US3232021 (Prod: MediSync Clinical Research Hattiesburg Clinic)

US3232021
Form: Participant Creation
Data signed: (b) (4) **02 Apr 2021 13:34:37**
Generated On: 11 Aug 2021 22:05:35

Participant ID	US3232021

mRNA-1273-P301 Completion Guidelines

US3232021

Folder: Screening

Form: Visit Date

Data signed: (b) (4)　　**18 Feb 2021 15:31:39**

Generated On: 11 Aug 2021 22:05:35

Was this visit performed?	Yes ●
	No ○
Visit date (dd MMM yyyy)	10 AUG 2020
Was visit performed at the participant's home or at the clinic?	Home ○
	Clinic ●
Folder OID	SCRN

US3232021

Folder: Screening

Form: Demographics

Data signed: (b) (4) **18 Feb 2021 15:31:39**

Generated On: 11 Aug 2021 22:05:35

Date of Birth (MMM yyyy)	(b) (6) 1973
Age	47
Age Units	YEARS
Age (Derived)	47
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

US3232021

Folder: Screening

Form: Enrollment

Data signed: (b) (4)　　**18 Feb 2021 15:31:39**

Generated On: 11 Aug 2021 22:05:35

Date of Informed Consent *(dd MMM yyyy)*	10 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

US3232021

Folder: Screening

Form: Inclusion/Exclusion Criteria Summary

Data signed: (b) (4)   **18 Feb 2021 15:31:39**

Generated On: 11 Aug 2021 22:05:35

Did the participant meet all eligibility criteria?   Yes ●

No ◯

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Folder: Screening

Form: Medical History Summary

Data signed: (b) (4)   **18 Feb 2021 15:31:39**

Generated On: 11 Aug 2021 22:05:35

Were any significant conditions reported?   Yes ●

                                                    No ◯

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Folder: Screening

Form: Medical History (1)

Data signed: (b) (4)   **18 Feb 2021 15:31:39**

Generated On: 11 Aug 2021 22:05:35

Condition	OSTEOARTHRITIS
Start date (dd MMM yyyy)	UN OCT 2018
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)	OCT 2018
Start Year (derived)	2018
Stop Month and Year (derived)	
Stop Year (derived)	

Folder: Screening

Form: Medical History (2)

Data signed: (b) (4)   **18 Feb 2021 15:31:39**

Generated On: 11 Aug 2021 22:05:35

Condition	ANXIETY
Start date (dd MMM yyyy)	UN UNK 2008
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 2008
Start Year (derived)	2008
Stop Month and Year (derived)	
Stop Year (derived)	

US3232021

Folder: Screening

Form: Medical History (3)

Data signed: (b) (4)   **18 Feb 2021 15:31:39**

Generated On: 11 Aug 2021 22:05:35

Condition	VITAMIN D DEFICIENCY
Start date (dd MMM yyyy)	UN MAY 2018
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)	MAY 2018
Start Year (derived)	2018
Stop Month and Year (derived)	
Stop Year (derived)	

US3232021

Folder: Screening

Form: Medical History (4)

Data signed: (b) (4)　　　**18 Feb 2021 15:31:39**

Generated On: 11 Aug 2021 22:05:35

Condition	PAST TOBACCO USE, CIGARETTES, 5 PER DAY
Start date (dd MMM yyyy)	
Start date completely unknown	True
Condition ongoing at study entry	Yes ◯
	No ⬤
If No, please specify the stop date (dd MMM yyyy)	UN UNK 2000
Stop date completely unknown	False
Start Month and Year (derived)	
Start Year (derived)	
Stop Month and Year (derived)	JAN 2000
Stop Year (derived)	2000

US3232021
Folder: Screening
Form: Vital Signs
Data signed: (b) (4)　　**18 Feb 2021 15:31:39**
Generated On: 11 Aug 2021 22:05:35

Were vital signs assessed?	Yes ●
	No ○

Date of assessment *(dd MMM yyyy)*	10 AUG 2020
Time of assessment *(00:00-23:59)*	11:07 (24 HR)
Vital Signs Date and Time (derived)	10 AUG 2020 11:07
Height *(xxx.x)*	166 cm
Weight *(xxx.x)*	67.6 kg
BMI *(xxx.x)*	24.53186 kg/m^2
BMI units	KG/M2
Temperature *(xxx.x)*	98.6 F
Route of measurement	Oral ●
	Axillary ○
	Other ○
If Other, specify	
Pulse *(xxx)*	63 beats/min
Pulse units	BPM
Respiratory Rate *(xxx)*	18 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure *(xxx)*	110 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure *(xxx)*	60 mmHg
Diastolic Blood Pressure units	MMHG
Height (derived)	
Weight (derived)	

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Folder: Screening

Form: Physical Examination

Data signed: (b) (4)   **18 Feb 2021 15:31:39**

Generated On: 11 Aug 2021 22:05:35

| Was the physical examination performed? | Yes ● |
| | No ○ |

Date of examination *(dd MMM yyyy)*   10 AUG 2020

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

Date of assessment *(dd MMM yyyy)*	10 AUG 2020
Is the participant of childbearing potential?	Yes ●
	No ○
If No, what is the reason?	Surgically sterile ○
	Post-menopausal ○
	Partner medically sterile ○
	Not reached age of Menarche ○
	Other ○
If Partner medically sterile or Other, specify	
If Surgically sterile, date of surgery *(dd MMM yyyy)*	
Date of surgery unknown	False
If Post-menopausal, date of last menstruation *(dd MMM yyyy)*	
Date of last menstruation unknown	False

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Folder: Screening

Form: Pregnancy Test

Data signed: (b) (4)   **18 Feb 2021 15:31:39**

Generated On: 11 Aug 2021 22:05:35

Was the pregnancy test performed?	Yes ●
	No ○
Date of test *(dd MMM yyyy)*	10 AUG 2020
Test performed	Urine ●
	Serum ○
Result	Positive ○
	Negative ●
Was FSH sample collected?	Yes ○
	No ●
Collection date	
Collection time	
Collection date and time (derived)	

Folder: Screening
Form: Risk of Exposure
Data signed: (b) (4)   **18 Feb 2021 15:31:39**
Generated On: 11 Aug 2021 22:05:35

Occupational Risk

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

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

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

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

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

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

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

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

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

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

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

Other
Yes ◯
No ⬤

Specify _____

Location and Living Circumstances Risk (check all that apply)

No Risk Identified   False

Resides in Nursing Home or Assisted Living Facility   False

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Folder: Screening

Form: Risk of Exposure

Data signed: (b) (4)   **18 Feb 2021 15:31:39**

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Resides in Multi-family dwelling (e.g., cohabitation in dwelling with > 5 people, includes grandparents living with children < 18yrs)	False
Resides in high density housing (e.g., high rise apartments with shared entrances or elevators)	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)	False
Other	True
Specify	RESIDENT IN A COMMUNITY WITH ONGOING PERSON TO PERSON TRANSMISSION

US3232021

Folder: Visit 1 Day 1

Form: Visit Date

Data signed: (b) (4)   **18 Feb 2021 15:31:39**

Generated On: 11 Aug 2021 22:05:35

Was this visit performed?	Yes ●
	No ○
Visit date (dd MMM yyyy)	10 AUG 2020
Was visit performed at the participant's home or at the clinic?	Home ○
	Clinic ●
Folder OID	VISIT1

What was the date of randomization? *(dd MMM yyyy)*	10 AUG 2020
What was the participant's randomization number?	102224

In what Cohort was the participant enrolled?

- ⬤ >=18 and <65 years and not at risk
- ◯ >=18 and <65 years and at risk
- ◯ >=65 years

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

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

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

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

Diabetes (Type I, Type 2, or gestational)
- Yes ◯
- No ⬤

Liver Disease
- Yes ◯
- No ⬤

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Data signed: (b) (4) **18 Feb 2021 15:31:39**

Generated On: 11 Aug 2021 22:05:35

Height	ND - Not Done
Weight	ND - Not Done

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Data signed: (b) (4)　　**18 Feb 2021 15:31:39**

Generated On: 11 Aug 2021 22:05:35

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)*	10 AUG 2020
Time of assessment *(00:00-23:59)*	11:07 (24 HR)
Vital Signs Date and Time (derived)	10 AUG 2020 11:07
Temperature *(xxx.x)*	98.6 F
Route of measurement	Oral ●
	Axillary ○
	Other ○
If Other, specify	
Pulse *(xxx)*	63 beats/min
Pulse units	BPM
Respiratory Rate *(xxx)*	18 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure *(xxx)*	110 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure *(xxx)*	60 mmHg
Diastolic Blood Pressure units	MMHG

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Data signed: (b) (4)　　18 Feb 2021 15:31:39

Generated On: 11 Aug 2021 22:05:35

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)*	10 AUG 2020
Time of assessment *(00:00-23:59)*	13:15 (24 HR)
Vital Signs Date and Time (derived)	10 AUG 2020 13:15
Temperature *(xxx.x)*	97.0 F
Route of measurement	Oral ⬭
	Axillary ⬭
	Other ⬤
If Other, specify	TEMPORAL
Pulse *(xxx)*	66 beats/min
Pulse units	BPM
Respiratory Rate *(xxx)*	14 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure *(xxx)*	115 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure *(xxx)*	55 mmHg
Diastolic Blood Pressure units	MMHG

US3232021

Folder: Visit 1 Day 1

Form: Physical Examination

Data signed: (b) (4)   **18 Feb 2021 15:31:39**

Generated On: 11 Aug 2021 22:05:35

Was the physical examination performed?   Yes ⬤

                                                                                        No ◯

Date of examination *(dd MMM yyyy)*   10 AUG 2020

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

Folder: Visit 1 Day 1
Form: Pregnancy Test
Data signed: (b) (4)   **18 Feb 2021 15:31:39**
Generated On: 11 Aug 2021 22:05:35

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)	

Was study treatment given?	Yes ●
	No ◯
If No, reason not given	Participant declined due to Adverse Event ◯
	Physician withheld dose due to Adverse Event ◯
	Death ◯
	Lost To Follow-Up ◯
	Physician Decision ◯
	Pregnancy ◯
	Protocol Deviation ◯
	Study Terminated by Sponsor ◯
	Withdrawal of Consent by Participant ◯
	Confirmed COVID-19 ◯
	Other ◯
If reason is Physician Decision, Withdrawal of Consent by Participant, Protocol Deviation, or Other, specify	
What was the study treatment?	MRNA-1273 OR PLACEBO
What was the treatment date? *(dd MMM yyyy)*	10 AUG 2020
What was the treatment time? *(00:00-23:59)*	12:44 (24 HR)
Treatment Date and Time (derived)	10 AUG 2020 12:44
Which arm was used to give treatment?	Left Arm ●
	Right Arm ◯
What was the frequency of the study treatment dosing?	ONCE
What was the route of administration for the study treatment?	INTRAMUSCULAR

FDA-CBER-2022-1614-0645871

US3232021

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Data signed: (b) (4)　　**18 Feb 2021 15:31:39**

Generated On: 11 Aug 2021 22:05:35

Was the sample collected?	Yes ⬤
	No ◯
Collection date *(dd MMM yyyy)*	10 AUG 2020
Collection time *(00:00-23:59)*	12:00 (24 HR)
Collection date and time (derived)	10 AUG 2020 12:00

US3232021

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab

Data signed: (b) (4)   **18 Feb 2021 15:31:39**

Generated On: 11 Aug 2021 22:05:35

Collection date *(dd MMM yyyy)*			10 AUG 2020
Lab Test	Was the sample collected?	Collection time *(00:00 - 23:59)*	Collection date and time (derived)
Nasopharyngeal Swab 1	Yes	11:20	10 AUG 2020 11:20
Nasopharyngeal Swab 2	No		

US3232021
Folder: Visit 1 Day 1
Form: Continuing
Data signed: (b) (4)   **18 Feb 2021 15:31:39**
Generated On: 11 Aug 2021 22:05:35

Is the participant continuing to the next visit?   Yes ●

No ○

Continuing Flag   1

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?	Yes ● / No ○
Please record your **TEMPERATURE in °F**	97.0 °F
Was any **MEDICATION TAKEN today for pain or fever**?	Yes ○ / No ●

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

PC Time Stamp	10 AUG 2020 13:04
PC Open Date & Time	10 AUG 2020 13:04
PC Close Date & Time	10 AUG 2020 15:34

TIMEPOINT	DAY 1, AFTER VACCINATION
	(AT HOME)

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

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

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

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

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

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

Was **TEMPERATURE** taken?	Yes ●
	No ○
Please record your **TEMPERATURE in °F**	98.2 °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	10 AUG 2020 19:40
PC Open Date & Time	10 AUG 2020 16:29
PC Close Date & Time	11 AUG 2020 11:59

US3232021
Folder: Diary Dose 1 (1)
Form: Temperature_Day(2)
Generated On: 11 Aug 2021 22:05:35

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**	98.4 °F
Was any **MEDICATION TAKEN today for pain or fever**?	Yes ●
	No ○

Please confirm reason for pain or fever medication (may select more than one):	
To **TREAT** pain or fever that has already occurred	True
To **PREVENT** pain or fever from occurring	False
PC Time Stamp	11 AUG 2020 14:20
PC Open Date & Time	11 AUG 2020 12:00
PC Close Date & Time	12 AUG 2020 11:59

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Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 11 Aug 2021 22:05:35

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**	98.2 °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	12 AUG 2020 21:44
PC Open Date & Time	12 AUG 2020 12:00
PC Close Date & Time	13 AUG 2020 11:59

US3232021
Folder: Diary Dose 1 (1)
Form: Temperature_Day(4)
Generated On: 11 Aug 2021 22:05:35

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):

PC Time Stamp	13 AUG 2020 12:02
PC Open Date & Time	13 AUG 2020 12:00
PC Close Date & Time	14 AUG 2020 11:59

TIMEPOINT	DAY 5

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

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

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

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

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

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

Was **TEMPERATURE** taken?	Yes ●
	No ○

Please record your **TEMPERATURE in °F**	97.8 °F

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

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

PC Time Stamp	14 AUG 2020 21:01
PC Open Date & Time	14 AUG 2020 12:00
PC Close Date & Time	15 AUG 2020 11:59

FDA-CBER-2022-1614-0645880

US3232021
Folder: Diary Dose 1 (1)
Form: Temperature_Day(6)
Generated On: 11 Aug 2021 22:05:35

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	15 AUG 2020 12:31
PC Open Date & Time	15 AUG 2020 12:00
PC Close Date & Time	16 AUG 2020 11:59

FDA-CBER-2022-1614-0645881

TIMEPOINT	DAY 7

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

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

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

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

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

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

Was **TEMPERATURE** taken?	Yes ●
	No ○
Please record your **TEMPERATURE in °F**	97.6 °F
Was any **MEDICATION TAKEN today for pain or fever**?	Yes ○
	No ●

Please confirm reason for pain or fever medication (may select more than one):	
PC Time Stamp	16 AUG 2020 22:33
PC Open Date & Time	16 AUG 2020 12:00
PC Close Date & Time	17 AUG 2020 11:59

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	10 AUG 2020 13:05
PC Open Date & Time	10 AUG 2020 13:04
PC Close Date & Time	10 AUG 2020 15:34

US3232021

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 11 Aug 2021 22:05:35

TIMEPOINT	DAY 1, AFTER VACCINATION (AT HOME)
Please record - **PAIN AT INJECTION SITE.** Please select one response below	None ○ Does not interfere with activity ● Repeated use of over-the-counter pain reliever > 24 hours or interferes with activity ○ Any use of prescription pain reliever or prevents daily activity ○
Is there any **REDNESS AT INJECTION SITE**?	Yes ○ No ●
Is there any **SWELLING/HARDNESS AT INJECTION SITE**?	Yes ○ No ●
Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.** Please select one response below	None ● Does not interfere with activity ○ Repeated use of over-the-counter pain reliever > 24 hours or interferes with some activity ○ Any use of prescription pain reliever or prevents daily activity ○
PC Time Stamp	10 AUG 2020 19:34
PC Open Date & Time	10 AUG 2020 16:29
PC Close Date & Time	11 AUG 2020 11:59

FDA-CBER-2022-1614-0645884

US3232021

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 11 Aug 2021 22:05:35

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 - **SWELLING/HARDNESS AT INJECTION SITE (in mm)** Measure the largest size across any injection site swelling/hardness with the ruler provided.	35

Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.** Please select one response below	None ●
	Does not interfere with activity ◯
	Repeated use of over-the-counter pain reliever > 24 hours or interferes with some activity ◯
	Any use of prescription pain reliever or prevents daily activity ◯

PC Time Stamp	11 AUG 2020 14:18
PC Open Date & Time	11 AUG 2020 12:00
PC Close Date & Time	12 AUG 2020 11:59

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	12 AUG 2020 21:42
PC Open Date & Time	12 AUG 2020 12:00
PC Close Date & Time	13 AUG 2020 11:59

FDA-CBER-2022-1614-0645886

US3232021

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 11 Aug 2021 22:05:35

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	13 AUG 2020 12:00
PC Open Date & Time	13 AUG 2020 12:00
PC Close Date & Time	14 AUG 2020 11:59

FDA-CBER-2022-1614-0645887

US3232021

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 11 Aug 2021 22:05:35

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	14 AUG 2020 21:00
PC Open Date & Time	14 AUG 2020 12:00
PC Close Date & Time	15 AUG 2020 11:59

US3232021
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(6)
Generated On: 11 Aug 2021 22:05:35

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	15 AUG 2020 12:30
PC Open Date & Time	15 AUG 2020 12:00
PC Close Date & Time	16 AUG 2020 11:59

US3232021

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 11 Aug 2021 22:05:35

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	16 AUG 2020 22:32
PC Open Date & Time	16 AUG 2020 12:00
PC Close Date & Time	17 AUG 2020 11:59

US3232021
Folder: Diary Dose 1 (1)
Form: General_Day(1/1)
Generated On: 11 Aug 2021 22:05:35

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

US3232021
Folder: Diary Dose 1 (1)
Form: General_Day(1/1)
Generated On: 11 Aug 2021 22:05:35

Did you receive any **MEDICAL ATTENTION (doctor visit, other)** for any illness or symptoms?	No ● Yes ○
PC Time stamp	10 AUG 2020 13:06
PC Open Date & Time	10 AUG 2020 13:04
PC Close Date & Time	10 AUG 2020 15:34

US3232021

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 11 Aug 2021 22:05:35

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	○

| Did you receive any **MEDICAL ATTENTION (doctor visit, other)** for any illness or symptoms? | No ● |
| | Yes ○ |

PC Time stamp	10 AUG 2020 19:35
PC Open Date & Time	10 AUG 2020 16:29
PC Close Date & Time	11 AUG 2020 11:59

US3232021
Folder: Diary Dose 1 (1)
Form: General_Day(2)
Generated On: 11 Aug 2021 22:05:35

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 ⬤

	Yes ◯
PC Time stamp	11 AUG 2020 14:19
PC Open Date & Time	11 AUG 2020 12:00
PC Close Date & Time	12 AUG 2020 11:59

US3232021

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 11 Aug 2021 22:05:35

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 ●

	Yes ◯
PC Time stamp	12 AUG 2020 21:41
PC Open Date & Time	12 AUG 2020 12:00
PC Close Date & Time	13 AUG 2020 11:59

US3232021
Folder: Diary Dose 1 (1)
Form: General_Day(4)
Generated On: 11 Aug 2021 22:05:35

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 ●

	Yes ◯
PC Time stamp	13 AUG 2020 12:00
PC Open Date & Time	13 AUG 2020 12:00
PC Close Date & Time	14 AUG 2020 11:59

US3232021

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 11 Aug 2021 22:05:35

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 ●

	Yes ◯
PC Time stamp	14 AUG 2020 21:00
PC Open Date & Time	14 AUG 2020 12:00
PC Close Date & Time	15 AUG 2020 11:59

US3232021
Folder: Diary Dose 1 (1)
Form: General_Day(6)
Generated On: 11 Aug 2021 22:05:35

TIMEPOINT	DAY 6

HEADACHE

- None ●
- No interference with activity ○
- Repeated use of over-the-counter pain reliever > 24 hours or some interference with activity ○
- Any use of prescription pain reliever or prevents daily activity ○

FATIGUE

- None ●
- No interference with activity ○
- Some interference with activity ○
- Significant; prevents daily activity ○

MUSCLE ACHES ALL OVER BODY

- None ●
- No interference with activity ○
- Some interference with activity ○
- Significant; prevents daily activity ○

JOINT ACHES IN SEVERAL JOINTS

- None ●
- No interference with activity ○
- Some interference with activity ○
- Significant; prevents daily activity ○

NAUSEA/VOMITING

- None ●
- No interference with activity or 1-2 episodes/24 hours ○
- Some interference with activity or >2 episodes/24 hours ○
- Prevents daily activity, requires outpatient IV hydration ○

CHILLS

- None ●
- No interference with activity ○
- Some interference with activity not requiring medical attention ○
- Prevents daily activity and requires medical attention ○

Did you receive any **MEDICAL ATTENTION (doctor visit, other)** for any illness or symptoms? — No ●

PRODUCTION RELEASE (v12.003 EAB) (1725)

	Yes ◯
PC Time stamp	15 AUG 2020 12:30
PC Open Date & Time	15 AUG 2020 12:00
PC Close Date & Time	16 AUG 2020 11:59

US3232021

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 11 Aug 2021 22:05:35

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 ●

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Yes ◯

PC Time stamp	16 AUG 2020 22:32
PC Open Date & Time	16 AUG 2020 12:00
PC Close Date & Time	17 AUG 2020 11:59

US3232021

Folder: Safety Call Day 8 (1)

Form: Safety Call

Data signed: (b) (4) **18 Feb 2021 15:31:39**

Generated On: 11 Aug 2021 22:05:35

Was Contact Attempted?	Yes ●
	No ○

Date of Contact or Contact Attempt *(dd MMM yyyy)*	17 AUG 2020
Please select one status for the follow-up contact	Contact Made ●
	Contact Not Made ○

Comments

If Contact Not Made, please provide Comments

US3232021
Folder: Safety Call Day 8 (1)
Form: Continuing
Data signed: (b) (4) **18 Feb 2021 15:31:39**
Generated On: 11 Aug 2021 22:05:35

Is the participant continuing to the next visit?   Yes ●

No ○

Continuing Flag   1

US3232021

Folder: Safety Call Day 15 (1)

Form: Safety Call

Data signed: (b) (4)　　　**18 Feb 2021 15:31:38**

Generated On: 11 Aug 2021 22:05:35

| Was Contact Attempted? | Yes ● |
| | No ◯ |

Date of Contact or Contact Attempt *(dd MMM yyyy)*	25 AUG 2020
Please select one status for the follow-up contact	Contact Made ●
	Contact Not Made ◯

Comments

If Contact Not Made, please provide Comments

US3232021

Folder: Safety Call Day 15 (1)

Form: Continuing

Data signed: (b) (4)　　18 Feb 2021 15:31:38

Generated On: 11 Aug 2021 22:05:35

Is the participant continuing to the next visit?　　　　　Yes ●

　　　　　　　　　　　　　　　　　　　　　　　　　　　No ○

Continuing Flag　　　　　　　　　　　　　　　　　　　　　　1

US3232021
Folder: Safety Call Day 22 (1)
Form: Safety Call
Data signed: (b) (4) **18 Feb 2021 15:31:39**
Generated On: 11 Aug 2021 22:05:35

| 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

US3232021

Folder: Safety Call Day 22 (1)

Form: Continuing

Data signed: (b) (4)　　　**18 Feb 2021 15:31:39**

Generated On: 11 Aug 2021 22:05:35

Is the participant continuing to the next visit?　　　　Yes ●

　　　　　　　　　　　　　　　　　　　　　　　　　No ◯

Continuing Flag　　　　　　　　　　　　　　　　　　　　1

US3232021
Folder: Visit 2 Day 29 (1)
Form: Visit Date
Data signed: (b) (4) **18 Feb 2021 15:31:39**
Generated On: 11 Aug 2021 22:05:35

Was this visit performed?	Yes ●
	No ○
Visit date (dd MMM yyyy)	11 SEP 2020
Was visit performed at the participant's home or at the clinic?	Home ○
	Clinic ●
Folder OID	VISIT2

FDA-CBER-2022-1614-0645913

Timepoint	Pre-Dose ⬤
	Post-Dose ◯
Were vital signs assessed?	Yes ⬤
	No ◯
Date of assessment *(dd MMM yyyy)*	11 SEP 2020
Time of assessment *(00:00-23:59)*	12:18 (24 HR)
Vital Signs Date and Time (derived)	11 SEP 2020 12:18
Temperature *(xxx.x)*	98.5 F
Route of measurement	Oral ⬤
	Axillary ◯
	Other ◯
If Other, specify	
Pulse *(xxx)*	65 beats/min
Pulse units	BPM
Respiratory Rate *(xxx)*	20 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure *(xxx)*	130 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure *(xxx)*	63 mmHg
Diastolic Blood Pressure units	MMHG

US3232021

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Data signed: (b) (4)　　**18 Feb 2021 15:31:39**

Generated On: 11 Aug 2021 22:05:35

Timepoint	Pre-Dose ◯
	Post-Dose ⬤
Were vital signs assessed?	Yes ◯
	No ⬤
Date of assessment *(dd MMM yyyy)*	_____
Time of assessment *(00:00-23:59)*	_____
Vital Signs Date and Time (derived)	_____
Temperature *(xxx.x)*	_____
Route of measurement	Oral ◯
	Axillary ◯
	Other ◯
If Other, specify	_____
Pulse *(xxx)*	_____
Pulse units	_____
Respiratory Rate *(xxx)*	_____
Respiratory Rate units	_____
Systolic Blood Pressure *(xxx)*	_____
Systolic Blood Pressure units	_____
Diastolic Blood Pressure *(xxx)*	_____
Diastolic Blood Pressure units	_____

US3232021

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Data signed: (b) (4)　　　**18 Feb 2021 15:31:39**

Generated On: 11 Aug 2021 22:05:35

Was the physical examination performed?　　　　Yes ●

No ○

Date of examination *(dd MMM yyyy)*　　　　11 SEP 2020

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

US3232021

Folder: Visit 2 Day 29 (1)

Form: Pregnancy Test

Data signed: (b) (4) **18 Feb 2021 15:31:39**

Generated On: 11 Aug 2021 22:05:35

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)	

Was study treatment given?   Yes ◯

                                                                         No ⬤

If No, reason not given   Participant declined due to ⬤
                                                          Adverse Event

                                            Physician withheld dose due to ◯
                                                          Adverse Event

                                                                  Death ◯

                                                      Lost To Follow-Up ◯

                                                     Physician Decision ◯

                                                             Pregnancy ◯

                                                    Protocol Deviation ◯

                                          Study Terminated by Sponsor ◯

                                          Withdrawal of Consent by ◯
                                                          Participant

                                               Confirmed COVID-19 ◯

                                                                 Other ◯

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

What was the study treatment?   _____

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

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

Treatment Date and Time (derived)   _____

Which arm was used to give treatment?   Left Arm ◯

                                                         Right Arm ◯

What was the frequency of the study treatment dosing?   _____

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

Was the sample collected?	Yes ●
	No ○

Collection date *(dd MMM yyyy)*	11 SEP 2020
Collection time *(00:00-23:59)*	12:20 (24 HR)
Collection date and time (derived)	11 SEP 2020 12:20

US3232021

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab

Data signed: (b) (4) **18 Feb 2021 15:31:39**

Generated On: 11 Aug 2021 22:05:35

Collection date *(dd MMM yyyy)*			11 SEP 2020
Lab Test	Was the sample collected?	Collection time *(00:00 - 23:59)*	Collection date and time (derived)
Nasopharyngeal Swab 1	Yes	12:18	11 SEP 2020 12:18
Nasopharyngeal Swab 2	No		

US3232021

Folder: Visit 2 Day 29 (1)

Form: Continuing

Data signed: (b) (4)   **18 Feb 2021 15:31:39**

Generated On: 11 Aug 2021 22:05:35

Is the participant continuing to the next visit?   Yes ●

                                                                No ◯

Continuing Flag   1

US3232021

Folder: Safety Call Day 36 (1)

Form: Safety Call

Data signed: (b) (4)　**18 Feb 2021 15:31:39**

Generated On: 11 Aug 2021 22:05:35

| Was Contact Attempted? | Yes ● |
| | No ○ |

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

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

Comments

If Contact Not Made, please provide Comments

US3232021

Folder: Safety Call Day 36 (1)

Form: Continuing

Data signed: (b) (4)   **18 Feb 2021 15:31:39**

Generated On: 11 Aug 2021 22:05:35

Is the participant continuing to the next visit?   Yes ●

No ○

Continuing Flag   1

US3232021

Folder: Safety Call Day 43 (1)

Form: Safety Call

Data signed: (b) (4)   **23 Apr 2021 15:20:41**

Generated On: 11 Aug 2021 22:05:35

| Was Contact Attempted? | Yes ◯ |
| | No ⬤ |

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

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

Comments   INADVERTENTLY MISSED

If Contact Not Made, please provide Comments

US3232021

Folder: Safety Call Day 43 (1)

Form: Continuing

Data signed: (b) (4)   **18 Feb 2021 15:31:39**

Generated On: 11 Aug 2021 22:05:35

Is the participant continuing to the next visit?   Yes ⬤

                                                                             No ◯

Continuing Flag   1

US3232021

Folder: Safety Call Day 50 (1)

Form: Safety Call

Data signed: (b) (4) **29 Mar 2021 19:02:10**

Generated On: 11 Aug 2021 22:05:35

| 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

US3232021

Folder: Safety Call Day 50 (1)

Form: Continuing

Data signed: (b) (4)   **29 Mar 2021 19:02:10**

Generated On: 11 Aug 2021 22:05:35

Is the participant continuing to the next visit?   Yes ⬤

No ◯

Continuing Flag   1

Was this visit performed?   Yes ◯

No ⬤

Visit date (dd MMM yyyy)   _____

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

Clinic ◯

Folder OID   VISIT3

US3232021
Folder: Visit 3 Day 57 (1)
Form: Vital Signs
Generated On: 11 Aug 2021 22:05:35

| Were vital signs assessed? | Yes ◯ |
| | No ◯ |

Date of assessment *(dd MMM yyyy)* _____

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

Vital Signs Date and Time (derived) _____

Temperature *(xxx.x)* _____

Route of measurement	Oral ◯
	Axillary ◯
	Other ◯

If Other, specify _____

Pulse *(xxx)* _____

Pulse units _____

Respiratory Rate *(xxx)* _____

Respiratory Rate units _____

Systolic Blood Pressure *(xxx)* _____

Systolic Blood Pressure units _____

Diastolic Blood Pressure *(xxx)* _____

Diastolic Blood Pressure units _____

Height (derived) _____

Weight (derived) _____

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.

Was the sample collected?   Yes ◯

                                                                     No ◯

Collection date *(dd MMM yyyy)*

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

Collection date and time (derived)

US3232021
Folder: Visit 3 Day 57 (1)
Form: Continuing
Data signed: (b) (4)　　29 Mar 2021 19:02:10
Generated On: 11 Aug 2021 22:05:35

Is the participant continuing to the next visit?　　　　　Yes ◯

No ⬤

Continuing Flag

US3232021

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:05:35

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 contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ◯
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No ◯ Yes ◯

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

Fever (Temperature ≥ 100.4°F/38°C)	_____
Chills	_____
Cough	_____
Shortness of breath	_____
Difficulty breathing	_____
Fatigue	_____
Muscle aches	_____
Body aches	_____
Headache	_____
New loss of taste	_____
New loss of smell	_____
Sore throat	_____
Congestion	_____
Runny nose	_____
Nausea	_____
Vomiting	_____
Diarrhea	_____
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ◯
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No ◯ Yes ◯

US3232021

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:05:35

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ◯
Date and time of submission	
Patient Cloud Open Date & Time	10 OCT 2020 00:01
Patient Cloud Close Date & Time	14 OCT 2020 23:59

US3232021

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:05:35

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 contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ○
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No ○ Yes ○

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

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

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ○
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No ○ Yes ○

US3232021

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:05:35

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ◯
Date and time of submission	
Patient Cloud Open Date & Time	17 OCT 2020 00:01
Patient Cloud Close Date & Time	21 OCT 2020 23:59

US3232021

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:05:35

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):

Fever (Temperature ≥ 100.4°F/38°C)	_____
Chills	_____
Cough	_____
Shortness of breath	_____
Difficulty breathing	_____
Fatigue	_____
Muscle aches	_____
Body aches	_____
Headache	_____
New loss of taste	_____
New loss of smell	_____
Sore throat	_____
Congestion	_____
Runny nose	_____
Nausea	_____
Vomiting	_____
Diarrhea	_____
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ⭕
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No ⭕ Yes ⭕

US3232021

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:05:35

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ◯
Date and time of submission	
Patient Cloud Open Date & Time	24 OCT 2020 00:01
Patient Cloud Close Date & Time	28 OCT 2020 23:59

TIMEPOINT   DAY 92

Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ◯
	Yes ◯
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ◯
	Yes ◯
Please contact your study clinic immediately. Click below to confirm that you have read this 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):

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

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ◯
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No ◯
	Yes ◯

FDA-CBER-2022-1614-0645939

US3232021

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:05:35

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ◯
Date and time of submission	
Patient Cloud Open Date & Time	07 NOV 2020 00:01
Patient Cloud Close Date & Time	11 NOV 2020 23:59

US3232021

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:05:35

TIMEPOINT	DAY 99
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ⃝ 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):

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

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ⃝
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No ⃝ Yes ⃝

FDA-CBER-2022-1614-0645941

US3232021

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:05:35

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ◯
Date and time of submission	
Patient Cloud Open Date & Time	14 NOV 2020 00:01
Patient Cloud Close Date & Time	18 NOV 2020 23:59

Folder: Cosmetic Injections and Dermal Fillers

Form: Cosmetic Injection_ Dermal Filler eDiary

Generated On: 11 Aug 2021 22:05:35

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

US3232021
Folder: Covid-19 Assessment (1)
Form: COVID-19 Contact
Generated On: 11 Aug 2021 22:05:35

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 ◯

US3232021
Folder: Covid-19 Assessment (1)
Form: Generate Next COVID-19 Assessment
Generated On: 11 Aug 2021 22:05:35

Generate Next COVID-19 Assessment	Yes ◯
	No ◯

US3232021

Folder: Adverse Events

Form: Adverse Events Summary

Data signed: (b) (4)   **12 Mar 2021 19:51:52**

Generated On: 11 Aug 2021 22:05:35

Did the participant experience any adverse events?   Yes ●

No ○

If Yes, enter details on the Adverse Events form.

US3232021

Folder: Adverse Events

Form: Adverse Events (1)

Data signed: (b) (4) **12 Mar 2021 19:51:52**

Generated On: 11 Aug 2021 22:05:35

AEID	
Adverse event	WORSENING UPPER EXTREMITIES ARTHRALGIA
Was this a medically-attended AE?	Yes ●
	No ○
Was this a Solicited Adverse Reaction?	Yes ○
	No ●
Is this event a confirmed diagnosis of Symptomatic Covid-19?	Yes ○
	No ●
Start date *(dd MMM yyyy)*	25 AUG 2020
Start time *(00:00-23:59)*	
AE start date and time (derived)	
Ongoing?	Yes ●
	No ○
If not Ongoing, end date *(dd MMM yyyy)*	
End time *(00:00-23:59)*	
AE End Date and Time (derived)	
Severity	Grade 1/Mild ●
	Grade 2/Moderate ○
	Grade 3/Severe ○
	Grade 4 ○
Is the adverse event serious?	Yes ○
	No ●
AE is serious due To (check all that apply)	
Death	False
Life threatening	False
Requires inpatient or prolongation of existing Hospitalization	False
Hospital Admission Date *(dd MMM yyyy)*	
Hospital Discharge Date *(dd MMM yyyy)*	
Admitted to ICU?	Yes ○
	No ○
	Unknown ○

Number of Days in ICU	
Persistent or significant disability or incapacity	False
Congenital anomaly or birth defect	False
Other medically important event	False

Relationship to investigational product

- Not Related ○
- Related ●
- Not Applicable ○

Relationship to Study Procedure

- Not Related ●
- Related ○
- Not Applicable ○

Action taken with investigational product

- None ○
- Dose Delayed ○
- Investigational Product Withdrawn ●
- Not Applicable ○

Other action taken (check all that apply)

None	False
Concomitant Medication	True
Concomitant Procedure	False

Outcome

- Fatal ○
- Not Recovered/Not Resolved ○
- Recovered/Resolved ○
- Recovered/Resolved with Sequelae ○
- Recovering/Resolving ●
- Unknown ○

If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:	
Narrative	
Serious Adverse Event Derived (CSA Programming Field Ony)	0
Medically Attended AE Derived (CSA Programming Field Only)	1
Admitted to ICU Derived (CSA Programming Field Only)	

AEID

Adverse event	WORSENING LOWER EXTREMETIES ARTHRALGIA

Was this a medically-attended AE?　　Yes ●　No ○

Was this a Solicited Adverse Reaction?　　Yes ○　No ●

Is this event a confirmed diagnosis of Symptomatic Covid-19?　　Yes ○　No ●

Start date *(dd MMM yyyy)*　　25 AUG 2020

Start time *(00:00-23:59)*

AE start date and time (derived)

Ongoing?　　Yes ●　No ○

　If not Ongoing, end date *(dd MMM yyyy)*

　End time *(00:00-23:59)*

AE End Date and Time (derived)

Severity　　Grade 1/Mild ●　Grade 2/Moderate ○　Grade 3/Severe ○　Grade 4 ○

Is the adverse event serious?　　Yes ○　No ●

AE is serious due To (check all that apply)

Death	False
Life threatening	False
Requires inpatient or prolongation of existing Hospitalization	False

　Hospital Admission Date *(dd MMM yyyy)*

　Hospital Discharge Date *(dd MMM yyyy)*

　Admitted to ICU?　　Yes ○　No ○　Unknown ○

Number of Days in ICU	
Persistent or significant disability or incapacity	False
Congenital anomaly or birth defect	False
Other medically important event	False

Relationship to investigational product

- Not Related ◯
- Related ⬤
- Not Applicable ◯

Relationship to Study Procedure

- Not Related ⬤
- Related ◯
- Not Applicable ◯

Action taken with investigational product

- None ◯
- Dose Delayed ◯
- Investigational Product Withdrawn ◯
- Not Applicable ⬤

Other action taken (check all that apply)

None	True
Concomitant Medication	False
Concomitant Procedure	False

Outcome

- Fatal ◯
- Not Recovered/Not Resolved ◯
- Recovered/Resolved ◯
- Recovered/Resolved with Sequelae ◯
- Recovering/Resolving ⬤
- Unknown ◯

If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:	
Narrative	
Serious Adverse Event Derived (CSA Programming Field Ony)	0
Medically Attended AE Derived (CSA Programming Field Only)	1
Admitted to ICU Derived (CSA Programming Field Only)	

US3232021

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination Summary

Data signed: (b) (4)   **02 Apr 2021 13:34:37**

Generated On: 11 Aug 2021 22:05:35

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

No ◯

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

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Data signed: (b) (4)　　**02 Apr 2021 13:34:37**

Generated On: 11 Aug 2021 22:05:35

Name of Medication	ZOLOFT
Prophylaxis	Yes ◯
	No ⬤
Indication	ANXIETY
Dose per administration	50
Dose unit	mg ⬤
	ug ◯
	mL ◯
	g ◯
	IU ◯
	tablet ◯
	capsule ◯
	puff ◯
	Other ◯
If dose unit is Other, specify	
Frequency	once daily ⬤
	twice daily ◯
	three times daily ◯
	four times daily ◯
	every other day ◯
	every week ◯
	every month ◯
	as needed ◯
	once ◯
	unknown ◯
	other ◯
If frequency is Other, specify	
Route of administration	Oral ⬤
	Topical ◯
	Subcutaneous ◯
	Transdermal ◯
	Intraocular ◯

PRODUCTION RELEASE (v12.003
EAB) (1725)

	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 2013
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 ●

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Data signed: (b) (4)   **02 Apr 2021 13:34:37**

Generated On: 11 Aug 2021 22:05:35

Name of Medication	MULTIVITAMIN
Prophylaxis	Yes ⬤
	No ◯
Indication	MAINTENANCE
Dose per administration	1
Dose unit	mg ◯
	ug ◯
	mL ◯
	g ◯
	IU ◯
	tablet ⬤
	capsule ◯
	puff ◯
	Other ◯
If dose unit is Other, specify	
Frequency	once daily ⬤
	twice daily ◯
	three times daily ◯
	four times daily ◯
	every other day ◯
	every week ◯
	every month ◯
	as needed ◯
	once ◯
	unknown ◯
	other ◯
If frequency is Other, specify	
Route of administration	Oral ⬤
	Topical ◯
	Subcutaneous ◯
	Transdermal ◯
	Intraocular ◯

	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 2020
Start date completely unknown	False
Ongoing?	Yes ●
	No ◯
If not Ongoing, End date *(dd MMM yyyy)*	
Was this medication taken for solicited event?	Yes ◯
	No ●
Separate Dosage Number (derived)	1
Interval Dosage Unit Number (derived)	1
Interval Dosage Definition (derived)	802 ◯
	803 ◯
	804 ●

Name of Medication	VITAMIN D3

Prophylaxis	Yes ⬭
	No ⬤

Indication	VITAMIN D DEFICIENCY

Dose per administration	5000

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 ⬭

	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 MAY 2018
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 ◯

Name of Medication	ADVIL

Prophylaxis	Yes ⭘
	No ⬤

Indication	UPPER EXTREMITY ARTHRALGIA

Dose per administration	400

Dose unit	mg ⬤
	ug ⭘
	mL ⭘
	g ⭘
	IU ⭘
	tablet ⭘
	capsule ⭘
	puff ⭘
	Other ⭘

If dose unit is Other, specify	

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

If frequency is Other, specify	

Route of administration	Oral ⬤
	Topical ⭘
	Subcutaneous ⭘
	Transdermal ⭘

FDA-CBER-2022-1614-0645958

Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (4)
Data signed: (b) (4)   **02 Apr 2021 13:34:37**
Generated On: 11 Aug 2021 22:05:35

Intraocular	◯
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)*	25 AUG 2020
Start date completely unknown	False
Ongoing?	Yes ⬤
	No ◯
If not Ongoing, End date *(dd MMM yyyy)*	
Was this medication taken for solicited event?	Yes ◯
	No ⬤
Separate Dosage Number (derived)	2
Interval Dosage Unit Number (derived)	1
Interval Dosage Definition (derived)	802 ◯
	803 ◯
	804 ⬤

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Data signed: (b) (4) **02 Apr 2021 13:34:37**

Generated On: 11 Aug 2021 22:05:35

Name of Medication	CELEBREX
Prophylaxis	Yes ⬭
	No ⬤
Indication	UPPER EXTREMITY ARTHRALGIA
Dose per administration	100
Dose unit	mg ⬤
	ug ⬭
	mL ⬭
	g ⬭
	IU ⬭
	tablet ⬭
	capsule ⬭
	puff ⬭
	Other ⬭
If dose unit is Other, specify	
Frequency	once daily ⬭
	twice daily ⬤
	three times daily ⬭
	four times daily ⬭
	every other day ⬭
	every week ⬭
	every month ⬭
	as needed ⬭
	once ⬭
	unknown ⬭
	other ⬭
If frequency is Other, specify	
Route of administration	Oral ⬤
	Topical ⬭
	Subcutaneous ⬭
	Transdermal ⬭

Intraocular	◯
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)*	16 SEP 2020
Start date completely unknown	False
Ongoing?	Yes ⬤
	No ◯

If not Ongoing, End date *(dd MMM yyyy)*	
Was this medication taken for solicited event?	Yes ◯
	No ⬤

Separate Dosage Number (derived)	2
Interval Dosage Unit Number (derived)	1
Interval Dosage Definition (derived)	802 ◯
	803 ◯
	804 ⬤

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Data signed: (b) (4)　　**02 Apr 2021 13:34:37**

Generated On: 11 Aug 2021 22:05:35

Name of Medication	ADVIL
Prophylaxis	Yes ◯
	No ⬤
Indication	INJECTION SITE PAIN
Dose per administration	400
Dose unit	mg ⬤
	ug ◯
	mL ◯
	g ◯
	IU ◯
	tablet ◯
	capsule ◯
	puff ◯
	Other ◯
If dose unit is Other, specify	
Frequency	once daily ⬤
	twice daily ◯
	three times daily ◯
	four times daily ◯
	every other day ◯
	every week ◯
	every month ◯
	as needed ◯
	once ◯
	unknown ◯
	other ◯
If frequency is Other, specify	
Route of administration	Oral ⬤
	Topical ◯
	Subcutaneous ◯
	Transdermal ◯
	Intraocular ◯

PRODUCTION RELEASE (v12.003
EAB) (1725)

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 AUG 2020
Start date completely unknown	False
Ongoing?	Yes ◯
	No ⬤
If not Ongoing, End date *(dd MMM yyyy)*	11 AUG 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 ⬤

US3232021

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures Summary

Data signed: (b) (4) **02 Apr 2021 13:34:37**

Generated On: 11 Aug 2021 22:05:35

Were any concomitant procedures performed?   Yes ◯

No ⬤

If yes, please complete Concomitant Procedures form.

US3232021

Folder: End of Study (1)

Form: Dosing Discontinuation

Data signed: (b) (4)　　**02 Apr 2021 13:34:37**

Generated On: 11 Aug 2021 22:05:35

Date of dosing discontinuation (dd MMM yyyy)	09 SEP 2020

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	SUBJECT ATTRIBUTING WORSENING FINGER JOINT PAIN TO IP DESPITE DIAGNOSIS OF OSTEOARTHRITIS

US3232021

Folder: End of Study (1)

Form: End of Study / Study Discontinuation

Data signed: (b) (4)   **23 Apr 2021 15:20:41**

Generated On: 11 Aug 2021 22:05:35

Date of study discontinuation/completion *(dd MMM yyyy)*	28 SEP 2020

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	PER SPONSOR, SUBJECT WAS NOT ELIGIBLE FOR RE-ENTRY DUE TO HER STOPPING COMMUNICATION VIA NOT COMPLETING SAFETY CALLS OR VISITS SINCE 28SEP2020

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

US3232021 (Prod: MediSync Clinical Research Hattiesburg Clinic)

US3232021
Form: Participant Creation
Generated On: 11 Aug 2021 22:05:35
Participant ID

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	02 May 2021 13:47:25
User signature succeeded.	Rambod Rouhbakhsh (b) (4)	02 Apr 2021 13:34:38
User entered 'US3232021'	RWS_ENDPOINT ENDPOINT (b) (4) (b) (4)	10 Aug 2020 16:04:40

mRNA-1273-P301 Completion Guidelines

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	02 May 2021 13:47:25

US3232021
Folder: Screening
Form: Visit Date
Generated On: 11 Aug 2021 22:05:35
Was this visit performed?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:23:38
User signature succeeded.	(b) (4), (b) (6) Rambod Rouhbakhsh	18 Feb 2021 15:31:39
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	10 Aug 2020 18:30:14
	(b) (4), (b) (6)	

US3232021
Folder: Screening
Form: Visit Date
Generated On: 11 Aug 2021 22:05:35

Visit date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:23:38
User signature succeeded.	(b) (4), (b) (6) Rambod Rouhbakhsh (b) (4)	18 Feb 2021 15:31:39
User entered '10 AUG 2020'	RWS_ENDPOINT ENDPOINT (b) (6) (b) (6)	10 Aug 2020 16:04:41

FDA-CBER-2022-1614-0645971

US3232021

Folder: Screening

Form: Visit Date

Generated On: 11 Aug 2021 22:05:35

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 21:23:38
User signature succeeded.	(b) (4), (b) (6) Rambod Rouhbakhsh	18 Feb 2021 15:31:39
User entered 'Clinic (Clinic)'	(b) (4) (b) (4), (b) (6)	10 Aug 2020 18:30:14
	(b) (4), (b) (6)	

US3232021
Folder: Screening
Form: Visit Date
Generated On: 11 Aug 2021 22:05:35
Folder OID

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:23:38
User entered 'SCRN'	(b) (4), (b) (6) System	10 Aug 2020 18:30:14

US3232021

Folder: Screening

Form: Demographics

Generated On: 11 Aug 2021 22:05:35

Date of Birth (MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:23:38
User signature succeeded.	(b) (4), (b) (6) Rambod Rouhbakhsh	18 Feb 2021 15:31:39
User entered (b) (6) 1973'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4) (b) (4)	10 Aug 2020 16:04:42

US3232021

Folder: Screening

Form: Demographics

Generated On: 11 Aug 2021 22:05:35

Age

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:23:38
User signature succeeded.	(b) (4), (b) (6) Rambod Rouhbakhsh	18 Feb 2021 15:31:39
User entered '47'	(b) (4) (b) (4), (b) (6) (b) (4), (b) (6)	10 Aug 2020 18:30:41

US3232021
Folder: Screening
Form: Demographics
Generated On: 11 Aug 2021 22:05:35
Age Units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	28 Apr 2021 21:23:38
User entered 'YEARS'	System	10 Aug 2020 18:30:41

US3232021

Folder: Screening

Form: Demographics

Generated On: 11 Aug 2021 22:05:35

Age (Derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:23:38
	(b) (4), (b) (6)	
User entered '47'	System	10 Aug 2020 17:47:00

US3232021
Folder: Screening
Form: Demographics
Generated On: 11 Aug 2021 22:05:35
Sex

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	28 Apr 2021 21:23:38
User signature succeeded.	Rambod Rouhbakhsh (b) (4)	18 Feb 2021 15:31:39
User entered 'Female (F)'	(b) (4), (b) (6) (b) (4), (b) (6)	10 Aug 2020 18:30:41

US3232021

Folder: Screening

Form: Demographics

Generated On: 11 Aug 2021 22:05:35

Ethnicity

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:23:38
User signature succeeded.	(b) (4), (b) (6) Rambod Rouhbakhsh	18 Feb 2021 15:31:39
User entered 'Not Hispanic or Latino (NOT HISPANIC OR LATINO)'	(b) (4) (b) (4), (b) (6) (b) (4), (b) (6)	10 Aug 2020 18:30:41

FDA-CBER-2022-1614-0645979

US3232021
Folder: Screening
Form: Demographics
Generated On: 11 Aug 2021 22:05:35
White

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:23:38
User signature succeeded.	(b) (4), (b) (6) Rambod Rouhbakhsh	18 Feb 2021 15:31:39
User entered '1'	(b) (4) (b) (4), (b) (6) (b) (4), (b) (6)	10 Aug 2020 18:30:41

US3232021

Folder: Screening

Form: Demographics

Generated On: 11 Aug 2021 22:05:35

Black

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:23:38
User signature succeeded.	(b) (4), (b) (6) Rambod Rouhbakhsh (b) (4)	18 Feb 2021 15:31:39
User entered '0'	(b) (4), (b) (6) (b) (4), (b) (6)	10 Aug 2020 18:30:41

US3232021
Folder: Screening
Form: Demographics
Generated On: 11 Aug 2021 22:05:35

Asian

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:23:38
User signature succeeded.	(b) (4), (b) (6) Rambod Rouhbakhsh	18 Feb 2021 15:31:39
User entered '0'	(b) (4) (b) (4), (b) (6) (b) (4), (b) (6)	10 Aug 2020 18:30:41

US3232021

Folder: Screening

Form: Demographics

Generated On: 11 Aug 2021 22:05:35

American Indian or Alaska Native

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:23:38
User signature succeeded.	(b) (4), (b) (6) Rambod Rouhbakhsh	18 Feb 2021 15:31:39
User entered '0'	(b) (4) (b) (4), (b) (6) (b) (4), (b) (6)	10 Aug 2020 18:30:41

US3232021

Folder: Screening

Form: Demographics

Generated On: 11 Aug 2021 22:05:35

Native Hawaiian or other Pacific Islander

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:23:38
User signature succeeded.	(b) (4), (b) (6) Rambod Rouhbakhsh	18 Feb 2021 15:31:39
User entered '0'	(b) (4) (b) (4), (b) (6) (b) (4), (b) (6)	10 Aug 2020 18:30:41

US3232021

Folder: Screening

Form: Demographics

Generated On: 11 Aug 2021 22:05:35

Other

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:23:38
User signature succeeded.	(b) (4), (b) (6) Rambod Rouhbakhsh	18 Feb 2021 15:31:39
User entered '0'	(b) (4) (b) (4), (b) (6) (b) (4), (b) (6)	10 Aug 2020 18:30:41

US3232021
Folder: Screening
Form: Demographics
Generated On: 11 Aug 2021 22:05:35
If race is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:23:38
User signature succeeded.	(b) (4), (b) (6) Rambod Rouhbakhsh	18 Feb 2021 15:31:39
User entered empty.	(b) (4) (b) (4), (b) (6) (b) (4), (b) (6)	10 Aug 2020 18:30:41

US3232021

Folder: Screening

Form: Demographics

Generated On: 11 Aug 2021 22:05:35

Unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:23:38
User signature succeeded.	(b) (4), (b) (6) Rambod Rouhbakhsh	18 Feb 2021 15:31:39
User entered '0'	(b) (4) (b) (4), (b) (6)	10 Aug 2020 18:30:41
	(b) (4), (b) (6)	

US3232021

Folder: Screening

Form: Demographics

Generated On: 11 Aug 2021 22:05:35

Not reported

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:23:38
User signature succeeded.	(b) (4), (b) (6) Rambod Rouhbakhsh	18 Feb 2021 15:31:39
User entered '0'	(b) (4) (b) (4), (b) (6) (b) (4), (b) (6)	10 Aug 2020 18:30:41

Date of Informed Consent *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:23:38
User signature succeeded.	(b) (4), (b) (6) Rambod Rouhbakhsh	18 Feb 2021 15:31:39
User entered '10 Aug 2020'	(b) (4) (b) (4), (b) (6) (b) (4), (b) (6)	10 Aug 2020 17:47:00

US3232021

Folder: Screening

Form: Enrollment

Generated On: 11 Aug 2021 22:05:35

Month and Year of Informed Consent (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	28 Apr 2021 21:23:38
User entered 'Aug 2020'	System	10 Aug 2020 17:47:00

US3232021
Folder: Screening
Form: Enrollment
Generated On: 11 Aug 2021 22:05:35
Year of Informed Consent (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:23:38
	(b) (4), (b) (6)	
User entered '2020'	System	10 Aug 2020 17:47:00

US3232021
Folder: Screening
Form: Enrollment
Generated On: 11 Aug 2021 22:05:35
Protocol Version

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:23:38
User signature succeeded.	(b) (4), (b) (6) Rambod Rouhbakhsh	18 Feb 2021 15:31:39
User entered 'Amendment 1 (1)'	(b) (4) (b) (4), (b) (6) (b) (4), (b) (6)	10 Aug 2020 17:47:00

US3232021

Folder: Screening

Form: Enrollment

Generated On: 11 Aug 2021 22:05:35

Was participant enrolled in the study?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:23:38
User signature succeeded.	(b) (4), (b) (6) Rambod Rouhbakhsh (b) (4)	18 Feb 2021 15:31:39
User entered 'Yes (Y)'	(b) (4), (b) (6) (b) (4), (b) (6)	10 Aug 2020 17:47:00

US3232021

Folder: Screening

Form: Enrollment

Generated On: 11 Aug 2021 22:05:35

If No, indicate reason for screen fail

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:23:38
User signature succeeded.	(b) (4), (b) (6) Rambod Rouhbakhsh	18 Feb 2021 15:31:39
User entered empty.	(b) (4) (b) (4), (b) (6)	10 Aug 2020 17:47:00
	(b) (4), (b) (6)	

US3232021

Folder: Screening

Form: Enrollment

Generated On: 11 Aug 2021 22:05:35

If reason for screen fail is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:23:38
User signature succeeded.	(b) (4), (b) (6) Rambod Rouhbakhsh	18 Feb 2021 15:31:39
User entered empty.	(b) (4) (b) (4), (b) (6) (b) (4), (b) (6)	10 Aug 2020 17:47:00

US3232021

Folder: Screening

Form: Enrollment

Generated On: 11 Aug 2021 22:05:35

Was this participant screened previously?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:23:38
User signature succeeded.	(b) (4), (b) (6) Rambod Rouhbakhsh	18 Feb 2021 15:31:39
User entered 'No (N)'	(b) (4) (b) (4), (b) (6) (b) (4), (b) (6)	10 Aug 2020 17:47:00

US3232021

Folder: Screening

Form: Enrollment

Generated On: 11 Aug 2021 22:05:35

If Yes, previous participant number

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	28 Apr 2021 21:23:38
User signature succeeded.	Rambod Rouhbakhsh (b) (4)	18 Feb 2021 15:31:39
User entered empty.	RWS_ENDPOINT ENDPOINT (b) (4) (b) (4)	10 Aug 2020 16:04:41

US3232021
Folder: Screening
Form: Enrollment
Generated On: 11 Aug 2021 22:05:35
Enrollment Trigger

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	28 Apr 2021 21:23:38
User entered '1'	System	10 Aug 2020 17:47:05

US3232021

Folder: Screening

Form: Inclusion/Exclusion Criteria Summary

Generated On: 11 Aug 2021 22:05:35

Did the participant meet all eligibility criteria?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:23:38
User signature succeeded.	(b) (4), (b) (6) Rambod Rouhbakhsh	18 Feb 2021 15:31:39
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6) (b) (4), (b) (6)	10 Aug 2020 17:47:05

US3232021

Folder: Screening

Form: Medical History Summary

Generated On: 11 Aug 2021 22:05:35

Were any significant conditions reported?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:23:38
User signature succeeded.	(b) (4), (b) (6) Rambod Rouhbakhsh	18 Feb 2021 15:31:39
User entered 'Yes (Y)' reason for change: Data Entry Error	(b) (4) (b) (4), (b) (6)	25 Aug 2020 14:10:20
User entered 'No (N)'	(b) (4), (b) (6) (b) (4), (b) (6)	10 Aug 2020 18:30:55

FDA-CBER-2022-1614-0646000

US3232021

Folder: Screening

Form: Medical History (1)

Generated On: 11 Aug 2021 22:05:35

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:23:38
User signature succeeded.	(b) (4), (b) (6) Rambod Rouhbakhsh (b) (4)	18 Feb 2021 15:31:39
Query 'Per DM CLR: Please specify the location of OSTEOARTHRITIS. Review and update medical history diagnosis as appropriate and ensure update to MHx is reconciled with any corresponding AE or ConMed entries, if applicable. ' canceled (Site from DM).	(b) (4), (b) (6) (b) (4), (b) (6)	05 Nov 2020 21:02:37
User opened query 'Per DM CLR: Please specify the location of OSTEOARTHRITIS. Review and update medical history diagnosis as appropriate and ensure update to MHx is reconciled with any corresponding AE or ConMed entries, if applicable. ' (Site from DM).	(b) (4), (b) (6) (b) (4), (b) (6)	11 Sep 2020 16:41:01
User coded data point as SOC: Musculoskeletal and connective tissue disorders, HLGT: Joint disorders, HLT: Osteoarthropathies, PT: Osteoarthritis, LLT: Osteoarthritis - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	25 Aug 2020 14:16:29
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	25 Aug 2020 14:16:29
Data point term sent to Coder	System	25 Aug 2020 14:15:48
User entered 'Osteoarthritis'	(b) (4), (b) (6) (b) (4), (b) (6)	25 Aug 2020 14:15:31

US3232021

Folder: Screening

Form: Medical History (1)

Generated On: 11 Aug 2021 22:05:35

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:23:38
User signature succeeded.	(b) (4), (b) (6) Rambod Rouhbakhsh	18 Feb 2021 15:31:39
User entered 'un Oct 2018'	(b) (4) (b) (4), (b) (6)	25 Aug 2020 14:15:31
	(b) (4), (b) (6)	

US3232021

Folder: Screening

Form: Medical History (1)

Generated On: 11 Aug 2021 22:05:35

Start date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:23:38
User signature succeeded.	(b) (4), (b) (6) Rambod Rouhbakhsh (b) (4)	18 Feb 2021 15:31:39
User entered '0'	(b) (4), (b) (6) (b) (4), (b) (6)	25 Aug 2020 14:15:31

US3232021

Folder: Screening

Form: Medical History (1)

Generated On: 11 Aug 2021 22:05:35

Condition ongoing at study entry

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:23:38
User signature succeeded.	(b) (4), (b) (6) Rambod Rouhbakhsh (b) (4)	18 Feb 2021 15:31:39
User entered 'Yes (Y)'	(b) (4), (b) (6) (b) (4), (b) (6)	25 Aug 2020 14:15:31

US3232021

Folder: Screening

Form: Medical History (1)

Generated On: 11 Aug 2021 22:05:35

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:23:38
User signature succeeded.	(b) (4), (b) (6) Rambod Rouhbakhsh	18 Feb 2021 15:31:39
User entered empty.	(b) (4) (b) (4), (b) (6)	25 Aug 2020 14:15:31
	(b) (4), (b) (6)	

US3232021

Folder: Screening

Form: Medical History (1)

Generated On: 11 Aug 2021 22:05:35

Stop date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:23:38
User signature succeeded.	(b) (4), (b) (6) Rambod Rouhbakhsh	18 Feb 2021 15:31:39
User entered '0'	(b) (4) (b) (4), (b) (6) (b) (4), (b) (6)	25 Aug 2020 14:15:31

US3232021

Folder: Screening

Form: Medical History (1)

Generated On: 11 Aug 2021 22:05:35

Start Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	28 Apr 2021 21:23:38
User entered 'Oct 2018'	System	25 Aug 2020 14:15:31

US3232021

Folder: Screening

Form: Medical History (1)

Generated On: 11 Aug 2021 22:05:35

Start Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:23:38
User entered '2018'	(b) (4), (b) (6) System	25 Aug 2020 14:15:31

US3232021

Folder: Screening

Form: Medical History (1)

Generated On: 11 Aug 2021 22:05:35

Stop Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	28 Apr 2021 21:23:38
User entered empty.	System	25 Aug 2020 14:15:31

US3232021
Folder: Screening
Form: Medical History (1)
Generated On: 11 Aug 2021 22:05:35

Stop Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	28 Apr 2021 21:23:38
User entered empty.	System	25 Aug 2020 14:15:31

US3232021
Folder: Screening
Form: Medical History (2)
Generated On: 11 Aug 2021 22:05:35
Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	28 Apr 2021 21:23:38
User signature succeeded.	(b) (4) Rambod Rouhbakhsh	18 Feb 2021 15:31:39
User coded data point as SOC: Psychiatric disorders, HLGT: Anxiety disorders and symptoms, HLT: Anxiety symptoms, PT: Anxiety, LLT: Anxiety - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	25 Aug 2020 14:17:29
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	25 Aug 2020 14:17:29
Data point term sent to Coder	System	25 Aug 2020 14:16:49
User entered 'anxiety'	(b) (4), (b) (6) (b) (4), (b) (6)	25 Aug 2020 14:15:53

US3232021

Folder: Screening

Form: Medical History (2)

Generated On: 11 Aug 2021 22:05:35

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:23:38
User signature succeeded.	(b) (4), (b) (6) Rambod Rouhbakhsh	18 Feb 2021 15:31:39
User entered 'un UNK 2008'	(b) (4) (b) (4), (b) (6) (b) (4), (b) (6)	25 Aug 2020 14:15:53

US3232021

Folder: Screening

Form: Medical History (2)

Generated On: 11 Aug 2021 22:05:35

Start date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:23:38
User signature succeeded.	(b) (4), (b) (6) Rambod Rouhbakhsh	18 Feb 2021 15:31:39
User entered '0'	(b) (4) (b) (4), (b) (6) (b) (4), (b) (6)	25 Aug 2020 14:15:53

US3232021

Folder: Screening

Form: Medical History (2)

Generated On: 11 Aug 2021 22:05:35

Condition ongoing at study entry

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:23:38
User signature succeeded.	(b) (4), (b) (6) Rambod Rouhbakhsh (b) (4)	18 Feb 2021 15:31:39
User entered 'Yes (Y)'	(b) (4), (b) (6) (b) (4), (b) (6)	25 Aug 2020 14:15:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:23:38
User signature succeeded.	(b) (4), (b) (6) Rambod Rouhbakhsh	18 Feb 2021 15:31:39
User entered empty.	(b) (4) (b) (4), (b) (6) (b) (4), (b) (6)	25 Aug 2020 14:15:53

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US3232021

Folder: Screening

Form: Medical History (2)

Generated On: 11 Aug 2021 22:05:35

Stop date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:23:38
User signature succeeded.	(b) (4), (b) (6) Rambod Rouhbakhsh	18 Feb 2021 15:31:39
User entered '0'	(b) (4) (b) (4), (b) (6) (b) (4), (b) (6)	25 Aug 2020 14:15:53

US3232021

Folder: Screening

Form: Medical History (2)

Generated On: 11 Aug 2021 22:05:35

Start Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	28 Apr 2021 21:23:38
User entered 'Jan 2008'	System	25 Aug 2020 14:15:53

US3232021

Folder: Screening

Form: Medical History (2)

Generated On: 11 Aug 2021 22:05:35

Start Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	28 Apr 2021 21:23:38
User entered '2008'	System	25 Aug 2020 14:15:53

Stop Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	28 Apr 2021 21:23:38
User entered empty.	System	25 Aug 2020 14:15:53

FDA-CBER-2022-1614-0646019

US3232021

Folder: Screening

Form: Medical History (2)

Generated On: 11 Aug 2021 22:05:35

Stop Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	28 Apr 2021 21:23:38
User entered empty.	System	25 Aug 2020 14:15:53

US3232021
Folder: Screening
Form: Medical History (3)
Generated On: 11 Aug 2021 22:05:35

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	28 Apr 2021 21:23:38
User signature succeeded.	(b) (4) Rambod Rouhbakhsh	18 Feb 2021 15:31:39
User coded data point as SOC: Metabolism and nutrition disorders, HLGT: Vitamin related disorders, HLT: Fat soluble vitamin deficiencies and disorders, PT: Vitamin D deficiency, LLT: Vitamin D deficiency - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	25 Aug 2020 14:18:32
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	25 Aug 2020 14:18:32
Data point term sent to Coder	System	25 Aug 2020 14:17:52
User entered 'vitamin D Deficiency'	(b) (4), (b) (6) (b) (4), (b) (6)	25 Aug 2020 14:16:54

US3232021

Folder: Screening

Form: Medical History (3)

Generated On: 11 Aug 2021 22:05:35

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:23:38
User signature succeeded.	(b) (4), (b) (6) Rambod Rouhbakhsh	18 Feb 2021 15:31:39
User entered 'un May 2018'	(b) (4) (b) (4), (b) (6) (b) (4), (b) (6)	25 Aug 2020 14:16:54

US3232021

Folder: Screening

Form: Medical History (3)

Generated On: 11 Aug 2021 22:05:35

Start date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:23:38
User signature succeeded.	(b) (4), (b) (6) Rambod Rouhbakhsh	18 Feb 2021 15:31:39
User entered '0'	(b) (4) (b) (4), (b) (6) (b) (4), (b) (6)	25 Aug 2020 14:16:54

US3232021

Folder: Screening

Form: Medical History (3)

Generated On: 11 Aug 2021 22:05:35

Condition ongoing at study entry

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:23:38
User signature succeeded.	(b) (4), (b) (6) Rambod Rouhbakhsh	18 Feb 2021 15:31:39
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6) (b) (4), (b) (6)	25 Aug 2020 14:16:54

US3232021

Folder: Screening

Form: Medical History (3)

Generated On: 11 Aug 2021 22:05:35

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:23:38
User signature succeeded.	(b) (4), (b) (6) Rambod Rouhbakhsh	18 Feb 2021 15:31:39
User entered empty.	(b) (4) (b) (4), (b) (6) (b) (4), (b) (6)	25 Aug 2020 14:16:54

US3232021

Folder: Screening

Form: Medical History (3)

Generated On: 11 Aug 2021 22:05:35

Stop date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:23:38
User signature succeeded.	(b) (4), (b) (6) Rambod Rouhbakhsh	18 Feb 2021 15:31:39
User entered '0'	(b) (4) (b) (4), (b) (6) (b) (4), (b) (6)	25 Aug 2020 14:16:54

US3232021

Folder: Screening

Form: Medical History (3)

Generated On: 11 Aug 2021 22:05:35

Start Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	28 Apr 2021 21:23:38
User entered 'May 2018'	System	25 Aug 2020 14:16:54

US3232021

Folder: Screening

Form: Medical History (3)

Generated On: 11 Aug 2021 22:05:35

Start Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	28 Apr 2021 21:23:38
User entered '2018'	System	25 Aug 2020 14:16:54

US3232021

Folder: Screening

Form: Medical History (3)

Generated On: 11 Aug 2021 22:05:35

Stop Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	28 Apr 2021 21:23:38
User entered empty.	System	25 Aug 2020 14:16:54

US3232021
Folder: Screening
Form: Medical History (3)
Generated On: 11 Aug 2021 22:05:35
Stop Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:23:38
	(b) (4), (b) (6)	
User entered empty.	System	25 Aug 2020 14:16:54

US3232021

Folder: Screening

Form: Medical History (4)

Generated On: 11 Aug 2021 22:05:35

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:23:38
User signature succeeded.	(b) (4), (b) (6) Rambod Rouhbakhsh	18 Feb 2021 15:31:39
User coded data point as SOC: Social circumstances, HLGT: Lifestyle issues, HLT: Tobacco use, PT: Tobacco user, LLT: Tobacco user - version MedDRA\\23.0.	(b) (4) Coder Import $^{(b)\ (4)}$ (b) (4)	25 Aug 2020 15:07:31
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import $^{(b)\ (4)}$ (b) (4)	25 Aug 2020 15:07:31
Data point term sent to Coder	System	25 Aug 2020 14:18:59
User entered 'Past Tobacco Use, Cigarettes, 5 per day'	(b) (4), (b) (6) (b) (4), (b) (6)	25 Aug 2020 14:18:10

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:23:38
User signature succeeded.	(b) (4), (b) (6) Rambod Rouhbakhsh	18 Feb 2021 15:31:39
User entered empty.	(b) (4) (b) (4), (b) (6) (b) (4), (b) (6)	25 Aug 2020 14:18:10

US3232021
Folder: Screening
Form: Medical History (4)
Generated On: 11 Aug 2021 22:05:35
Start date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:23:38
User signature succeeded.	(b) (4), (b) (6) Rambod Rouhbakhsh	18 Feb 2021 15:31:39
User entered '1'	(b) (4) (b) (4), (b) (6) (b) (4), (b) (6)	25 Aug 2020 14:18:10

US3232021

Folder: Screening

Form: Medical History (4)

Generated On: 11 Aug 2021 22:05:35

Condition ongoing at study entry

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:23:38
User signature succeeded.	(b) (4), (b) (6) Rambod Rouhbakhsh	18 Feb 2021 15:31:39
User entered 'No (N)'	(b) (4) (b) (4), (b) (6) (b) (4), (b) (6)	25 Aug 2020 14:18:10

US3232021

Folder: Screening

Form: Medical History (4)

Generated On: 11 Aug 2021 22:05:35

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:23:38
User signature succeeded.	(b) (4), (b) (6) Rambod Rouhbakhsh	18 Feb 2021 15:31:39
User entered 'un UNK 2000'	(b) (4) (b) (4), (b) (6)	25 Aug 2020 14:18:10
	(b) (4), (b) (6)	

Stop date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:23:38
User signature succeeded.	(b) (4), (b) (6) Rambod Rouhbakhsh	18 Feb 2021 15:31:39
User entered '0'	(b) (4) (b) (4), (b) (6) (b) (4), (b) (6)	25 Aug 2020 14:18:10

Start Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	28 Apr 2021 21:23:38
User entered empty.	System	25 Aug 2020 14:18:10

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Folder: Screening

Form: Medical History (4)

Generated On: 11 Aug 2021 22:05:35

Start Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	28 Apr 2021 21:23:38
User entered empty.	System	25 Aug 2020 14:18:10

Stop Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	28 Apr 2021 21:23:38
User entered 'Jan 2000'	System	25 Aug 2020 14:18:10

US3232021

Folder: Screening

Form: Medical History (4)

Generated On: 11 Aug 2021 22:05:35

Stop Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:23:38
	(b) (4), (b) (6)	
User entered '2000'	System	25 Aug 2020 14:18:10

US3232021

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 22:05:35

Were vital signs assessed?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:23:38
User signature succeeded.	(b) (4), (b) (6) Rambod Rouhbakhsh	18 Feb 2021 15:31:39
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	10 Aug 2020 18:32:02
	(b) (4), (b) (6)	

US3232021

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 22:05:35

Date of assessment *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:23:38
User signature succeeded.	(b) (4), (b) (6) Rambod Rouhbakhsh	18 Feb 2021 15:31:39
User entered '10 Aug 2020'	(b) (4) (b) (4), (b) (6)	10 Aug 2020 18:32:02
	(b) (4), (b) (6)	

US3232021

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 22:05:35

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:23:38
	(b) (4), (b) (6)	
User signature succeeded.	Rambod Rouhbakhsh	18 Feb 2021 15:31:39
	(b) (4)	
User entered '11:07'	(b) (4), (b) (6)	10 Aug 2020 18:32:02
	(b) (4), (b) (6)	

US3232021
Folder: Screening
Form: Vital Signs
Generated On: 11 Aug 2021 22:05:35

Vital Signs Date and Time (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	28 Apr 2021 21:23:38
User entered '10 Aug 2020 11:07'	System	10 Aug 2020 18:32:02

US3232021

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 22:05:35

Height *(xxx.x)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:23:38
User signature succeeded.	(b) (4), (b) (6) Rambod Rouhbakhsh	18 Feb 2021 15:31:39
User entered '166' cm	(b) (4) (b) (4), (b) (6)	10 Aug 2020 18:32:02
DataPoint set to visible.	(b) (4), (b) (6) System	10 Aug 2020 17:47:05

US3232021
Folder: Screening
Form: Vital Signs
Generated On: 11 Aug 2021 22:05:35

Weight *(xxx.x)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:23:38
User signature succeeded.	(b) (4), (b) (6) Rambod Rouhbakhsh	18 Feb 2021 15:31:39
User entered '67.6' kg	(b) (4) (b) (4), (b) (6)	10 Aug 2020 18:32:02
DataPoint set to visible.	(b) (4), (b) (6) System	10 Aug 2020 17:47:05

US3232021
Folder: Screening
Form: Vital Signs
Generated On: 11 Aug 2021 22:05:35

BMI *(xxx.x)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	28 Apr 2021 21:23:38
Amendment Manager: User entered '24.53186'	System	16 Sep 2020 23:49:56
User entered '24.5'	System	10 Aug 2020 18:32:02
DataPoint set to visible.	System	10 Aug 2020 17:47:05

US3232021
Folder: Screening
Form: Vital Signs
Generated On: 11 Aug 2021 22:05:35
BMI units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	28 Apr 2021 21:23:38
User entered 'kg/m2'	System	10 Aug 2020 18:32:02
DataPoint set to visible.	System	10 Aug 2020 17:47:05

US3232021

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 22:05:35

Temperature *(xxx.x)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	28 Apr 2021 21:23:38
User signature succeeded.	Rambod Rouhbakhsh (b) (4)	18 Feb 2021 15:31:39
User entered '98.6' F	(b) (4), (b) (6) (b) (4), (b) (6)	10 Aug 2020 18:32:02

US3232021

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 22:05:35

Route of measurement

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:23:38
User signature succeeded.	(b) (4), (b) (6) Rambod Rouhbakhsh	18 Feb 2021 15:31:39
User entered 'Oral (Oral)'	(b) (4) (b) (4), (b) (6) (b) (4), (b) (6)	10 Aug 2020 18:32:02

US3232021
Folder: Screening
Form: Vital Signs
Generated On: 11 Aug 2021 22:05:35
If Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:23:38
User signature succeeded.	(b) (4), (b) (6) Rambod Rouhbakhsh	18 Feb 2021 15:31:39
User entered empty.	(b) (4) (b) (4), (b) (6) (b) (4), (b) (6)	10 Aug 2020 18:32:02

US3232021

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 22:05:35

Pulse *(xxx)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:23:38
User signature succeeded.	(b) (4), (b) (6) Rambod Rouhbakhsh	18 Feb 2021 15:31:39
User entered '63'	(b) (4) (b) (4), (b) (6) (b) (4), (b) (6)	10 Aug 2020 18:32:02

US3232021
Folder: Screening
Form: Vital Signs
Generated On: 11 Aug 2021 22:05:35
Pulse units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	28 Apr 2021 21:23:38
User entered 'bpm'	System	10 Aug 2020 18:32:02

Respiratory Rate *(xxx)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:23:38
User signature succeeded.	(b) (4), (b) (6) Rambod Rouhbakhsh	18 Feb 2021 15:31:39
User entered '18'	(b) (4) (b) (4), (b) (6) (b) (4), (b) (6)	10 Aug 2020 18:32:02

US3232021
Folder: Screening
Form: Vital Signs
Generated On: 11 Aug 2021 22:05:35
Respiratory Rate units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:23:38
User entered 'breaths/min'	(b) (4), (b) (6) System	10 Aug 2020 18:32:02

US3232021

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 22:05:35

Systolic Blood Pressure *(xxx)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:23:38
User signature succeeded.	(b) (4), (b) (6) Rambod Rouhbakhsh	18 Feb 2021 15:31:39
User entered '110'	(b) (4) (b) (4), (b) (6) (b) (4), (b) (6)	10 Aug 2020 18:32:02

US3232021
Folder: Screening
Form: Vital Signs
Generated On: 11 Aug 2021 22:05:35
Systolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:23:38
	(b) (4), (b) (6)	
User entered 'mmHg'	System	10 Aug 2020 18:32:02

US3232021
Folder: Screening
Form: Vital Signs
Generated On: 11 Aug 2021 22:05:35
Diastolic Blood Pressure *(xxx)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:23:38
User signature succeeded.	(b) (4), (b) (6) Rambod Rouhbakhsh	18 Feb 2021 15:31:39
User entered '60'	(b) (4) (b) (4), (b) (6)	10 Aug 2020 18:32:02
	(b) (4), (b) (6)	

US3232021
Folder: Screening
Form: Vital Signs
Generated On: 11 Aug 2021 22:05:35
Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	28 Apr 2021 21:23:38
User entered 'mmHg'	System	10 Aug 2020 18:32:02

US3232021
Folder: Screening
Form: Vital Signs
Generated On: 11 Aug 2021 22:05:35
Height (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	28 Apr 2021 21:23:38

Weight (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	28 Apr 2021 21:23:38

Was the physical examination performed?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:23:38
User signature succeeded.	(b) (4), (b) (6) Rambod Rouhbakhsh	18 Feb 2021 15:31:39
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6) (b) (4), (b) (6)	10 Aug 2020 18:32:15

US3232021

Folder: Screening

Form: Physical Examination

Generated On: 11 Aug 2021 22:05:35

Date of examination *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:23:38
User signature succeeded.	(b) (4), (b) (6) Rambod Rouhbakhsh	18 Feb 2021 15:31:39
Query 'The Physical Examination Date is prior to the Screening Visit Date. Please review and reconcile.' canceled (Site from System).	(b) (4) (b) (4), (b) (6) (b) (4), (b) (6)	23 Sep 2020 16:51:12
User opened query 'The Physical Examination Date is prior to the Screening Visit Date. Please review and reconcile.' (Site from System).	System	16 Sep 2020 18:37:31
User entered '10 Aug 2020'	(b) (4), (b) (6) (b) (4), (b) (6)	10 Aug 2020 18:32:15

US3232021

Folder: Screening

Form: Childbearing Potential

Generated On: 11 Aug 2021 22:05:35

Date of assessment *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:23:38
User signature succeeded.	(b) (4), (b) (6) Rambod Rouhbakhsh (b) (4)	18 Feb 2021 15:31:39
User entered '10 Aug 2020'	(b) (4), (b) (6) (b) (4), (b) (6)	10 Aug 2020 18:32:51

US3232021

Folder: Screening

Form: Childbearing Potential

Generated On: 11 Aug 2021 22:05:35

Is the participant of childbearing potential?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:23:38
User signature succeeded.	(b) (4), (b) (6) Rambod Rouhbakhsh	18 Feb 2021 15:31:39
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6) (b) (4), (b) (6)	10 Aug 2020 18:32:51

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Folder: Screening

Form: Childbearing Potential

Generated On: 11 Aug 2021 22:05:35

If No, what is the reason?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:23:38
User signature succeeded.	(b) (4), (b) (6) Rambod Rouhbakhsh	18 Feb 2021 15:31:39
User entered empty.	(b) (4) (b) (4), (b) (6)	10 Aug 2020 18:32:51
	(b) (4), (b) (6)	

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Folder: Screening

Form: Childbearing Potential

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If Partner medically sterile or Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:23:38
User signature succeeded.	(b) (4), (b) (6) Rambod Rouhbakhsh	18 Feb 2021 15:31:39
User entered empty.	(b) (4) (b) (4), (b) (6)	10 Aug 2020 18:32:51
	(b) (4), (b) (6)	

US3232021

Folder: Screening

Form: Childbearing Potential

Generated On: 11 Aug 2021 22:05:35

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:23:38
User signature succeeded.	(b) (4), (b) (6) Rambod Rouhbakhsh	18 Feb 2021 15:31:39
User entered empty.	(b) (4) (b) (4), (b) (6) (b) (4), (b) (6)	10 Aug 2020 18:32:51

US3232021

Folder: Screening

Form: Childbearing Potential

Generated On: 11 Aug 2021 22:05:35

Date of surgery unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:23:38
User signature succeeded.	(b) (4), (b) (6) Rambod Rouhbakhsh	18 Feb 2021 15:31:39
User entered '0'	(b) (4) (b) (4), (b) (6) (b) (4), (b) (6)	10 Aug 2020 18:32:51

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	28 Apr 2021 21:23:38
User signature succeeded.	Rambod Rouhbakhsh (b) (4)	18 Feb 2021 15:31:39
User entered empty.	(b) (4), (b) (6) (b) (4), (b) (6)	10 Aug 2020 18:32:51

US3232021

Folder: Screening

Form: Childbearing Potential

Generated On: 11 Aug 2021 22:05:35

Date of last menstruation unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:23:38
User signature succeeded.	(b) (4), (b) (6) Rambod Rouhbakhsh	18 Feb 2021 15:31:39
User entered '0'	(b) (4) (b) (4), (b) (6)	10 Aug 2020 18:32:51
	(b) (4), (b) (6)	

US3232021

Folder: Screening

Form: Pregnancy Test

Generated On: 11 Aug 2021 22:05:35

Was the pregnancy test performed?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:23:38
User signature succeeded.	(b) (4), (b) (6) Rambod Rouhbakhsh (b) (4)	18 Feb 2021 15:31:39
User closed query 'Per CDM; Childbearing potential noted as "yes", yet pregnancy test not performed, please review and update.' (Site from DM).	(b) (4), (b) (6) (b) (4), (b) (6)	06 Oct 2020 17:49:42
Query 'Per CDM; Childbearing potential noted as "yes", yet pregnancy test not performed, please review and update.' answered with 'UPDATED PER QUERY RESOLUTION' (Site from DM).	(b) (4), (b) (6) (b) (4), (b) (6)	24 Sep 2020 17:13:31
User entered 'Yes (Y)' reason for change: Data Entry Error	(b) (4), (b) (6) (b) (4), (b) (6)	24 Sep 2020 17:13:27
User opened query 'Per CDM; Childbearing potential noted as "yes", yet pregnancy test not performed, please review and update.' (Site from DM).	(b) (4), (b) (6) (b) (4), (b) (6)	23 Sep 2020 15:13:35
User entered 'No (N)'	(b) (4), (b) (6) (b) (4), (b) (6)	28 Aug 2020 23:50:58

FDA-CBER-2022-1614-0646072

US3232021

Folder: Screening

Form: Pregnancy Test

Generated On: 11 Aug 2021 22:05:35

Date of test *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:23:38
	(b) (4), (b) (6)	
User signature succeeded.	Rambod Rouhbakhsh	18 Feb 2021 15:31:39
	(b) (4)	
User entered '10 Aug 2020' reason for change: Data Entry Error	(b) (4), (b) (6)	24 Sep 2020 17:13:27
	(b) (4), (b) (6)	
User entered empty.	(b) (4), (b) (6)	28 Aug 2020 23:50:58
	(b) (4), (b) (6)	

US3232021

Folder: Screening

Form: Pregnancy Test

Generated On: 11 Aug 2021 22:05:35

Test performed

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:23:38
User signature succeeded.	(b) (4), (b) (6) Rambod Rouhbakhsh	18 Feb 2021 15:31:39
User entered 'Urine (URINE)' reason for change:	(b) (4) (b) (4), (b) (6)	24 Sep 2020 17:13:27
Data Entry Error	(b) (4), (b) (6)	
User entered empty.	(b) (4), (b) (6) (b) (4), (b) (6)	28 Aug 2020 23:50:58

US3232021
Folder: Screening
Form: Pregnancy Test
Generated On: 11 Aug 2021 22:05:35
Result

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:23:38
	(b) (4), (b) (6)	
User signature succeeded.	Rambod Rouhbakhsh	18 Feb 2021 15:31:39
	(b) (4)	
User entered 'Negative (NEGATIVE)' reason for change: Data Entry Error	(b) (4), (b) (6)	24 Sep 2020 17:13:27
	(b) (4), (b) (6)	
User entered empty.	(b) (4), (b) (6)	28 Aug 2020 23:50:58
	(b) (4), (b) (6)	

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Folder: Screening

Form: Pregnancy Test

Generated On: 11 Aug 2021 22:05:35

Was FSH sample collected?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:23:38
User signature succeeded.	(b) (4), (b) (6) Rambod Rouhbakhsh	18 Feb 2021 15:31:39
User entered 'No (N)' reason for change: Data Entry Error	(b) (4) (b) (4), (b) (6) (b) (4), (b) (6)	24 Sep 2020 17:13:27
User entered empty.	(b) (4), (b) (6) (b) (4), (b) (6)	28 Aug 2020 23:50:58

Collection date

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:23:38
User signature succeeded.	(b) (4), (b) (6) Rambod Rouhbakhsh	18 Feb 2021 15:31:39
User entered empty.	(b) (4) (b) (4), (b) (6) (b) (4), (b) (6)	28 Aug 2020 23:50:58

FDA-CBER-2022-1614-0646077

US3232021

Folder: Screening

Form: Pregnancy Test

Generated On: 11 Aug 2021 22:05:35

Collection time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	28 Apr 2021 21:23:38
User signature succeeded.	Rambod Rouhbakhsh (b) (4)	18 Feb 2021 15:31:39
User entered empty.	(b) (4), (b) (6) (b) (4), (b) (6)	28 Aug 2020 23:50:58

US3232021

Folder: Screening

Form: Pregnancy Test

Generated On: 11 Aug 2021 22:05:35

Collection date and time (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:23:38
	(b) (4), (b) (6)	
User entered empty.	System	28 Aug 2020 23:50:58

US3232021

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 22:05:35

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 21:23:38
User signature succeeded.	(b) (4), (b) (6) Rambod Rouhbakhsh (b) (4)	18 Feb 2021 15:31:39
User entered 'No (N)'	(b) (4), (b) (6) (b) (4), (b) (6)	10 Aug 2020 18:33:52

US3232021
Folder: Screening
Form: Risk of Exposure
Generated On: 11 Aug 2021 22:05:35
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 21:23:38
User signature succeeded.	(b) (4), (b) (6) Rambod Rouhbakhsh	18 Feb 2021 15:31:39
User entered 'No (N)'	(b) (4) (b) (4), (b) (6) (b) (4), (b) (6)	10 Aug 2020 18:33:52

US3232021

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 22:05:35

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) (b) (4), (b) (6)	28 Apr 2021 21:23:38
User signature succeeded.	Rambod Rouhbakhsh (b) (4)	18 Feb 2021 15:31:39
User entered 'No (N)'	(b) (4), (b) (6) (b) (4), (b) (6)	10 Aug 2020 18:33:52

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Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 22:05:35

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 21:23:38
User signature succeeded.	(b) (4), (b) (6) Rambod Rouhbakhsh	18 Feb 2021 15:31:39
User entered 'No (N)'	(b) (4) (b) (4), (b) (6) (b) (4), (b) (6)	10 Aug 2020 18:33:52

US3232021

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 22:05:35

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 21:23:38
User signature succeeded.	(b) (4), (b) (6) Rambod Rouhbakhsh	18 Feb 2021 15:31:39
User entered 'No (N)'	(b) (4) (b) (4), (b) (6) (b) (4), (b) (6)	10 Aug 2020 18:33:52

US3232021

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 22:05:35

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 21:23:38
User signature succeeded.	(b) (4), (b) (6) Rambod Rouhbakhsh	18 Feb 2021 15:31:39
User entered 'No (N)'	(b) (4) (b) (4), (b) (6) (b) (4), (b) (6)	10 Aug 2020 18:33:52

US3232021

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 22:05:35

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) (b) (4), (b) (6)	28 Apr 2021 21:23:38
User signature succeeded.	Rambod Rouhbakhsh (b) (4)	18 Feb 2021 15:31:39
User entered 'No (N)'	(b) (4), (b) (6) (b) (4), (b) (6)	10 Aug 2020 18:33:52

US3232021

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 22:05:35

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 21:23:38
User signature succeeded.	(b) (4), (b) (6) Rambod Rouhbakhsh	18 Feb 2021 15:31:39
User entered 'No (N)'	(b) (4) (b) (4), (b) (6) (b) (4), (b) (6)	10 Aug 2020 18:33:52

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Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 22:05:35

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 21:23:38
User signature succeeded.	(b) (4), (b) (6) Rambod Rouhbakhsh	18 Feb 2021 15:31:39
User entered 'No (N)'	(b) (4) (b) (4), (b) (6) (b) (4), (b) (6)	10 Aug 2020 18:33:52

US3232021

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 22:05:35

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) (b) (4), (b) (6)	28 Apr 2021 21:23:38
User signature succeeded.	Rambod Rouhbakhsh (b) (4)	18 Feb 2021 15:31:39
User entered 'No (N)'	(b) (4), (b) (6) (b) (4), (b) (6)	10 Aug 2020 18:33:52

US3232021

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 22:05:35

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) (b) (4), (b) (6)	28 Apr 2021 21:23:38
User signature succeeded.	Rambod Rouhbakhsh (b) (4)	18 Feb 2021 15:31:39
User entered 'No (N)'	(b) (4), (b) (6) (b) (4), (b) (6)	10 Aug 2020 18:33:52

US3232021
Folder: Screening
Form: Risk of Exposure
Generated On: 11 Aug 2021 22:05:35
Other

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:23:38
User signature succeeded.	(b) (4), (b) (6) Rambod Rouhbakhsh	18 Feb 2021 15:31:39
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	10 Aug 2020 18:33:52
	(b) (4), (b) (6)	

US3232021
Folder: Screening
Form: Risk of Exposure
Generated On: 11 Aug 2021 22:05:35
Specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:23:38
User signature succeeded.	(b) (4), (b) (6) Rambod Rouhbakhsh	18 Feb 2021 15:31:39
User entered empty.	(b) (4) (b) (4), (b) (6) (b) (4), (b) (6)	10 Aug 2020 18:33:52

US3232021

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 22:05:35

No Risk Identified

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:23:38
User signature succeeded.	(b) (4), (b) (6) Rambod Rouhbakhsh (b) (4)	18 Feb 2021 15:31:39
User entered '0'	(b) (4), (b) (6) (b) (4), (b) (6)	10 Aug 2020 18:33:52

US3232021

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 22:05:35

Resides in Nursing Home or Assisted Living Facility

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:23:38
User signature succeeded.	(b) (4), (b) (6) Rambod Rouhbakhsh	18 Feb 2021 15:31:39
User entered '0'	(b) (4) (b) (4), (b) (6) (b) (4), (b) (6)	10 Aug 2020 18:33:52

US3232021

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 22:05:35

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) (b) (4), (b) (6)	28 Apr 2021 21:23:38
User signature succeeded.	Rambod Rouhbakhsh (b) (4)	18 Feb 2021 15:31:39
User entered '0'	(b) (4), (b) (6) (b) (4), (b) (6)	10 Aug 2020 18:33:52

US3232021

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 22:05:35

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 21:23:38
User signature succeeded.	(b) (4), (b) (6) Rambod Rouhbakhsh	18 Feb 2021 15:31:39
User entered '0'	(b) (4) (b) (4), (b) (6) (b) (4), (b) (6)	10 Aug 2020 18:33:52

US3232021

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 22:05:35

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 21:23:38
User signature succeeded.	(b) (4), (b) (6) Rambod Rouhbakhsh	18 Feb 2021 15:31:39
User entered '0'	(b) (4) (b) (4), (b) (6) (b) (4), (b) (6)	10 Aug 2020 18:33:52

US3232021

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 22:05:35

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:23:38
User signature succeeded.	(b) (4), (b) (6) Rambod Rouhbakhsh	18 Feb 2021 15:31:39
User entered '0'	(b) (4) (b) (4), (b) (6) (b) (4), (b) (6)	10 Aug 2020 18:33:52

US3232021
Folder: Screening
Form: Risk of Exposure
Generated On: 11 Aug 2021 22:05:35
Other

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:23:38
User signature succeeded.	(b) (4), (b) (6) Rambod Rouhbakhsh	18 Feb 2021 15:31:39
User entered '1'	(b) (4) (b) (4), (b) (6) (b) (4), (b) (6)	10 Aug 2020 18:33:52

US3232021

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 22:05:35

Specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:23:38
User signature succeeded.	(b) (4), (b) (6) Rambod Rouhbakhsh	18 Feb 2021 15:31:39
User entered 'resident in a community with ongoing person to person transmission'	(b) (4) (b) (4), (b) (6) (b) (4), (b) (6)	10 Aug 2020 18:33:52

US3232021
Folder: Visit 1 Day 1
Form: Visit Date
Generated On: 11 Aug 2021 22:05:35
Was this visit performed?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	03 Apr 2021 15:39:42
User signature succeeded.	Rambod Rouhbakhsh (b) (4)	18 Feb 2021 15:31:39
User entered 'Yes (Y)'	(b) (4), (b) (6) (b) (4), (b) (6)	10 Aug 2020 18:34:19

US3232021

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 11 Aug 2021 22:05:35

Visit date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	03 Apr 2021 15:39:42
User signature succeeded.	Rambod Rouhbakhsh (b) (4)	18 Feb 2021 15:31:39
User entered '10 Aug 2020'	(b) (4), (b) (6) (b) (4), (b) (6)	10 Aug 2020 18:34:19

US3232021
Folder: Visit 1 Day 1
Form: Visit Date
Generated On: 11 Aug 2021 22:05:35

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	03 Apr 2021 15:39:42
User signature succeeded.	Rambod Rouhbakhsh (b) (4)	18 Feb 2021 15:31:39
User entered 'Clinic (Clinic)'	(b) (4), (b) (6) (b) (4), (b) (6)	10 Aug 2020 18:34:19

US3232021
Folder: Visit 1 Day 1
Form: Visit Date
Generated On: 11 Aug 2021 22:05:35
Folder OID

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	03 Apr 2021 15:39:42
User entered 'VISIT1'	System	10 Aug 2020 18:34:19

US3232021

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 11 Aug 2021 22:05:35

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	03 Apr 2021 15:39:42
User signature succeeded.	Rambod Rouhbakhsh (b) (4)	18 Feb 2021 15:31:39
User entered '10 AUG 2020'	RWS_ENDPOINT ENDPOINT (b) (4) (b) (4)	10 Aug 2020 17:19:18

US3232021

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 11 Aug 2021 22:05:35

What was the participant's randomization number?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	03 Apr 2021 15:39:42
User signature succeeded.	Rambod Rouhbakhsh (b) (4)	18 Feb 2021 15:31:39
Amendment Manager: User closed query 'Data entered is non-conformant. Please correct.' (Site from System).	System	21 Aug 2020 03:17:38
Amendment Manager: Data point set to conformant.	System	21 Aug 2020 03:17:37
User opened query 'Data entered is non-conformant. Please correct.' (Site from System).	System	10 Aug 2020 17:19:18
User entered '102224' (non-conformant).	RWS_ENDPOINT ENDPOINT (b) (4) (b) (4)	10 Aug 2020 17:19:18

US3232021

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 11 Aug 2021 22:05:35

In what Cohort was the participant enrolled?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	03 Apr 2021 15:39:42
User signature succeeded.	Rambod Rouhbakhsh (b) (4)	18 Feb 2021 15:31:39
User entered '>=18 and <65 years and not at risk (1)'	RWS_ENDPOINT ENDPOINT (b) (4) (b) (4)	10 Aug 2020 17:19:18

US3232021

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 11 Aug 2021 22:05:35

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) (b) (4), (b) (6)	03 Apr 2021 15:39:42
User signature succeeded.	Rambod Rouhbakhsh (b) (4)	18 Feb 2021 15:31:39
User entered 'No (N)'	(b) (4), (b) (6) (b) (4), (b) (6)	10 Aug 2020 18:35:15

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) (b) (4), (b) (6)	03 Apr 2021 15:39:42
User signature succeeded.	Rambod Rouhbakhsh (b) (4)	18 Feb 2021 15:31:39
User entered 'No (N)'	(b) (4), (b) (6) (b) (4), (b) (6)	10 Aug 2020 18:35:15

Folder: Visit 1 Day 1
Form: Randomization
Generated On: 11 Aug 2021 22:05:35

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	03 Apr 2021 15:39:42
User signature succeeded.	Rambod Rouhbakhsh (b) (4)	18 Feb 2021 15:31:39
User entered 'No (N)'	(b) (4), (b) (6) (b) (4), (b) (6)	10 Aug 2020 18:35:15

US3232021
Folder: Visit 1 Day 1
Form: Randomization
Generated On: 11 Aug 2021 22:05:35
Diabetes (Type I, Type 2, or gestational)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	03 Apr 2021 15:39:42
User signature succeeded.	Rambod Rouhbakhsh (b) (4)	18 Feb 2021 15:31:39
User entered 'No (N)'	(b) (4), (b) (6) (b) (4), (b) (6)	10 Aug 2020 18:35:15

US3232021
Folder: Visit 1 Day 1
Form: Randomization
Generated On: 11 Aug 2021 22:05:35

Liver Disease

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	03 Apr 2021 15:39:42
User signature succeeded.	Rambod Rouhbakhsh (b) (4)	18 Feb 2021 15:31:39
User entered 'No (N)'	(b) (4), (b) (6) (b) (4), (b) (6)	10 Aug 2020 18:35:15

US3232021
Folder: Visit 1 Day 1
Form: Vital Signs - Dosing
Generated On: 11 Aug 2021 22:05:35
Height

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	03 Apr 2021 15:39:42
User signature succeeded.	Rambod Rouhbakhsh (b) (4)	18 Feb 2021 15:31:39
User closed query '"Per CDM: Per CCGs pages 15-16, "Height and Weight" should be marked as "ND." Please review and update else clarify".' (Site from DM).	(b) (4), (b) (6) (b) (4), (b) (6)	01 Sep 2020 11:22:15
Query '"Per CDM: Per CCGs pages 15-16, "Height and Weight" should be marked as "ND." Please review and update else clarify".' answered with 'corrected' (Site from DM).	Jerrica Sullivan (b) (4) (b) (4)	28 Aug 2020 16:32:49
User entered missing code ND - Not Done; reason for change Data Entry Error	Jerrica Sullivan (b) (4) (b) (4)	28 Aug 2020 16:32:43
User opened query '"Per CDM: Per CCGs pages 15-16, "Height and Weight" should be marked as "ND." Please review and update else clarify".' (Site from DM).	(b) (4), (b) (6) (b) (4), (b) (6)	28 Aug 2020 15:04:05
User entered '166' cm	(b) (4), (b) (6) (b) (4), (b) (6)	10 Aug 2020 18:38:19

US3232021
Folder: Visit 1 Day 1
Form: Vital Signs - Dosing
Generated On: 11 Aug 2021 22:05:35
Weight

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	03 Apr 2021 15:39:42
User signature succeeded.	Rambod Rouhbakhsh (b) (4)	18 Feb 2021 15:31:39
User closed query '"Per CDM: Per CCGs pages 15-16, "Height and Weight" should be marked as "ND." Please review and update else clarify".' (Site from DM).	(b) (4), (b) (6) (b) (4), (b) (6)	01 Sep 2020 11:22:17
Query '"Per CDM: Per CCGs pages 15-16, "Height and Weight" should be marked as "ND." Please review and update else clarify".' answered with 'corrected' (Site from DM).	Jerrica Sullivan (b) (4) (b) (4)	28 Aug 2020 16:32:53
User entered missing code ND - Not Done; reason for change Data Entry Error	Jerrica Sullivan (b) (4) (b) (4)	28 Aug 2020 16:32:43
User opened query '"Per CDM: Per CCGs pages 15-16, "Height and Weight" should be marked as "ND." Please review and update else clarify".' (Site from DM).	(b) (4), (b) (6) (b) (4), (b) (6)	28 Aug 2020 15:04:11
User entered '67.6' kg	(b) (4), (b) (6) (b) (4), (b) (6)	10 Aug 2020 18:38:19

US3232021
Folder: Visit 1 Day 1
Form: Vital Signs - Dosing
Generated On: 11 Aug 2021 22:05:35
Height

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	03 Apr 2021 15:39:42
User signature succeeded.	Rambod Rouhbakhsh (b) (4)	18 Feb 2021 15:31:39
User closed query '"Per CDM: Per CCGs pages 15-16, "Height and Weight" should be marked as "ND." Please review and update else clarify".' (Site from DM).	(b) (4), (b) (6) (b) (4), (b) (6)	01 Sep 2020 11:22:15
Query '"Per CDM: Per CCGs pages 15-16, "Height and Weight" should be marked as "ND." Please review and update else clarify".' answered with 'corrected' (Site from DM).	Jerrica Sullivan (b) (4) (b) (4)	28 Aug 2020 16:32:49
User entered missing code ND - Not Done; reason for change Data Entry Error	Jerrica Sullivan (b) (4) (b) (4)	28 Aug 2020 16:32:43
User opened query '"Per CDM: Per CCGs pages 15-16, "Height and Weight" should be marked as "ND." Please review and update else clarify".' (Site from DM).	(b) (4), (b) (6) (b) (4), (b) (6)	28 Aug 2020 15:04:05
User entered '166' cm	(b) (4), (b) (6) (b) (4), (b) (6)	10 Aug 2020 18:38:19

US3232021
Folder: Visit 1 Day 1
Form: Vital Signs - Dosing
Generated On: 11 Aug 2021 22:05:35
Weight

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	03 Apr 2021 15:39:42
User signature succeeded.	Rambod Rouhbakhsh (b) (4)	18 Feb 2021 15:31:39
User closed query '"Per CDM: Per CCGs pages 15-16, "Height and Weight" should be marked as "ND." Please review and update else clarify".' (Site from DM).	(b) (4), (b) (6) (b) (4), (b) (6)	01 Sep 2020 11:22:17
Query '"Per CDM: Per CCGs pages 15-16, "Height and Weight" should be marked as "ND." Please review and update else clarify".' answered with 'corrected' (Site from DM).	Jerrica Sullivan (b) (4) (b) (4)	28 Aug 2020 16:32:53
User entered missing code ND - Not Done; reason for change Data Entry Error	Jerrica Sullivan (b) (4) (b) (4)	28 Aug 2020 16:32:43
User opened query '"Per CDM: Per CCGs pages 15-16, "Height and Weight" should be marked as "ND." Please review and update else clarify".' (Site from DM).	(b) (4), (b) (6) (b) (4), (b) (6)	28 Aug 2020 15:04:11
User entered '67.6' kg	(b) (4), (b) (6) (b) (4), (b) (6)	10 Aug 2020 18:38:19

US3232021

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:05:35

Timepoint

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	03 Apr 2021 15:39:42
User accepted default value 'Pre-Dose (PREDOSE)'	(b) (4), (b) (6) (b) (4), (b) (6)	10 Aug 2020 18:38:19

US3232021

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:05:35

Were vital signs assessed?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	03 Apr 2021 15:39:42
User signature succeeded.	Rambod Rouhbakhsh (b) (4)	18 Feb 2021 15:31:39
User entered 'Yes (Y)'	(b) (4), (b) (6) (b) (4), (b) (6)	10 Aug 2020 18:38:19

US3232021

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:05:35

Date of assessment *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	03 Apr 2021 15:39:42
User signature succeeded.	Rambod Rouhbakhsh (b) (4)	18 Feb 2021 15:31:39
User entered '10 Aug 2020'	(b) (4), (b) (6) (b) (4), (b) (6)	10 Aug 2020 18:38:19

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	03 Apr 2021 15:39:42
User signature succeeded.	Rambod Rouhbakhsh (b) (4)	18 Feb 2021 15:31:39
User entered '11:07'	(b) (4), (b) (6) (b) (4), (b) (6)	10 Aug 2020 18:38:19

FDA-CBER-2022-1614-0646120

US3232021

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:05:35

Vital Signs Date and Time (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	03 Apr 2021 15:39:42
User entered '10 Aug 2020 11:07'	System	10 Aug 2020 18:38:19

US3232021

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:05:35

Temperature *(xxx.x)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	03 Apr 2021 15:39:42
User signature succeeded.	Rambod Rouhbakhsh (b) (4)	18 Feb 2021 15:31:39
User entered '98.6' F	(b) (4), (b) (6) (b) (4), (b) (6)	10 Aug 2020 18:38:19

US3232021

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:05:35

Route of measurement

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	03 Apr 2021 15:39:42
User signature succeeded.	Rambod Rouhbakhsh (b) (4)	18 Feb 2021 15:31:39
User entered 'Oral (Oral)'	(b) (4), (b) (6) (b) (4), (b) (6)	10 Aug 2020 18:38:19

If Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	03 Apr 2021 15:39:42
User signature succeeded.	Rambod Rouhbakhsh (b) (4)	18 Feb 2021 15:31:39
User entered empty.	(b) (4), (b) (6) (b) (4), (b) (6)	10 Aug 2020 18:38:19

FDA-CBER-2022-1614-0646124

Folder: Visit 1 Day 1
Form: Vital Signs - Dosing (1)
Generated On: 11 Aug 2021 22:05:35

Pulse *(xxx)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	03 Apr 2021 15:39:42
User signature succeeded.	Rambod Rouhbakhsh (b) (4)	18 Feb 2021 15:31:39
User entered '63'	(b) (4), (b) (6) (b) (4), (b) (6)	10 Aug 2020 18:38:19

US3232021
Folder: Visit 1 Day 1
Form: Vital Signs - Dosing (1)
Generated On: 11 Aug 2021 22:05:35
Pulse units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	03 Apr 2021 15:39:42
User entered 'bpm'	System	10 Aug 2020 18:38:19

Respiratory Rate *(xxx)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	03 Apr 2021 15:39:42
User signature succeeded.	Rambod Rouhbakhsh (b) (4)	18 Feb 2021 15:31:39
User entered '18'	(b) (4), (b) (6) (b) (4), (b) (6)	10 Aug 2020 18:38:19

FDA-CBER-2022-1614-0646127

US3232021

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:05:35

Respiratory Rate units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:39:42
User entered 'breaths/min'	(b) (4), (b) (6) System	10 Aug 2020 18:38:19

US3232021

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:05:35

Systolic Blood Pressure *(xxx)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:39:42
	(b) (4), (b) (6)	
User signature succeeded.	Rambod Rouhbakhsh	18 Feb 2021 15:31:39
	(b) (4)	
User entered '110'	(b) (4), (b) (6)	10 Aug 2020 18:38:19
	(b) (4), (b) (6)	

Systolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	03 Apr 2021 15:39:42
User entered 'mmHg'	System	10 Aug 2020 18:38:19

FDA-CBER-2022-1614-0646130

US3232021

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:05:35

Diastolic Blood Pressure *(xxx)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	03 Apr 2021 15:39:42
User signature succeeded.	Rambod Rouhbakhsh (b) (4)	18 Feb 2021 15:31:39
User entered '60'	(b) (4), (b) (6) (b) (4), (b) (6)	10 Aug 2020 18:38:19

US3232021

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:05:35

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	03 Apr 2021 15:39:42
User entered 'mmHg'	System	10 Aug 2020 18:38:19

US3232021
Folder: Visit 1 Day 1
Form: Vital Signs - Dosing
Generated On: 11 Aug 2021 22:05:35
Height

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	03 Apr 2021 15:39:42
User signature succeeded.	Rambod Rouhbakhsh (b) (4)	18 Feb 2021 15:31:39
User closed query '"Per CDM: Per CCGs pages 15-16, "Height and Weight" should be marked as "ND." Please review and update else clarify".' (Site from DM).	(b) (4), (b) (6) (b) (4), (b) (6)	01 Sep 2020 11:22:15
Query '"Per CDM: Per CCGs pages 15-16, "Height and Weight" should be marked as "ND." Please review and update else clarify".' answered with 'corrected' (Site from DM).	Jerrica Sullivan (b) (4) (b) (4)	28 Aug 2020 16:32:49
User entered missing code ND - Not Done; reason for change Data Entry Error	Jerrica Sullivan (b) (4) (b) (4)	28 Aug 2020 16:32:43
User opened query '"Per CDM: Per CCGs pages 15-16, "Height and Weight" should be marked as "ND." Please review and update else clarify".' (Site from DM).	(b) (4), (b) (6) (b) (4), (b) (6)	28 Aug 2020 15:04:05
User entered '166' cm	(b) (4), (b) (6) (b) (4), (b) (6)	10 Aug 2020 18:38:19

US3232021
Folder: Visit 1 Day 1
Form: Vital Signs - Dosing
Generated On: 11 Aug 2021 22:05:35
Weight

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:39:42
	(b) (4), (b) (6)	
User signature succeeded.	Rambod Rouhbakhsh	18 Feb 2021 15:31:39
	(b) (4)	
User closed query '"Per CDM: Per CCGs pages 15-16, "Height and Weight" should be marked as "ND." Please review and update else clarify".' (Site from DM).	(b) (4), (b) (6)	01 Sep 2020 11:22:17
	(b) (4), (b) (6)	
Query '"Per CDM: Per CCGs pages 15-16, "Height and Weight" should be marked as "ND." Please review and update else clarify".' answered with 'corrected' (Site from DM).	Jerrica Sullivan (b) (4) (b) (4)	28 Aug 2020 16:32:53
User entered missing code ND - Not Done; reason for change Data Entry Error	Jerrica Sullivan (b) (4) (b) (4)	28 Aug 2020 16:32:43
User opened query '"Per CDM: Per CCGs pages 15-16, "Height and Weight" should be marked as "ND." Please review and update else clarify".' (Site from DM).	(b) (4), (b) (6) (b) (4), (b) (6)	28 Aug 2020 15:04:11
User entered '67.6' kg	(b) (4), (b) (6)	10 Aug 2020 18:38:19
	(b) (4), (b) (6)	

US3232021

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:05:35

Timepoint

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	03 Apr 2021 15:39:42
User accepted default value 'Post-Dose (POSTDOSE)'	(b) (4), (b) (6) (b) (4), (b) (6)	10 Aug 2020 18:38:19

US3232021

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:05:35

Were vital signs assessed?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	03 Apr 2021 15:39:42
User signature succeeded.	Rambod Rouhbakhsh (b) (4)	18 Feb 2021 15:31:39
User entered 'Yes (Y)'	(b) (4), (b) (6) (b) (4), (b) (6)	10 Aug 2020 18:38:19

US3232021

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:05:35

Date of assessment *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	03 Apr 2021 15:39:42
User signature succeeded.	Rambod Rouhbakhsh (b) (4)	18 Feb 2021 15:31:39
User entered '10 Aug 2020'	(b) (4), (b) (6) (b) (4), (b) (6)	10 Aug 2020 18:38:19

US3232021

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:05:35

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	03 Apr 2021 15:39:42
User signature succeeded.	Rambod Rouhbakhsh (b) (4)	18 Feb 2021 15:31:39
Query 'Post-dose vital signs time is prior to or less than 60 minutes after the Dose Time. Please review and reconcile.' canceled (Site from System).	(b) (4), (b) (6) (b) (4), (b) (6)	18 Aug 2020 09:56:19
User opened query 'Post-dose vital signs time is prior to or less than 60 minutes after the Dose Time. Please review and reconcile.' (Site from System).	System	10 Aug 2020 18:38:19
User entered '13:15'	(b) (4), (b) (6) (b) (4), (b) (6)	10 Aug 2020 18:38:19

US3232021

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:05:35

Vital Signs Date and Time (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	03 Apr 2021 15:39:42
User entered '10 Aug 2020 13:15'	System	10 Aug 2020 18:38:19

US3232021

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:05:35

Temperature *(xxx.x)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	03 Apr 2021 15:39:42
User signature succeeded.	Rambod Rouhbakhsh (b) (4)	18 Feb 2021 15:31:39
User entered '97.0' F	(b) (4), (b) (6) (b) (4), (b) (6)	10 Aug 2020 18:38:19

US3232021

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:05:35

Route of measurement

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	03 Apr 2021 15:39:42
User signature succeeded.	Rambod Rouhbakhsh (b) (4)	18 Feb 2021 15:31:39
User entered 'Other (Other)'	(b) (4), (b) (6) (b) (4), (b) (6)	10 Aug 2020 18:38:19

US3232021

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:05:35

If Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	03 Apr 2021 15:39:42
User signature succeeded.	Rambod Rouhbakhsh (b) (4)	18 Feb 2021 15:31:39
User entered 'temporal'	(b) (4), (b) (6) (b) (4), (b) (6)	10 Aug 2020 18:38:19

US3232021
Folder: Visit 1 Day 1
Form: Vital Signs - Dosing (2)
Generated On: 11 Aug 2021 22:05:35

Pulse *(xxx)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	03 Apr 2021 15:39:42
User signature succeeded.	Rambod Rouhbakhsh (b) (4)	18 Feb 2021 15:31:39
User entered '66'	(b) (4), (b) (6) (b) (4), (b) (6)	10 Aug 2020 18:38:19

US3232021
Folder: Visit 1 Day 1
Form: Vital Signs - Dosing (2)
Generated On: 11 Aug 2021 22:05:35
Pulse units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:39:42
User entered 'bpm'	System	10 Aug 2020 18:38:19

US3232021

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:05:35

Respiratory Rate *(xxx)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	03 Apr 2021 15:39:42
User signature succeeded.	Rambod Rouhbakhsh (b) (4)	18 Feb 2021 15:31:39
User entered '14'	(b) (4), (b) (6) (b) (4), (b) (6)	10 Aug 2020 18:38:19

US3232021
Folder: Visit 1 Day 1
Form: Vital Signs - Dosing (2)
Generated On: 11 Aug 2021 22:05:35
Respiratory Rate units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	03 Apr 2021 15:39:42
User entered 'breaths/min'	System	10 Aug 2020 18:38:19

US3232021

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:05:35

Systolic Blood Pressure *(xxx)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	03 Apr 2021 15:39:42
User signature succeeded.	Rambod Rouhbakhsh (b) (4)	18 Feb 2021 15:31:39
User entered '115'	(b) (4), (b) (6) (b) (4), (b) (6)	10 Aug 2020 18:38:19

US3232021

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:05:35

Systolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	03 Apr 2021 15:39:42
User entered 'mmHg'	System	10 Aug 2020 18:38:19

US3232021

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:05:35

Diastolic Blood Pressure *(xxx)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	03 Apr 2021 15:39:42
User signature succeeded.	Rambod Rouhbakhsh (b) (4)	18 Feb 2021 15:31:39
User closed query 'Diastolic Blood Pressure reported is out of range < 60 or > 110 per protocol considered grade 3. Please indicate if CS/NCS and report as AE, if appropriate.' (Site from System).	(b) (4), (b) (6) (b) (4), (b) (6)	13 Oct 2020 10:56:28
Query 'Diastolic Blood Pressure reported is out of range < 60 or > 110 per protocol considered grade 3. Please indicate if CS/NCS and report as AE, if appropriate.' answered with 'ncs' (Site from System).	(b) (4), (b) (6) (b) (4), (b) (6)	12 Oct 2020 13:43:26
Amendment Manager: User opened query 'Diastolic Blood Pressure reported is out of range < 60 or > 110 per protocol considered grade 3. Please indicate if CS/NCS and report as AE, if appropriate.' (Site from System).	System	16 Sep 2020 23:49:56
User entered '55'	(b) (4), (b) (6) (b) (4), (b) (6)	10 Aug 2020 18:38:19

US3232021

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:05:35

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	03 Apr 2021 15:39:42
User entered 'mmHg'	System	10 Aug 2020 18:38:19

US3232021

Folder: Visit 1 Day 1

Form: Physical Examination

Generated On: 11 Aug 2021 22:05:35

Was the physical examination performed?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	03 Apr 2021 15:39:42
User signature succeeded.	Rambod Rouhbakhsh (b) (4)	18 Feb 2021 15:31:39
User entered 'Yes (Y)'	(b) (4), (b) (6) (b) (4), (b) (6)	10 Aug 2020 18:39:23

US3232021

Folder: Visit 1 Day 1

Form: Physical Examination

Generated On: 11 Aug 2021 22:05:35

Date of examination *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	03 Apr 2021 15:39:42
User signature succeeded.	Rambod Rouhbakhsh (b) (4)	18 Feb 2021 15:31:39
User closed query 'Future date has been entered. Please correct.' (Site from System).	System	10 Aug 2020 18:39:29
User closed query 'The Physical Examination Date is not equal to Visit Date. Please review and reconcile.' (Site from System).	System	10 Aug 2020 18:39:29
User entered '10 Aug 2020' reason for change: Data Entry Error	(b) (4), (b) (6) (b) (4), (b) (6)	10 Aug 2020 18:39:29
User opened query 'Future date has been entered. Please correct.' (Site from System).	System	10 Aug 2020 18:39:23
User opened query 'The Physical Examination Date is not equal to Visit Date. Please review and reconcile.' (Site from System).	System	10 Aug 2020 18:39:23
User entered '10 Sep 2020'	(b) (4), (b) (6) (b) (4), (b) (6)	10 Aug 2020 18:39:23

US3232021
Folder: Visit 1 Day 1
Form: Pregnancy Test
Generated On: 11 Aug 2021 22:05:35
Was the pregnancy test performed?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	03 Apr 2021 15:39:42
User signature succeeded.	Rambod Rouhbakhsh (b) (4)	18 Feb 2021 15:31:39
User closed query 'Per CDM: As Per CCG, If Screening and dosing are done on the same day. Pregnancy test page should be marked as 'No' at V1D1. Please update accordingly.' (Site from DM).	(b) (4), (b) (6) (b) (4), (b) (6)	06 Oct 2020 17:53:47
Query 'Per CDM: As Per CCG, If Screening and dosing are done on the same day. Pregnancy test page should be marked as 'No' at V1D1. Please update accordingly.' answered with 'UPDATED PER QUERY RESOLUTION' (Site from DM).	(b) (4), (b) (6) (b) (4), (b) (6)	24 Sep 2020 17:15:34
User entered 'No (N)' reason for change: Data Entry Error	(b) (4), (b) (6) (b) (4), (b) (6)	24 Sep 2020 17:13:54
User opened query 'Per CDM: As Per CCG, If Screening and dosing are done on the same day. Pregnancy test page should be marked as 'No' at V1D1. Please update accordingly.' (Site from DM).	(b) (4), (b) (6) (b) (4), (b) (6)	23 Sep 2020 15:14:21
User entered 'Yes (Y)'	(b) (4), (b) (6) (b) (4), (b) (6)	10 Aug 2020 18:41:23

US3232021

Folder: Visit 1 Day 1

Form: Pregnancy Test

Generated On: 11 Aug 2021 22:05:35

Date of test *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:39:42
	(b) (4), (b) (6)	
User signature succeeded.	Rambod Rouhbakhsh	18 Feb 2021 15:31:39
	(b) (4)	
User entered empty; reason for change Data Entry Error	(b) (4), (b) (6)	24 Sep 2020 17:13:54
	(b) (4), (b) (6)	
User entered '10 Aug 2020'	(b) (4), (b) (6)	10 Aug 2020 18:41:23
	(b) (4), (b) (6)	

US3232021

Folder: Visit 1 Day 1

Form: Pregnancy Test

Generated On: 11 Aug 2021 22:05:35

Test performed

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	03 Apr 2021 15:39:42
User signature succeeded.	Rambod Rouhbakhsh (b) (4)	18 Feb 2021 15:31:39
User entered empty; reason for change Data Entry Error	(b) (4), (b) (6) (b) (4), (b) (6)	24 Sep 2020 17:13:54
User entered 'Urine (URINE)'	(b) (4), (b) (6) (b) (4), (b) (6)	10 Aug 2020 18:41:23

US3232021
Folder: Visit 1 Day 1
Form: Pregnancy Test
Generated On: 11 Aug 2021 22:05:35
Result

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	03 Apr 2021 15:39:42
User signature succeeded.	Rambod Rouhbakhsh (b) (4)	18 Feb 2021 15:31:39
User entered empty; reason for change Data Entry Error	(b) (4), (b) (6) (b) (4), (b) (6)	24 Sep 2020 17:13:54
User entered 'Negative (NEGATIVE)'	(b) (4), (b) (6) (b) (4), (b) (6)	10 Aug 2020 18:41:23

US3232021

Folder: Visit 1 Day 1

Form: Pregnancy Test

Generated On: 11 Aug 2021 22:05:35

Was FSH sample collected?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	03 Apr 2021 15:39:42
User signature succeeded.	(b) (4), (b) (6) Rambod Rouhbakhsh	18 Feb 2021 15:31:39
User closed query 'Per CDM: Please note the FSH sample collected is answered as "YES" but the collection date and time are both missing. Please review and update accordingly.' (Site from DM).	(b) (4) (b) (4), (b) (6) (b) (4), (b) (6)	06 Oct 2020 17:54:03
Query 'Per CDM: Please note the FSH sample collected is answered as "YES" but the collection date and time are both missing. Please review and update accordingly.' answered with 'UPDATED PER QUERY RESOLUTION' (Site from DM).	(b) (4), (b) (6) (b) (4), (b) (6)	24 Sep 2020 17:16:05
User entered 'No (N)' reason for change: Data Entry Error	(b) (4), (b) (6) (b) (4), (b) (6)	24 Sep 2020 17:16:01
User entered empty; reason for change Data Entry Error	(b) (4), (b) (6) (b) (4), (b) (6)	24 Sep 2020 17:13:54
User opened query 'Per CDM: Please note the FSH sample collected is answered as "YES" but the collection date and time are both missing. Please review and update accordingly.' (Site from DM).	(b) (4), (b) (6) (b) (4), (b) (6)	23 Sep 2020 15:11:47
User entered 'Yes (Y)'	(b) (4), (b) (6) (b) (4), (b) (6)	10 Aug 2020 18:41:23

US3232021

Folder: Visit 1 Day 1

Form: Pregnancy Test

Generated On: 11 Aug 2021 22:05:35

Collection date

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	03 Apr 2021 15:39:42
User signature succeeded.	Rambod Rouhbakhsh (b) (4)	18 Feb 2021 15:31:39
User entered empty; reason for change Data Entry Error	Jerrica Sullivan (b) (4) (b) (4)	02 Sep 2020 18:48:59
User entered '10 Aug 2020'	(b) (4), (b) (6) (b) (4), (b) (6)	10 Aug 2020 18:41:23

US3232021

Folder: Visit 1 Day 1

Form: Pregnancy Test

Generated On: 11 Aug 2021 22:05:35

Collection time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	03 Apr 2021 15:39:42
User signature succeeded.	Rambod Rouhbakhsh (b) (4)	18 Feb 2021 15:31:39
User entered empty; reason for change Data Entry Error	Jerrica Sullivan (b) (4) (b) (4)	02 Sep 2020 18:45:53
User entered '10:53'	(b) (4), (b) (6) (b) (4), (b) (6)	10 Aug 2020 18:41:23

US3232021

Folder: Visit 1 Day 1

Form: Pregnancy Test

Generated On: 11 Aug 2021 22:05:35

Collection date and time (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	03 Apr 2021 15:39:42
User entered empty.	System	02 Sep 2020 18:45:53
User entered '10 Aug 2020 10:53'	System	10 Aug 2020 18:41:23

US3232021
Folder: Visit 1 Day 1
Form: Exposure
Generated On: 11 Aug 2021 22:05:35

Was study treatment given?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:39:42
	(b) (4), (b) (6)	
User signature succeeded.	Rambod Rouhbakhsh	18 Feb 2021 15:31:39
	(b) (4)	
User entered 'Yes (Y)'	(b) (4), (b) (6)	10 Aug 2020 17:47:41
	(b) (4), (b) (6)	

US3232021
Folder: Visit 1 Day 1
Form: Exposure
Generated On: 11 Aug 2021 22:05:35

If No, reason not given

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	03 Apr 2021 15:39:42
User signature succeeded.	Rambod Rouhbakhsh (b) (4)	18 Feb 2021 15:31:39
User entered empty.	(b) (4), (b) (6) (b) (4), (b) (6)	10 Aug 2020 17:47:41

US3232021

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 11 Aug 2021 22:05:35

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) (b) (4), (b) (6)	03 Apr 2021 15:39:42
User signature succeeded.	Rambod Rouhbakhsh (b) (4)	18 Feb 2021 15:31:39
User entered empty.	(b) (4), (b) (6) (b) (4), (b) (6)	10 Aug 2020 17:47:41

US3232021
Folder: Visit 1 Day 1
Form: Exposure
Generated On: 11 Aug 2021 22:05:35
What was the study treatment?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	03 Apr 2021 15:39:42
User entered 'MRNA-1273 OR PLACEBO'	System	10 Aug 2020 17:47:41

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	03 Apr 2021 15:39:42
User signature succeeded.	Rambod Rouhbakhsh (b) (4)	18 Feb 2021 15:31:39
User entered '10 Aug 2020'	(b) (4), (b) (6) (b) (4), (b) (6)	10 Aug 2020 17:47:41

US3232021

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 11 Aug 2021 22:05:35

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	03 Apr 2021 15:39:42
User signature succeeded.	Rambod Rouhbakhsh (b) (4)	18 Feb 2021 15:31:39
User entered '12:44'	(b) (4), (b) (6) (b) (4), (b) (6)	10 Aug 2020 17:47:41

US3232021
Folder: Visit 1 Day 1
Form: Exposure
Generated On: 11 Aug 2021 22:05:35
Treatment Date and Time (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:39:42
User entered '10 Aug 2020 12:44'	System	10 Aug 2020 17:47:41

US3232021
Folder: Visit 1 Day 1
Form: Exposure
Generated On: 11 Aug 2021 22:05:35
Which arm was used to give treatment?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	03 Apr 2021 15:39:42
User signature succeeded.	Rambod Rouhbakhsh (b) (4)	18 Feb 2021 15:31:39
User entered 'Left Arm (LEFT ARM)'	(b) (4), (b) (6) (b) (4), (b) (6)	10 Aug 2020 17:47:41

US3232021
Folder: Visit 1 Day 1
Form: Exposure
Generated On: 11 Aug 2021 22:05:35
What was the frequency of the study treatment dosing?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:39:42
User entered 'ONCE'	(b) (4), (b) (6) System	10 Aug 2020 17:47:41

US3232021
Folder: Visit 1 Day 1
Form: Exposure
Generated On: 11 Aug 2021 22:05:35
What was the route of administration for the study treatment?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:39:42
User entered 'INTRAMUSCULAR'	(b) (4), (b) (6) System	10 Aug 2020 17:47:41

US3232021

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 22:05:35

Was the sample collected?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	03 Apr 2021 15:39:42
User signature succeeded.	Rambod Rouhbakhsh (b) (4)	18 Feb 2021 15:31:39
User entered 'Yes (Y)'	(b) (4), (b) (6) (b) (4), (b) (6)	10 Aug 2020 18:46:39

Collection date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	03 Apr 2021 15:39:42
User signature succeeded.	Rambod Rouhbakhsh (b) (4)	18 Feb 2021 15:31:39
User entered '10 Aug 2020'	(b) (4), (b) (6) (b) (4), (b) (6)	10 Aug 2020 18:46:39

US3232021

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 22:05:35

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	03 Apr 2021 15:39:42
User signature succeeded.	Rambod Rouhbakhsh (b) (4)	18 Feb 2021 15:31:39
User entered '12:00'	(b) (4), (b) (6) (b) (4), (b) (6)	10 Aug 2020 18:46:39

US3232021
Folder: Visit 1 Day 1
Form: Immunogenicity Assessment
Generated On: 11 Aug 2021 22:05:35
Collection date and time (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	03 Apr 2021 15:39:42
User entered '10 Aug 2020 12:00'	System	10 Aug 2020 18:46:39

Collection date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:39:42
	(b) (4), (b) (6)	
User signature succeeded.	Rambod Rouhbakhsh	18 Feb 2021 15:31:39
	(b) (4)	
User entered '10 Aug 2020'	(b) (4), (b) (6)	10 Aug 2020 18:47:28
	(b) (4), (b) (6)	

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US3232021

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 11 Aug 2021 22:05:35

Lab Test

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	03 Apr 2021 15:39:42
User accepted default value 'Nasopharyngeal Swab 1 (NASAL1)'	(b) (4), (b) (6) (b) (4), (b) (6)	10 Aug 2020 18:47:28

US3232021

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 11 Aug 2021 22:05:35

Was the sample collected?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	03 Apr 2021 15:39:42
User signature succeeded.	Rambod Rouhbakhsh (b) (4)	18 Feb 2021 15:31:39
User entered 'Yes (Y)'	(b) (4), (b) (6) (b) (4), (b) (6)	10 Aug 2020 18:47:28

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:39:42
	(b) (4), (b) (6)	
User signature succeeded.	Rambod Rouhbakhsh	18 Feb 2021 15:31:39
	(b) (4)	
User entered '11:20'	(b) (4), (b) (6)	10 Aug 2020 18:47:28
	(b) (4), (b) (6)	

US3232021

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 11 Aug 2021 22:05:35

Collection date and time (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	03 Apr 2021 15:39:42
User entered '10 Aug 2020 11:20'	System	10 Aug 2020 18:47:28

US3232021

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 11 Aug 2021 22:05:35

Lab Test

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	03 Apr 2021 15:39:42
User accepted default value 'Nasopharyngeal Swab 2 (NASAL2)'	(b) (4), (b) (6) (b) (4), (b) (6)	10 Aug 2020 18:47:28

US3232021

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 11 Aug 2021 22:05:35

Was the sample collected?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	03 Apr 2021 15:39:42
User signature succeeded.	Rambod Rouhbakhsh (b) (4)	18 Feb 2021 15:31:39
User entered 'No (N)'	(b) (4), (b) (6) (b) (4), (b) (6)	10 Aug 2020 18:47:28

US3232021

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 11 Aug 2021 22:05:35

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:39:42
	(b) (4), (b) (6)	
User signature succeeded.	Rambod Rouhbakhsh	18 Feb 2021 15:31:39
	(b) (4)	
User entered empty.	(b) (4), (b) (6)	10 Aug 2020 18:47:28
	(b) (4), (b) (6)	

US3232021

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 11 Aug 2021 22:05:35

Collection date and time (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:39:42
User entered empty.	System	10 Aug 2020 18:47:28

US3232021

Folder: Visit 1 Day 1

Form: Continuing

Generated On: 11 Aug 2021 22:05:35

Is the participant continuing to the next visit?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	03 Apr 2021 15:39:42
User signature succeeded.	Rambod Rouhbakhsh (b) (4)	18 Feb 2021 15:31:39
User entered 'Yes (Y)'	(b) (4), (b) (6) (b) (4), (b) (6)	10 Aug 2020 18:47:32

US3232021
Folder: Visit 1 Day 1
Form: Continuing
Generated On: 11 Aug 2021 22:05:35
Continuing Flag

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	03 Apr 2021 15:39:42
User entered '1'	System	10 Aug 2020 18:47:32

US3232021
Folder: Diary Dose 1 (1)
Form: Temperature_Day(1/1)
Generated On: 11 Aug 2021 22:05:35
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	05 Mar 2021 04:11:35
Data entry locked.	System	10 Aug 2020 17:47:41
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	10 Aug 2020 17:47:41

US3232021

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 11 Aug 2021 22:05:35

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	05 Mar 2021 04:11:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1179BDB4-134B-4DDE-B0FD-B886B117B21A)', Time: '2020-08-10T13:04:24', User OID: 'PatientReportedOutcome (US3232021)', ODM File OID: '23f44094-eaff-4c59-9a6d-bc63f184f38f'	System	10 Aug 2020 18:04:46
User entered 'Yes (Y)'	System	10 Aug 2020 18:04:46

US3232021

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 11 Aug 2021 22:05:35

Please record your **TEMPERATURE in °F**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	05 Mar 2021 04:11:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1179BDB4-134B-4DDE-B0FD-B886B117B21A)', Time: '2020-08-10T13:04:31', User OID: 'PatientReportedOutcome (US3232021)', ODM File OID: '23f44094-eaff-4c59-9a6d-bc63f184f38f'	System	10 Aug 2020 18:04:46
User entered '97.0'	System	10 Aug 2020 18:04:46

US3232021

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 11 Aug 2021 22:05:35

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	05 Mar 2021 04:11:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1179BDB4-134B-4DDE-B0FD-B886B117B21A)', Time: '2020-08-10T13:04:35', User OID: 'PatientReportedOutcome (US3232021)', ODM File OID: '23f44094-eaff-4c59-9a6d-bc63f184f38f'	System	10 Aug 2020 18:04:46
User entered 'No (N)'	System	10 Aug 2020 18:04:46

US3232021
Folder: Diary Dose 1 (1)
Form: Temperature_Day(1/1)
Generated On: 11 Aug 2021 22:05:35
PC Time Stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	05 Mar 2021 04:11:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1179BDB4-134B-4DDE-B0FD-B886B117B21A)', Time: '2020-08-10T13:04:44', User OID: 'PatientReportedOutcome (US3232021)', ODM File OID: '23f44094-eaff-4c59-9a6d-bc63f184f38f'	System	10 Aug 2020 18:04:46
User entered '10 Aug 2020 13:04'	System	10 Aug 2020 18:04:46

US3232021
Folder: Diary Dose 1 (1)
Form: Temperature_Day(1/1)
Generated On: 11 Aug 2021 22:05:35
PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	05 Mar 2021 04:11:35
User entered '10 Aug 2020 13:04'	System	10 Aug 2020 17:47:41

US3232021
Folder: Diary Dose 1 (1)
Form: Temperature_Day(1/1)
Generated On: 11 Aug 2021 22:05:35

PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	05 Mar 2021 04:11:35
User entered '10 Aug 2020 15:34'	System	10 Aug 2020 17:47:41

US3232021
Folder: Diary Dose 1 (1)
Form: Temperature_Day(1/2)
Generated On: 11 Aug 2021 22:05:35
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:11:35
	(b) (4), (b) (6)	
Data entry locked.	System	10 Aug 2020 17:47:41
User entered 'Day 1, after vaccination (at home)'	System	10 Aug 2020 17:47:41

US3232021
Folder: Diary Dose 1 (1)
Form: Temperature_Day(1/2)
Generated On: 11 Aug 2021 22:05:35
Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	05 Mar 2021 04:11:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1179BDB4-134B-4DDE-B0FD-B886B117B21A)', Time: '2020-08-10T19:36:59', User OID: 'PatientReportedOutcome (US3232021)', ODM File OID: '650d2c43-ef15-44fa-837c-1a64357be19a'	System	11 Aug 2020 00:40:34
User entered 'Yes (Y)'	System	11 Aug 2020 00:40:34

US3232021

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 11 Aug 2021 22:05:35

Please record your **TEMPERATURE in °F**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	05 Mar 2021 04:11:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1179BDB4-134B-4DDE-B0FD-B886B117B21A)', Time: '2020-08-10T19:40:23', User OID: 'PatientReportedOutcome (US3232021)', ODM File OID: '650d2c43-ef15-44fa-837c-1a64357be19a'	System	11 Aug 2020 00:40:34
User entered '98.2'	System	11 Aug 2020 00:40:34

US3232021

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 11 Aug 2021 22:05:35

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	05 Mar 2021 04:11:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1179BDB4-134B-4DDE-B0FD-B886B117B21A)', Time: '2020-08-10T19:40:26', User OID: 'PatientReportedOutcome (US3232021)', ODM File OID: '650d2c43-ef15-44fa-837c-1a64357be19a'	System	11 Aug 2020 00:40:34
User entered 'No (N)'	System	11 Aug 2020 00:40:34

FDA-CBER-2022-1614-0646196

US3232021
Folder: Diary Dose 1 (1)
Form: Temperature_Day(1/2)
Generated On: 11 Aug 2021 22:05:35
PC Time Stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	05 Mar 2021 04:11:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1179BDB4-134B-4DDE-B0FD-B886B117B21A)', Time: '2020-08-10T19:40:31', User OID: 'PatientReportedOutcome (US3232021)', ODM File OID: '650d2c43-ef15-44fa-837c-1a64357be19a'	System	11 Aug 2020 00:40:34
User entered '10 Aug 2020 19:40'	System	11 Aug 2020 00:40:34

US3232021
Folder: Diary Dose 1 (1)
Form: Temperature_Day(1/2)
Generated On: 11 Aug 2021 22:05:35

PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	05 Mar 2021 04:11:35
User entered '10 Aug 2020 16:29'	System	10 Aug 2020 17:47:41

US3232021
Folder: Diary Dose 1 (1)
Form: Temperature_Day(1/2)
Generated On: 11 Aug 2021 22:05:35
PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	05 Mar 2021 04:11:35
User entered '11 Aug 2020 11:59'	System	10 Aug 2020 17:47:41

US3232021
Folder: Diary Dose 1 (1)
Form: Temperature_Day(2)
Generated On: 11 Aug 2021 22:05:35
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	05 Mar 2021 04:11:35
Data entry locked.	System	10 Aug 2020 17:47:41
User entered 'Day 2'	System	10 Aug 2020 17:47:41

US3232021
Folder: Diary Dose 1 (1)
Form: Temperature_Day(2)
Generated On: 11 Aug 2021 22:05:35
Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	05 Mar 2021 04:11:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1179BDB4-134B-4DDE-B0FD-B886B117B21A)', Time: '2020-08-11T14:19:22', User OID: 'PatientReportedOutcome (US3232021)', ODM File OID: '3f933dc6-58df-479b-95fd-11929367c965'	System	11 Aug 2020 19:20:55
User entered 'Yes (Y)'	System	11 Aug 2020 19:20:55

US3232021

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 11 Aug 2021 22:05:35

Please record your **TEMPERATURE in °F**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	05 Mar 2021 04:11:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1179BDB4-134B-4DDE-B0FD-B886B117B21A)', Time: '2020-08-11T14:20:31', User OID: 'PatientReportedOutcome (US3232021)', ODM File OID: '3f933dc6-58df-479b-95fd-11929367c965'	System	11 Aug 2020 19:20:55
User entered '98.4'	System	11 Aug 2020 19:20:55

US3232021
Folder: Diary Dose 1 (1)
Form: Temperature_Day(2)
Generated On: 11 Aug 2021 22:05:35
Was any **MEDICATION TAKEN today for pain or fever**?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	05 Mar 2021 04:11:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1179BDB4-134B-4DDE-B0FD-B886B117B21A)', Time: '2020-08-11T14:20:40', User OID: 'PatientReportedOutcome (US3232021)', ODM File OID: '3f933dc6-58df-479b-95fd-11929367c965'	System	11 Aug 2020 19:20:55
User entered 'Yes (Y)'	System	11 Aug 2020 19:20:55

US3232021
Folder: Diary Dose 1 (1)
Form: Temperature_Day(2)
Generated On: 11 Aug 2021 22:05:35
To **TREAT** pain or fever that has already occurred

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	05 Mar 2021 04:11:35
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) (b) (4), (b) (6)	18 Aug 2020 13:40:03
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 'Nurse called and spoke with patient regarding entry. States took 400mg Advil 08/11/2020 for soreness to injection site with relief. Denies and fever or redness. ' (Site from System).	(b) (4), (b) (6) (b) (4), (b) (6)	12 Aug 2020 18:57:30
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	11 Aug 2020 19:20:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1179BDB4-134B-4DDE-B0FD-B886B117B21A)', Time: '2020-08-11T14:20:47', User OID: 'PatientReportedOutcome (US3232021)', ODM File OID: '3f933dc6-58df-479b-95fd-11929367c965'	System	11 Aug 2020 19:20:55
User entered '1'	System	11 Aug 2020 19:20:55

US3232021

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 11 Aug 2021 22:05:35

To **PREVENT** pain or fever from occurring

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	05 Mar 2021 04:11:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1179BDB4-134B-4DDE-B0FD-B886B117B21A)', Time: '2020-08-11T14:20:47', User OID: 'PatientReportedOutcome (US3232021)', ODM File OID: '3f933dc6-58df-479b-95fd-11929367c965'	System	11 Aug 2020 19:20:55
User entered '0'	System	11 Aug 2020 19:20:55

US3232021
Folder: Diary Dose 1 (1)
Form: Temperature_Day(2)
Generated On: 11 Aug 2021 22:05:35
PC Time Stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	05 Mar 2021 04:11:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1179BDB4-134B-4DDE-B0FD-B886B117B21A)', Time: '2020-08-11T14:20:51', User OID: 'PatientReportedOutcome (US3232021)', ODM File OID: '3f933dc6-58df-479b-95fd-11929367c965'	System	11 Aug 2020 19:20:55
User entered '11 Aug 2020 14:20'	System	11 Aug 2020 19:20:55

US3232021
Folder: Diary Dose 1 (1)
Form: Temperature_Day(2)
Generated On: 11 Aug 2021 22:05:35

PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	05 Mar 2021 04:11:35
User entered '11 Aug 2020 12:00'	System	10 Aug 2020 17:47:41

US3232021
Folder: Diary Dose 1 (1)
Form: Temperature_Day(2)
Generated On: 11 Aug 2021 22:05:35
PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	05 Mar 2021 04:11:35
User entered '12 Aug 2020 11:59'	System	10 Aug 2020 17:47:41

US3232021

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 11 Aug 2021 22:05:35

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	05 Mar 2021 04:11:35
Data entry locked.	System	10 Aug 2020 17:47:41
User entered 'Day 3'	System	10 Aug 2020 17:47:41

US3232021

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 11 Aug 2021 22:05:35

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	05 Mar 2021 04:11:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1179BDB4-134B-4DDE-B0FD-B886B117B21A)', Time: '2020-08-12T21:42:08', User OID: 'PatientReportedOutcome (US3232021)', ODM File OID: 'ae44550d-4b64-4923-94a7-0c4cc2ee56d3'	System	13 Aug 2020 02:44:04
User entered 'Yes (Y)'	System	13 Aug 2020 02:44:04

US3232021

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 11 Aug 2021 22:05:35

Please record your **TEMPERATURE in °F**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	05 Mar 2021 04:11:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1179BDB4-134B-4DDE-B0FD-B886B117B21A)', Time: '2020-08-12T21:43:49', User OID: 'PatientReportedOutcome (US3232021)', ODM File OID: 'ae44550d-4b64-4923-94a7-0c4cc2ee56d3'	System	13 Aug 2020 02:44:04
User entered '98.2'	System	13 Aug 2020 02:44:04

US3232021

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 11 Aug 2021 22:05:35

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	05 Mar 2021 04:11:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1179BDB4-134B-4DDE-B0FD-B886B117B21A)', Time: '2020-08-12T21:43:59', User OID: 'PatientReportedOutcome (US3232021)', ODM File OID: 'ae44550d-4b64-4923-94a7-0c4cc2ee56d3'	System	13 Aug 2020 02:44:04
User entered 'No (N)'	System	13 Aug 2020 02:44:04

US3232021
Folder: Diary Dose 1 (1)
Form: Temperature_Day(3)
Generated On: 11 Aug 2021 22:05:35
PC Time Stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	05 Mar 2021 04:11:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1179BDB4-134B-4DDE-B0FD-B886B117B21A)', Time: '2020-08-12T21:44:02', User OID: 'PatientReportedOutcome (US3232021)', ODM File OID: 'ae44550d-4b64-4923-94a7-0c4cc2ee56d3'	System	13 Aug 2020 02:44:04
User entered '12 Aug 2020 21:44'	System	13 Aug 2020 02:44:04

US3232021
Folder: Diary Dose 1 (1)
Form: Temperature_Day(3)
Generated On: 11 Aug 2021 22:05:35
PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:11:35
User entered '12 Aug 2020 12:00'	System	10 Aug 2020 17:47:41

US3232021
Folder: Diary Dose 1 (1)
Form: Temperature_Day(3)
Generated On: 11 Aug 2021 22:05:35
PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:11:35
User entered '13 Aug 2020 11:59'	System	10 Aug 2020 17:47:41

US3232021

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 11 Aug 2021 22:05:35

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	05 Mar 2021 04:11:35
Data entry locked.	System	10 Aug 2020 17:47:41
User entered 'Day 4'	System	10 Aug 2020 17:47:41

US3232021
Folder: Diary Dose 1 (1)
Form: Temperature_Day(4)
Generated On: 11 Aug 2021 22:05:35
Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	05 Mar 2021 04:11:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1179BDB4-134B-4DDE-B0FD-B886B117B21A)', Time: '2020-08-13T12:01:15', User OID: 'PatientReportedOutcome (US3232021)', ODM File OID: '25de3956-df39-40d2-b266-c9b3711acc12'	System	13 Aug 2020 17:02:51
User entered 'Yes (Y)'	System	13 Aug 2020 17:02:51

US3232021
Folder: Diary Dose 1 (1)
Form: Temperature_Day(4)
Generated On: 11 Aug 2021 22:05:35

Please record your **TEMPERATURE in °F**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	05 Mar 2021 04:11:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1179BDB4-134B-4DDE-B0FD-B886B117B21A)', Time: '2020-08-13T12:02:42', User OID: 'PatientReportedOutcome (US3232021)', ODM File OID: '25de3956-df39-40d2-b266-c9b3711acc12'	System	13 Aug 2020 17:02:51
User entered '98.8'	System	13 Aug 2020 17:02:51

US3232021

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 11 Aug 2021 22:05:35

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	05 Mar 2021 04:11:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1179BDB4-134B-4DDE-B0FD-B886B117B21A)', Time: '2020-08-13T12:02:44', User OID: 'PatientReportedOutcome (US3232021)', ODM File OID: '25de3956-df39-40d2-b266-c9b3711acc12'	System	13 Aug 2020 17:02:51
User entered 'No (N)'	System	13 Aug 2020 17:02:51

US3232021
Folder: Diary Dose 1 (1)
Form: Temperature_Day(4)
Generated On: 11 Aug 2021 22:05:35
PC Time Stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	05 Mar 2021 04:11:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1179BDB4-134B-4DDE-B0FD-B886B117B21A)', Time: '2020-08-13T12:02:47', User OID: 'PatientReportedOutcome (US3232021)', ODM File OID: '25de3956-df39-40d2-b266-c9b3711acc12'	System	13 Aug 2020 17:02:51
User entered '13 Aug 2020 12:02'	System	13 Aug 2020 17:02:51

US3232021
Folder: Diary Dose 1 (1)
Form: Temperature_Day(4)
Generated On: 11 Aug 2021 22:05:35
PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:11:35
User entered '13 Aug 2020 12:00'	System	10 Aug 2020 17:47:41

US3232021
Folder: Diary Dose 1 (1)
Form: Temperature_Day(4)
Generated On: 11 Aug 2021 22:05:35
PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	05 Mar 2021 04:11:35
User entered '14 Aug 2020 11:59'	System	10 Aug 2020 17:47:41

US3232021

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 11 Aug 2021 22:05:35

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	05 Mar 2021 04:11:35
Data entry locked.	System	10 Aug 2020 17:47:41
User entered 'Day 5'	System	10 Aug 2020 17:47:41

US3232021

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 11 Aug 2021 22:05:35

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	05 Mar 2021 04:11:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1179BDB4-134B-4DDE-B0FD-B886B117B21A)', Time: '2020-08-14T21:00:38', User OID: 'PatientReportedOutcome (US3232021)', ODM File OID: '2d512af8-ce45-4234-869e-fbdd49ae1534'	System	15 Aug 2020 02:02:01
User entered 'Yes (Y)'	System	15 Aug 2020 02:02:01

US3232021

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 11 Aug 2021 22:05:35

Please record your **TEMPERATURE in °F**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	05 Mar 2021 04:11:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1179BDB4-134B-4DDE-B0FD-B886B117B21A)', Time: '2020-08-14T21:01:51', User OID: 'PatientReportedOutcome (US3232021)', ODM File OID: '2d512af8-ce45-4234-869e-fbdd49ae1534'	System	15 Aug 2020 02:02:01
User entered '97.8'	System	15 Aug 2020 02:02:01

US3232021
Folder: Diary Dose 1 (1)
Form: Temperature_Day(5)
Generated On: 11 Aug 2021 22:05:35
Was any **MEDICATION TAKEN today for pain or fever**?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	05 Mar 2021 04:11:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1179BDB4-134B-4DDE-B0FD-B886B117B21A)', Time: '2020-08-14T21:01:55', User OID: 'PatientReportedOutcome (US3232021)', ODM File OID: '2d512af8-ce45-4234-869e-fbdd49ae1534'	System	15 Aug 2020 02:02:01
User entered 'No (N)'	System	15 Aug 2020 02:02:01

US3232021
Folder: Diary Dose 1 (1)
Form: Temperature_Day(5)
Generated On: 11 Aug 2021 22:05:35
PC Time Stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	05 Mar 2021 04:11:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1179BDB4-134B-4DDE-B0FD-B886B117B21A)', Time: '2020-08-14T21:01:59', User OID: 'PatientReportedOutcome (US3232021)', ODM File OID: '2d512af8-ce45-4234-869e-fbdd49ae1534'	System	15 Aug 2020 02:02:01
User entered '14 Aug 2020 21:01'	System	15 Aug 2020 02:02:01

US3232021

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 11 Aug 2021 22:05:35

PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:11:35
User entered '14 Aug 2020 12:00'	System	10 Aug 2020 17:47:41

US3232021
Folder: Diary Dose 1 (1)
Form: Temperature_Day(5)
Generated On: 11 Aug 2021 22:05:35
PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	05 Mar 2021 04:11:35
User entered '15 Aug 2020 11:59'	System	10 Aug 2020 17:47:41

US3232021

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 11 Aug 2021 22:05:35

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	05 Mar 2021 04:11:35
Data entry locked.	System	10 Aug 2020 17:47:41
User entered 'Day 6'	System	10 Aug 2020 17:47:41

US3232021
Folder: Diary Dose 1 (1)
Form: Temperature_Day(6)
Generated On: 11 Aug 2021 22:05:35
Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	05 Mar 2021 04:11:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1179BDB4-134B-4DDE-B0FD-B886B117B21A)', Time: '2020-08-15T12:30:57', User OID: 'PatientReportedOutcome (US3232021)', ODM File OID: 'c432d504-69f0-47da-a819-1d1f6e298863'	System	15 Aug 2020 17:31:24
User entered 'Yes (Y)'	System	15 Aug 2020 17:31:24

US3232021
Folder: Diary Dose 1 (1)
Form: Temperature_Day(6)
Generated On: 11 Aug 2021 22:05:35

Please record your **TEMPERATURE in °F**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	05 Mar 2021 04:11:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1179BDB4-134B-4DDE-B0FD-B886B117B21A)', Time: '2020-08-15T12:31:10', User OID: 'PatientReportedOutcome (US3232021)', ODM File OID: 'c432d504-69f0-47da-a819-1d1f6e298863'	System	15 Aug 2020 17:31:24
User entered '98.7'	System	15 Aug 2020 17:31:24

FDA-CBER-2022-1614-0646232

US3232021
Folder: Diary Dose 1 (1)
Form: Temperature_Day(6)
Generated On: 11 Aug 2021 22:05:35

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	05 Mar 2021 04:11:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1179BDB4-134B-4DDE-B0FD-B886B117B21A)', Time: '2020-08-15T12:31:16', User OID: 'PatientReportedOutcome (US3232021)', ODM File OID: 'c432d504-69f0-47da-a819-1d1f6e298863'	System	15 Aug 2020 17:31:24
User entered 'No (N)'	System	15 Aug 2020 17:31:24

FDA-CBER-2022-1614-0646233

US3232021

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 11 Aug 2021 22:05:35

PC Time Stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	05 Mar 2021 04:11:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1179BDB4-134B-4DDE-B0FD-B886B117B21A)', Time: '2020-08-15T12:31:20', User OID: 'PatientReportedOutcome (US3232021)', ODM File OID: 'c432d504-69f0-47da-a819-1d1f6e298863'	System	15 Aug 2020 17:31:24
User entered '15 Aug 2020 12:31'	System	15 Aug 2020 17:31:24

US3232021
Folder: Diary Dose 1 (1)
Form: Temperature_Day(6)
Generated On: 11 Aug 2021 22:05:35
PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:11:35
User entered '15 Aug 2020 12:00'	System	10 Aug 2020 17:47:41

US3232021

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 11 Aug 2021 22:05:35

PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:11:35
User entered '16 Aug 2020 11:59'	System	10 Aug 2020 17:47:41

US3232021
Folder: Diary Dose 1 (1)
Form: Temperature_Day(7)
Generated On: 11 Aug 2021 22:05:35
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	05 Mar 2021 04:11:35
Data entry locked.	System	10 Aug 2020 17:47:41
User entered 'Day 7'	System	10 Aug 2020 17:47:41

US3232021
Folder: Diary Dose 1 (1)
Form: Temperature_Day(7)
Generated On: 11 Aug 2021 22:05:35
Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	05 Mar 2021 04:11:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1179BDB4-134B-4DDE-B0FD-B886B117B21A)', Time: '2020-08-16T22:32:45', User OID: 'PatientReportedOutcome (US3232021)', ODM File OID: 'd324b500-5042-4e71-953a-f99c100adcc1'	System	17 Aug 2020 03:33:37
User entered 'Yes (Y)'	System	17 Aug 2020 03:33:37

US3232021

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 11 Aug 2021 22:05:35

Please record your **TEMPERATURE in °F**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	05 Mar 2021 04:11:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1179BDB4-134B-4DDE-B0FD-B886B117B21A)', Time: '2020-08-16T22:33:28', User OID: 'PatientReportedOutcome (US3232021)', ODM File OID: 'd324b500-5042-4e71-953a-f99c100adcc1'	System	17 Aug 2020 03:33:37
User entered '97.6'	System	17 Aug 2020 03:33:37

US3232021

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 11 Aug 2021 22:05:35

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	05 Mar 2021 04:11:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1179BDB4-134B-4DDE-B0FD-B886B117B21A)', Time: '2020-08-16T22:33:31', User OID: 'PatientReportedOutcome (US3232021)', ODM File OID: 'd324b500-5042-4e71-953a-f99c100adcc1'	System	17 Aug 2020 03:33:37
User entered 'No (N)'	System	17 Aug 2020 03:33:37

US3232021
Folder: Diary Dose 1 (1)
Form: Temperature_Day(7)
Generated On: 11 Aug 2021 22:05:35
PC Time Stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	05 Mar 2021 04:11:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1179BDB4-134B-4DDE-B0FD-B886B117B21A)', Time: '2020-08-16T22:33:34', User OID: 'PatientReportedOutcome (US3232021)', ODM File OID: 'd324b500-5042-4e71-953a-f99c100adcc1'	System	17 Aug 2020 03:33:37
User entered '16 Aug 2020 22:33'	System	17 Aug 2020 03:33:37

US3232021
Folder: Diary Dose 1 (1)
Form: Temperature_Day(7)
Generated On: 11 Aug 2021 22:05:35

PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:11:35
User entered '16 Aug 2020 12:00'	System	10 Aug 2020 17:47:41

US3232021
Folder: Diary Dose 1 (1)
Form: Temperature_Day(7)
Generated On: 11 Aug 2021 22:05:35
PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:11:35
User entered '17 Aug 2020 11:59'	System	10 Aug 2020 17:47:41

US3232021
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(1/1)
Generated On: 11 Aug 2021 22:05:35
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	05 Mar 2021 04:11:35
Data entry locked.	System	10 Aug 2020 17:47:41
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	10 Aug 2020 17:47:41

FDA-CBER-2022-1614-0646244

US3232021

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 11 Aug 2021 22:05:35

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	05 Mar 2021 04:11:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1179BDB4-134B-4DDE-B0FD-B886B117B21A)', Time: '2020-08-10T13:04:59', User OID: 'PatientReportedOutcome (US3232021)', ODM File OID: '1690c863-21eb-499f-ab79-4edb6c57d781'	System	10 Aug 2020 18:05:46
User entered 'None (1)'	System	10 Aug 2020 18:05:46

US3232021

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 11 Aug 2021 22:05:35

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	05 Mar 2021 04:11:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1179BDB4-134B-4DDE-B0FD-B886B117B21A)', Time: '2020-08-10T13:05:21', User OID: 'PatientReportedOutcome (US3232021)', ODM File OID: '1690c863-21eb-499f-ab79-4edb6c57d781'	System	10 Aug 2020 18:05:46
User entered 'No (N)'	System	10 Aug 2020 18:05:46

FDA-CBER-2022-1614-0646246

US3232021
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(1/1)
Generated On: 11 Aug 2021 22:05:35

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	05 Mar 2021 04:11:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1179BDB4-134B-4DDE-B0FD-B886B117B21A)', Time: '2020-08-10T13:05:29', User OID: 'PatientReportedOutcome (US3232021)', ODM File OID: '1690c863-21eb-499f-ab79-4edb6c57d781'	System	10 Aug 2020 18:05:46
User entered 'No (N)'	System	10 Aug 2020 18:05:46

US3232021

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 11 Aug 2021 22:05:35

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	05 Mar 2021 04:11:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1179BDB4-134B-4DDE-B0FD-B886B117B21A)', Time: '2020-08-10T13:05:37', User OID: 'PatientReportedOutcome (US3232021)', ODM File OID: '1690c863-21eb-499f-ab79-4edb6c57d781'	System	10 Aug 2020 18:05:46
User entered 'None (1)'	System	10 Aug 2020 18:05:46

US3232021
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(1/1)
Generated On: 11 Aug 2021 22:05:35
PC Time Stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	05 Mar 2021 04:11:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1179BDB4-134B-4DDE-B0FD-B886B117B21A)', Time: '2020-08-10T13:05:43', User OID: 'PatientReportedOutcome (US3232021)', ODM File OID: '1690c863-21eb-499f-ab79-4edb6c57d781'	System	10 Aug 2020 18:05:46
User entered '10 Aug 2020 13:05'	System	10 Aug 2020 18:05:46

US3232021
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(1/1)
Generated On: 11 Aug 2021 22:05:35

PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	05 Mar 2021 04:11:35
User entered '10 Aug 2020 13:04'	System	10 Aug 2020 17:47:41

US3232021

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 11 Aug 2021 22:05:35

PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	05 Mar 2021 04:11:35
User entered '10 Aug 2020 15:34'	System	10 Aug 2020 17:47:41

US3232021
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(1/2)
Generated On: 11 Aug 2021 22:05:35
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	05 Mar 2021 04:11:35
Data entry locked.	System	10 Aug 2020 17:47:41
User entered 'Day 1, after vaccination (at home)'	System	10 Aug 2020 17:47:41

US3232021

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 11 Aug 2021 22:05:35

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	05 Mar 2021 04:11:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1179BDB4-134B-4DDE-B0FD-B886B117B21A)', Time: '2020-08-10T19:33:04', User OID: 'PatientReportedOutcome (US3232021)', ODM File OID: '22effc2d-d9a6-4ea5-adfc-2ac3db0f9b28'	System	11 Aug 2020 00:34:43
User entered 'Does not interfere with activity (2)'	System	11 Aug 2020 00:34:43

US3232021
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(1/2)
Generated On: 11 Aug 2021 22:05:35
Is there any **REDNESS AT INJECTION SITE**?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	05 Mar 2021 04:11:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1179BDB4-134B-4DDE-B0FD-B886B117B21A)', Time: '2020-08-10T19:33:17', User OID: 'PatientReportedOutcome (US3232021)', ODM File OID: '22effc2d-d9a6-4ea5-adfc-2ac3db0f9b28'	System	11 Aug 2020 00:34:43
User entered 'No (N)'	System	11 Aug 2020 00:34:43

US3232021

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 11 Aug 2021 22:05:35

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	05 Mar 2021 04:11:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1179BDB4-134B-4DDE-B0FD-B886B117B21A)', Time: '2020-08-10T19:33:55', User OID: 'PatientReportedOutcome (US3232021)', ODM File OID: '22effc2d-d9a6-4ea5-adfc-2ac3db0f9b28'	System	11 Aug 2020 00:34:43
User entered 'No (N)'	System	11 Aug 2020 00:34:43

US3232021

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 11 Aug 2021 22:05:35

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	05 Mar 2021 04:11:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1179BDB4-134B-4DDE-B0FD-B886B117B21A)', Time: '2020-08-10T19:34:32', User OID: 'PatientReportedOutcome (US3232021)', ODM File OID: '22effc2d-d9a6-4ea5-adfc-2ac3db0f9b28'	System	11 Aug 2020 00:34:43
User entered 'None (1)'	System	11 Aug 2020 00:34:43

US3232021
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(1/2)
Generated On: 11 Aug 2021 22:05:35
PC Time Stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	05 Mar 2021 04:11:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1179BDB4-134B-4DDE-B0FD-B886B117B21A)', Time: '2020-08-10T19:34:41', User OID: 'PatientReportedOutcome (US3232021)', ODM File OID: '22effc2d-d9a6-4ea5-adfc-2ac3db0f9b28'	System	11 Aug 2020 00:34:43
User entered '10 Aug 2020 19:34'	System	11 Aug 2020 00:34:43

US3232021

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 11 Aug 2021 22:05:35

PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	05 Mar 2021 04:11:35
User entered '10 Aug 2020 16:29'	System	10 Aug 2020 17:47:41

US3232021

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 11 Aug 2021 22:05:35

PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	05 Mar 2021 04:11:35
User entered '11 Aug 2020 11:59'	System	10 Aug 2020 17:47:41

US3232021
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(2)
Generated On: 11 Aug 2021 22:05:35
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	05 Mar 2021 04:11:35
Data entry locked.	System	10 Aug 2020 17:47:41
User entered 'Day 2'	System	10 Aug 2020 17:47:41

US3232021

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 11 Aug 2021 22:05:35

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	05 Mar 2021 04:11:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1179BDB4-134B-4DDE-B0FD-B886B117B21A)', Time: '2020-08-11T14:16:22', User OID: 'PatientReportedOutcome (US3232021)', ODM File OID: '8496b4db-288a-4042-a828-8ad37da7e5ff'	System	11 Aug 2020 19:18:53
User entered 'Repeated use of over-the-counter pain reliever > 24 hours or interferes with activity (3)'	System	11 Aug 2020 19:18:53

US3232021
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(2)
Generated On: 11 Aug 2021 22:05:35
Is there any **REDNESS AT INJECTION SITE**?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	05 Mar 2021 04:11:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1179BDB4-134B-4DDE-B0FD-B886B117B21A)', Time: '2020-08-11T14:16:41', User OID: 'PatientReportedOutcome (US3232021)', ODM File OID: '8496b4db-288a-4042-a828-8ad37da7e5ff'	System	11 Aug 2020 19:18:53
User entered 'No (N)'	System	11 Aug 2020 19:18:53

US3232021

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 11 Aug 2021 22:05:35

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	05 Mar 2021 04:11:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1179BDB4-134B-4DDE-B0FD-B886B117B21A)', Time: '2020-08-11T14:16:46', User OID: 'PatientReportedOutcome (US3232021)', ODM File OID: '8496b4db-288a-4042-a828-8ad37da7e5ff'	System	11 Aug 2020 19:18:53
User entered 'Yes (Y)'	System	11 Aug 2020 19:18:53

US3232021

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 11 Aug 2021 22:05:35

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) (b) (4), (b) (6)	05 Mar 2021 04:11:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1179BDB4-134B-4DDE-B0FD-B886B117B21A)', Time: '2020-08-11T14:18:37', User OID: 'PatientReportedOutcome (US3232021)', ODM File OID: '8496b4db-288a-4042-a828-8ad37da7e5ff'	System	11 Aug 2020 19:18:53
User entered '35'	System	11 Aug 2020 19:18:53

US3232021

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 11 Aug 2021 22:05:35

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	05 Mar 2021 04:11:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1179BDB4-134B-4DDE-B0FD-B886B117B21A)', Time: '2020-08-11T14:18:45', User OID: 'PatientReportedOutcome (US3232021)', ODM File OID: '8496b4db-288a-4042-a828-8ad37da7e5ff'	System	11 Aug 2020 19:18:53
User entered 'None (1)'	System	11 Aug 2020 19:18:53

FDA-CBER-2022-1614-0646265

US3232021
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(2)
Generated On: 11 Aug 2021 22:05:35
PC Time Stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	05 Mar 2021 04:11:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1179BDB4-134B-4DDE-B0FD-B886B117B21A)', Time: '2020-08-11T14:18:51', User OID: 'PatientReportedOutcome (US3232021)', ODM File OID: '8496b4db-288a-4042-a828-8ad37da7e5ff'	System	11 Aug 2020 19:18:53
User entered '11 Aug 2020 14:18'	System	11 Aug 2020 19:18:53

US3232021
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(2)
Generated On: 11 Aug 2021 22:05:35

PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	05 Mar 2021 04:11:35
User entered '11 Aug 2020 12:00'	System	10 Aug 2020 17:47:41

US3232021
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(2)
Generated On: 11 Aug 2021 22:05:35
PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	05 Mar 2021 04:11:35
User entered '12 Aug 2020 11:59'	System	10 Aug 2020 17:47:41

US3232021

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 11 Aug 2021 22:05:35

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	05 Mar 2021 04:11:35
Data entry locked.	System	10 Aug 2020 17:47:41
User entered 'Day 3'	System	10 Aug 2020 17:47:41

US3232021

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 11 Aug 2021 22:05:35

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	05 Mar 2021 04:11:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1179BDB4-134B-4DDE-B0FD-B886B117B21A)', Time: '2020-08-12T21:41:37', User OID: 'PatientReportedOutcome (US3232021)', ODM File OID: 'f14c39d8-b147-49a0-b2a0-062c76f9e0e2'	System	13 Aug 2020 02:42:05
User entered 'None (1)'	System	13 Aug 2020 02:42:05

US3232021
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(3)
Generated On: 11 Aug 2021 22:05:35
Is there any **REDNESS AT INJECTION SITE**?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	05 Mar 2021 04:11:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1179BDB4-134B-4DDE-B0FD-B886B117B21A)', Time: '2020-08-12T21:41:40', User OID: 'PatientReportedOutcome (US3232021)', ODM File OID: 'f14c39d8-b147-49a0-b2a0-062c76f9e0e2'	System	13 Aug 2020 02:42:05
User entered 'No (N)'	System	13 Aug 2020 02:42:05

US3232021

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 11 Aug 2021 22:05:35

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	05 Mar 2021 04:11:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1179BDB4-134B-4DDE-B0FD-B886B117B21A)', Time: '2020-08-12T21:41:45', User OID: 'PatientReportedOutcome (US3232021)', ODM File OID: 'f14c39d8-b147-49a0-b2a0-062c76f9e0e2'	System	13 Aug 2020 02:42:05
User entered 'No (N)'	System	13 Aug 2020 02:42:05

US3232021

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 11 Aug 2021 22:05:35

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	05 Mar 2021 04:11:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1179BDB4-134B-4DDE-B0FD-B886B117B21A)', Time: '2020-08-12T21:41:59', User OID: 'PatientReportedOutcome (US3232021)', ODM File OID: 'f14c39d8-b147-49a0-b2a0-062c76f9e0e2'	System	13 Aug 2020 02:42:05
User entered 'None (1)'	System	13 Aug 2020 02:42:05

US3232021
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(3)
Generated On: 11 Aug 2021 22:05:35
PC Time Stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	05 Mar 2021 04:11:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1179BDB4-134B-4DDE-B0FD-B886B117B21A)', Time: '2020-08-12T21:42:02', User OID: 'PatientReportedOutcome (US3232021)', ODM File OID: 'f14c39d8-b147-49a0-b2a0-062c76f9e0e2'	System	13 Aug 2020 02:42:05
User entered '12 Aug 2020 21:42'	System	13 Aug 2020 02:42:05

US3232021
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(3)
Generated On: 11 Aug 2021 22:05:35
PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	05 Mar 2021 04:11:35
User entered '12 Aug 2020 12:00'	System	10 Aug 2020 17:47:41

US3232021
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(3)
Generated On: 11 Aug 2021 22:05:35
PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	05 Mar 2021 04:11:35
User entered '13 Aug 2020 11:59'	System	10 Aug 2020 17:47:41

US3232021
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(4)
Generated On: 11 Aug 2021 22:05:35
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	05 Mar 2021 04:11:35
Data entry locked.	System	10 Aug 2020 17:47:41
User entered 'Day 4'	System	10 Aug 2020 17:47:41

US3232021

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 11 Aug 2021 22:05:35

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	05 Mar 2021 04:11:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1179BDB4-134B-4DDE-B0FD-B886B117B21A)', Time: '2020-08-13T12:00:38', User OID: 'PatientReportedOutcome (US3232021)', ODM File OID: 'ad9e53b4-91cc-421e-a562-5e98a5d7afc6'	System	13 Aug 2020 17:00:57
User entered 'None (1)'	System	13 Aug 2020 17:00:57

US3232021
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(4)
Generated On: 11 Aug 2021 22:05:35
Is there any **REDNESS AT INJECTION SITE**?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	05 Mar 2021 04:11:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1179BDB4-134B-4DDE-B0FD-B886B117B21A)', Time: '2020-08-13T12:00:41', User OID: 'PatientReportedOutcome (US3232021)', ODM File OID: 'ad9e53b4-91cc-421e-a562-5e98a5d7afc6'	System	13 Aug 2020 17:00:57
User entered 'No (N)'	System	13 Aug 2020 17:00:57

US3232021

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 11 Aug 2021 22:05:35

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	05 Mar 2021 04:11:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1179BDB4-134B-4DDE-B0FD-B886B117B21A)', Time: '2020-08-13T12:00:43', User OID: 'PatientReportedOutcome (US3232021)', ODM File OID: 'ad9e53b4-91cc-421e-a562-5e98a5d7afc6'	System	13 Aug 2020 17:00:57
User entered 'No (N)'	System	13 Aug 2020 17:00:57

US3232021

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 11 Aug 2021 22:05:35

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	05 Mar 2021 04:11:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1179BDB4-134B-4DDE-B0FD-B886B117B21A)', Time: '2020-08-13T12:00:51', User OID: 'PatientReportedOutcome (US3232021)', ODM File OID: 'ad9e53b4-91cc-421e-a562-5e98a5d7afc6'	System	13 Aug 2020 17:00:57
User entered 'None (1)'	System	13 Aug 2020 17:00:57

US3232021
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(4)
Generated On: 11 Aug 2021 22:05:35
PC Time Stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	05 Mar 2021 04:11:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1179BDB4-134B-4DDE-B0FD-B886B117B21A)', Time: '2020-08-13T12:00:54', User OID: 'PatientReportedOutcome (US3232021)', ODM File OID: 'ad9e53b4-91cc-421e-a562-5e98a5d7afc6'	System	13 Aug 2020 17:00:57
User entered '13 Aug 2020 12:00'	System	13 Aug 2020 17:00:57

US3232021

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 11 Aug 2021 22:05:35

PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	05 Mar 2021 04:11:35
User entered '13 Aug 2020 12:00'	System	10 Aug 2020 17:47:41

US3232021
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(4)
Generated On: 11 Aug 2021 22:05:35
PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	05 Mar 2021 04:11:35
User entered '14 Aug 2020 11:59'	System	10 Aug 2020 17:47:41

US3232021
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(5)
Generated On: 11 Aug 2021 22:05:35
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	05 Mar 2021 04:11:35
Data entry locked.	System	10 Aug 2020 17:47:41
User entered 'Day 5'	System	10 Aug 2020 17:47:41

US3232021

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 11 Aug 2021 22:05:35

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	05 Mar 2021 04:11:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1179BDB4-134B-4DDE-B0FD-B886B117B21A)', Time: '2020-08-14T21:00:11', User OID: 'PatientReportedOutcome (US3232021)', ODM File OID: '052d888d-52fe-4d6f-bb3f-3e1a8bc37925'	System	15 Aug 2020 02:00:35
User entered 'None (1)'	System	15 Aug 2020 02:00:35

US3232021
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(5)
Generated On: 11 Aug 2021 22:05:35
Is there any **REDNESS AT INJECTION SITE**?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	05 Mar 2021 04:11:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1179BDB4-134B-4DDE-B0FD-B886B117B21A)', Time: '2020-08-14T21:00:14', User OID: 'PatientReportedOutcome (US3232021)', ODM File OID: '052d888d-52fe-4d6f-bb3f-3e1a8bc37925'	System	15 Aug 2020 02:00:35
User entered 'No (N)'	System	15 Aug 2020 02:00:35

FDA-CBER-2022-1614-0646287

US3232021

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 11 Aug 2021 22:05:35

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	05 Mar 2021 04:11:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1179BDB4-134B-4DDE-B0FD-B886B117B21A)', Time: '2020-08-14T21:00:16', User OID: 'PatientReportedOutcome (US3232021)', ODM File OID: '052d888d-52fe-4d6f-bb3f-3e1a8bc37925'	System	15 Aug 2020 02:00:35
User entered 'No (N)'	System	15 Aug 2020 02:00:35

US3232021

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 11 Aug 2021 22:05:35

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	05 Mar 2021 04:11:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1179BDB4-134B-4DDE-B0FD-B886B117B21A)', Time: '2020-08-14T21:00:25', User OID: 'PatientReportedOutcome (US3232021)', ODM File OID: '052d888d-52fe-4d6f-bb3f-3e1a8bc37925'	System	15 Aug 2020 02:00:35
User entered 'None (1)'	System	15 Aug 2020 02:00:35

US3232021

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 11 Aug 2021 22:05:35

PC Time Stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	05 Mar 2021 04:11:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1179BDB4-134B-4DDE-B0FD-B886B117B21A)', Time: '2020-08-14T21:00:32', User OID: 'PatientReportedOutcome (US3232021)', ODM File OID: '052d888d-52fe-4d6f-bb3f-3e1a8bc37925'	System	15 Aug 2020 02:00:35
User entered '14 Aug 2020 21:00'	System	15 Aug 2020 02:00:35

US3232021

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 11 Aug 2021 22:05:35

PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	05 Mar 2021 04:11:35
User entered '14 Aug 2020 12:00'	System	10 Aug 2020 17:47:41

US3232021
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(5)
Generated On: 11 Aug 2021 22:05:35
PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	05 Mar 2021 04:11:35
User entered '15 Aug 2020 11:59'	System	10 Aug 2020 17:47:41

US3232021

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 11 Aug 2021 22:05:35

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	05 Mar 2021 04:11:35
Data entry locked.	System	10 Aug 2020 17:47:41
User entered 'Day 6'	System	10 Aug 2020 17:47:41

US3232021

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 11 Aug 2021 22:05:35

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	05 Mar 2021 04:11:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1179BDB4-134B-4DDE-B0FD-B886B117B21A)', Time: '2020-08-15T12:30:44', User OID: 'PatientReportedOutcome (US3232021)', ODM File OID: 'c0addf00-35f1-44b0-bc3b-b80de505748a'	System	15 Aug 2020 17:30:56
User entered 'None (1)'	System	15 Aug 2020 17:30:56

US3232021

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 11 Aug 2021 22:05:35

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	05 Mar 2021 04:11:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1179BDB4-134B-4DDE-B0FD-B886B117B21A)', Time: '2020-08-15T12:30:46', User OID: 'PatientReportedOutcome (US3232021)', ODM File OID: 'c0addf00-35f1-44b0-bc3b-b80de505748a'	System	15 Aug 2020 17:30:56
User entered 'No (N)'	System	15 Aug 2020 17:30:56

US3232021
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(6)
Generated On: 11 Aug 2021 22:05:35
Is there any **SWELLING/HARDNESS AT INJECTION SITE**?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	05 Mar 2021 04:11:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1179BDB4-134B-4DDE-B0FD-B886B117B21A)', Time: '2020-08-15T12:30:48', User OID: 'PatientReportedOutcome (US3232021)', ODM File OID: 'c0addf00-35f1-44b0-bc3b-b80de505748a'	System	15 Aug 2020 17:30:56
User entered 'No (N)'	System	15 Aug 2020 17:30:56

FDA-CBER-2022-1614-0646296

US3232021

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 11 Aug 2021 22:05:35

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	05 Mar 2021 04:11:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1179BDB4-134B-4DDE-B0FD-B886B117B21A)', Time: '2020-08-15T12:30:50', User OID: 'PatientReportedOutcome (US3232021)', ODM File OID: 'c0addf00-35f1-44b0-bc3b-b80de505748a'	System	15 Aug 2020 17:30:56
User entered 'None (1)'	System	15 Aug 2020 17:30:56

US3232021
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(6)
Generated On: 11 Aug 2021 22:05:35
PC Time Stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	05 Mar 2021 04:11:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1179BDB4-134B-4DDE-B0FD-B886B117B21A)', Time: '2020-08-15T12:30:52', User OID: 'PatientReportedOutcome (US3232021)', ODM File OID: 'c0addf00-35f1-44b0-bc3b-b80de505748a'	System	15 Aug 2020 17:30:56
User entered '15 Aug 2020 12:30'	System	15 Aug 2020 17:30:56

US3232021
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(6)
Generated On: 11 Aug 2021 22:05:35
PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:11:35
User entered '15 Aug 2020 12:00'	System	10 Aug 2020 17:47:41

US3232021
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(6)
Generated On: 11 Aug 2021 22:05:35
PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	05 Mar 2021 04:11:35
User entered '16 Aug 2020 11:59'	System	10 Aug 2020 17:47:41

US3232021
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(7)
Generated On: 11 Aug 2021 22:05:35
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	05 Mar 2021 04:11:35
Data entry locked.	System	10 Aug 2020 17:47:41
User entered 'Day 7'	System	10 Aug 2020 17:47:41

US3232021

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 11 Aug 2021 22:05:35

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	05 Mar 2021 04:11:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1179BDB4-134B-4DDE-B0FD-B886B117B21A)', Time: '2020-08-16T22:32:31', User OID: 'PatientReportedOutcome (US3232021)', ODM File OID: '3472b70d-5065-481a-84e5-2d05d970bcb9'	System	17 Aug 2020 03:32:43
User entered 'None (1)'	System	17 Aug 2020 03:32:43

US3232021

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 11 Aug 2021 22:05:35

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	05 Mar 2021 04:11:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1179BDB4-134B-4DDE-B0FD-B886B117B21A)', Time: '2020-08-16T22:32:33', User OID: 'PatientReportedOutcome (US3232021)', ODM File OID: '3472b70d-5065-481a-84e5-2d05d970bcb9'	System	17 Aug 2020 03:32:43
User entered 'No (N)'	System	17 Aug 2020 03:32:43

US3232021

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 11 Aug 2021 22:05:35

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	05 Mar 2021 04:11:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1179BDB4-134B-4DDE-B0FD-B886B117B21A)', Time: '2020-08-16T22:32:35', User OID: 'PatientReportedOutcome (US3232021)', ODM File OID: '3472b70d-5065-481a-84e5-2d05d970bcb9'	System	17 Aug 2020 03:32:43
User entered 'No (N)'	System	17 Aug 2020 03:32:43

US3232021

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 11 Aug 2021 22:05:35

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	05 Mar 2021 04:11:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1179BDB4-134B-4DDE-B0FD-B886B117B21A)', Time: '2020-08-16T22:32:37', User OID: 'PatientReportedOutcome (US3232021)', ODM File OID: '3472b70d-5065-481a-84e5-2d05d970bcb9'	System	17 Aug 2020 03:32:43
User entered 'None (1)'	System	17 Aug 2020 03:32:43

US3232021
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(7)
Generated On: 11 Aug 2021 22:05:35
PC Time Stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	05 Mar 2021 04:11:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1179BDB4-134B-4DDE-B0FD-B886B117B21A)', Time: '2020-08-16T22:32:40', User OID: 'PatientReportedOutcome (US3232021)', ODM File OID: '3472b70d-5065-481a-84e5-2d05d970bcb9'	System	17 Aug 2020 03:32:43
User entered '16 Aug 2020 22:32'	System	17 Aug 2020 03:32:43

US3232021
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(7)
Generated On: 11 Aug 2021 22:05:35
PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:11:35
User entered '16 Aug 2020 12:00'	System	10 Aug 2020 17:47:41

US3232021
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(7)
Generated On: 11 Aug 2021 22:05:35
PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	05 Mar 2021 04:11:35
User entered '17 Aug 2020 11:59'	System	10 Aug 2020 17:47:41

US3232021
Folder: Diary Dose 1 (1)
Form: General_Day(1/1)
Generated On: 11 Aug 2021 22:05:35
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	05 Mar 2021 04:11:35
Data entry locked.	System	10 Aug 2020 17:47:41
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	10 Aug 2020 17:47:41

US3232021
Folder: Diary Dose 1 (1)
Form: General_Day(1/1)
Generated On: 11 Aug 2021 22:05:35
HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	05 Mar 2021 04:11:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1179BDB4-134B-4DDE-B0FD-B886B117B21A)', Time: '2020-08-10T13:05:50', User OID: 'PatientReportedOutcome (US3232021)', ODM File OID: '6998483a-5129-434a-bb6d-eeadcb4d850b'	System	10 Aug 2020 18:06:30
User entered 'None (0)'	System	10 Aug 2020 18:06:30

US3232021
Folder: Diary Dose 1 (1)
Form: General_Day(1/1)
Generated On: 11 Aug 2021 22:05:35
FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	05 Mar 2021 04:11:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1179BDB4-134B-4DDE-B0FD-B886B117B21A)', Time: '2020-08-10T13:06:02', User OID: 'PatientReportedOutcome (US3232021)', ODM File OID: '6998483a-5129-434a-bb6d-eeadcb4d850b'	System	10 Aug 2020 18:06:30
User entered 'None (0)'	System	10 Aug 2020 18:06:30

US3232021
Folder: Diary Dose 1 (1)
Form: General_Day(1/1)
Generated On: 11 Aug 2021 22:05:35
MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	05 Mar 2021 04:11:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1179BDB4-134B-4DDE-B0FD-B886B117B21A)', Time: '2020-08-10T13:06:04', User OID: 'PatientReportedOutcome (US3232021)', ODM File OID: '6998483a-5129-434a-bb6d-eeadcb4d850b'	System	10 Aug 2020 18:06:30
User entered 'None (0)'	System	10 Aug 2020 18:06:30

US3232021
Folder: Diary Dose 1 (1)
Form: General_Day(1/1)
Generated On: 11 Aug 2021 22:05:35
JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	05 Mar 2021 04:11:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1179BDB4-134B-4DDE-B0FD-B886B117B21A)', Time: '2020-08-10T13:06:13', User OID: 'PatientReportedOutcome (US3232021)', ODM File OID: '6998483a-5129-434a-bb6d-eeadcb4d850b'	System	10 Aug 2020 18:06:30
User entered 'None (0)'	System	10 Aug 2020 18:06:30

US3232021
Folder: Diary Dose 1 (1)
Form: General_Day(1/1)
Generated On: 11 Aug 2021 22:05:35
NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	05 Mar 2021 04:11:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1179BDB4-134B-4DDE-B0FD-B886B117B21A)', Time: '2020-08-10T13:06:15', User OID: 'PatientReportedOutcome (US3232021)', ODM File OID: '6998483a-5129-434a-bb6d-eeadcb4d850b'	System	10 Aug 2020 18:06:30
User entered 'None (0)'	System	10 Aug 2020 18:06:30

US3232021
Folder: Diary Dose 1 (1)
Form: General_Day(1/1)
Generated On: 11 Aug 2021 22:05:35
CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	05 Mar 2021 04:11:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1179BDB4-134B-4DDE-B0FD-B886B117B21A)', Time: '2020-08-10T13:06:17', User OID: 'PatientReportedOutcome (US3232021)', ODM File OID: '6998483a-5129-434a-bb6d-eeadcb4d850b'	System	10 Aug 2020 18:06:30
User entered 'None (0)'	System	10 Aug 2020 18:06:30

US3232021

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 11 Aug 2021 22:05:35

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) (b) (4), (b) (6)	05 Mar 2021 04:11:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1179BDB4-134B-4DDE-B0FD-B886B117B21A)', Time: '2020-08-10T13:06:21', User OID: 'PatientReportedOutcome (US3232021)', ODM File OID: '6998483a-5129-434a-bb6d-eeadcb4d850b'	System	10 Aug 2020 18:06:30
User entered 'No (N)'	System	10 Aug 2020 18:06:30

US3232021

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 11 Aug 2021 22:05:35

PC Time stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	05 Mar 2021 04:11:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1179BDB4-134B-4DDE-B0FD-B886B117B21A)', Time: '2020-08-10T13:06:26', User OID: 'PatientReportedOutcome (US3232021)', ODM File OID: '6998483a-5129-434a-bb6d-eeadcb4d850b'	System	10 Aug 2020 18:06:30
User entered '10 Aug 2020 13:06'	System	10 Aug 2020 18:06:30

US3232021

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 11 Aug 2021 22:05:35

PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	05 Mar 2021 04:11:35
User entered '10 Aug 2020 13:04'	System	10 Aug 2020 17:47:41

US3232021
Folder: Diary Dose 1 (1)
Form: General_Day(1/1)
Generated On: 11 Aug 2021 22:05:35
PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	05 Mar 2021 04:11:35
User entered '10 Aug 2020 15:34'	System	10 Aug 2020 17:47:41

US3232021
Folder: Diary Dose 1 (1)
Form: General_Day(1/2)
Generated On: 11 Aug 2021 22:05:35
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	05 Mar 2021 04:11:35
Data entry locked.	System	10 Aug 2020 17:47:41
User entered 'Day 1, after vaccination (at home)'	System	10 Aug 2020 17:47:41

US3232021
Folder: Diary Dose 1 (1)
Form: General_Day(1/2)
Generated On: 11 Aug 2021 22:05:35
HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	05 Mar 2021 04:11:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1179BDB4-134B-4DDE-B0FD-B886B117B21A)', Time: '2020-08-10T19:34:46', User OID: 'PatientReportedOutcome (US3232021)', ODM File OID: 'e06066dd-00f3-4468-a960-a5ef59543e91'	System	11 Aug 2020 00:35:38
User entered 'None (0)'	System	11 Aug 2020 00:35:38

US3232021
Folder: Diary Dose 1 (1)
Form: General_Day(1/2)
Generated On: 11 Aug 2021 22:05:35
FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	05 Mar 2021 04:11:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1179BDB4-134B-4DDE-B0FD-B886B117B21A)', Time: '2020-08-10T19:34:53', User OID: 'PatientReportedOutcome (US3232021)', ODM File OID: 'e06066dd-00f3-4468-a960-a5ef59543e91'	System	11 Aug 2020 00:35:38
User entered 'None (0)'	System	11 Aug 2020 00:35:38

US3232021

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 11 Aug 2021 22:05:35

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	05 Mar 2021 04:11:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1179BDB4-134B-4DDE-B0FD-B886B117B21A)', Time: '2020-08-10T19:34:56', User OID: 'PatientReportedOutcome (US3232021)', ODM File OID: 'e06066dd-00f3-4468-a960-a5ef59543e91'	System	11 Aug 2020 00:35:38
User entered 'None (0)'	System	11 Aug 2020 00:35:38

US3232021

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 11 Aug 2021 22:05:35

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	05 Mar 2021 04:11:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1179BDB4-134B-4DDE-B0FD-B886B117B21A)', Time: '2020-08-10T19:34:59', User OID: 'PatientReportedOutcome (US3232021)', ODM File OID: 'e06066dd-00f3-4468-a960-a5ef59543e91'	System	11 Aug 2020 00:35:38
User entered 'None (0)'	System	11 Aug 2020 00:35:38

US3232021
Folder: Diary Dose 1 (1)
Form: General_Day(1/2)
Generated On: 11 Aug 2021 22:05:35
NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	05 Mar 2021 04:11:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1179BDB4-134B-4DDE-B0FD-B886B117B21A)', Time: '2020-08-10T19:35:01', User OID: 'PatientReportedOutcome (US3232021)', ODM File OID: 'e06066dd-00f3-4468-a960-a5ef59543e91'	System	11 Aug 2020 00:35:38
User entered 'None (0)'	System	11 Aug 2020 00:35:38

US3232021
Folder: Diary Dose 1 (1)
Form: General_Day(1/2)
Generated On: 11 Aug 2021 22:05:35
CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	05 Mar 2021 04:11:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1179BDB4-134B-4DDE-B0FD-B886B117B21A)', Time: '2020-08-10T19:35:03', User OID: 'PatientReportedOutcome (US3232021)', ODM File OID: 'e06066dd-00f3-4468-a960-a5ef59543e91'	System	11 Aug 2020 00:35:38
User entered 'None (0)'	System	11 Aug 2020 00:35:38

US3232021

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 11 Aug 2021 22:05:35

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) (b) (4), (b) (6)	05 Mar 2021 04:11:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1179BDB4-134B-4DDE-B0FD-B886B117B21A)', Time: '2020-08-10T19:35:29', User OID: 'PatientReportedOutcome (US3232021)', ODM File OID: 'e06066dd-00f3-4468-a960-a5ef59543e91'	System	11 Aug 2020 00:35:38
User entered 'No (N)'	System	11 Aug 2020 00:35:38

US3232021

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 11 Aug 2021 22:05:35

PC Time stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	05 Mar 2021 04:11:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1179BDB4-134B-4DDE-B0FD-B886B117B21A)', Time: '2020-08-10T19:35:37', User OID: 'PatientReportedOutcome (US3232021)', ODM File OID: 'e06066dd-00f3-4468-a960-a5ef59543e91'	System	11 Aug 2020 00:35:38
User entered '10 Aug 2020 19:35'	System	11 Aug 2020 00:35:38

US3232021

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 11 Aug 2021 22:05:35

PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	05 Mar 2021 04:11:35
User entered '10 Aug 2020 16:29'	System	10 Aug 2020 17:47:41

US3232021

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 11 Aug 2021 22:05:35

PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:11:35
User entered '11 Aug 2020 11:59'	System	10 Aug 2020 17:47:41

US3232021
Folder: Diary Dose 1 (1)
Form: General_Day(2)
Generated On: 11 Aug 2021 22:05:35
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	05 Mar 2021 04:11:35
Data entry locked.	System	10 Aug 2020 17:47:41
User entered 'Day 2'	System	10 Aug 2020 17:47:41

US3232021
Folder: Diary Dose 1 (1)
Form: General_Day(2)
Generated On: 11 Aug 2021 22:05:35
HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	05 Mar 2021 04:11:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1179BDB4-134B-4DDE-B0FD-B886B117B21A)', Time: '2020-08-11T14:18:55', User OID: 'PatientReportedOutcome (US3232021)', ODM File OID: '3000e5f8-6c63-472f-a470-9c6621a87b2b'	System	11 Aug 2020 19:19:21
User entered 'None (0)'	System	11 Aug 2020 19:19:21

US3232021
Folder: Diary Dose 1 (1)
Form: General_Day(2)
Generated On: 11 Aug 2021 22:05:35
FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	05 Mar 2021 04:11:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1179BDB4-134B-4DDE-B0FD-B886B117B21A)', Time: '2020-08-11T14:19:00', User OID: 'PatientReportedOutcome (US3232021)', ODM File OID: '3000e5f8-6c63-472f-a470-9c6621a87b2b'	System	11 Aug 2020 19:19:21
User entered 'None (0)'	System	11 Aug 2020 19:19:21

US3232021
Folder: Diary Dose 1 (1)
Form: General_Day(2)
Generated On: 11 Aug 2021 22:05:35
MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	05 Mar 2021 04:11:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1179BDB4-134B-4DDE-B0FD-B886B117B21A)', Time: '2020-08-11T14:19:03', User OID: 'PatientReportedOutcome (US3232021)', ODM File OID: '3000e5f8-6c63-472f-a470-9c6621a87b2b'	System	11 Aug 2020 19:19:21
User entered 'None (0)'	System	11 Aug 2020 19:19:21

US3232021
Folder: Diary Dose 1 (1)
Form: General_Day(2)
Generated On: 11 Aug 2021 22:05:35
JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	05 Mar 2021 04:11:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1179BDB4-134B-4DDE-B0FD-B886B117B21A)', Time: '2020-08-11T14:19:04', User OID: 'PatientReportedOutcome (US3232021)', ODM File OID: '3000e5f8-6c63-472f-a470-9c6621a87b2b'	System	11 Aug 2020 19:19:21
User entered 'None (0)'	System	11 Aug 2020 19:19:21

US3232021
Folder: Diary Dose 1 (1)
Form: General_Day(2)
Generated On: 11 Aug 2021 22:05:35
NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	05 Mar 2021 04:11:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1179BDB4-134B-4DDE-B0FD-B886B117B21A)', Time: '2020-08-11T14:19:06', User OID: 'PatientReportedOutcome (US3232021)', ODM File OID: '3000e5f8-6c63-472f-a470-9c6621a87b2b'	System	11 Aug 2020 19:19:21
User entered 'None (0)'	System	11 Aug 2020 19:19:21

US3232021
Folder: Diary Dose 1 (1)
Form: General_Day(2)
Generated On: 11 Aug 2021 22:05:35
CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	05 Mar 2021 04:11:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1179BDB4-134B-4DDE-B0FD-B886B117B21A)', Time: '2020-08-11T14:19:08', User OID: 'PatientReportedOutcome (US3232021)', ODM File OID: '3000e5f8-6c63-472f-a470-9c6621a87b2b'	System	11 Aug 2020 19:19:21
User entered 'None (0)'	System	11 Aug 2020 19:19:21

US3232021

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 11 Aug 2021 22:05:35

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) (b) (4), (b) (6)	05 Mar 2021 04:11:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1179BDB4-134B-4DDE-B0FD-B886B117B21A)', Time: '2020-08-11T14:19:13', User OID: 'PatientReportedOutcome (US3232021)', ODM File OID: '3000e5f8-6c63-472f-a470-9c6621a87b2b'	System	11 Aug 2020 19:19:21
User entered 'No (N)'	System	11 Aug 2020 19:19:21

US3232021

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 11 Aug 2021 22:05:35

PC Time stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	05 Mar 2021 04:11:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1179BDB4-134B-4DDE-B0FD-B886B117B21A)', Time: '2020-08-11T14:19:16', User OID: 'PatientReportedOutcome (US3232021)', ODM File OID: '3000e5f8-6c63-472f-a470-9c6621a87b2b'	System	11 Aug 2020 19:19:21
User entered '11 Aug 2020 14:19'	System	11 Aug 2020 19:19:21

US3232021
Folder: Diary Dose 1 (1)
Form: General_Day(2)
Generated On: 11 Aug 2021 22:05:35
PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:11:35
User entered '11 Aug 2020 12:00'	System	10 Aug 2020 17:47:41

US3232021
Folder: Diary Dose 1 (1)
Form: General_Day(2)
Generated On: 11 Aug 2021 22:05:35
PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	05 Mar 2021 04:11:35
User entered '12 Aug 2020 11:59'	System	10 Aug 2020 17:47:41

US3232021
Folder: Diary Dose 1 (1)
Form: General_Day(3)
Generated On: 11 Aug 2021 22:05:35
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	05 Mar 2021 04:11:35
Data entry locked.	System	10 Aug 2020 17:47:41
User entered 'Day 3'	System	10 Aug 2020 17:47:41

US3232021
Folder: Diary Dose 1 (1)
Form: General_Day(3)
Generated On: 11 Aug 2021 22:05:35
HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	05 Mar 2021 04:11:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1179BDB4-134B-4DDE-B0FD-B886B117B21A)', Time: '2020-08-12T21:41:15', User OID: 'PatientReportedOutcome (US3232021)', ODM File OID: 'f7a391e6-b38f-40c4-a286-842f59a83df3'	System	13 Aug 2020 02:41:38
User entered 'None (0)'	System	13 Aug 2020 02:41:38

US3232021
Folder: Diary Dose 1 (1)
Form: General_Day(3)
Generated On: 11 Aug 2021 22:05:35
FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	05 Mar 2021 04:11:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1179BDB4-134B-4DDE-B0FD-B886B117B21A)', Time: '2020-08-12T21:41:17', User OID: 'PatientReportedOutcome (US3232021)', ODM File OID: 'f7a391e6-b38f-40c4-a286-842f59a83df3'	System	13 Aug 2020 02:41:38
User entered 'None (0)'	System	13 Aug 2020 02:41:38

US3232021
Folder: Diary Dose 1 (1)
Form: General_Day(3)
Generated On: 11 Aug 2021 22:05:35
MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	05 Mar 2021 04:11:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1179BDB4-134B-4DDE-B0FD-B886B117B21A)', Time: '2020-08-12T21:41:19', User OID: 'PatientReportedOutcome (US3232021)', ODM File OID: 'f7a391e6-b38f-40c4-a286-842f59a83df3'	System	13 Aug 2020 02:41:38
User entered 'None (0)'	System	13 Aug 2020 02:41:38

US3232021
Folder: Diary Dose 1 (1)
Form: General_Day(3)
Generated On: 11 Aug 2021 22:05:35
JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	05 Mar 2021 04:11:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1179BDB4-134B-4DDE-B0FD-B886B117B21A)', Time: '2020-08-12T21:41:21', User OID: 'PatientReportedOutcome (US3232021)', ODM File OID: 'f7a391e6-b38f-40c4-a286-842f59a83df3'	System	13 Aug 2020 02:41:38
User entered 'None (0)'	System	13 Aug 2020 02:41:38

US3232021
Folder: Diary Dose 1 (1)
Form: General_Day(3)
Generated On: 11 Aug 2021 22:05:35
NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	05 Mar 2021 04:11:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1179BDB4-134B-4DDE-B0FD-B886B117B21A)', Time: '2020-08-12T21:41:23', User OID: 'PatientReportedOutcome (US3232021)', ODM File OID: 'f7a391e6-b38f-40c4-a286-842f59a83df3'	System	13 Aug 2020 02:41:38
User entered 'None (0)'	System	13 Aug 2020 02:41:38

US3232021
Folder: Diary Dose 1 (1)
Form: General_Day(3)
Generated On: 11 Aug 2021 22:05:35
CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	05 Mar 2021 04:11:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1179BDB4-134B-4DDE-B0FD-B886B117B21A)', Time: '2020-08-12T21:41:25', User OID: 'PatientReportedOutcome (US3232021)', ODM File OID: 'f7a391e6-b38f-40c4-a286-842f59a83df3'	System	13 Aug 2020 02:41:38
User entered 'None (0)'	System	13 Aug 2020 02:41:38

US3232021

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 11 Aug 2021 22:05:35

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) (b) (4), (b) (6)	05 Mar 2021 04:11:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1179BDB4-134B-4DDE-B0FD-B886B117B21A)', Time: '2020-08-12T21:41:30', User OID: 'PatientReportedOutcome (US3232021)', ODM File OID: 'f7a391e6-b38f-40c4-a286-842f59a83df3'	System	13 Aug 2020 02:41:38
User entered 'No (N)'	System	13 Aug 2020 02:41:38

US3232021
Folder: Diary Dose 1 (1)
Form: General_Day(3)
Generated On: 11 Aug 2021 22:05:35
PC Time stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	05 Mar 2021 04:11:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1179BDB4-134B-4DDE-B0FD-B886B117B21A)', Time: '2020-08-12T21:41:32', User OID: 'PatientReportedOutcome (US3232021)', ODM File OID: 'f7a391e6-b38f-40c4-a286-842f59a83df3'	System	13 Aug 2020 02:41:38
User entered '12 Aug 2020 21:41'	System	13 Aug 2020 02:41:38

US3232021
Folder: Diary Dose 1 (1)
Form: General_Day(3)
Generated On: 11 Aug 2021 22:05:35

PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	05 Mar 2021 04:11:35
User entered '12 Aug 2020 12:00'	System	10 Aug 2020 17:47:41

US3232021
Folder: Diary Dose 1 (1)
Form: General_Day(3)
Generated On: 11 Aug 2021 22:05:35
PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:11:35
User entered '13 Aug 2020 11:59'	System	10 Aug 2020 17:47:41

US3232021

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 11 Aug 2021 22:05:35

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	05 Mar 2021 04:11:35
Data entry locked.	System	10 Aug 2020 17:47:41
User entered 'Day 4'	System	10 Aug 2020 17:47:41

US3232021
Folder: Diary Dose 1 (1)
Form: General_Day(4)
Generated On: 11 Aug 2021 22:05:35
HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	05 Mar 2021 04:11:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1179BDB4-134B-4DDE-B0FD-B886B117B21A)', Time: '2020-08-13T12:00:18', User OID: 'PatientReportedOutcome (US3232021)', ODM File OID: '99496f93-4c7d-4822-89f4-8d6ba50bb48d'	System	13 Aug 2020 17:00:39
User entered 'None (0)'	System	13 Aug 2020 17:00:39

US3232021
Folder: Diary Dose 1 (1)
Form: General_Day(4)
Generated On: 11 Aug 2021 22:05:35
FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	05 Mar 2021 04:11:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1179BDB4-134B-4DDE-B0FD-B886B117B21A)', Time: '2020-08-13T12:00:21', User OID: 'PatientReportedOutcome (US3232021)', ODM File OID: '99496f93-4c7d-4822-89f4-8d6ba50bb48d'	System	13 Aug 2020 17:00:39
User entered 'None (0)'	System	13 Aug 2020 17:00:39

US3232021
Folder: Diary Dose 1 (1)
Form: General_Day(4)
Generated On: 11 Aug 2021 22:05:35
MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	05 Mar 2021 04:11:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1179BDB4-134B-4DDE-B0FD-B886B117B21A)', Time: '2020-08-13T12:00:23', User OID: 'PatientReportedOutcome (US3232021)', ODM File OID: '99496f93-4c7d-4822-89f4-8d6ba50bb48d'	System	13 Aug 2020 17:00:39
User entered 'None (0)'	System	13 Aug 2020 17:00:39

US3232021
Folder: Diary Dose 1 (1)
Form: General_Day(4)
Generated On: 11 Aug 2021 22:05:35
JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	05 Mar 2021 04:11:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1179BDB4-134B-4DDE-B0FD-B886B117B21A)', Time: '2020-08-13T12:00:25', User OID: 'PatientReportedOutcome (US3232021)', ODM File OID: '99496f93-4c7d-4822-89f4-8d6ba50bb48d'	System	13 Aug 2020 17:00:39
User entered 'None (0)'	System	13 Aug 2020 17:00:39

US3232021
Folder: Diary Dose 1 (1)
Form: General_Day(4)
Generated On: 11 Aug 2021 22:05:35
NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	05 Mar 2021 04:11:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1179BDB4-134B-4DDE-B0FD-B886B117B21A)', Time: '2020-08-13T12:00:27', User OID: 'PatientReportedOutcome (US3232021)', ODM File OID: '99496f93-4c7d-4822-89f4-8d6ba50bb48d'	System	13 Aug 2020 17:00:39
User entered 'None (0)'	System	13 Aug 2020 17:00:39

US3232021
Folder: Diary Dose 1 (1)
Form: General_Day(4)
Generated On: 11 Aug 2021 22:05:35
CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	05 Mar 2021 04:11:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1179BDB4-134B-4DDE-B0FD-B886B117B21A)', Time: '2020-08-13T12:00:28', User OID: 'PatientReportedOutcome (US3232021)', ODM File OID: '99496f93-4c7d-4822-89f4-8d6ba50bb48d'	System	13 Aug 2020 17:00:39
User entered 'None (0)'	System	13 Aug 2020 17:00:39

US3232021

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 11 Aug 2021 22:05:35

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) (b) (4), (b) (6)	05 Mar 2021 04:11:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1179BDB4-134B-4DDE-B0FD-B886B117B21A)', Time: '2020-08-13T12:00:31', User OID: 'PatientReportedOutcome (US3232021)', ODM File OID: '99496f93-4c7d-4822-89f4-8d6ba50bb48d'	System	13 Aug 2020 17:00:39
User entered 'No (N)'	System	13 Aug 2020 17:00:39

US3232021

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 11 Aug 2021 22:05:35

PC Time stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:11:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1179BDB4-134B-4DDE-B0FD-B886B117B21A)', Time: '2020-08-13T12:00:34', User OID: 'PatientReportedOutcome (US3232021)', ODM File OID: '99496f93-4c7d-4822-89f4-8d6ba50bb48d'	System	13 Aug 2020 17:00:39
User entered '13 Aug 2020 12:00'	System	13 Aug 2020 17:00:39

US3232021
Folder: Diary Dose 1 (1)
Form: General_Day(4)
Generated On: 11 Aug 2021 22:05:35

PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:11:35
User entered '13 Aug 2020 12:00'	System	10 Aug 2020 17:47:41

US3232021
Folder: Diary Dose 1 (1)
Form: General_Day(4)
Generated On: 11 Aug 2021 22:05:35

PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	05 Mar 2021 04:11:35
User entered '14 Aug 2020 11:59'	System	10 Aug 2020 17:47:41

US3232021
Folder: Diary Dose 1 (1)
Form: General_Day(5)
Generated On: 11 Aug 2021 22:05:35
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	05 Mar 2021 04:11:35
Data entry locked.	System	10 Aug 2020 17:47:41
User entered 'Day 5'	System	10 Aug 2020 17:47:41

US3232021
Folder: Diary Dose 1 (1)
Form: General_Day(5)
Generated On: 11 Aug 2021 22:05:35
HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	05 Mar 2021 04:11:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1179BDB4-134B-4DDE-B0FD-B886B117B21A)', Time: '2020-08-14T20:59:44', User OID: 'PatientReportedOutcome (US3232021)', ODM File OID: '9f2cca32-6a75-4206-a2bf-e1bd57c4e912'	System	15 Aug 2020 02:00:13
User entered 'None (0)'	System	15 Aug 2020 02:00:13

US3232021
Folder: Diary Dose 1 (1)
Form: General_Day(5)
Generated On: 11 Aug 2021 22:05:35
FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	05 Mar 2021 04:11:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1179BDB4-134B-4DDE-B0FD-B886B117B21A)', Time: '2020-08-14T20:59:52', User OID: 'PatientReportedOutcome (US3232021)', ODM File OID: '9f2cca32-6a75-4206-a2bf-e1bd57c4e912'	System	15 Aug 2020 02:00:13
User entered 'None (0)'	System	15 Aug 2020 02:00:13

US3232021
Folder: Diary Dose 1 (1)
Form: General_Day(5)
Generated On: 11 Aug 2021 22:05:35

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	05 Mar 2021 04:11:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1179BDB4-134B-4DDE-B0FD-B886B117B21A)', Time: '2020-08-14T20:59:54', User OID: 'PatientReportedOutcome (US3232021)', ODM File OID: '9f2cca32-6a75-4206-a2bf-e1bd57c4e912'	System	15 Aug 2020 02:00:13
User entered 'None (0)'	System	15 Aug 2020 02:00:13

US3232021
Folder: Diary Dose 1 (1)
Form: General_Day(5)
Generated On: 11 Aug 2021 22:05:35
JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	05 Mar 2021 04:11:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1179BDB4-134B-4DDE-B0FD-B886B117B21A)', Time: '2020-08-14T20:59:56', User OID: 'PatientReportedOutcome (US3232021)', ODM File OID: '9f2cca32-6a75-4206-a2bf-e1bd57c4e912'	System	15 Aug 2020 02:00:13
User entered 'None (0)'	System	15 Aug 2020 02:00:13

US3232021
Folder: Diary Dose 1 (1)
Form: General_Day(5)
Generated On: 11 Aug 2021 22:05:35
NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	05 Mar 2021 04:11:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1179BDB4-134B-4DDE-B0FD-B886B117B21A)', Time: '2020-08-14T20:59:58', User OID: 'PatientReportedOutcome (US3232021)', ODM File OID: '9f2cca32-6a75-4206-a2bf-e1bd57c4e912'	System	15 Aug 2020 02:00:13
User entered 'None (0)'	System	15 Aug 2020 02:00:13

US3232021
Folder: Diary Dose 1 (1)
Form: General_Day(5)
Generated On: 11 Aug 2021 22:05:35
CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	05 Mar 2021 04:11:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1179BDB4-134B-4DDE-B0FD-B886B117B21A)', Time: '2020-08-14T21:00:01', User OID: 'PatientReportedOutcome (US3232021)', ODM File OID: '9f2cca32-6a75-4206-a2bf-e1bd57c4e912'	System	15 Aug 2020 02:00:13
User entered 'None (0)'	System	15 Aug 2020 02:00:13

US3232021

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 11 Aug 2021 22:05:35

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) (b) (4), (b) (6)	05 Mar 2021 04:11:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1179BDB4-134B-4DDE-B0FD-B886B117B21A)', Time: '2020-08-14T21:00:04', User OID: 'PatientReportedOutcome (US3232021)', ODM File OID: '9f2cca32-6a75-4206-a2bf-e1bd57c4e912'	System	15 Aug 2020 02:00:13
User entered 'No (N)'	System	15 Aug 2020 02:00:13

US3232021
Folder: Diary Dose 1 (1)
Form: General_Day(5)
Generated On: 11 Aug 2021 22:05:35
PC Time stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	05 Mar 2021 04:11:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1179BDB4-134B-4DDE-B0FD-B886B117B21A)', Time: '2020-08-14T21:00:07', User OID: 'PatientReportedOutcome (US3232021)', ODM File OID: '9f2cca32-6a75-4206-a2bf-e1bd57c4e912'	System	15 Aug 2020 02:00:13
User entered '14 Aug 2020 21:00'	System	15 Aug 2020 02:00:13

US3232021

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 11 Aug 2021 22:05:35

PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:11:35
	(b) (4), (b) (6)	
User entered '14 Aug 2020 12:00'	System	10 Aug 2020 17:47:41

US3232021

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 11 Aug 2021 22:05:35

PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	05 Mar 2021 04:11:35
User entered '15 Aug 2020 11:59'	System	10 Aug 2020 17:47:41

US3232021

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 11 Aug 2021 22:05:35

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	05 Mar 2021 04:11:35
Data entry locked.	System	10 Aug 2020 17:47:41
User entered 'Day 6'	System	10 Aug 2020 17:47:41

US3232021
Folder: Diary Dose 1 (1)
Form: General_Day(6)
Generated On: 11 Aug 2021 22:05:35

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	05 Mar 2021 04:11:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1179BDB4-134B-4DDE-B0FD-B886B117B21A)', Time: '2020-08-15T12:30:24', User OID: 'PatientReportedOutcome (US3232021)', ODM File OID: '01c40d0a-5803-49db-b87a-d06a7db9f088'	System	15 Aug 2020 17:30:43
User entered 'None (0)'	System	15 Aug 2020 17:30:43

US3232021
Folder: Diary Dose 1 (1)
Form: General_Day(6)
Generated On: 11 Aug 2021 22:05:35
FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	05 Mar 2021 04:11:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1179BDB4-134B-4DDE-B0FD-B886B117B21A)', Time: '2020-08-15T12:30:26', User OID: 'PatientReportedOutcome (US3232021)', ODM File OID: '01c40d0a-5803-49db-b87a-d06a7db9f088'	System	15 Aug 2020 17:30:43
User entered 'None (0)'	System	15 Aug 2020 17:30:43

US3232021
Folder: Diary Dose 1 (1)
Form: General_Day(6)
Generated On: 11 Aug 2021 22:05:35
MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	05 Mar 2021 04:11:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1179BDB4-134B-4DDE-B0FD-B886B117B21A)', Time: '2020-08-15T12:30:29', User OID: 'PatientReportedOutcome (US3232021)', ODM File OID: '01c40d0a-5803-49db-b87a-d06a7db9f088'	System	15 Aug 2020 17:30:43
User entered 'None (0)'	System	15 Aug 2020 17:30:43

US3232021
Folder: Diary Dose 1 (1)
Form: General_Day(6)
Generated On: 11 Aug 2021 22:05:35
JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	05 Mar 2021 04:11:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1179BDB4-134B-4DDE-B0FD-B886B117B21A)', Time: '2020-08-15T12:30:31', User OID: 'PatientReportedOutcome (US3232021)', ODM File OID: '01c40d0a-5803-49db-b87a-d06a7db9f088'	System	15 Aug 2020 17:30:43
User entered 'None (0)'	System	15 Aug 2020 17:30:43

US3232021
Folder: Diary Dose 1 (1)
Form: General_Day(6)
Generated On: 11 Aug 2021 22:05:35
NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	05 Mar 2021 04:11:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1179BDB4-134B-4DDE-B0FD-B886B117B21A)', Time: '2020-08-15T12:30:33', User OID: 'PatientReportedOutcome (US3232021)', ODM File OID: '01c40d0a-5803-49db-b87a-d06a7db9f088'	System	15 Aug 2020 17:30:43
User entered 'None (0)'	System	15 Aug 2020 17:30:43

US3232021
Folder: Diary Dose 1 (1)
Form: General_Day(6)
Generated On: 11 Aug 2021 22:05:35
CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	05 Mar 2021 04:11:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1179BDB4-134B-4DDE-B0FD-B886B117B21A)', Time: '2020-08-15T12:30:35', User OID: 'PatientReportedOutcome (US3232021)', ODM File OID: '01c40d0a-5803-49db-b87a-d06a7db9f088'	System	15 Aug 2020 17:30:43
User entered 'None (0)'	System	15 Aug 2020 17:30:43

US3232021

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 11 Aug 2021 22:05:35

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) (b) (4), (b) (6)	05 Mar 2021 04:11:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1179BDB4-134B-4DDE-B0FD-B886B117B21A)', Time: '2020-08-15T12:30:37', User OID: 'PatientReportedOutcome (US3232021)', ODM File OID: '01c40d0a-5803-49db-b87a-d06a7db9f088'	System	15 Aug 2020 17:30:43
User entered 'No (N)'	System	15 Aug 2020 17:30:43

US3232021

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 11 Aug 2021 22:05:35

PC Time stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	05 Mar 2021 04:11:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1179BDB4-134B-4DDE-B0FD-B886B117B21A)', Time: '2020-08-15T12:30:40', User OID: 'PatientReportedOutcome (US3232021)', ODM File OID: '01c40d0a-5803-49db-b87a-d06a7db9f088'	System	15 Aug 2020 17:30:43
User entered '15 Aug 2020 12:30'	System	15 Aug 2020 17:30:43

US3232021

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 11 Aug 2021 22:05:35

PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	05 Mar 2021 04:11:35
User entered '15 Aug 2020 12:00'	System	10 Aug 2020 17:47:41

US3232021
Folder: Diary Dose 1 (1)
Form: General_Day(6)
Generated On: 11 Aug 2021 22:05:35

PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	05 Mar 2021 04:11:35
User entered '16 Aug 2020 11:59'	System	10 Aug 2020 17:47:41

US3232021

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 11 Aug 2021 22:05:35

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	05 Mar 2021 04:11:35
Data entry locked.	System	10 Aug 2020 17:47:41
User entered 'Day 7'	System	10 Aug 2020 17:47:41

US3232021
Folder: Diary Dose 1 (1)
Form: General_Day(7)
Generated On: 11 Aug 2021 22:05:35
HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	05 Mar 2021 04:11:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1179BDB4-134B-4DDE-B0FD-B886B117B21A)', Time: '2020-08-16T22:32:12', User OID: 'PatientReportedOutcome (US3232021)', ODM File OID: 'bd5f3ca9-efa9-4a48-92d5-c1c7c7fb9924'	System	17 Aug 2020 03:32:30
User entered 'None (0)'	System	17 Aug 2020 03:32:30

US3232021
Folder: Diary Dose 1 (1)
Form: General_Day(7)
Generated On: 11 Aug 2021 22:05:35
FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	05 Mar 2021 04:11:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1179BDB4-134B-4DDE-B0FD-B886B117B21A)', Time: '2020-08-16T22:32:14', User OID: 'PatientReportedOutcome (US3232021)', ODM File OID: 'bd5f3ca9-efa9-4a48-92d5-c1c7c7fb9924'	System	17 Aug 2020 03:32:30
User entered 'None (0)'	System	17 Aug 2020 03:32:30

US3232021

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 11 Aug 2021 22:05:35

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	05 Mar 2021 04:11:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1179BDB4-134B-4DDE-B0FD-B886B117B21A)', Time: '2020-08-16T22:32:16', User OID: 'PatientReportedOutcome (US3232021)', ODM File OID: 'bd5f3ca9-efa9-4a48-92d5-c1c7c7fb9924'	System	17 Aug 2020 03:32:30
User entered 'None (0)'	System	17 Aug 2020 03:32:30

US3232021
Folder: Diary Dose 1 (1)
Form: General_Day(7)
Generated On: 11 Aug 2021 22:05:35
JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	05 Mar 2021 04:11:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1179BDB4-134B-4DDE-B0FD-B886B117B21A)', Time: '2020-08-16T22:32:18', User OID: 'PatientReportedOutcome (US3232021)', ODM File OID: 'bd5f3ca9-efa9-4a48-92d5-c1c7c7fb9924'	System	17 Aug 2020 03:32:30
User entered 'None (0)'	System	17 Aug 2020 03:32:30

US3232021
Folder: Diary Dose 1 (1)
Form: General_Day(7)
Generated On: 11 Aug 2021 22:05:35
NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	05 Mar 2021 04:11:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1179BDB4-134B-4DDE-B0FD-B886B117B21A)', Time: '2020-08-16T22:32:21', User OID: 'PatientReportedOutcome (US3232021)', ODM File OID: 'bd5f3ca9-efa9-4a48-92d5-c1c7c7fb9924'	System	17 Aug 2020 03:32:30
User entered 'None (0)'	System	17 Aug 2020 03:32:30

US3232021
Folder: Diary Dose 1 (1)
Form: General_Day(7)
Generated On: 11 Aug 2021 22:05:35
CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	05 Mar 2021 04:11:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1179BDB4-134B-4DDE-B0FD-B886B117B21A)', Time: '2020-08-16T22:32:22', User OID: 'PatientReportedOutcome (US3232021)', ODM File OID: 'bd5f3ca9-efa9-4a48-92d5-c1c7c7fb9924'	System	17 Aug 2020 03:32:30
User entered 'None (0)'	System	17 Aug 2020 03:32:30

US3232021

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 11 Aug 2021 22:05:35

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) (b) (4), (b) (6)	05 Mar 2021 04:11:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1179BDB4-134B-4DDE-B0FD-B886B117B21A)', Time: '2020-08-16T22:32:25', User OID: 'PatientReportedOutcome (US3232021)', ODM File OID: 'bd5f3ca9-efa9-4a48-92d5-c1c7c7fb9924'	System	17 Aug 2020 03:32:30
User entered 'No (N)'	System	17 Aug 2020 03:32:30

FDA-CBER-2022-1614-0646393

US3232021

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 11 Aug 2021 22:05:35

PC Time stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	05 Mar 2021 04:11:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1179BDB4-134B-4DDE-B0FD-B886B117B21A)', Time: '2020-08-16T22:32:27', User OID: 'PatientReportedOutcome (US3232021)', ODM File OID: 'bd5f3ca9-efa9-4a48-92d5-c1c7c7fb9924'	System	17 Aug 2020 03:32:30
User entered '16 Aug 2020 22:32'	System	17 Aug 2020 03:32:30

PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:11:35
User entered '16 Aug 2020 12:00'	System	10 Aug 2020 17:47:41

US3232021
Folder: Diary Dose 1 (1)
Form: General_Day(7)
Generated On: 11 Aug 2021 22:05:35
PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	05 Mar 2021 04:11:35
User entered '17 Aug 2020 11:59'	System	10 Aug 2020 17:47:41

Was Contact Attempted?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	03 Apr 2021 15:39:42
User signature succeeded.	Rambod Rouhbakhsh (b) (4)	18 Feb 2021 15:31:39
User entered 'Yes (Y)'	Jerrica Sullivan (b) (4) (b) (4)	18 Aug 2020 18:35:28

US3232021

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:05:35

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	03 Apr 2021 15:39:42
User signature succeeded.	Rambod Rouhbakhsh (b) (4)	18 Feb 2021 15:31:39
User entered '17 Aug 2020'	Jerrica Sullivan (b) (4) (b) (4)	18 Aug 2020 18:35:28

Please select one status for the follow-up contact

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	03 Apr 2021 15:39:42
User signature succeeded.	Rambod Rouhbakhsh (b) (4)	18 Feb 2021 15:31:39
User entered 'Contact Made (CONTACT MADE)'	Jerrica Sullivan (b) (4) (b) (4)	18 Aug 2020 18:35:28

FDA-CBER-2022-1614-0646399

US3232021

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:05:35

Comments

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	03 Apr 2021 15:39:42
User signature succeeded.	Rambod Rouhbakhsh (b) (4)	18 Feb 2021 15:31:39
User entered empty.	Jerrica Sullivan (b) (4) (b) (4)	18 Aug 2020 18:35:28

US3232021

Folder: Safety Call Day 8 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:05:35

Is the participant continuing to the next visit?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	03 Apr 2021 15:39:42
User signature succeeded.	Rambod Rouhbakhsh (b) (4)	18 Feb 2021 15:31:39
User entered 'Yes (Y)'	Jerrica Sullivan (b) (4) (b) (4)	18 Aug 2020 18:36:00

US3232021
Folder: Safety Call Day 8 (1)
Form: Continuing
Generated On: 11 Aug 2021 22:05:35
Continuing Flag

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:39:42
User entered '1'	(b) (4), (b) (6) System	18 Aug 2020 18:36:00

US3232021

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:05:35

Was Contact Attempted?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	03 Apr 2021 15:39:42
User signature succeeded.	Rambod Rouhbakhsh (b) (4)	18 Feb 2021 15:31:39
User entered 'Yes (Y)'	Jerrica Sullivan (b) (4) (b) (4)	31 Aug 2020 20:30:23

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	03 Apr 2021 15:39:42
User signature succeeded.	Rambod Rouhbakhsh (b) (4)	18 Feb 2021 15:31:39
User entered '25 Aug 2020'	Jerrica Sullivan (b) (4) (b) (4)	31 Aug 2020 20:30:23

FDA-CBER-2022-1614-0646404

US3232021
Folder: Safety Call Day 15 (1)
Form: Safety Call
Generated On: 11 Aug 2021 22:05:35
Please select one status for the follow-up contact

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	03 Apr 2021 15:39:42
User signature succeeded.	Rambod Rouhbakhsh (b) (4)	18 Feb 2021 15:31:39
User entered 'Contact Made (CONTACT MADE)'	Jerrica Sullivan (b) (4) (b) (4)	31 Aug 2020 20:30:23

US3232021
Folder: Safety Call Day 15 (1)
Form: Safety Call
Generated On: 11 Aug 2021 22:05:35
Comments

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:39:42
User signature succeeded.	(b) (4), (b) (6) Rambod Rouhbakhsh (b) (4)	18 Feb 2021 15:31:39
User entered empty.	Jerrica Sullivan (b) (4) (b) (4)	31 Aug 2020 20:30:23

US3232021
Folder: Safety Call Day 15 (1)
Form: Continuing
Generated On: 11 Aug 2021 22:05:35

Is the participant continuing to the next visit?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	03 Apr 2021 15:39:42
User signature succeeded.	Rambod Rouhbakhsh (b) (4)	18 Feb 2021 15:31:39
User entered 'Yes (Y)'	Jerrica Sullivan (b) (4) (b) (4)	31 Aug 2020 20:30:30

US3232021
Folder: Safety Call Day 15 (1)
Form: Continuing
Generated On: 11 Aug 2021 22:05:35
Continuing Flag

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	03 Apr 2021 15:39:42
User entered '1'	System	31 Aug 2020 20:30:30

US3232021
Folder: Safety Call Day 22 (1)
Form: Safety Call
Generated On: 11 Aug 2021 22:05:35

Was Contact Attempted?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	30 Apr 2021 04:30:44
User signature succeeded.	Rambod Rouhbakhsh (b) (4)	18 Feb 2021 15:31:39
User entered 'Yes (Y)'	Jerrica Sullivan (b) (4) (b) (4)	31 Aug 2020 20:30:42

US3232021

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:05:35

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 04:30:44
User signature succeeded.	(b) (4), (b) (6) Rambod Rouhbakhsh (b) (4)	18 Feb 2021 15:31:39
User entered '31 Aug 2020'	Jerrica Sullivan (b) (4) (b) (4)	31 Aug 2020 20:30:42

US3232021

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:05:35

Please select one status for the follow-up contact

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 04:30:44
User signature succeeded.	(b) (4), (b) (6) Rambod Rouhbakhsh	18 Feb 2021 15:31:39
User entered 'Contact Made (CONTACT MADE)'	(b) (4) Jerrica Sullivan (b) (4) (b) (4)	31 Aug 2020 20:30:42

US3232021
Folder: Safety Call Day 22 (1)
Form: Safety Call
Generated On: 11 Aug 2021 22:05:35
Comments

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	30 Apr 2021 04:30:44
User signature succeeded.	Rambod Rouhbakhsh (b) (4)	18 Feb 2021 15:31:39
User entered empty.	Jerrica Sullivan (b) (4) (b) (4)	31 Aug 2020 20:30:42

US3232021

Folder: Safety Call Day 22 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:05:35

Is the participant continuing to the next visit?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 04:30:44
User signature succeeded.	(b) (4), (b) (6) Rambod Rouhbakhsh (b) (4)	18 Feb 2021 15:31:39
User entered 'Yes (Y)'	Jerrica Sullivan (b) (4) (b) (4)	31 Aug 2020 20:30:59

US3232021
Folder: Safety Call Day 22 (1)
Form: Continuing
Generated On: 11 Aug 2021 22:05:35
Continuing Flag

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	30 Apr 2021 04:30:44
User entered '1'	System	31 Aug 2020 20:30:59

Was this visit performed?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	30 Apr 2021 08:05:18
User signature succeeded.	Rambod Rouhbakhsh (b) (4)	18 Feb 2021 15:31:39
User entered 'Yes (Y)'	(b) (4), (b) (6) (b) (4), (b) (6)	16 Sep 2020 18:37:31

US3232021
Folder: Visit 2 Day 29 (1)
Form: Visit Date
Generated On: 11 Aug 2021 22:05:35

Visit date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	30 Apr 2021 08:05:18
User closed query 'Visit Date is after Date of study discontinuation/completion. Please reconcile.' (Site from System).	System	30 Mar 2021 13:34:08
User opened query 'Visit Date is after Date of study discontinuation/completion. Please reconcile.' (Site from System).	System	30 Mar 2021 12:50:53
User signature succeeded.	Rambod Rouhbakhsh (b) (4)	18 Feb 2021 15:31:39
User entered '11 Sep 2020'	(b) (4), (b) (6) (b) (4), (b) (6)	16 Sep 2020 18:37:31

US3232021

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 11 Aug 2021 22:05:35

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	30 Apr 2021 08:05:18
User signature succeeded.	Rambod Rouhbakhsh (b) (4)	18 Feb 2021 15:31:39
User entered 'Clinic (Clinic)'	(b) (4), (b) (6) (b) (4), (b) (6)	16 Sep 2020 18:37:31

US3232021
Folder: Visit 2 Day 29 (1)
Form: Visit Date
Generated On: 11 Aug 2021 22:05:35
Folder OID

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:05:18
	(b) (4), (b) (6)	
User entered 'VISIT2'	System	16 Sep 2020 18:37:31

US3232021
Folder: Visit 2 Day 29 (1)
Form: Vital Signs - Dosing (1)
Generated On: 11 Aug 2021 22:05:35

Timepoint

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	30 Apr 2021 08:05:18
User accepted default value 'Pre-Dose (PREDOSE)'	(b) (4), (b) (6) (b) (4), (b) (6)	16 Sep 2020 18:39:17

US3232021

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:05:35

Were vital signs assessed?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	30 Apr 2021 08:05:18
User signature succeeded.	Rambod Rouhbakhsh (b) (4)	18 Feb 2021 15:31:39
User entered 'Yes (Y)'	(b) (4), (b) (6) (b) (4), (b) (6)	16 Sep 2020 18:39:17

US3232021

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:05:35

Date of assessment *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	30 Apr 2021 08:05:18
User closed query 'Date of Assessment is after Assessment Date of study discontinuation/completion on the End of Study/Study Discontinuation form. Please review and provide any needed correction.' (Site from System).	System	30 Mar 2021 13:34:08
User opened query 'Date of Assessment is after Assessment Date of study discontinuation/completion on the End of Study/Study Discontinuation form. Please review and provide any needed correction.' (Site from System).	System	30 Mar 2021 12:50:53
User signature succeeded.	Rambod Rouhbakhsh (b) (4)	18 Feb 2021 15:31:39
User entered '11 Sep 2020'	(b) (4), (b) (6) (b) (4), (b) (6)	16 Sep 2020 18:39:17

US3232021

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:05:35

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	30 Apr 2021 08:05:18
User signature succeeded.	Rambod Rouhbakhsh (b) (4)	18 Feb 2021 15:31:39
User entered '12:18'	(b) (4), (b) (6) (b) (4), (b) (6)	16 Sep 2020 18:39:17

US3232021

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:05:35

Vital Signs Date and Time (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	30 Apr 2021 08:05:18
User entered '11 Sep 2020 12:18'	System	16 Sep 2020 18:39:17

US3232021

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:05:35

Temperature *(xxx.x)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	30 Apr 2021 08:05:18
User signature succeeded.	Rambod Rouhbakhsh (b) (4)	18 Feb 2021 15:31:39
User entered '98.5' F	(b) (4), (b) (6) (b) (4), (b) (6)	16 Sep 2020 18:39:17

US3232021

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:05:35

Route of measurement

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	30 Apr 2021 08:05:18
User signature succeeded.	Rambod Rouhbakhsh (b) (4)	18 Feb 2021 15:31:39
User entered 'Oral (Oral)'	(b) (4), (b) (6) (b) (4), (b) (6)	16 Sep 2020 18:39:17

US3232021
Folder: Visit 2 Day 29 (1)
Form: Vital Signs - Dosing (1)
Generated On: 11 Aug 2021 22:05:35
If Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	30 Apr 2021 08:05:18
User signature succeeded.	Rambod Rouhbakhsh (b) (4)	18 Feb 2021 15:31:39
User entered empty.	(b) (4), (b) (6) (b) (4), (b) (6)	16 Sep 2020 18:39:17

US3232021

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:05:35

Pulse *(xxx)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	30 Apr 2021 08:05:18
User signature succeeded.	Rambod Rouhbakhsh (b) (4)	18 Feb 2021 15:31:39
User entered '65'	(b) (4), (b) (6) (b) (4), (b) (6)	16 Sep 2020 18:39:17

US3232021
Folder: Visit 2 Day 29 (1)
Form: Vital Signs - Dosing (1)
Generated On: 11 Aug 2021 22:05:35
Pulse units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	30 Apr 2021 08:05:18
User entered 'bpm'	System	16 Sep 2020 18:39:17

US3232021

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:05:35

Respiratory Rate *(xxx)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	30 Apr 2021 08:05:18
User signature succeeded.	Rambod Rouhbakhsh (b) (4)	18 Feb 2021 15:31:39
User closed query 'Data is required. Please provide.' (Site from System).	System	29 Oct 2020 15:19:26
Query 'Data is required. Please provide.' answered by data change (Site from System).	System	29 Oct 2020 15:19:26
User entered '20' reason for change: Data Entry Error	Jerrica Sullivan (b) (4) (b) (4)	29 Oct 2020 15:19:26
User opened query 'Data is required. Please provide.' (Site from System).	System	16 Sep 2020 18:39:17
User entered empty.	(b) (4), (b) (6) (b) (4), (b) (6)	16 Sep 2020 18:39:17

Respiratory Rate units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	30 Apr 2021 08:05:18
User entered 'breaths/min'	System	29 Oct 2020 15:19:26
User entered empty.	System	16 Sep 2020 18:39:17

Systolic Blood Pressure *(xxx)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	30 Apr 2021 08:05:18
User signature succeeded.	Rambod Rouhbakhsh (b) (4)	18 Feb 2021 15:31:39
User entered '130'	(b) (4), (b) (6) (b) (4), (b) (6)	16 Sep 2020 18:39:17

FDA-CBER-2022-1614-0646431

US3232021

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:05:35

Systolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	30 Apr 2021 08:05:18
User entered 'mmHg'	System	16 Sep 2020 18:39:17

Diastolic Blood Pressure *(xxx)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	30 Apr 2021 08:05:18
User signature succeeded.	Rambod Rouhbakhsh (b) (4)	18 Feb 2021 15:31:39
User entered '63'	(b) (4), (b) (6) (b) (4), (b) (6)	16 Sep 2020 18:39:17

FDA-CBER-2022-1614-0646433

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:05:35

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	30 Apr 2021 08:05:18
User entered 'mmHg'	System	16 Sep 2020 18:39:17

US3232021
Folder: Visit 2 Day 29 (1)
Form: Vital Signs - Dosing (2)
Generated On: 11 Aug 2021 22:05:35
Timepoint

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	30 Apr 2021 08:05:18
User accepted default value 'Post-Dose (POSTDOSE)'	(b) (4), (b) (6) (b) (4), (b) (6)	16 Sep 2020 18:39:17

US3232021

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:05:35

Were vital signs assessed?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	30 Apr 2021 08:05:18
User signature succeeded.	Rambod Rouhbakhsh (b) (4)	18 Feb 2021 15:31:39
User entered 'No (N)'	(b) (4), (b) (6) (b) (4), (b) (6)	16 Sep 2020 18:39:17

Date of assessment *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	30 Apr 2021 08:05:18
User signature succeeded.	Rambod Rouhbakhsh (b) (4)	18 Feb 2021 15:31:39
User entered empty.	(b) (4), (b) (6) (b) (4), (b) (6)	16 Sep 2020 18:39:17

US3232021

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:05:35

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	30 Apr 2021 08:05:18
User signature succeeded.	Rambod Rouhbakhsh (b) (4)	18 Feb 2021 15:31:39
User entered empty.	(b) (4), (b) (6) (b) (4), (b) (6)	16 Sep 2020 18:39:17

US3232021

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:05:35

Vital Signs Date and Time (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	30 Apr 2021 08:05:18
User entered empty.	System	16 Sep 2020 18:39:17

Temperature *(xxx.x)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	30 Apr 2021 08:05:18
User signature succeeded.	Rambod Rouhbakhsh (b) (4)	18 Feb 2021 15:31:39
User entered empty.	(b) (4), (b) (6) (b) (4), (b) (6)	16 Sep 2020 18:39:17

FDA-CBER-2022-1614-0646440

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:05:35

Route of measurement

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	30 Apr 2021 08:05:18
User signature succeeded.	Rambod Rouhbakhsh (b) (4)	18 Feb 2021 15:31:39
User entered empty.	(b) (4), (b) (6) (b) (4), (b) (6)	16 Sep 2020 18:39:17

US3232021

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:05:35

If Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	30 Apr 2021 08:05:18
User signature succeeded.	Rambod Rouhbakhsh (b) (4)	18 Feb 2021 15:31:39
User entered empty.	(b) (4), (b) (6) (b) (4), (b) (6)	16 Sep 2020 18:39:17

Pulse *(xxx)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	30 Apr 2021 08:05:18
User signature succeeded.	Rambod Rouhbakhsh (b) (4)	18 Feb 2021 15:31:39
User entered empty.	(b) (4), (b) (6) (b) (4), (b) (6)	16 Sep 2020 18:39:17

FDA-CBER-2022-1614-0646443

US3232021
Folder: Visit 2 Day 29 (1)
Form: Vital Signs - Dosing (2)
Generated On: 11 Aug 2021 22:05:35
Pulse units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	30 Apr 2021 08:05:18
User entered empty.	System	16 Sep 2020 18:39:17

US3232021

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:05:35

Respiratory Rate *(xxx)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	30 Apr 2021 08:05:18
User signature succeeded.	Rambod Rouhbakhsh (b) (4)	18 Feb 2021 15:31:39
User entered empty.	(b) (4), (b) (6) (b) (4), (b) (6)	16 Sep 2020 18:39:17

Respiratory Rate units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	30 Apr 2021 08:05:18
User entered empty.	System	16 Sep 2020 18:39:17

Systolic Blood Pressure *(xxx)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	30 Apr 2021 08:05:18
User signature succeeded.	Rambod Rouhbakhsh (b) (4)	18 Feb 2021 15:31:39
User entered empty.	(b) (4), (b) (6) (b) (4), (b) (6)	16 Sep 2020 18:39:17

FDA-CBER-2022-1614-0646447

US3232021
Folder: Visit 2 Day 29 (1)
Form: Vital Signs - Dosing (2)
Generated On: 11 Aug 2021 22:05:35
Systolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	30 Apr 2021 08:05:18
User entered empty.	System	16 Sep 2020 18:39:17

Diastolic Blood Pressure *(xxx)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	30 Apr 2021 08:05:18
User signature succeeded.	Rambod Rouhbakhsh (b) (4)	18 Feb 2021 15:31:39
User entered empty.	(b) (4), (b) (6) (b) (4), (b) (6)	16 Sep 2020 18:39:17

US3232021

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:05:35

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	30 Apr 2021 08:05:18
User entered empty.	System	16 Sep 2020 18:39:17

Folder: Visit 2 Day 29 (1)
Form: Physical Examination
Generated On: 11 Aug 2021 22:05:35

Was the physical examination performed?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	30 Apr 2021 08:05:18
User signature succeeded.	Rambod Rouhbakhsh (b) (4)	18 Feb 2021 15:31:39
User entered 'Yes (Y)'	(b) (4), (b) (6) (b) (4), (b) (6)	16 Sep 2020 18:39:32

US3232021

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Generated On: 11 Aug 2021 22:05:35

Date of examination *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	30 Apr 2021 08:05:18
User closed query 'The Physical Examination Date is greater than Date of study discontinuation/completion. Please review and reconcile.' (Site from System).	System	30 Mar 2021 13:34:08
User opened query 'The Physical Examination Date is greater than Date of study discontinuation/completion. Please review and reconcile.' (Site from System).	System	30 Mar 2021 12:50:53
User signature succeeded.	Rambod Rouhbakhsh (b) (4)	18 Feb 2021 15:31:39
User entered '11 Sep 2020'	(b) (4), (b) (6) (b) (4), (b) (6)	16 Sep 2020 18:39:32

US3232021
Folder: Visit 2 Day 29 (1)
Form: Pregnancy Test
Generated On: 11 Aug 2021 22:05:35
Was the pregnancy test performed?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	30 Apr 2021 08:05:18
User signature succeeded.	Rambod Rouhbakhsh (b) (4)	18 Feb 2021 15:31:39
User closed query 'Per CDM: Childbearing potential noted as "yes" yet pregnancy test not completed. Kindly review and update else clarify."' (Site from DM).	(b) (4), (b) (6) (b) (4), (b) (6)	11 Nov 2020 16:02:16
Query 'Per CDM: Childbearing potential noted as "yes" yet pregnancy test not completed. Kindly revie and update else clarify."' answered with 'visit 2 was note for a second dose it was only for a physical and letting the subject know she was excluded. no pregnancy test taken ' (Site from DM).	(b) (4), (b) (6) (b) (4), (b) (6)	29 Oct 2020 14:10:49
User opened query 'Per CDM: Childbearing potential noted as "yes" yet pregnancy test not completed. Kindly review and update else clarify."' (Site from DM).	(b) (4), (b) (6) (b) (4), (b) (6)	09 Oct 2020 14:11:10
User entered 'No (N)'	(b) (4), (b) (6) (b) (4), (b) (6)	16 Sep 2020 18:39:46

US3232021
Folder: Visit 2 Day 29 (1)
Form: Pregnancy Test
Generated On: 11 Aug 2021 22:05:35

Date of test *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	30 Apr 2021 08:05:18
User signature succeeded.	Rambod Rouhbakhsh (b) (4)	18 Feb 2021 15:31:39
User entered empty.	(b) (4), (b) (6) (b) (4), (b) (6)	16 Sep 2020 18:39:46

US3232021

Folder: Visit 2 Day 29 (1)

Form: Pregnancy Test

Generated On: 11 Aug 2021 22:05:35

Test performed

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	30 Apr 2021 08:05:18
User signature succeeded.	Rambod Rouhbakhsh (b) (4)	18 Feb 2021 15:31:39
User entered empty.	(b) (4), (b) (6) (b) (4), (b) (6)	16 Sep 2020 18:39:46

US3232021

Folder: Visit 2 Day 29 (1)

Form: Pregnancy Test

Generated On: 11 Aug 2021 22:05:35

Result

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	30 Apr 2021 08:05:18
User signature succeeded.	Rambod Rouhbakhsh (b) (4)	18 Feb 2021 15:31:39
User entered empty.	(b) (4), (b) (6) (b) (4), (b) (6)	16 Sep 2020 18:39:46

US3232021

Folder: Visit 2 Day 29 (1)

Form: Pregnancy Test

Generated On: 11 Aug 2021 22:05:35

Was FSH sample collected?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	30 Apr 2021 08:05:18
User signature succeeded.	Rambod Rouhbakhsh (b) (4)	18 Feb 2021 15:31:39
User closed query 'Per CDM: Please provide response to ' Was FSH sample collected?' (Yes/No). If 'Yes' then record FSH collection date/time. ' (Site from DM).	(b) (4), (b) (6) (b) (4), (b) (6)	09 Oct 2020 14:11:36
Query 'Per CDM: Please provide response to ' Was FSH sample collected?' (Yes/No). If 'Yes' then record FSH collection date/time. ' answered with 'updated per query resolution ' (Site from DM).	(b) (4), (b) (6) (b) (4), (b) (6)	29 Sep 2020 13:07:14
User entered 'No (N)' reason for change: Data Entry Error	(b) (4), (b) (6) (b) (4), (b) (6)	29 Sep 2020 13:06:59
User opened query 'Per CDM: Please provide response to ' Was FSH sample collected?' (Yes/No). If 'Yes' then record FSH collection date/time. ' (Site from DM).	(b) (4), (b) (6) (b) (4), (b) (6)	23 Sep 2020 15:16:58
User entered empty.	(b) (4), (b) (6) (b) (4), (b) (6)	16 Sep 2020 18:39:46

US3232021

Folder: Visit 2 Day 29 (1)

Form: Pregnancy Test

Generated On: 11 Aug 2021 22:05:35

Collection date

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	30 Apr 2021 08:05:18
User signature succeeded.	Rambod Rouhbakhsh (b) (4)	18 Feb 2021 15:31:39
User entered empty.	(b) (4), (b) (6) (b) (4), (b) (6)	16 Sep 2020 18:39:46

US3232021

Folder: Visit 2 Day 29 (1)

Form: Pregnancy Test

Generated On: 11 Aug 2021 22:05:35

Collection time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	30 Apr 2021 08:05:18
User signature succeeded.	Rambod Rouhbakhsh (b) (4)	18 Feb 2021 15:31:39
User entered empty.	(b) (4), (b) (6) (b) (4), (b) (6)	16 Sep 2020 18:39:46

US3232021
Folder: Visit 2 Day 29 (1)
Form: Pregnancy Test
Generated On: 11 Aug 2021 22:05:35
Collection date and time (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	30 Apr 2021 08:05:18
User entered empty.	System	16 Sep 2020 18:39:46

US3232021

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 11 Aug 2021 22:05:35

Was study treatment given?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	30 Apr 2021 08:05:18
User signature succeeded.	Rambod Rouhbakhsh (b) (4)	18 Feb 2021 15:31:39
User entered 'No (N)'	(b) (4), (b) (6) (b) (4), (b) (6)	16 Sep 2020 18:42:19

US3232021

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 11 Aug 2021 22:05:35

If No, reason not given

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:05:18
User signature succeeded.	(b) (4), (b) (6) Rambod Rouhbakhsh	18 Feb 2021 15:31:39
User closed query 'Per CDM: Please update AE form. ' (Site from DM).	(b) (4) (b) (4), (b) (6)	13 Oct 2020 09:03:07
Query 'Per CDM: Please update AE form. ' answered with 'updated' (Site from DM).	(b) (4), (b) (6) (b) (4), (b) (6)	29 Sep 2020 14:13:42
User opened query 'Per CDM: Please update AE form. ' (Site from DM).	(b) (4), (b) (6) (b) (4), (b) (6)	28 Sep 2020 21:26:18
User entered 'Participant declined due to Adverse Event (ADVERSE EVENT)'	(b) (4), (b) (6) (b) (4), (b) (6)	16 Sep 2020 18:42:19

US3232021

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 11 Aug 2021 22:05:35

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)	30 Apr 2021 08:05:18
	(b) (4), (b) (6)	
User signature succeeded.	Rambod Rouhbakhsh	18 Feb 2021 15:31:39
	(b) (4)	
User entered empty.	(b) (4), (b) (6)	16 Sep 2020 18:42:19
	(b) (4), (b) (6)	

What was the study treatment?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	30 Apr 2021 08:05:18
User entered empty.	System	16 Sep 2020 18:42:19

FDA-CBER-2022-1614-0646464

Folder: Visit 2 Day 29 (1)
Form: Exposure
Generated On: 11 Aug 2021 22:05:35

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	30 Apr 2021 08:05:18
User signature succeeded.	Rambod Rouhbakhsh (b) (4)	18 Feb 2021 15:31:39
User entered empty.	(b) (4), (b) (6) (b) (4), (b) (6)	16 Sep 2020 18:42:19

Folder: Visit 2 Day 29 (1)
Form: Exposure
Generated On: 11 Aug 2021 22:05:35

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	30 Apr 2021 08:05:18
User signature succeeded.	Rambod Rouhbakhsh (b) (4)	18 Feb 2021 15:31:39
User entered empty.	(b) (4), (b) (6) (b) (4), (b) (6)	16 Sep 2020 18:42:19

US3232021
Folder: Visit 2 Day 29 (1)
Form: Exposure
Generated On: 11 Aug 2021 22:05:35
Treatment Date and Time (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	30 Apr 2021 08:05:18
User entered empty.	System	16 Sep 2020 18:42:19

US3232021
Folder: Visit 2 Day 29 (1)
Form: Exposure
Generated On: 11 Aug 2021 22:05:35
Which arm was used to give treatment?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	30 Apr 2021 08:05:18
User signature succeeded.	Rambod Rouhbakhsh (b) (4)	18 Feb 2021 15:31:39
User entered empty.	(b) (4), (b) (6) (b) (4), (b) (6)	16 Sep 2020 18:42:19

US3232021
Folder: Visit 2 Day 29 (1)
Form: Exposure
Generated On: 11 Aug 2021 22:05:35
What was the frequency of the study treatment dosing?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:05:18
	(b) (4), (b) (6)	
User entered empty.	System	16 Sep 2020 18:42:19

What was the route of administration for the study treatment?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	30 Apr 2021 08:05:18
User entered empty.	System	16 Sep 2020 18:42:19

FDA-CBER-2022-1614-0646470

US3232021

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 22:05:35

Was the sample collected?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	30 Apr 2021 08:05:18
User signature succeeded.	Rambod Rouhbakhsh (b) (4)	18 Feb 2021 15:31:39
User entered 'Yes (Y)'	(b) (4), (b) (6) (b) (4), (b) (6)	16 Sep 2020 18:42:28

US3232021

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 22:05:35

Collection date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	30 Apr 2021 08:05:18
User closed query 'The Collection Date is greater than the Date of study discontinuation/completion. Please review and reconcile.' (Site from System).	System	30 Mar 2021 13:34:08
User opened query 'The Collection Date is greater than the Date of study discontinuation/completion. Please review and reconcile.' (Site from System).	System	30 Mar 2021 12:50:53
User signature succeeded.	Rambod Rouhbakhsh (b) (4)	18 Feb 2021 15:31:39
User closed query 'Data is required. Please provide.' (Site from System).	System	07 Oct 2020 20:57:10
User entered '11 Sep 2020' reason for change: Data Entry Error	(b) (4), (b) (6) (b) (4), (b) (6)	07 Oct 2020 20:57:10
User opened query 'Data is required. Please provide.' (Site from System).	System	16 Sep 2020 18:42:28
User entered empty.	(b) (4), (b) (6) (b) (4), (b) (6)	16 Sep 2020 18:42:28

US3232021

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 22:05:35

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	30 Apr 2021 08:05:18
User signature succeeded.	Rambod Rouhbakhsh (b) (4)	18 Feb 2021 15:31:39
User closed query 'Data is required. Please provide.' (Site from System).	System	07 Oct 2020 20:57:10
User entered '12:20' reason for change: Data Entry Error	(b) (4), (b) (6) (b) (4), (b) (6)	07 Oct 2020 20:57:10
User opened query 'Data is required. Please provide.' (Site from System).	System	16 Sep 2020 18:42:28
User entered empty.	(b) (4), (b) (6) (b) (4), (b) (6)	16 Sep 2020 18:42:28

Collection date and time (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	30 Apr 2021 08:05:18
User entered '11 Sep 2020 12:20'	System	07 Oct 2020 20:57:10
User entered empty.	System	16 Sep 2020 18:42:28

US3232021

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab

Generated On: 11 Aug 2021 22:05:35

Collection date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	30 Apr 2021 08:05:18
User closed query 'Collection Date is after Assessment Date of study discontinuation/completion on the End of Study/Study Discontinuation form. Please review and provide any needed correction.' (Site from System).	System	30 Mar 2021 13:34:08
User opened query 'Collection Date is after Assessment Date of study discontinuation/completion on the End of Study/Study Discontinuation form. Please review and provide any needed correction.' (Site from System).	System	30 Mar 2021 12:50:53
User signature succeeded.	Rambod Rouhbakhsh (b) (4)	18 Feb 2021 15:31:39
User entered '11 Sep 2020'	(b) (4), (b) (6) (b) (4), (b) (6)	16 Sep 2020 18:42:54

US3232021

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 11 Aug 2021 22:05:35

Lab Test

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	30 Apr 2021 08:05:18
User accepted default value 'Nasopharyngeal Swab 1 (NASAL1)'	(b) (4), (b) (6) (b) (4), (b) (6)	16 Sep 2020 18:42:54

US3232021

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 11 Aug 2021 22:05:35

Was the sample collected?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	30 Apr 2021 08:05:18
User signature succeeded.	Rambod Rouhbakhsh (b) (4)	18 Feb 2021 15:31:39
User entered 'Yes (Y)'	(b) (4), (b) (6) (b) (4), (b) (6)	16 Sep 2020 18:42:54

US3232021

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 11 Aug 2021 22:05:35

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	30 Apr 2021 08:05:18
User signature succeeded.	Rambod Rouhbakhsh (b) (4)	18 Feb 2021 15:31:39
User entered '12:18'	(b) (4), (b) (6) (b) (4), (b) (6)	16 Sep 2020 18:42:54

Collection date and time (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	30 Apr 2021 08:05:18
User entered '11 Sep 2020 12:18'	System	16 Sep 2020 18:42:54

US3232021

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 11 Aug 2021 22:05:35

Lab Test

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	30 Apr 2021 08:05:18
User accepted default value 'Nasopharyngeal Swab 2 (NASAL2)'	(b) (4), (b) (6) (b) (4), (b) (6)	16 Sep 2020 18:42:54

US3232021

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 11 Aug 2021 22:05:35

Was the sample collected?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	30 Apr 2021 08:05:18
User signature succeeded.	Rambod Rouhbakhsh (b) (4)	18 Feb 2021 15:31:39
User entered 'No (N)'	(b) (4), (b) (6) (b) (4), (b) (6)	16 Sep 2020 18:42:54

US3232021

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 11 Aug 2021 22:05:35

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	30 Apr 2021 08:05:18
User signature succeeded.	Rambod Rouhbakhsh (b) (4)	18 Feb 2021 15:31:39
User entered empty.	(b) (4), (b) (6) (b) (4), (b) (6)	16 Sep 2020 18:42:54

US3232021

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 11 Aug 2021 22:05:35

Collection date and time (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	30 Apr 2021 08:05:18
User entered empty.	System	16 Sep 2020 18:42:54

US3232021

Folder: Visit 2 Day 29 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:05:35

Is the participant continuing to the next visit?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	30 Apr 2021 08:05:18
User signature succeeded.	Rambod Rouhbakhsh (b) (4)	18 Feb 2021 15:31:39
User entered 'Yes (Y)' reason for change: Data Entry Error	Jerrica Sullivan (b) (4) (b) (4)	22 Sep 2020 14:34:05
User entered 'No (N)'	(b) (4), (b) (6) (b) (4), (b) (6)	16 Sep 2020 18:42:59

US3232021
Folder: Visit 2 Day 29 (1)
Form: Continuing
Generated On: 11 Aug 2021 22:05:35
Continuing Flag

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	30 Apr 2021 08:05:18
User entered '1'	System	22 Sep 2020 14:34:05
User entered empty.	System	16 Sep 2020 18:42:59

US3232021
Folder: Safety Call Day 36 (1)
Form: Safety Call
Generated On: 11 Aug 2021 22:05:35

Was Contact Attempted?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	29 Apr 2021 18:35:40
User signature succeeded.	Rambod Rouhbakhsh (b) (4)	18 Feb 2021 15:31:39
User entered 'Yes (Y)'	Jerrica Sullivan (b) (4) (b) (4)	22 Sep 2020 14:34:16

US3232021

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:05:35

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	29 Apr 2021 18:35:40
User closed query 'Date of Contact or Contact Attempt is after Assessment Date of study discontinuation/completion on the End of Study/Study Discontinuation form. Please review and provide any needed correction.' (Site from System).	System	30 Mar 2021 13:34:08
User opened query 'Date of Contact or Contact Attempt is after Assessment Date of study discontinuation/completion on the End of Study/Study Discontinuation form. Please review and provide any needed correction.' (Site from System).	System	30 Mar 2021 12:50:53
User signature succeeded.	Rambod Rouhbakhsh (b) (4)	18 Feb 2021 15:31:39
User entered '21 Sep 2020'	Jerrica Sullivan (b) (4) (b) (4)	22 Sep 2020 14:34:16

US3232021

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:05:35

Please select one status for the follow-up contact

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 18:35:40
User signature succeeded.	(b) (4), (b) (6) Rambod Rouhbakhsh	18 Feb 2021 15:31:39
User entered 'Contact Made (CONTACT MADE)'	(b) (4) Jerrica Sullivan (b) (4) (b) (4)	22 Sep 2020 14:34:16

US3232021

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:05:35

Comments

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	29 Apr 2021 18:35:40
User signature succeeded.	Rambod Rouhbakhsh (b) (4)	18 Feb 2021 15:31:39
User entered empty.	Jerrica Sullivan (b) (4) (b) (4)	22 Sep 2020 14:34:16

US3232021

Folder: Safety Call Day 36 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:05:35

Is the participant continuing to the next visit?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 18:35:40
User signature succeeded.	(b) (4), (b) (6) Rambod Rouhbakhsh (b) (4)	18 Feb 2021 15:31:39
User entered 'Yes (Y)'	Jerrica Sullivan (b) (4) (b) (4)	22 Sep 2020 14:34:20

US3232021

Folder: Safety Call Day 36 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:05:35

Continuing Flag

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 18:35:40
User entered '1'	(b) (4), (b) (6) System	22 Sep 2020 14:34:20

US3232021
Folder: Safety Call Day 43 (1)
Form: Safety Call
Generated On: 11 Aug 2021 22:05:35
Was Contact Attempted?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 18:51:03
User signature succeeded.	(b) (4), (b) (6) Rambod Rouhbakhsh (b) (4)	23 Apr 2021 15:20:41
User closed query ' Was Contact Attempted? = No and 'Date of Contact or Contact Attempt' or ' Please select one status for the follow-up contact' is provided. Please review and reconcile. ' (Site from DM).	(b) (4), (b) (6) (b) (4), (b) (6)	22 Apr 2021 13:46:36
Query ' Was Contact Attempted? = No and 'Date of Contact or Contact Attempt' or ' Please select one status for the follow-up contact' is provided. Please review and reconcile. ' answered with 'no contact made with patient, inadvertently missed ' (Site from DM).	Jerrica Sullivan (b) (4) (b) (4)	21 Apr 2021 13:03:14
User opened query ' Was Contact Attempted? = No and 'Date of Contact or Contact Attempt' or ' Please select one status for the follow-up contact' is provided. Please review and reconcile. ' (Site from DM).	(b) (4), (b) (6) (b) (4), (b) (6)	20 Apr 2021 20:45:49
Query 'Was Contact Attempted? = No and 'Date of Contact or Contact Attempt' or ' Please select one status for the follow-up contact' is provided. Please review and reconcile.' canceled (Site from System).	(b) (4), (b) (6) (b) (4), (b) (6)	20 Apr 2021 20:45:41
User opened query 'Was Contact Attempted? = No and 'Date of Contact or Contact Attempt' or ' Please select one status for the follow-up contact' is provided. Please review and reconcile.' (Site from System).	System	26 Mar 2021 12:59:53
Signature has been broken.	Jerrica Sullivan (b) (4)	26 Mar 2021 12:59:53
User entered 'No (N)' reason for change: Data Entry Error	(b) (4) Jerrica Sullivan (b) (4) (b) (4)	26 Mar 2021 12:59:53
User signature succeeded.	Rambod Rouhbakhsh (b) (4)	18 Feb 2021 15:31:39
User entered 'Yes (Y)'	Jerrica Sullivan (b) (4) (b) (4)	28 Sep 2020 13:40:59

US3232021
Folder: Safety Call Day 43 (1)
Form: Safety Call
Generated On: 11 Aug 2021 22:05:35
Date of Contact or Contact Attempt *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 18:51:03
User closed query ' ' Was Contact Attempted? = No and 'Date of Contact or Contact Attempt' or ' Please select one status for the follow-up contact' is provided. Please review and reconcile. ' ' (Site from DM).	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 08:42:50
User signature succeeded.	Rambod Rouhbakhsh (b) (4)	23 Apr 2021 15:20:41
Query ' ' Was Contact Attempted? = No and 'Date of Contact or Contact Attempt' or ' Please select one status for the follow-up contact' is provided. Please review and reconcile. ' ' answered with 'no contact attempted, no date to enter ' (Site from DM).	Jerrica Sullivan (b) (4) (b) (4)	22 Apr 2021 14:43:21
User opened query ' ' Was Contact Attempted? = No and 'Date of Contact or Contact Attempt' or ' Please select one status for the follow-up contact' is provided. Please review and reconcile. ' ' (Site from DM).	(b) (4), (b) (6) (b) (4), (b) (6)	22 Apr 2021 13:49:31
Signature has been broken.	Jerrica Sullivan (b) (4) (b) (4)	26 Mar 2021 12:59:53
User entered empty; reason for change Data Entry Error	Jerrica Sullivan (b) (4) (b) (4)	26 Mar 2021 12:59:53
User signature succeeded.	Rambod Rouhbakhsh (b) (4)	18 Feb 2021 15:31:39
User closed query 'The 'Date of Contact or Contact Attempt' is before the 'Date of Informed Consent'. Please review and reconcile.' (Site from System).	System	28 Sep 2020 13:41:09
User entered '28 Sep 2020' reason for change: Data Entry Error	Jerrica Sullivan (b) (4) (b) (4)	28 Sep 2020 13:41:09
User opened query 'The 'Date of Contact or Contact Attempt' is before the 'Date of Informed Consent'. Please review and reconcile.' (Site from System).	System	28 Sep 2020 13:40:59
User entered '28 Jan 2020'	Jerrica Sullivan (b) (4) (b) (4)	28 Sep 2020 13:40:59

US3232021
Folder: Safety Call Day 43 (1)
Form: Safety Call
Generated On: 11 Aug 2021 22:05:35

Please select one status for the follow-up contact

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 18:51:03
User signature succeeded.	(b) (4), (b) (6) Rambod Rouhbakhsh	23 Apr 2021 15:20:41
Signature has been broken.	(b) (4) Jerrica Sullivan (b) (4)	26 Mar 2021 12:59:53
User entered 'Contact Not Made (CONTACT NOT MADE)' reason for change: Data Entry Error	(b) (4) Jerrica Sullivan (b) (4)	26 Mar 2021 12:59:53
User signature succeeded.	(b) (4) Rambod Rouhbakhsh	18 Feb 2021 15:31:39
User entered 'Contact Made (CONTACT MADE)'	(b) (4) Jerrica Sullivan (b) (4)	28 Sep 2020 13:40:59
	(b) (4)	

US3232021
Folder: Safety Call Day 43 (1)
Form: Safety Call
Generated On: 11 Aug 2021 22:05:35
Comments

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	29 Apr 2021 18:51:03
User signature succeeded.	Rambod Rouhbakhsh (b) (4)	23 Apr 2021 15:20:41
Signature has been broken.	Jerrica Sullivan (b) (4) (b) (4)	26 Mar 2021 12:59:53
User entered 'inadvertently missed' reason for change: Data Entry Error	Jerrica Sullivan (b) (4) (b) (4)	26 Mar 2021 12:59:53
User signature succeeded.	Rambod Rouhbakhsh (b) (4)	18 Feb 2021 15:31:39
User entered empty.	Jerrica Sullivan (b) (4) (b) (4)	28 Sep 2020 13:40:59

US3232021
Folder: Safety Call Day 43 (1)
Form: Continuing
Generated On: 11 Aug 2021 22:05:35

Is the participant continuing to the next visit?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 18:51:03
User signature succeeded.	(b) (4), (b) (6) Rambod Rouhbakhsh (b) (4)	18 Feb 2021 15:31:39
User entered 'Yes (Y)'	Jerrica Sullivan (b) (4) (b) (4)	28 Sep 2020 13:41:14

US3232021

Folder: Safety Call Day 43 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:05:35

Continuing Flag

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 18:51:03
User entered '1'	(b) (4), (b) (6) System	28 Sep 2020 13:41:14

US3232021
Folder: Safety Call Day 50 (1)
Form: Safety Call
Generated On: 11 Aug 2021 22:05:35
Was Contact Attempted?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	29 Apr 2021 18:57:02
User signature succeeded.	Rambod Rouhbakhsh (b) (4)	29 Mar 2021 19:02:10
User closed query 'Was Contact Attempted? = Yes and 'Date of Contact or Contact Attempt' or ' Please select one status for the follow-up contact' is missing. Please review and reconcile.' (Site from System).	System	08 Mar 2021 21:23:04
User opened query 'Was Contact Attempted? = Yes and 'Date of Contact or Contact Attempt' or ' Please select one status for the follow-up contact' is missing. Please review and reconcile.' (Site from System).	System	08 Mar 2021 21:22:04
User entered 'Yes (Y)' reason for change: Data Entry Error	(b) (4), (b) (6) (b) (4), (b) (6)	08 Mar 2021 21:22:04
User entered 'No (N)'	(b) (4), (b) (6) (b) (4), (b) (6)	08 Mar 2021 21:20:10

US3232021
Folder: Safety Call Day 50 (1)
Form: Safety Call
Generated On: 11 Aug 2021 22:05:35

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	29 Apr 2021 18:57:02
User closed query 'Date of Contact or Contact Attempt is after Assessment Date of study discontinuation/completion on the End of Study/Study Discontinuation form. Please review and provide any needed correction.' (Site from System).	System	30 Mar 2021 13:55:11
User opened query 'Date of Contact or Contact Attempt is after Assessment Date of study discontinuation/completion on the End of Study/Study Discontinuation form. Please review and provide any needed correction.' (Site from System).	System	30 Mar 2021 12:50:53
User signature succeeded.	Rambod Rouhbakhsh (b) (4)	29 Mar 2021 19:02:10
User closed query 'Visits Safety Call Day 43 and Safety Call Day 50 are both dated 28SEP2020, however it is not possible for these two visits to be on the same day per the schedule of events. Please confirm the date for each visit or amend one of them to 'No' if it was not completed. ' (Site from DM).	(b) (4), (b) (6) (b) (4), (b) (6)	29 Mar 2021 11:39:38
Query 'Visits Safety Call Day 43 and Safety Call Day 50 are both dated 28SEP2020, however it is not possible for these two visits to be on the same day per the schedule of events. Please confirm the date for each visit or amend one of them to 'No' if it was not completed. ' answered with 'updated' (Site from DM).	Jerrica Sullivan (b) (4) (b) (4)	26 Mar 2021 13:00:19
User opened query 'Visits Safety Call Day 43 and Safety Call Day 50 are both dated 28SEP2020, however it is not possible for these two visits to be on the same day per the schedule of events. Please confirm the date for each visit or amend one of them to 'No' if it was not completed. ' (Site from DM).	(b) (4), (b) (6) (b) (4), (b) (6)	26 Mar 2021 10:51:51
User entered '28 Sep 2020' reason for change: Data Entry Error	(b) (4), (b) (6) (b) (4), (b) (6)	08 Mar 2021 21:22:04
User entered empty.	(b) (4), (b) (6) (b) (4), (b) (6)	08 Mar 2021 21:20:10

US3232021

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:05:35

Please select one status for the follow-up contact

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 18:57:02
User signature succeeded.	(b) (4), (b) (6) Rambod Rouhbakhsh	29 Mar 2021 19:02:10
User entered 'Contact Made (CONTACT MADE)' reason for change: Data Entry Error	(b) (4) (b) (4), (b) (6) (b) (4), (b) (6)	08 Mar 2021 21:23:04
User entered empty.	(b) (4), (b) (6) (b) (4), (b) (6)	08 Mar 2021 21:20:10

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	29 Apr 2021 18:57:02
User signature succeeded.	Rambod Rouhbakhsh (b) (4)	29 Mar 2021 19:02:10
User entered empty.	(b) (4), (b) (6) (b) (4), (b) (6)	08 Mar 2021 21:20:10

US3232021
Folder: Safety Call Day 50 (1)
Form: Continuing
Generated On: 11 Aug 2021 22:05:35

Is the participant continuing to the next visit?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 18:57:02
User signature succeeded.	(b) (4), (b) (6) Rambod Rouhbakhsh	29 Mar 2021 19:02:10
User entered 'Yes (Y)' reason for change: Data Entry Error	(b) (4) (b) (4), (b) (6)	08 Mar 2021 21:21:51
User entered 'No (N)'	(b) (4), (b) (6) (b) (4), (b) (6)	08 Mar 2021 21:20:14

US3232021
Folder: Safety Call Day 50 (1)
Form: Continuing
Generated On: 11 Aug 2021 22:05:35
Continuing Flag

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	29 Apr 2021 18:57:02
User entered '1'	System	08 Mar 2021 21:21:51
User entered empty.	System	08 Mar 2021 21:20:14

US3232021
Folder: Visit 3 Day 57 (1)
Form: Visit Date
Generated On: 11 Aug 2021 22:05:35
Was this visit performed?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	02 May 2021 13:47:25
User signature succeeded.	Rambod Rouhbakhsh (b) (4)	29 Mar 2021 19:02:10
User entered 'No (N)'	(b) (4), (b) (6) (b) (4), (b) (6)	08 Mar 2021 21:23:17

US3232021
Folder: Visit 3 Day 57 (1)
Form: Visit Date
Generated On: 11 Aug 2021 22:05:35

Visit date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	02 May 2021 13:47:25
User signature succeeded.	Rambod Rouhbakhsh (b) (4)	29 Mar 2021 19:02:10
User entered empty.	(b) (4), (b) (6) (b) (4), (b) (6)	08 Mar 2021 21:23:17

US3232021
Folder: Visit 3 Day 57 (1)
Form: Visit Date
Generated On: 11 Aug 2021 22:05:35

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	02 May 2021 13:47:25
User signature succeeded.	Rambod Rouhbakhsh (b) (4)	29 Mar 2021 19:02:10
User entered empty.	(b) (4), (b) (6) (b) (4), (b) (6)	08 Mar 2021 21:23:17

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	02 May 2021 13:47:25
User entered 'VISIT3'	System	08 Mar 2021 21:23:17

US3232021
Folder: Visit 3 Day 57 (1)
Form: Continuing
Generated On: 11 Aug 2021 22:05:35

Is the participant continuing to the next visit?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	02 May 2021 13:47:25
User signature succeeded.	Rambod Rouhbakhsh (b) (4)	29 Mar 2021 19:02:10
User entered 'No (N)'	(b) (4), (b) (6) (b) (4), (b) (6)	08 Mar 2021 21:23:52

US3232021

Folder: Visit 3 Day 57 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:05:35

Continuing Flag

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	02 May 2021 13:47:25
User entered empty.	System	08 Mar 2021 21:23:52

US3232021

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:05:35

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	02 May 2021 13:47:25
DataPoint activated (WR#5348247)	System	13 Apr 2021 18:12:59
DataPoint Inactivated.	System	12 Apr 2021 12:53:35
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 17:12:09
Data entry locked.	System	10 Aug 2020 17:47:41
User entered 'Day 64'	System	10 Aug 2020 17:47:41

US3232021

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:05:35

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) (b) (4), (b) (6)	02 May 2021 13:47:25
DataPoint activated (WR#5348247)	System	13 Apr 2021 18:12:59
DataPoint Inactivated.	System	12 Apr 2021 12:53:35
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 17:12:09

US3232021

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:05:35

Have you been exposed to someone with 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) (b) (4), (b) (6)	02 May 2021 13:47:25
DataPoint activated (WR#5348247)	System	13 Apr 2021 18:12:59
DataPoint Inactivated.	System	12 Apr 2021 12:53:35
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 17:12:09

US3232021

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:05:35

Please 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) (b) (4), (b) (6)	02 May 2021 13:47:25
DataPoint activated (WR#5348247)	System	13 Apr 2021 18:12:59
DataPoint Inactivated.	System	12 Apr 2021 12:53:35
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 17:12:09

US3232021

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:05:35

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) (b) (4), (b) (6)	02 May 2021 13:47:25
DataPoint activated (WR#5348247)	System	13 Apr 2021 18:12:59
DataPoint Inactivated.	System	12 Apr 2021 12:53:35
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 17:12:09

US3232021
Folder: Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 22:05:35
Fever (Temperature ≥ 100.4°F/38°C)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	02 May 2021 13:47:25
DataPoint activated (WR#5348247)	System	13 Apr 2021 18:12:59
DataPoint Inactivated.	System	12 Apr 2021 12:53:35
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 17:12:09

US3232021
Folder: Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 22:05:35
Chills

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	02 May 2021 13:47:25
DataPoint activated (WR#5348247)	System	13 Apr 2021 18:12:59
DataPoint Inactivated.	System	12 Apr 2021 12:53:35
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 17:12:09

US3232021
Folder: Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 22:05:35

Cough

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	02 May 2021 13:47:25
DataPoint activated (WR#5348247)	System	13 Apr 2021 18:12:59
DataPoint Inactivated.	System	12 Apr 2021 12:53:35
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 17:12:09

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US3232021
Folder: Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 22:05:35

Shortness of breath

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	02 May 2021 13:47:25
DataPoint activated (WR#5348247)	System	13 Apr 2021 18:12:59
DataPoint Inactivated.	System	12 Apr 2021 12:53:35
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 17:12:09

US3232021
Folder: Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 22:05:35
Difficulty breathing

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	02 May 2021 13:47:25
DataPoint activated (WR#5348247)	System	13 Apr 2021 18:12:59
DataPoint Inactivated.	System	12 Apr 2021 12:53:35
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 17:12:09

US3232021
Folder: Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 22:05:35
Fatigue

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	02 May 2021 13:47:25
DataPoint activated (WR#5348247)	System	13 Apr 2021 18:12:59
DataPoint Inactivated.	System	12 Apr 2021 12:53:35
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 17:12:09

US3232021
Folder: Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 22:05:35
Muscle aches

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	02 May 2021 13:47:25
DataPoint activated (WR#5348247)	System	13 Apr 2021 18:12:59
DataPoint Inactivated.	System	12 Apr 2021 12:53:35
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 17:12:09

US3232021
Folder: Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 22:05:35
Body aches

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	02 May 2021 13:47:25
DataPoint activated (WR#5348247)	System	13 Apr 2021 18:12:59
DataPoint Inactivated.	System	12 Apr 2021 12:53:35
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 17:12:09

US3232021
Folder: Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 22:05:35
Headache

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	02 May 2021 13:47:25
DataPoint activated (WR#5348247)	System	13 Apr 2021 18:12:59
DataPoint Inactivated.	System	12 Apr 2021 12:53:35
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 17:12:09

FDA-CBER-2022-1614-0646523

US3232021
Folder: Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 22:05:35

New loss of taste

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	02 May 2021 13:47:25
DataPoint activated (WR#5348247)	System	13 Apr 2021 18:12:59
DataPoint Inactivated.	System	12 Apr 2021 12:53:35
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 17:12:09

US3232021
Folder: Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 22:05:35
New loss of smell

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	02 May 2021 13:47:25
DataPoint activated (WR#5348247)	System	13 Apr 2021 18:12:59
DataPoint Inactivated.	System	12 Apr 2021 12:53:35
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 17:12:09

US3232021
Folder: Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 22:05:35
Sore throat

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	02 May 2021 13:47:25
DataPoint activated (WR#5348247)	System	13 Apr 2021 18:12:59
DataPoint Inactivated.	System	12 Apr 2021 12:53:35
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 17:12:09

US3232021
Folder: Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 22:05:35

Congestion

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	02 May 2021 13:47:25
DataPoint activated (WR#5348247)	System	13 Apr 2021 18:12:59
DataPoint Inactivated.	System	12 Apr 2021 12:53:35
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 17:12:09

US3232021
Folder: Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 22:05:35

Runny nose

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	02 May 2021 13:47:25
DataPoint activated (WR#5348247)	System	13 Apr 2021 18:12:59
DataPoint Inactivated.	System	12 Apr 2021 12:53:35
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 17:12:09

US3232021
Folder: Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 22:05:35
Nausea

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	02 May 2021 13:47:25
DataPoint activated (WR#5348247)	System	13 Apr 2021 18:12:59
DataPoint Inactivated.	System	12 Apr 2021 12:53:35
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 17:12:09

US3232021
Folder: Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 22:05:35

Vomiting

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	02 May 2021 13:47:25
DataPoint activated (WR#5348247)	System	13 Apr 2021 18:12:59
DataPoint Inactivated.	System	12 Apr 2021 12:53:35
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 17:12:09

US3232021
Folder: Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 22:05:35
Diarrhea

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	02 May 2021 13:47:25
DataPoint activated (WR#5348247)	System	13 Apr 2021 18:12:59
DataPoint Inactivated.	System	12 Apr 2021 12:53:35
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 17:12:09

FDA-CBER-2022-1614-0646531

US3232021

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:05:35

Please 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) (b) (4), (b) (6)	02 May 2021 13:47:25
DataPoint activated (WR#5348247)	System	13 Apr 2021 18:12:59
DataPoint Inactivated.	System	12 Apr 2021 12:53:35
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 17:12:09

US3232021

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:05:35

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) (b) (4), (b) (6)	02 May 2021 13:47:25
DataPoint activated (WR#5348247)	System	13 Apr 2021 18:12:59
DataPoint Inactivated.	System	12 Apr 2021 12:53:35
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 17:12:09

US3232021

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:05:35

Please 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) (b) (4), (b) (6)	02 May 2021 13:47:25
DataPoint activated (WR#5348247)	System	13 Apr 2021 18:12:59
DataPoint Inactivated.	System	12 Apr 2021 12:53:35
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 17:12:09

US3232021
Folder: Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 22:05:35
Date and time of submission

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	02 May 2021 13:47:25
DataPoint activated (WR#5348247)	System	13 Apr 2021 18:12:59
DataPoint Inactivated.	System	12 Apr 2021 12:53:35
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 17:12:09

US3232021
Folder: Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 22:05:35
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	02 May 2021 13:47:25
DataPoint activated (WR#5348247)	System	13 Apr 2021 18:12:59
DataPoint Inactivated.	System	12 Apr 2021 12:53:35
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 17:12:09
Data entry locked.	System	10 Aug 2020 17:47:41
User entered '10 Oct 2020 00:01'	System	10 Aug 2020 17:47:41

US3232021
Folder: Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 22:05:35

Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	02 May 2021 13:47:25
DataPoint activated (WR#5348247)	System	13 Apr 2021 18:12:59
DataPoint Inactivated.	System	12 Apr 2021 12:53:35
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 17:12:09
Data entry locked.	System	10 Aug 2020 17:47:41
User entered '14 Oct 2020 23:59'	System	10 Aug 2020 17:47:41

US3232021
Folder: Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 22:05:35
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	02 May 2021 13:47:25
DataPoint activated (WR#5348247)	System	13 Apr 2021 18:12:59
DataPoint Inactivated.	System	12 Apr 2021 12:53:35
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 17:12:09
Data entry locked.	System	10 Aug 2020 17:47:41
User entered 'Day 71'	System	10 Aug 2020 17:47:41

US3232021

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:05:35

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) (b) (4), (b) (6)	02 May 2021 13:47:25
DataPoint activated (WR#5348247)	System	13 Apr 2021 18:12:59
DataPoint Inactivated.	System	12 Apr 2021 12:53:35
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 17:12:09

US3232021

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:05:35

Have you been exposed to someone with 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) (b) (4), (b) (6)	02 May 2021 13:47:25
DataPoint activated (WR#5348247)	System	13 Apr 2021 18:12:59
DataPoint Inactivated.	System	12 Apr 2021 12:53:35
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 17:12:09

US3232021

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:05:35

Please 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) (b) (4), (b) (6)	02 May 2021 13:47:25
DataPoint activated (WR#5348247)	System	13 Apr 2021 18:12:59
DataPoint Inactivated.	System	12 Apr 2021 12:53:35
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 17:12:09

US3232021

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:05:35

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) (b) (4), (b) (6)	02 May 2021 13:47:25
DataPoint activated (WR#5348247)	System	13 Apr 2021 18:12:59
DataPoint Inactivated.	System	12 Apr 2021 12:53:35
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 17:12:09

US3232021
Folder: Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 22:05:35
Fever (Temperature ≥ 100.4°F/38°C)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	02 May 2021 13:47:25
DataPoint activated (WR#5348247)	System	13 Apr 2021 18:12:59
DataPoint Inactivated.	System	12 Apr 2021 12:53:35
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 17:12:09

US3232021
Folder: Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 22:05:35
Chills

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	02 May 2021 13:47:25
DataPoint activated (WR#5348247)	System	13 Apr 2021 18:12:59
DataPoint Inactivated.	System	12 Apr 2021 12:53:35
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 17:12:09

FDA-CBER-2022-1614-0646544

US3232021
Folder: Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 22:05:35
Cough

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	02 May 2021 13:47:25
DataPoint activated (WR#5348247)	System	13 Apr 2021 18:12:59
DataPoint Inactivated.	System	12 Apr 2021 12:53:35
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 17:12:09

FDA-CBER-2022-1614-0646545

US3232021
Folder: Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 22:05:35
Shortness of breath

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	02 May 2021 13:47:25
DataPoint activated (WR#5348247)	System	13 Apr 2021 18:12:59
DataPoint Inactivated.	System	12 Apr 2021 12:53:35
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 17:12:09

US3232021
Folder: Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 22:05:35
Difficulty breathing

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	02 May 2021 13:47:25
DataPoint activated (WR#5348247)	System	13 Apr 2021 18:12:59
DataPoint Inactivated.	System	12 Apr 2021 12:53:35
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 17:12:09

US3232021
Folder: Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 22:05:35

Fatigue

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	02 May 2021 13:47:25
DataPoint activated (WR#5348247)	System	13 Apr 2021 18:12:59
DataPoint Inactivated.	System	12 Apr 2021 12:53:35
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 17:12:09

FDA-CBER-2022-1614-0646548

US3232021

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:05:35

Muscle aches

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	02 May 2021 13:47:25
DataPoint activated (WR#5348247)	System	13 Apr 2021 18:12:59
DataPoint Inactivated.	System	12 Apr 2021 12:53:35
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 17:12:09

US3232021
Folder: Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 22:05:35

Body aches

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	02 May 2021 13:47:25
DataPoint activated (WR#5348247)	System	13 Apr 2021 18:12:59
DataPoint Inactivated.	System	12 Apr 2021 12:53:35
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 17:12:09

US3232021
Folder: Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 22:05:35

Headache

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	02 May 2021 13:47:25
DataPoint activated (WR#5348247)	System	13 Apr 2021 18:12:59
DataPoint Inactivated.	System	12 Apr 2021 12:53:35
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 17:12:09

FDA-CBER-2022-1614-0646551

US3232021
Folder: Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 22:05:35

New loss of taste

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	02 May 2021 13:47:25
DataPoint activated (WR#5348247)	System	13 Apr 2021 18:12:59
DataPoint Inactivated.	System	12 Apr 2021 12:53:35
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 17:12:09

US3232021

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:05:35

New loss of smell

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	02 May 2021 13:47:25
DataPoint activated (WR#5348247)	System	13 Apr 2021 18:12:59
DataPoint Inactivated.	System	12 Apr 2021 12:53:35
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 17:12:09

US3232021

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:05:35

Sore throat

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	02 May 2021 13:47:25
DataPoint activated (WR#5348247)	System	13 Apr 2021 18:12:59
DataPoint Inactivated.	System	12 Apr 2021 12:53:35
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 17:12:09

US3232021
Folder: Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 22:05:35
Congestion

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	02 May 2021 13:47:25
DataPoint activated (WR#5348247)	System	13 Apr 2021 18:12:59
DataPoint Inactivated.	System	12 Apr 2021 12:53:35
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 17:12:09

US3232021

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:05:35

Runny nose

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	02 May 2021 13:47:25
DataPoint activated (WR#5348247)	System	13 Apr 2021 18:12:59
DataPoint Inactivated.	System	12 Apr 2021 12:53:35
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 17:12:09

FDA-CBER-2022-1614-0646556

US3232021
Folder: Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 22:05:35
Nausea

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	02 May 2021 13:47:25
DataPoint activated (WR#5348247)	System	13 Apr 2021 18:12:59
DataPoint Inactivated.	System	12 Apr 2021 12:53:35
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 17:12:09

FDA-CBER-2022-1614-0646557

US3232021
Folder: Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 22:05:35

Vomiting

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:47:25
DataPoint activated (WR#5348247)	System	13 Apr 2021 18:12:59
DataPoint Inactivated.	System	12 Apr 2021 12:53:35
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 17:12:09

US3232021
Folder: Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 22:05:35
Diarrhea

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	02 May 2021 13:47:25
DataPoint activated (WR#5348247)	System	13 Apr 2021 18:12:59
DataPoint Inactivated.	System	12 Apr 2021 12:53:35
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 17:12:09

US3232021

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:05:35

Please 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) (b) (4), (b) (6)	02 May 2021 13:47:25
DataPoint activated (WR#5348247)	System	13 Apr 2021 18:12:59
DataPoint Inactivated.	System	12 Apr 2021 12:53:35
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 17:12:09

US3232021

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:05:35

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) (b) (4), (b) (6)	02 May 2021 13:47:25
DataPoint activated (WR#5348247)	System	13 Apr 2021 18:12:59
DataPoint Inactivated.	System	12 Apr 2021 12:53:35
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 17:12:09

US3232021

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:05:35

Please 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) (b) (4), (b) (6)	02 May 2021 13:47:25
DataPoint activated (WR#5348247)	System	13 Apr 2021 18:12:59
DataPoint Inactivated.	System	12 Apr 2021 12:53:35
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 17:12:09

US3232021

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:05:35

Date and time of submission

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	02 May 2021 13:47:25
DataPoint activated (WR#5348247)	System	13 Apr 2021 18:12:59
DataPoint Inactivated.	System	12 Apr 2021 12:53:35
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 17:12:09

FDA-CBER-2022-1614-0646563

US3232021
Folder: Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 22:05:35
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	02 May 2021 13:47:25
DataPoint activated (WR#5348247)	System	13 Apr 2021 18:12:59
DataPoint Inactivated.	System	12 Apr 2021 12:53:35
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 17:12:09
Data entry locked.	System	10 Aug 2020 17:47:41
User entered '17 Oct 2020 00:01'	System	10 Aug 2020 17:47:41

US3232021
Folder: Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 22:05:35
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	02 May 2021 13:47:25
DataPoint activated (WR#5348247)	System	13 Apr 2021 18:12:59
DataPoint Inactivated.	System	12 Apr 2021 12:53:35
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 17:12:09
Data entry locked.	System	10 Aug 2020 17:47:41
User entered '21 Oct 2020 23:59'	System	10 Aug 2020 17:47:41

US3232021
Folder: Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 22:05:35
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	02 May 2021 13:47:25
DataPoint activated (WR#5348247)	System	13 Apr 2021 18:12:59
DataPoint Inactivated.	System	12 Apr 2021 12:53:35
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 17:12:09
Data entry locked.	System	10 Aug 2020 17:47:41
User entered 'Day 78'	System	10 Aug 2020 17:47:41

US3232021

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:05:35

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) (b) (4), (b) (6)	02 May 2021 13:47:25
DataPoint activated (WR#5348247)	System	13 Apr 2021 18:12:59
DataPoint Inactivated.	System	12 Apr 2021 12:53:35
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 17:12:09

US3232021

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:05:35

Have you been exposed to someone with 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) (b) (4), (b) (6)	02 May 2021 13:47:25
DataPoint activated (WR#5348247)	System	13 Apr 2021 18:12:59
DataPoint Inactivated.	System	12 Apr 2021 12:53:35
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 17:12:09

US3232021

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:05:35

Please 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) (b) (4), (b) (6)	02 May 2021 13:47:25
DataPoint activated (WR#5348247)	System	13 Apr 2021 18:12:59
DataPoint Inactivated.	System	12 Apr 2021 12:53:35
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 17:12:09

US3232021

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:05:35

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) (b) (4), (b) (6)	02 May 2021 13:47:25
DataPoint activated (WR#5348247)	System	13 Apr 2021 18:12:59
DataPoint Inactivated.	System	12 Apr 2021 12:53:35
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 17:12:09

US3232021
Folder: Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 22:05:35
Fever (Temperature ≥ 100.4°F/38°C)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	02 May 2021 13:47:25
DataPoint activated (WR#5348247)	System	13 Apr 2021 18:12:59
DataPoint Inactivated.	System	12 Apr 2021 12:53:35
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 17:12:09

US3232021
Folder: Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 22:05:35
Chills

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	02 May 2021 13:47:25
DataPoint activated (WR#5348247)	System	13 Apr 2021 18:12:59
DataPoint Inactivated.	System	12 Apr 2021 12:53:35
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 17:12:09

US3232021
Folder: Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 22:05:35
Cough

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	02 May 2021 13:47:25
DataPoint activated (WR#5348247)	System	13 Apr 2021 18:12:59
DataPoint Inactivated.	System	12 Apr 2021 12:53:35
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 17:12:09

US3232021
Folder: Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 22:05:35
Shortness of breath

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	02 May 2021 13:47:25
DataPoint activated (WR#5348247)	System	13 Apr 2021 18:12:59
DataPoint Inactivated.	System	12 Apr 2021 12:53:35
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 17:12:09

US3232021

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:05:35

Difficulty breathing

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	02 May 2021 13:47:25
DataPoint activated (WR#5348247)	System	13 Apr 2021 18:12:59
DataPoint Inactivated.	System	12 Apr 2021 12:53:35
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 17:12:09

US3232021
Folder: Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 22:05:35
Fatigue

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	02 May 2021 13:47:25
DataPoint activated (WR#5348247)	System	13 Apr 2021 18:12:59
DataPoint Inactivated.	System	12 Apr 2021 12:53:35
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 17:12:09

US3232021
Folder: Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 22:05:35

Muscle aches

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	02 May 2021 13:47:25
DataPoint activated (WR#5348247)	System	13 Apr 2021 18:12:59
DataPoint Inactivated.	System	12 Apr 2021 12:53:35
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 17:12:09

US3232021
Folder: Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 22:05:35

Body aches

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	02 May 2021 13:47:25
DataPoint activated (WR#5348247)	System	13 Apr 2021 18:12:59
DataPoint Inactivated.	System	12 Apr 2021 12:53:35
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 17:12:09

US3232021
Folder: Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 22:05:35
Headache

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	02 May 2021 13:47:25
DataPoint activated (WR#5348247)	System	13 Apr 2021 18:12:59
DataPoint Inactivated.	System	12 Apr 2021 12:53:35
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 17:12:09

US3232021

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:05:35

New loss of taste

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	02 May 2021 13:47:25
DataPoint activated (WR#5348247)	System	13 Apr 2021 18:12:59
DataPoint Inactivated.	System	12 Apr 2021 12:53:35
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 17:12:09

US3232021

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:05:35

New loss of smell

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	02 May 2021 13:47:25
DataPoint activated (WR#5348247)	System	13 Apr 2021 18:12:59
DataPoint Inactivated.	System	12 Apr 2021 12:53:35
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 17:12:09

US3232021
Folder: Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 22:05:35
Sore throat

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	02 May 2021 13:47:25
DataPoint activated (WR#5348247)	System	13 Apr 2021 18:12:59
DataPoint Inactivated.	System	12 Apr 2021 12:53:35
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 17:12:09

US3232021
Folder: Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 22:05:35
Congestion

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	02 May 2021 13:47:25
DataPoint activated (WR#5348247)	System	13 Apr 2021 18:12:59
DataPoint Inactivated.	System	12 Apr 2021 12:53:35
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 17:12:09

US3232021
Folder: Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 22:05:35

Runny nose

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	02 May 2021 13:47:25
DataPoint activated (WR#5348247)	System	13 Apr 2021 18:12:59
DataPoint Inactivated.	System	12 Apr 2021 12:53:35
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 17:12:09

US3232021
Folder: Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 22:05:35
Nausea

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	02 May 2021 13:47:25
DataPoint activated (WR#5348247)	System	13 Apr 2021 18:12:59
DataPoint Inactivated.	System	12 Apr 2021 12:53:35
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 17:12:09

US3232021
Folder: Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 22:05:35

Vomiting

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	02 May 2021 13:47:25
DataPoint activated (WR#5348247)	System	13 Apr 2021 18:12:59
DataPoint Inactivated.	System	12 Apr 2021 12:53:35
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 17:12:09

US3232021
Folder: Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 22:05:35
Diarrhea

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	02 May 2021 13:47:25
DataPoint activated (WR#5348247)	System	13 Apr 2021 18:12:59
DataPoint Inactivated.	System	12 Apr 2021 12:53:35
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 17:12:09

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US3232021

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:05:35

Please 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) (b) (4), (b) (6)	02 May 2021 13:47:25
DataPoint activated (WR#5348247)	System	13 Apr 2021 18:12:59
DataPoint Inactivated.	System	12 Apr 2021 12:53:35
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 17:12:09

US3232021

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:05:35

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) (b) (4), (b) (6)	02 May 2021 13:47:25
DataPoint activated (WR#5348247)	System	13 Apr 2021 18:12:59
DataPoint Inactivated.	System	12 Apr 2021 12:53:35
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 17:12:09

US3232021

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:05:35

Please 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) (b) (4), (b) (6)	02 May 2021 13:47:25
DataPoint activated (WR#5348247)	System	13 Apr 2021 18:12:59
DataPoint Inactivated.	System	12 Apr 2021 12:53:35
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 17:12:09

US3232021

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:05:35

Date and time of submission

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	02 May 2021 13:47:25
DataPoint activated (WR#5348247)	System	13 Apr 2021 18:12:59
DataPoint Inactivated.	System	12 Apr 2021 12:53:35
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 17:12:09

US3232021
Folder: Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 22:05:35
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	02 May 2021 13:47:25
DataPoint activated (WR#5348247)	System	13 Apr 2021 18:12:59
DataPoint Inactivated.	System	12 Apr 2021 12:53:35
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 17:12:09
Data entry locked.	System	10 Aug 2020 17:47:41
User entered '24 Oct 2020 00:01'	System	10 Aug 2020 17:47:41

US3232021
Folder: Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 22:05:35
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	02 May 2021 13:47:25
DataPoint activated (WR#5348247)	System	13 Apr 2021 18:12:59
DataPoint Inactivated.	System	12 Apr 2021 12:53:35
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 17:12:09
Data entry locked.	System	10 Aug 2020 17:47:41
User entered '28 Oct 2020 23:59'	System	10 Aug 2020 17:47:41

US3232021
Folder: Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 22:05:35
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	02 May 2021 13:47:25
DataPoint activated (WR#5348247)	System	13 Apr 2021 18:12:59
DataPoint Inactivated.	System	12 Apr 2021 12:53:35
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 17:12:09
Data entry locked.	System	10 Aug 2020 17:47:41
User entered 'Day 92'	System	10 Aug 2020 17:47:41

US3232021

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:05:35

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) (b) (4), (b) (6)	02 May 2021 13:47:25
DataPoint activated (WR#5348247)	System	13 Apr 2021 18:12:59
DataPoint Inactivated.	System	12 Apr 2021 12:53:35
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 17:12:09

US3232021

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:05:35

Have you been exposed to someone with 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) (b) (4), (b) (6)	02 May 2021 13:47:25
DataPoint activated (WR#5348247)	System	13 Apr 2021 18:12:59
DataPoint Inactivated.	System	12 Apr 2021 12:53:35
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 17:12:09

US3232021

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:05:35

Please 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) (b) (4), (b) (6)	02 May 2021 13:47:25
DataPoint activated (WR#5348247)	System	13 Apr 2021 18:12:59
DataPoint Inactivated.	System	12 Apr 2021 12:53:35
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 17:12:09

US3232021

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:05:35

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) (b) (4), (b) (6)	02 May 2021 13:47:25
DataPoint activated (WR#5348247)	System	13 Apr 2021 18:12:59
DataPoint Inactivated.	System	12 Apr 2021 12:53:35
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 17:12:09

US3232021
Folder: Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 22:05:35
Fever (Temperature ≥ 100.4°F/38°C)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	02 May 2021 13:47:25
DataPoint activated (WR#5348247)	System	13 Apr 2021 18:12:59
DataPoint Inactivated.	System	12 Apr 2021 12:53:35
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 17:12:09

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	02 May 2021 13:47:25
DataPoint activated (WR#5348247)	System	13 Apr 2021 18:12:59
DataPoint Inactivated.	System	12 Apr 2021 12:53:35
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 17:12:09

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US3232021
Folder: Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 22:05:35
Cough

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	02 May 2021 13:47:25
DataPoint activated (WR#5348247)	System	13 Apr 2021 18:12:59
DataPoint Inactivated.	System	12 Apr 2021 12:53:35
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 17:12:09

FDA-CBER-2022-1614-0646601

US3232021
Folder: Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 22:05:35
Shortness of breath

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	02 May 2021 13:47:25
DataPoint activated (WR#5348247)	System	13 Apr 2021 18:12:59
DataPoint Inactivated.	System	12 Apr 2021 12:53:35
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 17:12:09

US3232021
Folder: Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 22:05:35
Difficulty breathing

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	02 May 2021 13:47:25
DataPoint activated (WR#5348247)	System	13 Apr 2021 18:12:59
DataPoint Inactivated.	System	12 Apr 2021 12:53:35
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 17:12:09

US3232021
Folder: Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 22:05:35
Fatigue

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	02 May 2021 13:47:25
DataPoint activated (WR#5348247)	System	13 Apr 2021 18:12:59
DataPoint Inactivated.	System	12 Apr 2021 12:53:35
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 17:12:09

US3232021
Folder: Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 22:05:35
Muscle aches

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	02 May 2021 13:47:25
DataPoint activated (WR#5348247)	System	13 Apr 2021 18:12:59
DataPoint Inactivated.	System	12 Apr 2021 12:53:35
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 17:12:09

US3232021
Folder: Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 22:05:35

Body aches

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	02 May 2021 13:47:25
DataPoint activated (WR#5348247)	System	13 Apr 2021 18:12:59
DataPoint Inactivated.	System	12 Apr 2021 12:53:35
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 17:12:09

US3232021
Folder: Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 22:05:35

Headache

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	02 May 2021 13:47:25
DataPoint activated (WR#5348247)	System	13 Apr 2021 18:12:59
DataPoint Inactivated.	System	12 Apr 2021 12:53:35
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 17:12:09

US3232021

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:05:35

New loss of taste

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	02 May 2021 13:47:25
DataPoint activated (WR#5348247)	System	13 Apr 2021 18:12:59
DataPoint Inactivated.	System	12 Apr 2021 12:53:35
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 17:12:09

FDA-CBER-2022-1614-0646608

US3232021
Folder: Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 22:05:35

New loss of smell

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	02 May 2021 13:47:25
DataPoint activated (WR#5348247)	System	13 Apr 2021 18:12:59
DataPoint Inactivated.	System	12 Apr 2021 12:53:35
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 17:12:09

US3232021
Folder: Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 22:05:35

Sore throat

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	02 May 2021 13:47:25
DataPoint activated (WR#5348247)	System	13 Apr 2021 18:12:59
DataPoint Inactivated.	System	12 Apr 2021 12:53:35
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 17:12:09

US3232021
Folder: Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 22:05:35

Congestion

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	02 May 2021 13:47:25
DataPoint activated (WR#5348247)	System	13 Apr 2021 18:12:59
DataPoint Inactivated.	System	12 Apr 2021 12:53:35
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 17:12:09

FDA-CBER-2022-1614-0646611

US3232021
Folder: Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 22:05:35

Runny nose

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	02 May 2021 13:47:25
DataPoint activated (WR#5348247)	System	13 Apr 2021 18:12:59
DataPoint Inactivated.	System	12 Apr 2021 12:53:35
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 17:12:09

US3232021
Folder: Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 22:05:35
Nausea

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:47:25
DataPoint activated (WR#5348247)	System	13 Apr 2021 18:12:59
DataPoint Inactivated.	System	12 Apr 2021 12:53:35
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 17:12:09

US3232021
Folder: Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 22:05:35

Vomiting

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	02 May 2021 13:47:25
DataPoint activated (WR#5348247)	System	13 Apr 2021 18:12:59
DataPoint Inactivated.	System	12 Apr 2021 12:53:35
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 17:12:09

US3232021
Folder: Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 22:05:35
Diarrhea

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	02 May 2021 13:47:25
DataPoint activated (WR#5348247)	System	13 Apr 2021 18:12:59
DataPoint Inactivated.	System	12 Apr 2021 12:53:35
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 17:12:09

US3232021

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:05:35

Please 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) (b) (4), (b) (6)	02 May 2021 13:47:25
DataPoint activated (WR#5348247)	System	13 Apr 2021 18:12:59
DataPoint Inactivated.	System	12 Apr 2021 12:53:35
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 17:12:09

US3232021

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:05:35

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) (b) (4), (b) (6)	02 May 2021 13:47:25
DataPoint activated (WR#5348247)	System	13 Apr 2021 18:12:59
DataPoint Inactivated.	System	12 Apr 2021 12:53:35
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 17:12:09

US3232021

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:05:35

Please 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) (b) (4), (b) (6)	02 May 2021 13:47:25
DataPoint activated (WR#5348247)	System	13 Apr 2021 18:12:59
DataPoint Inactivated.	System	12 Apr 2021 12:53:35
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 17:12:09

US3232021
Folder: Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 22:05:35
Date and time of submission

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	02 May 2021 13:47:25
DataPoint activated (WR#5348247)	System	13 Apr 2021 18:12:59
DataPoint Inactivated.	System	12 Apr 2021 12:53:35
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 17:12:09

US3232021
Folder: Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 22:05:35
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	02 May 2021 13:47:25
DataPoint activated (WR#5348247)	System	13 Apr 2021 18:12:59
DataPoint Inactivated.	System	12 Apr 2021 12:53:35
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 17:12:09
Data entry locked.	System	10 Aug 2020 17:47:41
User entered '07 Nov 2020 00:01'	System	10 Aug 2020 17:47:41

US3232021
Folder: Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 22:05:35
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	02 May 2021 13:47:25
DataPoint activated (WR#5348247)	System	13 Apr 2021 18:12:59
DataPoint Inactivated.	System	12 Apr 2021 12:53:35
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 17:12:09
Data entry locked.	System	10 Aug 2020 17:47:41
User entered '11 Nov 2020 23:59'	System	10 Aug 2020 17:47:41

US3232021
Folder: Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 22:05:35
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	02 May 2021 13:47:25
DataPoint activated (WR#5348247)	System	13 Apr 2021 18:12:59
DataPoint Inactivated.	System	12 Apr 2021 12:53:35
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 17:12:09
Data entry locked.	System	10 Aug 2020 17:47:41
User entered 'Day 99'	System	10 Aug 2020 17:47:41

US3232021

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:05:35

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) (b) (4), (b) (6)	02 May 2021 13:47:25
DataPoint activated (WR#5348247)	System	13 Apr 2021 18:12:59
DataPoint Inactivated.	System	12 Apr 2021 12:53:35
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 17:12:09

US3232021

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:05:35

Have you been exposed to someone with 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) (b) (4), (b) (6)	02 May 2021 13:47:25
DataPoint activated (WR#5348247)	System	13 Apr 2021 18:12:59
DataPoint Inactivated.	System	12 Apr 2021 12:53:35
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 17:12:09

FDA-CBER-2022-1614-0646624

US3232021

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:05:35

Please 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) (b) (4), (b) (6)	02 May 2021 13:47:25
DataPoint activated (WR#5348247)	System	13 Apr 2021 18:12:59
DataPoint Inactivated.	System	12 Apr 2021 12:53:35
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 17:12:09

US3232021

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:05:35

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) (b) (4), (b) (6)	02 May 2021 13:47:25
DataPoint activated (WR#5348247)	System	13 Apr 2021 18:12:59
DataPoint Inactivated.	System	12 Apr 2021 12:53:35
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 17:12:09

US3232021
Folder: Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 22:05:35
Fever (Temperature ≥ 100.4°F/38°C)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	02 May 2021 13:47:25
DataPoint activated (WR#5348247)	System	13 Apr 2021 18:12:59
DataPoint Inactivated.	System	12 Apr 2021 12:53:35
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 17:12:09

US3232021
Folder: Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 22:05:35
Chills

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	02 May 2021 13:47:25
DataPoint activated (WR#5348247)	System	13 Apr 2021 18:12:59
DataPoint Inactivated.	System	12 Apr 2021 12:53:35
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 17:12:09

US3232021
Folder: Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 22:05:35
Cough

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	02 May 2021 13:47:25
DataPoint activated (WR#5348247)	System	13 Apr 2021 18:12:59
DataPoint Inactivated.	System	12 Apr 2021 12:53:35
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 17:12:09

US3232021

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:05:35

Shortness of breath

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	02 May 2021 13:47:25
DataPoint activated (WR#5348247)	System	13 Apr 2021 18:12:59
DataPoint Inactivated.	System	12 Apr 2021 12:53:35
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 17:12:09

US3232021
Folder: Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 22:05:35
Difficulty breathing

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	02 May 2021 13:47:25
DataPoint activated (WR#5348247)	System	13 Apr 2021 18:12:59
DataPoint Inactivated.	System	12 Apr 2021 12:53:35
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 17:12:09

US3232021
Folder: Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 22:05:35

Fatigue

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	02 May 2021 13:47:25
DataPoint activated (WR#5348247)	System	13 Apr 2021 18:12:59
DataPoint Inactivated.	System	12 Apr 2021 12:53:35
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 17:12:09

FDA-CBER-2022-1614-0646632

US3232021
Folder: Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 22:05:35
Muscle aches

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	02 May 2021 13:47:25
DataPoint activated (WR#5348247)	System	13 Apr 2021 18:12:59
DataPoint Inactivated.	System	12 Apr 2021 12:53:35
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 17:12:09

FDA-CBER-2022-1614-0646633

US3232021
Folder: Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 22:05:35
Body aches

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	02 May 2021 13:47:25
DataPoint activated (WR#5348247)	System	13 Apr 2021 18:12:59
DataPoint Inactivated.	System	12 Apr 2021 12:53:35
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 17:12:09

US3232021
Folder: Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 22:05:35
Headache

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	02 May 2021 13:47:25
DataPoint activated (WR#5348247)	System	13 Apr 2021 18:12:59
DataPoint Inactivated.	System	12 Apr 2021 12:53:35
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 17:12:09

US3232021
Folder: Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 22:05:35
New loss of taste

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	02 May 2021 13:47:25
DataPoint activated (WR#5348247)	System	13 Apr 2021 18:12:59
DataPoint Inactivated.	System	12 Apr 2021 12:53:35
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 17:12:09

US3232021
Folder: Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 22:05:35
New loss of smell

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	02 May 2021 13:47:25
DataPoint activated (WR#5348247)	System	13 Apr 2021 18:12:59
DataPoint Inactivated.	System	12 Apr 2021 12:53:35
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 17:12:09

US3232021
Folder: Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 22:05:35
Sore throat

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	02 May 2021 13:47:25
DataPoint activated (WR#5348247)	System	13 Apr 2021 18:12:59
DataPoint Inactivated.	System	12 Apr 2021 12:53:35
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 17:12:09

US3232021

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:05:35

Congestion

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	02 May 2021 13:47:25
DataPoint activated (WR#5348247)	System	13 Apr 2021 18:12:59
DataPoint Inactivated.	System	12 Apr 2021 12:53:35
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 17:12:09

US3232021
Folder: Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 22:05:35

Runny nose

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	02 May 2021 13:47:25
DataPoint activated (WR#5348247)	System	13 Apr 2021 18:12:59
DataPoint Inactivated.	System	12 Apr 2021 12:53:35
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 17:12:09

US3232021
Folder: Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 22:05:35
Nausea

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	02 May 2021 13:47:25
DataPoint activated (WR#5348247)	System	13 Apr 2021 18:12:59
DataPoint Inactivated.	System	12 Apr 2021 12:53:35
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 17:12:09

US3232021
Folder: Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 22:05:35

Vomiting

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	02 May 2021 13:47:25
DataPoint activated (WR#5348247)	System	13 Apr 2021 18:12:59
DataPoint Inactivated.	System	12 Apr 2021 12:53:35
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 17:12:09

US3232021
Folder: Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 22:05:35
Diarrhea

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	02 May 2021 13:47:25
DataPoint activated (WR#5348247)	System	13 Apr 2021 18:12:59
DataPoint Inactivated.	System	12 Apr 2021 12:53:35
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 17:12:09

US3232021

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:05:35

Please 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) (b) (4), (b) (6)	02 May 2021 13:47:25
DataPoint activated (WR#5348247)	System	13 Apr 2021 18:12:59
DataPoint Inactivated.	System	12 Apr 2021 12:53:35
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 17:12:09

US3232021

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:05:35

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) (b) (4), (b) (6)	02 May 2021 13:47:25
DataPoint activated (WR#5348247)	System	13 Apr 2021 18:12:59
DataPoint Inactivated.	System	12 Apr 2021 12:53:35
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 17:12:09

US3232021

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:05:35

Please 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) (b) (4), (b) (6)	02 May 2021 13:47:25
DataPoint activated (WR#5348247)	System	13 Apr 2021 18:12:59
DataPoint Inactivated.	System	12 Apr 2021 12:53:35
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 17:12:09

US3232021
Folder: Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 22:05:35
Date and time of submission

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	02 May 2021 13:47:25
DataPoint activated (WR#5348247)	System	13 Apr 2021 18:12:59
DataPoint Inactivated.	System	12 Apr 2021 12:53:35
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 17:12:09

US3232021
Folder: Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 22:05:35
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	02 May 2021 13:47:25
DataPoint activated (WR#5348247)	System	13 Apr 2021 18:12:59
DataPoint Inactivated.	System	12 Apr 2021 12:53:35
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 17:12:09
Data entry locked.	System	10 Aug 2020 17:47:41
User entered '14 Nov 2020 00:01'	System	10 Aug 2020 17:47:41

US3232021
Folder: Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 22:05:35
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	02 May 2021 13:47:25
DataPoint activated (WR#5348247)	System	13 Apr 2021 18:12:59
DataPoint Inactivated.	System	12 Apr 2021 12:53:35
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 17:12:09
Data entry locked.	System	10 Aug 2020 17:47:41
User entered '18 Nov 2020 23:59'	System	10 Aug 2020 17:47:41

US3232021
Folder: Adverse Events
Form: Adverse Events Summary
Generated On: 11 Aug 2021 22:05:35

Did the participant experience any adverse events?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	02 May 2021 13:47:25
User signature succeeded.	Rambod Rouhbakhsh (b) (4)	12 Mar 2021 19:51:52
User entered 'Yes (Y)'	(b) (4), (b) (6) (b) (4), (b) (6)	29 Sep 2020 13:30:06

US3232021
Folder: Adverse Events
Form: Adverse Events (1)
Generated On: 11 Aug 2021 22:05:35
AEID

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	02 May 2021 13:47:25

Adverse event

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	02 May 2021 13:47:25
User signature succeeded.	Rambod Rouhbakhsh (b) (4)	12 Mar 2021 19:51:52
User closed query 'Per DM CLR: Please review if this is symptom is a worsening of the patient's ongoing Med History condition of OSTEOARTHRITIS. If yes, please update the AE term to reflect the worsening of this condition and ensure that severity is greater than baseline. Otherwise, clarify.' (Site from DM).	(b) (4), (b) (6) (b) (4), (b) (6)	23 Nov 2020 14:11:25
User coded data point as SOC: Musculoskeletal and connective tissue disorders, HLGT: Joint disorders, HLT: Joint related signs and symptoms, PT: Arthralgia, LLT: Arthralgia - version MedDRA\\23.0.	Coder Import ^{(b) (4)} (b) (4)	20 Nov 2020 05:29:54
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import ^{(b) (4)} (b) (4)	20 Nov 2020 05:29:54
Data point term sent to Coder	System	19 Nov 2020 20:26:29
Query 'Per DM CLR: Please review if this is symptom is a worsening of the patient's ongoing Med History condition of OSTEOARTHRITIS. If yes, please update the AE term to reflect the worsening of this condition and ensure that severity is greater than baseline. Otherwise, clarify.' answered with 'corrected ' (Site from DM).	Jerrica Sullivan (b) (4) (b) (4)	19 Nov 2020 20:25:52
Coding entries removed.	Jerrica Sullivan (b) (4) (b) (4)	19 Nov 2020 20:25:46
User entered 'worsening UPPER EXTREMITIES ARTHRALGIA' reason for change: Data Entry Error	Jerrica Sullivan (b) (4) (b) (4)	19 Nov 2020 20:25:46
User opened query 'Per DM CLR: Please review if this is symptom is a worsening of the patient's ongoing Med History condition of OSTEOARTHRITIS. If yes, please update the AE term to reflect the worsening of this condition and ensure that severity is greater than baseline. Otherwise, clarify.' (Site from DM).	(b) (4), (b) (6) (b) (4), (b) (6)	01 Nov 2020 02:29:44
User coded data point as SOC: Musculoskeletal and connective tissue disorders, HLGT: Joint disorders, HLT: Joint related signs and symptoms, PT: Arthralgia, LLT: Arthralgia - version MedDRA\\23.0.	Coder Import ^{(b) (4)} (b) (4)	29 Sep 2020 16:14:38

US3232021

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:05:35

Adverse event

Audit	User	Time (GMT)
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import ^{(b) (4)} (b) (4)	29 Sep 2020 16:14:38
Data point term sent to Coder	System	29 Sep 2020 13:31:44
User entered 'upper extremities arthralgia'	(b) (4), (b) (6) (b) (4), (b) (6)	29 Sep 2020 13:31:42

US3232021

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:05:35

Was this a medically-attended AE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	02 May 2021 13:47:25
User signature succeeded.	Rambod Rouhbakhsh (b) (4)	12 Mar 2021 19:51:52
User entered 'Yes (Y)'	(b) (4), (b) (6) (b) (4), (b) (6)	29 Sep 2020 13:31:42

US3232021

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:05:35

Was this a Solicited Adverse Reaction?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	02 May 2021 13:47:25
User signature succeeded.	Rambod Rouhbakhsh (b) (4)	12 Mar 2021 19:51:52
User entered 'No (N)'	(b) (4), (b) (6) (b) (4), (b) (6)	29 Sep 2020 13:31:42

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	02 May 2021 13:47:25
User signature succeeded.	Rambod Rouhbakhsh (b) (4)	12 Mar 2021 19:51:52
User entered 'No (N)'	(b) (4), (b) (6) (b) (4), (b) (6)	29 Sep 2020 13:31:42

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US3232021

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:05:35

Start date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	02 May 2021 13:47:25
User signature succeeded.	Rambod Rouhbakhsh (b) (4)	12 Mar 2021 19:51:52
User entered '25 Aug 2020'	(b) (4), (b) (6) (b) (4), (b) (6)	29 Sep 2020 13:31:42

US3232021

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:05:35

Start time *(00:00-23:59)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	02 May 2021 13:47:25
User signature succeeded.	Rambod Rouhbakhsh (b) (4)	12 Mar 2021 19:51:52
User entered empty.	(b) (4), (b) (6) (b) (4), (b) (6)	29 Sep 2020 13:31:42

US3232021
Folder: Adverse Events
Form: Adverse Events (1)
Generated On: 11 Aug 2021 22:05:35
AE start date and time (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	02 May 2021 13:47:25
User entered empty.	System	29 Sep 2020 13:31:42

US3232021
Folder: Adverse Events
Form: Adverse Events (1)
Generated On: 11 Aug 2021 22:05:35
Ongoing?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	02 May 2021 13:47:25
User signature succeeded.	Rambod Rouhbakhsh (b) (4)	12 Mar 2021 19:51:52
User closed query 'Per DM CLR: Please review the status of this AE and verify if this already resolved and end date is already available. If yes, please update eCRF as appropriate. Otherwise, confirm if it is still ongoing or if it occurs intermittently, please update the AE term to include "INTERMITTENT". ' (Site from DM).	(b) (4), (b) (6) (b) (4), (b) (6)	18 Dec 2020 11:24:24
Query 'Per DM CLR: Please review the status of this AE and verify if this already resolved and end date is already available. If yes, please update eCRF as appropriate. Otherwise, confirm if it is still ongoing or if it occurs intermittently, please update the AE term to include "INTERMITTENT". ' answered with 'unknown at this time due to subject withdrawing consent' (Site from DM).	Jerrica Sullivan (b) (4) (b) (4)	15 Dec 2020 19:09:47
User opened query 'Per DM CLR: Please review the status of this AE and verify if this already resolved and end date is already available. If yes, please update eCRF as appropriate. Otherwise, confirm if it is still ongoing or if it occurs intermittently, please update the AE term to include "INTERMITTENT". ' (Site from DM).	(b) (4), (b) (6) (b) (4), (b) (6)	25 Nov 2020 07:23:52
User entered 'Yes (Y)'	(b) (4), (b) (6) (b) (4), (b) (6)	29 Sep 2020 13:31:42

US3232021

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:05:35

If not Ongoing, end date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	02 May 2021 13:47:25
User signature succeeded.	Rambod Rouhbakhsh (b) (4)	12 Mar 2021 19:51:52
User entered empty.	(b) (4), (b) (6) (b) (4), (b) (6)	29 Sep 2020 13:31:42

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	02 May 2021 13:47:25
User signature succeeded.	Rambod Rouhbakhsh (b) (4)	12 Mar 2021 19:51:52
User entered empty.	(b) (4), (b) (6) (b) (4), (b) (6)	29 Sep 2020 13:31:42

US3232021

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:05:35

AE End Date and Time (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	02 May 2021 13:47:25
User entered empty.	System	29 Sep 2020 13:31:42

US3232021
Folder: Adverse Events
Form: Adverse Events (1)
Generated On: 11 Aug 2021 22:05:35
Severity

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	02 May 2021 13:47:25
User signature succeeded.	Rambod Rouhbakhsh (b) (4)	12 Mar 2021 19:51:52
User closed query 'Per DM CLR: Please verify the severity as a Worsening of the Med History condition would be expected to be > Grade of MH. Please confirm/update the severity or remove if a duplicate from baseline medical history. ' (Site from DM).	(b) (4), (b) (6) (b) (4), (b) (6)	22 Dec 2020 10:14:07
Query 'Per DM CLR: Please verify the severity as a Worsening of the Med History condition would be expected to be > Grade of MH. Please confirm/update the severity or remove if a duplicate from baseline medical history. ' answered with 'confirm as entered' (Site from DM).	Jerrica Sullivan (b) (4) (b) (4)	15 Dec 2020 19:09:56
User opened query 'Per DM CLR: Please verify the severity as a Worsening of the Med History condition would be expected to be > Grade of MH. Please confirm/update the severity or remove if a duplicate from baseline medical history. ' (Site from DM).	(b) (4), (b) (6) (b) (4), (b) (6)	08 Dec 2020 03:02:00
User entered 'Grade 1/Mild (Grade 1/Mild)'	(b) (4), (b) (6) (b) (4), (b) (6)	29 Sep 2020 13:31:42

US3232021
Folder: Adverse Events
Form: Adverse Events (1)
Generated On: 11 Aug 2021 22:05:35
Is the adverse event serious?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	02 May 2021 13:47:25
User signature succeeded.	Rambod Rouhbakhsh (b) (4)	12 Mar 2021 19:51:52
User entered 'No (N)'	(b) (4), (b) (6) (b) (4), (b) (6)	29 Sep 2020 13:31:42

US3232021

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:05:35

Death

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	02 May 2021 13:47:25
User signature succeeded.	Rambod Rouhbakhsh (b) (4)	12 Mar 2021 19:51:52
User entered '0'	(b) (4), (b) (6) (b) (4), (b) (6)	29 Sep 2020 13:31:42

US3232021

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:05:35

Life threatening

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	02 May 2021 13:47:25
User signature succeeded.	Rambod Rouhbakhsh (b) (4)	12 Mar 2021 19:51:52
User entered '0'	(b) (4), (b) (6) (b) (4), (b) (6)	29 Sep 2020 13:31:42

US3232021

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:05:35

Requires inpatient or prolongation of existing Hospitalization

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	02 May 2021 13:47:25
User signature succeeded.	Rambod Rouhbakhsh (b) (4)	12 Mar 2021 19:51:52
User entered '0'	(b) (4), (b) (6) (b) (4), (b) (6)	29 Sep 2020 13:31:42

US3232021
Folder: Adverse Events
Form: Adverse Events (1)
Generated On: 11 Aug 2021 22:05:35

Hospital Admission Date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	02 May 2021 13:47:25
User signature succeeded.	Rambod Rouhbakhsh (b) (4)	12 Mar 2021 19:51:52
User entered empty.	(b) (4), (b) (6) (b) (4), (b) (6)	29 Sep 2020 13:31:42

US3232021

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:05:35

Hospital Discharge Date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	02 May 2021 13:47:25
User signature succeeded.	Rambod Rouhbakhsh (b) (4)	12 Mar 2021 19:51:52
User entered empty.	(b) (4), (b) (6) (b) (4), (b) (6)	29 Sep 2020 13:31:42

US3232021

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:05:35

Admitted to ICU?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	02 May 2021 13:47:25
User signature succeeded.	Rambod Rouhbakhsh (b) (4)	12 Mar 2021 19:51:52
User entered empty.	(b) (4), (b) (6) (b) (4), (b) (6)	29 Sep 2020 13:31:42

US3232021
Folder: Adverse Events
Form: Adverse Events (1)
Generated On: 11 Aug 2021 22:05:35

Number of Days in ICU

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	02 May 2021 13:47:25
User signature succeeded.	Rambod Rouhbakhsh (b) (4)	12 Mar 2021 19:51:52
User entered empty.	(b) (4), (b) (6) (b) (4), (b) (6)	29 Sep 2020 13:31:42

US3232021

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:05:35

Persistent or significant disability or incapacity

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	02 May 2021 13:47:25
User signature succeeded.	Rambod Rouhbakhsh (b) (4)	12 Mar 2021 19:51:52
User entered '0'	(b) (4), (b) (6) (b) (4), (b) (6)	29 Sep 2020 13:31:42

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:05:35

Congenital anomaly or birth defect

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	02 May 2021 13:47:25
User signature succeeded.	Rambod Rouhbakhsh (b) (4)	12 Mar 2021 19:51:52
User entered '0'	(b) (4), (b) (6) (b) (4), (b) (6)	29 Sep 2020 13:31:42

US3232021

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:05:35

Other medically important event

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	02 May 2021 13:47:25
User signature succeeded.	Rambod Rouhbakhsh (b) (4)	12 Mar 2021 19:51:52
User entered '0'	(b) (4), (b) (6) (b) (4), (b) (6)	29 Sep 2020 13:31:42

US3232021

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:05:35

Relationship to investigational product

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	02 May 2021 13:47:25
User signature succeeded.	Rambod Rouhbakhsh (b) (4)	12 Mar 2021 19:51:52
User closed query 'Data is required. Please complete.' (Site from System).	System	19 Oct 2020 14:01:03
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	19 Oct 2020 14:01:03
User entered 'Related (RELATED)' reason for change: Data Entry Error	(b) (4), (b) (6) (b) (4), (b) (6)	19 Oct 2020 14:01:03
User opened query 'Data is required. Please complete.' (Site from System).	System	29 Sep 2020 13:31:42
User entered empty.	(b) (4), (b) (6) (b) (4), (b) (6)	29 Sep 2020 13:31:42

FDA-CBER-2022-1614-0646676

US3232021

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:05:35

Relationship to Study Procedure

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	02 May 2021 13:47:25
User signature succeeded.	Rambod Rouhbakhsh (b) (4)	12 Mar 2021 19:51:52
User closed query 'Data is required. Please complete.' (Site from System).	System	19 Oct 2020 14:01:03
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	19 Oct 2020 14:01:03
User entered 'Not Related (NOT RELATED)' reason for change: Data Entry Error	(b) (4), (b) (6) (b) (4), (b) (6)	19 Oct 2020 14:01:03
User opened query 'Data is required. Please complete.' (Site from System).	System	29 Sep 2020 13:31:42
User entered empty.	(b) (4), (b) (6) (b) (4), (b) (6)	29 Sep 2020 13:31:42

FDA-CBER-2022-1614-0646677

US3232021
Folder: Adverse Events
Form: Adverse Events (1)
Generated On: 11 Aug 2021 22:05:35
Action taken with investigational product

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	02 May 2021 13:47:25
User signature succeeded.	Rambod Rouhbakhsh (b) (4)	12 Mar 2021 19:51:52
User closed query 'Action Taken with Investigational Product is Withdrawn, however Primary reason for Dosing Discontinuation is NOT AE (specify) or SAE (specify). Please review and reconcile.' (Site from System).	(b) (4), (b) (6) (b) (4), (b) (6)	23 Nov 2020 21:35:54
User closed query 'Per CDM: Response noted however, the Dosing Discontinuation form is not complete. Kindly review and update as appropriate.' (Site from DM).	(b) (4), (b) (6) (b) (4), (b) (6)	23 Nov 2020 21:35:48
Query 'Action Taken with Investigational Product is Withdrawn, however Primary reason for Dosing Discontinuation is NOT AE (specify) or SAE (specify). Please review and reconcile.' answered with 'confirm correct as entered ' (Site from System).	Jerrica Sullivan (b) (4) (b) (4)	23 Nov 2020 18:12:28
Query 'Per CDM: Response noted however, the Dosing Discontinuation form is not complete. Kindly review and update as appropriate.' answered with 'corrected ' (Site from DM).	Jerrica Sullivan (b) (4) (b) (4)	23 Nov 2020 17:56:18
User opened query 'Action Taken with Investigational Product is Withdrawn, however Primary reason for Dosing Discontinuation is NOT AE (specify) or SAE (specify). Please review and reconcile.' (Site from System).	System	23 Nov 2020 17:53:46
User closed query 'Per CDM: there are more than 1 record with action of IP Withdrawn. Please review and reconcile as the main reason (only 1 record) for IP Withdrawn should be recorded.' (Site from DM).	(b) (4), (b) (6) (b) (4), (b) (6)	23 Nov 2020 14:23:33
User opened query 'Per CDM: Response noted however, the Dosing Discontinuation form is not complete. Kindly review and update as appropriate.' (Site from DM).	(b) (4), (b) (6) (b) (4), (b) (6)	23 Nov 2020 14:22:23
User closed query 'Per DM CLR: Action Taken with Investigational Product = Investigational Product Withdrawn. Ensure this is reflected in dosing discontinuation if applicable. Review and update. Else, clarify.' (Site from DM).	(b) (4), (b) (6) (b) (4), (b) (6)	23 Nov 2020 14:22:23

US3232021

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:05:35

Action taken with investigational product

Audit	User	Time (GMT)
Query 'Per DM CLR: Action Taken with Investigational Product = Investigational Product Withdrawn. Ensure this is reflected in dosing discontinuation if applicable. Review and update. Else, clarify.' answered with 'corrected' (Site from DM).	Jerrica Sullivan (b) (4) (b) (4)	19 Nov 2020 18:45:58
Query 'Per CDM: there are more than 1 record with action of IP Withdrawn. Please review and reconcile as the main reason (only 1 record) for IP Withdrawn should be recorded.' answered with 'corrected' (Site from DM).	Jerrica Sullivan (b) (4) (b) (4)	19 Nov 2020 18:45:54
User opened query 'Per CDM: there are more than 1 record with action of IP Withdrawn. Please review and reconcile as the main reason (only 1 record) for IP Withdrawn should be recorded.' (Site from DM).	(b) (4), (b) (6) (b) (4), (b) (6)	18 Nov 2020 22:41:33
User opened query 'Per DM CLR: Action Taken with Investigational Product = Investigational Product Withdrawn. Ensure this is reflected in dosing discontinuation if applicable. Review and update. Else, clarify.' (Site from DM).	(b) (4), (b) (6) (b) (4), (b) (6)	01 Nov 2020 02:29:19
User entered 'Investigational Product Withdrawn (WITHDRAWN)'	(b) (4), (b) (6) (b) (4), (b) (6)	29 Sep 2020 13:31:42

US3232021

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:05:35

None

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	02 May 2021 13:47:25
User signature succeeded.	Rambod Rouhbakhsh (b) (4)	12 Mar 2021 19:51:52
User entered '0' reason for change: Data Entry Error	Jerrica Sullivan (b) (4) (b) (4)	11 Mar 2021 16:03:48
User entered '1'	(b) (4), (b) (6) (b) (4), (b) (6)	29 Sep 2020 13:31:42

US3232021

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:05:35

Concomitant Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	02 May 2021 13:47:25
User signature succeeded.	Rambod Rouhbakhsh (b) (4)	12 Mar 2021 19:51:52
User entered '1' reason for change: Data Entry Error	Jerrica Sullivan (b) (4) (b) (4)	11 Mar 2021 16:03:48
User entered '0'	(b) (4), (b) (6) (b) (4), (b) (6)	29 Sep 2020 13:31:42

US3232021
Folder: Adverse Events
Form: Adverse Events (1)
Generated On: 11 Aug 2021 22:05:35
Concomitant Procedure

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	02 May 2021 13:47:25
User signature succeeded.	Rambod Rouhbakhsh (b) (4)	12 Mar 2021 19:51:52
User entered '0'	(b) (4), (b) (6) (b) (4), (b) (6)	29 Sep 2020 13:31:42

US3232021

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:05:35

Outcome

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	02 May 2021 13:47:25
User signature succeeded.	Rambod Rouhbakhsh (b) (4)	12 Mar 2021 19:51:52
User entered 'Recovering/Resolving (RECOVERING/RESOLVING)'	(b) (4), (b) (6) (b) (4), (b) (6)	29 Sep 2020 13:31:42

If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	02 May 2021 13:47:25
User signature succeeded.	Rambod Rouhbakhsh (b) (4)	12 Mar 2021 19:51:52
User entered empty.	(b) (4), (b) (6) (b) (4), (b) (6)	29 Sep 2020 13:31:42

US3232021
Folder: Adverse Events
Form: Adverse Events (1)
Generated On: 11 Aug 2021 22:05:35
Narrative

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	02 May 2021 13:47:25
User signature succeeded.	Rambod Rouhbakhsh (b) (4)	12 Mar 2021 19:51:52
User entered empty.	(b) (4), (b) (6) (b) (4), (b) (6)	29 Sep 2020 13:31:42

US3232021

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:05:35

Serious Adverse Event Derived (CSA Programming Field Ony)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	02 May 2021 13:47:25
User entered '0'	System	29 Sep 2020 13:31:42

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:47:25
User entered '1'	System	29 Sep 2020 13:31:42

US3232021
Folder: Adverse Events
Form: Adverse Events (1)
Generated On: 11 Aug 2021 22:05:35
Admitted to ICU Derived (CSA Programming Field Only)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	02 May 2021 13:47:25

US3232021
Folder: Adverse Events
Form: Adverse Events (2)
Generated On: 11 Aug 2021 22:05:35
AEID

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	02 May 2021 13:47:25

US3232021
Folder: Adverse Events
Form: Adverse Events (2)
Generated On: 11 Aug 2021 22:05:35
Adverse event

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	02 May 2021 13:47:25
User signature succeeded.	Rambod Rouhbakhsh (b) (4)	12 Mar 2021 19:51:52
User closed query 'Per DM CLR: Please review if this is symptom is a worsening of the patient's ongoing Med History condition of OSTEOARTHRITIS. If yes, please update the AE term to reflect the worsening of this condition and ensure that severity is greater than baseline. Otherwise, clarify.' (Site from DM).	(b) (4), (b) (6) (b) (4), (b) (6)	23 Nov 2020 21:36:27
User coded data point as SOC: Musculoskeletal and connective tissue disorders, HLGT: Joint disorders, HLT: Joint related signs and symptoms, PT: Arthralgia, LLT: Arthralgia - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	20 Nov 2020 05:42:59
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	20 Nov 2020 05:42:59
Data point term sent to Coder	System	19 Nov 2020 20:26:29
Query 'Per DM CLR: Please review if this is symptom is a worsening of the patient's ongoing Med History condition of OSTEOARTHRITIS. If yes, please update the AE term to reflect the worsening of this condition and ensure that severity is greater than baseline. Otherwise, clarify.' answered with 'corrected' (Site from DM).	Jerrica Sullivan (b) (4) (b) (4)	19 Nov 2020 20:26:06
Coding entries removed.	Jerrica Sullivan (b) (4) (b) (4)	19 Nov 2020 20:26:01
User entered 'worsening LOWER EXTREMETIES ARTHRALGIA' reason for change: Data Entry Error	Jerrica Sullivan (b) (4) (b) (4)	19 Nov 2020 20:26:01
User opened query 'Per DM CLR: Please review if this is symptom is a worsening of the patient's ongoing Med History condition of OSTEOARTHRITIS. If yes, please update the AE term to reflect the worsening of this condition and ensure that severity is greater than baseline. Otherwise, clarify.' (Site from DM).	(b) (4), (b) (6) (b) (4), (b) (6)	01 Nov 2020 02:30:13
User coded data point as SOC: Musculoskeletal and connective tissue disorders, HLGT: Joint disorders, HLT: Joint related signs and symptoms, PT: Arthralgia, LLT: Arthralgia - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	29 Sep 2020 14:45:42

US3232021

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 11 Aug 2021 22:05:35

Adverse event

Audit	User	Time (GMT)
User coded data point as Term Coded data point by User (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	29 Sep 2020 14:45:42
Data point term sent to Coder	System	29 Sep 2020 13:32:47
User entered 'lower extremeties arthralgia'	(b) (4), (b) (6) (b) (4), (b) (6)	29 Sep 2020 13:32:46

US3232021

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 11 Aug 2021 22:05:35

Was this a medically-attended AE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	02 May 2021 13:47:25
User signature succeeded.	Rambod Rouhbakhsh (b) (4)	12 Mar 2021 19:51:52
User entered 'Yes (Y)'	(b) (4), (b) (6) (b) (4), (b) (6)	29 Sep 2020 13:32:46

US3232021
Folder: Adverse Events
Form: Adverse Events (2)
Generated On: 11 Aug 2021 22:05:35

Was this a Solicited Adverse Reaction?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	02 May 2021 13:47:25
User signature succeeded.	Rambod Rouhbakhsh (b) (4)	12 Mar 2021 19:51:52
User entered 'No (N)'	(b) (4), (b) (6) (b) (4), (b) (6)	29 Sep 2020 13:32:46

US3232021

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 11 Aug 2021 22:05:35

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	02 May 2021 13:47:25
User signature succeeded.	Rambod Rouhbakhsh (b) (4)	12 Mar 2021 19:51:52
User entered 'No (N)'	(b) (4), (b) (6) (b) (4), (b) (6)	29 Sep 2020 13:32:46

US3232021

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 11 Aug 2021 22:05:35

Start date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	02 May 2021 13:47:25
User signature succeeded.	Rambod Rouhbakhsh (b) (4)	12 Mar 2021 19:51:52
User entered '25 Aug 2020'	(b) (4), (b) (6) (b) (4), (b) (6)	29 Sep 2020 13:32:46

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	02 May 2021 13:47:25
User signature succeeded.	Rambod Rouhbakhsh (b) (4)	12 Mar 2021 19:51:52
User entered empty.	(b) (4), (b) (6) (b) (4), (b) (6)	29 Sep 2020 13:32:46

US3232021

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 11 Aug 2021 22:05:35

AE start date and time (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	02 May 2021 13:47:25
User entered empty.	System	29 Sep 2020 13:32:46

US3232021
Folder: Adverse Events
Form: Adverse Events (2)
Generated On: 11 Aug 2021 22:05:35
Ongoing?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	02 May 2021 13:47:25
User signature succeeded.	Rambod Rouhbakhsh (b) (4)	12 Mar 2021 19:51:52
User closed query 'Per DM CLR: Please review the status of this AE and verify if this already resolved and end date is already available. If yes, please update eCRF as appropriate. Otherwise, confirm if it is still ongoing or if it occurs intermittently, please update the AE term to include "INTERMITTENT". ' (Site from DM).	(b) (4), (b) (6) (b) (4), (b) (6)	18 Dec 2020 11:24:57
Query 'Per DM CLR: Please review the status of this AE and verify if this already resolved and end date is already available. If yes, please update eCRF as appropriate. Otherwise, confirm if it is still ongoing or if it occurs intermittently, please update the AE term to include "INTERMITTENT". ' answered with 'unknown at this time due to subject withdrawing consent' (Site from DM).	Jerrica Sullivan (b) (4) (b) (4)	15 Dec 2020 19:10:03
User opened query 'Per DM CLR: Please review the status of this AE and verify if this already resolved and end date is already available. If yes, please update eCRF as appropriate. Otherwise, confirm if it is still ongoing or if it occurs intermittently, please update the AE term to include "INTERMITTENT". ' (Site from DM).	(b) (4), (b) (6) (b) (4), (b) (6)	25 Nov 2020 07:23:43
User entered 'Yes (Y)'	(b) (4), (b) (6) (b) (4), (b) (6)	29 Sep 2020 13:32:46

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 11 Aug 2021 22:05:35

If not Ongoing, end date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	02 May 2021 13:47:25
User signature succeeded.	Rambod Rouhbakhsh (b) (4)	12 Mar 2021 19:51:52
User entered empty.	(b) (4), (b) (6) (b) (4), (b) (6)	29 Sep 2020 13:32:46

US3232021
Folder: Adverse Events
Form: Adverse Events (2)
Generated On: 11 Aug 2021 22:05:35

End time *(00:00-23:59)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	02 May 2021 13:47:25
User signature succeeded.	Rambod Rouhbakhsh (b) (4)	12 Mar 2021 19:51:52
User entered empty.	(b) (4), (b) (6) (b) (4), (b) (6)	29 Sep 2020 13:32:46

AE End Date and Time (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	02 May 2021 13:47:25
User entered empty.	System	29 Sep 2020 13:32:46

US3232021
Folder: Adverse Events
Form: Adverse Events (2)
Generated On: 11 Aug 2021 22:05:35
Severity

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	02 May 2021 13:47:25
User signature succeeded.	Rambod Rouhbakhsh (b) (4)	12 Mar 2021 19:51:52
User closed query 'Per DM CLR: Please verify the severity as a Worsening of the Med History condition would be expected to be > Grade of MH. Please confirm/update the severity or remove if a duplicate from baseline medical history. ' (Site from DM).	(b) (4), (b) (6) (b) (4), (b) (6)	22 Dec 2020 10:14:34
Query 'Per DM CLR: Please verify the severity as a Worsening of the Med History condition would be expected to be > Grade of MH. Please confirm/update the severity or remove if a duplicate from baseline medical history. ' answered with 'confirm as entered ' (Site from DM).	Jerrica Sullivan (b) (4) (b) (4)	15 Dec 2020 19:10:12
User opened query 'Per DM CLR: Please verify the severity as a Worsening of the Med History condition would be expected to be > Grade of MH. Please confirm/update the severity or remove if a duplicate from baseline medical history. ' (Site from DM).	(b) (4), (b) (6) (b) (4), (b) (6)	08 Dec 2020 03:02:25
User entered 'Grade 1/Mild (Grade 1/Mild)'	(b) (4), (b) (6) (b) (4), (b) (6)	29 Sep 2020 13:32:46

FDA-CBER-2022-1614-0646702

US3232021
Folder: Adverse Events
Form: Adverse Events (2)
Generated On: 11 Aug 2021 22:05:35
Is the adverse event serious?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	02 May 2021 13:47:25
User signature succeeded.	Rambod Rouhbakhsh (b) (4)	12 Mar 2021 19:51:52
User entered 'No (N)'	(b) (4), (b) (6) (b) (4), (b) (6)	29 Sep 2020 13:32:46

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 11 Aug 2021 22:05:35

Death

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	02 May 2021 13:47:25
User signature succeeded.	Rambod Rouhbakhsh (b) (4)	12 Mar 2021 19:51:52
User entered '0'	(b) (4), (b) (6) (b) (4), (b) (6)	29 Sep 2020 13:32:46

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 11 Aug 2021 22:05:35

Life threatening

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	02 May 2021 13:47:25
User signature succeeded.	Rambod Rouhbakhsh (b) (4)	12 Mar 2021 19:51:52
User entered '0'	(b) (4), (b) (6) (b) (4), (b) (6)	29 Sep 2020 13:32:46

US3232021

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 11 Aug 2021 22:05:35

Requires inpatient or prolongation of existing Hospitalization

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	02 May 2021 13:47:25
User signature succeeded.	Rambod Rouhbakhsh (b) (4)	12 Mar 2021 19:51:52
User entered '0'	(b) (4), (b) (6) (b) (4), (b) (6)	29 Sep 2020 13:32:46

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 11 Aug 2021 22:05:35

Hospital Admission Date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	02 May 2021 13:47:25
User signature succeeded.	Rambod Rouhbakhsh (b) (4)	12 Mar 2021 19:51:52
User entered empty.	(b) (4), (b) (6) (b) (4), (b) (6)	29 Sep 2020 13:32:46

Hospital Discharge Date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	02 May 2021 13:47:25
User signature succeeded.	Rambod Rouhbakhsh (b) (4)	12 Mar 2021 19:51:52
User entered empty.	(b) (4), (b) (6) (b) (4), (b) (6)	29 Sep 2020 13:32:46

US3232021
Folder: Adverse Events
Form: Adverse Events (2)
Generated On: 11 Aug 2021 22:05:35
Admitted to ICU?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	02 May 2021 13:47:25
User signature succeeded.	Rambod Rouhbakhsh (b) (4)	12 Mar 2021 19:51:52
User entered empty.	(b) (4), (b) (6) (b) (4), (b) (6)	29 Sep 2020 13:32:46

US3232021
Folder: Adverse Events
Form: Adverse Events (2)
Generated On: 11 Aug 2021 22:05:35

Number of Days in ICU

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	02 May 2021 13:47:25
User signature succeeded.	Rambod Rouhbakhsh (b) (4)	12 Mar 2021 19:51:52
User entered empty.	(b) (4), (b) (6) (b) (4), (b) (6)	29 Sep 2020 13:32:46

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 11 Aug 2021 22:05:35

Persistent or significant disability or incapacity

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	02 May 2021 13:47:25
User signature succeeded.	Rambod Rouhbakhsh (b) (4)	12 Mar 2021 19:51:52
User entered '0'	(b) (4), (b) (6) (b) (4), (b) (6)	29 Sep 2020 13:32:46

US3232021

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 11 Aug 2021 22:05:35

Congenital anomaly or birth defect

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	02 May 2021 13:47:25
User signature succeeded.	Rambod Rouhbakhsh (b) (4)	12 Mar 2021 19:51:52
User entered '0'	(b) (4), (b) (6) (b) (4), (b) (6)	29 Sep 2020 13:32:46

US3232021
Folder: Adverse Events
Form: Adverse Events (2)
Generated On: 11 Aug 2021 22:05:35
Other medically important event

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	02 May 2021 13:47:25
User signature succeeded.	Rambod Rouhbakhsh (b) (4)	12 Mar 2021 19:51:52
User entered '0'	(b) (4), (b) (6) (b) (4), (b) (6)	29 Sep 2020 13:32:46

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 11 Aug 2021 22:05:35

Relationship to investigational product

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	02 May 2021 13:47:25
User signature succeeded.	Rambod Rouhbakhsh (b) (4)	12 Mar 2021 19:51:52
User closed query 'Data is required. Please complete.' (Site from System).	System	19 Oct 2020 14:01:16
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	19 Oct 2020 14:01:16
User entered 'Related (RELATED)' reason for change: Data Entry Error	(b) (4), (b) (6) (b) (4), (b) (6)	19 Oct 2020 14:01:16
User opened query 'Data is required. Please complete.' (Site from System).	System	29 Sep 2020 13:32:46
User entered empty.	(b) (4), (b) (6) (b) (4), (b) (6)	29 Sep 2020 13:32:46

US3232021
Folder: Adverse Events
Form: Adverse Events (2)
Generated On: 11 Aug 2021 22:05:35
Relationship to Study Procedure

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	02 May 2021 13:47:25
User signature succeeded.	Rambod Rouhbakhsh (b) (4)	12 Mar 2021 19:51:52
User closed query 'Data is required. Please complete.' (Site from System).	System	19 Oct 2020 14:01:16
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	19 Oct 2020 14:01:16
User entered 'Not Related (NOT RELATED)' reason for change: Data Entry Error	(b) (4), (b) (6) (b) (4), (b) (6)	19 Oct 2020 14:01:16
User opened query 'Data is required. Please complete.' (Site from System).	System	29 Sep 2020 13:32:46
User entered empty.	(b) (4), (b) (6) (b) (4), (b) (6)	29 Sep 2020 13:32:46

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 11 Aug 2021 22:05:35

Action taken with investigational product

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	02 May 2021 13:47:25
User signature succeeded.	Rambod Rouhbakhsh (b) (4)	12 Mar 2021 19:51:52
User closed query 'Per DM CLR: Action Taken with Investigational Product = Investigational Product Withdrawn. Ensure this is reflected in dosing discontinuation if applicable. Review and update. Else, clarify.' (Site from DM).	(b) (4), (b) (6) (b) (4), (b) (6)	23 Nov 2020 14:23:12
Query 'Per DM CLR: Action Taken with Investigational Product = Investigational Product Withdrawn. Ensure this is reflected in dosing discontinuation if applicable. Review and update. Else, clarify.' answered with 'corrected' (Site from DM).	Jerrica Sullivan (b) (4) (b) (4)	19 Nov 2020 18:46:20
User entered 'Not Applicable (NOT APPLICABLE)' reason for change: Data Entry Error	Jerrica Sullivan (b) (4) (b) (4)	19 Nov 2020 18:46:11
User opened query 'Per DM CLR: Action Taken with Investigational Product = Investigational Product Withdrawn. Ensure this is reflected in dosing discontinuation if applicable. Review and update. Else, clarify.' (Site from DM).	(b) (4), (b) (6) (b) (4), (b) (6)	01 Nov 2020 02:30:03
User entered 'Investigational Product Withdrawn (WITHDRAWN)'	(b) (4), (b) (6) (b) (4), (b) (6)	29 Sep 2020 13:32:46

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 11 Aug 2021 22:05:35

None

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	02 May 2021 13:47:25
User signature succeeded.	Rambod Rouhbakhsh (b) (4)	12 Mar 2021 19:51:52
User entered '1'	(b) (4), (b) (6) (b) (4), (b) (6)	29 Sep 2020 13:32:46

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Folder: Adverse Events
Form: Adverse Events (2)
Generated On: 11 Aug 2021 22:05:35
Concomitant Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	02 May 2021 13:47:25
User signature succeeded.	Rambod Rouhbakhsh (b) (4)	12 Mar 2021 19:51:52
User entered '0'	(b) (4), (b) (6) (b) (4), (b) (6)	29 Sep 2020 13:32:46

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 11 Aug 2021 22:05:35

Concomitant Procedure

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	02 May 2021 13:47:25
User signature succeeded.	Rambod Rouhbakhsh (b) (4)	12 Mar 2021 19:51:52
User entered '0'	(b) (4), (b) (6) (b) (4), (b) (6)	29 Sep 2020 13:32:46

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 11 Aug 2021 22:05:35

Outcome

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	02 May 2021 13:47:25
User signature succeeded.	Rambod Rouhbakhsh (b) (4)	12 Mar 2021 19:51:52
User entered 'Recovering/Resolving (RECOVERING/RESOLVING)'	(b) (4), (b) (6) (b) (4), (b) (6)	29 Sep 2020 13:32:46

US3232021
Folder: Adverse Events
Form: Adverse Events (2)
Generated On: 11 Aug 2021 22:05:35

If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	02 May 2021 13:47:25
User signature succeeded.	Rambod Rouhbakhsh (b) (4)	12 Mar 2021 19:51:52
User entered empty.	(b) (4), (b) (6) (b) (4), (b) (6)	29 Sep 2020 13:32:46

US3232021
Folder: Adverse Events
Form: Adverse Events (2)
Generated On: 11 Aug 2021 22:05:35
Narrative

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	02 May 2021 13:47:25
User signature succeeded.	Rambod Rouhbakhsh (b) (4)	12 Mar 2021 19:51:52
User entered empty.	(b) (4), (b) (6) (b) (4), (b) (6)	29 Sep 2020 13:32:46

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 11 Aug 2021 22:05:35

Serious Adverse Event Derived (CSA Programming Field Ony)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	02 May 2021 13:47:25
User entered '0'	System	29 Sep 2020 13:32:46

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 11 Aug 2021 22:05:35

Medically Attended AE Derived (CSA Programming Field Only)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	02 May 2021 13:47:25
User entered '1'	System	29 Sep 2020 13:32:46

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	02 May 2021 13:47:25

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination Summary

Generated On: 11 Aug 2021 22:05:35

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	02 May 2021 13:47:25
User signature succeeded.	Rambod Rouhbakhsh (b) (4)	02 Apr 2021 13:34:38
User closed query 'Per DM CLR: Per Diary Dose 1 Day 2, Pain at Injection Site = Repeated use of over-the-counter pain reliever > 24 hours or some interference with activity, however, there is no corresponding Conmed recorded that matches this information in the ConMed eCRF page. Please reconcile and update to record the medication given as appropriate, otherwise clarify. ' (Site from DM).	(b) (4), (b) (6) (b) (4), (b) (6)	03 Feb 2021 12:01:38
Query 'Per DM CLR: Per Diary Dose 1 Day 2, Pain at Injection Site = Repeated use of over-the-counter pain reliever > 24 hours or some interference with activity, however, there is no corresponding Conmed recorded that matches this information in the ConMed eCRF page. Please reconcile and update to record the medication given as appropriate, otherwise clarify. ' answered with 'CM LOG UPDATED' (Site from DM).	Jerrica Sullivan (b) (4) (b) (4)	02 Feb 2021 20:17:04
User opened query 'Per DM CLR: Per Diary Dose 1 Day 2, Pain at Injection Site = Repeated use of over-the-counter pain reliever > 24 hours or some interference with activity, however, there is no corresponding Conmed recorded that matches this information in the ConMed eCRF page. Please reconcile and update to record the medication given as appropriate, otherwise clarify. ' (Site from DM).	(b) (4), (b) (6) (b) (4), (b) (6)	01 Feb 2021 08:33:06
User entered 'Yes (Y)' reason for change: Data Entry Error	(b) (4), (b) (6) (b) (4), (b) (6)	25 Aug 2020 14:18:27
User entered 'No (N)'	Jerrica Sullivan (b) (4) (b) (4)	12 Aug 2020 16:26:08

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 11 Aug 2021 22:05:35

Name of Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	02 May 2021 13:47:25
User signature succeeded.	Rambod Rouhbakhsh (b) (4)	02 Apr 2021 13:34:38
User coded data point as ATC: NERVOUS SYSTEM, ATC: PSYCHOLEPTICS, ATC: ANXIOLYTICS, ATC: OTHER ANXIOLYTICS, PRODUCT: SERTRALINE HYDROCHLORIDE, PRODUCTSYNONYM: ZOLOFT - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	25 Aug 2020 14:22:31
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	25 Aug 2020 14:22:31
Data point term sent to Coder	System	25 Aug 2020 14:21:03
User entered 'zoloft'	(b) (4), (b) (6) (b) (4), (b) (6)	25 Aug 2020 14:20:42

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 11 Aug 2021 22:05:35

Prophylaxis

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	02 May 2021 13:47:25
User signature succeeded.	Rambod Rouhbakhsh (b) (4)	02 Apr 2021 13:34:38
User entered 'No (N)'	(b) (4), (b) (6) (b) (4), (b) (6)	25 Aug 2020 14:20:42

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 11 Aug 2021 22:05:35

Indication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	02 May 2021 13:47:25
User signature succeeded.	Rambod Rouhbakhsh (b) (4)	02 Apr 2021 13:34:38
User entered 'anxiety'	(b) (4), (b) (6) (b) (4), (b) (6)	25 Aug 2020 14:20:42

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 11 Aug 2021 22:05:35

Dose per administration

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	02 May 2021 13:47:25
User signature succeeded.	Rambod Rouhbakhsh (b) (4)	02 Apr 2021 13:34:38
User entered '50'	(b) (4), (b) (6) (b) (4), (b) (6)	25 Aug 2020 14:20:42

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

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Dose unit

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	02 May 2021 13:47:25
User signature succeeded.	Rambod Rouhbakhsh (b) (4)	02 Apr 2021 13:34:38
User entered 'mg (mg)'	(b) (4), (b) (6) (b) (4), (b) (6)	25 Aug 2020 14:20:42

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 11 Aug 2021 22:05:35

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	02 May 2021 13:47:25
User signature succeeded.	Rambod Rouhbakhsh (b) (4)	02 Apr 2021 13:34:38
User entered empty.	(b) (4), (b) (6) (b) (4), (b) (6)	25 Aug 2020 14:20:42

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 11 Aug 2021 22:05:35

Frequency

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	02 May 2021 13:47:25
User signature succeeded.	Rambod Rouhbakhsh (b) (4)	02 Apr 2021 13:34:38
User entered 'once daily (QD)'	(b) (4), (b) (6) (b) (4), (b) (6)	25 Aug 2020 14:20:42

US3232021

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 11 Aug 2021 22:05:35

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	02 May 2021 13:47:25
User signature succeeded.	Rambod Rouhbakhsh (b) (4)	02 Apr 2021 13:34:38
User entered empty.	(b) (4), (b) (6) (b) (4), (b) (6)	25 Aug 2020 14:20:42

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 11 Aug 2021 22:05:35

Route of administration

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	02 May 2021 13:47:25
User signature succeeded.	Rambod Rouhbakhsh (b) (4)	02 Apr 2021 13:34:38
User entered 'Oral (ORAL)'	(b) (4), (b) (6) (b) (4), (b) (6)	25 Aug 2020 14:20:42

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 11 Aug 2021 22:05:35

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	02 May 2021 13:47:25
User signature succeeded.	Rambod Rouhbakhsh (b) (4)	02 Apr 2021 13:34:38
User entered empty.	(b) (4), (b) (6) (b) (4), (b) (6)	25 Aug 2020 14:20:42

US3232021

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 11 Aug 2021 22:05:35

Start date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	02 May 2021 13:47:25
User signature succeeded.	Rambod Rouhbakhsh (b) (4)	02 Apr 2021 13:34:38
User entered 'un UNK 2013'	(b) (4), (b) (6) (b) (4), (b) (6)	25 Aug 2020 14:20:42

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 11 Aug 2021 22:05:35

Start date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	02 May 2021 13:47:25
User signature succeeded.	Rambod Rouhbakhsh (b) (4)	02 Apr 2021 13:34:38
User entered '0'	(b) (4), (b) (6) (b) (4), (b) (6)	25 Aug 2020 14:20:42

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 11 Aug 2021 22:05:35

Ongoing?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	02 May 2021 13:47:25
User signature succeeded.	Rambod Rouhbakhsh (b) (4)	02 Apr 2021 13:34:38
User entered 'Yes (Y)'	(b) (4), (b) (6) (b) (4), (b) (6)	25 Aug 2020 14:20:42

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 11 Aug 2021 22:05:35

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	02 May 2021 13:47:25
User signature succeeded.	Rambod Rouhbakhsh (b) (4)	02 Apr 2021 13:34:38
User entered empty.	(b) (4), (b) (6) (b) (4), (b) (6)	25 Aug 2020 14:20:42

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

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Was this medication taken for solicited event?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	02 May 2021 13:47:25
User signature succeeded.	Rambod Rouhbakhsh (b) (4)	02 Apr 2021 13:34:38
User entered 'No (N)'	(b) (4), (b) (6) (b) (4), (b) (6)	25 Aug 2020 14:20:42

US3232021

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 11 Aug 2021 22:05:35

Separate Dosage Number (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	02 May 2021 13:47:25
User entered '1'	System	25 Aug 2020 14:20:42

US3232021

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 11 Aug 2021 22:05:35

Interval Dosage Unit Number (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	02 May 2021 13:47:25
User entered '1'	System	25 Aug 2020 14:20:42

US3232021

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 11 Aug 2021 22:05:35

Interval Dosage Definition (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	02 May 2021 13:47:25
User entered '804 (804)'	System	25 Aug 2020 14:20:42

US3232021

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 11 Aug 2021 22:05:35

Name of Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	02 May 2021 13:47:25
User signature succeeded.	Rambod Rouhbakhsh (b) (4)	02 Apr 2021 13:34:38
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: VITAMINS, ATC: MULTIVITAMINS, PLAIN, ATC: MULTIVITAMINS, PLAIN, PRODUCT: VITAMINS NOS, PRODUCTSYNONYM: MULTIVITAMIN [VITAMINS NOS] - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	25 Aug 2020 14:24:32
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	25 Aug 2020 14:24:32
Data point term sent to Coder	System	25 Aug 2020 14:23:06
User entered 'Multivitamin'	(b) (4), (b) (6) (b) (4), (b) (6)	25 Aug 2020 14:22:40

US3232021

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 11 Aug 2021 22:05:35

Prophylaxis

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	02 May 2021 13:47:25
User signature succeeded.	Rambod Rouhbakhsh (b) (4)	02 Apr 2021 13:34:38
User closed query 'Per CDM: Please review the response as this medication appears to be given as prophylaxis. Note that supplements, vitamins, contraceptives/birth control, prophylactically indicated drugs, & heart health medications are examples of it. Update response as appropriate. Otherwise, clarify' (Site from DM).	(b) (4), (b) (6) (b) (4), (b) (6)	05 Feb 2021 14:57:48
Query 'Per CDM: Please review the response as this medication appears to be given as prophylaxis. Note that supplements, vitamins, contraceptives/birth control, prophylactically indicated drugs, & heart health medications are examples of it. Update response as appropriate. Otherwise, clarify' answered with 'updated' (Site from DM).	Jerrica Sullivan (b) (4) (b) (4)	04 Feb 2021 14:05:36
User entered 'Yes (Y)' reason for change: Data Entry Error	Jerrica Sullivan (b) (4) (b) (4)	04 Feb 2021 14:05:29
User opened query 'Per CDM: Please review the response as this medication appears to be given as prophylaxis. Note that supplements, vitamins, contraceptives/birth control, prophylactically indicated drugs, & heart health medications are examples of it. Update response as appropriate. Otherwise, clarify' (Site from DM).	(b) (4), (b) (6) (b) (4), (b) (6)	03 Feb 2021 12:01:21
User entered 'No (N)'	(b) (4), (b) (6) (b) (4), (b) (6)	25 Aug 2020 14:22:40

US3232021

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 11 Aug 2021 22:05:35

Indication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	02 May 2021 13:47:25
User signature succeeded.	Rambod Rouhbakhsh (b) (4)	02 Apr 2021 13:34:38
User entered 'Maintenance'	(b) (4), (b) (6) (b) (4), (b) (6)	25 Aug 2020 14:22:40

US3232021

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 11 Aug 2021 22:05:35

Dose per administration

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	02 May 2021 13:47:25
User signature succeeded.	Rambod Rouhbakhsh (b) (4)	02 Apr 2021 13:34:38
User entered '1'	(b) (4), (b) (6) (b) (4), (b) (6)	25 Aug 2020 14:22:40

US3232021

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 11 Aug 2021 22:05:35

Dose unit

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	02 May 2021 13:47:25
User signature succeeded.	Rambod Rouhbakhsh (b) (4)	02 Apr 2021 13:34:38
User entered 'tablet (TABLET)'	(b) (4), (b) (6) (b) (4), (b) (6)	25 Aug 2020 14:22:40

US3232021

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 11 Aug 2021 22:05:35

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	02 May 2021 13:47:25
User signature succeeded.	Rambod Rouhbakhsh (b) (4)	02 Apr 2021 13:34:38
User entered empty.	(b) (4), (b) (6) (b) (4), (b) (6)	25 Aug 2020 14:22:40

US3232021

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 11 Aug 2021 22:05:35

Frequency

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	02 May 2021 13:47:25
User signature succeeded.	Rambod Rouhbakhsh (b) (4)	02 Apr 2021 13:34:38
User entered 'once daily (QD)'	(b) (4), (b) (6) (b) (4), (b) (6)	25 Aug 2020 14:22:40

US3232021

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 11 Aug 2021 22:05:35

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	02 May 2021 13:47:25
User signature succeeded.	Rambod Rouhbakhsh (b) (4)	02 Apr 2021 13:34:38
User entered empty.	(b) (4), (b) (6) (b) (4), (b) (6)	25 Aug 2020 14:22:40

US3232021

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 11 Aug 2021 22:05:35

Route of administration

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	02 May 2021 13:47:25
User signature succeeded.	Rambod Rouhbakhsh (b) (4)	02 Apr 2021 13:34:38
User entered 'Oral (ORAL)'	(b) (4), (b) (6) (b) (4), (b) (6)	25 Aug 2020 14:22:40

US3232021

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 11 Aug 2021 22:05:35

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	02 May 2021 13:47:25
User signature succeeded.	Rambod Rouhbakhsh (b) (4)	02 Apr 2021 13:34:38
User entered empty.	(b) (4), (b) (6) (b) (4), (b) (6)	25 Aug 2020 14:22:40

US3232021

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 11 Aug 2021 22:05:35

Start date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	02 May 2021 13:47:25
User signature succeeded.	Rambod Rouhbakhsh (b) (4)	02 Apr 2021 13:34:38
User entered 'un UNK 2020'	(b) (4), (b) (6) (b) (4), (b) (6)	25 Aug 2020 14:22:40

US3232021

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 11 Aug 2021 22:05:35

Start date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	02 May 2021 13:47:25
User signature succeeded.	Rambod Rouhbakhsh (b) (4)	02 Apr 2021 13:34:38
User entered '0'	(b) (4), (b) (6) (b) (4), (b) (6)	25 Aug 2020 14:22:40

US3232021

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 11 Aug 2021 22:05:35

Ongoing?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	02 May 2021 13:47:25
User signature succeeded.	Rambod Rouhbakhsh (b) (4)	02 Apr 2021 13:34:38
User entered 'Yes (Y)'	(b) (4), (b) (6) (b) (4), (b) (6)	25 Aug 2020 14:22:40

US3232021

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 11 Aug 2021 22:05:35

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	02 May 2021 13:47:25
User signature succeeded.	Rambod Rouhbakhsh (b) (4)	02 Apr 2021 13:34:38
User entered empty.	(b) (4), (b) (6) (b) (4), (b) (6)	25 Aug 2020 14:22:40

US3232021

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 11 Aug 2021 22:05:35

Was this medication taken for solicited event?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	02 May 2021 13:47:25
User signature succeeded.	Rambod Rouhbakhsh (b) (4)	02 Apr 2021 13:34:38
User entered 'No (N)'	(b) (4), (b) (6) (b) (4), (b) (6)	25 Aug 2020 14:22:40

US3232021

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 11 Aug 2021 22:05:35

Separate Dosage Number (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	02 May 2021 13:47:25
User entered '1'	System	25 Aug 2020 14:22:40

US3232021

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 11 Aug 2021 22:05:35

Interval Dosage Unit Number (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	02 May 2021 13:47:25
User entered '1'	System	25 Aug 2020 14:22:40

Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (2)
Generated On: 11 Aug 2021 22:05:35

Interval Dosage Definition (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	02 May 2021 13:47:25
User entered '804 (804)'	System	25 Aug 2020 14:22:40

Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (3)
Generated On: 11 Aug 2021 22:05:35

Name of Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	02 May 2021 13:47:25
User signature succeeded.	Rambod Rouhbakhsh (b) (4)	02 Apr 2021 13:34:38
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: VITAMINS, ATC: VITAMIN A AND D, INCL. COMBINATIONS OF THE TWO, ATC: VITAMIN D AND ANALOGUES, PRODUCT: COLECALCIFEROL, PRODUCTSYNONYM: VITAMIN D3 - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	25 Aug 2020 14:29:32
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	25 Aug 2020 14:29:32
Data point term sent to Coder	System	25 Aug 2020 14:28:20
Data point term sent to Coder	System	25 Aug 2020 14:27:19
User entered 'vitamin D3'	(b) (4), (b) (6) (b) (4), (b) (6)	25 Aug 2020 14:27:17

US3232021

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 11 Aug 2021 22:05:35

Prophylaxis

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	02 May 2021 13:47:25
User signature succeeded.	Rambod Rouhbakhsh (b) (4)	02 Apr 2021 13:34:38
User entered 'No (N)'	(b) (4), (b) (6) (b) (4), (b) (6)	25 Aug 2020 14:27:17

US3232021

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 11 Aug 2021 22:05:35

Indication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	02 May 2021 13:47:25
User signature succeeded.	Rambod Rouhbakhsh (b) (4)	02 Apr 2021 13:34:38
User entered 'Vitamin D Deficiency'	(b) (4), (b) (6) (b) (4), (b) (6)	25 Aug 2020 14:27:17

US3232021

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 11 Aug 2021 22:05:35

Dose per administration

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	02 May 2021 13:47:25
User signature succeeded.	Rambod Rouhbakhsh (b) (4)	02 Apr 2021 13:34:38
User entered '5000'	(b) (4), (b) (6) (b) (4), (b) (6)	25 Aug 2020 14:27:17

US3232021

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 11 Aug 2021 22:05:35

Dose unit

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	02 May 2021 13:47:25
User signature succeeded.	Rambod Rouhbakhsh (b) (4)	02 Apr 2021 13:34:38
User entered 'IU (IU)'	(b) (4), (b) (6) (b) (4), (b) (6)	25 Aug 2020 14:27:17

US3232021

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 11 Aug 2021 22:05:35

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	02 May 2021 13:47:25
User signature succeeded.	Rambod Rouhbakhsh (b) (4)	02 Apr 2021 13:34:38
User entered empty.	(b) (4), (b) (6) (b) (4), (b) (6)	25 Aug 2020 14:27:17

US3232021

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 11 Aug 2021 22:05:35

Frequency

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	02 May 2021 13:47:25
User signature succeeded.	Rambod Rouhbakhsh (b) (4)	02 Apr 2021 13:34:38
User entered 'every week (QS)'	(b) (4), (b) (6) (b) (4), (b) (6)	25 Aug 2020 14:27:17

US3232021

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 11 Aug 2021 22:05:35

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	02 May 2021 13:47:25
User signature succeeded.	Rambod Rouhbakhsh (b) (4)	02 Apr 2021 13:34:38
User entered empty.	(b) (4), (b) (6) (b) (4), (b) (6)	25 Aug 2020 14:27:17

US3232021

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 11 Aug 2021 22:05:35

Route of administration

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	02 May 2021 13:47:25
User signature succeeded.	Rambod Rouhbakhsh (b) (4)	02 Apr 2021 13:34:38
User closed query 'Data is required. Please complete.' (Site from System).	System	25 Aug 2020 14:27:28
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	25 Aug 2020 14:27:28
User entered 'Oral (ORAL)' reason for change: Data Entry Error	(b) (4), (b) (6) (b) (4), (b) (6)	25 Aug 2020 14:27:28
User opened query 'Data is required. Please complete.' (Site from System).	System	25 Aug 2020 14:27:17
User entered empty.	(b) (4), (b) (6) (b) (4), (b) (6)	25 Aug 2020 14:27:17

US3232021

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 11 Aug 2021 22:05:35

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	02 May 2021 13:47:25
User signature succeeded.	Rambod Rouhbakhsh (b) (4)	02 Apr 2021 13:34:38
User entered empty.	(b) (4), (b) (6) (b) (4), (b) (6)	25 Aug 2020 14:27:17

US3232021

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 11 Aug 2021 22:05:35

Start date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	02 May 2021 13:47:25
User signature succeeded.	Rambod Rouhbakhsh (b) (4)	02 Apr 2021 13:34:38
User entered 'un May 2018'	(b) (4), (b) (6) (b) (4), (b) (6)	25 Aug 2020 14:27:17

US3232021

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 11 Aug 2021 22:05:35

Start date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	02 May 2021 13:47:25
User signature succeeded.	Rambod Rouhbakhsh (b) (4)	02 Apr 2021 13:34:38
User entered '0'	(b) (4), (b) (6) (b) (4), (b) (6)	25 Aug 2020 14:27:17

US3232021

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 11 Aug 2021 22:05:35

Ongoing?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	02 May 2021 13:47:25
User signature succeeded.	Rambod Rouhbakhsh (b) (4)	02 Apr 2021 13:34:38
User entered 'Yes (Y)'	(b) (4), (b) (6) (b) (4), (b) (6)	25 Aug 2020 14:27:17

US3232021

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 11 Aug 2021 22:05:35

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	02 May 2021 13:47:25
User signature succeeded.	Rambod Rouhbakhsh (b) (4)	02 Apr 2021 13:34:38
User entered empty.	(b) (4), (b) (6) (b) (4), (b) (6)	25 Aug 2020 14:27:17

US3232021

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 11 Aug 2021 22:05:35

Was this medication taken for solicited event?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	02 May 2021 13:47:25
User signature succeeded.	Rambod Rouhbakhsh (b) (4)	02 Apr 2021 13:34:38
User entered 'No (N)'	(b) (4), (b) (6) (b) (4), (b) (6)	25 Aug 2020 14:27:17

US3232021

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 11 Aug 2021 22:05:35

Separate Dosage Number (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	02 May 2021 13:47:25
User entered '1'	System	25 Aug 2020 14:27:17

US3232021

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 11 Aug 2021 22:05:35

Interval Dosage Unit Number (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	02 May 2021 13:47:25
User entered '1'	System	25 Aug 2020 14:27:17

US3232021

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 11 Aug 2021 22:05:35

Interval Dosage Definition (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	02 May 2021 13:47:25
User entered '803 (803)'	System	25 Aug 2020 14:27:17

US3232021

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 11 Aug 2021 22:05:35

Name of Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	02 May 2021 13:47:25
User signature succeeded.	Rambod Rouhbakhsh (b) (4)	02 Apr 2021 13:34:38
User closed query 'Per DM CLR: This Conmed is given for the AE#1. It seems that "Other Action Taken" on the AE eCRF does not reflect that a CM was given. Please review and reconcile CM and AE eCRF as appropriate. Otherwise, provide clarification. ' (Site from DM).	(b) (4), (b) (6) (b) (4), (b) (6)	12 Mar 2021 12:41:18
Query 'Per DM CLR: This Conmed is given for the AE#1. It seems that "Other Action Taken" on the AE eCRF does not reflect that a CM was given. Please review and reconcile CM and AE eCRF as appropriate. Otherwise, provide clarification. ' answered with 'updated' (Site from DM).	Jerrica Sullivan (b) (4) (b) (4)	11 Mar 2021 16:04:19
User opened query 'Per DM CLR: This Conmed is given for the AE#1. It seems that "Other Action Taken" on the AE eCRF does not reflect that a CM was given. Please review and reconcile CM and AE eCRF as appropriate. Otherwise, provide clarification. ' (Site from DM).	(b) (4), (b) (6) (b) (4), (b) (6)	11 Mar 2021 07:52:36
User coded data point as ATC: MUSCULO-SKELETAL SYSTEM, ATC: ANTIINFLAMMATORY AND ANTIRHEUMATIC PRODUCTS, ATC: ANTIINFLAMMATORY AND ANTIRHEUMATIC PRODUCTS, NON-STEROIDS, ATC: PROPIONIC ACID DERIVATIVES, PRODUCT: IBUPROFEN, PRODUCTSYNONYM: ADVIL [IBUPROFEN] - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	25 Feb 2021 06:22:07
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	25 Feb 2021 06:22:07
Data point term sent to Coder	System	23 Feb 2021 15:28:39
Coding entries removed.	Jerrica Sullivan (b) (4) (b) (4)	23 Feb 2021 15:28:09

FDA-CBER-2022-1614-0646781

US3232021

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 11 Aug 2021 22:05:35

Name of Medication

Audit	User	Time (GMT)
User coded data point as ATC: MUSCULO-SKELETAL SYSTEM, ATC: ANTIINFLAMMATORY AND ANTIRHEUMATIC PRODUCTS, ATC: ANTIINFLAMMATORY AND ANTIRHEUMATIC PRODUCTS, NON-STEROIDS, ATC: PROPIONIC ACID DERIVATIVES, PRODUCT: IBUPROFEN, PRODUCTSYNONYM: ADVIL [IBUPROFEN] - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	02 Feb 2021 20:18:32
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	02 Feb 2021 20:18:32
Data point term sent to Coder	System	02 Feb 2021 20:17:42
User entered 'ADVIL'	Jerrica Sullivan (b) (4) (b) (4)	02 Feb 2021 20:17:37

US3232021

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 11 Aug 2021 22:05:35

Prophylaxis

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	02 May 2021 13:47:25
User signature succeeded.	Rambod Rouhbakhsh (b) (4)	02 Apr 2021 13:34:38
User entered 'No (N)'	Jerrica Sullivan (b) (4) (b) (4)	02 Feb 2021 20:17:37

US3232021

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 11 Aug 2021 22:05:35

Indication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	02 May 2021 13:47:25
User signature succeeded.	Rambod Rouhbakhsh (b) (4)	02 Apr 2021 13:34:38
User closed query 'Per DM CLR: Please note there is no ongoing MH condition or AE that matches this Con Med indication. Please review the Con Med use and add a medical condition and all applicable details to the appropriate MH or AE eCRF.' (Site from DM).	(b) (4), (b) (6) (b) (4), (b) (6)	25 Feb 2021 12:42:43
Query 'Per DM CLR: Please note there is no ongoing MH condition or AE that matches this Con Med indication. Please review the Con Med use and add a medical condition and all applicable details to the appropriate MH or AE eCRF.' answered with 'indication updated' (Site from DM).	Jerrica Sullivan (b) (4) (b) (4)	23 Feb 2021 15:28:21
User entered 'Upper extremity arthralgia' reason for change: Data Entry Error	Jerrica Sullivan (b) (4) (b) (4)	23 Feb 2021 15:28:09
User opened query 'Per DM CLR: Please note there is no ongoing MH condition or AE that matches this Con Med indication. Please review the Con Med use and add a medical condition and all applicable details to the appropriate MH or AE eCRF.' (Site from DM).	(b) (4), (b) (6) (b) (4), (b) (6)	21 Feb 2021 08:42:59
User entered 'JOINT PAIN'	Jerrica Sullivan (b) (4) (b) (4)	02 Feb 2021 20:17:37

US3232021

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 11 Aug 2021 22:05:35

Dose per administration

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	02 May 2021 13:47:25
User signature succeeded.	Rambod Rouhbakhsh (b) (4)	02 Apr 2021 13:34:38
User entered '400'	Jerrica Sullivan (b) (4) (b) (4)	02 Feb 2021 20:17:37

US3232021

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 11 Aug 2021 22:05:35

Dose unit

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	02 May 2021 13:47:25
User signature succeeded.	Rambod Rouhbakhsh (b) (4)	02 Apr 2021 13:34:38
User entered 'mg (mg)'	Jerrica Sullivan (b) (4) (b) (4)	02 Feb 2021 20:17:37

US3232021

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 11 Aug 2021 22:05:35

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	02 May 2021 13:47:25
User signature succeeded.	Rambod Rouhbakhsh (b) (4)	02 Apr 2021 13:34:38
User entered empty.	Jerrica Sullivan (b) (4) (b) (4)	02 Feb 2021 20:17:37

US3232021

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 11 Aug 2021 22:05:35

Frequency

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	02 May 2021 13:47:25
User signature succeeded.	Rambod Rouhbakhsh (b) (4)	02 Apr 2021 13:34:38
User entered 'twice daily (BID)'	Jerrica Sullivan (b) (4) (b) (4)	02 Feb 2021 20:17:37

US3232021

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 11 Aug 2021 22:05:35

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	02 May 2021 13:47:25
User signature succeeded.	Rambod Rouhbakhsh (b) (4)	02 Apr 2021 13:34:38
User entered empty.	Jerrica Sullivan (b) (4) (b) (4)	02 Feb 2021 20:17:37

US3232021

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 11 Aug 2021 22:05:35

Route of administration

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	02 May 2021 13:47:25
User signature succeeded.	Rambod Rouhbakhsh (b) (4)	02 Apr 2021 13:34:38
User entered 'Oral (ORAL)'	Jerrica Sullivan (b) (4) (b) (4)	02 Feb 2021 20:17:37

US3232021

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 11 Aug 2021 22:05:35

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	02 May 2021 13:47:25
User signature succeeded.	Rambod Rouhbakhsh (b) (4)	02 Apr 2021 13:34:38
User entered empty.	Jerrica Sullivan (b) (4) (b) (4)	02 Feb 2021 20:17:37

US3232021

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 11 Aug 2021 22:05:35

Start date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	02 May 2021 13:47:25
User signature succeeded.	Rambod Rouhbakhsh (b) (4)	02 Apr 2021 13:34:38
User entered '25 Aug 2020'	Jerrica Sullivan (b) (4) (b) (4)	02 Feb 2021 20:17:37

US3232021

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 11 Aug 2021 22:05:35

Start date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	02 May 2021 13:47:25
User signature succeeded.	Rambod Rouhbakhsh (b) (4)	02 Apr 2021 13:34:38
User entered '0'	Jerrica Sullivan (b) (4) (b) (4)	02 Feb 2021 20:17:37

US3232021

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 11 Aug 2021 22:05:35

Ongoing?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	02 May 2021 13:47:25
User signature succeeded.	Rambod Rouhbakhsh (b) (4)	02 Apr 2021 13:34:38
User entered 'Yes (Y)'	Jerrica Sullivan (b) (4) (b) (4)	02 Feb 2021 20:17:37

US3232021

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 11 Aug 2021 22:05:35

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	02 May 2021 13:47:25
User signature succeeded.	Rambod Rouhbakhsh (b) (4)	02 Apr 2021 13:34:38
User entered empty.	Jerrica Sullivan (b) (4) (b) (4)	02 Feb 2021 20:17:37

US3232021

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 11 Aug 2021 22:05:35

Was this medication taken for solicited event?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	02 May 2021 13:47:25
User signature succeeded.	Rambod Rouhbakhsh (b) (4)	02 Apr 2021 13:34:38
User entered 'No (N)'	Jerrica Sullivan (b) (4) (b) (4)	02 Feb 2021 20:17:37

US3232021

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 11 Aug 2021 22:05:35

Separate Dosage Number (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	02 May 2021 13:47:25
User entered '2'	System	02 Feb 2021 20:17:37

US3232021

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 11 Aug 2021 22:05:35

Interval Dosage Unit Number (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	02 May 2021 13:47:25
User entered '1'	System	02 Feb 2021 20:17:37

US3232021

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 11 Aug 2021 22:05:35

Interval Dosage Definition (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	02 May 2021 13:47:25
User entered '804 (804)'	System	02 Feb 2021 20:17:37

US3232021

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 11 Aug 2021 22:05:35

Name of Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	02 May 2021 13:47:25
User signature succeeded.	Rambod Rouhbakhsh (b) (4)	02 Apr 2021 13:34:38
User closed query 'Per DM CLR: This Conmed is given for the AE#1. It seems that "Other Action Taken" on the AE eCRF does not reflect that a CM was given. Please review and reconcile CM and AE eCRF as appropriate. Otherwise, provide clarification. ' (Site from DM).	(b) (4) (b) (4)	12 Mar 2021 12:41:33
Query 'Per DM CLR: This Conmed is given for the AE#1. It seems that "Other Action Taken" on the AE eCRF does not reflect that a CM was given. Please review and reconcile CM and AE eCRF as appropriate. Otherwise, provide clarification. ' answered with 'updated' (Site from DM).	Jerrica Sullivan (b) (4) (b) (4)	11 Mar 2021 16:04:06
User opened query 'Per DM CLR: This Conmed is given for the AE#1. It seems that "Other Action Taken" on the AE eCRF does not reflect that a CM was given. Please review and reconcile CM and AE eCRF as appropriate. Otherwise, provide clarification. ' (Site from DM).	(b) (4), (b) (6) (b) (4), (b) (6)	11 Mar 2021 07:52:44
User coded data point as ATC: MUSCULO-SKELETAL SYSTEM, ATC: ANTIINFLAMMATORY AND ANTIRHEUMATIC PRODUCTS, ATC: ANTIINFLAMMATORY AND ANTIRHEUMATIC PRODUCTS, NON-STEROIDS, ATC: COXIBS, PRODUCT: CELECOXIB, PRODUCTSYNONYM: CELEBREX - version WHODrug-Global-B3\\202003.	Coder Import ^{(b) (4)} (b) (4)	25 Feb 2021 13:20:15
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import ^{(b) (4)} (b) (4)	25 Feb 2021 13:20:15
Data point term sent to Coder	System	23 Feb 2021 15:28:39
Coding entries removed.	Jerrica Sullivan (b) (4) (b) (4)	23 Feb 2021 15:28:35

US3232021

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 11 Aug 2021 22:05:35

Name of Medication

Audit	User	Time (GMT)
User coded data point as ATC: MUSCULO-SKELETAL SYSTEM, ATC: ANTIINFLAMMATORY AND ANTIRHEUMATIC PRODUCTS, ATC: ANTIINFLAMMATORY AND ANTIRHEUMATIC PRODUCTS, NON-STEROIDS, ATC: COXIBS, PRODUCT: CELECOXIB, PRODUCTSYNONYM: CELEBREX - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	02 Feb 2021 20:19:37
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	02 Feb 2021 20:19:37
Data point term sent to Coder	System	02 Feb 2021 20:18:45
User entered 'CELEBREX'	Jerrica Sullivan (b) (4) (b) (4)	02 Feb 2021 20:18:01

US3232021

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 11 Aug 2021 22:05:35

Prophylaxis

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	02 May 2021 13:47:25
User signature succeeded.	Rambod Rouhbakhsh (b) (4)	02 Apr 2021 13:34:38
User entered 'No (N)'	Jerrica Sullivan (b) (4) (b) (4)	02 Feb 2021 20:18:01

US3232021

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 11 Aug 2021 22:05:35

Indication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	02 May 2021 13:47:25
User signature succeeded.	Rambod Rouhbakhsh (b) (4)	02 Apr 2021 13:34:38
User entered 'UPPER EXTREMITY ARTHRALGIA' reason for change: Data Entry Error	Jerrica Sullivan (b) (4) (b) (4)	23 Feb 2021 15:28:35
User entered 'JOINT PAIN'	Jerrica Sullivan (b) (4) (b) (4)	02 Feb 2021 20:18:01

US3232021

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 11 Aug 2021 22:05:35

Dose per administration

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	02 May 2021 13:47:25
User signature succeeded.	Rambod Rouhbakhsh (b) (4)	02 Apr 2021 13:34:38
User entered '100'	Jerrica Sullivan (b) (4) (b) (4)	02 Feb 2021 20:18:01

US3232021

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 11 Aug 2021 22:05:35

Dose unit

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	02 May 2021 13:47:25
User signature succeeded.	Rambod Rouhbakhsh (b) (4)	02 Apr 2021 13:34:38
User entered 'mg (mg)'	Jerrica Sullivan (b) (4) (b) (4)	02 Feb 2021 20:18:01

US3232021

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 11 Aug 2021 22:05:35

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	02 May 2021 13:47:25
User signature succeeded.	Rambod Rouhbakhsh (b) (4)	02 Apr 2021 13:34:38
User entered empty.	Jerrica Sullivan (b) (4) (b) (4)	02 Feb 2021 20:18:01

US3232021

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 11 Aug 2021 22:05:35

Frequency

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	02 May 2021 13:47:25
User signature succeeded.	Rambod Rouhbakhsh (b) (4)	02 Apr 2021 13:34:38
User entered 'twice daily (BID)'	Jerrica Sullivan (b) (4) (b) (4)	02 Feb 2021 20:18:01

US3232021

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 11 Aug 2021 22:05:35

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	02 May 2021 13:47:25
User signature succeeded.	Rambod Rouhbakhsh (b) (4)	02 Apr 2021 13:34:38
User entered empty.	Jerrica Sullivan (b) (4) (b) (4)	02 Feb 2021 20:18:01

US3232021

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 11 Aug 2021 22:05:35

Route of administration

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	02 May 2021 13:47:25
User signature succeeded.	Rambod Rouhbakhsh (b) (4)	02 Apr 2021 13:34:38
User entered 'Oral (ORAL)'	Jerrica Sullivan (b) (4) (b) (4)	02 Feb 2021 20:18:01

US3232021

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 11 Aug 2021 22:05:35

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	02 May 2021 13:47:25
User signature succeeded.	Rambod Rouhbakhsh (b) (4)	02 Apr 2021 13:34:38
User entered empty.	Jerrica Sullivan (b) (4) (b) (4)	02 Feb 2021 20:18:01

US3232021

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 11 Aug 2021 22:05:35

Start date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	02 May 2021 13:47:25
User signature succeeded.	Rambod Rouhbakhsh (b) (4)	02 Apr 2021 13:34:38
User closed query 'Start Date is after Assessment Date of study discontinuation/completion on the End of Study/Study Discontinuation form. Please review and provide any needed correction.' (Site from System).	System	30 Mar 2021 13:34:08
User opened query 'Start Date is after Assessment Date of study discontinuation/completion on the End of Study/Study Discontinuation form. Please review and provide any needed correction.' (Site from System).	System	30 Mar 2021 12:50:53
User entered '16 Sep 2020'	Jerrica Sullivan (b) (4) (b) (4)	02 Feb 2021 20:18:01

US3232021

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 11 Aug 2021 22:05:35

Start date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	02 May 2021 13:47:25
User signature succeeded.	Rambod Rouhbakhsh (b) (4)	02 Apr 2021 13:34:38
User entered '0'	Jerrica Sullivan (b) (4) (b) (4)	02 Feb 2021 20:18:01

US3232021

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 11 Aug 2021 22:05:35

Ongoing?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	02 May 2021 13:47:25
User signature succeeded.	Rambod Rouhbakhsh (b) (4)	02 Apr 2021 13:34:38
User entered 'Yes (Y)'	Jerrica Sullivan (b) (4) (b) (4)	02 Feb 2021 20:18:01

US3232021

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 11 Aug 2021 22:05:35

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	02 May 2021 13:47:25
User signature succeeded.	Rambod Rouhbakhsh (b) (4)	02 Apr 2021 13:34:38
User entered empty.	Jerrica Sullivan (b) (4) (b) (4)	02 Feb 2021 20:18:01

US3232021

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 11 Aug 2021 22:05:35

Was this medication taken for solicited event?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	02 May 2021 13:47:25
User signature succeeded.	Rambod Rouhbakhsh (b) (4)	02 Apr 2021 13:34:38
User entered 'No (N)'	Jerrica Sullivan (b) (4) (b) (4)	02 Feb 2021 20:18:01

US3232021

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 11 Aug 2021 22:05:35

Separate Dosage Number (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	02 May 2021 13:47:25
User entered '2'	System	02 Feb 2021 20:18:01

US3232021

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 11 Aug 2021 22:05:35

Interval Dosage Unit Number (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	02 May 2021 13:47:25
User entered '1'	System	02 Feb 2021 20:18:01

US3232021

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 11 Aug 2021 22:05:35

Interval Dosage Definition (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	02 May 2021 13:47:25
User entered '804 (804)'	System	02 Feb 2021 20:18:01

US3232021

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 11 Aug 2021 22:05:35

Name of Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	28 Apr 2021 12:38:56
User signature succeeded.	Rambod Rouhbakhsh (b) (4)	02 Apr 2021 13:34:38
User coded data point as ATC: MUSCULO-SKELETAL SYSTEM, ATC: ANTIINFLAMMATORY AND ANTIRHEUMATIC PRODUCTS, ATC: ANTIINFLAMMATORY AND ANTIRHEUMATIC PRODUCTS, NON-STEROIDS, ATC: PROPIONIC ACID DERIVATIVES, PRODUCT: IBUPROFEN, PRODUCTSYNONYM: ADVIL [IBUPROFEN] - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	02 Feb 2021 20:19:38
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	02 Feb 2021 20:19:38
Data point term sent to Coder	System	02 Feb 2021 20:18:46
User entered 'ADVIL'	Jerrica Sullivan (b) (4) (b) (4)	02 Feb 2021 20:18:27

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 11 Aug 2021 22:05:35

Prophylaxis

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	28 Apr 2021 12:38:56
User signature succeeded.	Rambod Rouhbakhsh (b) (4)	02 Apr 2021 13:34:38
User entered 'No (N)'	Jerrica Sullivan (b) (4) (b) (4)	02 Feb 2021 20:18:27

US3232021

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 11 Aug 2021 22:05:35

Indication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:38:56
User signature succeeded.	(b) (4), (b) (6) Rambod Rouhbakhsh	02 Apr 2021 13:34:38
User closed query 'Per DM CLR: Please note that there is no AE that matches this Con Med indication during this timeframe. If the INJECTION SITE PAIN is considered a solicited local or systemic adverse reaction, and meets any of the following criteria:results in a visit to a healthcare provider (MAAE), leads to withdrawal from the study of study vaccination, or otherwise meets the definition of an SAE, please add an entry and applicable details to the AE ecrf as appropriate. Otherwise, please confirm in query response that the solicited adverse reaction of INJECTION SITE PAIN did not meet the AE reporting criteria.' (Site from DM).	(b) (4) (b) (4), (b) (6) (b) (4), (b) (6)	23 Feb 2021 13:17:17
Query 'Per DM CLR: Please note that there is no AE that matches this Con Med indication during this timeframe. If the INJECTION SITE PAIN is considered a solicited local or systemic adverse reaction, and meets any of the following criteria:results in a visit to a healthcare provider (MAAE), leads to withdrawal from the study of study vaccination, or otherwise meets the definition of an SAE, please add an entry and applicable details to the AE ecrf as appropriate. Otherwise, please confirm in query response that the solicited adverse reaction of INJECTION SITE PAIN did not meet the AE reporting criteria.' answered with 'captured in ediary and does not meet ae guidelines' (Site from DM).	Jerrica Sullivan (b) (4) (b) (4)	22 Feb 2021 18:31:10

US3232021

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 11 Aug 2021 22:05:35

Indication

Audit	User	Time (GMT)
User opened query 'Per DM CLR: Please note that there is no AE that matches this Con Med indication during this timeframe. If the INJECTION SITE PAIN is considered a solicited local or systemic adverse reaction, and meets any of the following criteria:results in a visit to a healthcare provider (MAAE), leads to withdrawal from the study of study vaccination, or otherwise meets the definition of an SAE, please add an entry and applicable details to the AE ecrf as appropriate. Otherwise, please confirm in query response that the solicited adverse reaction of INJECTION SITE PAIN did not meet the AE reporting criteria.' (Site from DM).	(b) (4), (b) (6) (b) (4), (b) (6)	21 Feb 2021 08:43:11
User entered 'INJECTION SITE PAIN'	Jerrica Sullivan (b) (4) (b) (4)	02 Feb 2021 20:18:27

US3232021

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 11 Aug 2021 22:05:35

Dose per administration

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:38:56
User signature succeeded.	(b) (4), (b) (6) Rambod Rouhbakhsh	02 Apr 2021 13:34:38
User entered '400'	(b) (4) Jerrica Sullivan (b) (4) (b) (4)	02 Feb 2021 20:18:27

US3232021

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 11 Aug 2021 22:05:35

Dose unit

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	28 Apr 2021 12:38:56
User signature succeeded.	Rambod Rouhbakhsh (b) (4)	02 Apr 2021 13:34:38
User entered 'mg (mg)'	Jerrica Sullivan (b) (4) (b) (4)	02 Feb 2021 20:18:27

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 11 Aug 2021 22:05:35

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	28 Apr 2021 12:38:56
User signature succeeded.	Rambod Rouhbakhsh (b) (4)	02 Apr 2021 13:34:38
User entered empty.	Jerrica Sullivan (b) (4) (b) (4)	02 Feb 2021 20:18:27

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 11 Aug 2021 22:05:35

Frequency

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	28 Apr 2021 12:38:56
User signature succeeded.	Rambod Rouhbakhsh (b) (4)	02 Apr 2021 13:34:38
User entered 'once daily (QD)'	Jerrica Sullivan (b) (4) (b) (4)	02 Feb 2021 20:18:27

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 11 Aug 2021 22:05:35

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	28 Apr 2021 12:38:56
User signature succeeded.	Rambod Rouhbakhsh (b) (4)	02 Apr 2021 13:34:38
User entered empty.	Jerrica Sullivan (b) (4) (b) (4)	02 Feb 2021 20:18:27

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 11 Aug 2021 22:05:35

Route of administration

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	28 Apr 2021 12:38:56
User signature succeeded.	Rambod Rouhbakhsh (b) (4)	02 Apr 2021 13:34:38
User entered 'Oral (ORAL)'	Jerrica Sullivan (b) (4) (b) (4)	02 Feb 2021 20:18:27

US3232021

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 11 Aug 2021 22:05:35

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	28 Apr 2021 12:38:56
User signature succeeded.	Rambod Rouhbakhsh (b) (4)	02 Apr 2021 13:34:38
User entered empty.	Jerrica Sullivan (b) (4) (b) (4)	02 Feb 2021 20:18:27

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 11 Aug 2021 22:05:35

Start date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	28 Apr 2021 12:38:56
User signature succeeded.	Rambod Rouhbakhsh (b) (4)	02 Apr 2021 13:34:38
User entered '11 Aug 2020'	Jerrica Sullivan (b) (4) (b) (4)	02 Feb 2021 20:18:27

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 11 Aug 2021 22:05:35

Start date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	28 Apr 2021 12:38:56
User signature succeeded.	Rambod Rouhbakhsh (b) (4)	02 Apr 2021 13:34:38
User entered '0'	Jerrica Sullivan (b) (4) (b) (4)	02 Feb 2021 20:18:27

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 11 Aug 2021 22:05:35

Ongoing?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	28 Apr 2021 12:38:56
User signature succeeded.	Rambod Rouhbakhsh (b) (4)	02 Apr 2021 13:34:38
User entered 'No (N)'	Jerrica Sullivan (b) (4) (b) (4)	02 Feb 2021 20:18:27

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 11 Aug 2021 22:05:35

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	28 Apr 2021 12:38:56
User signature succeeded.	Rambod Rouhbakhsh (b) (4)	02 Apr 2021 13:34:38
User entered '11 Aug 2020'	Jerrica Sullivan (b) (4) (b) (4)	02 Feb 2021 20:18:27

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 11 Aug 2021 22:05:35

Was this medication taken for solicited event?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:38:56
User signature succeeded.	(b) (4), (b) (6) Rambod Rouhbakhsh (b) (4)	02 Apr 2021 13:34:38
User closed query 'Per DM CLR: Was this medication taken for solicited event?=NO. However, there is a record of this event in Diary within 7-day reporting of Solicited Adverse Reaction. Review if this should be updated. Else, provide clarification on query response.' (Site from DM).	(b) (4), (b) (6) (b) (4), (b) (6)	23 Feb 2021 13:17:26
Query 'Per DM CLR: Was this medication taken for solicited event?=NO. However, there is a record of this event in Diary within 7-day reporting of Solicited Adverse Reaction. Review if this should be updated. Else, provide clarification on query response.' answered with 'updated' (Site from DM).	Jerrica Sullivan (b) (4) (b) (4)	22 Feb 2021 18:31:16
User entered 'Yes (Y)' reason for change: Data Entry Error	Jerrica Sullivan (b) (4) (b) (4)	22 Feb 2021 18:31:04
User opened query 'Per DM CLR: Was this medication taken for solicited event?=NO. However, there is a record of this event in Diary within 7-day reporting of Solicited Adverse Reaction. Review if this should be updated. Else, provide clarification on query response.' (Site from DM).	(b) (4), (b) (6) (b) (4), (b) (6)	21 Feb 2021 08:43:18
User entered 'No (N)'	Jerrica Sullivan (b) (4) (b) (4)	02 Feb 2021 20:18:27

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 11 Aug 2021 22:05:35

Separate Dosage Number (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	28 Apr 2021 12:38:56
User entered '1'	System	02 Feb 2021 20:18:27

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 11 Aug 2021 22:05:35

Interval Dosage Unit Number (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	28 Apr 2021 12:38:56
User entered '1'	System	02 Feb 2021 20:18:27

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 11 Aug 2021 22:05:35

Interval Dosage Definition (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	28 Apr 2021 12:38:56
User entered '804 (804)'	System	02 Feb 2021 20:18:27

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Folder: Concomitant Procedures (1)

Form: Concomitant Procedures Summary

Generated On: 11 Aug 2021 22:05:35

Were any concomitant procedures performed?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	02 May 2021 13:47:25
User signature succeeded.	Rambod Rouhbakhsh (b) (4)	02 Apr 2021 13:34:38
User entered 'No (N)'	Jerrica Sullivan (b) (4) (b) (4)	12 Aug 2020 16:26:12

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Folder: End of Study (1)

Form: Dosing Discontinuation

Generated On: 11 Aug 2021 22:05:35

Date of dosing discontinuation (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	27 Apr 2021 07:52:50
User signature succeeded.	Rambod Rouhbakhsh (b) (4)	02 Apr 2021 13:34:38
User entered '09 Sep 2020'	Jerrica Sullivan (b) (4) (b) (4)	23 Nov 2020 17:53:46

US3232021

Folder: End of Study (1)

Form: Dosing Discontinuation

Generated On: 11 Aug 2021 22:05:35

Primary reason for dosing discontinuation

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	27 Apr 2021 07:52:50
User signature succeeded.	Rambod Rouhbakhsh (b) (4)	02 Apr 2021 13:34:38
User entered 'Physician decision (specify) (PHYSICIAN DECISION)'	Jerrica Sullivan (b) (4) (b) (4)	23 Nov 2020 17:53:46

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Folder: End of Study (1)

Form: Dosing Discontinuation

Generated On: 11 Aug 2021 22:05:35

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) (b) (4), (b) (6)	27 Apr 2021 07:52:50
User signature succeeded.	Rambod Rouhbakhsh (b) (4)	02 Apr 2021 13:34:38
User closed query 'Primary reason for dosing discontinuation is AE, SAE, Physician Decision, Withdrawal of consent by participant, Protocol deviation, or Other, however specify is missing. Please provide.' (Site from System).	System	23 Nov 2020 17:55:55
User entered 'subject attributing worsening finger joint pain to IP despite diagnosis of osteoarthritis' reason for change: Data Entry Error	Jerrica Sullivan (b) (4) (b) (4)	23 Nov 2020 17:55:55
User opened query 'Primary reason for dosing discontinuation is AE, SAE, Physician Decision, Withdrawal of consent by participant, Protocol deviation, or Other, however specify is missing. Please provide.' (Site from System).	System	23 Nov 2020 17:53:46
User entered empty.	Jerrica Sullivan (b) (4) (b) (4)	23 Nov 2020 17:53:46

Date of study discontinuation/completion *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	30 Apr 2021 19:03:21
User signature succeeded.	Rambod Rouhbakhsh (b) (4)	16 Apr 2021 15:59:37
User entered '28 Sep 2020' reason for change: Data Entry Error	Jerrica Sullivan (b) (4) (b) (4)	12 Apr 2021 13:10:11
Signature has been broken.	Jerrica Sullivan (b) (4) (b) (4)	12 Apr 2021 12:53:35
User entered '22 Dec 2020' reason for change: Data Entry Error	Jerrica Sullivan (b) (4) (b) (4)	12 Apr 2021 12:53:35
User signature succeeded.	Rambod Rouhbakhsh (b) (4)	02 Apr 2021 13:34:38
User entered '28 Sep 2020' reason for change: Data Entry Error	Jerrica Sullivan (b) (4) (b) (4)	30 Mar 2021 13:55:11
User entered '21 Sep 2020' reason for change: Data Entry Error	Jerrica Sullivan (b) (4) (b) (4)	30 Mar 2021 13:34:08
User entered '09 Sep 2020'	Jerrica Sullivan (b) (4) (b) (4)	30 Mar 2021 12:50:53

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Folder: End of Study (1)
Form: End of Study / Study Discontinuation
Generated On: 11 Aug 2021 22:05:35
Reason for discontinuation

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	30 Apr 2021 19:03:21
User closed query 'Per CDM: This study has not been terminated by sponsor. Please verify accurate reason for Study Termination.' (Site from DM).	(b) (4), (b) (6) (b) (4), (b) (6)	29 Apr 2021 06:47:27
User signature succeeded.	Rambod Rouhbakhsh (b) (4)	23 Apr 2021 15:20:41
Query 'Per CDM: This study has not been terminated by sponsor. Please verify accurate reason for Study Termination.' answered with 'UPDATED' (Site from DM).	Jerrica Sullivan (b) (4) (b) (4)	20 Apr 2021 17:08:03
User entered 'Other (OTHER)' reason for change: Data Entry Error	Jerrica Sullivan (b) (4) (b) (4)	20 Apr 2021 17:07:35
User entered 'Study Terminated By Sponsor (STUDY TERMINATED BY SPONSOR)' reason for change: Data Entry Error	Jerrica Sullivan (b) (4) (b) (4)	20 Apr 2021 17:03:41
Signature has been broken.	Jerrica Sullivan (b) (4) (b) (4)	20 Apr 2021 17:03:22
User entered 'Physician decision (specify) (PHYSICIAN DECISION)' reason for change: Data Entry Error	Jerrica Sullivan (b) (4) (b) (4)	20 Apr 2021 17:03:22
User opened query 'Per CDM: This study has not been terminated by sponsor. Please verify accurate reason for Study Termination.' (Site from DM).	(b) (4), (b) (6) (b) (4), (b) (6)	18 Apr 2021 16:17:40
User signature succeeded.	Rambod Rouhbakhsh (b) (4)	02 Apr 2021 13:34:38
User entered 'Study Terminated By Sponsor (STUDY TERMINATED BY SPONSOR)' reason for change: Data Entry Error	Jerrica Sullivan (b) (4) (b) (4)	30 Mar 2021 12:51:33
User entered 'Withdrawal of consent by participant (specify) (WITHDRAWAL OF CONSENT)'	Jerrica Sullivan (b) (4) (b) (4)	30 Mar 2021 12:50:53

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Folder: End of Study (1)

Form: End of Study / Study Discontinuation

Generated On: 11 Aug 2021 22:05:35

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) (b) (4), (b) (6)	30 Apr 2021 19:03:21
User signature succeeded.	Rambod Rouhbakhsh (b) (4)	23 Apr 2021 15:20:41
Signature has been broken.	Jerrica Sullivan (b) (4) (b) (4)	20 Apr 2021 17:07:35
User entered 'Per SPONSOR, SUBJECT WAS NOT ELIGIBLE FOR RE-ENTRY DUE TO HER STOPPING COMMUNICATION VIA NOT COMPLETING SAFETY CALLS OR VISITS SINCE 28SEP2020' reason for change: Data Entry Error	Jerrica Sullivan (b) (4) (b) (4)	20 Apr 2021 17:07:35
User closed query 'Primary reason for dosing discontinuation is AE, SAE, Physician Decision, Withdrawal of consent by participant, Protocol deviation, or Other, however specify is missing. Please provide.' (Site from System).	System	20 Apr 2021 17:03:41
User opened query 'Primary reason for dosing discontinuation is AE, SAE, Physician Decision, Withdrawal of consent by participant, Protocol deviation, or Other, however specify is missing. Please provide.' (Site from System).	System	20 Apr 2021 17:03:22
User signature succeeded.	Rambod Rouhbakhsh (b) (4)	02 Apr 2021 13:34:38
User closed query 'Primary reason for dosing discontinuation is AE, SAE, Physician Decision, Withdrawal of consent by participant, Protocol deviation, or Other, however specify is missing. Please provide.' (Site from System).	System	30 Mar 2021 12:51:33
User opened query 'Primary reason for dosing discontinuation is AE, SAE, Physician Decision, Withdrawal of consent by participant, Protocol deviation, or Other, however specify is missing. Please provide.' (Site from System).	System	30 Mar 2021 12:50:53
User entered empty.	Jerrica Sullivan (b) (4) (b) (4)	30 Mar 2021 12:50:53

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Folder: End of Study (1)

Form: End of Study / Study Discontinuation

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If reason for discontinuation is Death, main cause of death

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	30 Apr 2021 19:03:21
User signature succeeded.	Rambod Rouhbakhsh (b) (4)	02 Apr 2021 13:34:38
User entered empty.	Jerrica Sullivan (b) (4) (b) (4)	30 Mar 2021 12:50:53

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Folder: End of Study (1)

Form: End of Study / Study Discontinuation

Generated On: 11 Aug 2021 22:05:35

If main cause of death is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	30 Apr 2021 19:03:21
User signature succeeded.	Rambod Rouhbakhsh (b) (4)	02 Apr 2021 13:34:38
User entered empty.	Jerrica Sullivan (b) (4) (b) (4)	30 Mar 2021 12:50:53

Folder: End of Study (1)
Form: End of Study / Study Discontinuation
Generated On: 11 Aug 2021 22:05:35

Date of death *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	30 Apr 2021 19:03:21
User signature succeeded.	Rambod Rouhbakhsh (b) (4)	02 Apr 2021 13:34:38
User entered empty.	Jerrica Sullivan (b) (4) (b) (4)	30 Mar 2021 12:50:53

Was autopsy performed?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	30 Apr 2021 19:03:21
User signature succeeded.	Rambod Rouhbakhsh (b) (4)	02 Apr 2021 13:34:38
User entered empty.	Jerrica Sullivan (b) (4) (b) (4)	30 Mar 2021 12:50:53

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