other, specify	
Route of administration	Oral ☐ Topical ☐ Subcutaneous ☐ Transdermal ☐ Intraocular ☐

FDA-CBER-2022-1614-2808772

	Intramuscular ■
	Respiratory (Inhalation) ☐
	Intralesional ☐
	Intraperiteoneal ☐
	Nasal ☐
	Vaginal ☐
	Rectal ☐
	Intravenous ☐
	Intravenous Bolus ☐
	Intravenous Drip ☐
	Other ☐
If route of administration is Other, specify	
Start date *(dd MMM yyyy)*	12 JAN 2021
Start date completely unknown	False
Ongoing?	Yes ☐
	No ■
If not Ongoing, End date *(dd MMM yyyy)*	12 JAN 2021
Was this medication taken for solicited event?	Yes ☐
	No ■
Separate Dosage Number (derived)	
Interval Dosage Unit Number (derived)	
Interval Dosage Definition (derived)	802 ☐
	803 ☐
	804 ☐

US3342142
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (4)
Data signed: (b) (4) **22 Mar 2021 13:27:19**
Generated On: 11 Aug 2021 22:33:31

Name of Medication	INFLUENZA VACCINE
Prophylaxis	Yes ■ No ☐
Indication	INFLUENZA PROPHYLAXIS
Dose per administration	0.5
Dose unit	mg ☐ ug ☐ mL ■ g ☐ IU ☐ tablet ☐ capsule ☐ puff ☐ Other ☐
If dose unit is Other, specify	
Frequency	once daily ☐ twice daily ☐ three times daily ☐ four times daily ☐ every other day ☐ every week ☐ every month ☐ as needed ☐ once ■ unknown ☐ other ☐
If frequency is Other, specify	
Route of administration	Oral ☐ Topical ☐ Subcutaneous ☐ Transdermal ☐ Intraocular ☐

FDA-CBER-2022-1614-2808774

	Intramuscular ■
	Respiratory (Inhalation) ☐
	Intralesional ☐
	Intraperiteoneal ☐
	Nasal ☐
	Vaginal ☐
	Rectal ☐
	Intravenous ☐
	Intravenous Bolus ☐
	Intravenous Drip ☐
	Other ☐
If route of administration is Other, specify	
Start date *(dd MMM yyyy)*	11 NOV 2020
Start date completely unknown	False
Ongoing?	Yes ☐
	No ■
If not Ongoing, End date *(dd MMM yyyy)*	11 NOV 2020
Was this medication taken for solicited event?	Yes ☐
	No ■
Separate Dosage Number (derived)	
Interval Dosage Unit Number (derived)	
Interval Dosage Definition (derived)	802 ☐
	803 ☐
	804 ☐

US3342142
Folder: Concomitant Procedures (1)
Form: Concomitant Procedures Summary
Data signed: (b) (4) **12 Mar 2021 23:16:47**
Generated On: 11 Aug 2021 22:33:31

Were any concomitant procedures performed?	Yes ☐ No ■

If yes, please complete Concomitant Procedures form.

FDA-CBER-2022-1614-2808776

US3342142
Folder: End of Study (1)
Form: Dosing Discontinuation
Generated On: 11 Aug 2021 22:33:31

Date of dosing discontinuation (dd MMM yyyy)	
Primary reason for dosing discontinuation	AE (specify) ☐ SAE (specify) ☐ Death ☐ Lost To Follow-up ☐ Physician decision (specify) ☐ Pregnancy ☐ Protocol deviation (specify) ☐ Study Terminated By Sponsor ☐ Withdrawal of consent by participant (specify) ☐ Due to SARS-COV-2 ☐ Other ☐
If reason is AE, SAE, Physician Decision, Withdrawal of consent by participant, Protocol deviation, or Other, specify	

US3342142
Folder: End of Study (1)
Form: End of Study / Study Discontinuation
Data signed: (b) (4) **12 Mar 2021 23:16:47**
Generated On: 11 Aug 2021 22:33:31

Date of study discontinuation/completion *(dd MMM yyyy)*	19 JAN 2021
Reason for discontinuation	AE (specify) ☐ SAE (specify) ☐ Complete ☐ Death ☐ Lost To Follow-up ☐ Physician decision (specify) ☐ Pregnancy ☐ Protocol deviation (specify) ■ Study Terminated By Sponsor ☐ Withdrawal of consent by participant (specify) ☐ Other ☐
If reason is AE, SAE, Physician Decision, Withdrawal of consent by participant, Protocol deviation, or Other, specify	SUBJECT RECEIVED COVID-19 VACCINE OUTSIDE STUDY ON 12JAN2021 (PFIZER PRODUCT OFFERED BY EMPLOYER, WORKS AS HCW).
If reason for discontinuation is Death, main cause of death	Adverse event ☐ Unknown ☐ Other ☐
If main cause of death is Other, specify	
Date of death *(dd MMM yyyy)*	
Was autopsy performed?	Yes ☐ No ☐ Unknown ☐

Audit

US3342142 (Prod: Tekton Research- Austin)

US3342142
Form: Participant Creation
Generated On: 11 Aug 2021 22:33:31
Participant ID

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:29:43
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 16:54:19
User signature succeeded.	Paul Pickrell (b) (4) (b) (4)	12 Mar 2021 23:16:43
User entered 'US3342142'	RWS_ENDPOINT ENDPOINT (b) (4)	24 Aug 2020 16:20:12

US3342142
Form: Participant Creation
Generated On: 11 Aug 2021 22:33:31

mRNA-1273-P301 Completion Guidelines

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:29:43

FDA-CBER-2022-1614-2808781

US3342142
Folder: Screening
Form: Visit Date
Generated On: 11 Aug 2021 22:33:31
Was this visit performed?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:29:43
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:16:48
User entered 'Yes (Y)'	John Luna (b) (4)	24 Aug 2020 17:07:20

FDA-CBER-2022-1614-2808782

US3342142
Folder: Screening
Form: Visit Date
Generated On: 11 Aug 2021 22:33:31
Visit date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:29:43
User signature succeeded.	Paul Pickrell (b) (4) (b) (4)	12 Mar 2021 23:16:48
User entered '24 AUG 2020'	RWS_ENDPOINT ENDPOINT (b) (4)	24 Aug 2020 16:20:13

FDA-CBER-2022-1614-2808783

US3342142
Folder: Screening
Form: Visit Date
Generated On: 11 Aug 2021 22:33:31
Was visit performed at the participant's home or at the clinic?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:29:43
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:16:48
User entered 'Clinic (Clinic)'	John Luna (b) (4)	24 Aug 2020 17:07:20

FDA-CBER-2022-1614-2808784

US3342142
Folder: Screening
Form: Visit Date
Generated On: 11 Aug 2021 22:33:31
Folder OID

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:29:43
User entered 'SCRN'	System	24 Aug 2020 17:07:20

FDA-CBER-2022-1614-2808785

US3342142
Folder: Screening
Form: Demographics
Generated On: 11 Aug 2021 22:33:31
Date of Birth (MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:29:43
User signature succeeded.	Paul Pickrell (b) (4) (b) (4)	12 Mar 2021 23:16:48
User entered (b) (6) 1983'	RWS_ENDPOINT ENDPOINT (b) (4)	24 Aug 2020 16:20:14

FDA-CBER-2022-1614-2808786

US3342142
Folder: Screening
Form: Demographics
Generated On: 11 Aug 2021 22:33:31
Age

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:29:43
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:16:48
User entered '37'	John Luna (b) (4)	24 Aug 2020 17:08:50

US3342142
Folder: Screening
Form: Demographics
Generated On: 11 Aug 2021 22:33:31
Age Units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:29:43
User entered 'YEARS'	System	24 Aug 2020 17:08:50

FDA-CBER-2022-1614-2808788

US3342142
Folder: Screening
Form: Demographics
Generated On: 11 Aug 2021 22:33:31
Age (Derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:29:43
User entered '37'	System	24 Aug 2020 17:09:02

US3342142
Folder: Screening
Form: Demographics
Generated On: 11 Aug 2021 22:33:31
Sex

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:29:43
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:16:48
User entered 'Female (F)'	John Luna (b) (4)	24 Aug 2020 17:08:50

FDA-CBER-2022-1614-2808790

US3342142
Folder: Screening
Form: Demographics
Generated On: 11 Aug 2021 22:33:31
Ethnicity

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:29:43
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:16:48
User entered 'Not Hispanic or Latino (NOT HISPANIC OR LATINO)'	John Luna (b) (4)	24 Aug 2020 17:08:50

FDA-CBER-2022-1614-2808791

US3342142
Folder: Screening
Form: Demographics
Generated On: 11 Aug 2021 22:33:31
White

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:29:43
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:16:48
User entered '1'	John Luna (b) (4)	24 Aug 2020 17:08:50

US3342142
Folder: Screening
Form: Demographics
Generated On: 11 Aug 2021 22:33:31
Black

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:29:43
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:16:48
User entered '0'	John Luna (b) (4)	24 Aug 2020 17:08:50

FDA-CBER-2022-1614-2808793

US3342142
Folder: Screening
Form: Demographics
Generated On: 11 Aug 2021 22:33:31
Asian

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:29:43
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:16:48
User entered '0'	John Luna (b) (4)	24 Aug 2020 17:08:50

FDA-CBER-2022-1614-2808794

US3342142
Folder: Screening
Form: Demographics
Generated On: 11 Aug 2021 22:33:31
American Indian or Alaska Native

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:29:43
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:16:48
User entered '0'	John Luna (b) (4)	24 Aug 2020 17:08:50

US3342142
Folder: Screening
Form: Demographics
Generated On: 11 Aug 2021 22:33:31
Native Hawaiian or other Pacific Islander

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:29:43
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:16:48
User entered '0'	John Luna (b) (4)	24 Aug 2020 17:08:50

FDA-CBER-2022-1614-2808796

US3342142
Folder: Screening
Form: Demographics
Generated On: 11 Aug 2021 22:33:31
Other

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:29:43
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:16:48
User entered '0'	John Luna (b) (4)	24 Aug 2020 17:08:50

FDA-CBER-2022-1614-2808797

US3342142
Folder: Screening
Form: Demographics
Generated On: 11 Aug 2021 22:33:31
If race is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:29:43
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:16:48
User entered empty.	John Luna (b) (4)	24 Aug 2020 17:08:50

FDA-CBER-2022-1614-2808798

US3342142
Folder: Screening
Form: Demographics
Generated On: 11 Aug 2021 22:33:31
Unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:29:43
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:16:48
User entered '0'	John Luna (b) (4)	24 Aug 2020 17:08:50

FDA-CBER-2022-1614-2808799

US3342142
Folder: Screening
Form: Demographics
Generated On: 11 Aug 2021 22:33:31
Not reported

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:29:43
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:16:48
User entered '0'	John Luna (b) (4)	24 Aug 2020 17:08:50

FDA-CBER-2022-1614-2808800

US3342142
Folder: Screening
Form: Enrollment
Generated On: 11 Aug 2021 22:33:31
Date of Informed Consent *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:29:43
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:16:48
User entered '24 Aug 2020'	John Luna (b) (4)	24 Aug 2020 17:09:02

FDA-CBER-2022-1614-2808801

US3342142
Folder: Screening
Form: Enrollment
Generated On: 11 Aug 2021 22:33:31
Month and Year of Informed Consent (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:29:43
User entered 'Aug 2020'	System	24 Aug 2020 17:09:02

US3342142
Folder: Screening
Form: Enrollment
Generated On: 11 Aug 2021 22:33:31
Year of Informed Consent (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:29:43
User entered '2020'	System	24 Aug 2020 17:09:02

FDA-CBER-2022-1614-2808803

US3342142
Folder: Screening
Form: Enrollment
Generated On: 11 Aug 2021 22:33:31
Protocol Version

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:29:43
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:16:48
User entered 'Amendment 2 (2)'	John Luna (b) (4)	24 Aug 2020 17:09:02

FDA-CBER-2022-1614-2808804

US3342142
Folder: Screening
Form: Enrollment
Generated On: 11 Aug 2021 22:33:31
Was participant enrolled in the study?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:29:43
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:16:48
User entered 'Yes (Y)'	John Luna (b) (4)	24 Aug 2020 17:09:02

FDA-CBER-2022-1614-2808805

US3342142
Folder: Screening
Form: Enrollment
Generated On: 11 Aug 2021 22:33:31
If No, indicate reason for screen fail

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:29:43
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:16:48
User entered empty.	John Luna (b) (4)	24 Aug 2020 17:09:02

FDA-CBER-2022-1614-2808806

US3342142
Folder: Screening
Form: Enrollment
Generated On: 11 Aug 2021 22:33:31
If reason for screen fail is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:29:43
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:16:48
User entered empty.	John Luna (b) (4)	24 Aug 2020 17:09:02

US3342142
Folder: Screening
Form: Enrollment
Generated On: 11 Aug 2021 22:33:31
Was this participant screened previously?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:29:43
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:16:48
User entered 'No (N)'	John Luna (b) (4)	24 Aug 2020 17:09:02

US3342142
Folder: Screening
Form: Enrollment
Generated On: 11 Aug 2021 22:33:31
If Yes, previous participant number

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:29:43
User signature succeeded.	Paul Pickrell (b) (4) (b) (4)	12 Mar 2021 23:16:48
User entered empty.	RWS_ENDPOINT ENDPOINT (b) (4)	24 Aug 2020 16:20:13

FDA-CBER-2022-1614-2808809

US3342142
Folder: Screening
Form: Enrollment
Generated On: 11 Aug 2021 22:33:31
Enrollment Trigger

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:29:43
User entered '1'	System	24 Aug 2020 17:09:07

US3342142
Folder: Screening
Form: Inclusion/Exclusion Criteria Summary
Generated On: 11 Aug 2021 22:33:31
Did the participant meet all eligibility criteria?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:29:43
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:16:48
User entered 'Yes (Y)'	John Luna (b) (4)	24 Aug 2020 17:09:07

FDA-CBER-2022-1614-2808811

US3342142
Folder: Screening
Form: Medical History Summary
Generated On: 11 Aug 2021 22:33:31
Were any significant conditions reported?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:29:43
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:16:48
User entered 'Yes (Y)'	John Luna (b) (4)	24 Aug 2020 17:11:13

US3342142
Folder: Screening
Form: Medical History (1)
Generated On: 11 Aug 2021 22:33:31
Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:29:43
User signature succeeded.	Paul Pickrell (b) (4) (b) (4)	12 Mar 2021 23:16:48
User coded data point as SOC: Cardiac disorders, HLGT: Cardiac arrhythmias, HLT: Supraventricular arrhythmias, PT: Supraventricular tachycardia, LLT: Supraventricular tachycardia - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	24 Aug 2020 17:13:40
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	24 Aug 2020 17:13:40
Data point term sent to Coder	System	24 Aug 2020 17:12:36
User entered 'Supraventricular Tachycardia'	John Luna (b) (4)	24 Aug 2020 17:11:55

US3342142
Folder: Screening
Form: Medical History (1)
Generated On: 11 Aug 2021 22:33:31
Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:29:43
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:16:48
User entered 'un UNK 2014'	John Luna (b) (4)	24 Aug 2020 17:11:55

FDA-CBER-2022-1614-2808814

US3342142
Folder: Screening
Form: Medical History (1)
Generated On: 11 Aug 2021 22:33:31
Start date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:29:43
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:16:48
User entered '0'	John Luna (b) (4)	24 Aug 2020 17:11:55

US3342142
Folder: Screening
Form: Medical History (1)
Generated On: 11 Aug 2021 22:33:31
Condition ongoing at study entry

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:29:43
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:16:48
User entered 'Yes (Y)'	John Luna (b) (4)	24 Aug 2020 17:11:55

US3342142
Folder: Screening
Form: Medical History (1)
Generated On: 11 Aug 2021 22:33:31
If No, please specify the stop date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:29:43
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:16:48
User entered empty.	John Luna (b) (4)	24 Aug 2020 17:11:55

FDA-CBER-2022-1614-2808817

US3342142
Folder: Screening
Form: Medical History (1)
Generated On: 11 Aug 2021 22:33:31
Stop date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:29:43
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:16:48
User entered '0'	John Luna (b) (4)	24 Aug 2020 17:11:55

US3342142
Folder: Screening
Form: Medical History (1)
Generated On: 11 Aug 2021 22:33:31
Start Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:29:43
User entered 'Jan 2014'	System	24 Aug 2020 17:11:55

FDA-CBER-2022-1614-2808819

US3342142
Folder: Screening
Form: Medical History (1)
Generated On: 11 Aug 2021 22:33:31
Start Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:29:43
User entered '2014'	System	24 Aug 2020 17:11:55

FDA-CBER-2022-1614-2808820

US3342142
Folder: Screening
Form: Medical History (1)
Generated On: 11 Aug 2021 22:33:31
Stop Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:29:43
User entered empty.	System	24 Aug 2020 17:11:55

FDA-CBER-2022-1614-2808821

US3342142
Folder: Screening
Form: Medical History (1)
Generated On: 11 Aug 2021 22:33:31
Stop Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:29:43
User entered empty.	System	24 Aug 2020 17:11:55

FDA-CBER-2022-1614-2808822

US3342142
Folder: Screening
Form: Medical History (2)
Generated On: 11 Aug 2021 22:33:31
Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:29:43
User signature succeeded.	Paul Pickrell (b) (4) (b) (4)	12 Mar 2021 23:16:48
User coded data point as SOC: Infections and infestations, HLGT: Viral infectious disorders, HLT: Herpes viral infections, PT: Genital herpes simplex, LLT: Genital herpes simplex - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	23 Oct 2020 22:02:41
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	23 Oct 2020 22:02:41
User closed query 'Per CDM: Please specify the location of HSV 1 and enter any ConMeds if necessary. Thank you' (Site from DM).	(b) (4), (b) (6)	23 Oct 2020 16:04:09
Data point term sent to Coder	System	22 Oct 2020 18:22:08
Query 'Per CDM: Please specify the location of HSV 1 and enter any ConMeds if necessary. Thank you' answered with 'Location entered. No medications reported.' (Site from DM).	Andrew Bell (b) (4) (b) (4)	22 Oct 2020 18:21:58
Coding entries removed.	Andrew Bell (b) (4) (b) (4)	22 Oct 2020 18:21:16
User entered 'HERPES SIMPLEX VIRUS I (GENITAL)' reason for change: Data Entry Error	Andrew Bell (b) (4) (b) (4)	22 Oct 2020 18:21:16
User opened query 'Per CDM: Please specify the location of HSV 1 and enter any ConMeds if necessary. Thank you' (Site from DM).	(b) (4), (b) (6)	02 Oct 2020 19:52:14
User closed query 'Per DM CLR: Please specify the location of Herpes Simplex 1. Review and update medical history diagnosis as appropriate and ensure update to MHx is reconciled with any corresponding AE or ConMed entries, if applicable. ' (Site from DM).	(b) (4), (b) (6)	02 Oct 2020 19:50:28
User coded data point as SOC: Infections and infestations, HLGT: Viral infectious disorders, HLT: Herpes viral infections, PT: Herpes simplex, LLT: Herpes simplex type I - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	23 Sep 2020 01:22:48
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	23 Sep 2020 01:22:48
Data point term sent to Coder	System	23 Sep 2020 01:21:57

US3342142
Folder: Screening
Form: Medical History (2)
Generated On: 11 Aug 2021 22:33:31
Condition

Audit	User	Time (GMT)
Query 'Per DM CLR: Please specify the location of Herpes Simplex 1. Review and update medical history diagnosis as appropriate and ensure update to MHx is reconciled with any corresponding AE or ConMed entries, if applicable. ' answered with 'updated' (Site from DM).	Eileen Euperio (b) (4) (b) (4)	23 Sep 2020 01:21:55
Coding entries removed.	Eileen Euperio (b) (4) (b) (4)	23 Sep 2020 01:21:47
User entered 'herpes simplex virus I' reason for change: Data Entry Error	Eileen Euperio (b) (4) (b) (4)	23 Sep 2020 01:21:47
User opened query 'Per DM CLR: Please specify the location of Herpes Simplex 1. Review and update medical history diagnosis as appropriate and ensure update to MHx is reconciled with any corresponding AE or ConMed entries, if applicable. ' (Site from DM).	(b) (4), (b) (6)	17 Sep 2020 12:48:14
User coded data point as SOC: Infections and infestations, HLGT: Viral infectious disorders, HLT: Herpes viral infections, PT: Herpes simplex, LLT: Herpes simplex type I - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	24 Aug 2020 17:13:40
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	24 Aug 2020 17:13:40
Data point term sent to Coder	System	24 Aug 2020 17:12:39
User entered 'HSV-1'	John Luna (b) (4)	24 Aug 2020 17:12:11

US3342142
Folder: Screening
Form: Medical History (2)
Generated On: 11 Aug 2021 22:33:31
Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:29:43
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:16:48
User entered 'un UNK 2003'	John Luna (b) (4)	24 Aug 2020 17:12:11

FDA-CBER-2022-1614-2808825

US3342142
Folder: Screening
Form: Medical History (2)
Generated On: 11 Aug 2021 22:33:31
Start date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:29:43
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:16:48
User entered '0'	John Luna (b) (4)	24 Aug 2020 17:12:11

FDA-CBER-2022-1614-2808826

US3342142
Folder: Screening
Form: Medical History (2)
Generated On: 11 Aug 2021 22:33:31
Condition ongoing at study entry

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:29:43
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:16:48
User entered 'Yes (Y)'	John Luna (b) (4)	24 Aug 2020 17:12:11

FDA-CBER-2022-1614-2808827

US3342142
Folder: Screening
Form: Medical History (2)
Generated On: 11 Aug 2021 22:33:31
If No, please specify the stop date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:29:43
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:16:48
User entered empty.	John Luna (b) (4)	24 Aug 2020 17:12:11

FDA-CBER-2022-1614-2808828

US3342142
Folder: Screening
Form: Medical History (2)
Generated On: 11 Aug 2021 22:33:31
Stop date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:29:43
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:16:48
User entered '0'	John Luna (b) (4)	24 Aug 2020 17:12:11

FDA-CBER-2022-1614-2808829

US3342142
Folder: Screening
Form: Medical History (2)
Generated On: 11 Aug 2021 22:33:31
Start Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:29:43
User entered 'Jan 2003'	System	24 Aug 2020 17:12:11

FDA-CBER-2022-1614-2808830

US3342142
Folder: Screening
Form: Medical History (2)
Generated On: 11 Aug 2021 22:33:31
Start Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:29:43
User entered '2003'	System	24 Aug 2020 17:12:11

FDA-CBER-2022-1614-2808831

US3342142
Folder: Screening
Form: Medical History (2)
Generated On: 11 Aug 2021 22:33:31
Stop Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:29:43
User entered empty.	System	24 Aug 2020 17:12:11

FDA-CBER-2022-1614-2808832

US3342142
Folder: Screening
Form: Medical History (2)
Generated On: 11 Aug 2021 22:33:31
Stop Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:29:43
User entered empty.	System	24 Aug 2020 17:12:11

FDA-CBER-2022-1614-2808833

US3342142
Folder: Screening
Form: Medical History (3)
Generated On: 11 Aug 2021 22:33:31
Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:29:43
User signature succeeded.	Paul Pickrell (b) (4) (b) (4)	12 Mar 2021 23:16:48
User coded data point as SOC: Congenital, familial and genetic disorders, HLGT: Cardiac and vascular disorders congenital, HLT: Cardiac septal defects congenital, PT: Ventricular septal defect, LLT: Ventricular septal defect - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	24 Aug 2020 17:14:35
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	24 Aug 2020 17:14:35
Data point term sent to Coder	System	24 Aug 2020 17:13:41
User entered 'ventricular septal defect'	John Luna (b) (4)	24 Aug 2020 17:12:57

FDA-CBER-2022-1614-2808834

US3342142
Folder: Screening
Form: Medical History (3)
Generated On: 11 Aug 2021 22:33:31
Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:29:43
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:16:48
User entered (b) (6) 1983'	John Luna (b) (4)	24 Aug 2020 17:12:57

FDA-CBER-2022-1614-2808835

US3342142
Folder: Screening
Form: Medical History (3)
Generated On: 11 Aug 2021 22:33:31
Start date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:29:43
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:16:48
User entered '0'	John Luna (b) (4)	24 Aug 2020 17:12:57

FDA-CBER-2022-1614-2808836

US3342142
Folder: Screening
Form: Medical History (3)
Generated On: 11 Aug 2021 22:33:31
Condition ongoing at study entry

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:29:43
User signature succeeded.	Paul Pickrell (b) (4) (b) (4)	12 Mar 2021 23:16:48
User entered 'No (N)'	John Luna (b) (4)	24 Aug 2020 17:12:57

US3342142
Folder: Screening
Form: Medical History (3)
Generated On: 11 Aug 2021 22:33:31
If No, please specify the stop date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:29:43
User signature succeeded.	Paul Pickrell (b) (4) (b) (4)	12 Mar 2021 23:16:48
User closed query 'Stop date is prior to Start date. Please correct.' (Site from System).	System	14 Sep 2020 21:16:21
User entered 'UN UNK 1985' reason for change: Data Entry Error	Darrell O'Brien (b) (4) (b) (4)	14 Sep 2020 21:16:21
User opened query 'Stop date is prior to Start date. Please correct.' (Site from System).	System	24 Aug 2020 17:12:57
User entered 'un (b) (6) 1983'	John Luna (b) (4)	24 Aug 2020 17:12:57

US3342142
Folder: Screening
Form: Medical History (3)
Generated On: 11 Aug 2021 22:33:31
Stop date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:29:43
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:16:48
User entered '0'	John Luna (b) (4)	24 Aug 2020 17:12:57

FDA-CBER-2022-1614-2808839

US3342142
Folder: Screening
Form: Medical History (3)
Generated On: 11 Aug 2021 22:33:31
Start Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:29:43
User entered (b) (6) 1983'	System	24 Aug 2020 17:12:57

FDA-CBER-2022-1614-2808840

US3342142
Folder: Screening
Form: Medical History (3)
Generated On: 11 Aug 2021 22:33:31
Start Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:29:43
User entered '1983'	System	24 Aug 2020 17:12:57

FDA-CBER-2022-1614-2808841

US3342142
Folder: Screening
Form: Medical History (3)
Generated On: 11 Aug 2021 22:33:31
Stop Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:29:43
User entered 'Jan 1985'	System	14 Sep 2020 21:16:21
User entered (b) (6) 1983'	System	24 Aug 2020 17:12:57

US3342142
Folder: Screening
Form: Medical History (3)
Generated On: 11 Aug 2021 22:33:31
Stop Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:29:43
User entered '1985'	System	14 Sep 2020 21:16:21
User entered '1983'	System	24 Aug 2020 17:12:57

US3342142
Folder: Screening
Form: Medical History (4)
Generated On: 11 Aug 2021 22:33:31
Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:29:43
User signature succeeded.	Paul Pickrell (b) (4) (b) (4)	12 Mar 2021 23:16:48
User coded data point as SOC: Immune system disorders, HLGT: Allergic conditions, HLT: Atopic disorders, PT: Seasonal allergy, LLT: Seasonal allergy - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	24 Aug 2020 17:14:35
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	24 Aug 2020 17:14:35
Data point term sent to Coder	System	24 Aug 2020 17:13:43
User entered 'Seasonal Allergies'	John Luna (b) (4)	24 Aug 2020 17:13:18

FDA-CBER-2022-1614-2808844

US3342142
Folder: Screening
Form: Medical History (4)
Generated On: 11 Aug 2021 22:33:31
Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:29:43
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:16:48
User entered 'un UNK 2015'	John Luna (b) (4)	24 Aug 2020 17:13:18

FDA-CBER-2022-1614-2808845

US3342142
Folder: Screening
Form: Medical History (4)
Generated On: 11 Aug 2021 22:33:31
Start date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:29:43
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:16:48
User entered '0'	John Luna (b) (4)	24 Aug 2020 17:13:18

FDA-CBER-2022-1614-2808846

US3342142
Folder: Screening
Form: Medical History (4)
Generated On: 11 Aug 2021 22:33:31
Condition ongoing at study entry

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:29:43
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:16:48
User entered 'Yes (Y)'	John Luna (b) (4)	24 Aug 2020 17:13:18

FDA-CBER-2022-1614-2808847

US3342142
Folder: Screening
Form: Medical History (4)
Generated On: 11 Aug 2021 22:33:31
If No, please specify the stop date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:29:43
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:16:48
User entered empty.	John Luna (b) (4)	24 Aug 2020 17:13:18

FDA-CBER-2022-1614-2808848

US3342142
Folder: Screening
Form: Medical History (4)
Generated On: 11 Aug 2021 22:33:31
Stop date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:29:43
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:16:48
User entered '0'	John Luna (b) (4)	24 Aug 2020 17:13:18

FDA-CBER-2022-1614-2808849

US3342142
Folder: Screening
Form: Medical History (4)
Generated On: 11 Aug 2021 22:33:31
Start Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:29:43
User entered 'Jan 2015'	System	24 Aug 2020 17:13:18

FDA-CBER-2022-1614-2808850

US3342142
Folder: Screening
Form: Medical History (4)
Generated On: 11 Aug 2021 22:33:31
Start Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:29:43
User entered '2015'	System	24 Aug 2020 17:13:18

FDA-CBER-2022-1614-2808851

US3342142
Folder: Screening
Form: Medical History (4)
Generated On: 11 Aug 2021 22:33:31
Stop Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:29:43
User entered empty.	System	24 Aug 2020 17:13:18

US3342142
Folder: Screening
Form: Medical History (4)
Generated On: 11 Aug 2021 22:33:31
Stop Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:29:43
User entered empty.	System	24 Aug 2020 17:13:18

FDA-CBER-2022-1614-2808853

US3342142
Folder: Screening
Form: Vital Signs
Generated On: 11 Aug 2021 22:33:31
Were vital signs assessed?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:29:43
User signature succeeded.	Paul Pickrell (b) (4) (b) (4)	12 Mar 2021 23:16:48
User entered 'Yes (Y)'	John Luna (b) (4)	24 Aug 2020 17:13:58

US3342142
Folder: Screening
Form: Vital Signs
Generated On: 11 Aug 2021 22:33:31
Date of assessment *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:29:43
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:16:48
User entered '24 Aug 2020'	John Luna (b) (4)	24 Aug 2020 17:13:58

FDA-CBER-2022-1614-2808855

US3342142
Folder: Screening
Form: Vital Signs
Generated On: 11 Aug 2021 22:33:31
Time of assessment *(00:00-23:59)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:29:43
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:16:48
User entered '11:20'	John Luna (b) (4)	24 Aug 2020 17:13:58

FDA-CBER-2022-1614-2808856

US3342142
Folder: Screening
Form: Vital Signs
Generated On: 11 Aug 2021 22:33:31
Vital Signs Date and Time (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:29:43
User entered '24 Aug 2020 11:20'	System	24 Aug 2020 17:13:58

FDA-CBER-2022-1614-2808857

US3342142
Folder: Screening
Form: Vital Signs
Generated On: 11 Aug 2021 22:33:31
Height *(xxx.x)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:29:43
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:16:48
User entered '167.0' cm	John Luna (b) (4)	24 Aug 2020 17:13:58
DataPoint set to visible.	System	24 Aug 2020 17:09:07

FDA-CBER-2022-1614-2808858

US3342142
Folder: Screening
Form: Vital Signs
Generated On: 11 Aug 2021 22:33:31
Weight *(xxx.x)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:29:43
User signature succeeded.	Paul Pickrell (b) (4) (b) (4)	12 Mar 2021 23:16:48
User entered '81.2' kg	John Luna (b) (4)	24 Aug 2020 17:13:58
DataPoint set to visible.	System	24 Aug 2020 17:09:07

US3342142
Folder: Screening
Form: Vital Signs
Generated On: 11 Aug 2021 22:33:31
BMI *(xxx.x)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:29:43
Amendment Manager: User entered '29.11542'	System	17 Sep 2020 00:21:20
User entered '29.1'	System	24 Aug 2020 17:13:58
DataPoint set to visible.	System	24 Aug 2020 17:09:07

FDA-CBER-2022-1614-2808860

US3342142
Folder: Screening
Form: Vital Signs
Generated On: 11 Aug 2021 22:33:31
BMI units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:29:43
User entered 'kg/m2'	System	24 Aug 2020 17:13:58
DataPoint set to visible.	System	24 Aug 2020 17:09:07

US3342142
Folder: Screening
Form: Vital Signs
Generated On: 11 Aug 2021 22:33:31
Temperature *(xxx.x)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:29:43
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:16:48
User entered missing code ND - Not Done.	John Luna (b) (4)	24 Aug 2020 17:13:58

US3342142
Folder: Screening
Form: Vital Signs
Generated On: 11 Aug 2021 22:33:31
Route of measurement

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:29:43
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:16:48
User entered empty.	John Luna (b) (4)	24 Aug 2020 17:13:58

US3342142
Folder: Screening
Form: Vital Signs
Generated On: 11 Aug 2021 22:33:31
If Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:29:43
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:16:48
User entered empty.	John Luna (b) (4)	24 Aug 2020 17:13:58

US3342142
Folder: Screening
Form: Vital Signs
Generated On: 11 Aug 2021 22:33:31
Pulse *(xxx)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:29:43
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:16:48
User entered missing code ND - Not Done.	John Luna (b) (4)	24 Aug 2020 17:13:58

US3342142
Folder: Screening
Form: Vital Signs
Generated On: 11 Aug 2021 22:33:31
Pulse units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:29:43
User entered 'bpm'	System	24 Aug 2020 17:13:58

FDA-CBER-2022-1614-2808866

US3342142
Folder: Screening
Form: Vital Signs
Generated On: 11 Aug 2021 22:33:31
Respiratory Rate *(xxx)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:29:43
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:16:48
User entered missing code ND - Not Done.	John Luna (b) (4)	24 Aug 2020 17:13:58

US3342142
Folder: Screening
Form: Vital Signs
Generated On: 11 Aug 2021 22:33:31
Respiratory Rate units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:29:43
User entered 'breaths/min'	System	24 Aug 2020 17:13:58

FDA-CBER-2022-1614-2808868

US3342142
Folder: Screening
Form: Vital Signs
Generated On: 11 Aug 2021 22:33:31
Systolic Blood Pressure *(xxx)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:29:43
User signature succeeded.	Paul Pickrell (b) (4) (b) (4)	12 Mar 2021 23:16:48
User entered missing code ND - Not Done.	John Luna (b) (4)	24 Aug 2020 17:13:58

FDA-CBER-2022-1614-2808869

US3342142
Folder: Screening
Form: Vital Signs
Generated On: 11 Aug 2021 22:33:31
Systolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:29:43
User entered 'mmHg'	System	24 Aug 2020 17:13:58

FDA-CBER-2022-1614-2808870

US3342142
Folder: Screening
Form: Vital Signs
Generated On: 11 Aug 2021 22:33:31
Diastolic Blood Pressure *(xxx)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:29:43
User signature succeeded.	Paul Pickrell (b) (4) (b) (4)	12 Mar 2021 23:16:48
User entered missing code ND - Not Done.	John Luna (b) (4)	24 Aug 2020 17:13:58

FDA-CBER-2022-1614-2808871

US3342142
Folder: Screening
Form: Vital Signs
Generated On: 11 Aug 2021 22:33:31
Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:29:43
User entered 'mmHg'	System	24 Aug 2020 17:13:58

US3342142
Folder: Screening
Form: Vital Signs
Generated On: 11 Aug 2021 22:33:31
Height (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:29:43

FDA-CBER-2022-1614-2808873

US3342142
Folder: Screening
Form: Vital Signs
Generated On: 11 Aug 2021 22:33:31
Weight (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:29:43

FDA-CBER-2022-1614-2808874

US3342142
Folder: Screening
Form: Physical Examination
Generated On: 11 Aug 2021 22:33:31
Was the physical examination performed?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:29:43
User signature succeeded.	Paul Pickrell (b) (4) (b) (4)	12 Mar 2021 23:16:48
User entered 'Yes (Y)'	John Luna (b) (4)	24 Aug 2020 17:14:06

US3342142
Folder: Screening
Form: Physical Examination
Generated On: 11 Aug 2021 22:33:31
Date of examination *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:29:43
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:16:48
User entered '24 Aug 2020'	John Luna (b) (4)	24 Aug 2020 17:14:06

FDA-CBER-2022-1614-2808876

US3342142
Folder: Screening
Form: Childbearing Potential
Generated On: 11 Aug 2021 22:33:31
Date of assessment *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:29:43
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:16:48
User entered '24 Aug 2020'	John Luna (b) (4)	24 Aug 2020 17:14:14

FDA-CBER-2022-1614-2808877

US3342142
Folder: Screening
Form: Childbearing Potential
Generated On: 11 Aug 2021 22:33:31
Is the participant of childbearing potential?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:29:43
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:16:48
User entered 'Yes (Y)'	John Luna (b) (4)	24 Aug 2020 17:14:14

US3342142
Folder: Screening
Form: Childbearing Potential
Generated On: 11 Aug 2021 22:33:31
If No, what is the reason?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:29:43
User signature succeeded.	Paul Pickrell (b) (4) (b) (4)	12 Mar 2021 23:16:48
User entered empty.	John Luna (b) (4)	24 Aug 2020 17:14:14

US3342142
Folder: Screening
Form: Childbearing Potential
Generated On: 11 Aug 2021 22:33:31
If Partner medically sterile or Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:29:43
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:16:48
User entered empty.	John Luna (b) (4)	24 Aug 2020 17:14:14

FDA-CBER-2022-1614-2808880

US3342142
Folder: Screening
Form: Childbearing Potential
Generated On: 11 Aug 2021 22:33:31
If Surgically sterile, date of surgery *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:29:43
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:16:48
User entered empty.	John Luna (b) (4)	24 Aug 2020 17:14:14

US3342142
Folder: Screening
Form: Childbearing Potential
Generated On: 11 Aug 2021 22:33:31
Date of surgery unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:29:43
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:16:48
User entered '0'	John Luna (b) (4)	24 Aug 2020 17:14:14

FDA-CBER-2022-1614-2808882

US3342142
Folder: Screening
Form: Childbearing Potential
Generated On: 11 Aug 2021 22:33:31
If Post-menopausal, date of last menstruation *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:29:43
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:16:48
User entered empty.	John Luna (b) (4)	24 Aug 2020 17:14:14

US3342142
Folder: Screening
Form: Childbearing Potential
Generated On: 11 Aug 2021 22:33:31
Date of last menstruation unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:29:43
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:16:48
User entered '0'	John Luna (b) (4)	24 Aug 2020 17:14:14

US3342142
Folder: Screening
Form: Pregnancy Test
Generated On: 11 Aug 2021 22:33:31
Was the pregnancy test performed?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:29:43
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:16:48
User entered 'Yes (Y)'	John Luna (b) (4)	24 Aug 2020 17:14:35

FDA-CBER-2022-1614-2808885

US3342142
Folder: Screening
Form: Pregnancy Test
Generated On: 11 Aug 2021 22:33:31
Date of test *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:29:43
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:16:48
User entered '24 Aug 2020'	John Luna (b) (4)	24 Aug 2020 17:14:35

FDA-CBER-2022-1614-2808886

US3342142
Folder: Screening
Form: Pregnancy Test
Generated On: 11 Aug 2021 22:33:31
Test performed

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:29:43
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:16:48
User entered 'Urine (URINE)'	John Luna (b) (4)	24 Aug 2020 17:14:35

FDA-CBER-2022-1614-2808887

US3342142
Folder: Screening
Form: Pregnancy Test
Generated On: 11 Aug 2021 22:33:31
Result

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:29:43
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:16:48
User entered 'Negative (NEGATIVE)'	John Luna (b) (4)	24 Aug 2020 17:14:35

FDA-CBER-2022-1614-2808888

US3342142
Folder: Screening
Form: Pregnancy Test
Generated On: 11 Aug 2021 22:33:31
Was FSH sample collected?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:29:43
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:16:48
User closed query 'Per CDM: Was FSH sample collected is recorded as "No", however collection date and time is recorded. Please refer to eCCGs and update.' (Site from DM).	(b) (4) (b) (4), (b) (6)	11 Sep 2020 05:44:08
Query 'Per CDM: Was FSH sample collected is recorded as "No", however collection date and time is recorded. Please refer to eCCGs and update.' answered with 'data corrected' (Site from DM).	John Luna (b) (4)	09 Sep 2020 23:35:59
User opened query 'Per CDM: Was FSH sample collected is recorded as "No", however collection date and time is recorded. Please refer to eCCGs and update.' (Site from DM).	(b) (4), (b) (6)	08 Sep 2020 09:22:33
User entered 'No (N)'	John Luna (b) (4)	24 Aug 2020 17:14:35

US3342142
Folder: Screening
Form: Pregnancy Test
Generated On: 11 Aug 2021 22:33:31
Collection date

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:29:43
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:16:48
User entered empty; reason for change Data Entry Error	John Luna (b) (4)	09 Sep 2020 23:36:09
User entered '24 Aug 2020'	John Luna (b) (4)	24 Aug 2020 17:14:35

US3342142
Folder: Screening
Form: Pregnancy Test
Generated On: 11 Aug 2021 22:33:31
Collection time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:29:43
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:16:48
User entered empty; reason for change Data Entry Error	John Luna (b) (4)	09 Sep 2020 23:36:09
User entered '11:31'	John Luna (b) (4)	24 Aug 2020 17:14:35

FDA-CBER-2022-1614-2808891

US3342142
Folder: Screening
Form: Pregnancy Test
Generated On: 11 Aug 2021 22:33:31
Collection date and time (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:29:43
User entered empty.	System	09 Sep 2020 23:36:09
User entered '24 Aug 2020 11:31'	System	24 Aug 2020 17:14:35

US3342142
Folder: Screening
Form: Risk of Exposure
Generated On: 11 Aug 2021 22:33:31
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 15:29:43
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:16:48
User entered 'Yes (Y)'	John Luna (b) (4)	24 Aug 2020 17:14:55

FDA-CBER-2022-1614-2808893

US3342142
Folder: Screening
Form: Risk of Exposure
Generated On: 11 Aug 2021 22:33:31
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 15:29:43
User signature succeeded.	Paul Pickrell (b) (4) (b) (4)	12 Mar 2021 23:16:48
User entered 'No (N)'	John Luna (b) (4)	24 Aug 2020 17:14:55

US3342142
Folder: Screening
Form: Risk of Exposure
Generated On: 11 Aug 2021 22:33:31
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 15:29:43
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:16:48
User entered 'No (N)'	John Luna (b) (4)	24 Aug 2020 17:14:55

US3342142
Folder: Screening
Form: Risk of Exposure
Generated On: 11 Aug 2021 22:33:31
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 15:29:43
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:16:48
User entered 'No (N)'	John Luna (b) (4)	24 Aug 2020 17:14:55

FDA-CBER-2022-1614-2808896

US3342142
Folder: Screening
Form: Risk of Exposure
Generated On: 11 Aug 2021 22:33:31
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 15:29:43
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:16:48
User entered 'No (N)'	John Luna (b) (4)	24 Aug 2020 17:14:55

FDA-CBER-2022-1614-2808897

US3342142
Folder: Screening
Form: Risk of Exposure
Generated On: 11 Aug 2021 22:33:31
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 15:29:43
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:16:48
User entered 'No (N)'	John Luna (b) (4)	24 Aug 2020 17:14:55

US3342142
Folder: Screening
Form: Risk of Exposure
Generated On: 11 Aug 2021 22:33:31
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 15:29:43
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:16:48
User entered 'No (N)'	John Luna (b) (4)	24 Aug 2020 17:14:55

US3342142
Folder: Screening
Form: Risk of Exposure
Generated On: 11 Aug 2021 22:33:31
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 15:29:43
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:16:48
User entered 'No (N)'	John Luna (b) (4)	24 Aug 2020 17:14:55

US3342142
Folder: Screening
Form: Risk of Exposure
Generated On: 11 Aug 2021 22:33:31
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 15:29:43
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:16:48
User entered 'No (N)'	John Luna (b) (4)	24 Aug 2020 17:14:55

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US3342142
Folder: Screening
Form: Risk of Exposure
Generated On: 11 Aug 2021 22:33:31
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 15:29:43
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:16:48
User entered 'No (N)'	John Luna (b) (4)	24 Aug 2020 17:14:55

US3342142
Folder: Screening
Form: Risk of Exposure
Generated On: 11 Aug 2021 22:33:31
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 15:29:43
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:16:48
User entered 'No (N)'	John Luna (b) (4)	24 Aug 2020 17:14:55

US3342142
Folder: Screening
Form: Risk of Exposure
Generated On: 11 Aug 2021 22:33:31
Other

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:29:43
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:16:48
User entered 'No (N)'	John Luna (b) (4)	24 Aug 2020 17:14:55

FDA-CBER-2022-1614-2808904

US3342142
Folder: Screening
Form: Risk of Exposure
Generated On: 11 Aug 2021 22:33:31
Specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:29:43
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:16:48
User entered empty.	John Luna (b) (4)	24 Aug 2020 17:14:55

US3342142
Folder: Screening
Form: Risk of Exposure
Generated On: 11 Aug 2021 22:33:31
No Risk Identified

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:29:43
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:16:48
User entered '0'	John Luna (b) (4)	24 Aug 2020 17:14:55

FDA-CBER-2022-1614-2808906

US3342142
Folder: Screening
Form: Risk of Exposure
Generated On: 11 Aug 2021 22:33:31
Resides in Nursing Home or Assisted Living Facility

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:29:43
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:16:48
User entered '0'	John Luna (b) (4)	24 Aug 2020 17:14:55

US3342142
Folder: Screening
Form: Risk of Exposure
Generated On: 11 Aug 2021 22:33:31
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 15:29:43
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:16:48
User entered '0'	John Luna (b) (4)	24 Aug 2020 17:14:55

US3342142
Folder: Screening
Form: Risk of Exposure
Generated On: 11 Aug 2021 22:33:31
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 15:29:43
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:16:48
User entered '0'	John Luna (b) (4)	24 Aug 2020 17:14:55

US3342142
Folder: Screening
Form: Risk of Exposure
Generated On: 11 Aug 2021 22:33:31
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 15:29:43
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:16:48
User entered '0'	John Luna (b) (4)	24 Aug 2020 17:14:55

US3342142
Folder: Screening
Form: Risk of Exposure
Generated On: 11 Aug 2021 22:33:31
Resides in a single family home (i.e., detached housing)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:29:43
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:16:48
User entered '1'	John Luna (b) (4)	24 Aug 2020 17:14:55

FDA-CBER-2022-1614-2808911

US3342142
Folder: Screening
Form: Risk of Exposure
Generated On: 11 Aug 2021 22:33:31
Other

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:29:43
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:16:48
User entered '0'	John Luna (b) (4)	24 Aug 2020 17:14:55

FDA-CBER-2022-1614-2808912

US3342142
Folder: Screening
Form: Risk of Exposure
Generated On: 11 Aug 2021 22:33:31
Specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:29:43
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:16:48
User entered empty.	John Luna (b) (4)	24 Aug 2020 17:14:55

FDA-CBER-2022-1614-2808913

US3342142
Folder: Visit 1 Day 1
Form: Visit Date
Generated On: 11 Aug 2021 22:33:31
Was this visit performed?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:29:43
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:16:48
User entered 'Yes (Y)'	John Luna (b) (4)	24 Aug 2020 17:15:05

FDA-CBER-2022-1614-2808914

US3342142
Folder: Visit 1 Day 1
Form: Visit Date
Generated On: 11 Aug 2021 22:33:31
Visit date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:29:43
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:16:48
User entered '24 Aug 2020'	John Luna (b) (4)	24 Aug 2020 17:15:05

FDA-CBER-2022-1614-2808915

US3342142
Folder: Visit 1 Day 1
Form: Visit Date
Generated On: 11 Aug 2021 22:33:31
Was visit performed at the participant's home or at the clinic?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:29:43
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:16:48
User entered 'Clinic (Clinic)'	John Luna (b) (4)	24 Aug 2020 17:15:05

FDA-CBER-2022-1614-2808916

US3342142
Folder: Visit 1 Day 1
Form: Visit Date
Generated On: 11 Aug 2021 22:33:31
Folder OID

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:29:43
User entered 'VISIT1'	System	24 Aug 2020 17:15:05

FDA-CBER-2022-1614-2808917

US3342142
Folder: Visit 1 Day 1
Form: Randomization
Generated On: 11 Aug 2021 22:33:31
What was the date of randomization? *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:29:43
User signature succeeded.	Paul Pickrell (b) (4) (b) (4)	12 Mar 2021 23:16:48
User entered '24 AUG 2020'	RWS_ENDPOINT ENDPOINT (b) (4)	24 Aug 2020 16:49:45

FDA-CBER-2022-1614-2808918

US3342142
Folder: Visit 1 Day 1
Form: Randomization
Generated On: 11 Aug 2021 22:33:31
What was the participant's randomization number?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:29:43
User signature succeeded.	Paul Pickrell (b) (4) (b) (4)	12 Mar 2021 23:16:48
User entered '106903'	RWS_ENDPOINT ENDPOINT (b) (4)	24 Aug 2020 16:49:45

FDA-CBER-2022-1614-2808919

US3342142
Folder: Visit 1 Day 1
Form: Randomization
Generated On: 11 Aug 2021 22:33:31
In what Cohort was the participant enrolled?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:29:43
User signature succeeded.	Paul Pickrell (b) (4) (b) (4)	12 Mar 2021 23:16:48
User entered '>=18 and <65 years and not at risk (1)'	RWS_ENDPOINT ENDPOINT (b) (4)	24 Aug 2020 16:49:45

FDA-CBER-2022-1614-2808920

US3342142
Folder: Visit 1 Day 1
Form: Randomization
Generated On: 11 Aug 2021 22:33:31
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 15:29:43
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:16:48
User entered 'No (N)'	John Luna (b) (4)	24 Aug 2020 17:15:14

FDA-CBER-2022-1614-2808921

US3342142
Folder: Visit 1 Day 1
Form: Randomization
Generated On: 11 Aug 2021 22:33:31

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 15:29:43
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:16:48
User entered 'No (N)'	John Luna (b) (4)	24 Aug 2020 17:15:14

FDA-CBER-2022-1614-2808922

US3342142
Folder: Visit 1 Day 1
Form: Randomization
Generated On: 11 Aug 2021 22:33:31
Severe obesity (body mass index > or = 40kg/m2

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:29:43
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:16:48
User entered 'No (N)'	John Luna (b) (4)	24 Aug 2020 17:15:14

US3342142
Folder: Visit 1 Day 1
Form: Randomization
Generated On: 11 Aug 2021 22:33:31
Diabetes (Type I, Type 2, or gestational)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:29:43
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:16:48
User entered 'No (N)'	John Luna (b) (4)	24 Aug 2020 17:15:14

FDA-CBER-2022-1614-2808924

US3342142
Folder: Visit 1 Day 1
Form: Randomization
Generated On: 11 Aug 2021 22:33:31
Liver Disease

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:29:43
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:16:48
User entered 'No (N)'	John Luna (b) (4)	24 Aug 2020 17:15:14

FDA-CBER-2022-1614-2808925

US3342142
Folder: Visit 1 Day 1
Form: Randomization
Generated On: 11 Aug 2021 22:33:31
Human Immunodeficiency Virus (HIV) infection

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:29:43
User signature succeeded.	Paul Pickrell (b) (4) (b) (4)	22 Mar 2021 13:27:19
User entered 'No (N)'	Ethan Shotton (b) (4) (b) (4)	18 Mar 2021 18:38:16
Amendment Manager: DataPoint set to visible.	System	19 Sep 2020 10:40:02
Amendment Manager inserted this DataPoint.	System	19 Sep 2020 02:39:54

FDA-CBER-2022-1614-2808926

US3342142
Folder: Visit 1 Day 1
Form: Vital Signs - Dosing
Generated On: 11 Aug 2021 22:33:31
Height

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:29:43
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:16:48
User entered missing code ND - Not Done.	John Luna (b) (4)	24 Aug 2020 17:44:03

FDA-CBER-2022-1614-2808927

US3342142
Folder: Visit 1 Day 1
Form: Vital Signs - Dosing
Generated On: 11 Aug 2021 22:33:31
Weight

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:29:43
User signature succeeded.	Paul Pickrell (b) (4) (b) (4)	12 Mar 2021 23:16:48
User entered missing code ND - Not Done.	John Luna (b) (4)	24 Aug 2020 17:44:03

FDA-CBER-2022-1614-2808928

US3342142
Folder: Visit 1 Day 1
Form: Vital Signs - Dosing
Generated On: 11 Aug 2021 22:33:31
Height

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:29:43
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:16:48
User entered missing code ND - Not Done.	John Luna (b) (4)	24 Aug 2020 17:44:03

FDA-CBER-2022-1614-2808929

US3342142
Folder: Visit 1 Day 1
Form: Vital Signs - Dosing
Generated On: 11 Aug 2021 22:33:31
Weight

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:29:43
User signature succeeded.	Paul Pickrell (b) (4) (b) (4)	12 Mar 2021 23:16:48
User entered missing code ND - Not Done.	John Luna (b) (4)	24 Aug 2020 17:44:03

FDA-CBER-2022-1614-2808930

US3342142
Folder: Visit 1 Day 1
Form: Vital Signs - Dosing (1)
Generated On: 11 Aug 2021 22:33:31
Timepoint

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:29:43
User accepted default value 'Pre-Dose (PREDOSE)'	John Luna (b) (4)	24 Aug 2020 17:44:03

FDA-CBER-2022-1614-2808931

US3342142
Folder: Visit 1 Day 1
Form: Vital Signs - Dosing (1)
Generated On: 11 Aug 2021 22:33:31
Were vital signs assessed?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:29:43
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:16:48
User entered 'Yes (Y)'	John Luna (b) (4)	24 Aug 2020 17:44:03

FDA-CBER-2022-1614-2808932

US3342142
Folder: Visit 1 Day 1
Form: Vital Signs - Dosing (1)
Generated On: 11 Aug 2021 22:33:31
Date of assessment *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:29:43
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:16:48
User entered '24 Aug 2020'	John Luna (b) (4)	24 Aug 2020 17:44:03

FDA-CBER-2022-1614-2808933

US3342142
Folder: Visit 1 Day 1
Form: Vital Signs - Dosing (1)
Generated On: 11 Aug 2021 22:33:31
Time of assessment *(00:00-23:59)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:29:43
User signature succeeded.	Paul Pickrell (b) (4) (b) (4)	12 Mar 2021 23:16:48
User closed query 'Data is required. Please provide.' (Site from System).	System	24 Aug 2020 18:00:59
Query 'Data is required. Please provide.' answered by data change (Site from System).	System	24 Aug 2020 18:00:59
User entered '11:20' reason for change: Data Entry Error	John Luna (b) (4)	24 Aug 2020 18:00:59
User opened query 'Data is required. Please provide.' (Site from System).	System	24 Aug 2020 17:44:03
User entered empty.	John Luna (b) (4)	24 Aug 2020 17:44:03

FDA-CBER-2022-1614-2808934

US3342142
Folder: Visit 1 Day 1
Form: Vital Signs - Dosing (1)
Generated On: 11 Aug 2021 22:33:31
Vital Signs Date and Time (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:29:43
User entered '24 Aug 2020 11:20'	System	24 Aug 2020 18:00:59
User entered empty.	System	24 Aug 2020 17:44:03

US3342142
Folder: Visit 1 Day 1
Form: Vital Signs - Dosing (1)
Generated On: 11 Aug 2021 22:33:31
Temperature *(xxx.x)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:29:43
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:16:48
User entered '97.5' F	John Luna (b) (4)	24 Aug 2020 17:44:03

FDA-CBER-2022-1614-2808936

US3342142
Folder: Visit 1 Day 1
Form: Vital Signs - Dosing (1)
Generated On: 11 Aug 2021 22:33:31
Route of measurement

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:29:43
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:16:48
User entered 'Oral (Oral)'	John Luna (b) (4)	24 Aug 2020 17:44:03

FDA-CBER-2022-1614-2808937

US3342142
Folder: Visit 1 Day 1
Form: Vital Signs - Dosing (1)
Generated On: 11 Aug 2021 22:33:31
If Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:29:43
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:16:48
User entered empty.	John Luna (b) (4)	24 Aug 2020 17:44:03

US3342142
Folder: Visit 1 Day 1
Form: Vital Signs - Dosing (1)
Generated On: 11 Aug 2021 22:33:31
Pulse *(xxx)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:29:43
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:16:48
User entered '68'	John Luna (b) (4)	24 Aug 2020 17:44:03

FDA-CBER-2022-1614-2808939

US3342142
Folder: Visit 1 Day 1
Form: Vital Signs - Dosing (1)
Generated On: 11 Aug 2021 22:33:31
Pulse units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:29:43
User entered 'bpm'	System	24 Aug 2020 17:44:03

FDA-CBER-2022-1614-2808940

US3342142
Folder: Visit 1 Day 1
Form: Vital Signs - Dosing (1)
Generated On: 11 Aug 2021 22:33:31
Respiratory Rate *(xxx)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:29:43
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:16:48
User entered '18'	John Luna (b) (4)	24 Aug 2020 17:44:03

FDA-CBER-2022-1614-2808941

US3342142
Folder: Visit 1 Day 1
Form: Vital Signs - Dosing (1)
Generated On: 11 Aug 2021 22:33:31
Respiratory Rate units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:29:43
User entered 'breaths/min'	System	24 Aug 2020 17:44:03

FDA-CBER-2022-1614-2808942

US3342142
Folder: Visit 1 Day 1
Form: Vital Signs - Dosing (1)
Generated On: 11 Aug 2021 22:33:31
Systolic Blood Pressure *(xxx)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:29:43
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:16:48
User entered '112'	John Luna (b) (4)	24 Aug 2020 17:44:03

FDA-CBER-2022-1614-2808943

US3342142
Folder: Visit 1 Day 1
Form: Vital Signs - Dosing (1)
Generated On: 11 Aug 2021 22:33:31
Systolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:29:43
User entered 'mmHg'	System	24 Aug 2020 17:44:03

FDA-CBER-2022-1614-2808944

US3342142
Folder: Visit 1 Day 1
Form: Vital Signs - Dosing (1)
Generated On: 11 Aug 2021 22:33:31
Diastolic Blood Pressure *(xxx)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:29:43
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:16:48
User entered '74'	John Luna (b) (4)	24 Aug 2020 17:44:03

FDA-CBER-2022-1614-2808945

US3342142
Folder: Visit 1 Day 1
Form: Vital Signs - Dosing (1)
Generated On: 11 Aug 2021 22:33:31
Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:29:43
User entered 'mmHg'	System	24 Aug 2020 17:44:03

FDA-CBER-2022-1614-2808946

US3342142
Folder: Visit 1 Day 1
Form: Vital Signs - Dosing
Generated On: 11 Aug 2021 22:33:31
Height

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:29:43
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:16:48
User entered missing code ND - Not Done.	John Luna (b) (4)	24 Aug 2020 17:44:03

FDA-CBER-2022-1614-2808947

US3342142
Folder: Visit 1 Day 1
Form: Vital Signs - Dosing
Generated On: 11 Aug 2021 22:33:31
Weight

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:29:43
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:16:48
User entered missing code ND - Not Done.	John Luna (b) (4)	24 Aug 2020 17:44:03

FDA-CBER-2022-1614-2808948

US3342142
Folder: Visit 1 Day 1
Form: Vital Signs - Dosing (2)
Generated On: 11 Aug 2021 22:33:31
Timepoint

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:29:43
User accepted default value 'Post-Dose (POSTDOSE)'	John Luna (b) (4)	24 Aug 2020 17:44:03

FDA-CBER-2022-1614-2808949

US3342142
Folder: Visit 1 Day 1
Form: Vital Signs - Dosing (2)
Generated On: 11 Aug 2021 22:33:31
Were vital signs assessed?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:29:43
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:16:48
User entered 'Yes (Y)'	John Luna (b) (4)	24 Aug 2020 17:44:03

FDA-CBER-2022-1614-2808950

US3342142
Folder: Visit 1 Day 1
Form: Vital Signs - Dosing (2)
Generated On: 11 Aug 2021 22:33:31
Date of assessment *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:29:43
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:16:48
User entered '24 Aug 2020'	John Luna (b) (4)	24 Aug 2020 17:44:03

FDA-CBER-2022-1614-2808951

US3342142
Folder: Visit 1 Day 1
Form: Vital Signs - Dosing (2)
Generated On: 11 Aug 2021 22:33:31
Time of assessment *(00:00-23:59)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:29:43
User signature succeeded.	Paul Pickrell (b) (4) (b) (4)	12 Mar 2021 23:16:48
User closed query 'Data is required. Please provide.' (Site from System).	System	24 Aug 2020 18:02:09
Query 'Data is required. Please provide.' answered by data change (Site from System).	System	24 Aug 2020 18:02:09
User entered '12:49' reason for change: Data Entry Error	John Luna (b) (4)	24 Aug 2020 18:02:09
User opened query 'Data is required. Please provide.' (Site from System).	System	24 Aug 2020 17:44:03
User entered empty.	John Luna (b) (4)	24 Aug 2020 17:44:03

FDA-CBER-2022-1614-2808952

US3342142
Folder: Visit 1 Day 1
Form: Vital Signs - Dosing (2)
Generated On: 11 Aug 2021 22:33:31
Vital Signs Date and Time (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:29:43
User entered '24 Aug 2020 12:49'	System	24 Aug 2020 18:02:09
User entered empty.	System	24 Aug 2020 17:44:03

US3342142
Folder: Visit 1 Day 1
Form: Vital Signs - Dosing (2)
Generated On: 11 Aug 2021 22:33:31
Temperature *(xxx.x)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:29:43
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:16:48
User closed query 'Data is required. Please provide.' (Site from System).	System	24 Aug 2020 18:02:09
Query 'Data is required. Please provide.' answered by data change (Site from System).	System	24 Aug 2020 18:02:09
User entered '97.7' F reason for change: Data Entry Error	John Luna (b) (4)	24 Aug 2020 18:02:09
User opened query 'Data is required. Please provide.' (Site from System).	System	24 Aug 2020 17:44:03
User entered empty.	John Luna (b) (4)	24 Aug 2020 17:44:03

FDA-CBER-2022-1614-2808954

US3342142
Folder: Visit 1 Day 1
Form: Vital Signs - Dosing (2)
Generated On: 11 Aug 2021 22:33:31
Route of measurement

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:29:43
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:16:48
User entered 'Oral (Oral)' reason for change: Data Entry Error	John Luna (b) (4)	24 Aug 2020 18:02:09
User entered empty.	John Luna (b) (4)	24 Aug 2020 17:44:03

FDA-CBER-2022-1614-2808955

US3342142
Folder: Visit 1 Day 1
Form: Vital Signs - Dosing (2)
Generated On: 11 Aug 2021 22:33:31
If Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:29:43
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:16:48
User entered empty.	John Luna (b) (4)	24 Aug 2020 17:44:03

FDA-CBER-2022-1614-2808956

US3342142
Folder: Visit 1 Day 1
Form: Vital Signs - Dosing (2)
Generated On: 11 Aug 2021 22:33:31
Pulse *(xxx)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:29:43
User signature succeeded.	Paul Pickrell (b) (4) (b) (4)	12 Mar 2021 23:16:48
User closed query 'Data is required. Please provide.' (Site from System).	System	24 Aug 2020 18:02:09
Query 'Data is required. Please provide.' answered by data change (Site from System).	System	24 Aug 2020 18:02:09
User entered '77' reason for change: Data Entry Error	John Luna (b) (4)	24 Aug 2020 18:02:09
User opened query 'Data is required. Please provide.' (Site from System).	System	24 Aug 2020 17:44:03
User entered empty.	John Luna (b) (4)	24 Aug 2020 17:44:03

FDA-CBER-2022-1614-2808957

US3342142
Folder: Visit 1 Day 1
Form: Vital Signs - Dosing (2)
Generated On: 11 Aug 2021 22:33:31
Pulse units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:29:43
User entered 'bpm'	System	24 Aug 2020 18:02:09
User entered empty.	System	24 Aug 2020 17:44:03

FDA-CBER-2022-1614-2808958

US3342142
Folder: Visit 1 Day 1
Form: Vital Signs - Dosing (2)
Generated On: 11 Aug 2021 22:33:31
Respiratory Rate *(xxx)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:29:43
User signature succeeded.	Paul Pickrell (b) (4) (b) (4)	12 Mar 2021 23:16:48
User closed query 'Data is required. Please provide.' (Site from System).	System	24 Aug 2020 18:02:09
Query 'Data is required. Please provide.' answered by data change (Site from System).	System	24 Aug 2020 18:02:09
User entered '16' reason for change: Data Entry Error	John Luna (b) (4)	24 Aug 2020 18:02:09
User opened query 'Data is required. Please provide.' (Site from System).	System	24 Aug 2020 17:44:03
User entered empty.	John Luna (b) (4)	24 Aug 2020 17:44:03

FDA-CBER-2022-1614-2808959

US3342142
Folder: Visit 1 Day 1
Form: Vital Signs - Dosing (2)
Generated On: 11 Aug 2021 22:33:31
Respiratory Rate units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:29:43
User entered 'breaths/min'	System	24 Aug 2020 18:02:09
User entered empty.	System	24 Aug 2020 17:44:03

US3342142
Folder: Visit 1 Day 1
Form: Vital Signs - Dosing (2)
Generated On: 11 Aug 2021 22:33:31
Systolic Blood Pressure *(xxx)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:29:43
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:16:48
User closed query 'Data is required. Please provide.' (Site from System).	System	24 Aug 2020 18:02:09
Query 'Data is required. Please provide.' answered by data change (Site from System).	System	24 Aug 2020 18:02:09
User entered '127' reason for change: Data Entry Error	John Luna (b) (4)	24 Aug 2020 18:02:09
User opened query 'Data is required. Please provide.' (Site from System).	System	24 Aug 2020 17:44:03
User entered empty.	John Luna (b) (4)	24 Aug 2020 17:44:03

FDA-CBER-2022-1614-2808961

US3342142
Folder: Visit 1 Day 1
Form: Vital Signs - Dosing (2)
Generated On: 11 Aug 2021 22:33:31
Systolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:29:43
User entered 'mmHg'	System	24 Aug 2020 18:02:09
User entered empty.	System	24 Aug 2020 17:44:03

FDA-CBER-2022-1614-2808962

US3342142
Folder: Visit 1 Day 1
Form: Vital Signs - Dosing (2)
Generated On: 11 Aug 2021 22:33:31
Diastolic Blood Pressure *(xxx)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:29:43
User signature succeeded.	Paul Pickrell (b) (4) (b) (4)	12 Mar 2021 23:16:48
User closed query 'Data is required. Please provide.' (Site from System).	System	24 Aug 2020 18:02:09
Query 'Data is required. Please provide.' answered by data change (Site from System).	System	24 Aug 2020 18:02:09
User entered '82' reason for change: Data Entry Error	John Luna (b) (4)	24 Aug 2020 18:02:09
User opened query 'Data is required. Please provide.' (Site from System).	System	24 Aug 2020 17:44:03
User entered empty.	John Luna (b) (4)	24 Aug 2020 17:44:03

FDA-CBER-2022-1614-2808963

US3342142
Folder: Visit 1 Day 1
Form: Vital Signs - Dosing (2)
Generated On: 11 Aug 2021 22:33:31
Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:29:43
User entered 'mmHg'	System	24 Aug 2020 18:02:09
User entered empty.	System	24 Aug 2020 17:44:03

FDA-CBER-2022-1614-2808964

US3342142
Folder: Visit 1 Day 1
Form: Physical Examination
Generated On: 11 Aug 2021 22:33:31
Was the physical examination performed?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:29:43
User signature succeeded.	Paul Pickrell (b) (4) (b) (4)	12 Mar 2021 23:16:48
User entered 'No (N)'	John Luna (b) (4)	24 Aug 2020 17:18:28

FDA-CBER-2022-1614-2808965

US3342142
Folder: Visit 1 Day 1
Form: Physical Examination
Generated On: 11 Aug 2021 22:33:31
Date of examination *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:29:43
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:16:48
User entered empty.	John Luna (b) (4)	24 Aug 2020 17:18:28

FDA-CBER-2022-1614-2808966

US3342142
Folder: Visit 1 Day 1
Form: Pregnancy Test
Generated On: 11 Aug 2021 22:33:31
Was the pregnancy test performed?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:29:43
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:16:48
User closed query 'Per CDM: Thank you. Per version 1.0 of the CCGs data was entered correctly, however; to eliminate duplicate data the newest version 2.0 of the CCGs will have updated data entry guidelines. Per Sponsor, If Screening and Visit 1 Day 1 are done on the same day, please enter Pregnancy Test (if applicable) at Screening, and select No at Visit 1 Day 1 Pregnancy Test. Thank you.' (Site from DM).	(b) (4) (b) (4), (b) (6)	06 Nov 2020 14:42:20
Query 'Per CDM: Thank you. Per version 1.0 of the CCGs data was entered correctly, however; to eliminate duplicate data the newest version 2.0 of the CCGs will have updated data entry guidelines. Per Sponsor, If Screening and Visit 1 Day 1 are done on the same day, please enter Pregnancy Test (if applicable) at Screening, and select No at Visit 1 Day 1 Pregnancy Test. Thank you.' answered with 'Pregnancy test listed only for screening visit ' (Site from DM).	(b) (4), (b) (6)	05 Nov 2020 22:40:28
User entered 'No (N)' reason for change: Data Entry Error	(b) (4), (b) (6)	05 Nov 2020 22:40:21
User opened query 'Per CDM: Thank you. Per version 1.0 of the CCGs data was entered correctly, however; to eliminate duplicate data the newest version 2.0 of the CCGs will have updated data entry guidelines. Per Sponsor, If Screening and Visit 1 Day 1 are done on the same day, please enter Pregnancy Test (if applicable) at Screening, and select No at Visit 1 Day 1 Pregnancy Test. Thank you.' (Site from DM).	(b) (4), (b) (6)	25 Sep 2020 20:03:17
User closed query 'Per CDM: Thank you for your answer. However, please be aware that Screening and Visit 1 Day 1 "Dates" are the same which means that Visit 1 Day 1 "Pregnancy Test" form is duplicate of the pregnancy test performed at screening visit. Kindly consider only keeping one record (at screening) and updating this assessment as "No". Thank you!' (Site from DM).	(b) (4), (b) (6)	25 Sep 2020 20:03:12

US3342142
Folder: Visit 1 Day 1
Form: Pregnancy Test
Generated On: 11 Aug 2021 22:33:31
Was the pregnancy test performed?

Audit	User	Time (GMT)
Query 'Per CDM: Thank you for your answer. However, please be aware that Screening and Visit 1 Day 1 "Dates" are the same which means that Visit 1 Day 1 "Pregnancy Test" form is duplicate of the pregnancy test performed at screening visit. Kindly consider only keeping one record (at screening) and updating this assessment as "No". Thank you!' answered with 'Per CRF guidelines, both screening and baseline pregnancy test CRFs are to be completed if dosed same day as screening' (Site from DM).	Eileen Euperio (b) (4) (b) (4)	25 Sep 2020 14:48:11
User opened query 'Per CDM: Thank you for your answer. However, please be aware that Screening and Visit 1 Day 1 "Dates" are the same which means that Visit 1 Day 1 "Pregnancy Test" form is duplicate of the pregnancy test performed at screening visit. Kindly consider only keeping one record (at screening) and updating this assessment as "No". Thank you!' (Site from DM).	(b) (4), (b) (6)	21 Sep 2020 08:12:15
User closed query 'Per CDM: Thank you for your answer. However, please be aware that Screening and Visit 1 Day 1 "Dates" are the same which means that Visit 1 Day 1 "Pregnancy Test" form is duplicate of the pregnancy test performed at screening visit. Kindly consider only keeping one record (at screening) and updating this assessment as "No". Thank you!' (Site from DM).	(b) (4), (b) (6)	14 Sep 2020 20:07:30
Query 'Per CDM: Thank you for your answer. However, please be aware that Screening and Visit 1 Day 1 "Dates" are the same which means that Visit 1 Day 1 "Pregnancy Test" form is duplicate of the pregnancy test performed at screening visit. Kindly consider only keeping one record (at screening) and updating this assessment as "No". Thank you!' answered with 'Understood. However, per the current eCRF Completion Guidelines, pages 15 and 16, under "DATA REQUIREMENTS", the information required to be input is listed as "Pregnancy Test (if applicable)" in the Screening Visit folder and again information is required to be input listed as "Pregnancy Test (if applicable)" in the Visit 1 Day 1 folder.' (Site from DM).	Darrell O'Brien (b) (4) (b) (4)	11 Sep 2020 23:12:55

US3342142
Folder: Visit 1 Day 1
Form: Pregnancy Test
Generated On: 11 Aug 2021 22:33:31
Was the pregnancy test performed?

Audit	User	Time (GMT)
User opened query 'Per CDM: Thank you for your answer. However, please be aware that Screening and Visit 1 Day 1 "Dates" are the same which means that Visit 1 Day 1 "Pregnancy Test" form is duplicate of the pregnancy test performed at screening visit. Kindly consider only keeping one record (at screening) and updating this assessment as "No". Thank you!' (Site from DM).	(b) (4), (b) (6)	11 Sep 2020 07:55:37
User closed query 'Per CDM: This data seems to be a duplicate of the pregnancy test performed at screening visit. Kindly consider only keeping one record (at screening) and updating this assessment as "No" and keeping the eCRF blank at Visit 1 Day 1.' (Site from DM).	(b) (4), (b) (6)	11 Sep 2020 07:55:37
Query 'Per CDM: This data seems to be a duplicate of the pregnancy test performed at screening visit. Kindly consider only keeping one record (at screening) and updating this assessment as "No" and keeping the eCRF blank at Visit 1 Day 1.' answered with 'Per eCRF guide, data entered on both pages.' (Site from DM).	John Luna (b) (4)	09 Sep 2020 23:34:38
User opened query 'Per CDM: This data seems to be a duplicate of the pregnancy test performed at screening visit. Kindly consider only keeping one record (at screening) and updating this assessment as "No" and keeping the eCRF blank at Visit 1 Day 1.' (Site from DM).	(b) (4), (b) (6)	08 Sep 2020 09:22:44
User entered 'Yes (Y)'	John Luna (b) (4)	24 Aug 2020 17:17:12

FDA-CBER-2022-1614-2808969

US3342142
Folder: Visit 1 Day 1
Form: Pregnancy Test
Generated On: 11 Aug 2021 22:33:31
Date of test *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:29:43
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:16:48
User entered empty; reason for change Data Entry Error	(b) (4) (b) (4), (b) (6)	05 Nov 2020 22:40:21
User entered '24 Aug 2020'	John Luna (b) (4)	24 Aug 2020 17:17:12

FDA-CBER-2022-1614-2808970

US3342142
Folder: Visit 1 Day 1
Form: Pregnancy Test
Generated On: 11 Aug 2021 22:33:31
Test performed

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:29:43
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:16:48
User entered empty; reason for change Data Entry Error	(b) (4) (b) (4), (b) (6)	05 Nov 2020 22:40:21
User entered 'Urine (URINE)'	John Luna (b) (4)	24 Aug 2020 17:17:12

FDA-CBER-2022-1614-2808971

US3342142
Folder: Visit 1 Day 1
Form: Pregnancy Test
Generated On: 11 Aug 2021 22:33:31
Result

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:29:43
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:16:48
User entered empty; reason for change Data Entry Error	(b) (4) (b) (4), (b) (6)	05 Nov 2020 22:40:21
User entered 'Negative (NEGATIVE)'	John Luna (b) (4)	24 Aug 2020 17:17:12

US3342142
Folder: Visit 1 Day 1
Form: Pregnancy Test
Generated On: 11 Aug 2021 22:33:31
Was FSH sample collected?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:29:43
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:16:48
User entered empty; reason for change Data Entry Error	(b) (4) (b) (4), (b) (6)	05 Nov 2020 22:40:21
User entered 'No (N)'	John Luna (b) (4)	24 Aug 2020 17:17:12

FDA-CBER-2022-1614-2808973

US3342142
Folder: Visit 1 Day 1
Form: Pregnancy Test
Generated On: 11 Aug 2021 22:33:31
Collection date

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:29:43
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:16:48
User entered empty; reason for change Data Entry Error	(b) (4) (b) (4), (b) (6)	05 Nov 2020 22:40:21
User entered '24 Aug 2020'	John Luna (b) (4)	24 Aug 2020 17:17:12

FDA-CBER-2022-1614-2808974

US3342142
Folder: Visit 1 Day 1
Form: Pregnancy Test
Generated On: 11 Aug 2021 22:33:31
Collection time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:29:43
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:16:48
User entered empty; reason for change Data Entry Error	(b) (4) (b) (4), (b) (6)	05 Nov 2020 22:40:21
User entered '11:31'	John Luna (b) (4)	24 Aug 2020 17:17:12

FDA-CBER-2022-1614-2808975

US3342142
Folder: Visit 1 Day 1
Form: Pregnancy Test
Generated On: 11 Aug 2021 22:33:31
Collection date and time (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:29:43
User entered empty.	System	05 Nov 2020 22:40:21
User entered '24 Aug 2020 11:31'	System	24 Aug 2020 17:17:12

US3342142
Folder: Visit 1 Day 1
Form: Exposure
Generated On: 11 Aug 2021 22:33:31
Was study treatment given?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:29:43
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:16:48
User entered 'Yes (Y)'	John Luna (b) (4)	24 Aug 2020 17:43:00

FDA-CBER-2022-1614-2808977

US3342142
Folder: Visit 1 Day 1
Form: Exposure
Generated On: 11 Aug 2021 22:33:31
If No, reason not given

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:29:43
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:16:48
User entered empty.	John Luna (b) (4)	24 Aug 2020 17:43:00

FDA-CBER-2022-1614-2808978

US3342142
Folder: Visit 1 Day 1
Form: Exposure
Generated On: 11 Aug 2021 22:33:31
If reason is Physician Decision, Withdrawal of Consent by Participant, Protocol Deviation, or Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:29:43
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:16:48
User entered empty.	John Luna (b) (4)	24 Aug 2020 17:43:00

US3342142
Folder: Visit 1 Day 1
Form: Exposure
Generated On: 11 Aug 2021 22:33:31
What was the study treatment?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:29:43
User entered 'MRNA-1273 OR PLACEBO'	System	24 Aug 2020 17:43:00

FDA-CBER-2022-1614-2808980

US3342142
Folder: Visit 1 Day 1
Form: Exposure
Generated On: 11 Aug 2021 22:33:31
What was the treatment date? *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:29:43
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:16:48
User entered '24 Aug 2020'	John Luna (b) (4)	24 Aug 2020 17:43:00

FDA-CBER-2022-1614-2808981

US3342142
Folder: Visit 1 Day 1
Form: Exposure
Generated On: 11 Aug 2021 22:33:31
What was the treatment time? *(00:00-23:59)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:29:43
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:16:48
User entered '12:19'	John Luna (b) (4)	24 Aug 2020 17:43:00

FDA-CBER-2022-1614-2808982

US3342142
Folder: Visit 1 Day 1
Form: Exposure
Generated On: 11 Aug 2021 22:33:31
Treatment Date and Time (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:29:43
User entered '24 Aug 2020 12:19'	System	24 Aug 2020 17:43:00

US3342142
Folder: Visit 1 Day 1
Form: Exposure
Generated On: 11 Aug 2021 22:33:31
Which arm was used to give treatment?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:29:43
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:16:48
User entered 'Left Arm (LEFT ARM)'	John Luna (b) (4)	24 Aug 2020 17:43:00

FDA-CBER-2022-1614-2808984

US3342142
Folder: Visit 1 Day 1
Form: Exposure
Generated On: 11 Aug 2021 22:33:31
What was the frequency of the study treatment dosing?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:29:43
User entered 'ONCE'	System	24 Aug 2020 17:43:00

FDA-CBER-2022-1614-2808985

US3342142
Folder: Visit 1 Day 1
Form: Exposure
Generated On: 11 Aug 2021 22:33:31
What was the route of administration for the study treatment?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:29:43
User entered 'INTRAMUSCULAR'	System	24 Aug 2020 17:43:00

FDA-CBER-2022-1614-2808986

US3342142
Folder: Visit 1 Day 1
Form: Immunogenicity Assessment
Generated On: 11 Aug 2021 22:33:31
Was the sample collected?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:29:43
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:16:48
User entered 'Yes (Y)'	John Luna (b) (4)	24 Aug 2020 17:18:02

FDA-CBER-2022-1614-2808987

US3342142
Folder: Visit 1 Day 1
Form: Immunogenicity Assessment
Generated On: 11 Aug 2021 22:33:31
Collection date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:29:43
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:16:48
User entered '24 Aug 2020'	John Luna (b) (4)	24 Aug 2020 17:18:02

FDA-CBER-2022-1614-2808988

US3342142
Folder: Visit 1 Day 1
Form: Immunogenicity Assessment
Generated On: 11 Aug 2021 22:33:31
Collection time *(00:00-23:59)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:29:43
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:16:48
User entered '11:48'	John Luna (b) (4)	24 Aug 2020 17:18:02

FDA-CBER-2022-1614-2808989

US3342142
Folder: Visit 1 Day 1
Form: Immunogenicity Assessment
Generated On: 11 Aug 2021 22:33:31
Collection date and time (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:29:43
User entered '24 Aug 2020 11:48'	System	24 Aug 2020 17:18:02

US3342142
Folder: Visit 1 Day 1
Form: Central Laboratory - Nasopharyngeal Swab
Generated On: 11 Aug 2021 22:33:31
Collection date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:29:43
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:16:48
User entered '24 Aug 2020'	John Luna (b) (4)	24 Aug 2020 17:18:16

FDA-CBER-2022-1614-2808991

US3342142
Folder: Visit 1 Day 1
Form: Central Laboratory - Nasopharyngeal Swab (1)
Generated On: 11 Aug 2021 22:33:31
Lab Test

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:29:43
User accepted default value 'Nasopharyngeal Swab 1 (NASAL1)'	John Luna (b) (4)	24 Aug 2020 17:18:16

FDA-CBER-2022-1614-2808992

US3342142
Folder: Visit 1 Day 1
Form: Central Laboratory - Nasopharyngeal Swab (1)
Generated On: 11 Aug 2021 22:33:31
Was the sample collected?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:29:43
User signature succeeded.	Paul Pickrell (b) (4) (b) (4)	12 Mar 2021 23:16:48
User entered 'Yes (Y)'	John Luna (b) (4)	24 Aug 2020 17:18:16

US3342142
Folder: Visit 1 Day 1
Form: Central Laboratory - Nasopharyngeal Swab (1)
Generated On: 11 Aug 2021 22:33:31
Collection time *(00:00 - 23:59)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:29:43
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:16:48
User entered '11:50'	John Luna (b) (4)	24 Aug 2020 17:18:16

FDA-CBER-2022-1614-2808994

US3342142
Folder: Visit 1 Day 1
Form: Central Laboratory - Nasopharyngeal Swab (1)
Generated On: 11 Aug 2021 22:33:31
Collection date and time (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:29:43
User entered '24 Aug 2020 11:50'	System	24 Aug 2020 17:18:16

FDA-CBER-2022-1614-2808995

US3342142
Folder: Visit 1 Day 1
Form: Central Laboratory - Nasopharyngeal Swab (2)
Generated On: 11 Aug 2021 22:33:31
Lab Test

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:29:43
User accepted default value 'Nasopharyngeal Swab 2 (NASAL2)'	John Luna (b) (4)	24 Aug 2020 17:18:16

FDA-CBER-2022-1614-2808996

US3342142
Folder: Visit 1 Day 1
Form: Central Laboratory - Nasopharyngeal Swab (2)
Generated On: 11 Aug 2021 22:33:31
Was the sample collected?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:29:43
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:16:48
User entered 'No (N)'	John Luna (b) (4)	24 Aug 2020 17:18:16

US3342142
Folder: Visit 1 Day 1
Form: Central Laboratory - Nasopharyngeal Swab (2)
Generated On: 11 Aug 2021 22:33:31
Collection time *(00:00 - 23:59)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:29:43
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:16:48
User entered empty.	John Luna (b) (4)	24 Aug 2020 17:18:16

FDA-CBER-2022-1614-2808998

US3342142
Folder: Visit 1 Day 1
Form: Central Laboratory - Nasopharyngeal Swab (2)
Generated On: 11 Aug 2021 22:33:31
Collection date and time (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:29:43
User entered empty.	System	24 Aug 2020 17:18:16

US3342142
Folder: Visit 1 Day 1
Form: Continuing
Generated On: 11 Aug 2021 22:33:31
Is the participant continuing to the next visit?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:29:43
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:16:48
User entered 'Yes (Y)'	John Luna (b) (4)	24 Aug 2020 17:18:21

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US3342142
Folder: Visit 1 Day 1
Form: Continuing
Generated On: 11 Aug 2021 22:33:31
Continuing Flag

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:29:43
User entered '1'	System	24 Aug 2020 17:18:21

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US3342142
Folder: Diary Dose 1 (1)
Form: Temperature_Day(1/1)
Generated On: 11 Aug 2021 22:33:31
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:52:22
Data entry locked.	System	24 Aug 2020 17:43:00
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	24 Aug 2020 17:43:00

FDA-CBER-2022-1614-2809002

US3342142
Folder: Diary Dose 1 (1)
Form: Temperature_Day(1/1)
Generated On: 11 Aug 2021 22:33:31
Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:52:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (01A85E90-DEE1-40E1-A1FD-349A8271449C)', Time: '2020-08-24T12:52:54', User OID: 'PatientReportedOutcome (US3342142)', ODM File OID: 'ec8505a0-db35-4821-b3dc-c28e92109ff8'	System	24 Aug 2020 17:53:12
User entered 'Yes (Y)'	System	24 Aug 2020 17:53:12

US3342142
Folder: Diary Dose 1 (1)
Form: Temperature_Day(1/1)
Generated On: 11 Aug 2021 22:33:31
Please record your **TEMPERATURE in °F**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:52:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (01A85E90-DEE1-40E1-A1FD-349A8271449C)', Time: '2020-08-24T12:52:57', User OID: 'PatientReportedOutcome (US3342142)', ODM File OID: 'ec8505a0-db35-4821-b3dc-c28e92109ff8'	System	24 Aug 2020 17:53:12
User entered '97.7'	System	24 Aug 2020 17:53:12

US3342142
Folder: Diary Dose 1 (1)
Form: Temperature_Day(1/1)
Generated On: 11 Aug 2021 22:33:31
Was any **MEDICATION TAKEN today for pain or fever**?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:52:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (01A85E90-DEE1-40E1-A1FD-349A8271449C)', Time: '2020-08-24T12:53:03', User OID: 'PatientReportedOutcome (US3342142)', ODM File OID: 'ec8505a0-db35-4821-b3dc-c28e92109ff8'	System	24 Aug 2020 17:53:12
User entered 'No (N)'	System	24 Aug 2020 17:53:12

US3342142
Folder: Diary Dose 1 (1)
Form: Temperature_Day(1/1)
Generated On: 11 Aug 2021 22:33:31
PC Time Stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:52:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (01A85E90-DEE1-40E1-A1FD-349A8271449C)', Time: '2020-08-24T12:53:09', User OID: 'PatientReportedOutcome (US3342142)', ODM File OID: 'ec8505a0-db35-4821-b3dc-c28e92109ff8'	System	24 Aug 2020 17:53:12
User entered '24 Aug 2020 12:53'	System	24 Aug 2020 17:53:12

US3342142
Folder: Diary Dose 1 (1)
Form: Temperature_Day(1/1)
Generated On: 11 Aug 2021 22:33:31
PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:52:22
User entered '24 Aug 2020 12:39'	System	24 Aug 2020 17:43:00

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US3342142
Folder: Diary Dose 1 (1)
Form: Temperature_Day(1/1)
Generated On: 11 Aug 2021 22:33:31
PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:52:22
User entered '24 Aug 2020 15:09'	System	24 Aug 2020 17:43:00

FDA-CBER-2022-1614-2809008

US3342142
Folder: Diary Dose 1 (1)
Form: Temperature_Day(1/2)
Generated On: 11 Aug 2021 22:33:31
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:52:22
Data entry locked.	System	24 Aug 2020 17:43:00
User entered 'Day 1, after vaccination (at home)'	System	24 Aug 2020 17:43:00

US3342142
Folder: Diary Dose 1 (1)
Form: Temperature_Day(1/2)
Generated On: 11 Aug 2021 22:33:31
Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:52:22

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US3342142
Folder: Diary Dose 1 (1)
Form: Temperature_Day(1/2)
Generated On: 11 Aug 2021 22:33:31
Please record your **TEMPERATURE in °F**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:52:22

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US3342142
Folder: Diary Dose 1 (1)
Form: Temperature_Day(1/2)
Generated On: 11 Aug 2021 22:33:31
Was any **MEDICATION TAKEN today for pain or fever**?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:52:22

US3342142
Folder: Diary Dose 1 (1)
Form: Temperature_Day(1/2)
Generated On: 11 Aug 2021 22:33:31
To **TREAT** pain or fever that has already occurred

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:52:22

US3342142
Folder: Diary Dose 1 (1)
Form: Temperature_Day(1/2)
Generated On: 11 Aug 2021 22:33:31
To **PREVENT** pain or fever from occurring

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:52:22

US3342142
Folder: Diary Dose 1 (1)
Form: Temperature_Day(1/2)
Generated On: 11 Aug 2021 22:33:31
PC Time Stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:52:22

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US3342142
Folder: Diary Dose 1 (1)
Form: Temperature_Day(1/2)
Generated On: 11 Aug 2021 22:33:31
PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:52:22
User entered '24 Aug 2020 16:04'	System	24 Aug 2020 17:43:00

FDA-CBER-2022-1614-2809016

US3342142
Folder: Diary Dose 1 (1)
Form: Temperature_Day(1/2)
Generated On: 11 Aug 2021 22:33:31
PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:52:22
User entered '25 Aug 2020 11:59'	System	24 Aug 2020 17:43:00

FDA-CBER-2022-1614-2809017

US3342142
Folder: Diary Dose 1 (1)
Form: Temperature_Day(2)
Generated On: 11 Aug 2021 22:33:31
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:52:22
Data entry locked.	System	24 Aug 2020 17:43:00
User entered 'Day 2'	System	24 Aug 2020 17:43:00

US3342142
Folder: Diary Dose 1 (1)
Form: Temperature_Day(2)
Generated On: 11 Aug 2021 22:33:31
Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:52:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (01A85E90-DEE1-40E1-A1FD-349A8271449C)', Time: '2020-08-25T20:16:38', User OID: 'PatientReportedOutcome (US3342142)', ODM File OID: 'b580e4b8-0c5f-4f5e-a070-b4bd92d710d2'	System	26 Aug 2020 01:16:52
User entered 'Yes (Y)'	System	26 Aug 2020 01:16:52

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US3342142
Folder: Diary Dose 1 (1)
Form: Temperature_Day(2)
Generated On: 11 Aug 2021 22:33:31
Please record your **TEMPERATURE in °F**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:52:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (01A85E90-DEE1-40E1-A1FD-349A8271449C)', Time: '2020-08-25T20:16:41', User OID: 'PatientReportedOutcome (US3342142)', ODM File OID: 'b580e4b8-0c5f-4f5e-a070-b4bd92d710d2'	System	26 Aug 2020 01:16:52
User entered '99.1'	System	26 Aug 2020 01:16:52

US3342142
Folder: Diary Dose 1 (1)
Form: Temperature_Day(2)
Generated On: 11 Aug 2021 22:33:31
Was any **MEDICATION TAKEN today for pain or fever**?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:52:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (01A85E90-DEE1-40E1-A1FD-349A8271449C)', Time: '2020-08-25T20:16:45', User OID: 'PatientReportedOutcome (US3342142)', ODM File OID: 'b580e4b8-0c5f-4f5e-a070-b4bd92d710d2'	System	26 Aug 2020 01:16:52
User entered 'No (N)'	System	26 Aug 2020 01:16:52

US3342142
Folder: Diary Dose 1 (1)
Form: Temperature_Day(2)
Generated On: 11 Aug 2021 22:33:31
PC Time Stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:52:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (01A85E90-DEE1-40E1-A1FD-349A8271449C)', Time: '2020-08-25T20:16:49', User OID: 'PatientReportedOutcome (US3342142)', ODM File OID: 'b580e4b8-0c5f-4f5e-a070-b4bd92d710d2'	System	26 Aug 2020 01:16:52
User entered '25 Aug 2020 20:16'	System	26 Aug 2020 01:16:52

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US3342142
Folder: Diary Dose 1 (1)
Form: Temperature_Day(2)
Generated On: 11 Aug 2021 22:33:31
PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:52:22
User entered '25 Aug 2020 12:00'	System	24 Aug 2020 17:43:00

FDA-CBER-2022-1614-2809023

US3342142
Folder: Diary Dose 1 (1)
Form: Temperature_Day(2)
Generated On: 11 Aug 2021 22:33:31
PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:52:22
User entered '26 Aug 2020 11:59'	System	24 Aug 2020 17:43:00

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US3342142
Folder: Diary Dose 1 (1)
Form: Temperature_Day(3)
Generated On: 11 Aug 2021 22:33:31
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:52:22
Data entry locked.	System	24 Aug 2020 17:43:00
User entered 'Day 3'	System	24 Aug 2020 17:43:00

US3342142
Folder: Diary Dose 1 (1)
Form: Temperature_Day(3)
Generated On: 11 Aug 2021 22:33:31
Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:52:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (01A85E90-DEE1-40E1-A1FD-349A8271449C)', Time: '2020-08-26T20:20:44', User OID: 'PatientReportedOutcome (US3342142)', ODM File OID: '77ae047d-7dd8-4314-a11e-4d47b7592564'	System	27 Aug 2020 01:20:57
User entered 'Yes (Y)'	System	27 Aug 2020 01:20:57

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US3342142
Folder: Diary Dose 1 (1)
Form: Temperature_Day(3)
Generated On: 11 Aug 2021 22:33:31
Please record your **TEMPERATURE in °F**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:52:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (01A85E90-DEE1-40E1-A1FD-349A8271449C)', Time: '2020-08-26T20:20:48', User OID: 'PatientReportedOutcome (US3342142)', ODM File OID: '77ae047d-7dd8-4314-a11e-4d47b7592564'	System	27 Aug 2020 01:20:57
User entered '99.1'	System	27 Aug 2020 01:20:57

US3342142
Folder: Diary Dose 1 (1)
Form: Temperature_Day(3)
Generated On: 11 Aug 2021 22:33:31
Was any **MEDICATION TAKEN today for pain or fever**?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:52:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (01A85E90-DEE1-40E1-A1FD-349A8271449C)', Time: '2020-08-26T20:20:50', User OID: 'PatientReportedOutcome (US3342142)', ODM File OID: '77ae047d-7dd8-4314-a11e-4d47b7592564'	System	27 Aug 2020 01:20:57
User entered 'No (N)'	System	27 Aug 2020 01:20:57

FDA-CBER-2022-1614-2809028

US3342142
Folder: Diary Dose 1 (1)
Form: Temperature_Day(3)
Generated On: 11 Aug 2021 22:33:31
PC Time Stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:52:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (01A85E90-DEE1-40E1-A1FD-349A8271449C)', Time: '2020-08-26T20:20:53', User OID: 'PatientReportedOutcome (US3342142)', ODM File OID: '77ae047d-7dd8-4314-a11e-4d47b7592564'	System	27 Aug 2020 01:20:57
User entered '26 Aug 2020 20:20'	System	27 Aug 2020 01:20:57

FDA-CBER-2022-1614-2809029

US3342142
Folder: Diary Dose 1 (1)
Form: Temperature_Day(3)
Generated On: 11 Aug 2021 22:33:31
PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:52:22
User entered '26 Aug 2020 12:00'	System	24 Aug 2020 17:43:00

FDA-CBER-2022-1614-2809030

US3342142
Folder: Diary Dose 1 (1)
Form: Temperature_Day(3)
Generated On: 11 Aug 2021 22:33:31
PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:52:22
User entered '27 Aug 2020 11:59'	System	24 Aug 2020 17:43:00

FDA-CBER-2022-1614-2809031

US3342142
Folder: Diary Dose 1 (1)
Form: Temperature_Day(4)
Generated On: 11 Aug 2021 22:33:31
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:52:22
Data entry locked.	System	24 Aug 2020 17:43:00
User entered 'Day 4'	System	24 Aug 2020 17:43:00

FDA-CBER-2022-1614-2809032

US3342142
Folder: Diary Dose 1 (1)
Form: Temperature_Day(4)
Generated On: 11 Aug 2021 22:33:31
Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:52:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (01A85E90-DEE1-40E1-A1FD-349A8271449C)', Time: '2020-08-27T23:31:13', User OID: 'PatientReportedOutcome (US3342142)', ODM File OID: 'a87f63e6-49f5-4805-bfca-f395942e6ba7'	System	28 Aug 2020 04:31:25
User entered 'Yes (Y)'	System	28 Aug 2020 04:31:25

US3342142
Folder: Diary Dose 1 (1)
Form: Temperature_Day(4)
Generated On: 11 Aug 2021 22:33:31
Please record your **TEMPERATURE in °F**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:52:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (01A85E90-DEE1-40E1-A1FD-349A8271449C)', Time: '2020-08-27T23:31:17', User OID: 'PatientReportedOutcome (US3342142)', ODM File OID: 'a87f63e6-49f5-4805-bfca-f395942e6ba7'	System	28 Aug 2020 04:31:25
User entered '98.7'	System	28 Aug 2020 04:31:25

US3342142
Folder: Diary Dose 1 (1)
Form: Temperature_Day(4)
Generated On: 11 Aug 2021 22:33:31
Was any **MEDICATION TAKEN today for pain or fever**?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:52:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (01A85E90-DEE1-40E1-A1FD-349A8271449C)', Time: '2020-08-27T23:31:19', User OID: 'PatientReportedOutcome (US3342142)', ODM File OID: 'a87f63e6-49f5-4805-bfca-f395942e6ba7'	System	28 Aug 2020 04:31:25
User entered 'No (N)'	System	28 Aug 2020 04:31:25

US3342142
Folder: Diary Dose 1 (1)
Form: Temperature_Day(4)
Generated On: 11 Aug 2021 22:33:31
PC Time Stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:52:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (01A85E90-DEE1-40E1-A1FD-349A8271449C)', Time: '2020-08-27T23:31:22', User OID: 'PatientReportedOutcome (US3342142)', ODM File OID: 'a87f63e6-49f5-4805-bfca-f395942e6ba7'	System	28 Aug 2020 04:31:25
User entered '27 Aug 2020 23:31'	System	28 Aug 2020 04:31:25

FDA-CBER-2022-1614-2809036

US3342142
Folder: Diary Dose 1 (1)
Form: Temperature_Day(4)
Generated On: 11 Aug 2021 22:33:31
PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:52:22
User entered '27 Aug 2020 12:00'	System	24 Aug 2020 17:43:00

FDA-CBER-2022-1614-2809037

US3342142
Folder: Diary Dose 1 (1)
Form: Temperature_Day(4)
Generated On: 11 Aug 2021 22:33:31
PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:52:22
User entered '28 Aug 2020 11:59'	System	24 Aug 2020 17:43:00

FDA-CBER-2022-1614-2809038

US3342142
Folder: Diary Dose 1 (1)
Form: Temperature_Day(5)
Generated On: 11 Aug 2021 22:33:31
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:52:22
Data entry locked.	System	24 Aug 2020 17:43:00
User entered 'Day 5'	System	24 Aug 2020 17:43:00

FDA-CBER-2022-1614-2809039

US3342142
Folder: Diary Dose 1 (1)
Form: Temperature_Day(5)
Generated On: 11 Aug 2021 22:33:31
Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:52:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (01A85E90-DEE1-40E1-A1FD-349A8271449C)', Time: '2020-08-29T07:24:15', User OID: 'PatientReportedOutcome (US3342142)', ODM File OID: '23ceb0fa-8e56-41ca-8406-9000655c415c'	System	29 Aug 2020 12:24:26
User entered 'Yes (Y)'	System	29 Aug 2020 12:24:26

FDA-CBER-2022-1614-2809040

US3342142
Folder: Diary Dose 1 (1)
Form: Temperature_Day(5)
Generated On: 11 Aug 2021 22:33:31
Please record your **TEMPERATURE in °F**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:52:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (01A85E90-DEE1-40E1-A1FD-349A8271449C)', Time: '2020-08-29T07:24:20', User OID: 'PatientReportedOutcome (US3342142)', ODM File OID: '23ceb0fa-8e56-41ca-8406-9000655c415c'	System	29 Aug 2020 12:24:26
User entered '98.7'	System	29 Aug 2020 12:24:26

US3342142
Folder: Diary Dose 1 (1)
Form: Temperature_Day(5)
Generated On: 11 Aug 2021 22:33:31
Was any **MEDICATION TAKEN today for pain or fever**?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:52:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (01A85E90-DEE1-40E1-A1FD-349A8271449C)', Time: '2020-08-29T07:24:22', User OID: 'PatientReportedOutcome (US3342142)', ODM File OID: '23ceb0fa-8e56-41ca-8406-9000655c415c'	System	29 Aug 2020 12:24:26
User entered 'No (N)'	System	29 Aug 2020 12:24:26

US3342142
Folder: Diary Dose 1 (1)
Form: Temperature_Day(5)
Generated On: 11 Aug 2021 22:33:31
PC Time Stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:52:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (01A85E90-DEE1-40E1-A1FD-349A8271449C)', Time: '2020-08-29T07:24:25', User OID: 'PatientReportedOutcome (US3342142)', ODM File OID: '23ceb0fa-8e56-41ca-8406-9000655c415c'	System	29 Aug 2020 12:24:26
User entered '29 Aug 2020 07:24'	System	29 Aug 2020 12:24:26

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US3342142
Folder: Diary Dose 1 (1)
Form: Temperature_Day(5)
Generated On: 11 Aug 2021 22:33:31
PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:52:22
User entered '28 Aug 2020 12:00'	System	24 Aug 2020 17:43:00

FDA-CBER-2022-1614-2809044

US3342142
Folder: Diary Dose 1 (1)
Form: Temperature_Day(5)
Generated On: 11 Aug 2021 22:33:31
PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:52:22
User entered '29 Aug 2020 11:59'	System	24 Aug 2020 17:43:00

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US3342142
Folder: Diary Dose 1 (1)
Form: Temperature_Day(6)
Generated On: 11 Aug 2021 22:33:31
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:52:22
Data entry locked.	System	24 Aug 2020 17:43:00
User entered 'Day 6'	System	24 Aug 2020 17:43:00

US3342142
Folder: Diary Dose 1 (1)
Form: Temperature_Day(6)
Generated On: 11 Aug 2021 22:33:31
Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:52:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (01A85E90-DEE1-40E1-A1FD-349A8271449C)', Time: '2020-08-29T20:01:01', User OID: 'PatientReportedOutcome (US3342142)', ODM File OID: '35629377-4d69-4740-b845-2f146aad5cb7'	System	30 Aug 2020 01:01:11
User entered 'Yes (Y)'	System	30 Aug 2020 01:01:11

US3342142
Folder: Diary Dose 1 (1)
Form: Temperature_Day(6)
Generated On: 11 Aug 2021 22:33:31
Please record your **TEMPERATURE in °F**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:52:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (01A85E90-DEE1-40E1-A1FD-349A8271449C)', Time: '2020-08-29T20:01:05', User OID: 'PatientReportedOutcome (US3342142)', ODM File OID: '35629377-4d69-4740-b845-2f146aad5cb7'	System	30 Aug 2020 01:01:11
User entered '98.5'	System	30 Aug 2020 01:01:11

US3342142
Folder: Diary Dose 1 (1)
Form: Temperature_Day(6)
Generated On: 11 Aug 2021 22:33:31
Was any **MEDICATION TAKEN today for pain or fever**?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:52:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (01A85E90-DEE1-40E1-A1FD-349A8271449C)', Time: '2020-08-29T20:01:07', User OID: 'PatientReportedOutcome (US3342142)', ODM File OID: '35629377-4d69-4740-b845-2f146aad5cb7'	System	30 Aug 2020 01:01:11
User entered 'No (N)'	System	30 Aug 2020 01:01:11

US3342142
Folder: Diary Dose 1 (1)
Form: Temperature_Day(6)
Generated On: 11 Aug 2021 22:33:31
PC Time Stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:52:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (01A85E90-DEE1-40E1-A1FD-349A8271449C)', Time: '2020-08-29T20:01:09', User OID: 'PatientReportedOutcome (US3342142)', ODM File OID: '35629377-4d69-4740-b845-2f146aad5cb7'	System	30 Aug 2020 01:01:11
User entered '29 Aug 2020 20:01'	System	30 Aug 2020 01:01:11

US3342142
Folder: Diary Dose 1 (1)
Form: Temperature_Day(6)
Generated On: 11 Aug 2021 22:33:31
PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:52:22
User entered '29 Aug 2020 12:00'	System	24 Aug 2020 17:43:00

US3342142
Folder: Diary Dose 1 (1)
Form: Temperature_Day(6)
Generated On: 11 Aug 2021 22:33:31
PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:52:22
User entered '30 Aug 2020 11:59'	System	24 Aug 2020 17:43:00

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US3342142
Folder: Diary Dose 1 (1)
Form: Temperature_Day(7)
Generated On: 11 Aug 2021 22:33:31
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:52:22
Data entry locked.	System	24 Aug 2020 17:43:00
User entered 'Day 7'	System	24 Aug 2020 17:43:00

US3342142
Folder: Diary Dose 1 (1)
Form: Temperature_Day(7)
Generated On: 11 Aug 2021 22:33:31
Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:52:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (01A85E90-DEE1-40E1-A1FD-349A8271449C)', Time: '2020-08-31T00:03:53', User OID: 'PatientReportedOutcome (US3342142)', ODM File OID: 'de3d2dc3-e5b1-4033-9e2a-10f08f831428'	System	31 Aug 2020 05:04:06
User entered 'Yes (Y)'	System	31 Aug 2020 05:04:06

FDA-CBER-2022-1614-2809054

US3342142
Folder: Diary Dose 1 (1)
Form: Temperature_Day(7)
Generated On: 11 Aug 2021 22:33:31
Please record your **TEMPERATURE in °F**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:52:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (01A85E90-DEE1-40E1-A1FD-349A8271449C)', Time: '2020-08-31T00:03:56', User OID: 'PatientReportedOutcome (US3342142)', ODM File OID: 'de3d2dc3-e5b1-4033-9e2a-10f08f831428'	System	31 Aug 2020 05:04:06
User entered '98.7'	System	31 Aug 2020 05:04:06

US3342142
Folder: Diary Dose 1 (1)
Form: Temperature_Day(7)
Generated On: 11 Aug 2021 22:33:31
Was any **MEDICATION TAKEN today for pain or fever**?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:52:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (01A85E90-DEE1-40E1-A1FD-349A8271449C)', Time: '2020-08-31T00:04:00', User OID: 'PatientReportedOutcome (US3342142)', ODM File OID: 'de3d2dc3-e5b1-4033-9e2a-10f08f831428'	System	31 Aug 2020 05:04:06
User entered 'No (N)'	System	31 Aug 2020 05:04:06

FDA-CBER-2022-1614-2809056

US3342142
Folder: Diary Dose 1 (1)
Form: Temperature_Day(7)
Generated On: 11 Aug 2021 22:33:31
PC Time Stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:52:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (01A85E90-DEE1-40E1-A1FD-349A8271449C)', Time: '2020-08-31T00:04:03', User OID: 'PatientReportedOutcome (US3342142)', ODM File OID: 'de3d2dc3-e5b1-4033-9e2a-10f08f831428'	System	31 Aug 2020 05:04:06
User entered '31 Aug 2020 00:04'	System	31 Aug 2020 05:04:06

FDA-CBER-2022-1614-2809057

US3342142
Folder: Diary Dose 1 (1)
Form: Temperature_Day(7)
Generated On: 11 Aug 2021 22:33:31
PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:52:22
User entered '30 Aug 2020 12:00'	System	24 Aug 2020 17:43:00

FDA-CBER-2022-1614-2809058

US3342142
Folder: Diary Dose 1 (1)
Form: Temperature_Day(7)
Generated On: 11 Aug 2021 22:33:31
PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:52:22
User entered '31 Aug 2020 11:59'	System	24 Aug 2020 17:43:00

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US3342142
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(1/1)
Generated On: 11 Aug 2021 22:33:31
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:52:22
Data entry locked.	System	24 Aug 2020 17:43:00
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	24 Aug 2020 17:43:00

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US3342142
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(1/1)
Generated On: 11 Aug 2021 22:33:31
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 14:52:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (01A85E90-DEE1-40E1-A1FD-349A8271449C)', Time: '2020-08-24T12:53:48', User OID: 'PatientReportedOutcome (US3342142)', ODM File OID: 'a074fafe-71df-42f5-8041-16078575211a'	System	24 Aug 2020 17:54:07
User entered 'None (1)'	System	24 Aug 2020 17:54:07

US3342142
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(1/1)
Generated On: 11 Aug 2021 22:33:31
Is there any **REDNESS AT INJECTION SITE**?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:52:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (01A85E90-DEE1-40E1-A1FD-349A8271449C)', Time: '2020-08-24T12:53:54', User OID: 'PatientReportedOutcome (US3342142)', ODM File OID: 'a074fafe-71df-42f5-8041-16078575211a'	System	24 Aug 2020 17:54:07
User entered 'No (N)'	System	24 Aug 2020 17:54:07

US3342142
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(1/1)
Generated On: 11 Aug 2021 22:33:31
Is there any **SWELLING/HARDNESS AT INJECTION SITE**?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:52:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (01A85E90-DEE1-40E1-A1FD-349A8271449C)', Time: '2020-08-24T12:53:57', User OID: 'PatientReportedOutcome (US3342142)', ODM File OID: 'a074fafe-71df-42f5-8041-16078575211a'	System	24 Aug 2020 17:54:07
User entered 'No (N)'	System	24 Aug 2020 17:54:07

US3342142
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(1/1)
Generated On: 11 Aug 2021 22:33:31
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 14:52:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (01A85E90-DEE1-40E1-A1FD-349A8271449C)', Time: '2020-08-24T12:54:02', User OID: 'PatientReportedOutcome (US3342142)', ODM File OID: 'a074fafe-71df-42f5-8041-16078575211a'	System	24 Aug 2020 17:54:07
User entered 'None (1)'	System	24 Aug 2020 17:54:07

US3342142
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(1/1)
Generated On: 11 Aug 2021 22:33:31
PC Time Stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:52:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (01A85E90-DEE1-40E1-A1FD-349A8271449C)', Time: '2020-08-24T12:54:05', User OID: 'PatientReportedOutcome (US3342142)', ODM File OID: 'a074fafe-71df-42f5-8041-16078575211a'	System	24 Aug 2020 17:54:07
User entered '24 Aug 2020 12:54'	System	24 Aug 2020 17:54:07

US3342142
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(1/1)
Generated On: 11 Aug 2021 22:33:31
PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:52:22
User entered '24 Aug 2020 12:39'	System	24 Aug 2020 17:43:00

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US3342142
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(1/1)
Generated On: 11 Aug 2021 22:33:31
PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:52:22
User entered '24 Aug 2020 15:09'	System	24 Aug 2020 17:43:00

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US3342142
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(1/2)
Generated On: 11 Aug 2021 22:33:31
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:52:22
Data entry locked.	System	24 Aug 2020 17:43:00
User entered 'Day 1, after vaccination (at home)'	System	24 Aug 2020 17:43:00

US3342142
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(1/2)
Generated On: 11 Aug 2021 22:33:31
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 14:52:22

US3342142
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(1/2)
Generated On: 11 Aug 2021 22:33:31
Is there any **REDNESS AT INJECTION SITE**?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:52:22

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US3342142
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(1/2)
Generated On: 11 Aug 2021 22:33:31
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 14:52:22

US3342142
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(1/2)
Generated On: 11 Aug 2021 22:33:31
Is there any **SWELLING/HARDNESS AT INJECTION SITE**?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:52:22

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US3342142
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(1/2)
Generated On: 11 Aug 2021 22:33:31
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 14:52:22

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US3342142
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(1/2)
Generated On: 11 Aug 2021 22:33:31
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 14:52:22

US3342142
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(1/2)
Generated On: 11 Aug 2021 22:33:31
PC Time Stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:52:22

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US3342142
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(1/2)
Generated On: 11 Aug 2021 22:33:31
PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:52:22
User entered '24 Aug 2020 16:04'	System	24 Aug 2020 17:43:00

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US3342142
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(1/2)
Generated On: 11 Aug 2021 22:33:31
PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:52:22
User entered '25 Aug 2020 11:59'	System	24 Aug 2020 17:43:00

FDA-CBER-2022-1614-2809077

US3342142
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(2)
Generated On: 11 Aug 2021 22:33:31
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:52:22
Data entry locked.	System	24 Aug 2020 17:43:00
User entered 'Day 2'	System	24 Aug 2020 17:43:00

US3342142
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(2)
Generated On: 11 Aug 2021 22:33:31
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 14:52:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (01A85E90-DEE1-40E1-A1FD-349A8271449C)', Time: '2020-08-25T20:17:18', User OID: 'PatientReportedOutcome (US3342142)', ODM File OID: '56d160bd-3f35-49d6-8d4c-9e8d18eb97bc'	System	26 Aug 2020 01:17:35
User entered 'Does not interfere with activity (2)'	System	26 Aug 2020 01:17:35

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US3342142
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(2)
Generated On: 11 Aug 2021 22:33:31
Is there any **REDNESS AT INJECTION SITE**?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:52:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (01A85E90-DEE1-40E1-A1FD-349A8271449C)', Time: '2020-08-25T20:17:21', User OID: 'PatientReportedOutcome (US3342142)', ODM File OID: '56d160bd-3f35-49d6-8d4c-9e8d18eb97bc'	System	26 Aug 2020 01:17:35
User entered 'No (N)'	System	26 Aug 2020 01:17:35

US3342142
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(2)
Generated On: 11 Aug 2021 22:33:31
Is there any **SWELLING/HARDNESS AT INJECTION SITE**?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:52:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (01A85E90-DEE1-40E1-A1FD-349A8271449C)', Time: '2020-08-25T20:17:23', User OID: 'PatientReportedOutcome (US3342142)', ODM File OID: '56d160bd-3f35-49d6-8d4c-9e8d18eb97bc'	System	26 Aug 2020 01:17:35
User entered 'No (N)'	System	26 Aug 2020 01:17:35

US3342142
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(2)
Generated On: 11 Aug 2021 22:33:31
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 14:52:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (01A85E90-DEE1-40E1-A1FD-349A8271449C)', Time: '2020-08-25T20:17:29', User OID: 'PatientReportedOutcome (US3342142)', ODM File OID: '56d160bd-3f35-49d6-8d4c-9e8d18eb97bc'	System	26 Aug 2020 01:17:35
User entered 'None (1)'	System	26 Aug 2020 01:17:35

US3342142
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(2)
Generated On: 11 Aug 2021 22:33:31
PC Time Stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:52:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (01A85E90-DEE1-40E1-A1FD-349A8271449C)', Time: '2020-08-25T20:17:33', User OID: 'PatientReportedOutcome (US3342142)', ODM File OID: '56d160bd-3f35-49d6-8d4c-9e8d18eb97bc'	System	26 Aug 2020 01:17:35
User entered '25 Aug 2020 20:17'	System	26 Aug 2020 01:17:35

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US3342142
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(2)
Generated On: 11 Aug 2021 22:33:31
PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:52:22
User entered '25 Aug 2020 12:00'	System	24 Aug 2020 17:43:00

US3342142
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(2)
Generated On: 11 Aug 2021 22:33:31
PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:52:22
User entered '26 Aug 2020 11:59'	System	24 Aug 2020 17:43:00

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US3342142
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(3)
Generated On: 11 Aug 2021 22:33:31
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:52:22
Data entry locked.	System	24 Aug 2020 17:43:00
User entered 'Day 3'	System	24 Aug 2020 17:43:00

US3342142
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(3)
Generated On: 11 Aug 2021 22:33:31
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 14:52:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (01A85E90-DEE1-40E1-A1FD-349A8271449C)', Time: '2020-08-26T20:20:57', User OID: 'PatientReportedOutcome (US3342142)', ODM File OID: '5409192c-047a-46f9-9554-3c8c3ffd6dc6'	System	27 Aug 2020 01:21:09
User entered 'None (1)'	System	27 Aug 2020 01:21:09

US3342142
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(3)
Generated On: 11 Aug 2021 22:33:31
Is there any **REDNESS AT INJECTION SITE**?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:52:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (01A85E90-DEE1-40E1-A1FD-349A8271449C)', Time: '2020-08-26T20:21:00', User OID: 'PatientReportedOutcome (US3342142)', ODM File OID: '5409192c-047a-46f9-9554-3c8c3ffd6dc6'	System	27 Aug 2020 01:21:09
User entered 'No (N)'	System	27 Aug 2020 01:21:09

US3342142
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(3)
Generated On: 11 Aug 2021 22:33:31
Is there any **SWELLING/HARDNESS AT INJECTION SITE**?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:52:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (01A85E90-DEE1-40E1-A1FD-349A8271449C)', Time: '2020-08-26T20:21:02', User OID: 'PatientReportedOutcome (US3342142)', ODM File OID: '5409192c-047a-46f9-9554-3c8c3ffd6dc6'	System	27 Aug 2020 01:21:09
User entered 'No (N)'	System	27 Aug 2020 01:21:09

US3342142
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(3)
Generated On: 11 Aug 2021 22:33:31
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 14:52:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (01A85E90-DEE1-40E1-A1FD-349A8271449C)', Time: '2020-08-26T20:21:05', User OID: 'PatientReportedOutcome (US3342142)', ODM File OID: '5409192c-047a-46f9-9554-3c8c3ffd6dc6'	System	27 Aug 2020 01:21:09
User entered 'None (1)'	System	27 Aug 2020 01:21:09

US3342142
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(3)
Generated On: 11 Aug 2021 22:33:31
PC Time Stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:52:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (01A85E90-DEE1-40E1-A1FD-349A8271449C)', Time: '2020-08-26T20:21:08', User OID: 'PatientReportedOutcome (US3342142)', ODM File OID: '5409192c-047a-46f9-9554-3c8c3ffd6dc6'	System	27 Aug 2020 01:21:09
User entered '26 Aug 2020 20:21'	System	27 Aug 2020 01:21:09

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US3342142
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(3)
Generated On: 11 Aug 2021 22:33:31
PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:52:22
User entered '26 Aug 2020 12:00'	System	24 Aug 2020 17:43:00

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US3342142
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(3)
Generated On: 11 Aug 2021 22:33:31
PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:52:22
User entered '27 Aug 2020 11:59'	System	24 Aug 2020 17:43:00

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US3342142
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(4)
Generated On: 11 Aug 2021 22:33:31
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:52:22
Data entry locked.	System	24 Aug 2020 17:43:00
User entered 'Day 4'	System	24 Aug 2020 17:43:00

FDA-CBER-2022-1614-2809094

US3342142
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(4)
Generated On: 11 Aug 2021 22:33:31
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 14:52:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (01A85E90-DEE1-40E1-A1FD-349A8271449C)', Time: '2020-08-27T23:31:25', User OID: 'PatientReportedOutcome (US3342142)', ODM File OID: '73d25f14-179e-41d1-8663-5a3cb3b1ceff'	System	28 Aug 2020 04:31:39
User entered 'None (1)'	System	28 Aug 2020 04:31:39

US3342142
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(4)
Generated On: 11 Aug 2021 22:33:31
Is there any **REDNESS AT INJECTION SITE**?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:52:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (01A85E90-DEE1-40E1-A1FD-349A8271449C)', Time: '2020-08-27T23:31:28', User OID: 'PatientReportedOutcome (US3342142)', ODM File OID: '73d25f14-179e-41d1-8663-5a3cb3b1ceff'	System	28 Aug 2020 04:31:39
User entered 'No (N)'	System	28 Aug 2020 04:31:39

US3342142
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(4)
Generated On: 11 Aug 2021 22:33:31
Is there any **SWELLING/HARDNESS AT INJECTION SITE**?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:52:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (01A85E90-DEE1-40E1-A1FD-349A8271449C)', Time: '2020-08-27T23:31:30', User OID: 'PatientReportedOutcome (US3342142)', ODM File OID: '73d25f14-179e-41d1-8663-5a3cb3b1ceff'	System	28 Aug 2020 04:31:39
User entered 'No (N)'	System	28 Aug 2020 04:31:39

US3342142
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(4)
Generated On: 11 Aug 2021 22:33:31
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 14:52:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (01A85E90-DEE1-40E1-A1FD-349A8271449C)', Time: '2020-08-27T23:31:32', User OID: 'PatientReportedOutcome (US3342142)', ODM File OID: '73d25f14-179e-41d1-8663-5a3cb3b1ceff'	System	28 Aug 2020 04:31:39
User entered 'None (1)'	System	28 Aug 2020 04:31:39

US3342142
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(4)
Generated On: 11 Aug 2021 22:33:31
PC Time Stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:52:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (01A85E90-DEE1-40E1-A1FD-349A8271449C)', Time: '2020-08-27T23:31:37', User OID: 'PatientReportedOutcome (US3342142)', ODM File OID: '73d25f14-179e-41d1-8663-5a3cb3b1ceff'	System	28 Aug 2020 04:31:39
User entered '27 Aug 2020 23:31'	System	28 Aug 2020 04:31:39

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US3342142
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(4)
Generated On: 11 Aug 2021 22:33:31
PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:52:22
User entered '27 Aug 2020 12:00'	System	24 Aug 2020 17:43:00

US3342142
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(4)
Generated On: 11 Aug 2021 22:33:31
PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:52:22
User entered '28 Aug 2020 11:59'	System	24 Aug 2020 17:43:00

FDA-CBER-2022-1614-2809101

US3342142
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(5)
Generated On: 11 Aug 2021 22:33:31
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:52:22
Data entry locked.	System	24 Aug 2020 17:43:00
User entered 'Day 5'	System	24 Aug 2020 17:43:00

FDA-CBER-2022-1614-2809102

US3342142
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(5)
Generated On: 11 Aug 2021 22:33:31
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 14:52:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (01A85E90-DEE1-40E1-A1FD-349A8271449C)', Time: '2020-08-29T07:24:28', User OID: 'PatientReportedOutcome (US3342142)', ODM File OID: '92994580-c4ca-4399-946a-66549c7ea1b5'	System	29 Aug 2020 12:24:38
User entered 'None (1)'	System	29 Aug 2020 12:24:38

US3342142
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(5)
Generated On: 11 Aug 2021 22:33:31
Is there any **REDNESS AT INJECTION SITE**?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:52:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (01A85E90-DEE1-40E1-A1FD-349A8271449C)', Time: '2020-08-29T07:24:30', User OID: 'PatientReportedOutcome (US3342142)', ODM File OID: '92994580-c4ca-4399-946a-66549c7ea1b5'	System	29 Aug 2020 12:24:38
User entered 'No (N)'	System	29 Aug 2020 12:24:38

US3342142
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(5)
Generated On: 11 Aug 2021 22:33:31
Is there any **SWELLING/HARDNESS AT INJECTION SITE**?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:52:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (01A85E90-DEE1-40E1-A1FD-349A8271449C)', Time: '2020-08-29T07:24:32', User OID: 'PatientReportedOutcome (US3342142)', ODM File OID: '92994580-c4ca-4399-946a-66549c7ea1b5'	System	29 Aug 2020 12:24:38
User entered 'No (N)'	System	29 Aug 2020 12:24:38

US3342142
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(5)
Generated On: 11 Aug 2021 22:33:31
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 14:52:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (01A85E90-DEE1-40E1-A1FD-349A8271449C)', Time: '2020-08-29T07:24:34', User OID: 'PatientReportedOutcome (US3342142)', ODM File OID: '92994580-c4ca-4399-946a-66549c7ea1b5'	System	29 Aug 2020 12:24:38
User entered 'None (1)'	System	29 Aug 2020 12:24:38

US3342142
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(5)
Generated On: 11 Aug 2021 22:33:31
PC Time Stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:52:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (01A85E90-DEE1-40E1-A1FD-349A8271449C)', Time: '2020-08-29T07:24:36', User OID: 'PatientReportedOutcome (US3342142)', ODM File OID: '92994580-c4ca-4399-946a-66549c7ea1b5'	System	29 Aug 2020 12:24:38
User entered '29 Aug 2020 07:24'	System	29 Aug 2020 12:24:38

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US3342142
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(5)
Generated On: 11 Aug 2021 22:33:31
PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:52:22
User entered '28 Aug 2020 12:00'	System	24 Aug 2020 17:43:00

US3342142
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(5)
Generated On: 11 Aug 2021 22:33:31
PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:52:22
User entered '29 Aug 2020 11:59'	System	24 Aug 2020 17:43:00

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US3342142
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(6)
Generated On: 11 Aug 2021 22:33:31
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:52:22
Data entry locked.	System	24 Aug 2020 17:43:00
User entered 'Day 6'	System	24 Aug 2020 17:43:00

US3342142
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(6)
Generated On: 11 Aug 2021 22:33:31
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 14:52:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (01A85E90-DEE1-40E1-A1FD-349A8271449C)', Time: '2020-08-29T20:01:12', User OID: 'PatientReportedOutcome (US3342142)', ODM File OID: '23d77e60-f044-4dc1-ab0c-16d6253dee92'	System	30 Aug 2020 01:01:23
User entered 'None (1)'	System	30 Aug 2020 01:01:23

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US3342142
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(6)
Generated On: 11 Aug 2021 22:33:31
Is there any **REDNESS AT INJECTION SITE**?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:52:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (01A85E90-DEE1-40E1-A1FD-349A8271449C)', Time: '2020-08-29T20:01:14', User OID: 'PatientReportedOutcome (US3342142)', ODM File OID: '23d77e60-f044-4dc1-ab0c-16d6253dee92'	System	30 Aug 2020 01:01:23
User entered 'No (N)'	System	30 Aug 2020 01:01:23

US3342142
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(6)
Generated On: 11 Aug 2021 22:33:31
Is there any **SWELLING/HARDNESS AT INJECTION SITE**?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:52:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (01A85E90-DEE1-40E1-A1FD-349A8271449C)', Time: '2020-08-29T20:01:16', User OID: 'PatientReportedOutcome (US3342142)', ODM File OID: '23d77e60-f044-4dc1-ab0c-16d6253dee92'	System	30 Aug 2020 01:01:23
User entered 'No (N)'	System	30 Aug 2020 01:01:23

US3342142
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(6)
Generated On: 11 Aug 2021 22:33:31
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 14:52:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (01A85E90-DEE1-40E1-A1FD-349A8271449C)', Time: '2020-08-29T20:01:18', User OID: 'PatientReportedOutcome (US3342142)', ODM File OID: '23d77e60-f044-4dc1-ab0c-16d6253dee92'	System	30 Aug 2020 01:01:23
User entered 'None (1)'	System	30 Aug 2020 01:01:23

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US3342142
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(6)
Generated On: 11 Aug 2021 22:33:31
PC Time Stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:52:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (01A85E90-DEE1-40E1-A1FD-349A8271449C)', Time: '2020-08-29T20:01:20', User OID: 'PatientReportedOutcome (US3342142)', ODM File OID: '23d77e60-f044-4dc1-ab0c-16d6253dee92'	System	30 Aug 2020 01:01:23
User entered '29 Aug 2020 20:01'	System	30 Aug 2020 01:01:23

FDA-CBER-2022-1614-2809115

US3342142
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(6)
Generated On: 11 Aug 2021 22:33:31
PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:52:22
User entered '29 Aug 2020 12:00'	System	24 Aug 2020 17:43:00

US3342142
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(6)
Generated On: 11 Aug 2021 22:33:31
PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:52:22
User entered '30 Aug 2020 11:59'	System	24 Aug 2020 17:43:00

FDA-CBER-2022-1614-2809117

US3342142
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(7)
Generated On: 11 Aug 2021 22:33:31
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:52:22
Data entry locked.	System	24 Aug 2020 17:43:00
User entered 'Day 7'	System	24 Aug 2020 17:43:00

US3342142
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(7)
Generated On: 11 Aug 2021 22:33:31
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 14:52:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (01A85E90-DEE1-40E1-A1FD-349A8271449C)', Time: '2020-08-31T00:04:06', User OID: 'PatientReportedOutcome (US3342142)', ODM File OID: '1987f3dc-d0f2-45f8-ac62-d04231810992'	System	31 Aug 2020 05:04:17
User entered 'None (1)'	System	31 Aug 2020 05:04:17

US3342142
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(7)
Generated On: 11 Aug 2021 22:33:31
Is there any **REDNESS AT INJECTION SITE**?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:52:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (01A85E90-DEE1-40E1-A1FD-349A8271449C)', Time: '2020-08-31T00:04:07', User OID: 'PatientReportedOutcome (US3342142)', ODM File OID: '1987f3dc-d0f2-45f8-ac62-d04231810992'	System	31 Aug 2020 05:04:17
User entered 'No (N)'	System	31 Aug 2020 05:04:17

US3342142
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(7)
Generated On: 11 Aug 2021 22:33:31
Is there any **SWELLING/HARDNESS AT INJECTION SITE**?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:52:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (01A85E90-DEE1-40E1-A1FD-349A8271449C)', Time: '2020-08-31T00:04:09', User OID: 'PatientReportedOutcome (US3342142)', ODM File OID: '1987f3dc-d0f2-45f8-ac62-d04231810992'	System	31 Aug 2020 05:04:17
User entered 'No (N)'	System	31 Aug 2020 05:04:17

FDA-CBER-2022-1614-2809121

US3342142
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(7)
Generated On: 11 Aug 2021 22:33:31
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 14:52:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (01A85E90-DEE1-40E1-A1FD-349A8271449C)', Time: '2020-08-31T00:04:11', User OID: 'PatientReportedOutcome (US3342142)', ODM File OID: '1987f3dc-d0f2-45f8-ac62-d04231810992'	System	31 Aug 2020 05:04:17
User entered 'None (1)'	System	31 Aug 2020 05:04:17

US3342142
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(7)
Generated On: 11 Aug 2021 22:33:31
PC Time Stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:52:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (01A85E90-DEE1-40E1-A1FD-349A8271449C)', Time: '2020-08-31T00:04:13', User OID: 'PatientReportedOutcome (US3342142)', ODM File OID: '1987f3dc-d0f2-45f8-ac62-d04231810992'	System	31 Aug 2020 05:04:17
User entered '31 Aug 2020 00:04'	System	31 Aug 2020 05:04:17

US3342142
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(7)
Generated On: 11 Aug 2021 22:33:31
PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:52:22
User entered '30 Aug 2020 12:00'	System	24 Aug 2020 17:43:00

US3342142
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(7)
Generated On: 11 Aug 2021 22:33:31
PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:52:22
User entered '31 Aug 2020 11:59'	System	24 Aug 2020 17:43:00

FDA-CBER-2022-1614-2809125

US3342142
Folder: Diary Dose 1 (1)
Form: General_Day(1/1)
Generated On: 11 Aug 2021 22:33:31
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:52:22
Data entry locked.	System	24 Aug 2020 17:43:00
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	24 Aug 2020 17:43:00

US3342142
Folder: Diary Dose 1 (1)
Form: General_Day(1/1)
Generated On: 11 Aug 2021 22:33:31
HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:52:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (01A85E90-DEE1-40E1-A1FD-349A8271449C)', Time: '2020-08-24T12:54:11', User OID: 'PatientReportedOutcome (US3342142)', ODM File OID: '788ad896-4794-48fb-affc-a11af2f800da'	System	24 Aug 2020 17:54:28
User entered 'None (0)'	System	24 Aug 2020 17:54:28

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US3342142
Folder: Diary Dose 1 (1)
Form: General_Day(1/1)
Generated On: 11 Aug 2021 22:33:31
FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:52:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (01A85E90-DEE1-40E1-A1FD-349A8271449C)', Time: '2020-08-24T12:54:14', User OID: 'PatientReportedOutcome (US3342142)', ODM File OID: '788ad896-4794-48fb-affc-a11af2f800da'	System	24 Aug 2020 17:54:28
User entered 'None (0)'	System	24 Aug 2020 17:54:28

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US3342142
Folder: Diary Dose 1 (1)
Form: General_Day(1/1)
Generated On: 11 Aug 2021 22:33:31
MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:52:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (01A85E90-DEE1-40E1-A1FD-349A8271449C)', Time: '2020-08-24T12:54:15', User OID: 'PatientReportedOutcome (US3342142)', ODM File OID: '788ad896-4794-48fb-affc-a11af2f800da'	System	24 Aug 2020 17:54:28
User entered 'None (0)'	System	24 Aug 2020 17:54:28

FDA-CBER-2022-1614-2809129

US3342142
Folder: Diary Dose 1 (1)
Form: General_Day(1/1)
Generated On: 11 Aug 2021 22:33:31
JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:52:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (01A85E90-DEE1-40E1-A1FD-349A8271449C)', Time: '2020-08-24T12:54:17', User OID: 'PatientReportedOutcome (US3342142)', ODM File OID: '788ad896-4794-48fb-affc-a11af2f800da'	System	24 Aug 2020 17:54:28
User entered 'None (0)'	System	24 Aug 2020 17:54:28

FDA-CBER-2022-1614-2809130

US3342142
Folder: Diary Dose 1 (1)
Form: General_Day(1/1)
Generated On: 11 Aug 2021 22:33:31
NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:52:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (01A85E90-DEE1-40E1-A1FD-349A8271449C)', Time: '2020-08-24T12:54:19', User OID: 'PatientReportedOutcome (US3342142)', ODM File OID: '788ad896-4794-48fb-affc-a11af2f800da'	System	24 Aug 2020 17:54:28
User entered 'None (0)'	System	24 Aug 2020 17:54:28

FDA-CBER-2022-1614-2809131

US3342142
Folder: Diary Dose 1 (1)
Form: General_Day(1/1)
Generated On: 11 Aug 2021 22:33:31
CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:52:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (01A85E90-DEE1-40E1-A1FD-349A8271449C)', Time: '2020-08-24T12:54:20', User OID: 'PatientReportedOutcome (US3342142)', ODM File OID: '788ad896-4794-48fb-affc-a11af2f800da'	System	24 Aug 2020 17:54:28
User entered 'None (0)'	System	24 Aug 2020 17:54:28

FDA-CBER-2022-1614-2809132

US3342142
Folder: Diary Dose 1 (1)
Form: General_Day(1/1)
Generated On: 11 Aug 2021 22:33:31
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 14:52:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (01A85E90-DEE1-40E1-A1FD-349A8271449C)', Time: '2020-08-24T12:54:24', User OID: 'PatientReportedOutcome (US3342142)', ODM File OID: '788ad896-4794-48fb-affc-a11af2f800da'	System	24 Aug 2020 17:54:28
User entered 'No (N)'	System	24 Aug 2020 17:54:28

US3342142
Folder: Diary Dose 1 (1)
Form: General_Day(1/1)
Generated On: 11 Aug 2021 22:33:31
PC Time stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:52:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (01A85E90-DEE1-40E1-A1FD-349A8271449C)', Time: '2020-08-24T12:54:26', User OID: 'PatientReportedOutcome (US3342142)', ODM File OID: '788ad896-4794-48fb-affc-a11af2f800da'	System	24 Aug 2020 17:54:28
User entered '24 Aug 2020 12:54'	System	24 Aug 2020 17:54:28

FDA-CBER-2022-1614-2809134

US3342142
Folder: Diary Dose 1 (1)
Form: General_Day(1/1)
Generated On: 11 Aug 2021 22:33:31
PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:52:22
User entered '24 Aug 2020 12:39'	System	24 Aug 2020 17:43:00

FDA-CBER-2022-1614-2809135

US3342142
Folder: Diary Dose 1 (1)
Form: General_Day(1/1)
Generated On: 11 Aug 2021 22:33:31
PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:52:22
User entered '24 Aug 2020 15:09'	System	24 Aug 2020 17:43:00

FDA-CBER-2022-1614-2809136

US3342142
Folder: Diary Dose 1 (1)
Form: General_Day(1/2)
Generated On: 11 Aug 2021 22:33:31
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:52:22
Data entry locked.	System	24 Aug 2020 17:43:00
User entered 'Day 1, after vaccination (at home)'	System	24 Aug 2020 17:43:00

US3342142
Folder: Diary Dose 1 (1)
Form: General_Day(1/2)
Generated On: 11 Aug 2021 22:33:31
HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:52:22

FDA-CBER-2022-1614-2809138

US3342142
Folder: Diary Dose 1 (1)
Form: General_Day(1/2)
Generated On: 11 Aug 2021 22:33:31
FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:52:22

FDA-CBER-2022-1614-2809139

US3342142
Folder: Diary Dose 1 (1)
Form: General_Day(1/2)
Generated On: 11 Aug 2021 22:33:31
MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:52:22

FDA-CBER-2022-1614-2809140

US3342142
Folder: Diary Dose 1 (1)
Form: General_Day(1/2)
Generated On: 11 Aug 2021 22:33:31
JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:52:22

FDA-CBER-2022-1614-2809141

US3342142
Folder: Diary Dose 1 (1)
Form: General_Day(1/2)
Generated On: 11 Aug 2021 22:33:31
NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:52:22

FDA-CBER-2022-1614-2809142

US3342142
Folder: Diary Dose 1 (1)
Form: General_Day(1/2)
Generated On: 11 Aug 2021 22:33:31
CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:52:22

FDA-CBER-2022-1614-2809143

US3342142
Folder: Diary Dose 1 (1)
Form: General_Day(1/2)
Generated On: 11 Aug 2021 22:33:31
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 14:52:22

FDA-CBER-2022-1614-2809144

US3342142
Folder: Diary Dose 1 (1)
Form: General_Day(1/2)
Generated On: 11 Aug 2021 22:33:31
PC Time stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:52:22

FDA-CBER-2022-1614-2809145

US3342142
Folder: Diary Dose 1 (1)
Form: General_Day(1/2)
Generated On: 11 Aug 2021 22:33:31
PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:52:22
User entered '24 Aug 2020 16:04'	System	24 Aug 2020 17:43:00

FDA-CBER-2022-1614-2809146

US3342142
Folder: Diary Dose 1 (1)
Form: General_Day(1/2)
Generated On: 11 Aug 2021 22:33:31
PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:52:22
User entered '25 Aug 2020 11:59'	System	24 Aug 2020 17:43:00

FDA-CBER-2022-1614-2809147

US3342142
Folder: Diary Dose 1 (1)
Form: General_Day(2)
Generated On: 11 Aug 2021 22:33:31
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:52:22
Data entry locked.	System	24 Aug 2020 17:43:00
User entered 'Day 2'	System	24 Aug 2020 17:43:00

US3342142
Folder: Diary Dose 1 (1)
Form: General_Day(2)
Generated On: 11 Aug 2021 22:33:31
HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:52:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (01A85E90-DEE1-40E1-A1FD-349A8271449C)', Time: '2020-08-25T20:17:39', User OID: 'PatientReportedOutcome (US3342142)', ODM File OID: '4acb0cca-34b2-4b7a-a17c-8f357a885366'	System	26 Aug 2020 01:18:14
User entered 'None (0)'	System	26 Aug 2020 01:18:14

FDA-CBER-2022-1614-2809149

US3342142
Folder: Diary Dose 1 (1)
Form: General_Day(2)
Generated On: 11 Aug 2021 22:33:31
FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:52:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (01A85E90-DEE1-40E1-A1FD-349A8271449C)', Time: '2020-08-25T20:17:43', User OID: 'PatientReportedOutcome (US3342142)', ODM File OID: '4acb0cca-34b2-4b7a-a17c-8f357a885366'	System	26 Aug 2020 01:18:14
User entered 'None (0)'	System	26 Aug 2020 01:18:14

FDA-CBER-2022-1614-2809150

US3342142
Folder: Diary Dose 1 (1)
Form: General_Day(2)
Generated On: 11 Aug 2021 22:33:31
MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:52:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (01A85E90-DEE1-40E1-A1FD-349A8271449C)', Time: '2020-08-25T20:17:45', User OID: 'PatientReportedOutcome (US3342142)', ODM File OID: '4acb0cca-34b2-4b7a-a17c-8f357a885366'	System	26 Aug 2020 01:18:14
User entered 'None (0)'	System	26 Aug 2020 01:18:14

FDA-CBER-2022-1614-2809151

US3342142
Folder: Diary Dose 1 (1)
Form: General_Day(2)
Generated On: 11 Aug 2021 22:33:31
JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:52:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (01A85E90-DEE1-40E1-A1FD-349A8271449C)', Time: '2020-08-25T20:17:47', User OID: 'PatientReportedOutcome (US3342142)', ODM File OID: '4acb0cca-34b2-4b7a-a17c-8f357a885366'	System	26 Aug 2020 01:18:14
User entered 'None (0)'	System	26 Aug 2020 01:18:14

FDA-CBER-2022-1614-2809152

US3342142
Folder: Diary Dose 1 (1)
Form: General_Day(2)
Generated On: 11 Aug 2021 22:33:31
NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:52:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (01A85E90-DEE1-40E1-A1FD-349A8271449C)', Time: '2020-08-25T20:17:50', User OID: 'PatientReportedOutcome (US3342142)', ODM File OID: '4acb0cca-34b2-4b7a-a17c-8f357a885366'	System	26 Aug 2020 01:18:14
User entered 'None (0)'	System	26 Aug 2020 01:18:14

FDA-CBER-2022-1614-2809153

US3342142
Folder: Diary Dose 1 (1)
Form: General_Day(2)
Generated On: 11 Aug 2021 22:33:31
CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:52:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (01A85E90-DEE1-40E1-A1FD-349A8271449C)', Time: '2020-08-25T20:17:54', User OID: 'PatientReportedOutcome (US3342142)', ODM File OID: '4acb0cca-34b2-4b7a-a17c-8f357a885366'	System	26 Aug 2020 01:18:14
User entered 'None (0)'	System	26 Aug 2020 01:18:14

US3342142
Folder: Diary Dose 1 (1)
Form: General_Day(2)
Generated On: 11 Aug 2021 22:33:31
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 14:52:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (01A85E90-DEE1-40E1-A1FD-349A8271449C)', Time: '2020-08-25T20:17:59', User OID: 'PatientReportedOutcome (US3342142)', ODM File OID: '4acb0cca-34b2-4b7a-a17c-8f357a885366'	System	26 Aug 2020 01:18:14
User entered 'No (N)'	System	26 Aug 2020 01:18:14

US3342142
Folder: Diary Dose 1 (1)
Form: General_Day(2)
Generated On: 11 Aug 2021 22:33:31
PC Time stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:52:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (01A85E90-DEE1-40E1-A1FD-349A8271449C)', Time: '2020-08-25T20:18:11', User OID: 'PatientReportedOutcome (US3342142)', ODM File OID: '4acb0cca-34b2-4b7a-a17c-8f357a885366'	System	26 Aug 2020 01:18:14
User entered '25 Aug 2020 20:18'	System	26 Aug 2020 01:18:14

FDA-CBER-2022-1614-2809156

US3342142
Folder: Diary Dose 1 (1)
Form: General_Day(2)
Generated On: 11 Aug 2021 22:33:31
PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:52:22
User entered '25 Aug 2020 12:00'	System	24 Aug 2020 17:43:00

FDA-CBER-2022-1614-2809157

US3342142
Folder: Diary Dose 1 (1)
Form: General_Day(2)
Generated On: 11 Aug 2021 22:33:31
PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:52:22
User entered '26 Aug 2020 11:59'	System	24 Aug 2020 17:43:00

FDA-CBER-2022-1614-2809158

US3342142
Folder: Diary Dose 1 (1)
Form: General_Day(3)
Generated On: 11 Aug 2021 22:33:31
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:52:22
Data entry locked.	System	24 Aug 2020 17:43:00
User entered 'Day 3'	System	24 Aug 2020 17:43:00

US3342142
Folder: Diary Dose 1 (1)
Form: General_Day(3)
Generated On: 11 Aug 2021 22:33:31
HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:52:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (01A85E90-DEE1-40E1-A1FD-349A8271449C)', Time: '2020-08-26T20:21:12', User OID: 'PatientReportedOutcome (US3342142)', ODM File OID: '93f520f3-ef20-47ce-8f8b-7a6ca24be259'	System	27 Aug 2020 01:21:28
User entered 'None (0)'	System	27 Aug 2020 01:21:28

US3342142
Folder: Diary Dose 1 (1)
Form: General_Day(3)
Generated On: 11 Aug 2021 22:33:31
FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:52:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (01A85E90-DEE1-40E1-A1FD-349A8271449C)', Time: '2020-08-26T20:21:14', User OID: 'PatientReportedOutcome (US3342142)', ODM File OID: '93f520f3-ef20-47ce-8f8b-7a6ca24be259'	System	27 Aug 2020 01:21:28
User entered 'None (0)'	System	27 Aug 2020 01:21:28

US3342142
Folder: Diary Dose 1 (1)
Form: General_Day(3)
Generated On: 11 Aug 2021 22:33:31
MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:52:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (01A85E90-DEE1-40E1-A1FD-349A8271449C)', Time: '2020-08-26T20:21:16', User OID: 'PatientReportedOutcome (US3342142)', ODM File OID: '93f520f3-ef20-47ce-8f8b-7a6ca24be259'	System	27 Aug 2020 01:21:28
User entered 'None (0)'	System	27 Aug 2020 01:21:28

US3342142
Folder: Diary Dose 1 (1)
Form: General_Day(3)
Generated On: 11 Aug 2021 22:33:31
JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:52:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (01A85E90-DEE1-40E1-A1FD-349A8271449C)', Time: '2020-08-26T20:21:18', User OID: 'PatientReportedOutcome (US3342142)', ODM File OID: '93f520f3-ef20-47ce-8f8b-7a6ca24be259'	System	27 Aug 2020 01:21:28
User entered 'None (0)'	System	27 Aug 2020 01:21:28

US3342142
Folder: Diary Dose 1 (1)
Form: General_Day(3)
Generated On: 11 Aug 2021 22:33:31
NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:52:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (01A85E90-DEE1-40E1-A1FD-349A8271449C)', Time: '2020-08-26T20:21:19', User OID: 'PatientReportedOutcome (US3342142)', ODM File OID: '93f520f3-ef20-47ce-8f8b-7a6ca24be259'	System	27 Aug 2020 01:21:28
User entered 'None (0)'	System	27 Aug 2020 01:21:28

US3342142
Folder: Diary Dose 1 (1)
Form: General_Day(3)
Generated On: 11 Aug 2021 22:33:31
CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:52:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (01A85E90-DEE1-40E1-A1FD-349A8271449C)', Time: '2020-08-26T20:21:21', User OID: 'PatientReportedOutcome (US3342142)', ODM File OID: '93f520f3-ef20-47ce-8f8b-7a6ca24be259'	System	27 Aug 2020 01:21:28
User entered 'None (0)'	System	27 Aug 2020 01:21:28

US3342142
Folder: Diary Dose 1 (1)
Form: General_Day(3)
Generated On: 11 Aug 2021 22:33:31
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 14:52:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (01A85E90-DEE1-40E1-A1FD-349A8271449C)', Time: '2020-08-26T20:21:24', User OID: 'PatientReportedOutcome (US3342142)', ODM File OID: '93f520f3-ef20-47ce-8f8b-7a6ca24be259'	System	27 Aug 2020 01:21:28
User entered 'No (N)'	System	27 Aug 2020 01:21:28

US3342142
Folder: Diary Dose 1 (1)
Form: General_Day(3)
Generated On: 11 Aug 2021 22:33:31
PC Time stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:52:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (01A85E90-DEE1-40E1-A1FD-349A8271449C)', Time: '2020-08-26T20:21:26', User OID: 'PatientReportedOutcome (US3342142)', ODM File OID: '93f520f3-ef20-47ce-8f8b-7a6ca24be259'	System	27 Aug 2020 01:21:28
User entered '26 Aug 2020 20:21'	System	27 Aug 2020 01:21:28

FDA-CBER-2022-1614-2809167

US3342142
Folder: Diary Dose 1 (1)
Form: General_Day(3)
Generated On: 11 Aug 2021 22:33:31
PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:52:22
User entered '26 Aug 2020 12:00'	System	24 Aug 2020 17:43:00

US3342142
Folder: Diary Dose 1 (1)
Form: General_Day(3)
Generated On: 11 Aug 2021 22:33:31
PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:52:22
User entered '27 Aug 2020 11:59'	System	24 Aug 2020 17:43:00

US3342142
Folder: Diary Dose 1 (1)
Form: General_Day(4)
Generated On: 11 Aug 2021 22:33:31
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:52:22
Data entry locked.	System	24 Aug 2020 17:43:00
User entered 'Day 4'	System	24 Aug 2020 17:43:00

US3342142
Folder: Diary Dose 1 (1)
Form: General_Day(4)
Generated On: 11 Aug 2021 22:33:31
HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:52:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (01A85E90-DEE1-40E1-A1FD-349A8271449C)', Time: '2020-08-27T23:31:41', User OID: 'PatientReportedOutcome (US3342142)', ODM File OID: '8f199a86-0774-40ea-9a28-0f7557ac9a07'	System	28 Aug 2020 04:32:35
User entered 'None (0)'	System	28 Aug 2020 04:32:35

FDA-CBER-2022-1614-2809171

US3342142
Folder: Diary Dose 1 (1)
Form: General_Day(4)
Generated On: 11 Aug 2021 22:33:31
FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:52:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (01A85E90-DEE1-40E1-A1FD-349A8271449C)', Time: '2020-08-27T23:32:17', User OID: 'PatientReportedOutcome (US3342142)', ODM File OID: '8f199a86-0774-40ea-9a28-0f7557ac9a07'	System	28 Aug 2020 04:32:35
User entered 'None (0)'	System	28 Aug 2020 04:32:35

FDA-CBER-2022-1614-2809172

US3342142
Folder: Diary Dose 1 (1)
Form: General_Day(4)
Generated On: 11 Aug 2021 22:33:31
MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:52:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (01A85E90-DEE1-40E1-A1FD-349A8271449C)', Time: '2020-08-27T23:32:19', User OID: 'PatientReportedOutcome (US3342142)', ODM File OID: '8f199a86-0774-40ea-9a28-0f7557ac9a07'	System	28 Aug 2020 04:32:35
User entered 'None (0)'	System	28 Aug 2020 04:32:35

FDA-CBER-2022-1614-2809173

US3342142
Folder: Diary Dose 1 (1)
Form: General_Day(4)
Generated On: 11 Aug 2021 22:33:31
JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:52:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (01A85E90-DEE1-40E1-A1FD-349A8271449C)', Time: '2020-08-27T23:32:22', User OID: 'PatientReportedOutcome (US3342142)', ODM File OID: '8f199a86-0774-40ea-9a28-0f7557ac9a07'	System	28 Aug 2020 04:32:35
User entered 'None (0)'	System	28 Aug 2020 04:32:35

FDA-CBER-2022-1614-2809174

US3342142
Folder: Diary Dose 1 (1)
Form: General_Day(4)
Generated On: 11 Aug 2021 22:33:31
NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:52:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (01A85E90-DEE1-40E1-A1FD-349A8271449C)', Time: '2020-08-27T23:32:24', User OID: 'PatientReportedOutcome (US3342142)', ODM File OID: '8f199a86-0774-40ea-9a28-0f7557ac9a07'	System	28 Aug 2020 04:32:35
User entered 'None (0)'	System	28 Aug 2020 04:32:35

FDA-CBER-2022-1614-2809175

US3342142
Folder: Diary Dose 1 (1)
Form: General_Day(4)
Generated On: 11 Aug 2021 22:33:31
CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:52:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (01A85E90-DEE1-40E1-A1FD-349A8271449C)', Time: '2020-08-27T23:32:26', User OID: 'PatientReportedOutcome (US3342142)', ODM File OID: '8f199a86-0774-40ea-9a28-0f7557ac9a07'	System	28 Aug 2020 04:32:35
User entered 'None (0)'	System	28 Aug 2020 04:32:35

US3342142
Folder: Diary Dose 1 (1)
Form: General_Day(4)
Generated On: 11 Aug 2021 22:33:31
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 14:52:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (01A85E90-DEE1-40E1-A1FD-349A8271449C)', Time: '2020-08-27T23:32:31', User OID: 'PatientReportedOutcome (US3342142)', ODM File OID: '8f199a86-0774-40ea-9a28-0f7557ac9a07'	System	28 Aug 2020 04:32:35
User entered 'No (N)'	System	28 Aug 2020 04:32:35

US3342142
Folder: Diary Dose 1 (1)
Form: General_Day(4)
Generated On: 11 Aug 2021 22:33:31
PC Time stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:52:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (01A85E90-DEE1-40E1-A1FD-349A8271449C)', Time: '2020-08-27T23:32:33', User OID: 'PatientReportedOutcome (US3342142)', ODM File OID: '8f199a86-0774-40ea-9a28-0f7557ac9a07'	System	28 Aug 2020 04:32:35
User entered '27 Aug 2020 23:32'	System	28 Aug 2020 04:32:35

FDA-CBER-2022-1614-2809178

US3342142
Folder: Diary Dose 1 (1)
Form: General_Day(4)
Generated On: 11 Aug 2021 22:33:31
PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:52:22
User entered '27 Aug 2020 12:00'	System	24 Aug 2020 17:43:00

US3342142
Folder: Diary Dose 1 (1)
Form: General_Day(4)
Generated On: 11 Aug 2021 22:33:31
PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:52:22
User entered '28 Aug 2020 11:59'	System	24 Aug 2020 17:43:00

US3342142
Folder: Diary Dose 1 (1)
Form: General_Day(5)
Generated On: 11 Aug 2021 22:33:31
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:52:22
Data entry locked.	System	24 Aug 2020 17:43:00
User entered 'Day 5'	System	24 Aug 2020 17:43:00

US3342142
Folder: Diary Dose 1 (1)
Form: General_Day(5)
Generated On: 11 Aug 2021 22:33:31
HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:52:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (01A85E90-DEE1-40E1-A1FD-349A8271449C)', Time: '2020-08-29T07:24:39', User OID: 'PatientReportedOutcome (US3342142)', ODM File OID: 'c6b47271-d8f3-4a0c-a0b6-bb8e8ec1c894'	System	29 Aug 2020 12:24:55
User entered 'None (0)'	System	29 Aug 2020 12:24:55

US3342142
Folder: Diary Dose 1 (1)
Form: General_Day(5)
Generated On: 11 Aug 2021 22:33:31
FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:52:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (01A85E90-DEE1-40E1-A1FD-349A8271449C)', Time: '2020-08-29T07:24:41', User OID: 'PatientReportedOutcome (US3342142)', ODM File OID: 'c6b47271-d8f3-4a0c-a0b6-bb8e8ec1c894'	System	29 Aug 2020 12:24:55
User entered 'None (0)'	System	29 Aug 2020 12:24:55

US3342142
Folder: Diary Dose 1 (1)
Form: General_Day(5)
Generated On: 11 Aug 2021 22:33:31
MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:52:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (01A85E90-DEE1-40E1-A1FD-349A8271449C)', Time: '2020-08-29T07:24:43', User OID: 'PatientReportedOutcome (US3342142)', ODM File OID: 'c6b47271-d8f3-4a0c-a0b6-bb8e8ec1c894'	System	29 Aug 2020 12:24:55
User entered 'None (0)'	System	29 Aug 2020 12:24:55

US3342142
Folder: Diary Dose 1 (1)
Form: General_Day(5)
Generated On: 11 Aug 2021 22:33:31
JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:52:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (01A85E90-DEE1-40E1-A1FD-349A8271449C)', Time: '2020-08-29T07:24:44', User OID: 'PatientReportedOutcome (US3342142)', ODM File OID: 'c6b47271-d8f3-4a0c-a0b6-bb8e8ec1c894'	System	29 Aug 2020 12:24:55
User entered 'None (0)'	System	29 Aug 2020 12:24:55

US3342142
Folder: Diary Dose 1 (1)
Form: General_Day(5)
Generated On: 11 Aug 2021 22:33:31
NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:52:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (01A85E90-DEE1-40E1-A1FD-349A8271449C)', Time: '2020-08-29T07:24:46', User OID: 'PatientReportedOutcome (US3342142)', ODM File OID: 'c6b47271-d8f3-4a0c-a0b6-bb8e8ec1c894'	System	29 Aug 2020 12:24:55
User entered 'None (0)'	System	29 Aug 2020 12:24:55

US3342142
Folder: Diary Dose 1 (1)
Form: General_Day(5)
Generated On: 11 Aug 2021 22:33:31
CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:52:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (01A85E90-DEE1-40E1-A1FD-349A8271449C)', Time: '2020-08-29T07:24:47', User OID: 'PatientReportedOutcome (US3342142)', ODM File OID: 'c6b47271-d8f3-4a0c-a0b6-bb8e8ec1c894'	System	29 Aug 2020 12:24:55
User entered 'None (0)'	System	29 Aug 2020 12:24:55

US3342142
Folder: Diary Dose 1 (1)
Form: General_Day(5)
Generated On: 11 Aug 2021 22:33:31
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 14:52:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (01A85E90-DEE1-40E1-A1FD-349A8271449C)', Time: '2020-08-29T07:24:51', User OID: 'PatientReportedOutcome (US3342142)', ODM File OID: 'c6b47271-d8f3-4a0c-a0b6-bb8e8ec1c894'	System	29 Aug 2020 12:24:55
User entered 'No (N)'	System	29 Aug 2020 12:24:55

US3342142
Folder: Diary Dose 1 (1)
Form: General_Day(5)
Generated On: 11 Aug 2021 22:33:31
PC Time stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:52:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (01A85E90-DEE1-40E1-A1FD-349A8271449C)', Time: '2020-08-29T07:24:53', User OID: 'PatientReportedOutcome (US3342142)', ODM File OID: 'c6b47271-d8f3-4a0c-a0b6-bb8e8ec1c894'	System	29 Aug 2020 12:24:55
User entered '29 Aug 2020 07:24'	System	29 Aug 2020 12:24:55

US3342142
Folder: Diary Dose 1 (1)
Form: General_Day(5)
Generated On: 11 Aug 2021 22:33:31
PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:52:22
User entered '28 Aug 2020 12:00'	System	24 Aug 2020 17:43:00

US3342142
Folder: Diary Dose 1 (1)
Form: General_Day(5)
Generated On: 11 Aug 2021 22:33:31
PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:52:22
User entered '29 Aug 2020 11:59'	System	24 Aug 2020 17:43:00

US3342142
Folder: Diary Dose 1 (1)
Form: General_Day(6)
Generated On: 11 Aug 2021 22:33:31
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:52:22
Data entry locked.	System	24 Aug 2020 17:43:00
User entered 'Day 6'	System	24 Aug 2020 17:43:00

US3342142
Folder: Diary Dose 1 (1)
Form: General_Day(6)
Generated On: 11 Aug 2021 22:33:31
HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:52:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (01A85E90-DEE1-40E1-A1FD-349A8271449C)', Time: '2020-08-29T20:01:23', User OID: 'PatientReportedOutcome (US3342142)', ODM File OID: '00b3d736-57ed-466b-bef5-b7d3687aed57'	System	30 Aug 2020 01:01:39
User entered 'None (0)'	System	30 Aug 2020 01:01:39

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US3342142
Folder: Diary Dose 1 (1)
Form: General_Day(6)
Generated On: 11 Aug 2021 22:33:31
FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:52:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (01A85E90-DEE1-40E1-A1FD-349A8271449C)', Time: '2020-08-29T20:01:24', User OID: 'PatientReportedOutcome (US3342142)', ODM File OID: '00b3d736-57ed-466b-bef5-b7d3687aed57'	System	30 Aug 2020 01:01:39
User entered 'None (0)'	System	30 Aug 2020 01:01:39

US3342142
Folder: Diary Dose 1 (1)
Form: General_Day(6)
Generated On: 11 Aug 2021 22:33:31
MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:52:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (01A85E90-DEE1-40E1-A1FD-349A8271449C)', Time: '2020-08-29T20:01:26', User OID: 'PatientReportedOutcome (US3342142)', ODM File OID: '00b3d736-57ed-466b-bef5-b7d3687aed57'	System	30 Aug 2020 01:01:39
User entered 'None (0)'	System	30 Aug 2020 01:01:39

FDA-CBER-2022-1614-2809195

US3342142
Folder: Diary Dose 1 (1)
Form: General_Day(6)
Generated On: 11 Aug 2021 22:33:31
JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:52:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (01A85E90-DEE1-40E1-A1FD-349A8271449C)', Time: '2020-08-29T20:01:27', User OID: 'PatientReportedOutcome (US3342142)', ODM File OID: '00b3d736-57ed-466b-bef5-b7d3687aed57'	System	30 Aug 2020 01:01:39
User entered 'None (0)'	System	30 Aug 2020 01:01:39

FDA-CBER-2022-1614-2809196

US3342142
Folder: Diary Dose 1 (1)
Form: General_Day(6)
Generated On: 11 Aug 2021 22:33:31
NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:52:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (01A85E90-DEE1-40E1-A1FD-349A8271449C)', Time: '2020-08-29T20:01:29', User OID: 'PatientReportedOutcome (US3342142)', ODM File OID: '00b3d736-57ed-466b-bef5-b7d3687aed57'	System	30 Aug 2020 01:01:39
User entered 'None (0)'	System	30 Aug 2020 01:01:39

FDA-CBER-2022-1614-2809197

US3342142
Folder: Diary Dose 1 (1)
Form: General_Day(6)
Generated On: 11 Aug 2021 22:33:31
CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:52:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (01A85E90-DEE1-40E1-A1FD-349A8271449C)', Time: '2020-08-29T20:01:30', User OID: 'PatientReportedOutcome (US3342142)', ODM File OID: '00b3d736-57ed-466b-bef5-b7d3687aed57'	System	30 Aug 2020 01:01:39
User entered 'None (0)'	System	30 Aug 2020 01:01:39

FDA-CBER-2022-1614-2809198

US3342142
Folder: Diary Dose 1 (1)
Form: General_Day(6)
Generated On: 11 Aug 2021 22:33:31
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 14:52:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (01A85E90-DEE1-40E1-A1FD-349A8271449C)', Time: '2020-08-29T20:01:32', User OID: 'PatientReportedOutcome (US3342142)', ODM File OID: '00b3d736-57ed-466b-bef5-b7d3687aed57'	System	30 Aug 2020 01:01:39
User entered 'No (N)'	System	30 Aug 2020 01:01:39

US3342142
Folder: Diary Dose 1 (1)
Form: General_Day(6)
Generated On: 11 Aug 2021 22:33:31
PC Time stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:52:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (01A85E90-DEE1-40E1-A1FD-349A8271449C)', Time: '2020-08-29T20:01:34', User OID: 'PatientReportedOutcome (US3342142)', ODM File OID: '00b3d736-57ed-466b-bef5-b7d3687aed57'	System	30 Aug 2020 01:01:39
User entered '29 Aug 2020 20:01'	System	30 Aug 2020 01:01:39

FDA-CBER-2022-1614-2809200

US3342142
Folder: Diary Dose 1 (1)
Form: General_Day(6)
Generated On: 11 Aug 2021 22:33:31
PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:52:22
User entered '29 Aug 2020 12:00'	System	24 Aug 2020 17:43:00

US3342142
Folder: Diary Dose 1 (1)
Form: General_Day(6)
Generated On: 11 Aug 2021 22:33:31
PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:52:22
User entered '30 Aug 2020 11:59'	System	24 Aug 2020 17:43:00

US3342142
Folder: Diary Dose 1 (1)
Form: General_Day(7)
Generated On: 11 Aug 2021 22:33:31
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:52:22
Data entry locked.	System	24 Aug 2020 17:43:00
User entered 'Day 7'	System	24 Aug 2020 17:43:00

US3342142
Folder: Diary Dose 1 (1)
Form: General_Day(7)
Generated On: 11 Aug 2021 22:33:31
HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:52:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (01A85E90-DEE1-40E1-A1FD-349A8271449C)', Time: '2020-08-31T00:04:21', User OID: 'PatientReportedOutcome (US3342142)', ODM File OID: '7ca9ba5f-7798-469d-945c-68de6f455853'	System	31 Aug 2020 05:04:38
User entered 'None (0)'	System	31 Aug 2020 05:04:38

US3342142
Folder: Diary Dose 1 (1)
Form: General_Day(7)
Generated On: 11 Aug 2021 22:33:31
FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:52:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (01A85E90-DEE1-40E1-A1FD-349A8271449C)', Time: '2020-08-31T00:04:23', User OID: 'PatientReportedOutcome (US3342142)', ODM File OID: '7ca9ba5f-7798-469d-945c-68de6f455853'	System	31 Aug 2020 05:04:38
User entered 'None (0)'	System	31 Aug 2020 05:04:38

US3342142
Folder: Diary Dose 1 (1)
Form: General_Day(7)
Generated On: 11 Aug 2021 22:33:31
MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:52:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (01A85E90-DEE1-40E1-A1FD-349A8271449C)', Time: '2020-08-31T00:04:24', User OID: 'PatientReportedOutcome (US3342142)', ODM File OID: '7ca9ba5f-7798-469d-945c-68de6f455853'	System	31 Aug 2020 05:04:38
User entered 'None (0)'	System	31 Aug 2020 05:04:38

US3342142
Folder: Diary Dose 1 (1)
Form: General_Day(7)
Generated On: 11 Aug 2021 22:33:31
JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:52:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (01A85E90-DEE1-40E1-A1FD-349A8271449C)', Time: '2020-08-31T00:04:26', User OID: 'PatientReportedOutcome (US3342142)', ODM File OID: '7ca9ba5f-7798-469d-945c-68de6f455853'	System	31 Aug 2020 05:04:38
User entered 'None (0)'	System	31 Aug 2020 05:04:38

US3342142
Folder: Diary Dose 1 (1)
Form: General_Day(7)
Generated On: 11 Aug 2021 22:33:31
NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:52:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (01A85E90-DEE1-40E1-A1FD-349A8271449C)', Time: '2020-08-31T00:04:27', User OID: 'PatientReportedOutcome (US3342142)', ODM File OID: '7ca9ba5f-7798-469d-945c-68de6f455853'	System	31 Aug 2020 05:04:38
User entered 'None (0)'	System	31 Aug 2020 05:04:38

US3342142
Folder: Diary Dose 1 (1)
Form: General_Day(7)
Generated On: 11 Aug 2021 22:33:31
CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:52:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (01A85E90-DEE1-40E1-A1FD-349A8271449C)', Time: '2020-08-31T00:04:28', User OID: 'PatientReportedOutcome (US3342142)', ODM File OID: '7ca9ba5f-7798-469d-945c-68de6f455853'	System	31 Aug 2020 05:04:38
User entered 'None (0)'	System	31 Aug 2020 05:04:38

US3342142
Folder: Diary Dose 1 (1)
Form: General_Day(7)
Generated On: 11 Aug 2021 22:33:31
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 14:52:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (01A85E90-DEE1-40E1-A1FD-349A8271449C)', Time: '2020-08-31T00:04:32', User OID: 'PatientReportedOutcome (US3342142)', ODM File OID: '7ca9ba5f-7798-469d-945c-68de6f455853'	System	31 Aug 2020 05:04:38
User entered 'No (N)'	System	31 Aug 2020 05:04:38

US3342142
Folder: Diary Dose 1 (1)
Form: General_Day(7)
Generated On: 11 Aug 2021 22:33:31
PC Time stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:52:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (01A85E90-DEE1-40E1-A1FD-349A8271449C)', Time: '2020-08-31T00:04:34', User OID: 'PatientReportedOutcome (US3342142)', ODM File OID: '7ca9ba5f-7798-469d-945c-68de6f455853'	System	31 Aug 2020 05:04:38
User entered '31 Aug 2020 00:04'	System	31 Aug 2020 05:04:38

FDA-CBER-2022-1614-2809211

US3342142
Folder: Diary Dose 1 (1)
Form: General_Day(7)
Generated On: 11 Aug 2021 22:33:31
PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:52:22
User entered '30 Aug 2020 12:00'	System	24 Aug 2020 17:43:00

US3342142
Folder: Diary Dose 1 (1)
Form: General_Day(7)
Generated On: 11 Aug 2021 22:33:31
PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:52:22
User entered '31 Aug 2020 11:59'	System	24 Aug 2020 17:43:00

US3342142
Folder: Safety Call Day 8 (1)
Form: Safety Call
Generated On: 11 Aug 2021 22:33:31
Was Contact Attempted?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:29:43
User signature succeeded.	Paul Pickrell (b) (4) (b) (4)	12 Mar 2021 23:16:48
User entered 'Yes (Y)'	Ethan Shotton (b) (4) (b) (4)	31 Aug 2020 22:18:49

US3342142
Folder: Safety Call Day 8 (1)
Form: Safety Call
Generated On: 11 Aug 2021 22:33:31
Date of Contact or Contact Attempt *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:29:43
User signature succeeded.	Paul Pickrell (b) (4) (b) (4)	12 Mar 2021 23:16:48
User entered '31 Aug 2020'	Ethan Shotton (b) (4) (b) (4)	31 Aug 2020 22:18:49

US3342142
Folder: Safety Call Day 8 (1)
Form: Safety Call
Generated On: 11 Aug 2021 22:33:31
Please select one status for the follow-up contact

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:29:43
User signature succeeded.	Paul Pickrell (b) (4) (b) (4)	12 Mar 2021 23:16:48
User entered 'Contact Made (CONTACT MADE)'	Ethan Shotton (b) (4) (b) (4)	31 Aug 2020 22:18:49

US3342142
Folder: Safety Call Day 8 (1)
Form: Safety Call
Generated On: 11 Aug 2021 22:33:31
Comments

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:29:43
User signature succeeded.	Paul Pickrell (b) (4) (b) (4)	12 Mar 2021 23:16:48
User entered empty.	Ethan Shotton (b) (4) (b) (4)	31 Aug 2020 22:18:49

US3342142
Folder: Safety Call Day 8 (1)
Form: Continuing
Generated On: 11 Aug 2021 22:33:31
Is the participant continuing to the next visit?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:29:43
User signature succeeded.	Paul Pickrell (b) (4) (b) (4)	12 Mar 2021 23:16:48
User entered 'Yes (Y)'	Ethan Shotton (b) (4) (b) (4)	31 Aug 2020 22:18:53

US3342142
Folder: Safety Call Day 8 (1)
Form: Continuing
Generated On: 11 Aug 2021 22:33:31
Continuing Flag

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:29:43
User entered '1'	System	31 Aug 2020 22:18:53

US3342142
Folder: Safety Call Day 15 (1)
Form: Safety Call
Generated On: 11 Aug 2021 22:33:31
Was Contact Attempted?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:29:43
User signature succeeded.	Paul Pickrell (b) (4) (b) (4)	12 Mar 2021 23:16:48
User entered 'Yes (Y)'	Ethan Shotton (b) (4) (b) (4)	08 Sep 2020 17:48:32

US3342142
Folder: Safety Call Day 15 (1)
Form: Safety Call
Generated On: 11 Aug 2021 22:33:31
Date of Contact or Contact Attempt *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:29:43
User signature succeeded.	Paul Pickrell (b) (4) (b) (4)	12 Mar 2021 23:16:48
User entered '8 Sep 2020'	Ethan Shotton (b) (4) (b) (4)	08 Sep 2020 17:48:32

US3342142
Folder: Safety Call Day 15 (1)
Form: Safety Call
Generated On: 11 Aug 2021 22:33:31
Please select one status for the follow-up contact

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:29:43
User signature succeeded.	Paul Pickrell (b) (4) (b) (4)	12 Mar 2021 23:16:48
User entered 'Contact Made (CONTACT MADE)'	Ethan Shotton (b) (4) (b) (4)	08 Sep 2020 17:48:32

US3342142
Folder: Safety Call Day 15 (1)
Form: Safety Call
Generated On: 11 Aug 2021 22:33:31
Comments

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:29:43
User signature succeeded.	Paul Pickrell (b) (4) (b) (4)	12 Mar 2021 23:16:48
User entered empty.	Ethan Shotton (b) (4) (b) (4)	08 Sep 2020 17:48:32

US3342142
Folder: Safety Call Day 15 (1)
Form: Continuing
Generated On: 11 Aug 2021 22:33:31
Is the participant continuing to the next visit?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:29:43
User signature succeeded.	Paul Pickrell (b) (4) (b) (4)	12 Mar 2021 23:16:48
User entered 'Yes (Y)'	Ethan Shotton (b) (4) (b) (4)	08 Sep 2020 17:48:36

US3342142
Folder: Safety Call Day 15 (1)
Form: Continuing
Generated On: 11 Aug 2021 22:33:31
Continuing Flag

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:29:43
User entered '1'	System	08 Sep 2020 17:48:36

US3342142
Folder: Safety Call Day 22 (1)
Form: Safety Call
Generated On: 11 Aug 2021 22:33:31
Was Contact Attempted?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:29:43
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:16:48
User entered 'Yes (Y)'	(b) (4), (b) (6)	21 Sep 2020 18:52:32

US3342142
Folder: Safety Call Day 22 (1)
Form: Safety Call
Generated On: 11 Aug 2021 22:33:31
Date of Contact or Contact Attempt *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:29:43
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:16:48
User entered '14 Sep 2020'	(b) (4) (b) (4), (b) (6)	21 Sep 2020 18:52:32

US3342142
Folder: Safety Call Day 22 (1)
Form: Safety Call
Generated On: 11 Aug 2021 22:33:31
Please select one status for the follow-up contact

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:29:43
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:16:48
User entered 'Contact Made (CONTACT MADE)'	(b) (4) (b) (4), (b) (6)	21 Sep 2020 18:52:32

FDA-CBER-2022-1614-2809228

US3342142
Folder: Safety Call Day 22 (1)
Form: Safety Call
Generated On: 11 Aug 2021 22:33:31
Comments

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:29:43
User signature succeeded.	Paul Pickrell (b) (4) (b) (4)	12 Mar 2021 23:16:48
User entered empty.	(b) (4), (b) (6)	21 Sep 2020 18:52:32

FDA-CBER-2022-1614-2809229

US3342142
Folder: Safety Call Day 22 (1)
Form: Continuing
Generated On: 11 Aug 2021 22:33:31
Is the participant continuing to the next visit?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:29:43
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:16:48
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	21 Sep 2020 18:52:48

FDA-CBER-2022-1614-2809230

US3342142
Folder: Safety Call Day 22 (1)
Form: Continuing
Generated On: 11 Aug 2021 22:33:31
Continuing Flag

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:29:43
User entered '1'	System	21 Sep 2020 18:52:48

US3342142
Folder: Visit 2 Day 29 (1)
Form: Visit Date
Generated On: 11 Aug 2021 22:33:31
Was this visit performed?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 12:53:53
User signature succeeded.	Paul Pickrell (b) (4) (b) (4)	12 Mar 2021 23:16:48
User entered 'Yes (Y)'	(b) (4), (b) (6)	21 Sep 2020 18:53:05

US3342142
Folder: Visit 2 Day 29 (1)
Form: Visit Date
Generated On: 11 Aug 2021 22:33:31
Visit date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 12:53:53
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:16:48
User entered '21 Sep 2020'	(b) (4), (b) (6)	21 Sep 2020 18:53:05

FDA-CBER-2022-1614-2809233

US3342142
Folder: Visit 2 Day 29 (1)
Form: Visit Date
Generated On: 11 Aug 2021 22:33:31
Was visit performed at the participant's home or at the clinic?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 12:53:53
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:16:48
User entered 'Clinic (Clinic)'	(b) (4), (b) (6)	21 Sep 2020 18:53:05

US3342142
Folder: Visit 2 Day 29 (1)
Form: Visit Date
Generated On: 11 Aug 2021 22:33:31
Folder OID

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 12:53:53
User entered 'VISIT2'	System	21 Sep 2020 18:53:05

FDA-CBER-2022-1614-2809235

US3342142
Folder: Visit 2 Day 29 (1)
Form: Vital Signs - Dosing (1)
Generated On: 11 Aug 2021 22:33:31
Timepoint

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 12:53:53
User accepted default value 'Pre-Dose (PREDOSE)'	(b) (4), (b) (6)	21 Sep 2020 18:54:27

FDA-CBER-2022-1614-2809236

US3342142
Folder: Visit 2 Day 29 (1)
Form: Vital Signs - Dosing (1)
Generated On: 11 Aug 2021 22:33:31
Were vital signs assessed?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 12:53:53
User signature succeeded.	Paul Pickrell (b) (4) (b) (4)	12 Mar 2021 23:16:48
User entered 'Yes (Y)'	(b) (4), (b) (6)	21 Sep 2020 18:54:27

FDA-CBER-2022-1614-2809237

US3342142
Folder: Visit 2 Day 29 (1)
Form: Vital Signs - Dosing (1)
Generated On: 11 Aug 2021 22:33:31
Date of assessment *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 12:53:53
User signature succeeded.	Paul Pickrell (b) (4) (b) (4)	12 Mar 2021 23:16:48
User entered '21 Sep 2020'	(b) (4), (b) (6)	21 Sep 2020 18:54:27

FDA-CBER-2022-1614-2809238

US3342142
Folder: Visit 2 Day 29 (1)
Form: Vital Signs - Dosing (1)
Generated On: 11 Aug 2021 22:33:31
Time of assessment *(00:00-23:59)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 12:53:53
User signature succeeded.	Paul Pickrell (b) (4) (b) (4)	12 Mar 2021 23:16:48
User closed query 'Pre-dose vital signs time is not prior to the Dose Time. Please review and reconcile.' (Site from System).	System	25 Sep 2020 21:12:30
User entered '13:12' reason for change: Data Entry Error	(b) (4), (b) (6)	25 Sep 2020 21:12:30
User opened query 'Pre-dose vital signs time is not prior to the Dose Time. Please review and reconcile.' (Site from System).	System	21 Sep 2020 19:31:17
User entered '13:51' reason for change: Data Entry Error	(b) (4), (b) (6)	21 Sep 2020 19:31:17
User entered '13:02'	(b) (4), (b) (6)	21 Sep 2020 18:54:27

FDA-CBER-2022-1614-2809239

US3342142
Folder: Visit 2 Day 29 (1)
Form: Vital Signs - Dosing (1)
Generated On: 11 Aug 2021 22:33:31
Vital Signs Date and Time (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 12:53:53
User entered '21 Sep 2020 13:12'	System	25 Sep 2020 21:12:30
User entered '21 Sep 2020 13:51'	System	21 Sep 2020 19:31:17
User entered '21 Sep 2020 13:02'	System	21 Sep 2020 18:54:27

FDA-CBER-2022-1614-2809240

US3342142
Folder: Visit 2 Day 29 (1)
Form: Vital Signs - Dosing (1)
Generated On: 11 Aug 2021 22:33:31
Temperature *(xxx.x)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 12:53:53
User signature succeeded.	Paul Pickrell (b) (4) (b) (4)	12 Mar 2021 23:16:48
User entered '98.7' F	(b) (4), (b) (6)	21 Sep 2020 18:54:27

FDA-CBER-2022-1614-2809241

US3342142
Folder: Visit 2 Day 29 (1)
Form: Vital Signs - Dosing (1)
Generated On: 11 Aug 2021 22:33:31
Route of measurement

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 12:53:53
User signature succeeded.	Paul Pickrell (b) (4) (b) (4)	12 Mar 2021 23:16:48
User entered 'Oral (Oral)'	(b) (4), (b) (6)	21 Sep 2020 18:54:27

FDA-CBER-2022-1614-2809242

US3342142
Folder: Visit 2 Day 29 (1)
Form: Vital Signs - Dosing (1)
Generated On: 11 Aug 2021 22:33:31
If Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 12:53:53
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:16:48
User entered empty.	(b) (4), (b) (6) (b) (4)	21 Sep 2020 18:54:27

US3342142
Folder: Visit 2 Day 29 (1)
Form: Vital Signs - Dosing (1)
Generated On: 11 Aug 2021 22:33:31
Pulse *(xxx)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 12:53:53
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:16:48
User entered '77'	(b) (4), (b) (6)	21 Sep 2020 18:54:27

US3342142
Folder: Visit 2 Day 29 (1)
Form: Vital Signs - Dosing (1)
Generated On: 11 Aug 2021 22:33:31
Pulse units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 12:53:53
User entered 'bpm'	System	21 Sep 2020 18:54:27

FDA-CBER-2022-1614-2809245

US3342142
Folder: Visit 2 Day 29 (1)
Form: Vital Signs - Dosing (1)
Generated On: 11 Aug 2021 22:33:31
Respiratory Rate *(xxx)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 12:53:53
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:16:48
User entered '12'	(b) (4), (b) (6) (b) (4)	21 Sep 2020 18:54:27

US3342142
Folder: Visit 2 Day 29 (1)
Form: Vital Signs - Dosing (1)
Generated On: 11 Aug 2021 22:33:31
Respiratory Rate units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 12:53:53
User entered 'breaths/min'	System	21 Sep 2020 18:54:27

FDA-CBER-2022-1614-2809247

US3342142
Folder: Visit 2 Day 29 (1)
Form: Vital Signs - Dosing (1)
Generated On: 11 Aug 2021 22:33:31
Systolic Blood Pressure *(xxx)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 12:53:53
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:16:48
User entered '132'	(b) (4), (b) (6) (b) (4)	21 Sep 2020 18:54:27

FDA-CBER-2022-1614-2809248

US3342142
Folder: Visit 2 Day 29 (1)
Form: Vital Signs - Dosing (1)
Generated On: 11 Aug 2021 22:33:31
Systolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 12:53:53
User entered 'mmHg'	System	21 Sep 2020 18:54:27

FDA-CBER-2022-1614-2809249

US3342142
Folder: Visit 2 Day 29 (1)
Form: Vital Signs - Dosing (1)
Generated On: 11 Aug 2021 22:33:31
Diastolic Blood Pressure *(xxx)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 12:53:53
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:16:48
User entered '81'	(b) (4), (b) (6) (b) (4)	21 Sep 2020 18:54:27

FDA-CBER-2022-1614-2809250

US3342142
Folder: Visit 2 Day 29 (1)
Form: Vital Signs - Dosing (1)
Generated On: 11 Aug 2021 22:33:31
Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 12:53:53
User entered 'mmHg'	System	21 Sep 2020 18:54:27

FDA-CBER-2022-1614-2809251

US3342142
Folder: Visit 2 Day 29 (1)
Form: Vital Signs - Dosing (2)
Generated On: 11 Aug 2021 22:33:31
Timepoint

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 12:53:53
User accepted default value 'Post-Dose (POSTDOSE)'	(b) (4), (b) (6)	21 Sep 2020 18:54:27

FDA-CBER-2022-1614-2809252

US3342142
Folder: Visit 2 Day 29 (1)
Form: Vital Signs - Dosing (2)
Generated On: 11 Aug 2021 22:33:31
Were vital signs assessed?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 12:53:53
User signature succeeded.	Paul Pickrell (b) (4) (b) (4)	12 Mar 2021 23:16:48
User closed query 'Data is required. Please complete.' (Site from System).	System	21 Sep 2020 19:28:20
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	21 Sep 2020 19:28:20
User entered 'Yes (Y)' reason for change: Data Entry Error	(b) (4), (b) (6)	21 Sep 2020 19:28:20
User opened query 'Data is required. Please complete.' (Site from System).	System	21 Sep 2020 18:54:27
User entered empty.	(b) (4), (b) (6)	21 Sep 2020 18:54:27

US3342142
Folder: Visit 2 Day 29 (1)
Form: Vital Signs - Dosing (2)
Generated On: 11 Aug 2021 22:33:31
Date of assessment *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 12:53:53
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:16:48
User entered '21 Sep 2020' reason for change: Data Entry Error	(b) (4), (b) (6)	21 Sep 2020 19:28:20
User entered empty.	(b) (4), (b) (6)	21 Sep 2020 18:54:27

US3342142
Folder: Visit 2 Day 29 (1)
Form: Vital Signs - Dosing (2)
Generated On: 11 Aug 2021 22:33:31
Time of assessment *(00:00-23:59)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 12:53:53
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:16:48
User entered '14:22' reason for change: Data Entry Error	(b) (4), (b) (6)	21 Sep 2020 19:31:17
User closed query 'Post-dose Time is prior to Pre-dose Time. Please review and reconcile.' (Site from System).	System	21 Sep 2020 19:29:35
User entered '14:52' reason for change: Data Entry Error	(b) (4), (b) (6)	21 Sep 2020 19:29:35
User opened query 'Post-dose Time is prior to Pre-dose Time. Please review and reconcile.' (Site from System).	System	21 Sep 2020 19:28:20
User entered '12:22' reason for change: Data Entry Error	(b) (4), (b) (6)	21 Sep 2020 19:28:20
User entered empty.	(b) (4), (b) (6)	21 Sep 2020 18:54:27

US3342142
Folder: Visit 2 Day 29 (1)
Form: Vital Signs - Dosing (2)
Generated On: 11 Aug 2021 22:33:31
Vital Signs Date and Time (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 12:53:53
User entered '21 Sep 2020 14:22'	System	21 Sep 2020 19:31:17
User entered '21 Sep 2020 14:52'	System	21 Sep 2020 19:29:35
User entered '21 Sep 2020 12:22'	System	21 Sep 2020 19:28:20
User entered empty.	System	21 Sep 2020 18:54:27

US3342142
Folder: Visit 2 Day 29 (1)
Form: Vital Signs - Dosing (2)
Generated On: 11 Aug 2021 22:33:31
Temperature *(xxx.x)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 12:53:53
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:16:48
User entered '98.8' F reason for change: Data Entry Error	(b) (4), (b) (6) (b) (4)	21 Sep 2020 19:28:20
User entered empty.	(b) (4), (b) (6)	21 Sep 2020 18:54:27

US3342142
Folder: Visit 2 Day 29 (1)
Form: Vital Signs - Dosing (2)
Generated On: 11 Aug 2021 22:33:31
Route of measurement

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 12:53:53
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:16:48
User entered 'Oral (Oral)' reason for change: Data Entry Error	(b) (4), (b) (6)	21 Sep 2020 19:28:20
User entered empty.	(b) (4), (b) (6)	21 Sep 2020 18:54:27

US3342142
Folder: Visit 2 Day 29 (1)
Form: Vital Signs - Dosing (2)
Generated On: 11 Aug 2021 22:33:31
If Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 12:53:53
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:16:48
User entered empty.	(b) (4), (b) (6)	21 Sep 2020 18:54:27

US3342142
Folder: Visit 2 Day 29 (1)
Form: Vital Signs - Dosing (2)
Generated On: 11 Aug 2021 22:33:31
Pulse *(xxx)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 12:53:53
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:16:48
User entered '66' reason for change: Data Entry Error	(b) (4), (b) (6)	21 Sep 2020 19:28:20
User entered empty.	(b) (4), (b) (6)	21 Sep 2020 18:54:27

US3342142
Folder: Visit 2 Day 29 (1)
Form: Vital Signs - Dosing (2)
Generated On: 11 Aug 2021 22:33:31
Pulse units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 12:53:53
User entered 'bpm'	System	21 Sep 2020 19:28:20
User entered empty.	System	21 Sep 2020 18:54:27

US3342142
Folder: Visit 2 Day 29 (1)
Form: Vital Signs - Dosing (2)
Generated On: 11 Aug 2021 22:33:31
Respiratory Rate *(xxx)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 12:53:53
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:16:48
User entered '12' reason for change: Data Entry Error	(b) (4), (b) (6)	21 Sep 2020 19:28:20
User entered empty.	(b) (4), (b) (6)	21 Sep 2020 18:54:27

US3342142
Folder: Visit 2 Day 29 (1)
Form: Vital Signs - Dosing (2)
Generated On: 11 Aug 2021 22:33:31
Respiratory Rate units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 12:53:53
User entered 'breaths/min'	System	21 Sep 2020 19:28:20
User entered empty.	System	21 Sep 2020 18:54:27

US3342142
Folder: Visit 2 Day 29 (1)
Form: Vital Signs - Dosing (2)
Generated On: 11 Aug 2021 22:33:31
Systolic Blood Pressure *(xxx)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 12:53:53
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:16:48
User entered '116' reason for change: Data Entry Error	(b) (4), (b) (6) (b) (4)	21 Sep 2020 19:28:20
User entered empty.	(b) (4), (b) (6)	21 Sep 2020 18:54:27

US3342142
Folder: Visit 2 Day 29 (1)
Form: Vital Signs - Dosing (2)
Generated On: 11 Aug 2021 22:33:31
Systolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 12:53:53
User entered 'mmHg'	System	21 Sep 2020 19:28:20
User entered empty.	System	21 Sep 2020 18:54:27

US3342142
Folder: Visit 2 Day 29 (1)
Form: Vital Signs - Dosing (2)
Generated On: 11 Aug 2021 22:33:31
Diastolic Blood Pressure *(xxx)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 12:53:53
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:16:48
User entered '76' reason for change: Data Entry Error	(b) (4), (b) (6) (b) (4)	21 Sep 2020 19:28:20
User entered empty.	(b) (4), (b) (6)	21 Sep 2020 18:54:27

US3342142
Folder: Visit 2 Day 29 (1)
Form: Vital Signs - Dosing (2)
Generated On: 11 Aug 2021 22:33:31
Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 12:53:53
User entered 'mmHg'	System	21 Sep 2020 19:28:20
User entered empty.	System	21 Sep 2020 18:54:27

US3342142
Folder: Visit 2 Day 29 (1)
Form: Physical Examination
Generated On: 11 Aug 2021 22:33:31
Was the physical examination performed?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 12:53:53
User signature succeeded.	Paul Pickrell (b) (4) (b) (4)	12 Mar 2021 23:16:48
User entered 'No (N)'	(b) (4), (b) (6)	21 Sep 2020 18:54:36

US3342142
Folder: Visit 2 Day 29 (1)
Form: Physical Examination
Generated On: 11 Aug 2021 22:33:31
Date of examination *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 12:53:53
User signature succeeded.	Paul Pickrell (b) (4) (b) (4)	12 Mar 2021 23:16:48
User entered empty.	(b) (4), (b) (6)	21 Sep 2020 18:54:36

US3342142
Folder: Visit 2 Day 29 (1)
Form: Pregnancy Test
Generated On: 11 Aug 2021 22:33:31
Was the pregnancy test performed?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 12:53:53
User signature succeeded.	Paul Pickrell (b) (4) (b) (4)	12 Mar 2021 23:16:48
User entered 'Yes (Y)'	Eileen Euperio (b) (4) (b) (4)	23 Nov 2020 14:00:06

US3342142
Folder: Visit 2 Day 29 (1)
Form: Pregnancy Test
Generated On: 11 Aug 2021 22:33:31
Date of test *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 12:53:53
User signature succeeded.	Paul Pickrell (b) (4) (b) (4)	12 Mar 2021 23:16:48
User entered '21 Sep 2020'	Eileen Euperio (b) (4) (b) (4)	23 Nov 2020 14:00:06

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US3342142
Folder: Visit 2 Day 29 (1)
Form: Pregnancy Test
Generated On: 11 Aug 2021 22:33:31
Test performed

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 12:53:53
User signature succeeded.	Paul Pickrell (b) (4) (b) (4)	12 Mar 2021 23:16:48
User entered 'Urine (URINE)'	Eileen Euperio (b) (4) (b) (4)	23 Nov 2020 14:00:06

US3342142
Folder: Visit 2 Day 29 (1)
Form: Pregnancy Test
Generated On: 11 Aug 2021 22:33:31
Result

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 12:53:53
User signature succeeded.	Paul Pickrell (b) (4) (b) (4)	12 Mar 2021 23:16:48
User entered 'Negative (NEGATIVE)'	Eileen Euperio (b) (4) (b) (4)	23 Nov 2020 14:00:06

US3342142
Folder: Visit 2 Day 29 (1)
Form: Pregnancy Test
Generated On: 11 Aug 2021 22:33:31
Was FSH sample collected?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 12:53:53
User signature succeeded.	Paul Pickrell (b) (4) (b) (4)	12 Mar 2021 23:16:48
User entered 'No (N)'	Eileen Euperio (b) (4) (b) (4)	23 Nov 2020 14:00:06

US3342142
Folder: Visit 2 Day 29 (1)
Form: Pregnancy Test
Generated On: 11 Aug 2021 22:33:31
Collection date

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 12:53:53
User signature succeeded.	Paul Pickrell (b) (4) (b) (4)	12 Mar 2021 23:16:48
User entered empty.	Eileen Euperio (b) (4) (b) (4)	23 Nov 2020 14:00:06

US3342142
Folder: Visit 2 Day 29 (1)
Form: Pregnancy Test
Generated On: 11 Aug 2021 22:33:31
Collection time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 12:53:53
User signature succeeded.	Paul Pickrell (b) (4) (b) (4)	12 Mar 2021 23:16:48
User entered empty.	Eileen Euperio (b) (4) (b) (4)	23 Nov 2020 14:00:06

US3342142
Folder: Visit 2 Day 29 (1)
Form: Pregnancy Test
Generated On: 11 Aug 2021 22:33:31
Collection date and time (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 12:53:53
User entered empty.	System	23 Nov 2020 14:00:06

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US3342142
Folder: Visit 2 Day 29 (1)
Form: Exposure
Generated On: 11 Aug 2021 22:33:31
Was study treatment given?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 12:53:53
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:16:48
User entered 'Yes (Y)'	(b) (4), (b) (6) (b) (4)	21 Sep 2020 18:56:07

US3342142
Folder: Visit 2 Day 29 (1)
Form: Exposure
Generated On: 11 Aug 2021 22:33:31
If No, reason not given

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 12:53:53
User signature succeeded.	Paul Pickrell (b) (4) (b) (4)	12 Mar 2021 23:16:48
User entered empty.	(b) (4), (b) (6)	21 Sep 2020 18:56:07

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US3342142
Folder: Visit 2 Day 29 (1)
Form: Exposure
Generated On: 11 Aug 2021 22:33:31
If reason is Physician Decision, Withdrawal of Consent by Participant, Protocol Deviation, or Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 12:53:53
User signature succeeded.	Paul Pickrell (b) (4) (b) (4)	12 Mar 2021 23:16:48
User entered empty.	(b) (4), (b) (6)	21 Sep 2020 18:56:07

US3342142
Folder: Visit 2 Day 29 (1)
Form: Exposure
Generated On: 11 Aug 2021 22:33:31
What was the study treatment?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 12:53:53
User entered 'MRNA-1273 OR PLACEBO'	System	21 Sep 2020 18:56:07

US3342142
Folder: Visit 2 Day 29 (1)
Form: Exposure
Generated On: 11 Aug 2021 22:33:31
What was the treatment date? *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 12:53:53
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:16:48
User entered '21 Sep 2020'	(b) (4), (b) (6)	21 Sep 2020 18:56:07

US3342142
Folder: Visit 2 Day 29 (1)
Form: Exposure
Generated On: 11 Aug 2021 22:33:31
What was the treatment time? *(00:00-23:59)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 12:53:53
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:16:48
User entered '13:51'	(b) (4), (b) (6) (b) (4)	21 Sep 2020 18:56:07

US3342142
Folder: Visit 2 Day 29 (1)
Form: Exposure
Generated On: 11 Aug 2021 22:33:31
Treatment Date and Time (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 12:53:53
User entered '21 Sep 2020 13:51'	System	21 Sep 2020 18:56:07

US3342142
Folder: Visit 2 Day 29 (1)
Form: Exposure
Generated On: 11 Aug 2021 22:33:31
Which arm was used to give treatment?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 12:53:53
User signature succeeded.	Paul Pickrell (b) (4) (b) (4)	12 Mar 2021 23:16:48
User entered 'Left Arm (LEFT ARM)'	(b) (4), (b) (6)	21 Sep 2020 18:56:07

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US3342142
Folder: Visit 2 Day 29 (1)
Form: Exposure
Generated On: 11 Aug 2021 22:33:31
What was the frequency of the study treatment dosing?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 12:53:53
User entered 'ONCE'	System	21 Sep 2020 18:56:07

FDA-CBER-2022-1614-2809286

US3342142
Folder: Visit 2 Day 29 (1)
Form: Exposure
Generated On: 11 Aug 2021 22:33:31
What was the route of administration for the study treatment?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 12:53:53
User entered 'INTRAMUSCULAR'	System	21 Sep 2020 18:56:07

FDA-CBER-2022-1614-2809287

US3342142
Folder: Visit 2 Day 29 (1)
Form: Immunogenicity Assessment
Generated On: 11 Aug 2021 22:33:31
Was the sample collected?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 12:53:53
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:16:48
User entered 'Yes (Y)'	(b) (4), (b) (6) (b) (4)	24 Sep 2020 15:08:41

FDA-CBER-2022-1614-2809288

US3342142
Folder: Visit 2 Day 29 (1)
Form: Immunogenicity Assessment
Generated On: 11 Aug 2021 22:33:31
Collection date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 12:53:53
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:16:48
User entered '21 Sep 2020'	(b) (4), (b) (6)	24 Sep 2020 15:08:41

FDA-CBER-2022-1614-2809289

US3342142
Folder: Visit 2 Day 29 (1)
Form: Immunogenicity Assessment
Generated On: 11 Aug 2021 22:33:31
Collection time *(00:00-23:59)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 12:53:53
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:16:48
User entered '13:35'	(b) (4), (b) (6)	24 Sep 2020 15:08:41

FDA-CBER-2022-1614-2809290

US3342142
Folder: Visit 2 Day 29 (1)
Form: Immunogenicity Assessment
Generated On: 11 Aug 2021 22:33:31
Collection date and time (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 12:53:53
User entered '21 Sep 2020 13:35'	System	24 Sep 2020 15:08:41

US3342142
Folder: Visit 2 Day 29 (1)
Form: Central Laboratory - Nasopharyngeal Swab
Generated On: 11 Aug 2021 22:33:31
Collection date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 12:53:53
User signature succeeded.	Paul Pickrell (b) (4) (b) (4)	12 Mar 2021 23:16:48
User entered '21 Sep 2020'	(b) (4), (b) (6)	24 Sep 2020 15:08:55

FDA-CBER-2022-1614-2809292

US3342142
Folder: Visit 2 Day 29 (1)
Form: Central Laboratory - Nasopharyngeal Swab (1)
Generated On: 11 Aug 2021 22:33:31
Lab Test

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 12:53:53
User accepted default value 'Nasopharyngeal Swab 1 (NASAL1)'	(b) (4), (b) (6)	24 Sep 2020 15:08:55

FDA-CBER-2022-1614-2809293

US3342142
Folder: Visit 2 Day 29 (1)
Form: Central Laboratory - Nasopharyngeal Swab (1)
Generated On: 11 Aug 2021 22:33:31
Was the sample collected?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 12:53:53
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:16:48
User entered 'Yes (Y)'	(b) (4), (b) (6) (b) (4)	24 Sep 2020 15:08:55

FDA-CBER-2022-1614-2809294

US3342142
Folder: Visit 2 Day 29 (1)
Form: Central Laboratory - Nasopharyngeal Swab (1)
Generated On: 11 Aug 2021 22:33:31
Collection time *(00:00 - 23:59)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 12:53:53
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:16:48
User entered '13:37'	(b) (4), (b) (6) (b) (4)	24 Sep 2020 15:08:55

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US3342142
Folder: Visit 2 Day 29 (1)
Form: Central Laboratory - Nasopharyngeal Swab (1)
Generated On: 11 Aug 2021 22:33:31
Collection date and time (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 12:53:53
User entered '21 Sep 2020 13:37'	System	24 Sep 2020 15:08:55

US3342142
Folder: Visit 2 Day 29 (1)
Form: Central Laboratory - Nasopharyngeal Swab (2)
Generated On: 11 Aug 2021 22:33:31
Lab Test

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 12:53:53
User accepted default value 'Nasopharyngeal Swab 2 (NASAL2)'	(b) (4), (b) (6)	24 Sep 2020 15:08:55

US3342142
Folder: Visit 2 Day 29 (1)
Form: Central Laboratory - Nasopharyngeal Swab (2)
Generated On: 11 Aug 2021 22:33:31
Was the sample collected?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 12:53:53
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:16:48
User entered 'No (N)'	(b) (4), (b) (6) (b) (4)	24 Sep 2020 15:08:55

US3342142
Folder: Visit 2 Day 29 (1)
Form: Central Laboratory - Nasopharyngeal Swab (2)
Generated On: 11 Aug 2021 22:33:31
Collection time *(00:00 - 23:59)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 12:53:53
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:16:48
User entered empty.	(b) (4), (b) (6) (b) (4)	24 Sep 2020 15:08:55

US3342142
Folder: Visit 2 Day 29 (1)
Form: Central Laboratory - Nasopharyngeal Swab (2)
Generated On: 11 Aug 2021 22:33:31
Collection date and time (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 12:53:53
User entered empty.	System	24 Sep 2020 15:08:55

US3342142
Folder: Visit 2 Day 29 (1)
Form: Continuing
Generated On: 11 Aug 2021 22:33:31
Is the participant continuing to the next visit?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 12:53:53
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:16:48
User entered 'Yes (Y)'	(b) (4), (b) (6)	24 Sep 2020 15:09:08

US3342142
Folder: Visit 2 Day 29 (1)
Form: Continuing
Generated On: 11 Aug 2021 22:33:31
Continuing Flag

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 12:53:53
User entered '1'	System	24 Sep 2020 15:09:08

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US3342142
Folder: Diary Dose 2 (1)
Form: Temperature_Day(1/1)
Generated On: 11 Aug 2021 22:33:31
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:52:24
Data entry locked.	System	21 Sep 2020 18:56:07
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	21 Sep 2020 18:56:07

US3342142
Folder: Diary Dose 2 (1)
Form: Temperature_Day(1/1)
Generated On: 11 Aug 2021 22:33:31
Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:52:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (01A85E90-DEE1-40E1-A1FD-349A8271449C)', Time: '2020-09-21T14:30:11', User OID: 'PatientReportedOutcome (US3342142)', ODM File OID: 'f933d59e-731a-41d5-a7d8-c528d475f2f9'	System	21 Sep 2020 19:30:24
User entered 'Yes (Y)'	System	21 Sep 2020 19:30:24

US3342142
Folder: Diary Dose 2 (1)
Form: Temperature_Day(1/1)
Generated On: 11 Aug 2021 22:33:31
Please record your **TEMPERATURE in °F**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:52:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (01A85E90-DEE1-40E1-A1FD-349A8271449C)', Time: '2020-09-21T14:30:15', User OID: 'PatientReportedOutcome (US3342142)', ODM File OID: 'f933d59e-731a-41d5-a7d8-c528d475f2f9'	System	21 Sep 2020 19:30:24
User entered '98.8'	System	21 Sep 2020 19:30:24

US3342142
Folder: Diary Dose 2 (1)
Form: Temperature_Day(1/1)
Generated On: 11 Aug 2021 22:33:31
Was any **MEDICATION TAKEN today for pain or fever**?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:52:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (01A85E90-DEE1-40E1-A1FD-349A8271449C)', Time: '2020-09-21T14:30:17', User OID: 'PatientReportedOutcome (US3342142)', ODM File OID: 'f933d59e-731a-41d5-a7d8-c528d475f2f9'	System	21 Sep 2020 19:30:24
User entered 'No (N)'	System	21 Sep 2020 19:30:24

US3342142
Folder: Diary Dose 2 (1)
Form: Temperature_Day(1/1)
Generated On: 11 Aug 2021 22:33:31
PC Time Stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:52:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (01A85E90-DEE1-40E1-A1FD-349A8271449C)', Time: '2020-09-21T14:30:20', User OID: 'PatientReportedOutcome (US3342142)', ODM File OID: 'f933d59e-731a-41d5-a7d8-c528d475f2f9'	System	21 Sep 2020 19:30:24
User entered '21 Sep 2020 14:30'	System	21 Sep 2020 19:30:24

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US3342142
Folder: Diary Dose 2 (1)
Form: Temperature_Day(1/1)
Generated On: 11 Aug 2021 22:33:31
PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:52:24
User entered '21 Sep 2020 14:11'	System	21 Sep 2020 18:56:07

FDA-CBER-2022-1614-2809308

US3342142
Folder: Diary Dose 2 (1)
Form: Temperature_Day(1/1)
Generated On: 11 Aug 2021 22:33:31
PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:52:24
User entered '21 Sep 2020 16:41'	System	21 Sep 2020 18:56:07

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US3342142
Folder: Diary Dose 2 (1)
Form: Temperature_Day(1/2)
Generated On: 11 Aug 2021 22:33:31
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:52:24
Data entry locked.	System	21 Sep 2020 18:56:07
User entered 'Day 1, after vaccination (at home)'	System	21 Sep 2020 18:56:07

US3342142
Folder: Diary Dose 2 (1)
Form: Temperature_Day(1/2)
Generated On: 11 Aug 2021 22:33:31
Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:52:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (01A85E90-DEE1-40E1-A1FD-349A8271449C)', Time: '2020-09-21T21:37:06', User OID: 'PatientReportedOutcome (US3342142)', ODM File OID: 'f8b194d0-9d8c-43a2-99b8-2c28a6d8230d'	System	22 Sep 2020 02:37:16
User entered 'Yes (Y)'	System	22 Sep 2020 02:37:16

FDA-CBER-2022-1614-2809311

US3342142
Folder: Diary Dose 2 (1)
Form: Temperature_Day(1/2)
Generated On: 11 Aug 2021 22:33:31
Please record your **TEMPERATURE in °F**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:52:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (01A85E90-DEE1-40E1-A1FD-349A8271449C)', Time: '2020-09-21T21:37:09', User OID: 'PatientReportedOutcome (US3342142)', ODM File OID: 'f8b194d0-9d8c-43a2-99b8-2c28a6d8230d'	System	22 Sep 2020 02:37:16
User entered '97.2'	System	22 Sep 2020 02:37:16

US3342142
Folder: Diary Dose 2 (1)
Form: Temperature_Day(1/2)
Generated On: 11 Aug 2021 22:33:31
Was any **MEDICATION TAKEN today for pain or fever**?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:52:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (01A85E90-DEE1-40E1-A1FD-349A8271449C)', Time: '2020-09-21T21:37:12', User OID: 'PatientReportedOutcome (US3342142)', ODM File OID: 'f8b194d0-9d8c-43a2-99b8-2c28a6d8230d'	System	22 Sep 2020 02:37:16
User entered 'No (N)'	System	22 Sep 2020 02:37:16

FDA-CBER-2022-1614-2809313

US3342142
Folder: Diary Dose 2 (1)
Form: Temperature_Day(1/2)
Generated On: 11 Aug 2021 22:33:31
PC Time Stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:52:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (01A85E90-DEE1-40E1-A1FD-349A8271449C)', Time: '2020-09-21T21:37:14', User OID: 'PatientReportedOutcome (US3342142)', ODM File OID: 'f8b194d0-9d8c-43a2-99b8-2c28a6d8230d'	System	22 Sep 2020 02:37:16
User entered '21 Sep 2020 21:37'	System	22 Sep 2020 02:37:16

FDA-CBER-2022-1614-2809314

US3342142
Folder: Diary Dose 2 (1)
Form: Temperature_Day(1/2)
Generated On: 11 Aug 2021 22:33:31
PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:52:24
User entered '21 Sep 2020 17:36'	System	21 Sep 2020 18:56:07

FDA-CBER-2022-1614-2809315

US3342142
Folder: Diary Dose 2 (1)
Form: Temperature_Day(1/2)
Generated On: 11 Aug 2021 22:33:31
PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:52:24
User entered '22 Sep 2020 11:59'	System	21 Sep 2020 18:56:07

FDA-CBER-2022-1614-2809316

US3342142
Folder: Diary Dose 2 (1)
Form: Temperature_Day(2)
Generated On: 11 Aug 2021 22:33:31
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:52:24
Data entry locked.	System	21 Sep 2020 18:56:07
User entered 'Day 2'	System	21 Sep 2020 18:56:07

US3342142
Folder: Diary Dose 2 (1)
Form: Temperature_Day(2)
Generated On: 11 Aug 2021 22:33:31
Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:52:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (01A85E90-DEE1-40E1-A1FD-349A8271449C)', Time: '2020-09-22T21:14:26', User OID: 'PatientReportedOutcome (US3342142)', ODM File OID: 'c5a8ee47-b1d4-472a-bbdf-449637142a23'	System	23 Sep 2020 02:14:40
User entered 'Yes (Y)'	System	23 Sep 2020 02:14:40

FDA-CBER-2022-1614-2809318

US3342142
Folder: Diary Dose 2 (1)
Form: Temperature_Day(2)
Generated On: 11 Aug 2021 22:33:31
Please record your **TEMPERATURE in °F**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:52:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (01A85E90-DEE1-40E1-A1FD-349A8271449C)', Time: '2020-09-22T21:14:31', User OID: 'PatientReportedOutcome (US3342142)', ODM File OID: 'c5a8ee47-b1d4-472a-bbdf-449637142a23'	System	23 Sep 2020 02:14:40
User entered '98.0'	System	23 Sep 2020 02:14:40

FDA-CBER-2022-1614-2809319

US3342142
Folder: Diary Dose 2 (1)
Form: Temperature_Day(2)
Generated On: 11 Aug 2021 22:33:31
Was any **MEDICATION TAKEN today for pain or fever**?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:52:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (01A85E90-DEE1-40E1-A1FD-349A8271449C)', Time: '2020-09-22T21:14:34', User OID: 'PatientReportedOutcome (US3342142)', ODM File OID: 'c5a8ee47-b1d4-472a-bbdf-449637142a23'	System	23 Sep 2020 02:14:40
User entered 'No (N)'	System	23 Sep 2020 02:14:40

FDA-CBER-2022-1614-2809320

US3342142
Folder: Diary Dose 2 (1)
Form: Temperature_Day(2)
Generated On: 11 Aug 2021 22:33:31
PC Time Stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:52:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (01A85E90-DEE1-40E1-A1FD-349A8271449C)', Time: '2020-09-22T21:14:36', User OID: 'PatientReportedOutcome (US3342142)', ODM File OID: 'c5a8ee47-b1d4-472a-bbdf-449637142a23'	System	23 Sep 2020 02:14:40
User entered '22 Sep 2020 21:14'	System	23 Sep 2020 02:14:40

FDA-CBER-2022-1614-2809321

US3342142
Folder: Diary Dose 2 (1)
Form: Temperature_Day(2)
Generated On: 11 Aug 2021 22:33:31
PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:52:24
User entered '22 Sep 2020 12:00'	System	21 Sep 2020 18:56:07

FDA-CBER-2022-1614-2809322

US3342142
Folder: Diary Dose 2 (1)
Form: Temperature_Day(2)
Generated On: 11 Aug 2021 22:33:31
PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:52:24
User entered '23 Sep 2020 11:59'	System	21 Sep 2020 18:56:07

FDA-CBER-2022-1614-2809323

US3342142
Folder: Diary Dose 2 (1)
Form: Temperature_Day(3)
Generated On: 11 Aug 2021 22:33:31
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:52:24
Data entry locked.	System	21 Sep 2020 18:56:07
User entered 'Day 3'	System	21 Sep 2020 18:56:07

US3342142
Folder: Diary Dose 2 (1)
Form: Temperature_Day(3)
Generated On: 11 Aug 2021 22:33:31
Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:52:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (01A85E90-DEE1-40E1-A1FD-349A8271449C)', Time: '2020-09-23T21:41:51', User OID: 'PatientReportedOutcome (US3342142)', ODM File OID: '973e037f-e8d7-424b-8a2d-1b5607ad016c'	System	24 Sep 2020 02:42:04
User entered 'Yes (Y)'	System	24 Sep 2020 02:42:04

FDA-CBER-2022-1614-2809325

US3342142
Folder: Diary Dose 2 (1)
Form: Temperature_Day(3)
Generated On: 11 Aug 2021 22:33:31
Please record your **TEMPERATURE in °F**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:52:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (01A85E90-DEE1-40E1-A1FD-349A8271449C)', Time: '2020-09-23T21:41:54', User OID: 'PatientReportedOutcome (US3342142)', ODM File OID: '973e037f-e8d7-424b-8a2d-1b5607ad016c'	System	24 Sep 2020 02:42:04
User entered '98.8'	System	24 Sep 2020 02:42:04

FDA-CBER-2022-1614-2809326

US3342142
Folder: Diary Dose 2 (1)
Form: Temperature_Day(3)
Generated On: 11 Aug 2021 22:33:31
Was any **MEDICATION TAKEN today for pain or fever**?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:52:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (01A85E90-DEE1-40E1-A1FD-349A8271449C)', Time: '2020-09-23T21:41:57', User OID: 'PatientReportedOutcome (US3342142)', ODM File OID: '973e037f-e8d7-424b-8a2d-1b5607ad016c'	System	24 Sep 2020 02:42:04
User entered 'No (N)'	System	24 Sep 2020 02:42:04

FDA-CBER-2022-1614-2809327

US3342142
Folder: Diary Dose 2 (1)
Form: Temperature_Day(3)
Generated On: 11 Aug 2021 22:33:31
PC Time Stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:52:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (01A85E90-DEE1-40E1-A1FD-349A8271449C)', Time: '2020-09-23T21:41:59', User OID: 'PatientReportedOutcome (US3342142)', ODM File OID: '973e037f-e8d7-424b-8a2d-1b5607ad016c'	System	24 Sep 2020 02:42:04
User entered '23 Sep 2020 21:41'	System	24 Sep 2020 02:42:04

FDA-CBER-2022-1614-2809328

US3342142
Folder: Diary Dose 2 (1)
Form: Temperature_Day(3)
Generated On: 11 Aug 2021 22:33:31
PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:52:24
User entered '23 Sep 2020 12:00'	System	21 Sep 2020 18:56:07

FDA-CBER-2022-1614-2809329

US3342142
Folder: Diary Dose 2 (1)
Form: Temperature_Day(3)
Generated On: 11 Aug 2021 22:33:31
PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:52:24
User entered '24 Sep 2020 11:59'	System	21 Sep 2020 18:56:07

FDA-CBER-2022-1614-2809330

US3342142
Folder: Diary Dose 2 (1)
Form: Temperature_Day(4)
Generated On: 11 Aug 2021 22:33:31
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:52:24
Data entry locked.	System	21 Sep 2020 18:56:07
User entered 'Day 4'	System	21 Sep 2020 18:56:07

US3342142
Folder: Diary Dose 2 (1)
Form: Temperature_Day(4)
Generated On: 11 Aug 2021 22:33:31
Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:52:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (01A85E90-DEE1-40E1-A1FD-349A8271449C)', Time: '2020-09-25T01:52:42', User OID: 'PatientReportedOutcome (US3342142)', ODM File OID: 'f8b166e0-6fbe-463a-ae6c-41f83f07ab73'	System	25 Sep 2020 06:53:18
User entered 'Yes (Y)'	System	25 Sep 2020 06:53:18

FDA-CBER-2022-1614-2809332

US3342142
Folder: Diary Dose 2 (1)
Form: Temperature_Day(4)
Generated On: 11 Aug 2021 22:33:31
Please record your **TEMPERATURE in °F**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:52:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (01A85E90-DEE1-40E1-A1FD-349A8271449C)', Time: '2020-09-25T01:52:46', User OID: 'PatientReportedOutcome (US3342142)', ODM File OID: 'f8b166e0-6fbe-463a-ae6c-41f83f07ab73'	System	25 Sep 2020 06:53:18
User entered '98.8'	System	25 Sep 2020 06:53:18

US3342142
Folder: Diary Dose 2 (1)
Form: Temperature_Day(4)
Generated On: 11 Aug 2021 22:33:31
Was any **MEDICATION TAKEN today for pain or fever**?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:52:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (01A85E90-DEE1-40E1-A1FD-349A8271449C)', Time: '2020-09-25T01:52:57', User OID: 'PatientReportedOutcome (US3342142)', ODM File OID: 'f8b166e0-6fbe-463a-ae6c-41f83f07ab73'	System	25 Sep 2020 06:53:18
User entered 'Yes (Y)'	System	25 Sep 2020 06:53:18

FDA-CBER-2022-1614-2809334

US3342142
Folder: Diary Dose 2 (1)
Form: Temperature_Day(4)
Generated On: 11 Aug 2021 22:33:31
To **TREAT** pain or fever that has already occurred

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:52:24
User closed query 'Per the participant response, medication was taken to treat pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' (Site from System).	(b) (4), (b) (6)	02 Oct 2020 12:00:58
Query 'Per the participant response, medication was taken to treat pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' answered with 'UPDATED' (Site from System).	Darrell O'Brien (b) (4) (b) (4)	29 Sep 2020 19:02:11
User opened query 'Per the participant response, medication was taken to treat pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' (Site from System).	System	25 Sep 2020 06:53:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (01A85E90-DEE1-40E1-A1FD-349A8271449C)', Time: '2020-09-25T01:53:09', User OID: 'PatientReportedOutcome (US3342142)', ODM File OID: 'f8b166e0-6fbe-463a-ae6c-41f83f07ab73'	System	25 Sep 2020 06:53:18
User entered '1'	System	25 Sep 2020 06:53:18

US3342142
Folder: Diary Dose 2 (1)
Form: Temperature_Day(4)
Generated On: 11 Aug 2021 22:33:31
To **PREVENT** pain or fever from occurring

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:52:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (01A85E90-DEE1-40E1-A1FD-349A8271449C)', Time: '2020-09-25T01:53:09', User OID: 'PatientReportedOutcome (US3342142)', ODM File OID: 'f8b166e0-6fbe-463a-ae6c-41f83f07ab73'	System	25 Sep 2020 06:53:18
User entered '0'	System	25 Sep 2020 06:53:18

FDA-CBER-2022-1614-2809336

US3342142
Folder: Diary Dose 2 (1)
Form: Temperature_Day(4)
Generated On: 11 Aug 2021 22:33:31
PC Time Stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:52:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (01A85E90-DEE1-40E1-A1FD-349A8271449C)', Time: '2020-09-25T01:53:14', User OID: 'PatientReportedOutcome (US3342142)', ODM File OID: 'f8b166e0-6fbe-463a-ae6c-41f83f07ab73'	System	25 Sep 2020 06:53:18
User entered '25 Sep 2020 01:53'	System	25 Sep 2020 06:53:18

FDA-CBER-2022-1614-2809337

US3342142
Folder: Diary Dose 2 (1)
Form: Temperature_Day(4)
Generated On: 11 Aug 2021 22:33:31
PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:52:24
User entered '24 Sep 2020 12:00'	System	21 Sep 2020 18:56:07

FDA-CBER-2022-1614-2809338

US3342142
Folder: Diary Dose 2 (1)
Form: Temperature_Day(4)
Generated On: 11 Aug 2021 22:33:31
PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:52:24
User entered '25 Sep 2020 11:59'	System	21 Sep 2020 18:56:07

FDA-CBER-2022-1614-2809339

US3342142
Folder: Diary Dose 2 (1)
Form: Temperature_Day(5)
Generated On: 11 Aug 2021 22:33:31
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:52:24
Data entry locked.	System	21 Sep 2020 18:56:07
User entered 'Day 5'	System	21 Sep 2020 18:56:07

US3342142
Folder: Diary Dose 2 (1)
Form: Temperature_Day(5)
Generated On: 11 Aug 2021 22:33:31
Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:52:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (01A85E90-DEE1-40E1-A1FD-349A8271449C)', Time: '2020-09-25T23:15:16', User OID: 'PatientReportedOutcome (US3342142)', ODM File OID: '8098a2f5-c322-4a17-950f-fece0366d6b3'	System	26 Sep 2020 04:15:36
User entered 'Yes (Y)'	System	26 Sep 2020 04:15:36

FDA-CBER-2022-1614-2809341

US3342142
Folder: Diary Dose 2 (1)
Form: Temperature_Day(5)
Generated On: 11 Aug 2021 22:33:31
Please record your **TEMPERATURE in °F**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:52:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (01A85E90-DEE1-40E1-A1FD-349A8271449C)', Time: '2020-09-25T23:15:19', User OID: 'PatientReportedOutcome (US3342142)', ODM File OID: '8098a2f5-c322-4a17-950f-fece0366d6b3'	System	26 Sep 2020 04:15:36
User entered '99.2'	System	26 Sep 2020 04:15:36

FDA-CBER-2022-1614-2809342

US3342142
Folder: Diary Dose 2 (1)
Form: Temperature_Day(5)
Generated On: 11 Aug 2021 22:33:31
Was any **MEDICATION TAKEN today for pain or fever**?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:52:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (01A85E90-DEE1-40E1-A1FD-349A8271449C)', Time: '2020-09-25T23:15:26', User OID: 'PatientReportedOutcome (US3342142)', ODM File OID: '8098a2f5-c322-4a17-950f-fece0366d6b3'	System	26 Sep 2020 04:15:36
User entered 'Yes (Y)'	System	26 Sep 2020 04:15:36

FDA-CBER-2022-1614-2809343

US3342142
Folder: Diary Dose 2 (1)
Form: Temperature_Day(5)
Generated On: 11 Aug 2021 22:33:31
To **TREAT** pain or fever that has already occurred

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:52:24
User closed query 'Per the participant response, medication was taken to treat pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' (Site from System).	(b) (4), (b) (6)	02 Oct 2020 12:01:01
Query 'Per the participant response, medication was taken to treat pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' answered with 'UPDATED' (Site from System).	Darrell O'Brien (b) (4) (b) (4)	29 Sep 2020 19:02:32
User opened query 'Per the participant response, medication was taken to treat pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' (Site from System).	System	26 Sep 2020 04:15:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (01A85E90-DEE1-40E1-A1FD-349A8271449C)', Time: '2020-09-25T23:15:30', User OID: 'PatientReportedOutcome (US3342142)', ODM File OID: '8098a2f5-c322-4a17-950f-fece0366d6b3'	System	26 Sep 2020 04:15:36
User entered '1'	System	26 Sep 2020 04:15:36

FDA-CBER-2022-1614-2809344

US3342142
Folder: Diary Dose 2 (1)
Form: Temperature_Day(5)
Generated On: 11 Aug 2021 22:33:31
To **PREVENT** pain or fever from occurring

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:52:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (01A85E90-DEE1-40E1-A1FD-349A8271449C)', Time: '2020-09-25T23:15:30', User OID: 'PatientReportedOutcome (US3342142)', ODM File OID: '8098a2f5-c322-4a17-950f-fece0366d6b3'	System	26 Sep 2020 04:15:36
User entered '0'	System	26 Sep 2020 04:15:36

FDA-CBER-2022-1614-2809345

US3342142
Folder: Diary Dose 2 (1)
Form: Temperature_Day(5)
Generated On: 11 Aug 2021 22:33:31
PC Time Stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:52:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (01A85E90-DEE1-40E1-A1FD-349A8271449C)', Time: '2020-09-25T23:15:33', User OID: 'PatientReportedOutcome (US3342142)', ODM File OID: '8098a2f5-c322-4a17-950f-fece0366d6b3'	System	26 Sep 2020 04:15:36
User entered '25 Sep 2020 23:15'	System	26 Sep 2020 04:15:36

FDA-CBER-2022-1614-2809346

US3342142
Folder: Diary Dose 2 (1)
Form: Temperature_Day(5)
Generated On: 11 Aug 2021 22:33:31
PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:52:24
User entered '25 Sep 2020 12:00'	System	21 Sep 2020 18:56:07

FDA-CBER-2022-1614-2809347

US3342142
Folder: Diary Dose 2 (1)
Form: Temperature_Day(5)
Generated On: 11 Aug 2021 22:33:31
PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:52:24
User entered '26 Sep 2020 11:59'	System	21 Sep 2020 18:56:07

FDA-CBER-2022-1614-2809348

US3342142
Folder: Diary Dose 2 (1)
Form: Temperature_Day(6)
Generated On: 11 Aug 2021 22:33:31
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:52:24
Data entry locked.	System	21 Sep 2020 18:56:07
User entered 'Day 6'	System	21 Sep 2020 18:56:07

US3342142
Folder: Diary Dose 2 (1)
Form: Temperature_Day(6)
Generated On: 11 Aug 2021 22:33:31
Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:52:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (01A85E90-DEE1-40E1-A1FD-349A8271449C)', Time: '2020-09-27T05:59:10', User OID: 'PatientReportedOutcome (US3342142)', ODM File OID: '5e6cd814-142a-495e-9449-a4151d504129'	System	27 Sep 2020 10:59:20
User entered 'Yes (Y)'	System	27 Sep 2020 10:59:20

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US3342142
Folder: Diary Dose 2 (1)
Form: Temperature_Day(6)
Generated On: 11 Aug 2021 22:33:31
Please record your **TEMPERATURE in °F**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:52:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (01A85E90-DEE1-40E1-A1FD-349A8271449C)', Time: '2020-09-27T05:59:14', User OID: 'PatientReportedOutcome (US3342142)', ODM File OID: '5e6cd814-142a-495e-9449-a4151d504129'	System	27 Sep 2020 10:59:20
User entered '98.8'	System	27 Sep 2020 10:59:20

FDA-CBER-2022-1614-2809351

US3342142
Folder: Diary Dose 2 (1)
Form: Temperature_Day(6)
Generated On: 11 Aug 2021 22:33:31
Was any **MEDICATION TAKEN today for pain or fever**?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:52:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (01A85E90-DEE1-40E1-A1FD-349A8271449C)', Time: '2020-09-27T05:59:16', User OID: 'PatientReportedOutcome (US3342142)', ODM File OID: '5e6cd814-142a-495e-9449-a4151d504129'	System	27 Sep 2020 10:59:20
User entered 'No (N)'	System	27 Sep 2020 10:59:20

FDA-CBER-2022-1614-2809352

US3342142
Folder: Diary Dose 2 (1)
Form: Temperature_Day(6)
Generated On: 11 Aug 2021 22:33:31
PC Time Stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:52:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (01A85E90-DEE1-40E1-A1FD-349A8271449C)', Time: '2020-09-27T05:59:19', User OID: 'PatientReportedOutcome (US3342142)', ODM File OID: '5e6cd814-142a-495e-9449-a4151d504129'	System	27 Sep 2020 10:59:20
User entered '27 Sep 2020 05:59'	System	27 Sep 2020 10:59:20

FDA-CBER-2022-1614-2809353

US3342142
Folder: Diary Dose 2 (1)
Form: Temperature_Day(6)
Generated On: 11 Aug 2021 22:33:31
PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:52:24
User entered '26 Sep 2020 12:00'	System	21 Sep 2020 18:56:07

FDA-CBER-2022-1614-2809354

US3342142
Folder: Diary Dose 2 (1)
Form: Temperature_Day(6)
Generated On: 11 Aug 2021 22:33:31
PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:52:24
User entered '27 Sep 2020 11:59'	System	21 Sep 2020 18:56:07

FDA-CBER-2022-1614-2809355

US3342142
Folder: Diary Dose 2 (1)
Form: Temperature_Day(7)
Generated On: 11 Aug 2021 22:33:31
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:52:24
Data entry locked.	System	21 Sep 2020 18:56:07
User entered 'Day 7'	System	21 Sep 2020 18:56:07

US3342142
Folder: Diary Dose 2 (1)
Form: Temperature_Day(7)
Generated On: 11 Aug 2021 22:33:31
Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:52:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (01A85E90-DEE1-40E1-A1FD-349A8271449C)', Time: '2020-09-28T00:24:12', User OID: 'PatientReportedOutcome (US3342142)', ODM File OID: '6593d170-0221-4b31-8143-85fea8f16bbb'	System	28 Sep 2020 05:24:30
User entered 'Yes (Y)'	System	28 Sep 2020 05:24:30

FDA-CBER-2022-1614-2809357

US3342142
Folder: Diary Dose 2 (1)
Form: Temperature_Day(7)
Generated On: 11 Aug 2021 22:33:31
Please record your **TEMPERATURE in °F**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:52:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (01A85E90-DEE1-40E1-A1FD-349A8271449C)', Time: '2020-09-28T00:24:21', User OID: 'PatientReportedOutcome (US3342142)', ODM File OID: '6593d170-0221-4b31-8143-85fea8f16bbb'	System	28 Sep 2020 05:24:30
User entered '98.7'	System	28 Sep 2020 05:24:30

FDA-CBER-2022-1614-2809358

US3342142
Folder: Diary Dose 2 (1)
Form: Temperature_Day(7)
Generated On: 11 Aug 2021 22:33:31
Was any **MEDICATION TAKEN today for pain or fever**?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:52:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (01A85E90-DEE1-40E1-A1FD-349A8271449C)', Time: '2020-09-28T00:24:23', User OID: 'PatientReportedOutcome (US3342142)', ODM File OID: '6593d170-0221-4b31-8143-85fea8f16bbb'	System	28 Sep 2020 05:24:30
User entered 'No (N)'	System	28 Sep 2020 05:24:30

FDA-CBER-2022-1614-2809359

US3342142
Folder: Diary Dose 2 (1)
Form: Temperature_Day(7)
Generated On: 11 Aug 2021 22:33:31
PC Time Stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:52:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (01A85E90-DEE1-40E1-A1FD-349A8271449C)', Time: '2020-09-28T00:24:26', User OID: 'PatientReportedOutcome (US3342142)', ODM File OID: '6593d170-0221-4b31-8143-85fea8f16bbb'	System	28 Sep 2020 05:24:30
User entered '28 Sep 2020 00:24'	System	28 Sep 2020 05:24:30

US3342142
Folder: Diary Dose 2 (1)
Form: Temperature_Day(7)
Generated On: 11 Aug 2021 22:33:31
PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:52:24
User entered '27 Sep 2020 12:00'	System	21 Sep 2020 18:56:07

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US3342142
Folder: Diary Dose 2 (1)
Form: Temperature_Day(7)
Generated On: 11 Aug 2021 22:33:31
PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:52:24
User entered '28 Sep 2020 11:59'	System	21 Sep 2020 18:56:07

FDA-CBER-2022-1614-2809362

US3342142
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(1/1)
Generated On: 11 Aug 2021 22:33:31
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:52:22
Data entry locked.	System	21 Sep 2020 18:56:07
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	21 Sep 2020 18:56:07

US3342142
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(1/1)
Generated On: 11 Aug 2021 22:33:31
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 14:52:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (01A85E90-DEE1-40E1-A1FD-349A8271449C)', Time: '2020-09-21T14:30:31', User OID: 'PatientReportedOutcome (US3342142)', ODM File OID: 'c2dbdf28-cb9f-4805-8f50-fd008b4a2460'	System	21 Sep 2020 19:31:04
User entered 'None (1)'	System	21 Sep 2020 19:31:04

US3342142
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(1/1)
Generated On: 11 Aug 2021 22:33:31
Is there any **REDNESS AT INJECTION SITE**?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:52:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (01A85E90-DEE1-40E1-A1FD-349A8271449C)', Time: '2020-09-21T14:30:45', User OID: 'PatientReportedOutcome (US3342142)', ODM File OID: 'c2dbdf28-cb9f-4805-8f50-fd008b4a2460'	System	21 Sep 2020 19:31:04
User entered 'No (N)'	System	21 Sep 2020 19:31:04

US3342142
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(1/1)
Generated On: 11 Aug 2021 22:33:31
Is there any **SWELLING/HARDNESS AT INJECTION SITE**?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:52:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (01A85E90-DEE1-40E1-A1FD-349A8271449C)', Time: '2020-09-21T14:30:47', User OID: 'PatientReportedOutcome (US3342142)', ODM File OID: 'c2dbdf28-cb9f-4805-8f50-fd008b4a2460'	System	21 Sep 2020 19:31:04
User entered 'No (N)'	System	21 Sep 2020 19:31:04

US3342142
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(1/1)
Generated On: 11 Aug 2021 22:33:31
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 14:52:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (01A85E90-DEE1-40E1-A1FD-349A8271449C)', Time: '2020-09-21T14:30:54', User OID: 'PatientReportedOutcome (US3342142)', ODM File OID: 'c2dbdf28-cb9f-4805-8f50-fd008b4a2460'	System	21 Sep 2020 19:31:04
User entered 'None (1)'	System	21 Sep 2020 19:31:04

US3342142
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(1/1)
Generated On: 11 Aug 2021 22:33:31
PC Time Stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:52:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (01A85E90-DEE1-40E1-A1FD-349A8271449C)', Time: '2020-09-21T14:30:56', User OID: 'PatientReportedOutcome (US3342142)', ODM File OID: 'c2dbdf28-cb9f-4805-8f50-fd008b4a2460'	System	21 Sep 2020 19:31:04
User entered '21 Sep 2020 14:30'	System	21 Sep 2020 19:31:04

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US3342142
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(1/1)
Generated On: 11 Aug 2021 22:33:31
PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:52:22
User entered '21 Sep 2020 14:11'	System	21 Sep 2020 18:56:07

US3342142
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(1/1)
Generated On: 11 Aug 2021 22:33:31
PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:52:22
User entered '21 Sep 2020 16:41'	System	21 Sep 2020 18:56:07

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US3342142
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(1/2)
Generated On: 11 Aug 2021 22:33:31
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:52:22
Data entry locked.	System	21 Sep 2020 18:56:07
User entered 'Day 1, after vaccination (at home)'	System	21 Sep 2020 18:56:07

US3342142
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(1/2)
Generated On: 11 Aug 2021 22:33:31
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 14:52:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (01A85E90-DEE1-40E1-A1FD-349A8271449C)', Time: '2020-09-21T21:37:20', User OID: 'PatientReportedOutcome (US3342142)', ODM File OID: 'c4bba007-1096-4353-98d1-6037501f5c54'	System	22 Sep 2020 02:37:31
User entered 'None (1)'	System	22 Sep 2020 02:37:31

US3342142
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(1/2)
Generated On: 11 Aug 2021 22:33:31
Is there any **REDNESS AT INJECTION SITE**?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:52:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (01A85E90-DEE1-40E1-A1FD-349A8271449C)', Time: '2020-09-21T21:37:22', User OID: 'PatientReportedOutcome (US3342142)', ODM File OID: 'c4bba007-1096-4353-98d1-6037501f5c54'	System	22 Sep 2020 02:37:31
User entered 'No (N)'	System	22 Sep 2020 02:37:31

US3342142
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(1/2)
Generated On: 11 Aug 2021 22:33:31
Is there any **SWELLING/HARDNESS AT INJECTION SITE**?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:52:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (01A85E90-DEE1-40E1-A1FD-349A8271449C)', Time: '2020-09-21T21:37:24', User OID: 'PatientReportedOutcome (US3342142)', ODM File OID: 'c4bba007-1096-4353-98d1-6037501f5c54'	System	22 Sep 2020 02:37:31
User entered 'No (N)'	System	22 Sep 2020 02:37:31

US3342142
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(1/2)
Generated On: 11 Aug 2021 22:33:31
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 14:52:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (01A85E90-DEE1-40E1-A1FD-349A8271449C)', Time: '2020-09-21T21:37:27', User OID: 'PatientReportedOutcome (US3342142)', ODM File OID: 'c4bba007-1096-4353-98d1-6037501f5c54'	System	22 Sep 2020 02:37:31
User entered 'None (1)'	System	22 Sep 2020 02:37:31

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US3342142
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(1/2)
Generated On: 11 Aug 2021 22:33:31
PC Time Stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:52:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (01A85E90-DEE1-40E1-A1FD-349A8271449C)', Time: '2020-09-21T21:37:29', User OID: 'PatientReportedOutcome (US3342142)', ODM File OID: 'c4bba007-1096-4353-98d1-6037501f5c54'	System	22 Sep 2020 02:37:31
User entered '21 Sep 2020 21:37'	System	22 Sep 2020 02:37:31

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US3342142
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(1/2)
Generated On: 11 Aug 2021 22:33:31
PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:52:22
User entered '21 Sep 2020 17:36'	System	21 Sep 2020 18:56:07

FDA-CBER-2022-1614-2809377

US3342142
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(1/2)
Generated On: 11 Aug 2021 22:33:31
PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:52:22
User entered '22 Sep 2020 11:59'	System	21 Sep 2020 18:56:07

FDA-CBER-2022-1614-2809378

US3342142
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(2)
Generated On: 11 Aug 2021 22:33:31
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:52:22
Data entry locked.	System	21 Sep 2020 18:56:07
User entered 'Day 2'	System	21 Sep 2020 18:56:07

US3342142
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(2)
Generated On: 11 Aug 2021 22:33:31
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 14:52:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (01A85E90-DEE1-40E1-A1FD-349A8271449C)', Time: '2020-09-22T21:14:40', User OID: 'PatientReportedOutcome (US3342142)', ODM File OID: '60e50498-ef81-4548-8186-e690cc42516a'	System	23 Sep 2020 02:15:06
User entered 'None (1)'	System	23 Sep 2020 02:15:06

US3342142
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(2)
Generated On: 11 Aug 2021 22:33:31
Is there any **REDNESS AT INJECTION SITE**?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:52:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (01A85E90-DEE1-40E1-A1FD-349A8271449C)', Time: '2020-09-22T21:14:42', User OID: 'PatientReportedOutcome (US3342142)', ODM File OID: '60e50498-ef81-4548-8186-e690cc42516a'	System	23 Sep 2020 02:15:06
User entered 'No (N)'	System	23 Sep 2020 02:15:06

US3342142
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(2)
Generated On: 11 Aug 2021 22:33:31
Is there any **SWELLING/HARDNESS AT INJECTION SITE**?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:52:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (01A85E90-DEE1-40E1-A1FD-349A8271449C)', Time: '2020-09-22T21:14:44', User OID: 'PatientReportedOutcome (US3342142)', ODM File OID: '60e50498-ef81-4548-8186-e690cc42516a'	System	23 Sep 2020 02:15:06
User entered 'No (N)'	System	23 Sep 2020 02:15:06

US3342142
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(2)
Generated On: 11 Aug 2021 22:33:31
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 14:52:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (01A85E90-DEE1-40E1-A1FD-349A8271449C)', Time: '2020-09-22T21:14:58', User OID: 'PatientReportedOutcome (US3342142)', ODM File OID: '60e50498-ef81-4548-8186-e690cc42516a'	System	23 Sep 2020 02:15:06
User entered 'None (1)'	System	23 Sep 2020 02:15:06

US3342142
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(2)
Generated On: 11 Aug 2021 22:33:31
PC Time Stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:52:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (01A85E90-DEE1-40E1-A1FD-349A8271449C)', Time: '2020-09-22T21:15:01', User OID: 'PatientReportedOutcome (US3342142)', ODM File OID: '60e50498-ef81-4548-8186-e690cc42516a'	System	23 Sep 2020 02:15:06
User entered '22 Sep 2020 21:15'	System	23 Sep 2020 02:15:06

US3342142
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(2)
Generated On: 11 Aug 2021 22:33:31
PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:52:22
User entered '22 Sep 2020 12:00'	System	21 Sep 2020 18:56:07

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US3342142
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(2)
Generated On: 11 Aug 2021 22:33:31
PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:52:22
User entered '23 Sep 2020 11:59'	System	21 Sep 2020 18:56:07

FDA-CBER-2022-1614-2809386

US3342142
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(3)
Generated On: 11 Aug 2021 22:33:31
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:52:22
Data entry locked.	System	21 Sep 2020 18:56:07
User entered 'Day 3'	System	21 Sep 2020 18:56:07

US3342142
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(3)
Generated On: 11 Aug 2021 22:33:31
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 14:52:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (01A85E90-DEE1-40E1-A1FD-349A8271449C)', Time: '2020-09-23T21:42:06', User OID: 'PatientReportedOutcome (US3342142)', ODM File OID: 'e5775098-fd72-4c6e-b787-fda14b26e905'	System	24 Sep 2020 02:42:18
User entered 'None (1)'	System	24 Sep 2020 02:42:18

US3342142
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(3)
Generated On: 11 Aug 2021 22:33:31
Is there any **REDNESS AT INJECTION SITE**?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:52:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (01A85E90-DEE1-40E1-A1FD-349A8271449C)', Time: '2020-09-23T21:42:08', User OID: 'PatientReportedOutcome (US3342142)', ODM File OID: 'e5775098-fd72-4c6e-b787-fda14b26e905'	System	24 Sep 2020 02:42:18
User entered 'No (N)'	System	24 Sep 2020 02:42:18

FDA-CBER-2022-1614-2809389

US3342142
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(3)
Generated On: 11 Aug 2021 22:33:31
Is there any **SWELLING/HARDNESS AT INJECTION SITE**?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:52:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (01A85E90-DEE1-40E1-A1FD-349A8271449C)', Time: '2020-09-23T21:42:11', User OID: 'PatientReportedOutcome (US3342142)', ODM File OID: 'e5775098-fd72-4c6e-b787-fda14b26e905'	System	24 Sep 2020 02:42:18
User entered 'No (N)'	System	24 Sep 2020 02:42:18

FDA-CBER-2022-1614-2809390

US3342142
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(3)
Generated On: 11 Aug 2021 22:33:31
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 14:52:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (01A85E90-DEE1-40E1-A1FD-349A8271449C)', Time: '2020-09-23T21:42:13', User OID: 'PatientReportedOutcome (US3342142)', ODM File OID: 'e5775098-fd72-4c6e-b787-fda14b26e905'	System	24 Sep 2020 02:42:18
User entered 'None (1)'	System	24 Sep 2020 02:42:18

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US3342142
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(3)
Generated On: 11 Aug 2021 22:33:31
PC Time Stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:52:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (01A85E90-DEE1-40E1-A1FD-349A8271449C)', Time: '2020-09-23T21:42:15', User OID: 'PatientReportedOutcome (US3342142)', ODM File OID: 'e5775098-fd72-4c6e-b787-fda14b26e905'	System	24 Sep 2020 02:42:18
User entered '23 Sep 2020 21:42'	System	24 Sep 2020 02:42:18

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US3342142
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(3)
Generated On: 11 Aug 2021 22:33:31
PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:52:22
User entered '23 Sep 2020 12:00'	System	21 Sep 2020 18:56:07

US3342142
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(3)
Generated On: 11 Aug 2021 22:33:31
PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:52:22
User entered '24 Sep 2020 11:59'	System	21 Sep 2020 18:56:07

US3342142
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(4)
Generated On: 11 Aug 2021 22:33:31
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:52:22
Data entry locked.	System	21 Sep 2020 18:56:07
User entered 'Day 4'	System	21 Sep 2020 18:56:07

US3342142
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(4)
Generated On: 11 Aug 2021 22:33:31
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 14:52:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (01A85E90-DEE1-40E1-A1FD-349A8271449C)', Time: '2020-09-25T01:53:17', User OID: 'PatientReportedOutcome (US3342142)', ODM File OID: 'c9af9adf-0148-4346-bb5d-9693fc5a8236'	System	25 Sep 2020 06:53:28
User entered 'None (1)'	System	25 Sep 2020 06:53:28

US3342142
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(4)
Generated On: 11 Aug 2021 22:33:31
Is there any **REDNESS AT INJECTION SITE**?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:52:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (01A85E90-DEE1-40E1-A1FD-349A8271449C)', Time: '2020-09-25T01:53:19', User OID: 'PatientReportedOutcome (US3342142)', ODM File OID: 'c9af9adf-0148-4346-bb5d-9693fc5a8236'	System	25 Sep 2020 06:53:28
User entered 'No (N)'	System	25 Sep 2020 06:53:28

US3342142
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(4)
Generated On: 11 Aug 2021 22:33:31
Is there any **SWELLING/HARDNESS AT INJECTION SITE**?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:52:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (01A85E90-DEE1-40E1-A1FD-349A8271449C)', Time: '2020-09-25T01:53:22', User OID: 'PatientReportedOutcome (US3342142)', ODM File OID: 'c9af9adf-0148-4346-bb5d-9693fc5a8236'	System	25 Sep 2020 06:53:28
User entered 'No (N)'	System	25 Sep 2020 06:53:28

US3342142
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(4)
Generated On: 11 Aug 2021 22:33:31
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 14:52:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (01A85E90-DEE1-40E1-A1FD-349A8271449C)', Time: '2020-09-25T01:53:24', User OID: 'PatientReportedOutcome (US3342142)', ODM File OID: 'c9af9adf-0148-4346-bb5d-9693fc5a8236'	System	25 Sep 2020 06:53:28
User entered 'None (1)'	System	25 Sep 2020 06:53:28

US3342142
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(4)
Generated On: 11 Aug 2021 22:33:31
PC Time Stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:52:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (01A85E90-DEE1-40E1-A1FD-349A8271449C)', Time: '2020-09-25T01:53:27', User OID: 'PatientReportedOutcome (US3342142)', ODM File OID: 'c9af9adf-0148-4346-bb5d-9693fc5a8236'	System	25 Sep 2020 06:53:28
User entered '25 Sep 2020 01:53'	System	25 Sep 2020 06:53:28

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US3342142
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(4)
Generated On: 11 Aug 2021 22:33:31
PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:52:22
User entered '24 Sep 2020 12:00'	System	21 Sep 2020 18:56:07

FDA-CBER-2022-1614-2809401

US3342142
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(4)
Generated On: 11 Aug 2021 22:33:31
PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:52:22
User entered '25 Sep 2020 11:59'	System	21 Sep 2020 18:56:07

FDA-CBER-2022-1614-2809402

US3342142
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(5)
Generated On: 11 Aug 2021 22:33:31
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:52:22
Data entry locked.	System	21 Sep 2020 18:56:07
User entered 'Day 5'	System	21 Sep 2020 18:56:07

US3342142
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(5)
Generated On: 11 Aug 2021 22:33:31
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 14:52:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (01A85E90-DEE1-40E1-A1FD-349A8271449C)', Time: '2020-09-25T23:15:36', User OID: 'PatientReportedOutcome (US3342142)', ODM File OID: '5bd5b846-a113-47f9-9169-2cc648c394b4'	System	26 Sep 2020 04:15:44
User entered 'None (1)'	System	26 Sep 2020 04:15:44

US3342142
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(5)
Generated On: 11 Aug 2021 22:33:31
Is there any **REDNESS AT INJECTION SITE**?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:52:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (01A85E90-DEE1-40E1-A1FD-349A8271449C)', Time: '2020-09-25T23:15:37', User OID: 'PatientReportedOutcome (US3342142)', ODM File OID: '5bd5b846-a113-47f9-9169-2cc648c394b4'	System	26 Sep 2020 04:15:44
User entered 'No (N)'	System	26 Sep 2020 04:15:44

US3342142
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(5)
Generated On: 11 Aug 2021 22:33:31
Is there any **SWELLING/HARDNESS AT INJECTION SITE**?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:52:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (01A85E90-DEE1-40E1-A1FD-349A8271449C)', Time: '2020-09-25T23:15:39', User OID: 'PatientReportedOutcome (US3342142)', ODM File OID: '5bd5b846-a113-47f9-9169-2cc648c394b4'	System	26 Sep 2020 04:15:44
User entered 'No (N)'	System	26 Sep 2020 04:15:44

US3342142
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(5)
Generated On: 11 Aug 2021 22:33:31
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 14:52:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (01A85E90-DEE1-40E1-A1FD-349A8271449C)', Time: '2020-09-25T23:15:40', User OID: 'PatientReportedOutcome (US3342142)', ODM File OID: '5bd5b846-a113-47f9-9169-2cc648c394b4'	System	26 Sep 2020 04:15:44
User entered 'None (1)'	System	26 Sep 2020 04:15:44

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US3342142
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(5)
Generated On: 11 Aug 2021 22:33:31
PC Time Stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:52:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (01A85E90-DEE1-40E1-A1FD-349A8271449C)', Time: '2020-09-25T23:15:43', User OID: 'PatientReportedOutcome (US3342142)', ODM File OID: '5bd5b846-a113-47f9-9169-2cc648c394b4'	System	26 Sep 2020 04:15:44
User entered '25 Sep 2020 23:15'	System	26 Sep 2020 04:15:44

FDA-CBER-2022-1614-2809408

US3342142
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(5)
Generated On: 11 Aug 2021 22:33:31
PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:52:22
User entered '25 Sep 2020 12:00'	System	21 Sep 2020 18:56:07

FDA-CBER-2022-1614-2809409

US3342142
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(5)
Generated On: 11 Aug 2021 22:33:31
PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:52:22
User entered '26 Sep 2020 11:59'	System	21 Sep 2020 18:56:07

FDA-CBER-2022-1614-2809410

US3342142
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(6)
Generated On: 11 Aug 2021 22:33:31
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:52:22
Data entry locked.	System	21 Sep 2020 18:56:07
User entered 'Day 6'	System	21 Sep 2020 18:56:07

US3342142
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(6)
Generated On: 11 Aug 2021 22:33:31
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 14:52:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (01A85E90-DEE1-40E1-A1FD-349A8271449C)', Time: '2020-09-27T05:59:21', User OID: 'PatientReportedOutcome (US3342142)', ODM File OID: 'eecf9591-2fc6-4676-9353-63e903b18b71'	System	27 Sep 2020 10:59:34
User entered 'None (1)'	System	27 Sep 2020 10:59:34

FDA-CBER-2022-1614-2809412

US3342142
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(6)
Generated On: 11 Aug 2021 22:33:31
Is there any **REDNESS AT INJECTION SITE**?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:52:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (01A85E90-DEE1-40E1-A1FD-349A8271449C)', Time: '2020-09-27T05:59:23', User OID: 'PatientReportedOutcome (US3342142)', ODM File OID: 'eecf9591-2fc6-4676-9353-63e903b18b71'	System	27 Sep 2020 10:59:34
User entered 'No (N)'	System	27 Sep 2020 10:59:34

FDA-CBER-2022-1614-2809413

US3342142
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(6)
Generated On: 11 Aug 2021 22:33:31
Is there any **SWELLING/HARDNESS AT INJECTION SITE**?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:52:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (01A85E90-DEE1-40E1-A1FD-349A8271449C)', Time: '2020-09-27T05:59:26', User OID: 'PatientReportedOutcome (US3342142)', ODM File OID: 'eecf9591-2fc6-4676-9353-63e903b18b71'	System	27 Sep 2020 10:59:34
User entered 'No (N)'	System	27 Sep 2020 10:59:34

US3342142
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(6)
Generated On: 11 Aug 2021 22:33:31
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 14:52:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (01A85E90-DEE1-40E1-A1FD-349A8271449C)', Time: '2020-09-27T05:59:29', User OID: 'PatientReportedOutcome (US3342142)', ODM File OID: 'eecf9591-2fc6-4676-9353-63e903b18b71'	System	27 Sep 2020 10:59:34
User entered 'None (1)'	System	27 Sep 2020 10:59:34

FDA-CBER-2022-1614-2809415

US3342142
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(6)
Generated On: 11 Aug 2021 22:33:31
PC Time Stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:52:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (01A85E90-DEE1-40E1-A1FD-349A8271449C)', Time: '2020-09-27T05:59:31', User OID: 'PatientReportedOutcome (US3342142)', ODM File OID: 'eecf9591-2fc6-4676-9353-63e903b18b71'	System	27 Sep 2020 10:59:34
User entered '27 Sep 2020 05:59'	System	27 Sep 2020 10:59:34

FDA-CBER-2022-1614-2809416

US3342142
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(6)
Generated On: 11 Aug 2021 22:33:31
PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:52:22
User entered '26 Sep 2020 12:00'	System	21 Sep 2020 18:56:07

FDA-CBER-2022-1614-2809417

US3342142
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(6)
Generated On: 11 Aug 2021 22:33:31
PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:52:22
User entered '27 Sep 2020 11:59'	System	21 Sep 2020 18:56:07

FDA-CBER-2022-1614-2809418

US3342142
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(7)
Generated On: 11 Aug 2021 22:33:31
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:52:22
Data entry locked.	System	21 Sep 2020 18:56:07
User entered 'Day 7'	System	21 Sep 2020 18:56:07

US3342142
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(7)
Generated On: 11 Aug 2021 22:33:31
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 14:52:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (01A85E90-DEE1-40E1-A1FD-349A8271449C)', Time: '2020-09-28T00:24:29', User OID: 'PatientReportedOutcome (US3342142)', ODM File OID: '361a4cf9-08e8-4b0d-809d-b9cdcb289899'	System	28 Sep 2020 05:24:43
User entered 'None (1)'	System	28 Sep 2020 05:24:43

US3342142
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(7)
Generated On: 11 Aug 2021 22:33:31
Is there any **REDNESS AT INJECTION SITE**?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:52:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (01A85E90-DEE1-40E1-A1FD-349A8271449C)', Time: '2020-09-28T00:24:31', User OID: 'PatientReportedOutcome (US3342142)', ODM File OID: '361a4cf9-08e8-4b0d-809d-b9cdcb289899'	System	28 Sep 2020 05:24:43
User entered 'No (N)'	System	28 Sep 2020 05:24:43

US3342142
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(7)
Generated On: 11 Aug 2021 22:33:31
Is there any **SWELLING/HARDNESS AT INJECTION SITE**?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:52:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (01A85E90-DEE1-40E1-A1FD-349A8271449C)', Time: '2020-09-28T00:24:33', User OID: 'PatientReportedOutcome (US3342142)', ODM File OID: '361a4cf9-08e8-4b0d-809d-b9cdcb289899'	System	28 Sep 2020 05:24:43
User entered 'No (N)'	System	28 Sep 2020 05:24:43

FDA-CBER-2022-1614-2809422

US3342142
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(7)
Generated On: 11 Aug 2021 22:33:31
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 14:52:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (01A85E90-DEE1-40E1-A1FD-349A8271449C)', Time: '2020-09-28T00:24:35', User OID: 'PatientReportedOutcome (US3342142)', ODM File OID: '361a4cf9-08e8-4b0d-809d-b9cdcb289899'	System	28 Sep 2020 05:24:43
User entered 'None (1)'	System	28 Sep 2020 05:24:43

US3342142
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(7)
Generated On: 11 Aug 2021 22:33:31
PC Time Stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:52:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (01A85E90-DEE1-40E1-A1FD-349A8271449C)', Time: '2020-09-28T00:24:41', User OID: 'PatientReportedOutcome (US3342142)', ODM File OID: '361a4cf9-08e8-4b0d-809d-b9cdcb289899'	System	28 Sep 2020 05:24:43
User entered '28 Sep 2020 00:24'	System	28 Sep 2020 05:24:43

FDA-CBER-2022-1614-2809424

US3342142
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(7)
Generated On: 11 Aug 2021 22:33:31
PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:52:22
User entered '27 Sep 2020 12:00'	System	21 Sep 2020 18:56:07

FDA-CBER-2022-1614-2809425

US3342142
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(7)
Generated On: 11 Aug 2021 22:33:31
PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:52:22
User entered '28 Sep 2020 11:59'	System	21 Sep 2020 18:56:07

FDA-CBER-2022-1614-2809426

US3342142
Folder: Diary Dose 2 (1)
Form: General_Day(1/1)
Generated On: 11 Aug 2021 22:33:31
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:52:22
Data entry locked.	System	21 Sep 2020 18:56:07
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	21 Sep 2020 18:56:07

US3342142
Folder: Diary Dose 2 (1)
Form: General_Day(1/1)
Generated On: 11 Aug 2021 22:33:31
HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:52:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (01A85E90-DEE1-40E1-A1FD-349A8271449C)', Time: '2020-09-21T14:31:00', User OID: 'PatientReportedOutcome (US3342142)', ODM File OID: 'd82ee0b7-2aa5-47be-9add-d95067dbaf7c'	System	21 Sep 2020 19:31:17
User entered 'None (0)'	System	21 Sep 2020 19:31:17

FDA-CBER-2022-1614-2809428

US3342142
Folder: Diary Dose 2 (1)
Form: General_Day(1/1)
Generated On: 11 Aug 2021 22:33:31
FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:52:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (01A85E90-DEE1-40E1-A1FD-349A8271449C)', Time: '2020-09-21T14:31:02', User OID: 'PatientReportedOutcome (US3342142)', ODM File OID: 'd82ee0b7-2aa5-47be-9add-d95067dbaf7c'	System	21 Sep 2020 19:31:17
User entered 'None (0)'	System	21 Sep 2020 19:31:17

FDA-CBER-2022-1614-2809429

US3342142
Folder: Diary Dose 2 (1)
Form: General_Day(1/1)
Generated On: 11 Aug 2021 22:33:31
MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:52:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (01A85E90-DEE1-40E1-A1FD-349A8271449C)', Time: '2020-09-21T14:31:04', User OID: 'PatientReportedOutcome (US3342142)', ODM File OID: 'd82ee0b7-2aa5-47be-9add-d95067dbaf7c'	System	21 Sep 2020 19:31:17
User entered 'None (0)'	System	21 Sep 2020 19:31:17

FDA-CBER-2022-1614-2809430

US3342142
Folder: Diary Dose 2 (1)
Form: General_Day(1/1)
Generated On: 11 Aug 2021 22:33:31
JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:52:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (01A85E90-DEE1-40E1-A1FD-349A8271449C)', Time: '2020-09-21T14:31:06', User OID: 'PatientReportedOutcome (US3342142)', ODM File OID: 'd82ee0b7-2aa5-47be-9add-d95067dbaf7c'	System	21 Sep 2020 19:31:17
User entered 'None (0)'	System	21 Sep 2020 19:31:17

FDA-CBER-2022-1614-2809431

US3342142
Folder: Diary Dose 2 (1)
Form: General_Day(1/1)
Generated On: 11 Aug 2021 22:33:31
NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:52:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (01A85E90-DEE1-40E1-A1FD-349A8271449C)', Time: '2020-09-21T14:31:07', User OID: 'PatientReportedOutcome (US3342142)', ODM File OID: 'd82ee0b7-2aa5-47be-9add-d95067dbaf7c'	System	21 Sep 2020 19:31:17
User entered 'None (0)'	System	21 Sep 2020 19:31:17

FDA-CBER-2022-1614-2809432

US3342142
Folder: Diary Dose 2 (1)
Form: General_Day(1/1)
Generated On: 11 Aug 2021 22:33:31
CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:52:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (01A85E90-DEE1-40E1-A1FD-349A8271449C)', Time: '2020-09-21T14:31:09', User OID: 'PatientReportedOutcome (US3342142)', ODM File OID: 'd82ee0b7-2aa5-47be-9add-d95067dbaf7c'	System	21 Sep 2020 19:31:17
User entered 'None (0)'	System	21 Sep 2020 19:31:17

FDA-CBER-2022-1614-2809433

US3342142
Folder: Diary Dose 2 (1)
Form: General_Day(1/1)
Generated On: 11 Aug 2021 22:33:31
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 14:52:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (01A85E90-DEE1-40E1-A1FD-349A8271449C)', Time: '2020-09-21T14:31:12', User OID: 'PatientReportedOutcome (US3342142)', ODM File OID: 'd82ee0b7-2aa5-47be-9add-d95067dbaf7c'	System	21 Sep 2020 19:31:17
User entered 'No (N)'	System	21 Sep 2020 19:31:17

US3342142
Folder: Diary Dose 2 (1)
Form: General_Day(1/1)
Generated On: 11 Aug 2021 22:33:31
PC Time stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:52:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (01A85E90-DEE1-40E1-A1FD-349A8271449C)', Time: '2020-09-21T14:31:15', User OID: 'PatientReportedOutcome (US3342142)', ODM File OID: 'd82ee0b7-2aa5-47be-9add-d95067dbaf7c'	System	21 Sep 2020 19:31:17
User entered '21 Sep 2020 14:31'	System	21 Sep 2020 19:31:17

FDA-CBER-2022-1614-2809435

US3342142
Folder: Diary Dose 2 (1)
Form: General_Day(1/1)
Generated On: 11 Aug 2021 22:33:31
PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:52:22
User entered '21 Sep 2020 14:11'	System	21 Sep 2020 18:56:07

FDA-CBER-2022-1614-2809436

US3342142
Folder: Diary Dose 2 (1)
Form: General_Day(1/1)
Generated On: 11 Aug 2021 22:33:31
PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:52:22
User entered '21 Sep 2020 16:41'	System	21 Sep 2020 18:56:07

FDA-CBER-2022-1614-2809437

US3342142
Folder: Diary Dose 2 (1)
Form: General_Day(1/2)
Generated On: 11 Aug 2021 22:33:31
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:52:22
Data entry locked.	System	21 Sep 2020 18:56:07
User entered 'Day 1, after vaccination (at home)'	System	21 Sep 2020 18:56:07

US3342142
Folder: Diary Dose 2 (1)
Form: General_Day(1/2)
Generated On: 11 Aug 2021 22:33:31
HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:52:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (01A85E90-DEE1-40E1-A1FD-349A8271449C)', Time: '2020-09-21T21:37:33', User OID: 'PatientReportedOutcome (US3342142)', ODM File OID: '027e6f84-ae54-4050-9406-b211ecef9d78'	System	22 Sep 2020 02:37:50
User entered 'None (0)'	System	22 Sep 2020 02:37:50

FDA-CBER-2022-1614-2809439

US3342142
Folder: Diary Dose 2 (1)
Form: General_Day(1/2)
Generated On: 11 Aug 2021 22:33:31
FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:52:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (01A85E90-DEE1-40E1-A1FD-349A8271449C)', Time: '2020-09-21T21:37:36', User OID: 'PatientReportedOutcome (US3342142)', ODM File OID: '027e6f84-ae54-4050-9406-b211ecef9d78'	System	22 Sep 2020 02:37:50
User entered 'None (0)'	System	22 Sep 2020 02:37:50

FDA-CBER-2022-1614-2809440

US3342142
Folder: Diary Dose 2 (1)
Form: General_Day(1/2)
Generated On: 11 Aug 2021 22:33:31
MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:52:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (01A85E90-DEE1-40E1-A1FD-349A8271449C)', Time: '2020-09-21T21:37:38', User OID: 'PatientReportedOutcome (US3342142)', ODM File OID: '027e6f84-ae54-4050-9406-b211ecef9d78'	System	22 Sep 2020 02:37:50
User entered 'None (0)'	System	22 Sep 2020 02:37:50

FDA-CBER-2022-1614-2809441

US3342142
Folder: Diary Dose 2 (1)
Form: General_Day(1/2)
Generated On: 11 Aug 2021 22:33:31
JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:52:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (01A85E90-DEE1-40E1-A1FD-349A8271449C)', Time: '2020-09-21T21:37:40', User OID: 'PatientReportedOutcome (US3342142)', ODM File OID: '027e6f84-ae54-4050-9406-b211ecef9d78'	System	22 Sep 2020 02:37:50
User entered 'None (0)'	System	22 Sep 2020 02:37:50

FDA-CBER-2022-1614-2809442

US3342142
Folder: Diary Dose 2 (1)
Form: General_Day(1/2)
Generated On: 11 Aug 2021 22:33:31
NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:52:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (01A85E90-DEE1-40E1-A1FD-349A8271449C)', Time: '2020-09-21T21:37:41', User OID: 'PatientReportedOutcome (US3342142)', ODM File OID: '027e6f84-ae54-4050-9406-b211ecef9d78'	System	22 Sep 2020 02:37:50
User entered 'None (0)'	System	22 Sep 2020 02:37:50

FDA-CBER-2022-1614-2809443

US3342142
Folder: Diary Dose 2 (1)
Form: General_Day(1/2)
Generated On: 11 Aug 2021 22:33:31
CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:52:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (01A85E90-DEE1-40E1-A1FD-349A8271449C)', Time: '2020-09-21T21:37:43', User OID: 'PatientReportedOutcome (US3342142)', ODM File OID: '027e6f84-ae54-4050-9406-b211ecef9d78'	System	22 Sep 2020 02:37:50
User entered 'None (0)'	System	22 Sep 2020 02:37:50

FDA-CBER-2022-1614-2809444

US3342142
Folder: Diary Dose 2 (1)
Form: General_Day(1/2)
Generated On: 11 Aug 2021 22:33:31
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 14:52:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (01A85E90-DEE1-40E1-A1FD-349A8271449C)', Time: '2020-09-21T21:37:46', User OID: 'PatientReportedOutcome (US3342142)', ODM File OID: '027e6f84-ae54-4050-9406-b211ecef9d78'	System	22 Sep 2020 02:37:50
User entered 'No (N)'	System	22 Sep 2020 02:37:50

FDA-CBER-2022-1614-2809445

US3342142
Folder: Diary Dose 2 (1)
Form: General_Day(1/2)
Generated On: 11 Aug 2021 22:33:31
PC Time stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:52:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (01A85E90-DEE1-40E1-A1FD-349A8271449C)', Time: '2020-09-21T21:37:48', User OID: 'PatientReportedOutcome (US3342142)', ODM File OID: '027e6f84-ae54-4050-9406-b211ecef9d78'	System	22 Sep 2020 02:37:50
User entered '21 Sep 2020 21:37'	System	22 Sep 2020 02:37:50

FDA-CBER-2022-1614-2809446

US3342142
Folder: Diary Dose 2 (1)
Form: General_Day(1/2)
Generated On: 11 Aug 2021 22:33:31
PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:52:22
User entered '21 Sep 2020 17:36'	System	21 Sep 2020 18:56:07

FDA-CBER-2022-1614-2809447

US3342142
Folder: Diary Dose 2 (1)
Form: General_Day(1/2)
Generated On: 11 Aug 2021 22:33:31
PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:52:22
User entered '22 Sep 2020 11:59'	System	21 Sep 2020 18:56:07

FDA-CBER-2022-1614-2809448

US3342142
Folder: Diary Dose 2 (1)
Form: General_Day(2)
Generated On: 11 Aug 2021 22:33:31
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:52:22
Data entry locked.	System	21 Sep 2020 18:56:07
User entered 'Day 2'	System	21 Sep 2020 18:56:07

FDA-CBER-2022-1614-2809449

US3342142
Folder: Diary Dose 2 (1)
Form: General_Day(2)
Generated On: 11 Aug 2021 22:33:31
HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:52:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (01A85E90-DEE1-40E1-A1FD-349A8271449C)', Time: '2020-09-22T21:15:17', User OID: 'PatientReportedOutcome (US3342142)', ODM File OID: 'ec9a7ce9-88dd-4d6f-bd0e-ade338332d22'	System	23 Sep 2020 02:15:57
User entered 'No interference with activity (1)'	System	23 Sep 2020 02:15:57

US3342142
Folder: Diary Dose 2 (1)
Form: General_Day(2)
Generated On: 11 Aug 2021 22:33:31
FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:52:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (01A85E90-DEE1-40E1-A1FD-349A8271449C)', Time: '2020-09-22T21:15:29', User OID: 'PatientReportedOutcome (US3342142)', ODM File OID: 'ec9a7ce9-88dd-4d6f-bd0e-ade338332d22'	System	23 Sep 2020 02:15:57
User entered 'None (0)'	System	23 Sep 2020 02:15:57

FDA-CBER-2022-1614-2809451

US3342142
Folder: Diary Dose 2 (1)
Form: General_Day(2)
Generated On: 11 Aug 2021 22:33:31
MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:52:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (01A85E90-DEE1-40E1-A1FD-349A8271449C)', Time: '2020-09-22T21:15:32', User OID: 'PatientReportedOutcome (US3342142)', ODM File OID: 'ec9a7ce9-88dd-4d6f-bd0e-ade338332d22'	System	23 Sep 2020 02:15:57
User entered 'None (0)'	System	23 Sep 2020 02:15:57

FDA-CBER-2022-1614-2809452

US3342142
Folder: Diary Dose 2 (1)
Form: General_Day(2)
Generated On: 11 Aug 2021 22:33:31
JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:52:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (01A85E90-DEE1-40E1-A1FD-349A8271449C)', Time: '2020-09-22T21:15:35', User OID: 'PatientReportedOutcome (US3342142)', ODM File OID: 'ec9a7ce9-88dd-4d6f-bd0e-ade338332d22'	System	23 Sep 2020 02:15:57
User entered 'None (0)'	System	23 Sep 2020 02:15:57

US3342142
Folder: Diary Dose 2 (1)
Form: General_Day(2)
Generated On: 11 Aug 2021 22:33:31
NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:52:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (01A85E90-DEE1-40E1-A1FD-349A8271449C)', Time: '2020-09-22T21:15:44', User OID: 'PatientReportedOutcome (US3342142)', ODM File OID: 'ec9a7ce9-88dd-4d6f-bd0e-ade338332d22'	System	23 Sep 2020 02:15:57
User entered 'None (0)'	System	23 Sep 2020 02:15:57

FDA-CBER-2022-1614-2809454

US3342142
Folder: Diary Dose 2 (1)
Form: General_Day(2)
Generated On: 11 Aug 2021 22:33:31
CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:52:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (01A85E90-DEE1-40E1-A1FD-349A8271449C)', Time: '2020-09-22T21:15:47', User OID: 'PatientReportedOutcome (US3342142)', ODM File OID: 'ec9a7ce9-88dd-4d6f-bd0e-ade338332d22'	System	23 Sep 2020 02:15:57
User entered 'None (0)'	System	23 Sep 2020 02:15:57

FDA-CBER-2022-1614-2809455

US3342142
Folder: Diary Dose 2 (1)
Form: General_Day(2)
Generated On: 11 Aug 2021 22:33:31
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 14:52:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (01A85E90-DEE1-40E1-A1FD-349A8271449C)', Time: '2020-09-22T21:15:50', User OID: 'PatientReportedOutcome (US3342142)', ODM File OID: 'ec9a7ce9-88dd-4d6f-bd0e-ade338332d22'	System	23 Sep 2020 02:15:57
User entered 'No (N)'	System	23 Sep 2020 02:15:57

FDA-CBER-2022-1614-2809456

US3342142
Folder: Diary Dose 2 (1)
Form: General_Day(2)
Generated On: 11 Aug 2021 22:33:31
PC Time stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:52:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (01A85E90-DEE1-40E1-A1FD-349A8271449C)', Time: '2020-09-22T21:15:52', User OID: 'PatientReportedOutcome (US3342142)', ODM File OID: 'ec9a7ce9-88dd-4d6f-bd0e-ade338332d22'	System	23 Sep 2020 02:15:57
User entered '22 Sep 2020 21:15'	System	23 Sep 2020 02:15:57

FDA-CBER-2022-1614-2809457

US3342142
Folder: Diary Dose 2 (1)
Form: General_Day(2)
Generated On: 11 Aug 2021 22:33:31
PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:52:22
User entered '22 Sep 2020 12:00'	System	21 Sep 2020 18:56:07

FDA-CBER-2022-1614-2809458

US3342142
Folder: Diary Dose 2 (1)
Form: General_Day(2)
Generated On: 11 Aug 2021 22:33:31
PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:52:22
User entered '23 Sep 2020 11:59'	System	21 Sep 2020 18:56:07

FDA-CBER-2022-1614-2809459

US3342142
Folder: Diary Dose 2 (1)
Form: General_Day(3)
Generated On: 11 Aug 2021 22:33:31
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:52:22
Data entry locked.	System	21 Sep 2020 18:56:07
User entered 'Day 3'	System	21 Sep 2020 18:56:07

US3342142
Folder: Diary Dose 2 (1)
Form: General_Day(3)
Generated On: 11 Aug 2021 22:33:31
HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:52:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (01A85E90-DEE1-40E1-A1FD-349A8271449C)', Time: '2020-09-23T21:42:21', User OID: 'PatientReportedOutcome (US3342142)', ODM File OID: 'a0fa1023-f602-4775-805e-e83a7d39514d'	System	24 Sep 2020 02:42:55
User entered 'None (0)'	System	24 Sep 2020 02:42:55

FDA-CBER-2022-1614-2809461

US3342142
Folder: Diary Dose 2 (1)
Form: General_Day(3)
Generated On: 11 Aug 2021 22:33:31
FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:52:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (01A85E90-DEE1-40E1-A1FD-349A8271449C)', Time: '2020-09-23T21:42:24', User OID: 'PatientReportedOutcome (US3342142)', ODM File OID: 'a0fa1023-f602-4775-805e-e83a7d39514d'	System	24 Sep 2020 02:42:55
User entered 'None (0)'	System	24 Sep 2020 02:42:55

FDA-CBER-2022-1614-2809462

US3342142
Folder: Diary Dose 2 (1)
Form: General_Day(3)
Generated On: 11 Aug 2021 22:33:31
MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:52:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (01A85E90-DEE1-40E1-A1FD-349A8271449C)', Time: '2020-09-23T21:42:30', User OID: 'PatientReportedOutcome (US3342142)', ODM File OID: 'a0fa1023-f602-4775-805e-e83a7d39514d'	System	24 Sep 2020 02:42:55
User entered 'None (0)'	System	24 Sep 2020 02:42:55

FDA-CBER-2022-1614-2809463

US3342142
Folder: Diary Dose 2 (1)
Form: General_Day(3)
Generated On: 11 Aug 2021 22:33:31
JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:52:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (01A85E90-DEE1-40E1-A1FD-349A8271449C)', Time: '2020-09-23T21:42:32', User OID: 'PatientReportedOutcome (US3342142)', ODM File OID: 'a0fa1023-f602-4775-805e-e83a7d39514d'	System	24 Sep 2020 02:42:55
User entered 'None (0)'	System	24 Sep 2020 02:42:55

FDA-CBER-2022-1614-2809464

US3342142
Folder: Diary Dose 2 (1)
Form: General_Day(3)
Generated On: 11 Aug 2021 22:33:31
NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:52:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (01A85E90-DEE1-40E1-A1FD-349A8271449C)', Time: '2020-09-23T21:42:34', User OID: 'PatientReportedOutcome (US3342142)', ODM File OID: 'a0fa1023-f602-4775-805e-e83a7d39514d'	System	24 Sep 2020 02:42:55
User entered 'None (0)'	System	24 Sep 2020 02:42:55

FDA-CBER-2022-1614-2809465

US3342142
Folder: Diary Dose 2 (1)
Form: General_Day(3)
Generated On: 11 Aug 2021 22:33:31
CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:52:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (01A85E90-DEE1-40E1-A1FD-349A8271449C)', Time: '2020-09-23T21:42:37', User OID: 'PatientReportedOutcome (US3342142)', ODM File OID: 'a0fa1023-f602-4775-805e-e83a7d39514d'	System	24 Sep 2020 02:42:55
User entered 'None (0)'	System	24 Sep 2020 02:42:55

FDA-CBER-2022-1614-2809466

US3342142
Folder: Diary Dose 2 (1)
Form: General_Day(3)
Generated On: 11 Aug 2021 22:33:31
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 14:52:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (01A85E90-DEE1-40E1-A1FD-349A8271449C)', Time: '2020-09-23T21:42:48', User OID: 'PatientReportedOutcome (US3342142)', ODM File OID: 'a0fa1023-f602-4775-805e-e83a7d39514d'	System	24 Sep 2020 02:42:55
User entered 'No (N)'	System	24 Sep 2020 02:42:55

US3342142
Folder: Diary Dose 2 (1)
Form: General_Day(3)
Generated On: 11 Aug 2021 22:33:31
PC Time stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:52:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (01A85E90-DEE1-40E1-A1FD-349A8271449C)', Time: '2020-09-23T21:42:50', User OID: 'PatientReportedOutcome (US3342142)', ODM File OID: 'a0fa1023-f602-4775-805e-e83a7d39514d'	System	24 Sep 2020 02:42:55
User entered '23 Sep 2020 21:42'	System	24 Sep 2020 02:42:55

US3342142
Folder: Diary Dose 2 (1)
Form: General_Day(3)
Generated On: 11 Aug 2021 22:33:31
PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:52:22
User entered '23 Sep 2020 12:00'	System	21 Sep 2020 18:56:07

US3342142
Folder: Diary Dose 2 (1)
Form: General_Day(3)
Generated On: 11 Aug 2021 22:33:31
PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:52:22
User entered '24 Sep 2020 11:59'	System	21 Sep 2020 18:56:07

US3342142
Folder: Diary Dose 2 (1)
Form: General_Day(4)
Generated On: 11 Aug 2021 22:33:31
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:52:22
Data entry locked.	System	21 Sep 2020 18:56:07
User entered 'Day 4'	System	21 Sep 2020 18:56:07

US3342142
Folder: Diary Dose 2 (1)
Form: General_Day(4)
Generated On: 11 Aug 2021 22:33:31
HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:52:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (01A85E90-DEE1-40E1-A1FD-349A8271449C)', Time: '2020-09-25T01:53:30', User OID: 'PatientReportedOutcome (US3342142)', ODM File OID: 'f26cdbe4-30e8-4877-baf7-b66abf490b2a'	System	25 Sep 2020 06:53:43
User entered 'None (0)'	System	25 Sep 2020 06:53:43

US3342142
Folder: Diary Dose 2 (1)
Form: General_Day(4)
Generated On: 11 Aug 2021 22:33:31
FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:52:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (01A85E90-DEE1-40E1-A1FD-349A8271449C)', Time: '2020-09-25T01:53:31', User OID: 'PatientReportedOutcome (US3342142)', ODM File OID: 'f26cdbe4-30e8-4877-baf7-b66abf490b2a'	System	25 Sep 2020 06:53:43
User entered 'None (0)'	System	25 Sep 2020 06:53:43

US3342142
Folder: Diary Dose 2 (1)
Form: General_Day(4)
Generated On: 11 Aug 2021 22:33:31
MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:52:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (01A85E90-DEE1-40E1-A1FD-349A8271449C)', Time: '2020-09-25T01:53:33', User OID: 'PatientReportedOutcome (US3342142)', ODM File OID: 'f26cdbe4-30e8-4877-baf7-b66abf490b2a'	System	25 Sep 2020 06:53:43
User entered 'None (0)'	System	25 Sep 2020 06:53:43

FDA-CBER-2022-1614-2809474

US3342142
Folder: Diary Dose 2 (1)
Form: General_Day(4)
Generated On: 11 Aug 2021 22:33:31
JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:52:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (01A85E90-DEE1-40E1-A1FD-349A8271449C)', Time: '2020-09-25T01:53:34', User OID: 'PatientReportedOutcome (US3342142)', ODM File OID: 'f26cdbe4-30e8-4877-baf7-b66abf490b2a'	System	25 Sep 2020 06:53:43
User entered 'None (0)'	System	25 Sep 2020 06:53:43

FDA-CBER-2022-1614-2809475

US3342142
Folder: Diary Dose 2 (1)
Form: General_Day(4)
Generated On: 11 Aug 2021 22:33:31
NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:52:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (01A85E90-DEE1-40E1-A1FD-349A8271449C)', Time: '2020-09-25T01:53:36', User OID: 'PatientReportedOutcome (US3342142)', ODM File OID: 'f26cdbe4-30e8-4877-baf7-b66abf490b2a'	System	25 Sep 2020 06:53:43
User entered 'None (0)'	System	25 Sep 2020 06:53:43

FDA-CBER-2022-1614-2809476

US3342142
Folder: Diary Dose 2 (1)
Form: General_Day(4)
Generated On: 11 Aug 2021 22:33:31
CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:52:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (01A85E90-DEE1-40E1-A1FD-349A8271449C)', Time: '2020-09-25T01:53:37', User OID: 'PatientReportedOutcome (US3342142)', ODM File OID: 'f26cdbe4-30e8-4877-baf7-b66abf490b2a'	System	25 Sep 2020 06:53:43
User entered 'None (0)'	System	25 Sep 2020 06:53:43

US3342142
Folder: Diary Dose 2 (1)
Form: General_Day(4)
Generated On: 11 Aug 2021 22:33:31
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 14:52:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (01A85E90-DEE1-40E1-A1FD-349A8271449C)', Time: '2020-09-25T01:53:39', User OID: 'PatientReportedOutcome (US3342142)', ODM File OID: 'f26cdbe4-30e8-4877-baf7-b66abf490b2a'	System	25 Sep 2020 06:53:43
User entered 'No (N)'	System	25 Sep 2020 06:53:43

FDA-CBER-2022-1614-2809478

US3342142
Folder: Diary Dose 2 (1)
Form: General_Day(4)
Generated On: 11 Aug 2021 22:33:31
PC Time stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:52:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (01A85E90-DEE1-40E1-A1FD-349A8271449C)', Time: '2020-09-25T01:53:41', User OID: 'PatientReportedOutcome (US3342142)', ODM File OID: 'f26cdbe4-30e8-4877-baf7-b66abf490b2a'	System	25 Sep 2020 06:53:43
User entered '25 Sep 2020 01:53'	System	25 Sep 2020 06:53:43

FDA-CBER-2022-1614-2809479

US3342142
Folder: Diary Dose 2 (1)
Form: General_Day(4)
Generated On: 11 Aug 2021 22:33:31
PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:52:22
User entered '24 Sep 2020 12:00'	System	21 Sep 2020 18:56:07

US3342142
Folder: Diary Dose 2 (1)
Form: General_Day(4)
Generated On: 11 Aug 2021 22:33:31
PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:52:22
User entered '25 Sep 2020 11:59'	System	21 Sep 2020 18:56:07

FDA-CBER-2022-1614-2809481

US3342142
Folder: Diary Dose 2 (1)
Form: General_Day(5)
Generated On: 11 Aug 2021 22:33:31
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:52:22
Data entry locked.	System	21 Sep 2020 18:56:07
User entered 'Day 5'	System	21 Sep 2020 18:56:07

US3342142
Folder: Diary Dose 2 (1)
Form: General_Day(5)
Generated On: 11 Aug 2021 22:33:31
HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:52:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (01A85E90-DEE1-40E1-A1FD-349A8271449C)', Time: '2020-09-25T23:15:56', User OID: 'PatientReportedOutcome (US3342142)', ODM File OID: '494bb1a1-8402-47de-bbfc-081d483bba65'	System	26 Sep 2020 04:16:10
User entered 'No interference with activity (1)'	System	26 Sep 2020 04:16:10

FDA-CBER-2022-1614-2809483

US3342142
Folder: Diary Dose 2 (1)
Form: General_Day(5)
Generated On: 11 Aug 2021 22:33:31
FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:52:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (01A85E90-DEE1-40E1-A1FD-349A8271449C)', Time: '2020-09-25T23:15:57', User OID: 'PatientReportedOutcome (US3342142)', ODM File OID: '494bb1a1-8402-47de-bbfc-081d483bba65'	System	26 Sep 2020 04:16:10
User entered 'None (0)'	System	26 Sep 2020 04:16:10

FDA-CBER-2022-1614-2809484

US3342142
Folder: Diary Dose 2 (1)
Form: General_Day(5)
Generated On: 11 Aug 2021 22:33:31
MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:52:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (01A85E90-DEE1-40E1-A1FD-349A8271449C)', Time: '2020-09-25T23:15:59', User OID: 'PatientReportedOutcome (US3342142)', ODM File OID: '494bb1a1-8402-47de-bbfc-081d483bba65'	System	26 Sep 2020 04:16:10
User entered 'None (0)'	System	26 Sep 2020 04:16:10

FDA-CBER-2022-1614-2809485

US3342142
Folder: Diary Dose 2 (1)
Form: General_Day(5)
Generated On: 11 Aug 2021 22:33:31
JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:52:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (01A85E90-DEE1-40E1-A1FD-349A8271449C)', Time: '2020-09-25T23:16:00', User OID: 'PatientReportedOutcome (US3342142)', ODM File OID: '494bb1a1-8402-47de-bbfc-081d483bba65'	System	26 Sep 2020 04:16:10
User entered 'None (0)'	System	26 Sep 2020 04:16:10

FDA-CBER-2022-1614-2809486

US3342142
Folder: Diary Dose 2 (1)
Form: General_Day(5)
Generated On: 11 Aug 2021 22:33:31
NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:52:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (01A85E90-DEE1-40E1-A1FD-349A8271449C)', Time: '2020-09-25T23:16:02', User OID: 'PatientReportedOutcome (US3342142)', ODM File OID: '494bb1a1-8402-47de-bbfc-081d483bba65'	System	26 Sep 2020 04:16:10
User entered 'None (0)'	System	26 Sep 2020 04:16:10

FDA-CBER-2022-1614-2809487

US3342142
Folder: Diary Dose 2 (1)
Form: General_Day(5)
Generated On: 11 Aug 2021 22:33:31
CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:52:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (01A85E90-DEE1-40E1-A1FD-349A8271449C)', Time: '2020-09-25T23:16:03', User OID: 'PatientReportedOutcome (US3342142)', ODM File OID: '494bb1a1-8402-47de-bbfc-081d483bba65'	System	26 Sep 2020 04:16:10
User entered 'None (0)'	System	26 Sep 2020 04:16:10

FDA-CBER-2022-1614-2809488

US3342142
Folder: Diary Dose 2 (1)
Form: General_Day(5)
Generated On: 11 Aug 2021 22:33:31
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 14:52:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (01A85E90-DEE1-40E1-A1FD-349A8271449C)', Time: '2020-09-25T23:16:05', User OID: 'PatientReportedOutcome (US3342142)', ODM File OID: '494bb1a1-8402-47de-bbfc-081d483bba65'	System	26 Sep 2020 04:16:10
User entered 'No (N)'	System	26 Sep 2020 04:16:10

FDA-CBER-2022-1614-2809489

US3342142
Folder: Diary Dose 2 (1)
Form: General_Day(5)
Generated On: 11 Aug 2021 22:33:31
PC Time stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:52:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (01A85E90-DEE1-40E1-A1FD-349A8271449C)', Time: '2020-09-25T23:16:07', User OID: 'PatientReportedOutcome (US3342142)', ODM File OID: '494bb1a1-8402-47de-bbfc-081d483bba65'	System	26 Sep 2020 04:16:10
User entered '25 Sep 2020 23:16'	System	26 Sep 2020 04:16:10

FDA-CBER-2022-1614-2809490

US3342142
Folder: Diary Dose 2 (1)
Form: General_Day(5)
Generated On: 11 Aug 2021 22:33:31
PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:52:22
User entered '25 Sep 2020 12:00'	System	21 Sep 2020 18:56:07

FDA-CBER-2022-1614-2809491

US3342142
Folder: Diary Dose 2 (1)
Form: General_Day(5)
Generated On: 11 Aug 2021 22:33:31
PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:52:22
User entered '26 Sep 2020 11:59'	System	21 Sep 2020 18:56:07

FDA-CBER-2022-1614-2809492

US3342142
Folder: Diary Dose 2 (1)
Form: General_Day(6)
Generated On: 11 Aug 2021 22:33:31
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:52:22
Data entry locked.	System	21 Sep 2020 18:56:07
User entered 'Day 6'	System	21 Sep 2020 18:56:07

US3342142
Folder: Diary Dose 2 (1)
Form: General_Day(6)
Generated On: 11 Aug 2021 22:33:31
HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:52:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (01A85E90-DEE1-40E1-A1FD-349A8271449C)', Time: '2020-09-27T05:59:34', User OID: 'PatientReportedOutcome (US3342142)', ODM File OID: '3a57ac1a-cca0-4583-bc17-40390ae64578'	System	27 Sep 2020 10:59:46
User entered 'None (0)'	System	27 Sep 2020 10:59:46

FDA-CBER-2022-1614-2809494

US3342142
Folder: Diary Dose 2 (1)
Form: General_Day(6)
Generated On: 11 Aug 2021 22:33:31
FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:52:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (01A85E90-DEE1-40E1-A1FD-349A8271449C)', Time: '2020-09-27T05:59:35', User OID: 'PatientReportedOutcome (US3342142)', ODM File OID: '3a57ac1a-cca0-4583-bc17-40390ae64578'	System	27 Sep 2020 10:59:46
User entered 'None (0)'	System	27 Sep 2020 10:59:46

FDA-CBER-2022-1614-2809495

US3342142
Folder: Diary Dose 2 (1)
Form: General_Day(6)
Generated On: 11 Aug 2021 22:33:31
MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:52:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (01A85E90-DEE1-40E1-A1FD-349A8271449C)', Time: '2020-09-27T05:59:37', User OID: 'PatientReportedOutcome (US3342142)', ODM File OID: '3a57ac1a-cca0-4583-bc17-40390ae64578'	System	27 Sep 2020 10:59:46
User entered 'None (0)'	System	27 Sep 2020 10:59:46

FDA-CBER-2022-1614-2809496

US3342142
Folder: Diary Dose 2 (1)
Form: General_Day(6)
Generated On: 11 Aug 2021 22:33:31
JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:52:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (01A85E90-DEE1-40E1-A1FD-349A8271449C)', Time: '2020-09-27T05:59:39', User OID: 'PatientReportedOutcome (US3342142)', ODM File OID: '3a57ac1a-cca0-4583-bc17-40390ae64578'	System	27 Sep 2020 10:59:46
User entered 'None (0)'	System	27 Sep 2020 10:59:46

FDA-CBER-2022-1614-2809497

US3342142
Folder: Diary Dose 2 (1)
Form: General_Day(6)
Generated On: 11 Aug 2021 22:33:31
NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:52:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (01A85E90-DEE1-40E1-A1FD-349A8271449C)', Time: '2020-09-27T05:59:40', User OID: 'PatientReportedOutcome (US3342142)', ODM File OID: '3a57ac1a-cca0-4583-bc17-40390ae64578'	System	27 Sep 2020 10:59:46
User entered 'None (0)'	System	27 Sep 2020 10:59:46

FDA-CBER-2022-1614-2809498

US3342142
Folder: Diary Dose 2 (1)
Form: General_Day(6)
Generated On: 11 Aug 2021 22:33:31
CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:52:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (01A85E90-DEE1-40E1-A1FD-349A8271449C)', Time: '2020-09-27T05:59:41', User OID: 'PatientReportedOutcome (US3342142)', ODM File OID: '3a57ac1a-cca0-4583-bc17-40390ae64578'	System	27 Sep 2020 10:59:46
User entered 'None (0)'	System	27 Sep 2020 10:59:46

FDA-CBER-2022-1614-2809499

US3342142
Folder: Diary Dose 2 (1)
Form: General_Day(6)
Generated On: 11 Aug 2021 22:33:31
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 14:52:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (01A85E90-DEE1-40E1-A1FD-349A8271449C)', Time: '2020-09-27T05:59:43', User OID: 'PatientReportedOutcome (US3342142)', ODM File OID: '3a57ac1a-cca0-4583-bc17-40390ae64578'	System	27 Sep 2020 10:59:46
User entered 'No (N)'	System	27 Sep 2020 10:59:46

US3342142
Folder: Diary Dose 2 (1)
Form: General_Day(6)
Generated On: 11 Aug 2021 22:33:31
PC Time stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:52:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (01A85E90-DEE1-40E1-A1FD-349A8271449C)', Time: '2020-09-27T05:59:45', User OID: 'PatientReportedOutcome (US3342142)', ODM File OID: '3a57ac1a-cca0-4583-bc17-40390ae64578'	System	27 Sep 2020 10:59:46
User entered '27 Sep 2020 05:59'	System	27 Sep 2020 10:59:46

FDA-CBER-2022-1614-2809501

US3342142
Folder: Diary Dose 2 (1)
Form: General_Day(6)
Generated On: 11 Aug 2021 22:33:31
PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:52:22
User entered '26 Sep 2020 12:00'	System	21 Sep 2020 18:56:07

FDA-CBER-2022-1614-2809502

US3342142
Folder: Diary Dose 2 (1)
Form: General_Day(6)
Generated On: 11 Aug 2021 22:33:31
PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:52:22
User entered '27 Sep 2020 11:59'	System	21 Sep 2020 18:56:07

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US3342142
Folder: Diary Dose 2 (1)
Form: General_Day(7)
Generated On: 11 Aug 2021 22:33:31
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:52:22
Data entry locked.	System	21 Sep 2020 18:56:07
User entered 'Day 7'	System	21 Sep 2020 18:56:07

US3342142
Folder: Diary Dose 2 (1)
Form: General_Day(7)
Generated On: 11 Aug 2021 22:33:31
HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:52:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (01A85E90-DEE1-40E1-A1FD-349A8271449C)', Time: '2020-09-28T00:24:45', User OID: 'PatientReportedOutcome (US3342142)', ODM File OID: '75880ae0-e188-4831-a0a2-84cfa671fc60'	System	28 Sep 2020 05:24:59
User entered 'None (0)'	System	28 Sep 2020 05:24:59

US3342142
Folder: Diary Dose 2 (1)
Form: General_Day(7)
Generated On: 11 Aug 2021 22:33:31
FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:52:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (01A85E90-DEE1-40E1-A1FD-349A8271449C)', Time: '2020-09-28T00:24:46', User OID: 'PatientReportedOutcome (US3342142)', ODM File OID: '75880ae0-e188-4831-a0a2-84cfa671fc60'	System	28 Sep 2020 05:24:59
User entered 'None (0)'	System	28 Sep 2020 05:24:59

US3342142
Folder: Diary Dose 2 (1)
Form: General_Day(7)
Generated On: 11 Aug 2021 22:33:31
MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:52:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (01A85E90-DEE1-40E1-A1FD-349A8271449C)', Time: '2020-09-28T00:24:48', User OID: 'PatientReportedOutcome (US3342142)', ODM File OID: '75880ae0-e188-4831-a0a2-84cfa671fc60'	System	28 Sep 2020 05:24:59
User entered 'None (0)'	System	28 Sep 2020 05:24:59

US3342142
Folder: Diary Dose 2 (1)
Form: General_Day(7)
Generated On: 11 Aug 2021 22:33:31
JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:52:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (01A85E90-DEE1-40E1-A1FD-349A8271449C)', Time: '2020-09-28T00:24:49', User OID: 'PatientReportedOutcome (US3342142)', ODM File OID: '75880ae0-e188-4831-a0a2-84cfa671fc60'	System	28 Sep 2020 05:24:59
User entered 'None (0)'	System	28 Sep 2020 05:24:59

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US3342142
Folder: Diary Dose 2 (1)
Form: General_Day(7)
Generated On: 11 Aug 2021 22:33:31
NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:52:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (01A85E90-DEE1-40E1-A1FD-349A8271449C)', Time: '2020-09-28T00:24:51', User OID: 'PatientReportedOutcome (US3342142)', ODM File OID: '75880ae0-e188-4831-a0a2-84cfa671fc60'	System	28 Sep 2020 05:24:59
User entered 'None (0)'	System	28 Sep 2020 05:24:59

US3342142
Folder: Diary Dose 2 (1)
Form: General_Day(7)
Generated On: 11 Aug 2021 22:33:31
CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:52:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (01A85E90-DEE1-40E1-A1FD-349A8271449C)', Time: '2020-09-28T00:24:52', User OID: 'PatientReportedOutcome (US3342142)', ODM File OID: '75880ae0-e188-4831-a0a2-84cfa671fc60'	System	28 Sep 2020 05:24:59
User entered 'None (0)'	System	28 Sep 2020 05:24:59

US3342142
Folder: Diary Dose 2 (1)
Form: General_Day(7)
Generated On: 11 Aug 2021 22:33:31
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 14:52:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (01A85E90-DEE1-40E1-A1FD-349A8271449C)', Time: '2020-09-28T00:24:55', User OID: 'PatientReportedOutcome (US3342142)', ODM File OID: '75880ae0-e188-4831-a0a2-84cfa671fc60'	System	28 Sep 2020 05:24:59
User entered 'Yes (Y)'	System	28 Sep 2020 05:24:59

US3342142
Folder: Diary Dose 2 (1)
Form: General_Day(7)
Generated On: 11 Aug 2021 22:33:31
PC Time stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:52:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (01A85E90-DEE1-40E1-A1FD-349A8271449C)', Time: '2020-09-28T00:24:57', User OID: 'PatientReportedOutcome (US3342142)', ODM File OID: '75880ae0-e188-4831-a0a2-84cfa671fc60'	System	28 Sep 2020 05:24:59
User entered '28 Sep 2020 00:24'	System	28 Sep 2020 05:24:59

US3342142
Folder: Diary Dose 2 (1)
Form: General_Day(7)
Generated On: 11 Aug 2021 22:33:31
PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:52:22
User entered '27 Sep 2020 12:00'	System	21 Sep 2020 18:56:07

US3342142
Folder: Diary Dose 2 (1)
Form: General_Day(7)
Generated On: 11 Aug 2021 22:33:31
PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:52:22
User entered '28 Sep 2020 11:59'	System	21 Sep 2020 18:56:07

FDA-CBER-2022-1614-2809514

US3342142
Folder: Safety Call Day 36 (1)
Form: Safety Call
Generated On: 11 Aug 2021 22:33:31
Was Contact Attempted?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 12:53:53
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:16:48
User entered 'Yes (Y)'	(b) (4), (b) (6) (b) (4)	28 Sep 2020 21:01:07

US3342142
Folder: Safety Call Day 36 (1)
Form: Safety Call
Generated On: 11 Aug 2021 22:33:31
Date of Contact or Contact Attempt *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 12:53:53
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:16:48
User entered '28 Sep 2020'	(b) (4), (b) (6)	28 Sep 2020 21:01:07

US3342142
Folder: Safety Call Day 36 (1)
Form: Safety Call
Generated On: 11 Aug 2021 22:33:31
Please select one status for the follow-up contact

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 12:53:53
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:16:48
User entered 'Contact Made (CONTACT MADE)'	(b) (4), (b) (6)	28 Sep 2020 21:01:07

US3342142
Folder: Safety Call Day 36 (1)
Form: Safety Call
Generated On: 11 Aug 2021 22:33:31
Comments

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 12:53:53
User signature succeeded.	Paul Pickrell (b) (4) (b) (4)	12 Mar 2021 23:16:48
User entered empty.	(b) (4), (b) (6)	28 Sep 2020 21:01:07

US3342142
Folder: Safety Call Day 36 (1)
Form: Continuing
Generated On: 11 Aug 2021 22:33:31
Is the participant continuing to the next visit?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 12:53:53
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:16:48
User entered 'Yes (Y)'	(b) (4), (b) (6)	28 Sep 2020 21:01:10

US3342142
Folder: Safety Call Day 36 (1)
Form: Continuing
Generated On: 11 Aug 2021 22:33:31
Continuing Flag

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 12:53:53
User entered '1'	System	28 Sep 2020 21:01:10

US3342142
Folder: Safety Call Day 43 (1)
Form: Safety Call
Generated On: 11 Aug 2021 22:33:31
Was Contact Attempted?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 12:53:53
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:16:48
User entered 'Yes (Y)'	(b) (4), (b) (6) (b) (4)	05 Oct 2020 16:10:02

US3342142
Folder: Safety Call Day 43 (1)
Form: Safety Call
Generated On: 11 Aug 2021 22:33:31
Date of Contact or Contact Attempt *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 12:53:53
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:16:48
User entered '5 Oct 2020'	(b) (4), (b) (6)	05 Oct 2020 16:10:02

US3342142
Folder: Safety Call Day 43 (1)
Form: Safety Call
Generated On: 11 Aug 2021 22:33:31
Please select one status for the follow-up contact

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 12:53:53
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:16:48
User entered 'Contact Made (CONTACT MADE)'	(b) (4), (b) (6) (b) (4)	05 Oct 2020 16:10:02

FDA-CBER-2022-1614-2809523

US3342142
Folder: Safety Call Day 43 (1)
Form: Safety Call
Generated On: 11 Aug 2021 22:33:31
Comments

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 12:53:53
User signature succeeded.	Paul Pickrell (b) (4) (b) (4)	12 Mar 2021 23:16:48
User entered empty.	(b) (4), (b) (6)	05 Oct 2020 16:10:02

FDA-CBER-2022-1614-2809524

US3342142
Folder: Safety Call Day 43 (1)
Form: Continuing
Generated On: 11 Aug 2021 22:33:31
Is the participant continuing to the next visit?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 12:53:53
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:16:48
User entered 'Yes (Y)'	(b) (4), (b) (6)	05 Oct 2020 16:09:54

US3342142
Folder: Safety Call Day 43 (1)
Form: Continuing
Generated On: 11 Aug 2021 22:33:31
Continuing Flag

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 12:53:53
User entered '1'	System	05 Oct 2020 16:09:54

FDA-CBER-2022-1614-2809526

US3342142
Folder: Safety Call Day 50 (1)
Form: Safety Call
Generated On: 11 Aug 2021 22:33:31
Was Contact Attempted?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 12:53:53
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:16:48
User entered 'Yes (Y)'	(b) (4), (b) (6) (b) (4)	12 Oct 2020 15:39:01

FDA-CBER-2022-1614-2809527

US3342142
Folder: Safety Call Day 50 (1)
Form: Safety Call
Generated On: 11 Aug 2021 22:33:31
Date of Contact or Contact Attempt *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 12:53:53
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:16:48
User entered '12 Oct 2020'	(b) (4), (b) (6)	12 Oct 2020 15:39:01

FDA-CBER-2022-1614-2809528

US3342142
Folder: Safety Call Day 50 (1)
Form: Safety Call
Generated On: 11 Aug 2021 22:33:31
Please select one status for the follow-up contact

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 12:53:53
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:16:48
User entered 'Contact Made (CONTACT MADE)'	(b) (4) (b) (4), (b) (6)	12 Oct 2020 15:39:01

FDA-CBER-2022-1614-2809529

US3342142
Folder: Safety Call Day 50 (1)
Form: Safety Call
Generated On: 11 Aug 2021 22:33:31
Comments

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 12:53:53
User signature succeeded.	Paul Pickrell (b) (4) (b) (4)	12 Mar 2021 23:16:48
User entered empty.	(b) (4), (b) (6)	12 Oct 2020 15:39:01

US3342142
Folder: Safety Call Day 50 (1)
Form: Continuing
Generated On: 11 Aug 2021 22:33:31
Is the participant continuing to the next visit?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 12:53:53
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:16:48
User entered 'Yes (Y)'	(b) (4), (b) (6)	12 Oct 2020 15:39:05

US3342142
Folder: Safety Call Day 50 (1)
Form: Continuing
Generated On: 11 Aug 2021 22:33:31
Continuing Flag

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 12:53:53
User entered '1'	System	12 Oct 2020 15:39:05

FDA-CBER-2022-1614-2809532

US3342142
Folder: Visit 3 Day 57 (1)
Form: Visit Date
Generated On: 11 Aug 2021 22:33:31
Was this visit performed?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 12:53:53
User signature succeeded.	Paul Pickrell (b) (4) (b) (4)	12 Mar 2021 23:16:48
User entered 'Yes (Y)'	Andrew Bell (b) (4) (b) (4)	22 Oct 2020 18:11:47

FDA-CBER-2022-1614-2809533

US3342142
Folder: Visit 3 Day 57 (1)
Form: Visit Date
Generated On: 11 Aug 2021 22:33:31
Visit date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 12:53:53
User signature succeeded.	Paul Pickrell (b) (4) (b) (4)	12 Mar 2021 23:16:48
User entered '22 Oct 2020'	Andrew Bell (b) (4) (b) (4)	22 Oct 2020 18:11:47

FDA-CBER-2022-1614-2809534

US3342142
Folder: Visit 3 Day 57 (1)
Form: Visit Date
Generated On: 11 Aug 2021 22:33:31
Was visit performed at the participant's home or at the clinic?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 12:53:53
User signature succeeded.	Paul Pickrell (b) (4) (b) (4)	12 Mar 2021 23:16:48
User entered 'Clinic (Clinic)'	Andrew Bell (b) (4) (b) (4)	22 Oct 2020 18:11:47

US3342142
Folder: Visit 3 Day 57 (1)
Form: Visit Date
Generated On: 11 Aug 2021 22:33:31
Folder OID

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 12:53:53
User entered 'VISIT3'	System	22 Oct 2020 18:11:47

FDA-CBER-2022-1614-2809536

US3342142
Folder: Visit 3 Day 57 (1)
Form: Vital Signs
Generated On: 11 Aug 2021 22:33:31
Were vital signs assessed?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 12:53:53
User signature succeeded.	Paul Pickrell (b) (4) (b) (4)	12 Mar 2021 23:16:48
User entered 'Yes (Y)'	Andrew Bell (b) (4) (b) (4)	22 Oct 2020 18:13:15

US3342142
Folder: Visit 3 Day 57 (1)
Form: Vital Signs
Generated On: 11 Aug 2021 22:33:31
Date of assessment *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 12:53:53
User signature succeeded.	Paul Pickrell (b) (4) (b) (4)	12 Mar 2021 23:16:48
User entered '22 Oct 2020'	Andrew Bell (b) (4) (b) (4)	22 Oct 2020 18:13:15

US3342142
Folder: Visit 3 Day 57 (1)
Form: Vital Signs
Generated On: 11 Aug 2021 22:33:31
Time of assessment *(00:00-23:59)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 12:53:53
User signature succeeded.	Paul Pickrell (b) (4) (b) (4)	12 Mar 2021 23:16:48
User entered '13:00'	Andrew Bell (b) (4) (b) (4)	22 Oct 2020 18:13:15

US3342142
Folder: Visit 3 Day 57 (1)
Form: Vital Signs
Generated On: 11 Aug 2021 22:33:31
Vital Signs Date and Time (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 12:53:53
User entered '22 Oct 2020 13:00'	System	22 Oct 2020 18:13:15

FDA-CBER-2022-1614-2809540

US3342142
Folder: Visit 3 Day 57 (1)
Form: Vital Signs
Generated On: 11 Aug 2021 22:33:31
Temperature *(xxx.x)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 12:53:53
User signature succeeded.	Paul Pickrell (b) (4) (b) (4)	12 Mar 2021 23:16:48
User entered '98.1' F	Andrew Bell (b) (4) (b) (4)	22 Oct 2020 18:13:15

FDA-CBER-2022-1614-2809541

US3342142
Folder: Visit 3 Day 57 (1)
Form: Vital Signs
Generated On: 11 Aug 2021 22:33:31
Route of measurement

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 12:53:53
User signature succeeded.	Paul Pickrell (b) (4) (b) (4)	12 Mar 2021 23:16:48
User entered 'Oral (Oral)'	Andrew Bell (b) (4) (b) (4)	22 Oct 2020 18:13:15

US3342142
Folder: Visit 3 Day 57 (1)
Form: Vital Signs
Generated On: 11 Aug 2021 22:33:31
If Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 12:53:53
User signature succeeded.	Paul Pickrell (b) (4) (b) (4)	12 Mar 2021 23:16:48
User entered empty.	Andrew Bell (b) (4) (b) (4)	22 Oct 2020 18:13:15

FDA-CBER-2022-1614-2809543

US3342142
Folder: Visit 3 Day 57 (1)
Form: Vital Signs
Generated On: 11 Aug 2021 22:33:31
Pulse *(xxx)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 12:53:53
User signature succeeded.	Paul Pickrell (b) (4) (b) (4)	12 Mar 2021 23:16:48
User entered '70'	Andrew Bell (b) (4) (b) (4)	22 Oct 2020 18:13:15

FDA-CBER-2022-1614-2809544

US3342142
Folder: Visit 3 Day 57 (1)
Form: Vital Signs
Generated On: 11 Aug 2021 22:33:31
Pulse units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 12:53:53
User entered 'bpm'	System	22 Oct 2020 18:13:15

FDA-CBER-2022-1614-2809545

US3342142
Folder: Visit 3 Day 57 (1)
Form: Vital Signs
Generated On: 11 Aug 2021 22:33:31
Respiratory Rate *(xxx)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 12:53:53
User signature succeeded.	Paul Pickrell (b) (4) (b) (4)	12 Mar 2021 23:16:48
User entered '14'	Andrew Bell (b) (4) (b) (4)	22 Oct 2020 18:13:15

FDA-CBER-2022-1614-2809546

US3342142
Folder: Visit 3 Day 57 (1)
Form: Vital Signs
Generated On: 11 Aug 2021 22:33:31
Respiratory Rate units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 12:53:53
User entered 'breaths/min'	System	22 Oct 2020 18:13:15

FDA-CBER-2022-1614-2809547

US3342142
Folder: Visit 3 Day 57 (1)
Form: Vital Signs
Generated On: 11 Aug 2021 22:33:31
Systolic Blood Pressure *(xxx)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 12:53:53
User signature succeeded.	Paul Pickrell (b) (4) (b) (4)	12 Mar 2021 23:16:48
User entered '119'	Andrew Bell (b) (4) (b) (4)	22 Oct 2020 18:13:15

FDA-CBER-2022-1614-2809548

US3342142
Folder: Visit 3 Day 57 (1)
Form: Vital Signs
Generated On: 11 Aug 2021 22:33:31
Systolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 12:53:53
User entered 'mmHg'	System	22 Oct 2020 18:13:15

FDA-CBER-2022-1614-2809549

US3342142
Folder: Visit 3 Day 57 (1)
Form: Vital Signs
Generated On: 11 Aug 2021 22:33:31
Diastolic Blood Pressure *(xxx)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 12:53:53
User signature succeeded.	Paul Pickrell (b) (4) (b) (4)	12 Mar 2021 23:16:48
User entered '78'	Andrew Bell (b) (4) (b) (4)	22 Oct 2020 18:13:15

FDA-CBER-2022-1614-2809550

US3342142
Folder: Visit 3 Day 57 (1)
Form: Vital Signs
Generated On: 11 Aug 2021 22:33:31
Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 12:53:53
User entered 'mmHg'	System	22 Oct 2020 18:13:15

FDA-CBER-2022-1614-2809551

US3342142
Folder: Visit 3 Day 57 (1)
Form: Vital Signs
Generated On: 11 Aug 2021 22:33:31
Height (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 12:53:53

FDA-CBER-2022-1614-2809552

US3342142
Folder: Visit 3 Day 57 (1)
Form: Vital Signs
Generated On: 11 Aug 2021 22:33:31
Weight (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 12:53:53

FDA-CBER-2022-1614-2809553

US3342142
Folder: Visit 3 Day 57 (1)
Form: Physical Examination
Generated On: 11 Aug 2021 22:33:31
Was the physical examination performed?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 12:53:53
User signature succeeded.	Paul Pickrell (b) (4) (b) (4)	12 Mar 2021 23:16:48
User entered 'No (N)'	Andrew Bell (b) (4) (b) (4)	22 Oct 2020 18:13:25

US3342142
Folder: Visit 3 Day 57 (1)
Form: Physical Examination
Generated On: 11 Aug 2021 22:33:31
Date of examination *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 12:53:53
User signature succeeded.	Paul Pickrell (b) (4) (b) (4)	12 Mar 2021 23:16:48
User entered empty.	Andrew Bell (b) (4) (b) (4)	22 Oct 2020 18:13:25

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US3342142
Folder: Visit 3 Day 57 (1)
Form: Immunogenicity Assessment
Generated On: 11 Aug 2021 22:33:31
Was the sample collected?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 12:53:53
User signature succeeded.	Paul Pickrell (b) (4) (b) (4)	12 Mar 2021 23:16:48
User entered 'Yes (Y)'	Morgan Schulle (b) (4) (b) (4)	28 Oct 2020 19:45:16

US3342142
Folder: Visit 3 Day 57 (1)
Form: Immunogenicity Assessment
Generated On: 11 Aug 2021 22:33:31
Collection date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 12:53:53
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:16:48
User closed query 'Per GCL Lab recon: Immunogenicity- Sample collection date for Visit 3 Day 57 is recorded as 22-OCT-2020. However, collection date is missing in GCL. Please confirm if 22-OCT-2020 is correct date to update in GCL records.' (Site from DM).	(b) (4), (b) (6)	30 Nov 2020 10:27:50
Query 'Per GCL Lab recon: Immunogenicity- Sample collection date for Visit 3 Day 57 is recorded as 22-OCT-2020. However, collection date is missing in GCL. Please confirm if 22-OCT-2020 is correct date to update in GCL records.' answered with 'Visit 3 Day 57 collection date confirmed as 22-OCT-2020.' (Site from DM).	Andrew Bell (b) (4)	12 Nov 2020 20:12:14
User opened query 'Per GCL Lab recon: Immunogenicity- Sample collection date for Visit 3 Day 57 is recorded as 22-OCT-2020. However, collection date is missing in GCL. Please confirm if 22-OCT-2020 is correct date to update in GCL records.' (Site from DM).	(b) (4), (b) (6)	10 Nov 2020 10:16:13
User entered '22 Oct 2020'	Morgan Schulle (b) (4)	28 Oct 2020 19:45:16

US3342142
Folder: Visit 3 Day 57 (1)
Form: Immunogenicity Assessment
Generated On: 11 Aug 2021 22:33:31
Collection time *(00:00-23:59)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 12:53:53
User signature succeeded.	Paul Pickrell (b) (4) (b) (4)	12 Mar 2021 23:16:48
User entered '13:20'	Morgan Schulle (b) (4) (b) (4)	28 Oct 2020 19:45:16

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US3342142
Folder: Visit 3 Day 57 (1)
Form: Immunogenicity Assessment
Generated On: 11 Aug 2021 22:33:31
Collection date and time (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 12:53:53
User entered '22 Oct 2020 13:20'	System	28 Oct 2020 19:45:16

US3342142
Folder: Visit 3 Day 57 (1)
Form: Continuing
Generated On: 11 Aug 2021 22:33:31
Is the participant continuing to the next visit?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 12:53:53
User signature succeeded.	Paul Pickrell (b) (4) (b) (4)	12 Mar 2021 23:16:48
User entered 'Yes (Y)'	Andrew Bell (b) (4) (b) (4)	22 Oct 2020 18:13:30

US3342142
Folder: Visit 3 Day 57 (1)
Form: Continuing
Generated On: 11 Aug 2021 22:33:31
Continuing Flag

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 12:53:53
User entered '1'	System	22 Oct 2020 18:13:30

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US3342142
Folder: Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 22:33:31
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:52:24
Data entry locked.	System	24 Aug 2020 17:43:00
User entered 'Day 64'	System	24 Aug 2020 17:43:00

US3342142

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

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 14:52:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (01A85E90-DEE1-40E1-A1FD-349A8271449C)', Time: '2020-10-28T11:59:15', User OID: 'PatientReportedOutcome (US3342142)', ODM File OID: '798ef56e-84d7-4ed6-8f58-96e89552a938'	System	28 Oct 2020 16:59:24
User entered 'No (N)'	System	28 Oct 2020 16:59:24

US3342142

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

Have you been exposed to someone with 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 14:52:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (01A85E90-DEE1-40E1-A1FD-349A8271449C)', Time: '2020-10-28T11:59:18', User OID: 'PatientReportedOutcome (US3342142)', ODM File OID: '798ef56e-84d7-4ed6-8f58-96e89552a938'	System	28 Oct 2020 16:59:24
User entered 'No (N)'	System	28 Oct 2020 16:59:24

US3342142
Folder: Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 22:33:31
Date and time of submission

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:52:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (01A85E90-DEE1-40E1-A1FD-349A8271449C)', Time: '2020-10-28T11:59:21', User OID: 'PatientReportedOutcome (US3342142)', ODM File OID: '798ef56e-84d7-4ed6-8f58-96e89552a938'	System	28 Oct 2020 16:59:24
User entered '28 Oct 2020 11:59:21'	System	28 Oct 2020 16:59:24

US3342142
Folder: Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 22:33:31
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:52:24
Data entry locked.	System	24 Aug 2020 17:43:00
User entered '24 Oct 2020 00:01'	System	24 Aug 2020 17:43:00

US3342142
Folder: Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 22:33:31
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:52:24
Data entry locked.	System	24 Aug 2020 17:43:00
User entered '28 Oct 2020 23:59'	System	24 Aug 2020 17:43:00

US3342142
Folder: Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 22:33:31
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:52:24
Data entry locked.	System	24 Aug 2020 17:43:00
User entered 'Day 71'	System	24 Aug 2020 17:43:00

US3342142

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

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 14:52:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (01A85E90-DEE1-40E1-A1FD-349A8271449C)', Time: '2020-10-31T05:40:17', User OID: 'PatientReportedOutcome (US3342142)', ODM File OID: 'ccb9588f-644c-44e6-9f20-842259636592'	System	31 Oct 2020 10:40:29
User entered 'No (N)'	System	31 Oct 2020 10:40:29

US3342142

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

Have you been exposed to someone with 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 14:52:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (01A85E90-DEE1-40E1-A1FD-349A8271449C)', Time: '2020-10-31T05:40:22', User OID: 'PatientReportedOutcome (US3342142)', ODM File OID: 'ccb9588f-644c-44e6-9f20-842259636592'	System	31 Oct 2020 10:40:29
User entered 'No (N)'	System	31 Oct 2020 10:40:29

US3342142
Folder: Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 22:33:31
Date and time of submission

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:52:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (01A85E90-DEE1-40E1-A1FD-349A8271449C)', Time: '2020-10-31T05:40:24', User OID: 'PatientReportedOutcome (US3342142)', ODM File OID: 'ccb9588f-644c-44e6-9f20-842259636592'	System	31 Oct 2020 10:40:29
User entered '31 Oct 2020 05:40:24'	System	31 Oct 2020 10:40:29

US3342142
Folder: Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 22:33:31
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:52:24
Data entry locked.	System	24 Aug 2020 17:43:00
User entered '31 Oct 2020 00:01'	System	24 Aug 2020 17:43:00

US3342142
Folder: Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 22:33:31
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:52:24
Data entry locked.	System	24 Aug 2020 17:43:00
User entered '04 Nov 2020 23:59'	System	24 Aug 2020 17:43:00

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US3342142
Folder: Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 22:33:31
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:52:24
Data entry locked.	System	24 Aug 2020 17:43:00
User entered 'Day 78'	System	24 Aug 2020 17:43:00

US3342142

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

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 14:52:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (01A85E90-DEE1-40E1-A1FD-349A8271449C)', Time: '2020-11-09T06:00:11', User OID: 'PatientReportedOutcome (US3342142)', ODM File OID: '87f84cd8-6f42-45e4-b6f7-15a2fe77134c'	System	09 Nov 2020 12:01:11
User entered 'Yes (Y)'	System	09 Nov 2020 12:01:11

US3342142

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

Have you been exposed to someone with 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 14:52:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (01A85E90-DEE1-40E1-A1FD-349A8271449C)', Time: '2020-11-09T06:00:35', User OID: 'PatientReportedOutcome (US3342142)', ODM File OID: '87f84cd8-6f42-45e4-b6f7-15a2fe77134c'	System	09 Nov 2020 12:01:11
User entered 'Yes (Y)'	System	09 Nov 2020 12:01:11

US3342142

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

Please 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 14:52:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (01A85E90-DEE1-40E1-A1FD-349A8271449C)', Time: '2020-11-09T06:00:43', User OID: 'PatientReportedOutcome (US3342142)', ODM File OID: '87f84cd8-6f42-45e4-b6f7-15a2fe77134c'	System	09 Nov 2020 12:01:11
User entered 'I confirm I have read this message and will call the study clinic immediately (9)'	System	09 Nov 2020 12:01:11

US3342142

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:52:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (01A85E90-DEE1-40E1-A1FD-349A8271449C)', Time: '2020-11-09T06:00:46', User OID: 'PatientReportedOutcome (US3342142)', ODM File OID: '87f84cd8-6f42-45e4-b6f7-15a2fe77134c'	System	09 Nov 2020 12:01:11
User entered 'No (N)'	System	09 Nov 2020 12:01:11

US3342142

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:52:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (01A85E90-DEE1-40E1-A1FD-349A8271449C)', Time: '2020-11-09T06:00:55', User OID: 'PatientReportedOutcome (US3342142)', ODM File OID: '87f84cd8-6f42-45e4-b6f7-15a2fe77134c'	System	09 Nov 2020 12:01:11
User entered 'No (N)'	System	09 Nov 2020 12:01:11

US3342142
Folder: Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 22:33:31
Date and time of submission

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:52:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (01A85E90-DEE1-40E1-A1FD-349A8271449C)', Time: '2020-11-09T06:01:02', User OID: 'PatientReportedOutcome (US3342142)', ODM File OID: '87f84cd8-6f42-45e4-b6f7-15a2fe77134c'	System	09 Nov 2020 12:01:11
User entered '09 Nov 2020 06:01:02'	System	09 Nov 2020 12:01:11

US3342142
Folder: Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 22:33:31
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:52:24
Data entry locked.	System	24 Aug 2020 17:43:00
User entered '07 Nov 2020 00:01'	System	24 Aug 2020 17:43:00

US3342142
Folder: Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 22:33:31
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:52:24
Data entry locked.	System	24 Aug 2020 17:43:00
User entered '11 Nov 2020 23:59'	System	24 Aug 2020 17:43:00

US3342142
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 22:33:31
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:29:43
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:45:41
Amendment Manager: User entered 'Day 89'	System	20 Nov 2020 01:45:41

US3342142

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:29:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (01A85E90-DEE1-40E1-A1FD-349A8271449C)', Time: '2020-11-21T09:59:51', User OID: 'PatientReportedOutcome (US3342142)', ODM File OID: 'f582b281-e3bb-4c5b-9547-7de8546d120a'	System	21 Nov 2020 16:00:07
User entered 'No (N)'	System	21 Nov 2020 16:00:07

US3342142

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:29:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (01A85E90-DEE1-40E1-A1FD-349A8271449C)', Time: '2020-11-21T09:59:54', User OID: 'PatientReportedOutcome (US3342142)', ODM File OID: 'f582b281-e3bb-4c5b-9547-7de8546d120a'	System	21 Nov 2020 16:00:07
User entered 'No (N)'	System	21 Nov 2020 16:00:07

US3342142
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 22:33:31
Date and time of submission

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:29:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (01A85E90-DEE1-40E1-A1FD-349A8271449C)', Time: '2020-11-21T09:59:57', User OID: 'PatientReportedOutcome (US3342142)', ODM File OID: 'f582b281-e3bb-4c5b-9547-7de8546d120a'	System	21 Nov 2020 16:00:07
User entered '21 Nov 2020 09:59:57'	System	21 Nov 2020 16:00:07

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US3342142
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 22:33:31
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:29:43
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:45:41
Amendment Manager: User entered '18 Nov 2020 00:01'	System	20 Nov 2020 01:45:41

FDA-CBER-2022-1614-2809587

US3342142
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 22:33:31
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:29:43
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:45:41
Amendment Manager: User entered '22 Nov 2020 23:59'	System	20 Nov 2020 01:45:41

US3342142
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 22:33:31
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:29:43
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:45:41
Amendment Manager: User entered 'Day 96'	System	20 Nov 2020 01:45:41

US3342142

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:29:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (01A85E90-DEE1-40E1-A1FD-349A8271449C)', Time: '2020-11-25T08:57:44', User OID: 'PatientReportedOutcome (US3342142)', ODM File OID: 'cba6fb35-5e4e-479e-97f9-dff9dfa0dda2'	System	25 Nov 2020 14:57:52
User entered 'No (N)'	System	25 Nov 2020 14:57:52

US3342142

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:29:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (01A85E90-DEE1-40E1-A1FD-349A8271449C)', Time: '2020-11-25T08:57:47', User OID: 'PatientReportedOutcome (US3342142)', ODM File OID: 'cba6fb35-5e4e-479e-97f9-dff9dfa0dda2'	System	25 Nov 2020 14:57:52
User entered 'No (N)'	System	25 Nov 2020 14:57:52

US3342142
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 22:33:31
Date and time of submission

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:29:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (01A85E90-DEE1-40E1-A1FD-349A8271449C)', Time: '2020-11-25T08:57:50', User OID: 'PatientReportedOutcome (US3342142)', ODM File OID: 'cba6fb35-5e4e-479e-97f9-dff9dfa0dda2'	System	25 Nov 2020 14:57:52
User entered '25 Nov 2020 08:57:50'	System	25 Nov 2020 14:57:52

US3342142
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 22:33:31
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:29:43
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:45:41
Amendment Manager: User entered '25 Nov 2020 00:01'	System	20 Nov 2020 01:45:41

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US3342142
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 22:33:31
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:29:43
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:45:41
Amendment Manager: User entered '29 Nov 2020 23:59'	System	20 Nov 2020 01:45:41

FDA-CBER-2022-1614-2809594

US3342142
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 22:33:31
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:29:43
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:45:41
Amendment Manager: User entered 'Day 103'	System	20 Nov 2020 01:45:41

US3342142

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:29:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (01A85E90-DEE1-40E1-A1FD-349A8271449C)', Time: '2020-12-02T10:36:51', User OID: 'PatientReportedOutcome (US3342142)', ODM File OID: '8d96ebb0-ea1c-4123-a6da-8e945082b664'	System	02 Dec 2020 16:36:59
User entered 'No (N)'	System	02 Dec 2020 16:36:59

US3342142

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:29:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (01A85E90-DEE1-40E1-A1FD-349A8271449C)', Time: '2020-12-02T10:36:53', User OID: 'PatientReportedOutcome (US3342142)', ODM File OID: '8d96ebb0-ea1c-4123-a6da-8e945082b664'	System	02 Dec 2020 16:36:59
User entered 'No (N)'	System	02 Dec 2020 16:36:59

US3342142
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 22:33:31
Date and time of submission

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:29:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (01A85E90-DEE1-40E1-A1FD-349A8271449C)', Time: '2020-12-02T10:36:56', User OID: 'PatientReportedOutcome (US3342142)', ODM File OID: '8d96ebb0-ea1c-4123-a6da-8e945082b664'	System	02 Dec 2020 16:36:59
User entered '02 Dec 2020 10:36:56'	System	02 Dec 2020 16:36:59

FDA-CBER-2022-1614-2809598

US3342142
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 22:33:31
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:29:43
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:45:41
Amendment Manager: User entered '02 Dec 2020 00:01'	System	20 Nov 2020 01:45:41

US3342142
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 22:33:31
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:29:43
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:45:41
Amendment Manager: User entered '06 Dec 2020 23:59'	System	20 Nov 2020 01:45:41

US3342142
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 22:33:31
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:29:43
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:45:41
Amendment Manager: User entered 'Day 110'	System	20 Nov 2020 01:45:41

US3342142

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:29:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (01A85E90-DEE1-40E1-A1FD-349A8271449C)', Time: '2020-12-09T05:40:20', User OID: 'PatientReportedOutcome (US3342142)', ODM File OID: 'ffe543ab-2a80-478e-8888-f5612f8f1d9b'	System	09 Dec 2020 11:40:29
User entered 'No (N)'	System	09 Dec 2020 11:40:29

US3342142

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:29:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (01A85E90-DEE1-40E1-A1FD-349A8271449C)', Time: '2020-12-09T05:40:23', User OID: 'PatientReportedOutcome (US3342142)', ODM File OID: 'ffe543ab-2a80-478e-8888-f5612f8f1d9b'	System	09 Dec 2020 11:40:29
User entered 'No (N)'	System	09 Dec 2020 11:40:29

US3342142
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 22:33:31
Date and time of submission

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:29:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (01A85E90-DEE1-40E1-A1FD-349A8271449C)', Time: '2020-12-09T05:40:25', User OID: 'PatientReportedOutcome (US3342142)', ODM File OID: 'ffe543ab-2a80-478e-8888-f5612f8f1d9b'	System	09 Dec 2020 11:40:29
User entered '09 Dec 2020 05:40:25'	System	09 Dec 2020 11:40:29

US3342142
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 22:33:31
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:29:43
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:45:41
Amendment Manager: User entered '09 Dec 2020 00:01'	System	20 Nov 2020 01:45:41

US3342142
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 22:33:31
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:29:43
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:45:41
Amendment Manager: User entered '13 Dec 2020 23:59'	System	20 Nov 2020 01:45:41

US3342142
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 22:33:31
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:29:43
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:45:41
Amendment Manager: User entered 'Day 117'	System	20 Nov 2020 01:45:41

US3342142

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:29:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (01A85E90-DEE1-40E1-A1FD-349A8271449C)', Time: '2020-12-16T10:00:26', User OID: 'PatientReportedOutcome (US3342142)', ODM File OID: '3feb33fb-f145-4e02-8e8e-8d61e5500301'	System	16 Dec 2020 17:00:42
User entered 'No (N)'	System	16 Dec 2020 17:00:42

US3342142

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:29:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (01A85E90-DEE1-40E1-A1FD-349A8271449C)', Time: '2020-12-16T10:00:28', User OID: 'PatientReportedOutcome (US3342142)', ODM File OID: '3feb33fb-f145-4e02-8e8e-8d61e5500301'	System	16 Dec 2020 17:00:42
User entered 'No (N)'	System	16 Dec 2020 17:00:42

US3342142
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 22:33:31
Date and time of submission

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:29:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (01A85E90-DEE1-40E1-A1FD-349A8271449C)', Time: '2020-12-16T10:00:31', User OID: 'PatientReportedOutcome (US3342142)', ODM File OID: '3feb33fb-f145-4e02-8e8e-8d61e5500301'	System	16 Dec 2020 17:00:42
User entered '16 Dec 2020 10:00:31'	System	16 Dec 2020 17:00:42

US3342142
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 22:33:31
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:29:43
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:45:41
Amendment Manager: User entered '16 Dec 2020 00:01'	System	20 Nov 2020 01:45:41

US3342142
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 22:33:31
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:29:43
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:45:41
Amendment Manager: User entered '20 Dec 2020 23:59'	System	20 Nov 2020 01:45:41

US3342142
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 22:33:31
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:29:43
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:45:41
Amendment Manager: User entered 'Day 124'	System	20 Nov 2020 01:45:41

US3342142

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:29:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (01A85E90-DEE1-40E1-A1FD-349A8271449C)', Time: '2020-12-23T05:30:21', User OID: 'PatientReportedOutcome (US3342142)', ODM File OID: '94f383dc-9b9d-4167-9c3e-bd20c1170c72'	System	23 Dec 2020 11:30:32
User entered 'No (N)'	System	23 Dec 2020 11:30:32

US3342142

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:29:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (01A85E90-DEE1-40E1-A1FD-349A8271449C)', Time: '2020-12-23T05:30:24', User OID: 'PatientReportedOutcome (US3342142)', ODM File OID: '94f383dc-9b9d-4167-9c3e-bd20c1170c72'	System	23 Dec 2020 11:30:32
User entered 'No (N)'	System	23 Dec 2020 11:30:32

US3342142
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 22:33:31
Date and time of submission

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:29:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (01A85E90-DEE1-40E1-A1FD-349A8271449C)', Time: '2020-12-23T05:30:28', User OID: 'PatientReportedOutcome (US3342142)', ODM File OID: '94f383dc-9b9d-4167-9c3e-bd20c1170c72'	System	23 Dec 2020 11:30:32
User entered '23 Dec 2020 05:30:28'	System	23 Dec 2020 11:30:32

US3342142
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 22:33:31
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:29:43
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:45:41
Amendment Manager: User entered '23 Dec 2020 00:01'	System	20 Nov 2020 01:45:41

US3342142
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 22:33:31
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:29:43
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:45:41
Amendment Manager: User entered '27 Dec 2020 23:59'	System	20 Nov 2020 01:45:41

US3342142
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 22:33:31
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:29:43
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:45:41
Amendment Manager: User entered 'Day 131'	System	20 Nov 2020 01:45:41

US3342142

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:29:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (01A85E90-DEE1-40E1-A1FD-349A8271449C)', Time: '2020-12-30T16:15:15', User OID: 'PatientReportedOutcome (US3342142)', ODM File OID: 'bb49fe32-1014-478e-b0b0-a3b96fb0df65'	System	30 Dec 2020 22:15:25
User entered 'No (N)'	System	30 Dec 2020 22:15:25

US3342142

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:29:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (01A85E90-DEE1-40E1-A1FD-349A8271449C)', Time: '2020-12-30T16:15:16', User OID: 'PatientReportedOutcome (US3342142)', ODM File OID: 'bb49fe32-1014-478e-b0b0-a3b96fb0df65'	System	30 Dec 2020 22:15:25
User entered 'No (N)'	System	30 Dec 2020 22:15:25

US3342142
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 22:33:31
Date and time of submission

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:29:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (01A85E90-DEE1-40E1-A1FD-349A8271449C)', Time: '2020-12-30T16:15:19', User OID: 'PatientReportedOutcome (US3342142)', ODM File OID: 'bb49fe32-1014-478e-b0b0-a3b96fb0df65'	System	30 Dec 2020 22:15:25
User entered '30 Dec 2020 16:15:19'	System	30 Dec 2020 22:15:25

FDA-CBER-2022-1614-2809622

US3342142
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 22:33:31
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:29:43
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:45:41
Amendment Manager: User entered '30 Dec 2020 00:01'	System	20 Nov 2020 01:45:41

US3342142
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 22:33:31
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:29:43
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:45:41
Amendment Manager: User entered '03 Jan 2021 23:59'	System	20 Nov 2020 01:45:41

US3342142
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 22:33:31
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:29:43
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:45:41
Amendment Manager: User entered 'Day 138'	System	20 Nov 2020 01:45:41

US3342142

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:29:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (01A85E90-DEE1-40E1-A1FD-349A8271449C)', Time: '2021-01-06T05:26:21', User OID: 'PatientReportedOutcome (US3342142)', ODM File OID: '60afc2c9-7848-4cec-84d3-347b089f8a79'	System	06 Jan 2021 11:26:28
User entered 'No (N)'	System	06 Jan 2021 11:26:28

US3342142

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:29:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (01A85E90-DEE1-40E1-A1FD-349A8271449C)', Time: '2021-01-06T05:26:23', User OID: 'PatientReportedOutcome (US3342142)', ODM File OID: '60afc2c9-7848-4cec-84d3-347b089f8a79'	System	06 Jan 2021 11:26:28
User entered 'No (N)'	System	06 Jan 2021 11:26:28

US3342142
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 22:33:31
Date and time of submission

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:29:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (01A85E90-DEE1-40E1-A1FD-349A8271449C)', Time: '2021-01-06T05:26:25', User OID: 'PatientReportedOutcome (US3342142)', ODM File OID: '60afc2c9-7848-4cec-84d3-347b089f8a79'	System	06 Jan 2021 11:26:28
User entered '06 Jan 2021 05:26:25'	System	06 Jan 2021 11:26:28

FDA-CBER-2022-1614-2809628

US3342142
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 22:33:31
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:29:43
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:45:41
Amendment Manager: User entered '06 Jan 2021 00:01'	System	20 Nov 2020 01:45:41

FDA-CBER-2022-1614-2809629

US3342142
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 22:33:31
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:29:43
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:45:41
Amendment Manager: User entered '10 Jan 2021 23:59'	System	20 Nov 2020 01:45:41

FDA-CBER-2022-1614-2809630

US3342142
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 22:33:31
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:29:43
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:45:41
Amendment Manager: User entered 'Day 145'	System	20 Nov 2020 01:45:41

US3342142

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:29:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (01A85E90-DEE1-40E1-A1FD-349A8271449C)', Time: '2021-01-15T12:00:33', User OID: 'PatientReportedOutcome (US3342142)', ODM File OID: '4aaff5bb-bf56-4f04-bfdd-81f6e813096d'	System	15 Jan 2021 18:00:46
User entered 'No (N)'	System	15 Jan 2021 18:00:46

US3342142

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:29:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (01A85E90-DEE1-40E1-A1FD-349A8271449C)', Time: '2021-01-15T12:00:35', User OID: 'PatientReportedOutcome (US3342142)', ODM File OID: '4aaff5bb-bf56-4f04-bfdd-81f6e813096d'	System	15 Jan 2021 18:00:46
User entered 'No (N)'	System	15 Jan 2021 18:00:46

US3342142
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 22:33:31
Date and time of submission

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:29:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (01A85E90-DEE1-40E1-A1FD-349A8271449C)', Time: '2021-01-15T12:00:37', User OID: 'PatientReportedOutcome (US3342142)', ODM File OID: '4aaff5bb-bf56-4f04-bfdd-81f6e813096d'	System	15 Jan 2021 18:00:46
User entered '15 Jan 2021 12:00:37'	System	15 Jan 2021 18:00:46

FDA-CBER-2022-1614-2809634

US3342142
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 22:33:31
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:29:43
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:45:41
Amendment Manager: User entered '13 Jan 2021 00:01'	System	20 Nov 2020 01:45:41

FDA-CBER-2022-1614-2809635

US3342142
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 22:33:31
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:29:43
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:45:41
Amendment Manager: User entered '17 Jan 2021 23:59'	System	20 Nov 2020 01:45:41

FDA-CBER-2022-1614-2809636

US3342142
Folder: Safety Call Day 85 (1)
Form: Safety Call
Generated On: 11 Aug 2021 22:33:31
Was Contact Attempted?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 12:53:53
User signature succeeded.	Paul Pickrell (b) (4) (b) (4)	12 Mar 2021 23:16:48
User entered 'Yes (Y)'	Eileen Euperio (b) (4) (b) (4)	13 Nov 2020 22:48:18

US3342142
Folder: Safety Call Day 85 (1)
Form: Safety Call
Generated On: 11 Aug 2021 22:33:31
Date of Contact or Contact Attempt *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 12:53:53
User signature succeeded.	Paul Pickrell (b) (4) (b) (4)	12 Mar 2021 23:16:48
User entered '13 Nov 2020'	Eileen Euperio (b) (4) (b) (4)	13 Nov 2020 22:48:18

US3342142
Folder: Safety Call Day 85 (1)
Form: Safety Call
Generated On: 11 Aug 2021 22:33:31
Please select one status for the follow-up contact

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 12:53:53
User signature succeeded.	Paul Pickrell (b) (4) (b) (4)	12 Mar 2021 23:16:48
User entered 'Contact Made (CONTACT MADE)'	Eileen Euperio (b) (4) (b) (4)	13 Nov 2020 22:48:18

US3342142
Folder: Safety Call Day 85 (1)
Form: Safety Call
Generated On: 11 Aug 2021 22:33:31
Comments

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 12:53:53
User signature succeeded.	Paul Pickrell (b) (4) (b) (4)	12 Mar 2021 23:16:48
User entered empty.	Eileen Euperio (b) (4) (b) (4)	13 Nov 2020 22:48:18

FDA-CBER-2022-1614-2809640

US3342142
Folder: Safety Call Day 85 (1)
Form: Continuing
Generated On: 11 Aug 2021 22:33:31
Is the participant continuing to the next visit?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 12:53:53
User signature succeeded.	Paul Pickrell (b) (4) (b) (4)	12 Mar 2021 23:16:48
User entered 'Yes (Y)'	Eileen Euperio (b) (4) (b) (4)	13 Nov 2020 22:48:26

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US3342142
Folder: Safety Call Day 85 (1)
Form: Continuing
Generated On: 11 Aug 2021 22:33:31
Continuing Flag

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 12:53:53
User entered '1'	System	13 Nov 2020 22:48:26

FDA-CBER-2022-1614-2809642

US3342142
Folder: Safety Call Day 119 (1)
Form: Safety Call
Generated On: 11 Aug 2021 22:33:31
Was Contact Attempted?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:29:43
User signature succeeded.	Paul Pickrell (b) (4) (b) (4)	12 Mar 2021 23:16:48
User entered 'Yes (Y)'	Ethan Shotton (b) (4) (b) (4)	18 Dec 2020 19:24:34

US3342142
Folder: Safety Call Day 119 (1)
Form: Safety Call
Generated On: 11 Aug 2021 22:33:31
Date of Contact or Contact Attempt *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:29:43
User signature succeeded.	Paul Pickrell (b) (4) (b) (4)	12 Mar 2021 23:16:48
User entered '18 Dec 2020'	Ethan Shotton (b) (4) (b) (4)	18 Dec 2020 19:24:34

FDA-CBER-2022-1614-2809644

US3342142
Folder: Safety Call Day 119 (1)
Form: Safety Call
Generated On: 11 Aug 2021 22:33:31
Please select one status for the follow-up contact

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:29:43
User signature succeeded.	Paul Pickrell (b) (4) (b) (4)	12 Mar 2021 23:16:48
User entered 'Contact Made (CONTACT MADE)'	Ethan Shotton (b) (4) (b) (4)	18 Dec 2020 19:24:34

US3342142
Folder: Safety Call Day 119 (1)
Form: Safety Call
Generated On: 11 Aug 2021 22:33:31
Comments

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:29:43
User signature succeeded.	Paul Pickrell (b) (4) (b) (4)	12 Mar 2021 23:16:48
User entered empty.	Ethan Shotton (b) (4) (b) (4)	18 Dec 2020 19:24:34

FDA-CBER-2022-1614-2809646

US3342142
Folder: Safety Call Day 119 (1)
Form: Continuing
Generated On: 11 Aug 2021 22:33:31
Is the participant continuing to the next visit?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:29:43
User signature succeeded.	Paul Pickrell (b) (4) (b) (4)	22 Mar 2021 13:27:19
Signature has been broken.	Ethan Shotton (b) (4) (b) (4)	18 Mar 2021 18:39:36
User entered 'No (N)' reason for change: Data Entry Error	Ethan Shotton (b) (4) (b) (4)	18 Mar 2021 18:39:36
User signature succeeded.	Paul Pickrell (b) (4) (b) (4)	12 Mar 2021 23:16:48
User entered 'Yes (Y)'	Ethan Shotton (b) (4) (b) (4)	18 Dec 2020 19:24:38

FDA-CBER-2022-1614-2809647

US3342142
Folder: Safety Call Day 119 (1)
Form: Continuing
Generated On: 11 Aug 2021 22:33:31
Continuing Flag

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:29:43
User entered empty.	System	18 Mar 2021 18:39:36
User entered '1'	System	18 Dec 2020 19:24:38

US3342142
Folder: Participant Decision Visit / OL-D1 (1)
Form: Unblinding
Generated On: 11 Aug 2021 22:33:31
Date of updated informed consent *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:29:43
User closed query 'Per CDM; Per IRT: Informed Consent Date is missing; Kindly update the data, Else clarify. Thank you!' (Site from DM).	(b) (4), (b) (6)	23 Apr 2021 12:54:29
Query 'Per CDM; Per IRT: Informed Consent Date is missing; Kindly update the data, Else clarify. Thank you!' answered with 'Subject was unblinded under Amd. 6, but never came in for OL-D1 as she was a nurse who was being offered an EUA approved COVID-19 vaccine at the time. With approval from the sponsor, subject was unblinded remotely on 05Jan2021. Subject was withdrawn from the study on 19Jan2021 due to receiving a EUA vaccine outside of the site and did not attend an OL-D1 visit to sign the updated informed consent.' (Site from DM).	Ethan Shotton (b) (4) (b) (4)	22 Apr 2021 16:23:30
User opened query 'Per CDM; Per IRT: Informed Consent Date is missing; Kindly update the data, Else clarify. Thank you!' (Site from DM).	(b) (4), (b) (6)	22 Apr 2021 08:04:22
User signature succeeded.	Paul Pickrell (b) (4) (b) (4)	12 Apr 2021 15:32:31
User closed query 'Per sponsor review, the date of updated informed consent" and "N/A - Subject Unblinded under Amendment 5 and Discontinued from Study" cannot both be blank. Please either update date subject signed updated informed consent or if Subject discontinued from the study under Amendment 5, tick the box.' (Site from DM).	(b) (4), (b) (6)	09 Apr 2021 15:51:38
Query 'Per sponsor review, the date of updated informed consent" and "N/A - Subject Unblinded under Amendment 5 and Discontinued from Study" cannot both be blank. Please either update date subject signed updated informed consent or if Subject discontinued from the study under Amendment 5, tick the box.' answered with 'corrected' (Site from DM).	Olivia Hapanowicz (b) (4) (b) (4)	08 Apr 2021 12:43:20

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US3342142
Folder: Participant Decision Visit / OL-D1 (1)
Form: Unblinding
Generated On: 11 Aug 2021 22:33:31
Date of updated informed consent *(dd MMM yyyy)*

Audit	User	Time (GMT)
User opened query 'Per sponsor review, the date of updated informed consent" and "N/A - Subject Unblinded under Amendment 5 and Discontinued from Study" cannot both be blank. Please either update date subject signed updated informed consent or if Subject discontinued from the study under Amendment 5, tick the box.' (Site from DM).	(b) (4), (b) (6)	08 Apr 2021 09:02:50
User entered empty.	(b) (4), (b) (6)	31 Mar 2021 18:36:38

US3342142
Folder: Participant Decision Visit / OL-D1 (1)
Form: Unblinding
Generated On: 11 Aug 2021 22:33:31
N/A - Subject Unblinded under Amendment 5 and Discontinued from Study

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:29:43
User closed query 'o Per CDM: 'NA unblinded under A5 and study discontinued' is not ticked and consent date is blank. Please review as one of these fields should be completed.' (Site from DM).	(b) (4), (b) (6)	14 Apr 2021 13:06:09
Query 'o Per CDM: 'NA unblinded under A5 and study discontinued' is not ticked and consent date is blank. Please review as one of these fields should be completed.' answered with 'pt did not come in for OL-D1 visit & was unblinded under amendment 6. please clarify how this should be reported in EDC as neither date of informed consent box nor 'NA subject unblinded under A5' box apply to this subject.' (Site from DM).	Olivia Hapanowicz (b) (4) (b) (4)	13 Apr 2021 12:22:17
User opened query 'o Per CDM: 'NA unblinded under A5 and study discontinued' is not ticked and consent date is blank. Please review as one of these fields should be completed.' (Site from DM).	(b) (4), (b) (6)	13 Apr 2021 05:22:27
User signature succeeded.	Paul Pickrell (b) (4) (b) (4)	12 Apr 2021 15:32:31
User entered '0' reason for change: Data Entry Error	Olivia Hapanowicz (b) (4) (b) (4)	08 Apr 2021 13:37:24
User entered '1' reason for change: Data Entry Error	Olivia Hapanowicz (b) (4) (b) (4)	08 Apr 2021 12:42:49
User entered '0'	(b) (4), (b) (6)	31 Mar 2021 18:36:38

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US3342142
Folder: Participant Decision Visit / OL-D1 (1)
Form: Unblinding
Generated On: 11 Aug 2021 22:33:31
Was the participant unblinded?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:29:43
User signature succeeded.	Paul Pickrell (b) (4)	12 Apr 2021 15:32:31
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	31 Mar 2021 18:36:38

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US3342142

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

Form: Unblinding

Generated On: 11 Aug 2021 22:33:31

Under what version of the Protocol was the Participant unblinded?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:29:43
User signature succeeded.	Paul Pickrell (b) (4)	12 Apr 2021 15:32:31
User closed query 'Per IRT system use and date, this subject was unblinded when the site was approved for A6. Subject was unblinded under A6, please review and update field.' (Site from DM).	(b) (4) (b) (4), (b) (6)	09 Apr 2021 15:51:40
Query 'Per IRT system use and date, this subject was unblinded when the site was approved for A6. Subject was unblinded under A6, please review and update field.' answered with 'corrected' (Site from DM).	Olivia Hapanowicz (b) (4) (b) (4)	08 Apr 2021 13:37:41
User entered 'Amendment 6 or later (Amendment 6 or later)' reason for change: Data Entry Error	Olivia Hapanowicz (b) (4) (b) (4)	08 Apr 2021 13:37:24
User opened query 'Per IRT system use and date, this subject was unblinded when the site was approved for A6. Subject was unblinded under A6, please review and update field.' (Site from DM).	(b) (4), (b) (6)	08 Apr 2021 12:48:43
User entered 'Amendment 5 (Amendment 5)'	(b) (4), (b) (6)	31 Mar 2021 18:36:38

US3342142
Folder: Participant Decision Visit / OL-D1 (1)
Form: Unblinding
Generated On: 11 Aug 2021 22:33:31
Date of unblinding *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:29:43
User signature succeeded.	Paul Pickrell (b) (4)	12 Apr 2021 15:32:31
User entered '5 Jan 2021'	(b) (4), (b) (6)	31 Mar 2021 18:36:38

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US3342142
Folder: Participant Decision Visit / OL-D1 (1)
Form: Unblinding
Generated On: 11 Aug 2021 22:33:31
Participant randomization assignment

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:29:43
User signature succeeded.	Paul Pickrell (b) (4)	12 Apr 2021 15:32:31
User entered 'Placebo (Placebo)'	(b) (4) (b) (4), (b) (6)	31 Mar 2021 18:36:38

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US3342142
Folder: Participant Decision Visit / OL-D1 (1)
Form: Unblinding
Generated On: 11 Aug 2021 22:33:31
Actual Dose 1

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:29:43
User signature succeeded.	Paul Pickrell (b) (4)	12 Apr 2021 15:32:31
User entered 'Placebo (Placebo)'	(b) (4) (b) (4), (b) (6)	31 Mar 2021 18:36:38

FDA-CBER-2022-1614-2809656

US3342142
Folder: Participant Decision Visit / OL-D1 (1)
Form: Unblinding
Generated On: 11 Aug 2021 22:33:31
Actual Dose 2

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:29:43
User signature succeeded.	Paul Pickrell (b) (4)	12 Apr 2021 15:32:31
User entered 'Placebo (Placebo)'	(b) (4) (b) (4), (b) (6)	31 Mar 2021 18:36:38

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US3342142
Folder: Participant Decision Visit / OL-D1 (1)
Form: Unblinding
Generated On: 11 Aug 2021 22:33:31
Will participant receive mRNA-1273?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:29:43
User signature succeeded.	Paul Pickrell (b) (4)	12 Apr 2021 15:32:31
User entered 'No (N)'	(b) (4), (b) (6) (b) (4)	31 Mar 2021 18:36:38

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US3342142
Folder: Participant Decision Visit / OL-D1 (1)
Form: Unblinding
Generated On: 11 Aug 2021 22:33:31
Placebo Only Flag

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:29:43
User entered '1'	System	31 Mar 2021 18:36:38

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US3342142
Folder: Participant Decision Visit / OL-D1 (1)
Form: Unblinding
Generated On: 11 Aug 2021 22:33:31
Continuing with mRNA-1273

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:29:43
User entered empty.	System	31 Mar 2021 18:36:38

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US3342142
Folder: Adverse Events
Form: Adverse Events Summary
Generated On: 11 Aug 2021 22:33:31
Did the participant experience any adverse events?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:29:43
User signature succeeded.	Paul Pickrell (b) (4) (b) (4)	12 Mar 2021 23:16:43
User entered 'No (N)'	Ethan Shotton (b) (4) (b) (4)	04 Mar 2021 00:05:59

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US3342142
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination Summary
Generated On: 11 Aug 2021 22:33:31
Were any prior/concomitant medications and/or vaccinations taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:29:43
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:16:48
User entered 'Yes (Y)'	John Luna (b) (4)	24 Aug 2020 18:38:02

FDA-CBER-2022-1614-2809662

US3342142
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (1)
Generated On: 11 Aug 2021 22:33:31
Name of Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:29:43
User signature succeeded.	Paul Pickrell (b) (4) (b) (4)	12 Mar 2021 23:16:43
User coded data point as ATC: RESPIRATORY SYSTEM, ATC: ANTIHISTAMINES FOR SYSTEMIC USE, ATC: ANTIHISTAMINES FOR SYSTEMIC USE, ATC: PIPERAZINE DERIVATIVES, PRODUCT: CETIRIZINE HYDROCHLORIDE, PRODUCTSYNONYM: ZYRTEC [CETIRIZINE HYDROCHLORIDE] - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	24 Aug 2020 18:40:41
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	24 Aug 2020 18:40:41
Data point term sent to Coder	System	24 Aug 2020 18:39:17
User entered 'Zyrtec'	John Luna (b) (4)	24 Aug 2020 18:38:44

US3342142
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (1)
Generated On: 11 Aug 2021 22:33:31
Prophylaxis

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:29:43
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:16:43
User entered 'No (N)'	John Luna (b) (4)	24 Aug 2020 18:38:44

FDA-CBER-2022-1614-2809664

US3342142
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (1)
Generated On: 11 Aug 2021 22:33:31
Indication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:29:43
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:16:43
User entered 'Seasonal Allergies'	John Luna (b) (4)	24 Aug 2020 18:38:44

US3342142
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (1)
Generated On: 11 Aug 2021 22:33:31
Dose per administration

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:29:43
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:16:43
User entered '10'	John Luna (b) (4)	24 Aug 2020 18:38:44

US3342142
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (1)
Generated On: 11 Aug 2021 22:33:31
Dose unit

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:29:43
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:16:43
User entered 'mg (mg)'	John Luna (b) (4)	24 Aug 2020 18:38:44

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US3342142
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (1)
Generated On: 11 Aug 2021 22:33:31
If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:29:43
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:16:43
User entered empty.	John Luna (b) (4)	24 Aug 2020 18:38:44

FDA-CBER-2022-1614-2809668

US3342142
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (1)
Generated On: 11 Aug 2021 22:33:31
Frequency

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:29:43
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:16:43
User entered 'once daily (QD)'	John Luna (b) (4)	24 Aug 2020 18:38:44

US3342142
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (1)
Generated On: 11 Aug 2021 22:33:31
If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:29:43
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:16:43
User entered empty.	John Luna (b) (4)	24 Aug 2020 18:38:44

FDA-CBER-2022-1614-2809670

US3342142
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (1)
Generated On: 11 Aug 2021 22:33:31
Route of administration

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:29:43
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:16:43
User entered 'Oral (ORAL)'	John Luna (b) (4)	24 Aug 2020 18:38:44

US3342142
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (1)
Generated On: 11 Aug 2021 22:33:31
If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:29:43
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:16:43
User entered empty.	John Luna (b) (4)	24 Aug 2020 18:38:44

FDA-CBER-2022-1614-2809672

US3342142
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (1)
Generated On: 11 Aug 2021 22:33:31
Start date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:29:43
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:16:43
User closed query 'Per DM CLR: Con Med start date is prior to the start date of the corresponding MH condition. Please review and reconcile Con Med and MH start dates as appropriate. Otherwise, clarify.' (Site from DM).	(b) (4) (b) (4), (b) (6)	09 Oct 2020 16:59:49
Query 'Per DM CLR: Con Med start date is prior to the start date of the corresponding MH condition. Please review and reconcile Con Med and MH start dates as appropriate. Otherwise, clarify.' answered with 'Updated' (Site from DM).	Darrell O'Brien (b) (4) (b) (4)	05 Oct 2020 16:18:45
User entered 'UN UNK 2016' reason for change: Data Entry Error	Darrell O'Brien (b) (4) (b) (4)	05 Oct 2020 16:18:38
User opened query 'Per DM CLR: Con Med start date is prior to the start date of the corresponding MH condition. Please review and reconcile Con Med and MH start dates as appropriate. Otherwise, clarify.' (Site from DM).	(b) (4), (b) (6)	22 Sep 2020 06:33:06
User entered 'un UNK 2010'	John Luna (b) (4)	24 Aug 2020 18:38:44

US3342142
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (1)
Generated On: 11 Aug 2021 22:33:31
Start date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:29:43
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:16:43
User entered '0'	John Luna (b) (4)	24 Aug 2020 18:38:44

FDA-CBER-2022-1614-2809674

US3342142
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (1)
Generated On: 11 Aug 2021 22:33:31
Ongoing?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:29:43
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:16:43
User entered 'Yes (Y)'	John Luna (b) (4)	24 Aug 2020 18:38:44

FDA-CBER-2022-1614-2809675

US3342142
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (1)
Generated On: 11 Aug 2021 22:33:31
If not Ongoing, End date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:29:43
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:16:43
User entered empty.	John Luna (b) (4)	24 Aug 2020 18:38:44

FDA-CBER-2022-1614-2809676

US3342142
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (1)
Generated On: 11 Aug 2021 22:33:31
Was this medication taken for solicited event?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:29:43
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:16:43
User entered 'No (N)'	John Luna (b) (4)	24 Aug 2020 18:38:44

US3342142
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (1)
Generated On: 11 Aug 2021 22:33:31
Separate Dosage Number (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:29:43
User entered '1'	System	24 Aug 2020 18:38:44

US3342142
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (1)
Generated On: 11 Aug 2021 22:33:31
Interval Dosage Unit Number (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:29:43
User entered '1'	System	24 Aug 2020 18:38:44

US3342142
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (1)
Generated On: 11 Aug 2021 22:33:31
Interval Dosage Definition (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:29:43
User entered '804 (804)'	System	24 Aug 2020 18:38:44

US3342142
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (2)
Generated On: 11 Aug 2021 22:33:31
Name of Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:29:43
User signature succeeded.	Paul Pickrell (b) (4) (b) (4)	12 Mar 2021 23:16:43
User coded data point as ATC: MUSCULO-SKELETAL SYSTEM, ATC: ANTIINFLAMMATORY AND ANTIRHEUMATIC PRODUCTS, ATC: ANTIINFLAMMATORY AND ANTIRHEUMATIC PRODUCTS, NON-STEROIDS, ATC: PROPIONIC ACID DERIVATIVES, PRODUCT: IBUPROFEN, PRODUCTSYNONYM: MOTRIN [IBUPROFEN] - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	29 Sep 2020 03:37:49
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 Sep 2020 03:37:49
Data point term sent to Coder	System	28 Sep 2020 21:02:59
User entered 'Ibuprofen (Motrin)'	(b) (4), (b) (6)	28 Sep 2020 21:02:17

US3342142
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (2)
Generated On: 11 Aug 2021 22:33:31
Prophylaxis

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:29:43
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:16:43
User entered 'No (N)'	(b) (4), (b) (6) (b) (4)	28 Sep 2020 21:02:17

FDA-CBER-2022-1614-2809682

US3342142
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (2)
Generated On: 11 Aug 2021 22:33:31
Indication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:29:43
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:16:43
User entered 'Headache'	(b) (4) (b) (4), (b) (6)	28 Sep 2020 21:02:17

US3342142
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (2)
Generated On: 11 Aug 2021 22:33:31
Dose per administration

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:29:43
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:16:43
User entered '200'	(b) (4), (b) (6)	28 Sep 2020 21:02:17

FDA-CBER-2022-1614-2809684

US3342142
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (2)
Generated On: 11 Aug 2021 22:33:31
Dose unit

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:29:43
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:16:43
User entered 'mg (mg)'	(b) (4), (b) (6)	28 Sep 2020 21:02:17

US3342142
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (2)
Generated On: 11 Aug 2021 22:33:31
If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:29:43
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:16:43
User entered empty.	(b) (4) (b) (4), (b) (6)	28 Sep 2020 21:02:17

FDA-CBER-2022-1614-2809686

US3342142
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (2)
Generated On: 11 Aug 2021 22:33:31
Frequency

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:29:43
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:16:43
User entered 'once daily (QD)'	(b) (4) (b) (4), (b) (6)	28 Sep 2020 21:02:17

US3342142
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (2)
Generated On: 11 Aug 2021 22:33:31
If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:29:43
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:16:43
User entered empty.	(b) (4) (b) (4), (b) (6)	28 Sep 2020 21:02:17

US3342142
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (2)
Generated On: 11 Aug 2021 22:33:31
Route of administration

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:29:43
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:16:43
User entered 'Oral (ORAL)'	(b) (4) (b) (4), (b) (6)	28 Sep 2020 21:02:17

US3342142
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (2)
Generated On: 11 Aug 2021 22:33:31
If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:29:43
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:16:43
User entered empty.	(b) (4) (b) (4), (b) (6)	28 Sep 2020 21:02:17

US3342142
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (2)
Generated On: 11 Aug 2021 22:33:31
Start date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:29:43
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:16:43
User entered '24 Sep 2020'	(b) (4), (b) (6)	28 Sep 2020 21:02:17

FDA-CBER-2022-1614-2809691

US3342142
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (2)
Generated On: 11 Aug 2021 22:33:31
Start date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:29:43
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:16:43
User entered '0'	(b) (4), (b) (6)	28 Sep 2020 21:02:17

US3342142
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (2)
Generated On: 11 Aug 2021 22:33:31
Ongoing?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:29:43
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:16:43
User entered 'No (N)'	(b) (4), (b) (6) (b) (4)	28 Sep 2020 21:02:17

US3342142
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (2)
Generated On: 11 Aug 2021 22:33:31
If not Ongoing, End date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:29:43
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:16:43
User entered '25 Sep 2020'	(b) (4) (b) (4), (b) (6)	28 Sep 2020 21:02:17

FDA-CBER-2022-1614-2809694

US3342142
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (2)
Generated On: 11 Aug 2021 22:33:31
Was this medication taken for solicited event?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:29:43
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:16:43
User closed query 'Per DM CLR: Was this medication taken for solicited event?=YES. However, there is no record of HEADACHE in eDiary and no AE has been recorded. Review if this is considered as unsolicited event per protocol. If yes, please update and record this condition in AE eCRFupdate this field to No. Else, provide clarification.' (Site from DM).	(b) (4) (b) (4), (b) (6)	04 Dec 2020 15:02:59
Query 'Per DM CLR: Was this medication taken for solicited event?=YES. However, there is no record of HEADACHE in eDiary and no AE has been recorded. Review if this is considered as unsolicited event per protocol. If yes, please update and record this condition in AE eCRFupdate this field to No. Else, provide clarification.' answered with 'did not meet AE reporting criteria per protocol' (Site from DM).	Eileen Euperio (b) (4) (b) (4)	03 Dec 2020 15:58:22
User opened query 'Per DM CLR: Was this medication taken for solicited event?=YES. However, there is no record of HEADACHE in eDiary and no AE has been recorded. Review if this is considered as unsolicited event per protocol. If yes, please update and record this condition in AE eCRFupdate this field to No. Else, provide clarification.' (Site from DM).	(b) (4), (b) (6)	02 Dec 2020 16:46:05
User entered 'Yes (Y)'	(b) (4), (b) (6)	28 Sep 2020 21:02:17

US3342142
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (2)
Generated On: 11 Aug 2021 22:33:31
Separate Dosage Number (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:29:43
User entered '1'	System	28 Sep 2020 21:02:17

US3342142
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (2)
Generated On: 11 Aug 2021 22:33:31
Interval Dosage Unit Number (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:29:43
User entered '1'	System	28 Sep 2020 21:02:17

US3342142
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (2)
Generated On: 11 Aug 2021 22:33:31
Interval Dosage Definition (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:29:43
User entered '804 (804)'	System	28 Sep 2020 21:02:17

US3342142
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (3)
Generated On: 11 Aug 2021 22:33:31
Name of Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:29:43
User signature succeeded.	Paul Pickrell (b) (4) (b) (4)	22 Mar 2021 13:27:19
User coded data point as ATC: ANTIINFECTIVES FOR SYSTEMIC USE, ATC: VACCINES, ATC: VIRAL VACCINES, ATC: OTHER VIRAL VACCINES, PRODUCT: OTHER VIRAL VACCINES - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	18 Mar 2021 19:24:42
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	18 Mar 2021 19:24:42
Data point term sent to Coder	System	18 Mar 2021 19:23:49
Coding entries removed.	Ethan Shotton (b) (4) (b) (4)	18 Mar 2021 19:23:16
Signature has been broken.	Ethan Shotton (b) (4) (b) (4)	18 Mar 2021 19:23:16
User entered 'BNT162B2 Vaccine' reason for change: Data Entry Error	Ethan Shotton (b) (4) (b) (4)	18 Mar 2021 19:23:16
User signature succeeded.	Paul Pickrell (b) (4) (b) (4)	12 Mar 2021 23:16:43
User coded data point as ATC: ANTIINFECTIVES FOR SYSTEMIC USE, ATC: VACCINES, ATC: VIRAL VACCINES, ATC: OTHER VIRAL VACCINES, PRODUCT: OTHER VIRAL VACCINES - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	02 Feb 2021 22:21:37
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 Feb 2021 22:21:37
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)	02 Feb 2021 21:53:33
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 Feb 2021 21:53:33

US3342142

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 11 Aug 2021 22:33:31

Name of Medication

Audit	User	Time (GMT)
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)	19 Jan 2021 22:53:10
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	19 Jan 2021 22:53:10
Data point term sent to Coder	System	19 Jan 2021 18:07:01
User entered 'BNT162b2'	Ethan Shotton (b) (4) (b) (4)	19 Jan 2021 18:06:53

US3342142
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (3)
Generated On: 11 Aug 2021 22:33:31
Prophylaxis

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:29:43
User signature succeeded.	Paul Pickrell (b) (4) (b) (4)	12 Mar 2021 23:16:43
User entered 'Yes (Y)'	Ethan Shotton (b) (4) (b) (4)	19 Jan 2021 18:06:53

US3342142
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (3)
Generated On: 11 Aug 2021 22:33:31
Indication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:29:43
User signature succeeded.	Paul Pickrell (b) (4) (b) (4)	12 Mar 2021 23:16:43
User entered 'COVID-19 Prophylaxis'	Ethan Shotton (b) (4) (b) (4)	19 Jan 2021 18:06:53

US3342142
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (3)
Generated On: 11 Aug 2021 22:33:31
Dose per administration

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:29:43
User signature succeeded.	Paul Pickrell (b) (4) (b) (4)	12 Mar 2021 23:16:43
User entered '30' reason for change: Data Entry Error	Ethan Shotton (b) (4) (b) (4)	22 Jan 2021 18:53:34
User entered '0.5'	Ethan Shotton (b) (4) (b) (4)	19 Jan 2021 18:06:53

US3342142
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (3)
Generated On: 11 Aug 2021 22:33:31
Dose unit

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:29:43
User signature succeeded.	Paul Pickrell (b) (4) (b) (4)	12 Mar 2021 23:16:43
User entered 'ug (ug)' reason for change: Data Entry Error	Ethan Shotton (b) (4) (b) (4)	22 Jan 2021 18:53:34
User entered 'mg (mg)'	Ethan Shotton (b) (4) (b) (4)	19 Jan 2021 18:06:53

US3342142
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (3)
Generated On: 11 Aug 2021 22:33:31
If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:29:43
User signature succeeded.	Paul Pickrell (b) (4) (b) (4)	12 Mar 2021 23:16:43
User entered empty.	Ethan Shotton (b) (4) (b) (4)	19 Jan 2021 18:06:53

US3342142
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (3)
Generated On: 11 Aug 2021 22:33:31
Frequency

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:29:43
User signature succeeded.	Paul Pickrell (b) (4) (b) (4)	12 Mar 2021 23:16:43
User entered 'once (ONCE)'	Ethan Shotton (b) (4) (b) (4)	19 Jan 2021 18:06:53

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US3342142
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (3)
Generated On: 11 Aug 2021 22:33:31
If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:29:43
User signature succeeded.	Paul Pickrell (b) (4) (b) (4)	12 Mar 2021 23:16:43
User entered empty.	Ethan Shotton (b) (4) (b) (4)	19 Jan 2021 18:06:53

US3342142
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (3)
Generated On: 11 Aug 2021 22:33:31
Route of administration

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:29:43
User signature succeeded.	Paul Pickrell (b) (4) (b) (4)	12 Mar 2021 23:16:43
User entered 'Intramuscular (INTRAMUSCULAR)'	Ethan Shotton (b) (4) (b) (4)	19 Jan 2021 18:06:53

US3342142
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (3)
Generated On: 11 Aug 2021 22:33:31
If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:29:43
User signature succeeded.	Paul Pickrell (b) (4) (b) (4)	12 Mar 2021 23:16:43
User entered empty.	Ethan Shotton (b) (4) (b) (4)	19 Jan 2021 18:06:53

US3342142
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (3)
Generated On: 11 Aug 2021 22:33:31
Start date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:29:43
User signature succeeded.	Paul Pickrell (b) (4) (b) (4)	12 Mar 2021 23:16:43
User entered '12 Jan 2021'	Ethan Shotton (b) (4) (b) (4)	19 Jan 2021 18:06:53

FDA-CBER-2022-1614-2809710

US3342142
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (3)
Generated On: 11 Aug 2021 22:33:31
Start date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:29:43
User signature succeeded.	Paul Pickrell (b) (4) (b) (4)	12 Mar 2021 23:16:43
User entered '0'	Ethan Shotton (b) (4) (b) (4)	19 Jan 2021 18:06:53

US3342142
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (3)
Generated On: 11 Aug 2021 22:33:31
Ongoing?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:29:43
User signature succeeded.	Paul Pickrell (b) (4) (b) (4)	12 Mar 2021 23:16:43
User entered 'No (N)'	Ethan Shotton (b) (4) (b) (4)	19 Jan 2021 18:06:53

US3342142
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (3)
Generated On: 11 Aug 2021 22:33:31
If not Ongoing, End date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:29:43
User signature succeeded.	Paul Pickrell (b) (4) (b) (4)	12 Mar 2021 23:16:43
User entered '12 Jan 2021'	Ethan Shotton (b) (4) (b) (4)	19 Jan 2021 18:06:53

FDA-CBER-2022-1614-2809713

US3342142
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (3)
Generated On: 11 Aug 2021 22:33:31
Was this medication taken for solicited event?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:29:43
User signature succeeded.	Paul Pickrell (b) (4) (b) (4)	12 Mar 2021 23:16:43
User entered 'No (N)'	Ethan Shotton (b) (4) (b) (4)	19 Jan 2021 18:06:53

US3342142
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (3)
Generated On: 11 Aug 2021 22:33:31
Separate Dosage Number (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:29:43
User entered empty.	System	19 Jan 2021 18:06:53

US3342142
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (3)
Generated On: 11 Aug 2021 22:33:31
Interval Dosage Unit Number (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:29:43
User entered empty.	System	19 Jan 2021 18:06:53

US3342142
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (3)
Generated On: 11 Aug 2021 22:33:31
Interval Dosage Definition (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:29:43
User entered empty.	System	19 Jan 2021 18:06:53

US3342142
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (4)
Generated On: 11 Aug 2021 22:33:31
Name of Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:29:43
User signature succeeded.	Paul Pickrell (b) (4) (b) (4)	22 Mar 2021 13:27:19
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) (b) (4)	18 Mar 2021 18:49:49
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	18 Mar 2021 18:49:49
Data point term sent to Coder	System	18 Mar 2021 18:48:08
User entered 'Influenza Vaccine'	Ethan Shotton (b) (4) (b) (4)	18 Mar 2021 18:47:31

US3342142
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (4)
Generated On: 11 Aug 2021 22:33:31
Prophylaxis

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:29:43
User signature succeeded.	Paul Pickrell (b) (4) (b) (4)	22 Mar 2021 13:27:19
User entered 'Yes (Y)'	Ethan Shotton (b) (4) (b) (4)	18 Mar 2021 18:47:31

US3342142
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (4)
Generated On: 11 Aug 2021 22:33:31
Indication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:29:43
User signature succeeded.	Paul Pickrell (b) (4) (b) (4)	22 Mar 2021 13:27:19
User entered 'Influenza prophylaxis'	Ethan Shotton (b) (4) (b) (4)	18 Mar 2021 18:47:31

US3342142
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (4)
Generated On: 11 Aug 2021 22:33:31
Dose per administration

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:29:43
User signature succeeded.	Paul Pickrell (b) (4) (b) (4)	22 Mar 2021 13:27:19
User entered '0.5'	Ethan Shotton (b) (4) (b) (4)	18 Mar 2021 18:47:31

US3342142
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (4)
Generated On: 11 Aug 2021 22:33:31
Dose unit

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:29:43
User signature succeeded.	Paul Pickrell (b) (4) (b) (4)	22 Mar 2021 13:27:19
User entered 'mL (mL)'	Ethan Shotton (b) (4) (b) (4)	18 Mar 2021 18:47:31

US3342142
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (4)
Generated On: 11 Aug 2021 22:33:31
If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:29:43
User signature succeeded.	Paul Pickrell (b) (4) (b) (4)	22 Mar 2021 13:27:19
User entered empty.	Ethan Shotton (b) (4) (b) (4)	18 Mar 2021 18:47:31

US3342142
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (4)
Generated On: 11 Aug 2021 22:33:31
Frequency

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:29:43
User signature succeeded.	Paul Pickrell (b) (4) (b) (4)	22 Mar 2021 13:27:19
User entered 'once (ONCE)'	Ethan Shotton (b) (4) (b) (4)	18 Mar 2021 18:47:31

US3342142
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (4)
Generated On: 11 Aug 2021 22:33:31
If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:29:43
User signature succeeded.	Paul Pickrell (b) (4) (b) (4)	22 Mar 2021 13:27:19
User entered empty.	Ethan Shotton (b) (4) (b) (4)	18 Mar 2021 18:47:31

US3342142
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (4)
Generated On: 11 Aug 2021 22:33:31
Route of administration

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:29:43
User signature succeeded.	Paul Pickrell (b) (4) (b) (4)	22 Mar 2021 13:27:19
User entered 'Intramuscular (INTRAMUSCULAR)'	Ethan Shotton (b) (4) (b) (4)	18 Mar 2021 18:47:31

US3342142
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (4)
Generated On: 11 Aug 2021 22:33:31
If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:29:43
User signature succeeded.	Paul Pickrell (b) (4) (b) (4)	22 Mar 2021 13:27:19
User entered empty.	Ethan Shotton (b) (4) (b) (4)	18 Mar 2021 18:47:31

US3342142
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (4)
Generated On: 11 Aug 2021 22:33:31
Start date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:29:43
User signature succeeded.	Paul Pickrell (b) (4) (b) (4)	22 Mar 2021 13:27:19
User entered '11 Nov 2020'	Ethan Shotton (b) (4) (b) (4)	18 Mar 2021 18:47:31

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US3342142
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (4)
Generated On: 11 Aug 2021 22:33:31
Start date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:29:43
User signature succeeded.	Paul Pickrell (b) (4) (b) (4)	22 Mar 2021 13:27:19
User entered '0'	Ethan Shotton (b) (4) (b) (4)	18 Mar 2021 18:47:31

US3342142
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (4)
Generated On: 11 Aug 2021 22:33:31
Ongoing?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:29:43
User signature succeeded.	Paul Pickrell (b) (4) (b) (4)	22 Mar 2021 13:27:19
User entered 'No (N)'	Ethan Shotton (b) (4) (b) (4)	18 Mar 2021 18:47:31

US3342142
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (4)
Generated On: 11 Aug 2021 22:33:31
If not Ongoing, End date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:29:43
User signature succeeded.	Paul Pickrell (b) (4) (b) (4)	22 Mar 2021 13:27:19
User entered '11 Nov 2020'	Ethan Shotton (b) (4) (b) (4)	18 Mar 2021 18:47:31

US3342142
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (4)
Generated On: 11 Aug 2021 22:33:31
Was this medication taken for solicited event?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:29:43
User signature succeeded.	Paul Pickrell (b) (4) (b) (4)	22 Mar 2021 13:27:19
User entered 'No (N)'	Ethan Shotton (b) (4) (b) (4)	18 Mar 2021 18:47:31

US3342142
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (4)
Generated On: 11 Aug 2021 22:33:31
Separate Dosage Number (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:29:43
User entered empty.	System	18 Mar 2021 18:47:31

US3342142
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (4)
Generated On: 11 Aug 2021 22:33:31
Interval Dosage Unit Number (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:29:43
User entered empty.	System	18 Mar 2021 18:47:31

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US3342142
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (4)
Generated On: 11 Aug 2021 22:33:31
Interval Dosage Definition (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:29:43
User entered empty.	System	18 Mar 2021 18:47:31

US3342142
Folder: Concomitant Procedures (1)
Form: Concomitant Procedures Summary
Generated On: 11 Aug 2021 22:33:31
Were any concomitant procedures performed?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:29:43
User signature succeeded.	Paul Pickrell (b) (4) (b) (4)	12 Mar 2021 23:16:48
User entered 'No (N)'	Ethan Shotton (b) (4) (b) (4)	04 Mar 2021 17:35:46

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US3342142
Folder: End of Study (1)
Form: End of Study / Study Discontinuation
Generated On: 11 Aug 2021 22:33:31
Date of study discontinuation/completion *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 12:38:39
User signature succeeded.	Paul Pickrell (b) (4) (b) (4)	12 Mar 2021 23:16:48
User entered '19 Jan 2021' reason for change: Data Entry Error	Ethan Shotton (b) (4) (b) (4)	22 Jan 2021 17:52:35
User entered '22 Jan 2021' reason for change: Data Entry Error	Ethan Shotton (b) (4) (b) (4)	22 Jan 2021 17:52:17
User entered '19 Jan 2021'	Darrell O'Brien (b) (4) (b) (4)	19 Jan 2021 17:47:20

US3342142
Folder: End of Study (1)
Form: End of Study / Study Discontinuation
Generated On: 11 Aug 2021 22:33:31
Reason for discontinuation

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 12:38:39
User signature succeeded.	Paul Pickrell (b) (4) (b) (4)	12 Mar 2021 23:16:48
User entered 'Protocol deviation (specify) (PROTOCOL DEVIATION)'	Darrell O'Brien (b) (4) (b) (4)	19 Jan 2021 17:47:20

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Folder: End of Study (1)

Form: End of Study / Study Discontinuation

Generated On: 11 Aug 2021 22:33:31

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 12:38:39
User signature succeeded.	Paul Pickrell (b) (4) (b) (4)	12 Mar 2021 23:16:48
User entered 'SUBJECT RECEIVED COVID-19 VACCINE OUTSIDE STUDY ON 12JAN2021 (PFIZER PRODUCT OFFERED BY EMPLOYER, WORKS AS HCW).' reason for change: Data Entry Error	Ethan Shotton (b) (4) (b) (4)	22 Jan 2021 17:52:35
User entered 'SUBJECT RECEIVED COVID-19 VACCINE OUTSIDE STUDY (MODERNA PRODUCT)' reason for change: Data Entry Error	Ethan Shotton (b) (4) (b) (4)	22 Jan 2021 17:52:17
User entered 'Subject received COVID-19 Vaccine outside study on 12JAN2021 (Pfizer product offered by employer, works as HCW).'	Darrell O'Brien (b) (4) (b) (4)	19 Jan 2021 17:47:20

US3342142
Folder: End of Study (1)
Form: End of Study / Study Discontinuation
Generated On: 11 Aug 2021 22:33:31
If reason for discontinuation is Death, main cause of death

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 12:38:39
User signature succeeded.	Paul Pickrell (b) (4) (b) (4)	12 Mar 2021 23:16:48
User entered empty.	Darrell O'Brien (b) (4) (b) (4)	19 Jan 2021 17:47:20

US3342142
Folder: End of Study (1)
Form: End of Study / Study Discontinuation
Generated On: 11 Aug 2021 22:33:31
If main cause of death is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 12:38:39
User signature succeeded.	Paul Pickrell (b) (4) (b) (4)	12 Mar 2021 23:16:48
User entered empty.	Darrell O'Brien (b) (4) (b) (4)	19 Jan 2021 17:47:20

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US3342142
Folder: End of Study (1)
Form: End of Study / Study Discontinuation
Generated On: 11 Aug 2021 22:33:31
Date of death *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 12:38:39
User signature succeeded.	Paul Pickrell (b) (4) (b) (4)	12 Mar 2021 23:16:48
User entered empty.	Darrell O'Brien (b) (4) (b) (4)	19 Jan 2021 17:47:20

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US3342142
Folder: End of Study (1)
Form: End of Study / Study Discontinuation
Generated On: 11 Aug 2021 22:33:31
Was autopsy performed?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 12:38:39
User signature succeeded.	Paul Pickrell (b) (4) (b) (4)	12 Mar 2021 23:16:48
User entered empty.	Darrell O'Brien (b) (4) (b) (4)	19 Jan 2021 17:47:20

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