

US3052005 (Prod: Carolina Institute for Clinical Research - M3 Wake Research)

Generated By: KC Joubran

Generated On: 09 Jun 2021 15:00:53

All time stamps listed in this document are displayed in GMT

US3052005

Form: Participant Creation

Data signed: (b) (4) 23 Feb 2021 07:32:25

Generated On: 09 Jun 2021 15:00:53

Participant ID

US3052005

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

US3052005

Folder: Screening

Form: Visit Date

Data signed: (b) (4) 23 Feb 2021 07:32:25

Generated On: 09 Jun 2021 15:00:53

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	30 JUL 2020
Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>
Folder OID	SCRN

US3052005

Folder: Screening

Form: Demographics

Data signed: (b) (4) 23 Feb 2021 07:32:24

Generated On: 09 Jun 2021 15:00:53

Date of Birth (MMM yyyy)	(b) (6) 1947
Age	72
Age Units	YEARS
Age (Derived)	72
Sex	Female <input type="radio"/> Male <input checked="" type="radio"/>
Ethnicity	Hispanic or Latino <input type="radio"/> Not Hispanic or Latino <input checked="" type="radio"/> Not Reported <input type="radio"/> Unknown <input type="radio"/>
Race (Check All That Apply)	
White	True
Black	False
Asian	False
American Indian or Alaska Native	False
Native Hawaiian or other Pacific Islander	False
Other	False
If race is Other, specify _____	
Unknown	False
Not reported	False

US3052005

Folder: Screening

Form: Enrollment

Data signed: (b) (4) 23 Feb 2021 07:32:24

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Date of Informed Consent (*dd MMM yyyy*) 30 JUL 2020

Month and Year of Informed Consent (derived) JUL 2020

Year of Informed Consent (derived) 2020

Protocol Version

Amendment 1	<input checked="" type="radio"/>
Amendment 2	<input type="radio"/>
Amendment 3	<input type="radio"/>
Amendment 4	<input type="radio"/>
Amendment 5	<input type="radio"/>

Was participant enrolled in the study?

Yes	<input checked="" type="radio"/>
No	<input type="radio"/>

If No, indicate reason for screen fail

Withdrew Consent	<input type="radio"/>
Inclusion/Exclusion	<input type="radio"/>
Cohort Full	<input type="radio"/>
Other	<input type="radio"/>

If reason for screen fail is Other, specify _____

Was this participant screened previously?

Yes	<input type="radio"/>
No	<input checked="" type="radio"/>

If Yes, previous participant number _____

Enrollment Trigger 1

US3052005

Folder: Screening

Form: Inclusion/Exclusion Criteria Summary

Data signed: (b) (4) 23 Feb 2021 07:32:24

Generated On: 09 Jun 2021 15:00:53

Did the participant meet all eligibility criteria?

Yes ☒

No ☐

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Folder: Screening

Form: Medical History Summary

Data signed: (b) (4) 23 Feb 2021 07:32:25

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Were any significant conditions reported?

Yes ☒

No ☐

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Folder: Screening

Form: Medical History (1)

Data signed: (b) (4) 23 Feb 2021 07:32:25

Generated On: 09 Jun 2021 15:00:53

Condition	HIGH CHOLESTEROL
Start date (dd MMM yyyy)	UN UNK 2005
Start date completely unknown	False
Condition ongoing at study entry	Yes <input checked="" type="radio"/> No <input type="radio"/>
If No, please specify the stop date (dd MMM yyyy)	
Stop date completely unknown	False
Start Month and Year (derived)	JAN 2005
Start Year (derived)	2005
Stop Month and Year (derived)	
Stop Year (derived)	

US3052005

Folder: Screening

Form: Medical History (2)

Data signed: (b) (4) 23 Feb 2021 07:32:25

Generated On: 09 Jun 2021 15:00:53

Condition	HTN
Start date (dd MMM yyyy)	UN UNK 2018
Start date completely unknown	False
Condition ongoing at study entry	Yes <input checked="" type="radio"/> No <input type="radio"/>
If No, please specify the stop date (dd MMM yyyy) _____	
Stop date completely unknown	False
Start Month and Year (derived)	JAN 2018
Start Year (derived)	2018
Stop Month and Year (derived)	_____
Stop Year (derived)	_____

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Folder: Screening

Form: Medical History (3)

Data signed: (b) (4) 23 Feb 2021 07:32:25

Generated On: 09 Jun 2021 15:00:53

Condition	A FIB
Start date (dd MMM yyyy)	UN UNK 2018
Start date completely unknown	False
Condition ongoing at study entry	Yes <input checked="" type="radio"/> No <input type="radio"/>
If No, please specify the stop date (dd MMM yyyy) _____	
Stop date completely unknown	False
Start Month and Year (derived)	JAN 2018
Start Year (derived)	2018
Stop Month and Year (derived)	_____
Stop Year (derived)	_____

US3052005

Folder: Screening

Form: Medical History (4)

Data signed: (b) (4) 23 Feb 2021 07:32:25

Generated On: 09 Jun 2021 15:00:53

Condition	BASAL CELL CARCINOMA-FACE
Start date (dd MMM yyyy)	
Start date completely unknown	True
Condition ongoing at study entry	Yes <input type="radio"/> No <input checked="" type="radio"/>
If No, please specify the stop date (dd MMM yyyy)	UN UNK 2018
Stop date completely unknown	False
Start Month and Year (derived)	
Start Year (derived)	
Stop Month and Year (derived)	JAN 2018
Stop Year (derived)	2018

US3052005

Folder: Screening

Form: Medical History (5)

Data signed: (b) (4) 23 Feb 2021 07:32:25

Generated On: 09 Jun 2021 15:00:53

Condition	ERECTILE DYSFUNCTION
Start date (dd MMM yyyy)	UN UNK 2018
Start date completely unknown	False
Condition ongoing at study entry	Yes <input checked="" type="radio"/> No <input type="radio"/>
If No, please specify the stop date (dd MMM yyyy) _____	
Stop date completely unknown	False
Start Month and Year (derived)	JAN 2018
Start Year (derived)	2018
Stop Month and Year (derived)	_____
Stop Year (derived)	_____

US3052005

Folder: Screening

Form: Medical History (6)

Data signed: (b) (4) 23 Feb 2021 07:32:25

Generated On: 09 Jun 2021 15:00:53

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

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Folder: Screening

Form: Medical History (7)

Data signed: (b) (4) 23 Feb 2021 07:32:25

Generated On: 09 Jun 2021 15:00:53

Condition	INGUINAL HERNIA
Start date (dd MMM yyyy)	
Start date completely unknown	True
Condition ongoing at study entry	Yes <input type="radio"/> No <input checked="" type="radio"/>
If No, please specify the stop date (dd MMM yyyy)	UN UNK 2018
Stop date completely unknown	False
Start Month and Year (derived)	
Start Year (derived)	
Stop Month and Year (derived)	JAN 2018
Stop Year (derived)	2018

US3052005

Folder: Screening

Form: Medical History (8)

Data signed: (b) (4) 23 Feb 2021 07:32:25

Generated On: 09 Jun 2021 15:00:53

Condition	INGUINAL HERNIA REPAIR
Start date (dd MMM yyyy)	
Start date completely unknown	True
Condition ongoing at study entry	Yes <input type="radio"/> No <input checked="" type="radio"/>
If No, please specify the stop date (dd MMM yyyy)	UN UNK 2018
Stop date completely unknown	False
Start Month and Year (derived)	
Start Year (derived)	
Stop Month and Year (derived)	JAN 2018
Stop Year (derived)	2018

US3052005

Folder: Screening

Form: Vital Signs

Data signed: (b) (4) 23 Feb 2021 07:32:25

Generated On: 09 Jun 2021 15:00:53

Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (<i>dd MMM yyyy</i>)	30 JUL 2020
Time of assessment (<i>00:00-23:59</i>)	10:13 (24 HR)
Vital Signs Date and Time (derived)	30 JUL 2020 10:13
Height (<i>xxx.x</i>)	75 in
Weight (<i>xxx.x</i>)	192 lb
BMI (<i>xxx.x</i>)	24.04853 kg/m ²
BMI units	KG/M2
Temperature (<i>xxx.x</i>)	ND - Not Done
Route of measurement	Oral <input type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	
Pulse (<i>xxx</i>)	ND - Not Done
Pulse units	BPM
Respiratory Rate (<i>xxx</i>)	ND - Not Done
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (<i>xxx</i>)	ND - Not Done
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (<i>xxx</i>)	ND - Not Done
Diastolic Blood Pressure units	MMHG
Height (derived)	
Weight (derived)	

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Folder: Screening

Form: Physical Examination

Data signed: (b) (4) 23 Feb 2021 07:32:25

Generated On: 09 Jun 2021 15:00:53

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

30 JUL 2020

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

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Folder: Screening

Form: Risk of Exposure

Data signed: (b) (4) 23 Feb 2021 07:32:25

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Occupational Risk

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

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

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

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

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

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

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

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

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

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

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

Other Yes ☐ No ☒

Specify

Location and Living Circumstances Risk (check all that apply)

No Risk Identified False

Resides in Nursing Home or Assisted Living Facility False

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Folder: Screening

Form: Risk of Exposure

Data signed: (b) (4) 23 Feb 2021 07:32:25

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

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Folder: Visit 1 Day 1

Form: Visit Date

Data signed: (b) (4) 23 Feb 2021 07:32:25

Generated On: 09 Jun 2021 15:00:53

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	30 JUL 2020
Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>
Folder OID	VISIT1

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Folder: Visit 1 Day 1

Form: Randomization

Data signed: (b) (4) 23 Feb 2021 07:32:25

Generated On: 09 Jun 2021 15:00:53

What was the date of randomization? (dd MMM yyyy) 30 JUL 2020

What was the participant's randomization number? 184229

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) 23 Feb 2021 07:32:25

Generated On: 09 Jun 2021 15:00:53

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) 23 Feb 2021 07:32:25

Generated On: 09 Jun 2021 15:00:53

Height	ND - Not Done
Weight	ND - Not Done
Timepoint	Pre-Dose <input checked="" type="radio"/> Post-Dose <input type="radio"/>
Were vital signs assessed?	Yes <input checked="" type="radio"/> No <input type="radio"/>
Date of assessment (dd MMM yyyy)	30 JUL 2020
Time of assessment (00:00-23:59)	10:13 (24 HR)
Vital Signs Date and Time (derived)	30 JUL 2020 10:13
Temperature (xxx.x)	98.4 F
Route of measurement	Oral <input checked="" type="radio"/> Axillary <input type="radio"/> Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	59 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	129 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	83 mmHg
Diastolic Blood Pressure units	MMHG

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Data signed: (b) (4) 23 Feb 2021 07:32:25

Generated On: 09 Jun 2021 15:00:53

Height	ND - Not Done
Weight	ND - Not Done
Timepoint	Pre-Dose <input type="radio"/> Post-Dose <input checked="" type="radio"/>
Were vital signs assessed?	Yes <input checked="" type="radio"/> No <input type="radio"/>
Date of assessment (dd MMM yyyy)	30 JUL 2020
Time of assessment (00:00-23:59)	11:57 (24 HR)
Vital Signs Date and Time (derived)	30 JUL 2020 11:57
Temperature (xxx.x)	96.4 F
Route of measurement	Oral <input checked="" type="radio"/> Axillary <input type="radio"/> Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	51 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	18 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	127 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	84 mmHg
Diastolic Blood Pressure units	MMHG

US3052005

Folder: Visit 1 Day 1

Form: Physical Examination

Data signed: (b) (4) 23 Feb 2021 07:32:25

Generated On: 09 Jun 2021 15:00:53

Was the physical examination performed?

Yes ☐

No ☒

Date of examination (dd MMM yyyy)

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

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Folder: Visit 1 Day 1

Form: Exposure

Data signed: (b) (4) 23 Feb 2021 07:32:24

Generated On: 09 Jun 2021 15:00:53

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) 30 JUL 2020

What was the treatment time? (00:00-23:59) 11:22 (24 HR)

Treatment Date and Time (derived) 30 JUL 2020 11:22

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

What was the frequency of the study treatment dosing? ONCE

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

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Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Data signed: (b) (4) 23 Feb 2021 07:32:24

Generated On: 09 Jun 2021 15:00:53

Was the sample collected?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Collection date (dd MMM yyyy)	30 JUL 2020
Collection time (00:00-23:59)	10:38 (24 HR)
Collection date and time (derived)	30 JUL 2020 10:38

US3052005

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab

Data signed: (b) (4) 23 Feb 2021 07:32:25

Generated On: 09 Jun 2021 15:00:53

Collection date (dd MMM yyyy)			30 JUL 2020
Lab Test	Was the sample collected?	Collection time (00:00 - 23:59)	Collection date and time (derived)
Nasopharyngeal Swab 1	Yes	10:34	30 JUL 2020 10:34
Nasopharyngeal Swab 2	No		

US3052005

Folder: Visit 1 Day 1

Form: Continuing

Data signed: (b) (4) 23 Feb 2021 07:32:24

Generated On: 09 Jun 2021 15:00:53

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3052005

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 15:00:53

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

96.4 °F

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

Yes ☐

No ☒

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

PC Time Stamp

30 JUL 2020 12:02

PC Open Date & Time

30 JUL 2020 11:42

PC Close Date & Time

30 JUL 2020 14:12

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Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 15:00:53

TIMEPOINT

DAY 1, AFTER VACCINATION
(AT HOME)

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

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

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

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

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

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

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

Was **TEMPERATURE** taken? Yes ☒ No ☐

Please record your **TEMPERATURE** in °F 96.0 °F

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

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

PC Time Stamp	30 JUL 2020 21:19
PC Open Date & Time	30 JUL 2020 15:07
PC Close Date & Time	31 JUL 2020 11:59

US3052005

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 15:00:53

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

97.7 °F

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

Yes ☐

No ☒

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

PC Time Stamp

31 JUL 2020 20:33

PC Open Date & Time

31 JUL 2020 12:00

PC Close Date & Time

01 AUG 2020 11:59

US3052005

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 15:00:53

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

97.4 °F

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

Yes ☐

No ☒

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

PC Time Stamp

01 AUG 2020 22:40

PC Open Date & Time

01 AUG 2020 12:00

PC Close Date & Time

02 AUG 2020 11:59

US3052005

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 15:00:53

TIMEPOINT

DAY 4

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.4 °F

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

Yes ☐

No ☒

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

PC Time Stamp

02 AUG 2020 19:08

PC Open Date & Time

02 AUG 2020 12:00

PC Close Date & Time

03 AUG 2020 11:59

US3052005

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 15:00:53

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

97.2 °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

04 AUG 2020 06:03

PC Open Date & Time

03 AUG 2020 12:00

PC Close Date & Time

04 AUG 2020 11:59

US3052005

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 15:00:53

TIMEPOINT

DAY 6

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.2 °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

04 AUG 2020 23:35

PC Open Date & Time

04 AUG 2020 12:00

PC Close Date & Time

05 AUG 2020 11:59

US3052005

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 15:00:53

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

97.8 °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

05 AUG 2020 21:46

PC Open Date & Time

05 AUG 2020 12:00

PC Close Date & Time

06 AUG 2020 11:59

US3052005

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 15:00:53

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

30 JUL 2020 12:02

PC Open Date & Time

30 JUL 2020 11:42

PC Close Date & Time

30 JUL 2020 14:12

US3052005

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 15:00:53

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

30 JUL 2020 21:20

PC Open Date & Time

30 JUL 2020 15:07

PC Close Date & Time

31 JUL 2020 11:59

US3052005

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 15:00:53

TIMEPOINT

DAY 2

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

31 JUL 2020 20:33

PC Open Date & Time

31 JUL 2020 12:00

PC Close Date & Time

01 AUG 2020 11:59

US3052005

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 15:00:53

TIMEPOINT

DAY 3

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

01 AUG 2020 22:40

PC Open Date & Time

01 AUG 2020 12:00

PC Close Date & Time

02 AUG 2020 11:59

US3052005

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 15:00:53

TIMEPOINT

DAY 4

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

02 AUG 2020 19:08

PC Open Date & Time

02 AUG 2020 12:00

PC Close Date & Time

03 AUG 2020 11:59

US3052005

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 15:00:53

TIMEPOINT

DAY 5

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

04 AUG 2020 06:03

PC Open Date & Time

03 AUG 2020 12:00

PC Close Date & Time

04 AUG 2020 11:59

US3052005

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 15:00:53

TIMEPOINT

DAY 6

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

04 AUG 2020 23:35

PC Open Date & Time

04 AUG 2020 12:00

PC Close Date & Time

05 AUG 2020 11:59

US3052005

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 15:00:53

TIMEPOINT

DAY 7

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

05 AUG 2020 21:46

PC Open Date & Time

05 AUG 2020 12:00

PC Close Date & Time

06 AUG 2020 11:59

US3052005

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 15:00:53

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 ☐

US3052005

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 15:00:53

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

No ☒

Yes ☐

PC Time stamp	30 JUL 2020 12:03
PC Open Date & Time	30 JUL 2020 11:42
PC Close Date & Time	30 JUL 2020 14:12

US3052005

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 15:00:53

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 ☐

US3052005

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 15:00:53

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

No ☒

Yes ☐

PC Time stamp	30 JUL 2020 21:20
PC Open Date & Time	30 JUL 2020 15:07
PC Close Date & Time	31 JUL 2020 11:59

US3052005

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 15:00:53

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 ☒

US3052005

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 15:00:53

Yes <input type="checkbox"/>	
PC Time stamp	31 JUL 2020 20:33
PC Open Date & Time	31 JUL 2020 12:00
PC Close Date & Time	01 AUG 2020 11:59

US3052005

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 15:00:53

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 ☒

PRODUCTION RELEASE (v12.003

51 of 2036

EAB) (1725)

US3052005

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 15:00:53

Yes <input type="checkbox"/>	
PC Time stamp	01 AUG 2020 22:40
PC Open Date & Time	01 AUG 2020 12:00
PC Close Date & Time	02 AUG 2020 11:59

US3052005

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 15:00:53

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 ☒

US3052005

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 15:00:53

Yes <input type="checkbox"/>	
PC Time stamp	02 AUG 2020 19:09
PC Open Date & Time	02 AUG 2020 12:00
PC Close Date & Time	03 AUG 2020 11:59

US3052005

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 15:00:53

TIMEPOINT

DAY 5

HEADACHE

None ☒

No interference with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

FATIGUE

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

NAUSEA/VOMITING

None ☒

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

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

Prevents daily activity, requires
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity
not requiring medical attention ☐

Prevents daily activity and
requires medical attention ☐

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

No ☒

PRODUCTION RELEASE (v12.003
EAB) (1725)

55 of 2036

US3052005

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 15:00:53

Yes <input type="checkbox"/>	
PC Time stamp	04 AUG 2020 06:04
PC Open Date & Time	03 AUG 2020 12:00
PC Close Date & Time	04 AUG 2020 11:59

US3052005

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 15:00:53

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 ☒

US3052005

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 15:00:53

Yes <input type="checkbox"/>	
PC Time stamp	04 AUG 2020 23:35
PC Open Date & Time	04 AUG 2020 12:00
PC Close Date & Time	05 AUG 2020 11:59

US3052005

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 15:00:53

TIMEPOINT

DAY 7

HEADACHE

None ☒

No interference with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

FATIGUE

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

NAUSEA/VOMITING

None ☒

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

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

Prevents daily activity, requires
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity
not requiring medical attention ☐

Prevents daily activity and
requires medical attention ☐

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

No ☒

PRODUCTION RELEASE (v12.003

59 of 2036

EAB) (1725)

US3052005

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 15:00:53

Yes <input type="checkbox"/>	
PC Time stamp	05 AUG 2020 21:47
PC Open Date & Time	05 AUG 2020 12:00
PC Close Date & Time	06 AUG 2020 11:59

US3052005

Folder: Safety Call Day 8 (1)

Form: Safety Call

Data signed: (b) (4) 23 Feb 2021 07:32:25

Generated On: 09 Jun 2021 15:00:53

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

09 AUG 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3052005

Folder: Safety Call Day 8 (1)

Form: Continuing

Data signed: (b) (4) 23 Feb 2021 07:32:24

Generated On: 09 Jun 2021 15:00:53

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3052005

Folder: Safety Call Day 15 (1)

Form: Safety Call

Data signed: (b) (4) 23 Feb 2021 07:32:25

Generated On: 09 Jun 2021 15:00:53

Was Contact Attempted? Yes ☒
No ☐

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

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

Comments

If Contact Not Made, please provide Comments

US3052005

Folder: Safety Call Day 15 (1)

Form: Continuing

Data signed: (b) (4) 23 Feb 2021 07:32:24

Generated On: 09 Jun 2021 15:00:53

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3052005

Folder: Safety Call Day 22 (1)

Form: Safety Call

Data signed: (b) (4) 23 Feb 2021 07:32:25

Generated On: 09 Jun 2021 15:00:53

Was Contact Attempted?

Yes ☐

No ☒

Date of Contact or Contact Attempt (dd MMM yyyy)

Please select one status for the follow-up contact

Contact Made ☐

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3052005

Folder: Safety Call Day 22 (1)

Form: Continuing

Data signed: (b) (4) 23 Feb 2021 07:32:24

Generated On: 09 Jun 2021 15:00:53

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3052005

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Data signed: (b) (4) 23 Feb 2021 07:32:25

Generated On: 09 Jun 2021 15:00:53

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	26 AUG 2020
Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>
Folder OID	VISIT2

US3052005

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Data signed: (b) (4) 23 Feb 2021 07:32:25

Generated On: 09 Jun 2021 15:00:53

Timepoint	Pre-Dose <input checked="" type="radio"/>
	Post-Dose <input type="radio"/>
Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (dd MMM yyyy)	26 AUG 2020
Time of assessment (00:00-23:59)	10:00 (24 HR)
Vital Signs Date and Time (derived)	26 AUG 2020 10:00
Temperature (xxx.x)	97.8 F
Route of measurement	Oral <input checked="" type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	58 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	18 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	112 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	72 mmHg
Diastolic Blood Pressure units	MMHG

US3052005

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Data signed: (b) (4) 23 Feb 2021 07:32:25

Generated On: 09 Jun 2021 15:00:53

Timepoint	Pre-Dose <input type="radio"/>
	Post-Dose <input checked="" type="radio"/>
Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (dd MMM yyyy)	26 AUG 2020
Time of assessment (00:00-23:59)	11:57 (24 HR)
Vital Signs Date and Time (derived)	26 AUG 2020 11:57
Temperature (xxx.x)	97.9 F
Route of measurement	Oral <input checked="" type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	52 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	18 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	122 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	83 mmHg
Diastolic Blood Pressure units	MMHG

US3052005

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Data signed: (b) (4) 23 Feb 2021 07:32:25

Generated On: 09 Jun 2021 15:00:53

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

26 AUG 2020

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

US3052005

Folder: Visit 2 Day 29 (1)

Form: Exposure

Data signed: (b) (4) 23 Feb 2021 07:32:24

Generated On: 09 Jun 2021 15:00:53

Was study treatment given? Yes ☒ No ☐

If No, reason not given

Participant declined due to Adverse Event ☐

Physician withheld dose due to Adverse Event ☐

Death ☐

Lost To Follow-Up ☐

Physician Decision ☐

Pregnancy ☐

Protocol Deviation ☐

Study Terminated by Sponsor ☐

Withdrawal of Consent by Participant ☐

Confirmed COVID-19 ☐

Other ☐

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

What was the study treatment? MRNA-1273 OR PLACEBO

What was the treatment date? (dd MMM yyyy) 26 AUG 2020

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

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

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

What was the frequency of the study treatment dosing? ONCE

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

US3052005

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 23 Feb 2021 07:32:24

Generated On: 09 Jun 2021 15:00:53

Was the sample collected?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Collection date (dd MMM yyyy)	26 AUG 2020
Collection time (00:00-23:59)	10:04 (24 HR)
Collection date and time (derived)	26 AUG 2020 10:04

US3052005

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab

Data signed: (b) (4) 23 Feb 2021 07:32:25

Generated On: 09 Jun 2021 15:00:53

Collection date (dd MMM yyyy)			26 AUG 2020
Lab Test	Was the sample collected?	Collection time (00:00 - 23:59)	Collection date and time (derived)
Nasopharyngeal Swab 1	Yes	10:07	26 AUG 2020 10:07
Nasopharyngeal Swab 2	No		

US3052005

Folder: Visit 2 Day 29 (1)

Form: Continuing

Data signed: (b) (4) 23 Feb 2021 07:32:24

Generated On: 09 Jun 2021 15:00:53

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3052005

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 15:00:53

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

97.9 °F

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

Yes ☐

No ☒

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

PC Time Stamp

26 AUG 2020 11:57

PC Open Date & Time

26 AUG 2020 11:47

PC Close Date & Time

26 AUG 2020 14:17

US3052005

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 15:00:53

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 95.7 °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	26 AUG 2020 17:45
PC Open Date & Time	26 AUG 2020 15:12
PC Close Date & Time	27 AUG 2020 11:59

US3052005

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 15:00:53

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

96.8 °F

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

Yes ☐

No ☒

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

PC Time Stamp

27 AUG 2020 18:23

PC Open Date & Time

27 AUG 2020 12:00

PC Close Date & Time

28 AUG 2020 11:59

US3052005

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 15:00:53

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

95.6 °F

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

Yes ☐

No ☒

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

PC Time Stamp

28 AUG 2020 20:37

PC Open Date & Time

28 AUG 2020 12:00

PC Close Date & Time

29 AUG 2020 11:59

US3052005

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 15:00:53

TIMEPOINT

DAY 4

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.7 °F

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

Yes ☐

No ☒

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

PC Time Stamp

29 AUG 2020 12:33

PC Open Date & Time

29 AUG 2020 12:00

PC Close Date & Time

30 AUG 2020 11:59

US3052005

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 15:00:53

TIMEPOINT

DAY 5

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

96.6 °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

30 AUG 2020 19:20

PC Open Date & Time

30 AUG 2020 12:00

PC Close Date & Time

31 AUG 2020 11:59

US3052005

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 15:00:53

TIMEPOINT

DAY 6

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

96.6 °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

01 SEP 2020 00:19

PC Open Date & Time

31 AUG 2020 12:00

PC Close Date & Time

01 SEP 2020 11:59

US3052005

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 15:00:53

TIMEPOINT

DAY 7

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

96.6 °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

01 SEP 2020 18:49

PC Open Date & Time

01 SEP 2020 12:00

PC Close Date & Time

02 SEP 2020 11:59

US3052005

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 15:00:53

TIMEPOINT

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

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

26 AUG 2020 11:54

PC Open Date & Time

26 AUG 2020 11:47

PC Close Date & Time

26 AUG 2020 14:17

US3052005

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 15:00:53

TIMEPOINT

DAY 1, AFTER VACCINATION
(AT HOME)

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

Please select one response below

None ☒

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

Please select one response below

None ☒

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

26 AUG 2020 17:45

PC Open Date & Time

26 AUG 2020 15:12

PC Close Date & Time

27 AUG 2020 11:59

US3052005

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 15:00:53

TIMEPOINT

DAY 2

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

27 AUG 2020 18:23

PC Open Date & Time

27 AUG 2020 12:00

PC Close Date & Time

28 AUG 2020 11:59

US3052005

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 15:00:53

TIMEPOINT

DAY 3

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

28 AUG 2020 20:38

PC Open Date & Time

28 AUG 2020 12:00

PC Close Date & Time

29 AUG 2020 11:59

US3052005

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 15:00:53

TIMEPOINT

DAY 4

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

29 AUG 2020 12:34

PC Open Date & Time

29 AUG 2020 12:00

PC Close Date & Time

30 AUG 2020 11:59

US3052005

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 15:00:53

TIMEPOINT

DAY 5

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

30 AUG 2020 19:21

PC Open Date & Time

30 AUG 2020 12:00

PC Close Date & Time

31 AUG 2020 11:59

US3052005

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 15:00:53

TIMEPOINT

DAY 6

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

01 SEP 2020 00:19

PC Open Date & Time

31 AUG 2020 12:00

PC Close Date & Time

01 SEP 2020 11:59

US3052005

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 15:00:53

TIMEPOINT

DAY 7

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

01 SEP 2020 18:49

PC Open Date & Time

01 SEP 2020 12:00

PC Close Date & Time

02 SEP 2020 11:59

US3052005

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 15:00:53

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 ☐

US3052005

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 15:00:53

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

No ☒

Yes ☐

PC Time stamp	26 AUG 2020 11:55
PC Open Date & Time	26 AUG 2020 11:47
PC Close Date & Time	26 AUG 2020 14:17

US3052005

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 15:00:53

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 ☐

US3052005

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 15:00:53

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

No ☒

Yes ☐

PC Time stamp	26 AUG 2020 17:46
PC Open Date & Time	26 AUG 2020 15:12
PC Close Date & Time	27 AUG 2020 11:59

US3052005

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 15:00:53

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 ☒

US3052005

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 15:00:53

Yes <input type="checkbox"/>	
PC Time stamp	27 AUG 2020 18:24
PC Open Date & Time	27 AUG 2020 12:00
PC Close Date & Time	28 AUG 2020 11:59

US3052005

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 15:00:53

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 ☒

US3052005

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 15:00:53

Yes <input type="checkbox"/>	
PC Time stamp	28 AUG 2020 20:38
PC Open Date & Time	28 AUG 2020 12:00
PC Close Date & Time	29 AUG 2020 11:59

US3052005

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 15:00:53

TIMEPOINT

DAY 4

HEADACHE

None ☒

No interference with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

FATIGUE

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

NAUSEA/VOMITING

None ☒

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

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

Prevents daily activity, requires
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity
not requiring medical attention ☐

Prevents daily activity and
requires medical attention ☐

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

No ☒

PRODUCTION RELEASE (v12.003

99 of 2036

EAB) (1725)

US3052005

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 15:00:53

Yes <input type="checkbox"/>	
PC Time stamp	29 AUG 2020 12:34
PC Open Date & Time	29 AUG 2020 12:00
PC Close Date & Time	30 AUG 2020 11:59

US3052005

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 15:00:53

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 ☒

US3052005

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 15:00:53

Yes <input type="checkbox"/>	
PC Time stamp	30 AUG 2020 19:21
PC Open Date & Time	30 AUG 2020 12:00
PC Close Date & Time	31 AUG 2020 11:59

US3052005

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 15:00:53

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 ☒

US3052005

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 15:00:53

Yes <input type="checkbox"/>	
PC Time stamp	01 SEP 2020 00:20
PC Open Date & Time	31 AUG 2020 12:00
PC Close Date & Time	01 SEP 2020 11:59

US3052005

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 15:00:53

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 ☒

US3052005

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 15:00:53

Yes <input type="checkbox"/>	
PC Time stamp	01 SEP 2020 18:49
PC Open Date & Time	01 SEP 2020 12:00
PC Close Date & Time	02 SEP 2020 11:59

US3052005

Folder: Safety Call Day 36 (1)

Form: Safety Call

Data signed: (b) (4) 23 Feb 2021 07:32:25

Generated On: 09 Jun 2021 15:00:53

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

04 SEP 2020

Please select one status for the follow-up contact

Contact Made ☐

Contact Not Made ☒

Comments

LEFT MESSAGE @2:13PM

If Contact Not Made, please provide Comments

US3052005

Folder: Safety Call Day 36 (1)

Form: Continuing

Data signed: (b) (4) 23 Feb 2021 07:32:24

Generated On: 09 Jun 2021 15:00:53

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3052005

Folder: Safety Call Day 43 (1)

Form: Safety Call

Data signed: (b) (4) 23 Feb 2021 07:32:25

Generated On: 09 Jun 2021 15:00:53

Was Contact Attempted?

Yes ☐

No ☒

Date of Contact or Contact Attempt (dd MMM yyyy)

Please select one status for the follow-up contact

Contact Made ☐

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3052005

Folder: Safety Call Day 43 (1)

Form: Continuing

Data signed: (b) (4) 23 Feb 2021 07:32:24

Generated On: 09 Jun 2021 15:00:53

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3052005

Folder: Safety Call Day 50 (1)

Form: Safety Call

Data signed: (b) (4) 23 Feb 2021 07:32:25

Generated On: 09 Jun 2021 15:00:53

Was Contact Attempted?

Yes ☐

No ☒

Date of Contact or Contact Attempt (dd MMM yyyy)

Please select one status for the follow-up contact

Contact Made ☐

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3052005

Folder: Safety Call Day 50 (1)

Form: Continuing

Data signed: (b) (4) 23 Feb 2021 07:32:24

Generated On: 09 Jun 2021 15:00:53

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3052005

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Data signed: (b) (4) 23 Feb 2021 07:32:25

Generated On: 09 Jun 2021 15:00:53

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	29 SEP 2020
Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>
Folder OID	VISIT3

US3052005

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Data signed: (b) (4) 23 Feb 2021 07:32:25

Generated On: 09 Jun 2021 15:00:53

Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (<i>dd MMM yyyy</i>)	29 SEP 2020
Time of assessment (<i>00:00-23:59</i>)	11:36 (24 HR)
Vital Signs Date and Time (derived)	29 SEP 2020 11:36
Temperature (<i>xxx.x</i>)	97.7 F
Route of measurement	Oral <input checked="" type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	
Pulse (<i>xxx</i>)	62 beats/min
Pulse units	BPM
Respiratory Rate (<i>xxx</i>)	15 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (<i>xxx</i>)	117 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (<i>xxx</i>)	78 mmHg
Diastolic Blood Pressure units	MMHG
Height (derived)	
Weight (derived)	

US3052005

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Data signed: (b) (4) 23 Feb 2021 07:32:25

Generated On: 09 Jun 2021 15:00:53

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

29 SEP 2020

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

US3052005

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 23 Feb 2021 07:32:24

Generated On: 09 Jun 2021 15:00:53

Was the sample collected?

Yes ☒

No ☐

Collection date (dd MMM yyyy)

29 SEP 2020

Collection time (00:00-23:59)

12:00 (24 HR)

Collection date and time (derived)

29 SEP 2020 12:00

US3052005

Folder: Visit 3 Day 57 (1)

Form: Continuing

Data signed: (b) (4) 23 Feb 2021 07:32:24

Generated On: 09 Jun 2021 15:00:53

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3052005

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:00:53

TIMEPOINT

DAY 64

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

01 OCT 2020 13:56:18

Patient Cloud Open Date & Time

29 SEP 2020 00:01

Patient Cloud Close Date & Time

03 OCT 2020 23:59

US3052005

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:00:53

TIMEPOINT

DAY 71

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

06 OCT 2020 20:21:49

Patient Cloud Open Date & Time

06 OCT 2020 00:01

Patient Cloud Close Date & Time

10 OCT 2020 23:59

US3052005

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:00:53

TIMEPOINT

DAY 78

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

16 OCT 2020 18:47:35

Patient Cloud Open Date & Time

13 OCT 2020 00:01

Patient Cloud Close Date & Time

17 OCT 2020 23:59

US3052005

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:00:53

TIMEPOINT	DAY 92
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature \geq 100.4°F/38°C)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

US3052005

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:00:53

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

I confirm I have read this message and will call the study clinic immediately ☐

Date and time of submission

Patient Cloud Open Date & Time

27 OCT 2020 00:01

Patient Cloud Close Date & Time

31 OCT 2020 23:59

US3052005

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:00:53

TIMEPOINT	DAY 99
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input checked="" type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input checked="" type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	05 NOV 2020 14:14:51
Patient Cloud Open Date & Time	03 NOV 2020 00:01
Patient Cloud Close Date & Time	07 NOV 2020 23:59

US3052005

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:00:53

TIMEPOINT

DAY 106

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

14 NOV 2020 12:00:17

Patient Cloud Open Date & Time

10 NOV 2020 00:01

Patient Cloud Close Date & Time

14 NOV 2020 23:59

US3052005

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:00:53

TIMEPOINT

DAY 113

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

17 NOV 2020 07:59:46

Patient Cloud Open Date & Time

17 NOV 2020 00:01

Patient Cloud Close Date & Time

21 NOV 2020 23:59

US3052005

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:00:53

TIMEPOINT

DAY 117

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

21 NOV 2020 03:28:39

Patient Cloud Open Date & Time

21 NOV 2020 00:01

Patient Cloud Close Date & Time

25 NOV 2020 23:59

US3052005

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:00:53

TIMEPOINT	DAY 124
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	01 DEC 2020 18:02:04
Patient Cloud Open Date & Time	28 NOV 2020 00:01
Patient Cloud Close Date & Time	02 DEC 2020 23:59

US3052005

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:00:53

TIMEPOINT

DAY 131

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

08 DEC 2020 19:23:30

Patient Cloud Open Date & Time

05 DEC 2020 00:01

Patient Cloud Close Date & Time

09 DEC 2020 23:59

US3052005

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:00:53

TIMEPOINT

DAY 138

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

15 DEC 2020 20:13:46

Patient Cloud Open Date & Time

12 DEC 2020 00:01

Patient Cloud Close Date & Time

16 DEC 2020 23:59

US3052005

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:00:53

TIMEPOINT	DAY 145
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input checked="" type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input checked="" type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	23 DEC 2020 10:54:43
Patient Cloud Open Date & Time	19 DEC 2020 00:01
Patient Cloud Close Date & Time	23 DEC 2020 23:59

US3052005

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:00:53

TIMEPOINT

DAY 152

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

28 DEC 2020 13:01:11

Patient Cloud Open Date & Time

26 DEC 2020 00:01

Patient Cloud Close Date & Time

30 DEC 2020 23:59

US3052005

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:00:53

TIMEPOINT	DAY 159
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	05 JAN 2021 18:33:12
Patient Cloud Open Date & Time	02 JAN 2021 00:01
Patient Cloud Close Date & Time	06 JAN 2021 23:59

US3052005

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:00:53

TIMEPOINT

DAY 166

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

11 JAN 2021 12:36:34

Patient Cloud Open Date & Time

09 JAN 2021 00:01

Patient Cloud Close Date & Time

13 JAN 2021 23:59

US3052005

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:00:53

TIMEPOINT

DAY 173

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

16 JAN 2021 07:50:55

Patient Cloud Open Date & Time

16 JAN 2021 00:01

Patient Cloud Close Date & Time

20 JAN 2021 23:59

US3052005

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:00:53

TIMEPOINT

DAY 180

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

23 JAN 2021 07:52:37

Patient Cloud Open Date & Time

23 JAN 2021 00:01

Patient Cloud Close Date & Time

27 JAN 2021 23:59

US3052005

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:00:53

TIMEPOINT	DAY 187
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	30 JAN 2021 08:51:22
Patient Cloud Open Date & Time	30 JAN 2021 00:01
Patient Cloud Close Date & Time	03 FEB 2021 23:59

US3052005

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:00:53

TIMEPOINT

DAY 194

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

09 FEB 2021 18:41:25

Patient Cloud Open Date & Time

06 FEB 2021 00:01

Patient Cloud Close Date & Time

10 FEB 2021 23:59

US3052005

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:00:53

TIMEPOINT

DAY 201

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

15 FEB 2021 12:00:41

Patient Cloud Open Date & Time

13 FEB 2021 00:01

Patient Cloud Close Date & Time

17 FEB 2021 23:59

US3052005

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:00:53

TIMEPOINT	DAY 208
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input checked="" type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input checked="" type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	21 FEB 2021 08:31:00
Patient Cloud Open Date & Time	20 FEB 2021 00:01
Patient Cloud Close Date & Time	24 FEB 2021 23:59

US3052005

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:00:53

TIMEPOINT

DAY 215

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

28 FEB 2021 00:39:42

Patient Cloud Open Date & Time

27 FEB 2021 00:01

Patient Cloud Close Date & Time

03 MAR 2021 23:59

US3052005

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:00:53

TIMEPOINT

DAY 222

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

08 MAR 2021 11:56:46

Patient Cloud Open Date & Time

06 MAR 2021 00:01

Patient Cloud Close Date & Time

10 MAR 2021 23:59

US3052005

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:00:53

TIMEPOINT

DAY 229

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

15 MAR 2021 12:30:46

Patient Cloud Open Date & Time

13 MAR 2021 00:01

Patient Cloud Close Date & Time

17 MAR 2021 23:59

US3052005

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:00:53

TIMEPOINT

DAY 236

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

22 MAR 2021 13:29:35

Patient Cloud Open Date & Time

20 MAR 2021 00:01

Patient Cloud Close Date & Time

24 MAR 2021 23:59

US3052005

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:00:53

TIMEPOINT

DAY 243

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

30 MAR 2021 02:58:21

Patient Cloud Open Date & Time

27 MAR 2021 00:01

Patient Cloud Close Date & Time

31 MAR 2021 23:59

US3052005

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:00:53

TIMEPOINT

DAY 250

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

05 APR 2021 12:00:46

Patient Cloud Open Date & Time

03 APR 2021 00:01

Patient Cloud Close Date & Time

07 APR 2021 23:59

US3052005

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:00:53

TIMEPOINT

DAY 257

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

12 APR 2021 12:00:36

Patient Cloud Open Date & Time

10 APR 2021 00:01

Patient Cloud Close Date & Time

14 APR 2021 23:59

US3052005

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:00:53

TIMEPOINT

DAY 264

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

20 APR 2021 19:02:42

Patient Cloud Open Date & Time

17 APR 2021 00:01

Patient Cloud Close Date & Time

21 APR 2021 23:59

US3052005

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:00:53

TIMEPOINT

DAY 271

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

26 APR 2021 12:05:45

Patient Cloud Open Date & Time

24 APR 2021 00:01

Patient Cloud Close Date & Time

28 APR 2021 23:59

US3052005

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:00:53

TIMEPOINT

DAY 278

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

03 MAY 2021 12:05:44

Patient Cloud Open Date & Time

01 MAY 2021 00:01

Patient Cloud Close Date & Time

05 MAY 2021 23:59

US3052005

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:00:53

TIMEPOINT	DAY 285
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

US3052005

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:00:53

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

08 MAY 2021 00:01

[Patient Cloud Close Date & Time](#)

12 MAY 2021 23:59

US3052005

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:00:53

TIMEPOINT

DAY 292

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

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

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

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

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

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

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

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

US3052005

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:00:53

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

15 MAY 2021 00:01

[Patient Cloud Close Date & Time](#)

19 MAY 2021 23:59

US3052005

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:00:53

TIMEPOINT	DAY 299
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

US3052005

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:00:53

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

[Patient Cloud Open Date & Time](#)

22 MAY 2021 00:01

[Patient Cloud Close Date & Time](#)

26 MAY 2021 23:59

US3052005

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:00:53

TIMEPOINT

DAY 306

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3052005

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:00:53

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

[Patient Cloud Open Date & Time](#)

29 MAY 2021 00:01

[Patient Cloud Close Date & Time](#)

02 JUN 2021 23:59

US3052005

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:00:53

TIMEPOINT

DAY 313

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

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

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

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

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

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

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

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

US3052005

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:00:53

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

[Patient Cloud Open Date & Time](#)

05 JUN 2021 00:01

[Patient Cloud Close Date & Time](#)

09 JUN 2021 23:59

US3052005

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:00:53

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

US3052005

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:00:53

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

12 JUN 2021 00:01

[Patient Cloud Close Date & Time](#)

16 JUN 2021 23:59

US3052005

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:00:53

TIMEPOINT

DAY 327

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

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

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

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

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

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

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

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

US3052005

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:00:53

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

[Patient Cloud Open Date & Time](#)

19 JUN 2021 00:01

[Patient Cloud Close Date & Time](#)

23 JUN 2021 23:59

US3052005

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:00:53

TIMEPOINT

DAY 334

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

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

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

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

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

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

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

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

US3052005

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:00:53

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
Patient Cloud Open Date & Time	26 JUN 2021 00:01
Patient Cloud Close Date & Time	30 JUN 2021 23:59

US3052005

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:00:53

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

US3052005

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:00:53

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

[Patient Cloud Open Date & Time](#)

03 JUL 2021 00:01

[Patient Cloud Close Date & Time](#)

07 JUL 2021 23:59

US3052005

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:00:53

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

US3052005

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:00:53

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
Patient Cloud Open Date & Time	10 JUL 2021 00:01
Patient Cloud Close Date & Time	14 JUL 2021 23:59

US3052005

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:00:53

TIMEPOINT

DAY 355

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

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

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

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

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

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

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

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

US3052005

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:00:53

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

US3052005

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:00:53

TIMEPOINT

DAY 362

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3052005

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:00:53

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

[Patient Cloud Open Date & Time](#)

24 JUL 2021 00:01

[Patient Cloud Close Date & Time](#)

28 JUL 2021 23:59

US3052005

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:00:53

TIMEPOINT

DAY 369

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

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

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

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

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

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

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

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

US3052005

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:00:53

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

[Patient Cloud Open Date & Time](#)

31 JUL 2021 00:01

[Patient Cloud Close Date & Time](#)

04 AUG 2021 23:59

US3052005

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:00:53

TIMEPOINT

DAY 376

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

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

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

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

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

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

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

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

US3052005

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:00:53

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

[Patient Cloud Open Date & Time](#)

07 AUG 2021 00:01

[Patient Cloud Close Date & Time](#)

11 AUG 2021 23:59

US3052005

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:00:53

TIMEPOINT

DAY 383

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3052005

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:00:53

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

Patient Cloud Open Date & Time	14 AUG 2021 00:01
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Patient Cloud Close Date & Time	18 AUG 2021 23:59
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US3052005

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:00:53

TIMEPOINT

DAY 390

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

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

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

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

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

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

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

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

US3052005

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:00:53

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
Patient Cloud Open Date & Time	21 AUG 2021 00:01
Patient Cloud Close Date & Time	25 AUG 2021 23:59

US3052005

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:00:53

TIMEPOINT

DAY 397

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3052005

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:00:53

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

I confirm I have read this message and will call the study clinic immediately ☐

Date and time of submission

[Patient Cloud Open Date & Time](#)

28 AUG 2021 00:01

[Patient Cloud Close Date & Time](#)

01 SEP 2021 23:59

US3052005

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:00:53

TIMEPOINT	DAY 404
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>

US3052005

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:00:53

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

[Patient Cloud Open Date & Time](#)

04 SEP 2021 00:01

[Patient Cloud Close Date & Time](#)

08 SEP 2021 23:59

US3052005

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:00:53

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

US3052005

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:00:53

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

[Patient Cloud Open Date & Time](#)

11 SEP 2021 00:01

[Patient Cloud Close Date & Time](#)

15 SEP 2021 23:59

US3052005

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:00:53

TIMEPOINT

DAY 418

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3052005

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:00:53

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

[Patient Cloud Open Date & Time](#)

18 SEP 2021 00:01

[Patient Cloud Close Date & Time](#)

22 SEP 2021 23:59

US3052005

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:00:53

TIMEPOINT

DAY 425

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

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

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

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

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

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

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

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

US3052005

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:00:53

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

Patient Cloud Open Date & Time	25 SEP 2021 00:01
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Patient Cloud Close Date & Time	29 SEP 2021 23:59
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US3052005

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:00:53

TIMEPOINT

DAY 432

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3052005

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:00:53

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

Patient Cloud Open Date & Time	02 OCT 2021 00:01
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Patient Cloud Close Date & Time	06 OCT 2021 23:59
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US3052005

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:00:53

TIMEPOINT

DAY 439

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

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

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

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

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

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

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

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

US3052005

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:00:53

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

09 OCT 2021 00:01

[Patient Cloud Close Date & Time](#)

13 OCT 2021 23:59

US3052005

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:00:53

TIMEPOINT

DAY 446

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3052005

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:00:53

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

[Patient Cloud Open Date & Time](#)

16 OCT 2021 00:01

[Patient Cloud Close Date & Time](#)

20 OCT 2021 23:59

US3052005

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:00:53

TIMEPOINT

DAY 453

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

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

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

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

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

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

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

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

US3052005

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:00:53

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
Patient Cloud Open Date & Time	23 OCT 2021 00:01
Patient Cloud Close Date & Time	27 OCT 2021 23:59

US3052005

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:00:53

TIMEPOINT

DAY 460

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3052005

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:00:53

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

I confirm I have read this message and will call the study clinic immediately ☐

Date and time of submission

[Patient Cloud Open Date & Time](#)

30 OCT 2021 00:01

[Patient Cloud Close Date & Time](#)

03 NOV 2021 23:59

US3052005

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:00:53

TIMEPOINT

DAY 467

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

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

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

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

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

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

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

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

US3052005

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:00:53

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

[Patient Cloud Open Date & Time](#)

06 NOV 2021 00:01

[Patient Cloud Close Date & Time](#)

10 NOV 2021 23:59

US3052005

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:00:53

TIMEPOINT

DAY 474

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

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

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

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

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

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

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

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

US3052005

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:00:53

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

US3052005

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:00:53

TIMEPOINT

DAY 481

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3052005

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:00:53

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

[Patient Cloud Open Date & Time](#)

20 NOV 2021 00:01

[Patient Cloud Close Date & Time](#)

24 NOV 2021 23:59

US3052005

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:00:53

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

US3052005

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:00:53

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

[Patient Cloud Open Date & Time](#)

27 NOV 2021 00:01

[Patient Cloud Close Date & Time](#)

01 DEC 2021 23:59

US3052005

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:00:53

TIMEPOINT

DAY 495

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

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

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

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

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

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

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

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

US3052005

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:00:53

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

[Patient Cloud Open Date & Time](#)

04 DEC 2021 00:01

[Patient Cloud Close Date & Time](#)

08 DEC 2021 23:59

US3052005

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:00:53

TIMEPOINT

DAY 502

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3052005

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:00:53

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

US3052005

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:00:53

TIMEPOINT

DAY 509

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3052005

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:00:53

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

[Patient Cloud Open Date & Time](#)

18 DEC 2021 00:01

[Patient Cloud Close Date & Time](#)

22 DEC 2021 23:59

US3052005

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:00:53

TIMEPOINT

DAY 516

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3052005

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:00:53

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
Patient Cloud Open Date & Time	25 DEC 2021 00:01
Patient Cloud Close Date & Time	29 DEC 2021 23:59

US3052005

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:00:53

TIMEPOINT

DAY 523

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

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

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

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

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

Fever (Temperature \geq 100.4°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 ☐

US3052005

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:00:53

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

[Patient Cloud Open Date & Time](#)

01 JAN 2022 00:01

[Patient Cloud Close Date & Time](#)

05 JAN 2022 23:59

US3052005

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:00:53

TIMEPOINT	DAY 530
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>

US3052005

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:00:53

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

[Patient Cloud Open Date & Time](#)

08 JAN 2022 00:01

[Patient Cloud Close Date & Time](#)

12 JAN 2022 23:59

US3052005

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:00:53

TIMEPOINT

DAY 537

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3052005

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:00:53

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
Patient Cloud Open Date & Time	15 JAN 2022 00:01
Patient Cloud Close Date & Time	19 JAN 2022 23:59

US3052005

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:00:53

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

US3052005

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:00:53

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

US3052005

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:00:53

TIMEPOINT

DAY 551

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

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

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

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

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

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

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

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

US3052005

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:00:53

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

[Patient Cloud Open Date & Time](#)

29 JAN 2022 00:01

[Patient Cloud Close Date & Time](#)

02 FEB 2022 23:59

US3052005

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:00:53

TIMEPOINT

DAY 558

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3052005

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:00:53

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

[Patient Cloud Open Date & Time](#)

05 FEB 2022 00:01

[Patient Cloud Close Date & Time](#)

09 FEB 2022 23:59

US3052005

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:00:53

TIMEPOINT

DAY 565

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

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

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

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

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

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

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

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

US3052005

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:00:53

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

[Patient Cloud Open Date & Time](#)

12 FEB 2022 00:01

[Patient Cloud Close Date & Time](#)

16 FEB 2022 23:59

US3052005

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:00:53

TIMEPOINT

DAY 572

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

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

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

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

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

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

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

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

US3052005

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:00:53

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

[Patient Cloud Open Date & Time](#)

19 FEB 2022 00:01

[Patient Cloud Close Date & Time](#)

23 FEB 2022 23:59

US3052005

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:00:53

TIMEPOINT

DAY 579

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

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

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

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

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

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

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

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

US3052005

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:00:53

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

[Patient Cloud Open Date & Time](#)

26 FEB 2022 00:01

[Patient Cloud Close Date & Time](#)

02 MAR 2022 23:59

US3052005

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:00:53

TIMEPOINT

DAY 586

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

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

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

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

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

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

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

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

US3052005

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:00:53

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

[Patient Cloud Open Date & Time](#)

05 MAR 2022 00:01

[Patient Cloud Close Date & Time](#)

09 MAR 2022 23:59

US3052005

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:00:53

TIMEPOINT

DAY 593

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

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

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

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

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

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

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

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

US3052005

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:00:53

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

12 MAR 2022 00:01

[Patient Cloud Close Date & Time](#)

16 MAR 2022 23:59

US3052005

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:00:53

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

US3052005

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:00:53

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

19 MAR 2022 00:01

[Patient Cloud Close Date & Time](#)

23 MAR 2022 23:59

US3052005

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:00:53

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

US3052005

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:00:53

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

[Patient Cloud Open Date & Time](#)

26 MAR 2022 00:01

[Patient Cloud Close Date & Time](#)

30 MAR 2022 23:59

US3052005

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:00:53

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

US3052005

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:00:53

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

I confirm I have read this message and will call the study clinic immediately ☐

Date and time of submission

[Patient Cloud Open Date & Time](#)

02 APR 2022 00:01

[Patient Cloud Close Date & Time](#)

06 APR 2022 23:59

US3052005

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:00:53

TIMEPOINT	DAY 621
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

US3052005

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:00:53

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

[Patient Cloud Open Date & Time](#)

09 APR 2022 00:01

[Patient Cloud Close Date & Time](#)

13 APR 2022 23:59

US3052005

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:00:53

TIMEPOINT

DAY 628

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

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

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

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

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

Fever (Temperature \geq 100.4°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 ☐

US3052005

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:00:53

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

I confirm I have read this message and will call the study clinic immediately ☐

Date and time of submission

[Patient Cloud Open Date & Time](#)

16 APR 2022 00:01

[Patient Cloud Close Date & Time](#)

20 APR 2022 23:59

US3052005

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:00:53

TIMEPOINT

DAY 635

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3052005

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:00:53

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

[Patient Cloud Open Date & Time](#)

23 APR 2022 00:01

[Patient Cloud Close Date & Time](#)

27 APR 2022 23:59

US3052005

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:00:53

TIMEPOINT

DAY 642

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

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

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

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

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

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

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

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

US3052005

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:00:53

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

[Patient Cloud Open Date & Time](#)

30 APR 2022 00:01

[Patient Cloud Close Date & Time](#)

04 MAY 2022 23:59

US3052005

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:00:53

TIMEPOINT	DAY 649
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

US3052005

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:00:53

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

[Patient Cloud Open Date & Time](#)

07 MAY 2022 00:01

[Patient Cloud Close Date & Time](#)

11 MAY 2022 23:59

US3052005

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:00:53

TIMEPOINT

DAY 656

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

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

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

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

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

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

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

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

US3052005

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:00:53

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

[Patient Cloud Open Date & Time](#)

14 MAY 2022 00:01

[Patient Cloud Close Date & Time](#)

18 MAY 2022 23:59

US3052005

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:00:53

TIMEPOINT

DAY 663

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3052005

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:00:53

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

[Patient Cloud Open Date & Time](#)

21 MAY 2022 00:01

[Patient Cloud Close Date & Time](#)

25 MAY 2022 23:59

US3052005

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:00:53

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

US3052005

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:00:53

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

[Patient Cloud Open Date & Time](#)

28 MAY 2022 00:01

[Patient Cloud Close Date & Time](#)

01 JUN 2022 23:59

US3052005

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:00:53

TIMEPOINT

DAY 677

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

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

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

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

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

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

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

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

US3052005

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:00:53

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

[Patient Cloud Open Date & Time](#)

04 JUN 2022 00:01

[Patient Cloud Close Date & Time](#)

08 JUN 2022 23:59

US3052005

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:00:53

TIMEPOINT

DAY 684

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

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

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

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

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

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

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

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

US3052005

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:00:53

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

[Patient Cloud Open Date & Time](#)

11 JUN 2022 00:01

[Patient Cloud Close Date & Time](#)

15 JUN 2022 23:59

US3052005

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:00:53

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

US3052005

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:00:53

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

[Patient Cloud Open Date & Time](#)

18 JUN 2022 00:01

[Patient Cloud Close Date & Time](#)

22 JUN 2022 23:59

US3052005

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:00:53

TIMEPOINT	DAY 698
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

US3052005

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:00:53

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

[Patient Cloud Open Date & Time](#)

25 JUN 2022 00:01

[Patient Cloud Close Date & Time](#)

29 JUN 2022 23:59

US3052005

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:00:53

TIMEPOINT	DAY 705
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>

US3052005

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:00:53

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

[Patient Cloud Open Date & Time](#)

02 JUL 2022 00:01

[Patient Cloud Close Date & Time](#)

06 JUL 2022 23:59

US3052005

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:00:53

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

US3052005

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:00:53

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

[Patient Cloud Open Date & Time](#)

09 JUL 2022 00:01

[Patient Cloud Close Date & Time](#)

13 JUL 2022 23:59

US3052005

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:00:53

TIMEPOINT

DAY 719

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

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

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

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

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

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

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

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

US3052005

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:00:53

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

[Patient Cloud Open Date & Time](#)

16 JUL 2022 00:01

[Patient Cloud Close Date & Time](#)

20 JUL 2022 23:59

US3052005

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:00:53

TIMEPOINT

DAY 726

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

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

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

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

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

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

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

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

US3052005

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:00:53

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

US3052005

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:00:53

TIMEPOINT

DAY 733

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3052005

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:00:53

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

[Patient Cloud Open Date & Time](#)

30 JUL 2022 00:01

[Patient Cloud Close Date & Time](#)

03 AUG 2022 23:59

US3052005

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:00:53

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

US3052005

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:00:53

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

[Patient Cloud Open Date & Time](#)

06 AUG 2022 00:01

[Patient Cloud Close Date & Time](#)

10 AUG 2022 23:59

US3052005

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:00:53

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

US3052005

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:00:53

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

Date and time of submission

Patient Cloud Open Date & Time	13 AUG 2022 00:01
--	-------------------

Patient Cloud Close Date & Time	17 AUG 2022 23:59
---	-------------------

US3052005

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:00:53

TIMEPOINT	DAY 754
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>

US3052005

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:00:53

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

[Patient Cloud Open Date & Time](#)

20 AUG 2022 00:01

[Patient Cloud Close Date & Time](#)

24 AUG 2022 23:59

US3052005

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:00:53

TIMEPOINT

DAY 761

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3052005

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:00:53

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

US3052005

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:00:53

TIMEPOINT

DAY 768

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

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

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

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

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

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

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

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

US3052005

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:00:53

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

[Patient Cloud Open Date & Time](#)

03 SEP 2022 00:01

[Patient Cloud Close Date & Time](#)

07 SEP 2022 23:59

US3052005

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:00:53

TIMEPOINT

DAY 775

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

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

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

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

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

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

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

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

US3052005

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:00:53

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

[Patient Cloud Open Date & Time](#)

10 SEP 2022 00:01

[Patient Cloud Close Date & Time](#)

14 SEP 2022 23:59

US3052005

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:00:53

TIMEPOINT

DAY 782

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

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

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

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

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

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

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

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

US3052005

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:00:53

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

[Patient Cloud Open Date & Time](#)

17 SEP 2022 00:01

[Patient Cloud Close Date & Time](#)

21 SEP 2022 23:59

US3052005

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:00:53

TIMEPOINT

DAY 789

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

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

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

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

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

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

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

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

US3052005

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:00:53

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

24 SEP 2022 00:01

[Patient Cloud Close Date & Time](#)

28 SEP 2022 23:59

US3052005

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:00:53

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

US3052005

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:00:53

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
Patient Cloud Open Date & Time	01 OCT 2022 00:01
Patient Cloud Close Date & Time	05 OCT 2022 23:59

US3052005

Folder: Cosmetic Injections and Dermal Fillers

Form: Cosmetic Injection_ Dermal Filler eDiary

Generated On: 09 Jun 2021 15:00:53

Have you ever received facial cosmetic injections, such as Juvederm, Voluma, Radiesse, Restylane, Botox or other?	Have you ever received a dermal filler, such as Juvederm, Voluma, Radiesse, Restylane, or Botox or other for a medical indication such as a migraine headache?	Date & Time of Submission
No		28 FEB 2021 00:39:57

US3052005

Folder: Safety Call Day 85 (1)

Form: Safety Call

Data signed: (b) (4) 23 Feb 2021 07:32:25

Generated On: 09 Jun 2021 15:00:53

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

20 OCT 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3052005

Folder: Safety Call Day 85 (1)

Form: Continuing

Data signed: (b) (4) 23 Feb 2021 07:32:24

Generated On: 09 Jun 2021 15:00:53

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3052005

Folder: Safety Call Day 119 (1)

Form: Safety Call

Data signed: (b) (4) 23 Feb 2021 07:32:25

Generated On: 09 Jun 2021 15:00:53

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

22 NOV 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3052005

Folder: Safety Call Day 119 (1)

Form: Continuing

Data signed: (b) (4) 23 Feb 2021 07:32:24

Generated On: 09 Jun 2021 15:00:53

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3052005

Folder: Safety Call Day 149 (1)

Form: Safety Call

Data signed: (b) (4) 23 Feb 2021 07:32:25

Generated On: 09 Jun 2021 15:00:53

Was Contact Attempted? Yes ☒
No ☐

Date of Contact or Contact Attempt (dd MMM yyyy) 23 DEC 2020

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

Comments LEFT VOICEMAIL

If Contact Not Made, please provide Comments

US3052005

Folder: Safety Call Day 149 (1)

Form: Continuing

Data signed: (b) (4) 23 Feb 2021 07:32:24

Generated On: 09 Jun 2021 15:00:53

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3052005

Folder: Safety Call Day 179 (1)

Form: Safety Call

Data signed: (b) (4) 15 Mar 2021 14:45:16

Generated On: 09 Jun 2021 15:00:53

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

28 JAN 2021

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3052005

Folder: Safety Call Day 179 (1)

Form: Continuing

Data signed: (b) (4) 15 Mar 2021 14:45:16

Generated On: 09 Jun 2021 15:00:53

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3052005

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Data signed: (b) (4) 08 Apr 2021 19:45:37

Generated On: 09 Jun 2021 15:00:53

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	7 APR 2021
Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>
Folder OID	VISIT4

US3052005

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Data signed: (b) (4) 08 Apr 2021 19:45:37

Generated On: 09 Jun 2021 15:00:53

Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (dd MMM yyyy)	7 APR 2021
Time of assessment (00:00-23:59)	10:20 (24 HR)
Vital Signs Date and Time (derived)	7 APR 2021 10:20
Temperature (xxx.x)	98.1 F
Route of measurement	Oral <input checked="" type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	67 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	15 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	137 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	85 mmHg
Diastolic Blood Pressure units	MMHG
Height (derived)	
Weight (derived)	

US3052005

Folder: Visit 4 Day 209 (1)

Form: Physical Examination

Data signed: (b) (4) 08 Apr 2021 19:45:37

Generated On: 09 Jun 2021 15:00:53

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

7 APR 2021

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

US3052005

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 08 Apr 2021 19:45:37

Generated On: 09 Jun 2021 15:00:53

Was the sample collected?

Yes ☒

No ☐

Collection date (dd MMM yyyy)

7 APR 2021

Collection time (00:00-23:59)

10:55 (24 HR)

Collection date and time (derived)

7 APR 2021 10:55

US3052005

Folder: Visit 4 Day 209 (1)

Form: Continuing

Data signed: (b) (4) 01 Apr 2021 13:22:50

Generated On: 09 Jun 2021 15:00:53

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3052005

Folder: Safety Call Day 239 (1)

Form: Safety Call

Data signed: (b) (4) 01 Apr 2021 13:22:50

Generated On: 09 Jun 2021 15:00:53

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

23 MAR 2021

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3052005

Folder: Safety Call Day 239 (1)

Form: Continuing

Data signed: (b) (4) 01 Apr 2021 13:22:50

Generated On: 09 Jun 2021 15:00:53

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3052005

Folder: Safety Call Day 269 (1)

Form: Safety Call

Data signed: (b) (4) 26 Apr 2021 20:34:31

Generated On: 09 Jun 2021 15:00:53

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

26 APR 2021

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3052005

Folder: Safety Call Day 269 (1)

Form: Continuing

Data signed: (b) (4) 26 Apr 2021 20:34:31

Generated On: 09 Jun 2021 15:00:53

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3052005

Folder: Safety Call Day 299 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:00:53

Was Contact Attempted? Yes ☐
No ☐

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

Please select one status for the follow-up contact

Contact Made ☐

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3052005

Folder: Safety Call Day 299 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:00:53

Is the participant continuing to the next visit?

Yes ☐

No ☐

Continuing Flag

US3052005

Folder: Covid-19 Assessment (1)

Form: COVID-19 Contact

Data signed: (b) (4) 23 Feb 2021 07:32:24

Generated On: 09 Jun 2021 15:00:53

Date of Contact	
Time of Contact	
Date and Time of Contact (derived)	
Type of Contact	<div>Clinic Visit - Scheduled<input type="checkbox"/></div> <div>Clinical Visit - Unscheduled<input type="checkbox"/></div> <div>Safety Call<input type="checkbox"/></div> <div>Convalescent Tele-visit<input type="checkbox"/></div>
Has the subject reported symptoms of SARS-COV-2?	<div>Yes<input type="checkbox"/></div> <div>No<input type="checkbox"/></div>

US3052005

Folder: Covid-19 Assessment (1)

Form: Generate Next COVID-19 Assessment

Data signed: (b) (4) 23 Feb 2021 07:32:24

Generated On: 09 Jun 2021 15:00:53

Generate Next COVID-19 Assessment

Yes ☐

No ☐

US3052005

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

Form: Visit Date

Data signed: (b) (4) 23 Feb 2021 07:32:25

Generated On: 09 Jun 2021 15:00:53

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

Visit date (dd MMM yyyy)	11 JAN 2021
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Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>

Folder OID	UNBLND_DECIDE
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US3052005

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

Form: Unblinding

Data signed: (b) (4) 15 Mar 2021 14:45:16

Generated On: 09 Jun 2021 15:00:53

Date of updated informed consent (dd MMM yyyy) 11 JAN 2021

N/A - Subject Unblinded under Amendment 5 and Discontinued from Study False

Was the participant unblinded? Yes ☒ No ☐

Under what version of the Protocol was the Participant unblinded? Amendment 5 ☐ Amendment 6 or later ☒

Date of unblinding (dd MMM yyyy) 11 JAN 2021

Participant randomization assignment mRNA-1273 ☒ Placebo ☐

Actual Dose 1 mRNA-1273 ☒ Placebo ☐ Not Administered ☐

Actual Dose 2 mRNA-1273 ☒ Placebo ☐ Not Administered ☐

Will participant receive mRNA-1273? Yes ☐ No ☒

Placebo Only Flag _____
Continuing with mRNA-1273 _____

US3052005

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

Form: Immunogenicity Assessment

Data signed: (b) (4) 23 Feb 2021 07:32:24

Generated On: 09 Jun 2021 15:00:53

Was the sample collected?

Yes ☒

No ☐

Collection date (dd MMM yyyy)

11 JAN 2021

Collection time (00:00-23:59)

09:37 (24 HR)

Collection date and time (derived)

11 JAN 2021 09:37

US3052005

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

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Data signed: (b) (4) 23 Feb 2021 07:32:25

Generated On: 09 Jun 2021 15:00:53

Was the sample collected?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Collection date (dd MMM yyyy)	11 JAN 2021
Collection time (00:00 - 23:59)	09:39
Collection Date and Time (derived)	11 JAN 2021 09:39

US3052005

Folder: Adverse Events

Form: Adverse Events Summary

Data signed: (b) (4) 08 Apr 2021 19:45:37

Generated On: 09 Jun 2021 15:00:53

Did the participant experience any adverse events?

Yes ☒

No ☐

If Yes, enter details on the Adverse Events form.

US3052005

Folder: Adverse Events

Form: Adverse Events (1)

Data signed: (b) (4) 16 Apr 2021 15:23:47

Generated On: 09 Jun 2021 15:00:53

AEID	USA-US117-2021-MRNA-1273-P30 1000007
Adverse event	RIGHT HIP JOINT REPLACEMENT (WORSENING OF OSTEOARTHRITIS)
Was this a medically-attended AE?	Yes <input checked="" type="radio"/> No <input type="radio"/>
Was this a Solicited Adverse Reaction?	Yes <input type="radio"/> No <input checked="" type="radio"/>
Is this event a confirmed diagnosis of Symptomatic Covid-19?	Yes <input type="radio"/> No <input checked="" type="radio"/>
Start date (dd MMM yyyy)	24 FEB 2021
Start time (00:00-23:59)	
AE start date and time (derived)	
Ongoing?	Yes <input type="radio"/> No <input checked="" type="radio"/>
If not Ongoing, end date (dd MMM yyyy)	25 FEB 2021
End time (00:00-23:59)	
AE End Date and Time (derived)	
Severity	Grade 1/Mild <input type="radio"/> Grade 2/Moderate <input type="radio"/> Grade 3/Severe <input checked="" type="radio"/> Grade 4 <input type="radio"/>
Is the adverse event serious?	Yes <input checked="" type="radio"/> No <input type="radio"/>
AE is serious due To (check all that apply)	
Death	False
Life threatening	False
Requires inpatient or prolongation of existing Hospitalization	True
Hospital Admission Date (dd MMM yyyy)	24 FEB 2021
Hospital Discharge Date (dd MMM yyyy)	25 FEB 2021
Admitted to ICU?	Yes <input type="radio"/> No <input checked="" type="radio"/>
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Folder: Adverse Events

Form: Adverse Events (1)

Data signed: (b) (4) 16 Apr 2021 15:23:47

Generated On: 09 Jun 2021 15:00:53

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

US3052005

Folder: Adverse Events

Form: Adverse Events (1)

Data signed: (b) (4) 16 Apr 2021 15:23:47

Generated On: 09 Jun 2021 15:00:53

SUBJECT HAD RIGHT HIP JOINT
REPLACEMENT
(RESURFACING) SURGERY ON
24 FEB 2021. HE WAS ADMITTED
TO THE HOSPITAL POST
SURGERY FOR OBSERVATION
AND DISCHARGED 25 FEB 2021

Serious Adverse Event Derived (CSA Programming Field Only)	1
Medically Attended AE Derived (CSA Programming Field Only)	1
Admitted to ICU Derived (CSA Programming Field Only)	0

US3052005

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination Summary

Data signed: (b) (4) 23 Feb 2021 07:32:24

Generated On: 09 Jun 2021 15:00:53

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

Yes ☒

No ☐

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

US3052005

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Data signed: (b) (4) 26 Apr 2021 20:34:31

Generated On: 09 Jun 2021 15:00:53

Name of Medication METOPROLOL

Prophylaxis Yes ☐
No ☒

Indication A-FIB/HTN

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 ☐

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US3052005

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Data signed: (b) (4) 26 Apr 2021 20:34:31

Generated On: 09 Jun 2021 15:00:53

	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	UN DEC 2018	
Start date completely unknown	False	
Ongoing?	Yes	<input checked="" type="radio"/>
	No	<input type="radio"/>
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived)	1	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input checked="" type="radio"/>

US3052005

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Data signed: (b) (4) 26 Apr 2021 20:34:31

Generated On: 09 Jun 2021 15:00:53

Name of Medication LOSARTAN

Prophylaxis Yes ☐
No ☒

Indication A-FIB/HTN

Dose per administration 25

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Data signed: (b) (4) 26 Apr 2021 20:34:31

Generated On: 09 Jun 2021 15:00:53

	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	UN DEC 2018	
Start date completely unknown	False	
Ongoing?	Yes	<input checked="" type="radio"/>
	No	<input type="radio"/>
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived)	1	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input checked="" type="radio"/>

US3052005

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Data signed: (b) (4) 26 Apr 2021 20:34:31

Generated On: 09 Jun 2021 15:00:53

Name of Medication ELIQUIS

Prophylaxis Yes ☐
No ☒

Indication A-FIB

Dose per administration 5

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Data signed: (b) (4) 26 Apr 2021 20:34:31

Generated On: 09 Jun 2021 15:00:53

	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	UN DEC 2018	
Start date completely unknown	False	
Ongoing?	Yes	<input checked="" type="radio"/>
	No	<input type="radio"/>
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived)	1	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input checked="" type="radio"/>

US3052005

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Data signed: (b) (4) 26 Apr 2021 20:34:31

Generated On: 09 Jun 2021 15:00:53

Name of Medication REPATHA

Prophylaxis Yes ☐
No ☒

Indication HIGH CHOLESTEROL

Dose per administration UNKNOWN

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

If dose unit is Other, specify DOSAGE NOT LISTED

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 TWICE A MONTH

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Data signed: (b) (4) 26 Apr 2021 20:34:31

Generated On: 09 Jun 2021 15:00:53

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Data signed: (b) (4) 26 Apr 2021 20:34:31

Generated On: 09 Jun 2021 15:00:53

Name of Medication SILDEAFIL

Prophylaxis Yes ☐
No ☒

Indication ERECTILE DYSFUNCTION

Dose per administration 80

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Data signed: (b) (4) 26 Apr 2021 20:34:31

Generated On: 09 Jun 2021 15:00:53

	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	UN UNK 2018	
Start date completely unknown	False	
Ongoing?	Yes	<input checked="" type="radio"/>
	No	<input type="radio"/>
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived)	1	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input checked="" type="radio"/>
	804	<input type="radio"/>

US3052005

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Data signed: (b) (4) 26 Apr 2021 20:34:31

Generated On: 09 Jun 2021 15:00:53

Name of Medication GLUCOSAMINE

Prophylaxis Yes ☒
No ☐

Indication SUPPLEMENT

Dose per administration 1

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Data signed: (b) (4) 26 Apr 2021 20:34:31

Generated On: 09 Jun 2021 15:00:53

	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	UN UNK 2005	
Start date completely unknown	False	
Ongoing?	Yes	<input checked="" type="radio"/>
	No	<input type="radio"/>
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived)	1	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input checked="" type="radio"/>

US3052005

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Data signed: (b) (4) 26 Apr 2021 20:34:31

Generated On: 09 Jun 2021 15:00:53

Name of Medication FISH OIL

Prophylaxis Yes ☐
No ☒

Indication HIGH CHOLESTEROL

Dose per administration 1200

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

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EAB) (1725)

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Data signed: (b) (4) 26 Apr 2021 20:34:31

Generated On: 09 Jun 2021 15:00:53

	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	UN UNK 2005	
Start date completely unknown	False	
Ongoing?	Yes	<input checked="" type="radio"/>
	No	<input type="radio"/>
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived)	2	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input checked="" type="radio"/>

US3052005

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Data signed: (b) (4) 26 Apr 2021 20:34:31

Generated On: 09 Jun 2021 15:00:53

Name of Medication VITAMIN C

Prophylaxis Yes ☐
No ☒

Indication HEALTH MAINTENANCE

Dose per administration 500

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Data signed: (b) (4) 26 Apr 2021 20:34:31

Generated On: 09 Jun 2021 15:00:53

	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	UN UNK 2010	
Start date completely unknown	False	
Ongoing?	Yes	<input checked="" type="radio"/>
	No	<input type="radio"/>
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived)	1	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input checked="" type="radio"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Data signed: (b) (4) 26 Apr 2021 20:34:31

Generated On: 09 Jun 2021 15:00:53

Name of Medication MULTI VITAMIN

Prophylaxis Yes ☒
No ☐

Indication HEALTH 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 ☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Data signed: (b) (4) 26 Apr 2021 20:34:31

Generated On: 09 Jun 2021 15:00:53

	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	UN UNK 2010	
Start date completely unknown	False	
Ongoing?	Yes	<input checked="" type="radio"/>
	No	<input type="radio"/>
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived)	1	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input checked="" type="radio"/>

US3052005

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Data signed: (b) (4) 26 Apr 2021 20:34:31

Generated On: 09 Jun 2021 15:00:53

Name of Medication INFLUENZA VACCINE

Prophylaxis Yes ☒
No ☐

Indication VACCINATION

Dose per administration 1

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

If dose unit is Other, specify INJECTION

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

If frequency is Other, specify

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

PRODUCTION RELEASE (v12.003

EAB) (1725)

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US3052005

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Data signed: (b) (4) 26 Apr 2021 20:34:31

Generated On: 09 Jun 2021 15:00:53

	Intramuscular	<input checked="" type="radio"/>
	Respiratory (Inhalation)	<input type="radio"/>
	Intralesional	<input type="radio"/>
	Intraperitoneal	<input type="radio"/>
	Nasal	<input type="radio"/>
	Vaginal	<input type="radio"/>
	Rectal	<input type="radio"/>
	Intravenous	<input type="radio"/>
	Intravenous Bolus	<input type="radio"/>
	Intravenous Drip	<input type="radio"/>
	Other	<input type="radio"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)		25 SEP 2020
Start date completely unknown		False
Ongoing?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
If not Ongoing, End date (dd MMM yyyy)		25 SEP 2020
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived) _____		
Interval Dosage Unit Number (derived) _____		
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input type="radio"/>

US3052005

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Data signed: (b) (4) 26 Apr 2021 20:34:31

Generated On: 09 Jun 2021 15:00:53

Name of Medication OXYCODONE

Prophylaxis Yes ☐
No ☒

Indication RIGHT HIP RESURFACING SURGERY

Dose per administration 5-325

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 ☐

PRODUCTION RELEASE (v12.003
EAB) (1725)

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US3052005

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Data signed: (b) (4) 26 Apr 2021 20:34:31

Generated On: 09 Jun 2021 15:00:53

	Intraocular	<input type="checkbox"/>
	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify		
Start date (dd MMM yyyy)	25 FEB 2021	
Start date completely unknown	False	
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)		26 FEB 2021
Was this medication taken for solicited event?	Yes	<input checked="" type="checkbox"/>
	No	<input type="checkbox"/>
Separate Dosage Number (derived)	1	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input checked="" type="checkbox"/>

US3052005

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Data signed: (b) (4) 26 Apr 2021 20:34:31

Generated On: 09 Jun 2021 15:00:53

Name of Medication TYLENOL

Prophylaxis Yes ☐
No ☒

Indication RIGHT HIP RESURFACING SURGERY

Dose per administration 1,000

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 ☐

PRODUCTION RELEASE (v12.003
EAB) (1725)

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US3052005

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Data signed: (b) (4) 26 Apr 2021 20:34:31

Generated On: 09 Jun 2021 15:00:53

	Intraocular	<input type="checkbox"/>
	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify		
Start date (dd MMM yyyy)	25 FEB 2021	
Start date completely unknown	False	
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)		11 APR 2021
Was this medication taken for solicited event?	Yes	<input checked="" type="checkbox"/>
	No	<input type="checkbox"/>
Separate Dosage Number (derived)	3	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input checked="" type="checkbox"/>

US3052005

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Data signed: (b) (4) 26 Apr 2021 20:34:31

Generated On: 09 Jun 2021 15:00:53

Name of Medication MELOXICAM

Prophylaxis Yes ☐
No ☒

Indication RIGHT HIP RESURFACING SURGERY

Dose per administration 7.5

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

If dose unit is Other, specify

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

If frequency is Other, specify

Route of administration Oral ☒
Topical ☐
Subcutaneous ☐
Transdermal ☐

PRODUCTION RELEASE (v12.003
EAB) (1725)

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US3052005

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Data signed: (b) (4) 26 Apr 2021 20:34:31

Generated On: 09 Jun 2021 15:00:53

	Intraocular	<input type="checkbox"/>
	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify		
Start date (dd MMM yyyy)	25 FEB 2021	
Start date completely unknown	False	
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)		11 APR 2021
Was this medication taken for solicited event?	Yes	<input checked="" type="checkbox"/>
	No	<input type="checkbox"/>
Separate Dosage Number (derived)	1	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input checked="" type="checkbox"/>

US3052005

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures Summary

Data signed: (b) (4) 08 Apr 2021 19:45:37

Generated On: 09 Jun 2021 15:00:53

Were any concomitant procedures performed?

Yes ☒

No ☐

If yes, please complete Concomitant Procedures form.

US3052005

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures

Data signed: (b) (4) 08 Apr 2021 19:45:37

Generated On: 09 Jun 2021 15:00:53

Procedure/Surgery date (dd MMM yyyy)	Procedure/Surgery	Indication	If indication is Other, specify
24 FEB 2021	RIGHT HIP RESURFACING SURGERY	Medical History	

US3052005

Folder: End of Study (1)

Form: Dosing Discontinuation

Data signed: (b) (4) 23 Feb 2021 07:32:24

Generated On: 09 Jun 2021 15:00:53

Date of dosing discontinuation (dd MMM yyyy)

Primary reason for dosing discontinuation

AE (specify) ☐

SAE (specify) ☐

Death ☐

Lost To Follow-up ☐

Physician decision (specify) ☐

Pregnancy ☐

Protocol deviation (specify) ☐

Study Terminated By Sponsor ☐

Withdrawal of consent by
participant (specify) ☐

Due to SARS-COV-2 ☐

Other ☐

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

US3052005

Folder: End of Study (1)

Form: End of Study / Study Discontinuation

Data signed: (b) (4) 23 Feb 2021 07:32:24

Generated On: 09 Jun 2021 15:00:53

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

Reason for discontinuation

AE (specify) ☐

SAE (specify) ☐

Complete ☐

Death ☐

Lost To Follow-up ☐

Physician decision (specify) ☐

Pregnancy ☐

Protocol deviation (specify) ☐

Study Terminated By Sponsor ☐

Withdrawal of consent by ☐

participant (specify)

Other ☐

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

If reason for discontinuation is Death, main cause of death

Adverse event ☐

Unknown ☐

Other ☐

If main cause of death is Other, specify

Date of death (*dd MMM yyyy*)

Was autopsy performed?

Yes ☐

No ☐

Unknown ☐

US3052005

Folder: SAE USA-US117-2021-MRNA-1273-P301000007

Form: Safety Report Form

Data signed: (b) (4) 26 Apr 2021 20:34:31

Generated On: 09 Jun 2021 15:00:53

SAEID	USA-US117-2021-MRNA-1273-P301000007
Serious	Yes <input checked="" type="radio"/> No <input type="radio"/>
Death	Yes <input type="radio"/> No <input checked="" type="radio"/>
Life threatening	Yes <input type="radio"/> No <input checked="" type="radio"/>
Requires inpatient or prolongation of existing Hospitalization	Yes <input checked="" type="radio"/> No <input type="radio"/>
Persistent or significant disability or incapacity	Yes <input type="radio"/> No <input checked="" type="radio"/>
Congenital anomaly or birth defect	Yes <input type="radio"/> No <input checked="" type="radio"/>
Other medically important event	Yes <input type="radio"/> No <input checked="" type="radio"/>
Investigator's First Name	YAA
Investigator's Last Name	OPPONG
Site Address: Street	1565 PURDUE DRIVE
Site Address: City	FAYETTEVILLE
Site Address: State	NC
Site Address: Postal Code	28314
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	4

US3052005

Folder: SAE USA-US117-2021-MRNA-1273-P301000007

Form: Safety Report Form (1)

Data signed: (b) (4) 26 Apr 2021 20:34:31

Generated On: 09 Jun 2021 15:00:53

SAEID	USA-US117-2021-MRNA-1273-P301000007
Serious	Yes <input checked="" type="radio"/> No <input type="radio"/>
Death	Yes <input type="radio"/> No <input checked="" type="radio"/>
Life threatening	Yes <input type="radio"/> No <input checked="" type="radio"/>
Requires inpatient or prolongation of existing Hospitalization	Yes <input checked="" type="radio"/> No <input type="radio"/>
Persistent or significant disability or incapacity	Yes <input type="radio"/> No <input checked="" type="radio"/>
Congenital anomaly or birth defect	Yes <input type="radio"/> No <input checked="" type="radio"/>
Other medically important event	Yes <input type="radio"/> No <input checked="" type="radio"/>
Investigator's First Name	YAA
Investigator's Last Name	OPPONG
Site Address: Street	1565 PURDUE DRIVE
Site Address: City	FAYETTEVILLE
Site Address: State	NC
Site Address: Postal Code	28314
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	4
Date of submission (Pre-filled from custom function)	08/APR/2021 19:31
Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.	True

US3052005

Folder: SAE USA-US117-2021-MRNA-1273-P301000007

Form: Safety Report Form (2)

Data signed: (b) (4) 26 Apr 2021 20:34:31

Generated On: 09 Jun 2021 15:00:53

SAEID	USA-US117-2021-MRNA-1273-P301000007
Serious	Yes <input checked="" type="radio"/> No <input type="radio"/>
Death	Yes <input type="radio"/> No <input checked="" type="radio"/>
Life threatening	Yes <input type="radio"/> No <input checked="" type="radio"/>
Requires inpatient or prolongation of existing Hospitalization	Yes <input checked="" type="radio"/> No <input type="radio"/>
Persistent or significant disability or incapacity	Yes <input type="radio"/> No <input checked="" type="radio"/>
Congenital anomaly or birth defect	Yes <input type="radio"/> No <input checked="" type="radio"/>
Other medically important event	Yes <input type="radio"/> No <input checked="" type="radio"/>
Investigator's First Name	YAA
Investigator's Last Name	OPPONG
Site Address: Street	1565 PURDUE DRIVE
Site Address: City	FAYETTEVILLE
Site Address: State	NC
Site Address: Postal Code	28314
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	4
Date of submission (Pre-filled from custom function)	15/APR/2021 09:03
Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.	True

US3052005

Folder: SAE USA-US117-2021-MRNA-1273-P301000007

Form: Safety Report Form (3)

Data signed: (b) (4) 26 Apr 2021 20:34:31

Generated On: 09 Jun 2021 15:00:53

SAEID	USA-US117-2021-MRNA-1273-P301000007
Serious	Yes <input checked="" type="radio"/> No <input type="radio"/>
Death	Yes <input type="radio"/> No <input checked="" type="radio"/>
Life threatening	Yes <input type="radio"/> No <input checked="" type="radio"/>
Requires inpatient or prolongation of existing Hospitalization	Yes <input checked="" type="radio"/> No <input type="radio"/>
Persistent or significant disability or incapacity	Yes <input type="radio"/> No <input checked="" type="radio"/>
Congenital anomaly or birth defect	Yes <input type="radio"/> No <input checked="" type="radio"/>
Other medically important event	Yes <input type="radio"/> No <input checked="" type="radio"/>
Investigator's First Name	YAA
Investigator's Last Name	OPPONG
Site Address: Street	1565 PURDUE DRIVE
Site Address: City	FAYETTEVILLE
Site Address: State	NC
Site Address: Postal Code	28314
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	4
Date of submission (Pre-filled from custom function)	15/APR/2021 14:11
Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.	True

US3052005

Folder: SAE USA-US117-2021-MRNA-1273-P301000007

Form: Safety Report Form (4)

Data signed: (b) (4) 26 Apr 2021 20:34:31

Generated On: 09 Jun 2021 15:00:53

SAEID	USA-US117-2021-MRNA-1273-P301000007
Serious	Yes <input checked="" type="radio"/> No <input type="radio"/>
Death	Yes <input type="radio"/> No <input checked="" type="radio"/>
Life threatening	Yes <input type="radio"/> No <input checked="" type="radio"/>
Requires inpatient or prolongation of existing Hospitalization	Yes <input checked="" type="radio"/> No <input type="radio"/>
Persistent or significant disability or incapacity	Yes <input type="radio"/> No <input checked="" type="radio"/>
Congenital anomaly or birth defect	Yes <input type="radio"/> No <input checked="" type="radio"/>
Other medically important event	Yes <input type="radio"/> No <input checked="" type="radio"/>
Investigator's First Name	YAA
Investigator's Last Name	OPPONG
Site Address: Street	1565 PURDUE DRIVE
Site Address: City	FAYETTEVILLE
Site Address: State	NC
Site Address: Postal Code	28314
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	4
Date of submission (Pre-filled from custom function)	26/APR/2021 09:25
Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.	True

Audit

US3052005 (Prod: Carolina Institute for Clinical Research - M3 Wake Research)

US3052005

Form: Participant Creation

Generated On: 09 Jun 2021 15:00:53

[Participant ID](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Borger (b) (4)	23 Feb 2021 07:32:26
User entered 'US3052005'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	30 Jul 2020 14:35:28

US3052005

Folder: Screening

Form: Visit Date

Generated On: 09 Jun 2021 15:00:53

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:57:35
User signature succeeded.	Judith Borger (b) (4)	23 Feb 2021 07:32:26
User entered 'Yes (Y)'	amy sheets (b) (4)	30 Jul 2020 15:58:16

US3052005

Folder: Screening

Form: Visit Date

Generated On: 09 Jun 2021 15:00:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:57:35
User signature succeeded.	Judith Borger (b) (4)	23 Feb 2021 07:32:26
User entered '30 JUL 2020'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	30 Jul 2020 14:35:29

US3052005

Folder: Screening

Form: Visit Date

Generated On: 09 Jun 2021 15:00:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:57:35
User signature succeeded.	Judith Borger (b) (4)	23 Feb 2021 07:32:26
User entered 'Clinic (Clinic)'	amy sheets (b) (4)	30 Jul 2020 15:58:16

US3052005

Folder: Screening

Form: Visit Date

Generated On: 09 Jun 2021 15:00:53

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:57:35
User entered 'SCRN'	System	30 Jul 2020 15:58:16

US3052005

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 15:00:53

Date of Birth (MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:57:35
User signature succeeded.	Judith Borger (b) (4)	23 Feb 2021 07:32:26
User entered (b) (6) 1947'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	30 Jul 2020 14:35:30

US3052005

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 15:00:53

[Age](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:57:35
User signature succeeded.	Judith Borger (b) (4)	23 Feb 2021 07:32:26
User closed query 'Per CDM: Please complete this form.' (Site from DM).	(b) (4)	24 Aug 2020 06:06:57
Query 'Per CDM: Please complete this form.' answered with 'done' (Site from DM).	amy sheets (b) (4)	20 Aug 2020 12:49:54
User entered '72'	(b) (4)	18 Aug 2020 14:06:50
User opened query 'Per CDM: Please complete this form.' (Site from DM).	amy sheets (b) (4)	18 Aug 2020 10:58:21

US3052005

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 15:00:53

[Age Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:57:35
User entered 'YEARS'	System	18 Aug 2020 14:06:50

US3052005

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 15:00:53

[Age \(Derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:57:35
User entered '72'	System	30 Jul 2020 15:58:55

US3052005

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 15:00:53

[Sex](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:57:35
User signature succeeded.	Judith Borger (b) (4)	23 Feb 2021 07:32:26
User entered 'Male (M)'	amy sheets (b) (4)	18 Aug 2020 14:06:50

US3052005

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 15:00:53

[Ethnicity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:57:35
User signature succeeded.	Judith Borger (b) (4)	23 Feb 2021 07:32:26
User entered 'Not Hispanic or Latino (NOT HISPANIC OR LATINO)'	(b) (4) amy sheets (b) (4) (b) (4)	18 Aug 2020 14:06:50

US3052005

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 15:00:53

[White](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:57:35
User signature succeeded.	Judith Borger (b) (4)	23 Feb 2021 07:32:26
User entered 'I'	amy sheets (b) (4)	18 Aug 2020 14:06:50

US3052005

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 15:00:53

Black

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:57:35
User signature succeeded.	Judith Borger (b) (4)	23 Feb 2021 07:32:26
User entered '0'	amy sheets (b) (4)	18 Aug 2020 14:06:50

US3052005

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 15:00:53

[Asian](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:57:35
User signature succeeded.	Judith Borger (b) (4)	23 Feb 2021 07:32:26
User entered '0'	amy sheets (b) (4)	18 Aug 2020 14:06:50

US3052005

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 15:00:53

[American Indian or Alaska Native](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:57:35
User signature succeeded.	Judith Borger (b) (4)	23 Feb 2021 07:32:26
User entered '0'	amy sheets (b) (4)	18 Aug 2020 14:06:50

US3052005

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 15:00:53

[Native Hawaiian or other Pacific Islander](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:57:35
User signature succeeded.	Judith Borger (b) (4)	23 Feb 2021 07:32:26
User entered '0'	amy sheets (b) (4)	18 Aug 2020 14:06:50

US3052005

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 15:00:53

[Other](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:57:35
User signature succeeded.	Judith Borger (b) (4)	23 Feb 2021 07:32:26
User entered '0'	amy sheets (b) (4)	18 Aug 2020 14:06:50

US3052005

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 15:00:53

If race is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:57:35
User signature succeeded.	Judith Borger (b) (4)	23 Feb 2021 07:32:26
User entered empty.	amy sheets (b) (4)	18 Aug 2020 14:06:50

US3052005

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 15:00:53

[Unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:57:35
User signature succeeded.	Judith Borger (b) (4)	23 Feb 2021 07:32:26
User entered '0'	amy sheets (b) (4)	18 Aug 2020 14:06:50

US3052005

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 15:00:53

[Not reported](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:57:35
User signature succeeded.	Judith Borger (b) (4)	23 Feb 2021 07:32:26
User entered '0'	amy sheets (b) (4)	18 Aug 2020 14:06:50

US3052005

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 15:00:53

Date of Informed Consent (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:57:35
User signature succeeded.	Judith Borger (b) (4)	23 Feb 2021 07:32:26
User entered '30 Jul 2020'	amy sheets (b) (4)	30 Jul 2020 15:58:55

US3052005

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 15:00:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:57:35
User entered 'Jul 2020'	System	30 Jul 2020 15:58:55

US3052005

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 15:00:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:57:35
User entered '2020'	System	30 Jul 2020 15:58:55

US3052005

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 15:00:53

[Protocol Version](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:57:35
User signature succeeded.	Judith Borger (b) (4)	23 Feb 2021 07:32:26
User entered 'Amendment 1 (1)'	amy sheets (b) (4)	30 Jul 2020 15:58:55

US3052005

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 15:00:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:57:35
User signature succeeded.	Judith Borger (b) (4)	23 Feb 2021 07:32:26
User entered 'Yes (Y)'	amy sheets (b) (4)	30 Jul 2020 15:58:55

US3052005

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 15:00:53

If No, indicate reason for screen fail

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:57:35
User signature succeeded.	Judith Borger (b) (4)	23 Feb 2021 07:32:26
User entered empty.	amy sheets (b) (4)	30 Jul 2020 15:58:55

US3052005

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 15:00:53

If reason for screen fail is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:57:35
User signature succeeded.	Judith Borger (b) (4)	23 Feb 2021 07:32:26
User entered empty.	amy sheets (b) (4)	30 Jul 2020 15:58:55

US3052005

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 15:00:53

[Was this participant screened previously?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:57:35
User signature succeeded.	Judith Borger (b) (4)	23 Feb 2021 07:32:26
User entered 'No (N)' reason for change: Data Entry Error	(b) (4)	
	amy sheets (b) (4)	08 Oct 2020 00:18:20
User entered 'Yes (Y)'	(b) (4)	
	amy sheets (b) (4)	30 Jul 2020 15:58:55
	(b) (4)	

US3052005

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 15:00:53

[If Yes, previous participant number](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:57:35
User signature succeeded.	Judith Borger (b) (4)	23 Feb 2021 07:32:26
User closed query 'Was this participant screened previously is Yes, however previous participant number is missing. Please provide.' (Site from System).	(b) (4) System	08 Oct 2020 00:18:20
User opened query 'Was this participant screened previously is Yes, however previous participant number is missing. Please provide.' (Site from System).	System	30 Jul 2020 15:58:55
User entered empty.	RWS_ENDPOINT ENDPOINT (b) (4)	30 Jul 2020 14:35:29

US3052005

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 15:00:53

[Enrollment Trigger](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:57:35
User entered 'I'	System	30 Jul 2020 15:59:04

US3052005

Folder: Screening

Form: Inclusion/Exclusion Criteria Summary

Generated On: 09 Jun 2021 15:00:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:57:35
User signature succeeded.	Judith Borger (b) (4)	23 Feb 2021 07:32:26
User entered 'Yes (Y)'	amy sheets (b) (4)	30 Jul 2020 15:59:04

US3052005

Folder: Screening

Form: Medical History Summary

Generated On: 09 Jun 2021 15:00:53

[Were any significant conditions reported?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:57:35
User signature succeeded.	Judith Borger (b) (4)	23 Feb 2021 07:32:26
User entered 'Yes (Y)'	(b) (4) amy sheets (b) (4) (b) (4)	18 Aug 2020 14:09:10

US3052005

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 15:00:53

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:57:35
User signature succeeded.	Judith Borger (b) (4)	23 Feb 2021 07:32:26
User coded data point as SOC: Investigations, HLGt: Lipid analyses, HLT: Cholesterol analyses, PT: Blood cholesterol increased, LLT: High cholesterol - version MedDRA\\23.0.	Coder Import (b) (4)	18 Aug 2020 14:12:25
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	18 Aug 2020 14:12:25
Data point term sent to Coder	System	18 Aug 2020 14:11:21
User entered 'High Cholesterol'	amy sheets (b) (4)	18 Aug 2020 14:11:09

US3052005

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 15:00:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:57:35
User signature succeeded.	Judith Borger (b) (4)	23 Feb 2021 07:32:26
User entered 'un UNK 2005'	(b) (4) amy sheets (b) (4) (b) (4)	18 Aug 2020 14:11:09

US3052005

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 15:00:53

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:57:35
User signature succeeded.	Judith Borger (b) (4)	23 Feb 2021 07:32:26
User entered '0'	amy sheets (b) (4)	18 Aug 2020 14:11:09

US3052005

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 15:00:53

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:57:35
User signature succeeded.	Judith Borger (b) (4)	23 Feb 2021 07:32:26
User entered 'Yes (Y)'	amy sheets (b) (4)	18 Aug 2020 14:11:09

US3052005

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 15:00:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:57:35
User signature succeeded.	Judith Borger (b) (4)	23 Feb 2021 07:32:26
User entered empty.	amy sheets (b) (4)	18 Aug 2020 14:11:09

US3052005

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 15:00:53

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:57:35
User signature succeeded.	Judith Borger (b) (4)	23 Feb 2021 07:32:26
User entered '0'	amy sheets (b) (4)	18 Aug 2020 14:11:09

US3052005

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 15:00:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:57:35
User entered 'Jan 2005'	System	18 Aug 2020 14:11:09

US3052005

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 15:00:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:57:35
User entered '2005'	System	18 Aug 2020 14:11:09

US3052005

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 15:00:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:57:35
User entered empty.	System	18 Aug 2020 14:11:09

US3052005

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 15:00:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:57:35
User entered empty.	System	18 Aug 2020 14:11:09

US3052005

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 15:00:53

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:57:35
User signature succeeded.	Judith Borger (b) (4)	23 Feb 2021 07:32:26
User coded data point as SOC: Vascular disorders, HLT: Vascular hypertensive disorders, HLT: Vascular hypertensive disorders NEC, PT: Hypertension, LLT: Hypertension - version MedDRA\\23.0.	Coder Import (b) (4)	18 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)	18 Aug 2020 14:16:29
Data point term sent to Coder	System	18 Aug 2020 14:14:24
User entered 'HTN'	amy sheets (b) (4)	18 Aug 2020 14:13:58

US3052005

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 15:00:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:57:35
User signature succeeded.	Judith Borger (b) (4)	23 Feb 2021 07:32:26
User entered 'un UNK 2018'	amy sheets (b) (4)	18 Aug 2020 14:13:58

US3052005

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 15:00:53

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:57:35
User signature succeeded.	Judith Borger (b) (4)	23 Feb 2021 07:32:26
User entered '0'	amy sheets (b) (4)	18 Aug 2020 14:13:58

US3052005

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 15:00:53

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:57:35
User signature succeeded.	Judith Borger (b) (4)	23 Feb 2021 07:32:26
User entered 'Yes (Y)'	amy sheets (b) (4)	18 Aug 2020 14:13:58

US3052005

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 15:00:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:57:35
User signature succeeded.	Judith Borger (b) (4)	23 Feb 2021 07:32:26
User entered empty.	amy sheets (b) (4)	18 Aug 2020 14:13:58

US3052005

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 15:00:53

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:57:35
User signature succeeded.	Judith Borger (b) (4)	23 Feb 2021 07:32:26
User entered '0'	amy sheets (b) (4)	18 Aug 2020 14:13:58

US3052005

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 15:00:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:57:35
User entered 'Jan 2018'	System	18 Aug 2020 14:13:58

US3052005

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 15:00:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:57:35
User entered '2018'	System	18 Aug 2020 14:13:58

US3052005

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 15:00:53

[Stop Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:57:35
User entered empty.	System	18 Aug 2020 14:13:58

US3052005

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 15:00:53

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:57:35
User entered empty.	System	18 Aug 2020 14:13:58

US3052005

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 15:00:53

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:57:35
User signature succeeded.	Judith Borger (b) (4)	23 Feb 2021 07:32:26
User coded data point as SOC: Cardiac disorders, HLT: Cardiac arrhythmias, HLT: Supraventricular arrhythmias, PT: Atrial fibrillation, LLT: Atrial fibrillation - version MedDRA\\23.0.	Coder Import (b) (4)	18 Aug 2020 14:16:30
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	18 Aug 2020 14:16:30
Data point term sent to Coder	System	18 Aug 2020 14:14:25
User entered 'A Fib'	amy sheets (b) (4)	18 Aug 2020 14:14:24

US3052005

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 15:00:53

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:57:35
User signature succeeded.	Judith Borger (b) (4)	23 Feb 2021 07:32:26
User entered 'un UNK 2018'	amy sheets (b) (4)	18 Aug 2020 14:14:24

US3052005

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 15:00:53

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:57:35
User signature succeeded.	Judith Borger (b) (4)	23 Feb 2021 07:32:26
User entered '0'	amy sheets (b) (4)	18 Aug 2020 14:14:24

US3052005

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 15:00:53

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:57:35
User signature succeeded.	Judith Borger (b) (4)	23 Feb 2021 07:32:26
User entered 'Yes (Y)'	amy sheets (b) (4)	18 Aug 2020 14:14:24

US3052005

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 15:00:53

[If No, please specify the stop date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:57:35
User signature succeeded.	Judith Borger (b) (4)	23 Feb 2021 07:32:26
User entered empty.	amy sheets (b) (4)	18 Aug 2020 14:14:24

US3052005

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 15:00:53

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:57:35
User signature succeeded.	Judith Borger (b) (4)	23 Feb 2021 07:32:26
User entered '0'	amy sheets (b) (4)	18 Aug 2020 14:14:24

US3052005

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 15:00:53

[Start Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:57:35
User entered 'Jan 2018'	System	18 Aug 2020 14:14:24

US3052005

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 15:00:53

[Start Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:57:35
User entered '2018'	System	18 Aug 2020 14:14:24

US3052005

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 15:00:53

[Stop Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:57:35
User entered empty.	System	18 Aug 2020 14:14:24

US3052005

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 15:00:53

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:57:35
User entered empty.	System	18 Aug 2020 14:14:24

US3052005

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 15:00:53

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:57:35
User signature succeeded.	Judith Borger (b) (4)	23 Feb 2021 07:32:26
User closed query 'Per DM CLR: Please review and ensure the associated condition which led to this procedure is also captured as a separate entry on the Med History eCRF. Please verify and update as appropriate. ' (Site from DM).	(b) (4) (b) (4), (b) (6)	16 Oct 2020 10:39:59
User coded data point as SOC: Neoplasms benign, malignant and unspecified (incl cysts and polyps), HLGT: Skin neoplasms malignant and unspecified, HLT: Skin neoplasms malignant and unspecified (excl melanoma), PT: Basal cell carcinoma, LLT: Basal cell carcinoma face - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	10 Oct 2020 21:08:23
User coded data point as Term Coded data point by User: Coder System - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	10 Oct 2020 21:08:23
Data point term sent to Coder	System	10 Oct 2020 21:07:24
User closed query 'DM-Coding: The verbatim cannot be referenced as reported. Please update this event with more details by amending /updating the reported term accordingly.' (Site from System).	System	10 Oct 2020 21:07:13
Query 'DM-Coding: The verbatim cannot be referenced as reported. Please update this event with more details by amending /updating the reported term accordingly.' answered with 'updated' (Site from System).	amy sheets (b) (4) (b) (4)	10 Oct 2020 21:07:13
User entered 'BASAL CELL carcinoma- FACE' reason for change: Data Entry Error	amy sheets (b) (4) (b) (4)	10 Oct 2020 21:07:03
User opened query 'DM-Coding: The verbatim cannot be referenced as reported. Please update this event with more details by amending /updating the reported term accordingly.' (Site from System).	Coder Import (b) (4) (b) (4)	09 Oct 2020 11:42:16
Data point term sent to Coder	System	08 Oct 2020 00:20:06
Query 'Per DM CLR: Please review and ensure the associated condition which led to this procedure is also captured as a separate entry on the Med History eCRF. Please verify and update as appropriate. ' answered with 'updated' (Site from DM).	amy sheets (b) (4) (b) (4)	08 Oct 2020 00:20:00
Coding entries removed.	amy sheets (b) (4) (b) (4)	08 Oct 2020 00:19:48

US3052005

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 15:00:53

Condition

Audit	User	Time (GMT)
User entered 'BASAL CELL- FACE' reason for change: Data Entry Error	amy sheets (b) (4)	08 Oct 2020 00:19:48
User opened query 'Per DM CLR: Please review and ensure the associated condition which led to this procedure is also captured as a separate entry on the Med History eCRF. Please verify and update as appropriate.	(b) (4)	
' (Site from DM).	(b) (4), (b) (6)	27 Aug 2020 09:23:53
User coded data point as SOC: Surgical and medical procedures, HLGT: Skin and subcutaneous tissue therapeutic procedures, HLT: Skin lesion excisions, PT: Skin neoplasm excision, LLT: Basal cell carcinoma excision - version MedDRA\23.0.	Coder Import (b) (4)	18 Aug 2020 16:11:08
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\23.0.	(b) (4)	18 Aug 2020 16:11:08
Data point term sent to Coder	System	18 Aug 2020 14:16:28
User entered 'Basal Cell- face (Removed)'	amy sheets (b) (4)	18 Aug 2020 14:16:02
	(b) (4)	

US3052005

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 15:00:53

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:57:35
User signature succeeded.	Judith Borger (b) (4)	23 Feb 2021 07:32:26
User entered empty.	amy sheets (b) (4)	18 Aug 2020 14:16:02

US3052005

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 15:00:53

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:57:35
User signature succeeded.	Judith Borger (b) (4)	23 Feb 2021 07:32:26
User entered 'I'	amy sheets (b) (4)	18 Aug 2020 14:16:02

US3052005

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 15:00:53

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:57:35
User signature succeeded.	Judith Borger (b) (4)	23 Feb 2021 07:32:26
User entered 'No (N)'	amy sheets (b) (4)	18 Aug 2020 14:16:02

US3052005

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 15:00:53

[If No, please specify the stop date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:57:35
User signature succeeded.	Judith Borger (b) (4)	23 Feb 2021 07:32:26
User entered 'un UNK 2018'	(b) (4) amy sheets (b) (4) (b) (4)	18 Aug 2020 14:16:02

US3052005

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 15:00:53

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:57:35
User signature succeeded.	Judith Borger (b) (4)	23 Feb 2021 07:32:26
User entered '0'	amy sheets (b) (4)	18 Aug 2020 14:16:02

US3052005

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 15:00:53

[Start Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:57:35
User entered empty.	System	18 Aug 2020 14:16:02

US3052005

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 15:00:53

[Start Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:57:35
User entered empty.	System	18 Aug 2020 14:16:02

US3052005

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 15:00:53

[Stop Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:57:35
User entered 'Jan 2018'	System	18 Aug 2020 14:16:02

US3052005

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 15:00:53

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:57:35
User entered '2018'	System	18 Aug 2020 14:16:02

US3052005

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 15:00:53

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:57:35
User signature succeeded.	Judith Borger (b) (4)	23 Feb 2021 07:32:26
User coded data point as SOC: Reproductive system and breast disorders, HLGT: Sexual function and fertility disorders, HLT: Erection and ejaculation conditions and disorders, PT: Erectile dysfunction, LLT: Erectile dysfunction - version MedDRA\\23.0.	Coder Import (b) (4)	18 Aug 2020 14:19:31
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	18 Aug 2020 14:19:31
Data point term sent to Coder	System	18 Aug 2020 14:18:31
User entered 'Erectile Dysfunction'	amy sheets (b) (4)	18 Aug 2020 14:17:39

US3052005

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 15:00:53

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:57:35
User signature succeeded.	Judith Borger (b) (4)	23 Feb 2021 07:32:26
User entered 'un UNK 2018'	amy sheets (b) (4)	18 Aug 2020 14:17:39

US3052005

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 15:00:53

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:57:35
User signature succeeded.	Judith Borger (b) (4)	23 Feb 2021 07:32:26
User entered '0'	amy sheets (b) (4)	18 Aug 2020 14:17:39

US3052005

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 15:00:53

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:57:35
User signature succeeded.	Judith Borger (b) (4)	23 Feb 2021 07:32:26
User entered 'Yes (Y)'	amy sheets (b) (4)	18 Aug 2020 14:17:39

US3052005

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 15:00:53

If No, please specify the stop date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:57:35
User signature succeeded.	Judith Borger (b) (4)	23 Feb 2021 07:32:26
User entered empty.	amy sheets (b) (4)	18 Aug 2020 14:17:39

US3052005

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 15:00:53

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:57:35
User signature succeeded.	Judith Borger (b) (4)	23 Feb 2021 07:32:26
User entered '0'	amy sheets (b) (4)	18 Aug 2020 14:17:39

US3052005

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 15:00:53

[Start Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:57:35
User entered 'Jan 2018'	System	18 Aug 2020 14:17:39

US3052005

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 15:00:53

[Start Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:57:35
User entered '2018'	System	18 Aug 2020 14:17:39

US3052005

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 15:00:53

[Stop Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:57:35
User entered empty.	System	18 Aug 2020 14:17:39

US3052005

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 15:00:53

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:57:35
User entered empty.	System	18 Aug 2020 14:17:39

US3052005

Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 15:00:53

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:57:35
User signature succeeded.	Judith Borger (b) (4)	23 Feb 2021 07:32:26
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)	18 Aug 2020 15:36:07
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4)	18 Aug 2020 15:36:07
Data point term sent to Coder	System	18 Aug 2020 14:19:32
User entered 'Osteoarthritis-Left Knee-Right Hip'	amy sheets (b) (4)	18 Aug 2020 14:19:06

US3052005

Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 15:00:53

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:57:35
User signature succeeded.	Judith Borger (b) (4)	23 Feb 2021 07:32:26
User entered 'un UNK 2010'	amy sheets (b) (4)	18 Aug 2020 14:19:06

US3052005

Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 15:00:53

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:57:35
User signature succeeded.	Judith Borger (b) (4)	23 Feb 2021 07:32:26
User entered '0'	amy sheets (b) (4)	18 Aug 2020 14:19:06

US3052005

Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 15:00:53

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:57:35
User signature succeeded.	Judith Borger (b) (4)	23 Feb 2021 07:32:26
User entered 'Yes (Y)'	amy sheets (b) (4)	18 Aug 2020 14:19:06

US3052005

Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 15:00:53

If No, please specify the stop date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:57:35
User signature succeeded.	Judith Borger (b) (4)	23 Feb 2021 07:32:26
User entered empty.	(b) (4) amy sheets (b) (4) (b) (4)	18 Aug 2020 14:19:06

US3052005

Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 15:00:53

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:57:35
User signature succeeded.	Judith Borger (b) (4)	23 Feb 2021 07:32:26
User entered '0'	amy sheets (b) (4)	18 Aug 2020 14:19:06

US3052005

Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 15:00:53

[Start Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:57:35
User entered 'Jan 2010'	System	18 Aug 2020 14:19:06

US3052005

Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 15:00:53

[Start Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:57:35
User entered '2010'	System	18 Aug 2020 14:19:06

US3052005

Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 15:00:53

[Stop Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:57:35
User entered empty.	System	18 Aug 2020 14:19:06

US3052005

Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 15:00:53

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:57:35
User entered empty.	System	18 Aug 2020 14:19:06

US3052005

Folder: Screening

Form: Medical History (7)

Generated On: 09 Jun 2021 15:00:53

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:57:35
User signature succeeded.	Judith Borger (b) (4)	23 Feb 2021 07:32:26
User closed query 'Per DM CLR: Please review and ensure the associated condition which led to this procedure is also captured as a separate entry on the Med History eCRF. Please verify and update as appropriate. ' (Site from DM).	(b) (4) (b) (4), (b) (6)	16 Oct 2020 10:40:21
User coded data point as SOC: Gastrointestinal disorders, HLGT: Abdominal hernias and other abdominal wall conditions, HLT: Inguinal hernias, PT: Inguinal hernia, LLT: Inguinal hernia - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	08 Oct 2020 00:21:13
User coded data point as Term Coded data point by User: Coder System - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	08 Oct 2020 00:21:13
Data point term sent to Coder	System	08 Oct 2020 00:21:06
Query 'Per DM CLR: Please review and ensure the associated condition which led to this procedure is also captured as a separate entry on the Med History eCRF. Please verify and update as appropriate. ' answered with 'updated' (Site from DM).	amy sheets (b) (4) (b) (4)	08 Oct 2020 00:21:00
Coding entries removed.	amy sheets (b) (4) (b) (4)	08 Oct 2020 00:20:47
User entered 'INGUINAL HERNIA' reason for change: Data Entry Error	amy sheets (b) (4) (b) (4)	08 Oct 2020 00:20:47
User opened query 'Per DM CLR: Please review and ensure the associated condition which led to this procedure is also captured as a separate entry on the Med History eCRF. Please verify and update as appropriate. ' (Site from DM).	(b) (4), (b) (6)	27 Aug 2020 09:25:48
User coded data point as SOC: Surgical and medical procedures, HLGT: Gastrointestinal therapeutic procedures, HLT: Hernia repairs, PT: Inguinal hernia repair, LLT: Inguinal hernia repair - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	18 Aug 2020 14:21:27
User coded data point as Term Coded data point by User: Coder System - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	18 Aug 2020 14:21:27
Data point term sent to Coder	System	18 Aug 2020 14:20:33

US3052005

Folder: Screening

Form: Medical History (7)

Generated On: 09 Jun 2021 15:00:53

[Condition](#)

Audit	User	Time (GMT)
User entered 'Inguinal hernia repair'	amy sheets (b) (4) (b) (4)	18 Aug 2020 14:20:30

US3052005

Folder: Screening

Form: Medical History (7)

Generated On: 09 Jun 2021 15:00:53

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:57:35
User signature succeeded.	Judith Borger (b) (4)	23 Feb 2021 07:32:26
User entered empty.	amy sheets (b) (4)	18 Aug 2020 14:20:30

US3052005

Folder: Screening

Form: Medical History (7)

Generated On: 09 Jun 2021 15:00:53

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:57:35
User signature succeeded.	Judith Borger (b) (4)	23 Feb 2021 07:32:26
User entered 'I'	amy sheets (b) (4)	18 Aug 2020 14:20:30

US3052005

Folder: Screening

Form: Medical History (7)

Generated On: 09 Jun 2021 15:00:53

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:57:35
User signature succeeded.	Judith Borger (b) (4)	23 Feb 2021 07:32:26
User entered 'No (N)'	amy sheets (b) (4)	18 Aug 2020 14:20:30

US3052005

Folder: Screening

Form: Medical History (7)

Generated On: 09 Jun 2021 15:00:53

[If No, please specify the stop date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:57:35
User signature succeeded.	Judith Borger (b) (4)	23 Feb 2021 07:32:26
User entered 'un UNK 2018'	(b) (4) amy sheets (b) (4) (b) (4)	18 Aug 2020 14:20:30

US3052005

Folder: Screening

Form: Medical History (7)

Generated On: 09 Jun 2021 15:00:53

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:57:35
User signature succeeded.	Judith Borger (b) (4)	23 Feb 2021 07:32:26
User entered '0'	amy sheets (b) (4)	18 Aug 2020 14:20:30

US3052005

Folder: Screening

Form: Medical History (7)

Generated On: 09 Jun 2021 15:00:53

[Start Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:57:35
User entered empty.	System	18 Aug 2020 14:20:30

US3052005

Folder: Screening

Form: Medical History (7)

Generated On: 09 Jun 2021 15:00:53

[Start Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:57:35
User entered empty.	System	18 Aug 2020 14:20:30

US3052005

Folder: Screening

Form: Medical History (7)

Generated On: 09 Jun 2021 15:00:53

[Stop Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:57:35
User entered 'Jan 2018'	System	18 Aug 2020 14:20:30

US3052005

Folder: Screening

Form: Medical History (7)

Generated On: 09 Jun 2021 15:00:53

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:57:35
User entered '2018'	System	18 Aug 2020 14:20:30

US3052005

Folder: Screening

Form: Medical History (8)

Generated On: 09 Jun 2021 15:00:53

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:57:35
User signature succeeded.	Judith Borger (b) (4)	23 Feb 2021 07:32:26
User coded data point as SOC: Surgical and medical procedures, HLGT: Gastrointestinal therapeutic procedures, HLT: Hernia repairs, PT: Inguinal hernia repair, LLT: Inguinal hernia repair - version MedDRA\\23.0.	Coder Import (b) (4)	08 Oct 2020 00:23:14
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	08 Oct 2020 00:23:14
Data point term sent to Coder	System	08 Oct 2020 00:22:07
User entered 'inguinal hernia repair'	amy sheets (b) (4)	08 Oct 2020 00:21:33

US3052005

Folder: Screening

Form: Medical History (8)

Generated On: 09 Jun 2021 15:00:53

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:57:35
User signature succeeded.	Judith Borger (b) (4)	23 Feb 2021 07:32:26
User entered empty.	amy sheets (b) (4)	08 Oct 2020 00:21:33

US3052005

Folder: Screening

Form: Medical History (8)

Generated On: 09 Jun 2021 15:00:53

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:57:35
User signature succeeded.	Judith Borger (b) (4)	23 Feb 2021 07:32:26
User entered 'I'	amy sheets (b) (4)	08 Oct 2020 00:21:33

US3052005

Folder: Screening

Form: Medical History (8)

Generated On: 09 Jun 2021 15:00:53

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:57:35
User signature succeeded.	Judith Borger (b) (4)	23 Feb 2021 07:32:26
User entered 'No (N)'	(b) (4) amy sheets (b) (4) (b) (4)	08 Oct 2020 00:21:33

US3052005

Folder: Screening

Form: Medical History (8)

Generated On: 09 Jun 2021 15:00:53

[If No, please specify the stop date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:57:35
User signature succeeded.	Judith Borger (b) (4)	23 Feb 2021 07:32:26
User entered 'un UNK 2018'	(b) (4) amy sheets (b) (4) (b) (4)	08 Oct 2020 00:21:33

US3052005

Folder: Screening

Form: Medical History (8)

Generated On: 09 Jun 2021 15:00:53

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:57:35
User signature succeeded.	Judith Borger (b) (4)	23 Feb 2021 07:32:26
User entered '0'	amy sheets (b) (4)	08 Oct 2020 00:21:33

US3052005

Folder: Screening

Form: Medical History (8)

Generated On: 09 Jun 2021 15:00:53

[Start Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:57:35
User entered empty.	System	08 Oct 2020 00:21:33

US3052005

Folder: Screening

Form: Medical History (8)

Generated On: 09 Jun 2021 15:00:53

[Start Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:57:35
User entered empty.	System	08 Oct 2020 00:21:33

US3052005

Folder: Screening

Form: Medical History (8)

Generated On: 09 Jun 2021 15:00:53

[Stop Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:57:35
User entered 'Jan 2018'	System	08 Oct 2020 00:21:33

US3052005

Folder: Screening

Form: Medical History (8)

Generated On: 09 Jun 2021 15:00:53

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:57:35
User entered '2018'	System	08 Oct 2020 00:21:33

US3052005

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 15:00:53

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:57:35
User signature succeeded.	Judith Borger (b) (4)	23 Feb 2021 07:32:26
User closed query 'Per CDM: Please complete this form.' (Site from DM).	(b) (4)	
Query 'Per CDM: Please complete this form.'	(b) (4), (b) (6)	08 Oct 2020 07:43:03
answered with 'updated' (Site from DM).	amy sheets (b) (4)	08 Oct 2020 00:22:21
User entered 'Yes (Y)'	(b) (4)	
	amy sheets (b) (4)	18 Aug 2020 14:22:08
	(b) (4)	
User opened query 'Per CDM: Please complete this form.' (Site from DM).	(b) (4), (b) (6)	18 Aug 2020 10:58:39

US3052005

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 15:00:53

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:57:35
User signature succeeded.	Judith Borger (b) (4)	23 Feb 2021 07:32:26
User entered '30 Jul 2020'	amy sheets (b) (4)	18 Aug 2020 14:22:08

US3052005

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 15:00:53

[Time of assessment \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:57:35
User signature succeeded.	Judith Borger (b) (4)	23 Feb 2021 07:32:26
User entered '10:13'	amy sheets (b) (4)	18 Aug 2020 14:22:08

US3052005

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 15:00:53

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:57:35
User entered '30 Jul 2020 10:13'	System	18 Aug 2020 14:22:08

US3052005

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 15:00:53

[Height \(xxx.x\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:57:35
User signature succeeded.	Judith Borger (b) (4)	23 Feb 2021 07:32:26
User entered '75' in	amy sheets (b) (4)	18 Aug 2020 14:22:08
DataPoint set to visible.	System	30 Jul 2020 15:59:04

US3052005

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 15:00:53

Weight (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:57:35
User signature succeeded.	Judith Borger (b) (4)	23 Feb 2021 07:32:26
User entered '192' lb	(b) (4) amy sheets (b) (4)	18 Aug 2020 14:22:08
DataPoint set to visible.	(b) (4) System	30 Jul 2020 15:59:04

US3052005

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 15:00:53

BMI (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:57:35
Amendment Manager: User entered '24.04853'	System	16 Sep 2020 23:38:45
User entered '24.0'	System	18 Aug 2020 14:22:08
DataPoint set to visible.	System	30 Jul 2020 15:59:04

US3052005

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 15:00:53

[BMI units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:57:35
User entered 'kg/m2'	System	18 Aug 2020 14:22:08
DataPoint set to visible.	System	30 Jul 2020 15:59:04

US3052005

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 15:00:53

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:57:35
User signature succeeded.	Judith Borger (b) (4)	23 Feb 2021 07:32:26
User closed query 'Per CDM: Per CCGs V2.0 pages 16-17, if Screening and Visit 1 Day 1 are on the same day, ND should be recorded for TEMPERATURE, PULSE, RESPIRATORY RATE, SYSTOLIC BP, and DIASTOLIC BP on this page (ND for "Not done" and not left empty). Please note that when ND is recorded for TEMPERATURE, the unit should not remain. Please review and update as appropriate. ' (Site from DM).	(b) (4) (b) (4), (b) (6)	09 Oct 2020 08:28:19
Query 'Per CDM: Per CCGs V2.0 pages 16-17, if Screening and Visit 1 Day 1 are on the same day, ND should be recorded for TEMPERATURE, PULSE, RESPIRATORY RATE, SYSTOLIC BP, and DIASTOLIC BP on this page (ND for "Not done" and not left empty). Please note that when ND is recorded for TEMPERATURE, the unit should not remain. Please review and update as appropriate. ' answered with 'Screening and Day 1 on same day.' (Site from DM).	Avia McClain-Stocker (b) (4)	08 Oct 2020 18:51:31
User entered missing code ND - Not Done; reason for change Data Entry Error	Avia McClain-Stocker (b) (4)	08 Oct 2020 18:51:16
User opened query 'Per CDM: Per CCGs V2.0 pages 16-17, if Screening and Visit 1 Day 1 are on the same day, ND should be recorded for TEMPERATURE, PULSE, RESPIRATORY RATE, SYSTOLIC BP, and DIASTOLIC BP on this page (ND for "Not done" and not left empty). Please note that when ND is recorded for TEMPERATURE, the unit should not remain. Please review and update as appropriate. ' (Site from DM).	(b) (4), (b) (6)	08 Oct 2020 11:06:51
User entered '98.4' F	amy sheets (b) (4) (b) (4)	18 Aug 2020 14:22:08

US3052005

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 15:00:53

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:57:35
User signature succeeded.	Judith Borger (b) (4)	23 Feb 2021 07:32:26
User closed query 'Data is required. Please provide.' (Site from System).	(b) (4)	08 Oct 2020 18:51:16
Query 'Data is required. Please provide.' answered by System data change (Site from System).	System	08 Oct 2020 18:51:16
User opened query 'Data is required. Please provide.' (Site from System).	System	08 Oct 2020 18:51:06
User entered empty; reason for change Data Entry Error	Avia McClain-Stocker	08 Oct 2020 18:51:06
User entered 'Oral (Oral)'	(b) (4)	18 Aug 2020 14:22:08
	amy sheets (b) (4)	
	(b) (4)	

US3052005

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 15:00:53

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:57:35
User signature succeeded.	Judith Borger (b) (4)	23 Feb 2021 07:32:26
User entered empty.	amy sheets (b) (4)	18 Aug 2020 14:22:08

US3052005

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 15:00:53

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:57:35
User signature succeeded.	Judith Borger (b) (4)	23 Feb 2021 07:32:26
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4)	08 Oct 2020 18:51:06
User entered '59'	Avia McClain-Stocker (b) (4)	18 Aug 2020 14:22:08
	amy sheets (b) (4)	
	(b) (4)	

US3052005

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 15:00:53

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:57:35
User entered 'bpm'	System	18 Aug 2020 14:22:08

US3052005

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 15:00:53

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:57:35
User signature succeeded.	Judith Borger (b) (4)	23 Feb 2021 07:32:26
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4)	08 Oct 2020 18:51:06
User entered '16'	Avia McClain-Stocker (b) (4)	18 Aug 2020 14:22:08
	amy sheets (b) (4)	
	(b) (4)	

US3052005

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 15:00:53

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:57:35
User entered 'breaths/min'	System	18 Aug 2020 14:22:08

US3052005

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 15:00:53

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:57:35
User signature succeeded.	Judith Borger (b) (4)	23 Feb 2021 07:32:26
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4)	08 Oct 2020 18:51:06
User entered '129'	Avia McClain-Stocker (b) (4)	18 Aug 2020 14:22:08
	amy sheets (b) (4)	
	(b) (4)	

US3052005

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 15:00:53

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:57:35
User entered 'mmHg'	System	18 Aug 2020 14:22:08

US3052005

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 15:00:53

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:57:35
User signature succeeded.	Judith Borger (b) (4)	23 Feb 2021 07:32:26
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4)	08 Oct 2020 18:51:06
User entered '83'	Avia McClain-Stocker (b) (4)	18 Aug 2020 14:22:08
	amy sheets (b) (4)	
	(b) (4)	

US3052005

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 15:00:53

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:57:35
User entered 'mmHg'	System	18 Aug 2020 14:22:08

US3052005

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 15:00:53

[Height \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:57:35

US3052005

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 15:00:53

Weight (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:57:35

US3052005

Folder: Screening

Form: Physical Examination

Generated On: 09 Jun 2021 15:00:53

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:57:35
User signature succeeded.	Judith Borger (b) (4)	23 Feb 2021 07:32:26
User entered 'Yes (Y)'	(b) (4) amy sheets (b) (4) (b) (4)	18 Aug 2020 14:26:48

US3052005

Folder: Screening

Form: Physical Examination

Generated On: 09 Jun 2021 15:00:53

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:57:35
User signature succeeded.	Judith Borger (b) (4)	23 Feb 2021 07:32:26
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)	27 Aug 2020 11:47:34
User opened query 'The Physical Examination Date is prior to the Screening Visit Date. Please review and reconcile.' (Site from System).	System	26 Aug 2020 15:03:25
User entered '30 Jul 2020'	amy sheets (b) (4) (b) (4)	18 Aug 2020 14:26:48

US3052005

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 15:00:53

Healthcare workers (e.g., doctors, nurses, dentists, hospital support staff, morgue/mortuary workers)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:57:35
User signature succeeded.	Judith Borger (b) (4)	23 Feb 2021 07:32:26
User entered 'Yes (Y)'	(b) (4) amy sheets (b) (4) (b) (4)	18 Aug 2020 14:29:10

US3052005

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 15:00:53

Emergency Response (e.g., Law enforcement officers, Firefighters, emergency medical service workers)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:57:35
User signature succeeded.	Judith Borger (b) (4)	23 Feb 2021 07:32:26
User entered 'No (N)'	(b) (4) amy sheets (b) (4) (b) (4)	18 Aug 2020 14:29:10

US3052005

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 15:00:53

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)	26 Apr 2021 11:57:35
User signature succeeded.	Judith Borger (b) (4)	23 Feb 2021 07:32:26
User entered 'No (N)'	amy sheets (b) (4)	18 Aug 2020 14:29:10

US3052005

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 15:00:53

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)	26 Apr 2021 11:57:35
User signature succeeded.	Judith Borger (b) (4)	23 Feb 2021 07:32:26
User entered 'No (N)'	amy sheets (b) (4)	18 Aug 2020 14:29:10

US3052005

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 15:00:53

Warehouse shipping and fulfillment centers and jobs (e.g., Amazon facilities)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:57:35
User signature succeeded.	Judith Borger (b) (4)	23 Feb 2021 07:32:26
User entered 'No (N)'	(b) (4) amy sheets (b) (4) (b) (4)	18 Aug 2020 14:29:10

US3052005

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 15:00:53

[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)	26 Apr 2021 11:57:35
User signature succeeded.	Judith Borger (b) (4)	23 Feb 2021 07:32:26
User entered 'No (N)'	amy sheets (b) (4)	18 Aug 2020 14:29:10

US3052005

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 15:00:53

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)	26 Apr 2021 11:57:35
User signature succeeded.	Judith Borger (b) (4)	23 Feb 2021 07:32:26
User entered 'No (N)'	amy sheets (b) (4)	18 Aug 2020 14:29:10

US3052005

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 15:00:53

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)	26 Apr 2021 11:57:35
User signature succeeded.	Judith Borger (b) (4)	23 Feb 2021 07:32:26
User entered 'No (N)'	amy sheets (b) (4)	18 Aug 2020 14:29:10

US3052005

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 15:00:53

[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)	26 Apr 2021 11:57:35
User signature succeeded.	Judith Borger (b) (4)	23 Feb 2021 07:32:26
User entered 'No (N)'	(b) (4) amy sheets (b) (4) (b) (4)	18 Aug 2020 14:29:10

US3052005

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 15:00:53

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)	26 Apr 2021 11:57:35
User signature succeeded.	Judith Borger (b) (4)	23 Feb 2021 07:32:26
User entered 'No (N)'	amy sheets (b) (4)	18 Aug 2020 14:29:10

US3052005

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 15:00:53

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)	26 Apr 2021 11:57:35
User signature succeeded.	Judith Borger (b) (4)	23 Feb 2021 07:32:26
User entered 'No (N)'	amy sheets (b) (4)	18 Aug 2020 14:29:10

US3052005

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 15:00:53

Other

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:57:35
User signature succeeded.	Judith Borger (b) (4)	23 Feb 2021 07:32:26
User entered 'No (N)'	amy sheets (b) (4)	18 Aug 2020 14:29:10

US3052005

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 15:00:53

[Specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:57:35
User signature succeeded.	Judith Borger (b) (4)	23 Feb 2021 07:32:26
User entered empty.	amy sheets (b) (4)	18 Aug 2020 14:29:10

US3052005

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 15:00:53

No Risk Identified

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:57:35
User signature succeeded.	Judith Borger (b) (4)	23 Feb 2021 07:32:26
User entered '0'	amy sheets (b) (4)	18 Aug 2020 14:29:10

US3052005

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 15:00:53

[Resides in Nursing Home or Assisted Living Facility](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:57:35
User signature succeeded.	Judith Borger (b) (4)	23 Feb 2021 07:32:26
User entered '0'	(b) (4) amy sheets (b) (4) (b) (4)	18 Aug 2020 14:29:10

US3052005

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 15:00:53

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)	26 Apr 2021 11:57:35
User signature succeeded.	Judith Borger (b) (4)	23 Feb 2021 07:32:26
User entered '0'	amy sheets (b) (4)	18 Aug 2020 14:29:10

US3052005

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 15:00:53

[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)	26 Apr 2021 11:57:35
User signature succeeded.	Judith Borger (b) (4)	23 Feb 2021 07:32:26
User entered '0'	(b) (4) amy sheets (b) (4) (b) (4)	18 Aug 2020 14:29:10

US3052005

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 15:00:53

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)	26 Apr 2021 11:57:35
User signature succeeded.	Judith Borger (b) (4)	23 Feb 2021 07:32:26
User entered '0'	amy sheets (b) (4)	18 Aug 2020 14:29:10

US3052005

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 15:00:53

[Resides in a single family home](#) (i.e., detached housing)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:57:35
User signature succeeded.	Judith Borger (b) (4)	23 Feb 2021 07:32:26
User entered 'I'	(b) (4) amy sheets (b) (4) (b) (4)	18 Aug 2020 14:29:10

US3052005

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 15:00:53

Other

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:57:35
User signature succeeded.	Judith Borger (b) (4)	23 Feb 2021 07:32:26
User entered '0'	amy sheets (b) (4)	18 Aug 2020 14:29:10

US3052005

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 15:00:53

[Specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:57:35
User signature succeeded.	Judith Borger (b) (4)	23 Feb 2021 07:32:26
User entered empty.	(b) (4) amy sheets (b) (4) (b) (4)	18 Aug 2020 14:29:10

US3052005

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 09 Jun 2021 15:00:53

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:41:16
User signature succeeded.	Judith Borger (b) (4)	23 Feb 2021 07:32:26
User entered 'Yes (Y)'	(b) (4) amy sheets (b) (4) (b) (4)	18 Aug 2020 14:30:17

US3052005

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 09 Jun 2021 15:00:53

Visit date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:41:16
User signature succeeded.	Judith Borger (b) (4)	23 Feb 2021 07:32:26
User entered '30 Jul 2020'	amy sheets (b) (4)	18 Aug 2020 14:30:17

US3052005

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 09 Jun 2021 15:00:53

[Was visit performed at the participant's home or at the clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:41:16
User signature succeeded.	Judith Borger (b) (4)	23 Feb 2021 07:32:26
User entered 'Clinic (Clinic)'	amy sheets (b) (4)	18 Aug 2020 14:30:17

US3052005

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 09 Jun 2021 15:00:53

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:41:16
User entered 'VISIT1'	System	18 Aug 2020 14:30:17

US3052005

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 15:00:53

What was the date of randomization? (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:41:16
User signature succeeded.	Judith Borger (b) (4)	23 Feb 2021 07:32:26
User entered '30 JUL 2020'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	30 Jul 2020 14:39:34

US3052005

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 15:00:53

[What was the participant's randomization number?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:41:16
User signature succeeded.	Judith Borger (b) (4)	23 Feb 2021 07:32:26
Amendment Manager: User closed query 'Data entered is non-conformant. Please correct.' (Site from System).	(b) (4) System	21 Aug 2020 01:21:16
Amendment Manager: Data point set to conformant.	System	21 Aug 2020 01:21:16
User opened query 'Data entered is non-conformant. Please correct.' (Site from System).	System	30 Jul 2020 14:39:34
User entered '184229' (non-conformant).	RWS_ENDPOINT ENDPOINT (b) (4)	30 Jul 2020 14:39:34

US3052005

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 15:00:53

[In what Cohort was the participant enrolled?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:41:16
User signature succeeded.	Judith Borger (b) (4)	23 Feb 2021 07:32:26
User entered '>=65 years (3)'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	30 Jul 2020 14:39:34

US3052005

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 15:00:53

Chronic lung disease (eg, emphysema and chronic bronchitis, idiopathic pulmonary fibrosis and cystic fibrosis, or moderate to severe asthma)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:41:16
User signature succeeded.	Judith Borger (b) (4)	23 Feb 2021 07:32:26
User entered 'No (N)'	(b) (4) amy sheets (b) (4) (b) (4)	18 Aug 2020 14:31:34

US3052005

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 15:00:53

Significant cardiac disease (eg, heart failure, coronary artery disease, congenital heart disease, cardiomyopathies, and pulmonary hypertension)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:41:16
User signature succeeded.	Judith Borger (b) (4)	23 Feb 2021 07:32:26
User entered 'No (N)'	(b) (4) amy sheets (b) (4) (b) (4)	18 Aug 2020 14:31:34

US3052005

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 15:00:53

Severe obesity (body mass index > or = 40kg/m2

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:41:16
User signature succeeded.	Judith Borger (b) (4)	23 Feb 2021 07:32:26
User entered 'No (N)'	(b) (4) amy sheets (b) (4) (b) (4)	18 Aug 2020 14:31:34

US3052005

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 15:00:53

Diabetes (Type I, Type 2, or gestational)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:41:16
User signature succeeded.	Judith Borger (b) (4)	23 Feb 2021 07:32:26
User entered 'No (N)'	amy sheets (b) (4)	18 Aug 2020 14:31:34

US3052005

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 15:00:53

[Liver Disease](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:41:16
User signature succeeded.	Judith Borger (b) (4)	23 Feb 2021 07:32:26
User entered 'No (N)'	amy sheets (b) (4)	18 Aug 2020 14:31:34

US3052005

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 15:00:53

Height

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:41:16
User signature succeeded.	Judith Borger (b) (4)	23 Feb 2021 07:32:26
User closed query 'Per CDM Please note as the Screening and Visit 1 is done on the same day, Height and weight to be recorded in screening and updated to "NOT Done " in Visit 1. Kindly remove the units as well .Thanks	(b) (4) (b) (4), (b) (6)	22 Oct 2020 17:01:53
' (Site from DM).		
Query 'Per CDM Please note as the Screening and Visit 1 is done on the same day, Height and weight to be recorded in screening and updated to "NOT Done " in Visit 1. Kindly remove the units as well .Thanks	Avia McClain-Stocker (b) (4)	21 Oct 2020 15:51:06
' answered with 'screening and day 1 same day. updated' (Site from DM).		
User opened query 'Per CDM Please note as the Screening and Visit 1 is done on the same day, Height and weight to be recorded in screening and updated to "NOT Done " in Visit 1. Kindly remove the units as well .Thanks	(b) (4), (b) (6)	13 Oct 2020 10:31:30
' (Site from DM).		
User entered missing code ND - Not Done; reason for change Data Entry Error	Avia McClain-Stocker (b) (4)	08 Oct 2020 18:50:23
User entered '75' in	amy sheets (b) (4) (b) (4)	18 Aug 2020 14:35:20

US3052005

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 15:00:53

Weight

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:41:16
User signature succeeded.	Judith Borger (b) (4)	23 Feb 2021 07:32:26
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4)	08 Oct 2020 18:50:23
User entered '192' lb	Avia McClain-Stocker (b) (4)	18 Aug 2020 14:35:20
	amy sheets (b) (4)	
	(b) (4)	

US3052005

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 15:00:53

Height

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:41:16
User signature succeeded.	Judith Borger (b) (4)	23 Feb 2021 07:32:26
User closed query 'Per CDM Please note as the Screening and Visit 1 is done on the same day, Height and weight to be recorded in screening and updated to "NOT Done " in Visit 1. Kindly remove the units as well .Thanks	(b) (4) (b) (4), (b) (6)	22 Oct 2020 17:01:53
' (Site from DM).		
Query 'Per CDM Please note as the Screening and Visit 1 is done on the same day, Height and weight to be recorded in screening and updated to "NOT Done " in Visit 1. Kindly remove the units as well .Thanks	Avia McClain-Stocker (b) (4)	21 Oct 2020 15:51:06
' answered with 'screening and day 1 same day. updated' (Site from DM).		
User opened query 'Per CDM Please note as the Screening and Visit 1 is done on the same day, Height and weight to be recorded in screening and updated to "NOT Done " in Visit 1. Kindly remove the units as well .Thanks	(b) (4), (b) (6)	13 Oct 2020 10:31:30
' (Site from DM).		
User entered missing code ND - Not Done; reason for change Data Entry Error	Avia McClain-Stocker (b) (4)	08 Oct 2020 18:50:23
User entered '75' in	amy sheets (b) (4) (b) (4)	18 Aug 2020 14:35:20

US3052005

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 15:00:53

Weight

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:41:16
User signature succeeded.	Judith Borger (b) (4)	23 Feb 2021 07:32:26
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4)	08 Oct 2020 18:50:23
User entered '192' lb	Avia McClain-Stocker (b) (4)	18 Aug 2020 14:35:20
	amy sheets (b) (4)	
	(b) (4)	

US3052005

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:00:53

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:41:16
User accepted default value 'Pre-Dose (PREDOSE)'	amy sheets (b) (4) (b) (4)	18 Aug 2020 14:35:20

US3052005

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:00:53

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:41:16
User signature succeeded.	Judith Borger (b) (4)	23 Feb 2021 07:32:26
User entered 'Yes (Y)'	(b) (4) amy sheets (b) (4) (b) (4)	18 Aug 2020 14:35:20

US3052005

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:00:53

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:41:16
User signature succeeded.	Judith Borger (b) (4)	23 Feb 2021 07:32:26
User entered '30 Jul 2020'	(b) (4) amy sheets (b) (4) (b) (4)	18 Aug 2020 14:35:20

US3052005

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:00:53

Time of assessment (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:41:16
User signature succeeded.	Judith Borger (b) (4)	23 Feb 2021 07:32:26
User entered '10:13'	(b) (4) amy sheets (b) (4) (b) (4)	18 Aug 2020 14:35:20

US3052005

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:00:53

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:41:16
User entered '30 Jul 2020 10:13'	System	18 Aug 2020 14:35:20

US3052005

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:00:53

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:41:16
User signature succeeded.	Judith Borger (b) (4)	23 Feb 2021 07:32:26
User entered '98.4' F	amy sheets (b) (4)	18 Aug 2020 14:35:20

US3052005

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:00:53

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:41:16
User signature succeeded.	Judith Borger (b) (4)	23 Feb 2021 07:32:26
User closed query 'Data is required. Please provide.' (Site from System).	System	18 Aug 2020 14:36:52
User entered 'Oral (Oral)' reason for change: New Information	amy sheets (b) (4)	18 Aug 2020 14:36:52
User opened query 'Data is required. Please provide.' (Site from System).	System	18 Aug 2020 14:35:20
User entered empty.	amy sheets (b) (4)	18 Aug 2020 14:35:20

US3052005

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:00:53

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:41:16
User signature succeeded.	Judith Borger (b) (4)	23 Feb 2021 07:32:26
User entered empty.	(b) (4) amy sheets (b) (4) (b) (4)	18 Aug 2020 14:35:20

US3052005

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:00:53

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:41:16
User signature succeeded.	Judith Borger (b) (4)	23 Feb 2021 07:32:26
User closed query 'Data is required. Please provide.' (Site from System).	(b) (4)	18 Aug 2020 14:36:52
Query 'Data is required. Please provide.' answered by System data change (Site from System).	System	18 Aug 2020 14:36:52
User entered '59' reason for change: New Information	amy sheets (b) (4)	18 Aug 2020 14:36:52
User opened query 'Data is required. Please provide.' (Site from System).	(b) (4)	18 Aug 2020 14:35:20
User entered empty.	System	18 Aug 2020 14:35:20
	amy sheets (b) (4)	18 Aug 2020 14:35:20
	(b) (4)	

US3052005

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:00:53

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:41:16
User entered 'bpm'	System	18 Aug 2020 14:36:52
User entered empty.	System	18 Aug 2020 14:35:20

US3052005

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:00:53

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:41:16
User signature succeeded.	Judith Borger (b) (4)	23 Feb 2021 07:32:26
User closed query 'Data is required. Please provide.' (Site from System).	(b) (4) System	18 Aug 2020 14:36:52
Query 'Data is required. Please provide.' answered by System data change (Site from System).		18 Aug 2020 14:36:52
User entered '16' reason for change: New Information	amy sheets (b) (4)	18 Aug 2020 14:36:52
User opened query 'Data is required. Please provide.' (Site from System).	(b) (4) System	18 Aug 2020 14:35:20
User entered empty.	amy sheets (b) (4)	18 Aug 2020 14:35:20
	(b) (4)	

US3052005

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:00:53

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:41:16
User entered 'breaths/min'	System	18 Aug 2020 14:36:52
User entered empty.	System	18 Aug 2020 14:35:20

US3052005

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:00:53

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:41:16
User signature succeeded.	Judith Borger (b) (4)	23 Feb 2021 07:32:26
User closed query 'Data is required. Please provide.' (Site from System).	System	18 Aug 2020 14:36:52
Query 'Data is required. Please provide.' answered by System data change (Site from System).		18 Aug 2020 14:36:52
User entered '129' reason for change: New Information	amy sheets (b) (4)	18 Aug 2020 14:36:52
User opened query 'Data is required. Please provide.' (Site from System).	System	18 Aug 2020 14:35:20
User entered empty.	amy sheets (b) (4)	18 Aug 2020 14:35:20

US3052005

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:00:53

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:41:16
User entered 'mmHg'	System	18 Aug 2020 14:36:52
User entered empty.	System	18 Aug 2020 14:35:20

US3052005

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:00:53

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:41:16
User signature succeeded.	Judith Borger (b) (4)	23 Feb 2021 07:32:26
User closed query 'Data is required. Please provide.' (Site from System).	(b) (4) System	18 Aug 2020 14:36:52
Query 'Data is required. Please provide.' answered by System data change (Site from System).		18 Aug 2020 14:36:52
User entered '83' reason for change: New Information	amy sheets (b) (4)	18 Aug 2020 14:36:52
User opened query 'Data is required. Please provide.' (Site from System).	(b) (4) System	18 Aug 2020 14:35:20
User entered empty.	amy sheets (b) (4)	18 Aug 2020 14:35:20
	(b) (4)	

US3052005

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:00:53

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:41:16
User entered 'mmHg'	System	18 Aug 2020 14:36:52
User entered empty.	System	18 Aug 2020 14:35:20

US3052005

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 15:00:53

Height

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:41:16
User signature succeeded.	Judith Borger (b) (4)	23 Feb 2021 07:32:26
User closed query 'Per CDM Please note as the Screening and Visit 1 is done on the same day, Height and weight to be recorded in screening and updated to "NOT Done " in Visit 1. Kindly remove the units as well .Thanks	(b) (4) (b) (4), (b) (6)	22 Oct 2020 17:01:53
' (Site from DM). Query 'Per CDM Please note as the Screening and Visit 1 is done on the same day, Height and weight to be recorded in screening and updated to "NOT Done " in Visit 1. Kindly remove the units as well .Thanks	Avia McClain-Stocker (b) (4)	21 Oct 2020 15:51:06
' answered with 'screening and day 1 same day. updated' (Site from DM). User opened query 'Per CDM Please note as the Screening and Visit 1 is done on the same day, Height and weight to be recorded in screening and updated to "NOT Done " in Visit 1. Kindly remove the units as well .Thanks	(b) (4), (b) (6)	13 Oct 2020 10:31:30
' (Site from DM). User entered missing code ND - Not Done; reason for change Data Entry Error User entered '75' in	Avia McClain-Stocker (b) (4) amy sheets (b) (4) (b) (4)	08 Oct 2020 18:50:23 18 Aug 2020 14:35:20

US3052005

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 15:00:53

Weight

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:41:16
User signature succeeded.	Judith Borger (b) (4)	23 Feb 2021 07:32:26
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4)	08 Oct 2020 18:50:23
User entered '192' lb	Avia McClain-Stocker (b) (4)	18 Aug 2020 14:35:20
	amy sheets (b) (4)	
	(b) (4)	

US3052005

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:00:53

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:41:16
User accepted default value 'Post-Dose (POSTDOSE)'	amy sheets (b) (4) (b) (4)	18 Aug 2020 14:35:20

US3052005

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:00:53

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:41:16
User signature succeeded.	Judith Borger (b) (4)	23 Feb 2021 07:32:26
User entered 'Yes (Y)'	(b) (4) amy sheets (b) (4) (b) (4)	18 Aug 2020 14:35:20

US3052005

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:00:53

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:41:16
User signature succeeded.	Judith Borger (b) (4)	23 Feb 2021 07:32:26
User entered '30 Jul 2020'	(b) (4) amy sheets (b) (4) (b) (4)	18 Aug 2020 14:35:20

US3052005

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:00:53

Time of assessment (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:41:16
User signature succeeded.	Judith Borger (b) (4)	23 Feb 2021 07:32:26
Amendment Manager: Query closed during migrationSystem process because the edit check no longer exists in target version.	(b) (4)	21 Aug 2020 01:21:13
User opened query 'Post-dose vital signs time is prior System to or less than 60 minutes after the Dose Time. Please review and reconcile.' (Site from System).		18 Aug 2020 14:35:20
User entered '11:57'	amy sheets (b) (4)	18 Aug 2020 14:35:20
	(b) (4)	

US3052005

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:00:53

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:41:16
User entered '30 Jul 2020 11:57'	System	18 Aug 2020 14:35:20

US3052005

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:00:53

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:41:16
User signature succeeded.	Judith Borger (b) (4)	23 Feb 2021 07:32:26
User closed query 'Temperature reported is out of range < 36C (96.8 F) per protocol considered grade 3. Please indicate if CS/NCS and report as AE, if appropriate.' (Site from System).	(b) (4) (b) (4), (b) (6)	08 Oct 2020 10:35:35
Query 'Temperature reported is out of range < 36C (96.8 F) per protocol considered grade 3. Please indicate if CS/NCS and report as AE, if appropriate.' answered with 'ncs' (Site from System).	amy sheets (b) (4) (b) (4)	08 Oct 2020 00:22:58
Amendment Manager: User opened query 'Temperature reported is out of range < 36C (96.8 F) per protocol considered grade 3. Please indicate if CS/NCS and report as AE, if appropriate.' (Site from System).	System	16 Sep 2020 23:38:45
User entered '96.4' F	amy sheets (b) (4) (b) (4)	18 Aug 2020 14:35:20

US3052005

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:00:53

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:41:16
User signature succeeded.	Judith Borger (b) (4)	23 Feb 2021 07:32:26
User closed query 'Data is required. Please provide.' (Site from System).	System	18 Aug 2020 14:38:49
User entered 'Oral (Oral)' reason for change: New Information	amy sheets (b) (4)	18 Aug 2020 14:38:49
User opened query 'Data is required. Please provide.' (Site from System).	System	18 Aug 2020 14:35:20
User entered empty.	amy sheets (b) (4)	18 Aug 2020 14:35:20

US3052005

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:00:53

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:41:16
User signature succeeded.	Judith Borger (b) (4)	23 Feb 2021 07:32:26
User entered empty.	(b) (4) amy sheets (b) (4) (b) (4)	18 Aug 2020 14:35:20

US3052005

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:00:53

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:41:16
User signature succeeded.	Judith Borger (b) (4)	23 Feb 2021 07:32:26
User closed query 'Data is required. Please provide.' (Site from System).	(b) (4)	18 Aug 2020 14:38:49
Query 'Data is required. Please provide.' answered by System data change (Site from System).	System	18 Aug 2020 14:38:49
User entered '51' reason for change: New Information	amy sheets (b) (4)	18 Aug 2020 14:38:49
User opened query 'Data is required. Please provide.' (Site from System).	(b) (4)	18 Aug 2020 14:35:20
User entered empty.	System	18 Aug 2020 14:35:20
	amy sheets (b) (4)	18 Aug 2020 14:35:20
	(b) (4)	

US3052005

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:00:53

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:41:16
User entered 'bpm'	System	18 Aug 2020 14:38:49
User entered empty.	System	18 Aug 2020 14:35:20

US3052005

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:00:53

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:41:16
User signature succeeded.	Judith Borger (b) (4)	23 Feb 2021 07:32:26
User closed query 'Data is required. Please provide.' (Site from System).	System	18 Aug 2020 14:38:49
Query 'Data is required. Please provide.' answered by System data change (Site from System).		18 Aug 2020 14:38:49
User entered '18' reason for change: New Information	amy sheets (b) (4)	18 Aug 2020 14:38:49
User opened query 'Data is required. Please provide.' (Site from System).	System	18 Aug 2020 14:35:20
User entered empty.	amy sheets (b) (4)	18 Aug 2020 14:35:20

US3052005

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:00:53

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:41:16
User entered 'breaths/min'	System	18 Aug 2020 14:38:49
User entered empty.	System	18 Aug 2020 14:35:20

US3052005

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:00:53

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:41:16
User signature succeeded.	Judith Borger (b) (4)	23 Feb 2021 07:32:26
User closed query 'Data is required. Please provide.' (Site from System).	(b) (4)	18 Aug 2020 14:38:49
Query 'Data is required. Please provide.' answered by System data change (Site from System).	System	18 Aug 2020 14:38:49
User entered '127' reason for change: New Information	amy sheets (b) (4)	18 Aug 2020 14:38:49
User opened query 'Data is required. Please provide.' (Site from System).	(b) (4)	18 Aug 2020 14:35:20
User entered empty.	System	18 Aug 2020 14:35:20
	amy sheets (b) (4)	18 Aug 2020 14:35:20
	(b) (4)	

US3052005

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:00:53

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:41:16
User entered 'mmHg'	System	18 Aug 2020 14:38:49
User entered empty.	System	18 Aug 2020 14:35:20

US3052005

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:00:53

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:41:16
User signature succeeded.	Judith Borger (b) (4)	23 Feb 2021 07:32:26
User closed query 'Data is required. Please provide.' (Site from System).	(b) (4) System	18 Aug 2020 14:38:49
Query 'Data is required. Please provide.' answered by System data change (Site from System).		18 Aug 2020 14:38:49
User entered '84' reason for change: New Information	amy sheets (b) (4)	18 Aug 2020 14:38:49
User opened query 'Data is required. Please provide.' (Site from System).	(b) (4) System	18 Aug 2020 14:35:20
User entered empty.	amy sheets (b) (4)	18 Aug 2020 14:35:20
	(b) (4)	

US3052005

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:00:53

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:41:16
User entered 'mmHg'	System	18 Aug 2020 14:38:49
User entered empty.	System	18 Aug 2020 14:35:20

US3052005

Folder: Visit 1 Day 1

Form: Physical Examination

Generated On: 09 Jun 2021 15:00:53

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:41:16
User signature succeeded.	Judith Borger (b) (4)	23 Feb 2021 07:32:26
User entered 'No (N)' reason for change: Data Entry Error	Avia McClain-Stocker (b) (4)	08 Oct 2020 18:50:36
User entered 'Yes (Y)'	amy sheets (b) (4)	18 Aug 2020 14:39:12

US3052005

Folder: Visit 1 Day 1

Form: Physical Examination

Generated On: 09 Jun 2021 15:00:53

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:41:16
User signature succeeded.	Judith Borger (b) (4)	23 Feb 2021 07:32:26
User entered empty; reason for change Data Entry Error	Avia McClain-Stocker (b) (4)	08 Oct 2020 18:50:36
User entered '30 Jul 2020'	amy sheets (b) (4)	18 Aug 2020 14:39:12

US3052005

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 15:00:53

[Was study treatment given?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:41:16
User signature succeeded.	Judith Borger (b) (4)	23 Feb 2021 07:32:26
User entered 'Yes (Y)'	(b) (4) amy sheets (b) (4) (b) (4)	30 Jul 2020 16:00:02

US3052005

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 15:00:53

If No, reason not given

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:41:16
User signature succeeded.	Judith Borger (b) (4)	23 Feb 2021 07:32:26
User entered empty.	(b) (4) amy sheets (b) (4) (b) (4)	30 Jul 2020 16:00:02

US3052005

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 15:00:53

If reason is Physician Decision, Withdrawal of Consent by Participant, Protocol Deviation, or Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:41:16
User signature succeeded.	Judith Borger (b) (4)	23 Feb 2021 07:32:26
User entered empty.	(b) (4) amy sheets (b) (4) (b) (4)	30 Jul 2020 16:00:02

US3052005

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 15:00:53

[What was the study treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:41:16
User entered 'MRNA-1273 OR PLACEBO'	System	30 Jul 2020 16:00:02

US3052005

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 15:00:53

What was the treatment date? (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:41:16
User signature succeeded.	Judith Borger (b) (4)	23 Feb 2021 07:32:26
User entered '30 Jul 2020'	(b) (4) amy sheets (b) (4) (b) (4)	30 Jul 2020 16:00:02

US3052005

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 15:00:53

[What was the treatment time? \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:41:16
User signature succeeded.	Judith Borger (b) (4)	23 Feb 2021 07:32:26
User entered '11:22'	(b) (4) amy sheets (b) (4) (b) (4)	30 Jul 2020 16:00:02

US3052005

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 15:00:53

[Treatment Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:41:16
User entered '30 Jul 2020 11:22'	System	30 Jul 2020 16:00:02

US3052005

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 15:00:53

Which arm was used to give treatment?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:41:16
User signature succeeded.	Judith Borger (b) (4)	23 Feb 2021 07:32:26
User entered 'Left Arm (LEFT ARM)'	(b) (4) amy sheets (b) (4) (b) (4)	30 Jul 2020 16:00:02

US3052005

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 15:00:53

What was the frequency of the study treatment dosing?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:41:16
User entered 'ONCE'	System	30 Jul 2020 16:00:02

US3052005

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 15:00:53

What was the route of administration for the study treatment?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:41:16
User entered 'INTRAMUSCULAR'	System	30 Jul 2020 16:00:02

US3052005

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 15:00:53

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:41:16
User signature succeeded.	Judith Borger (b) (4)	23 Feb 2021 07:32:26
User entered 'Yes (Y)'	(b) (4) amy sheets (b) (4) (b) (4)	18 Aug 2020 14:39:59

US3052005

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 15:00:53

Collection date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:41:16
User signature succeeded.	Judith Borger (b) (4)	23 Feb 2021 07:32:26
User closed query 'Per IMMUNO Lab Recon: it appears a sample was collected on 30JUL2020; however, it has not been received by GCL. Please clarify and, if shipped, please provide tracking details.' (Site from DM).	(b) (4) (b) (4), (b) (6)	04 Nov 2020 15:16:31
Query 'Per IMMUNO Lab Recon: it appears a sample was collected on 30JUL2020; however, it has not been received by GCL. Please clarify and, if shipped, please provide tracking details.' answered with 'Collection was shipped. ' (Site from DM).	Avia McClain-Stocker (b) (4)	07 Oct 2020 19:52:08
User opened query 'Per IMMUNO Lab Recon: it appears a sample was collected on 30JUL2020; however, it has not been received by GCL. Please clarify and, if shipped, please provide tracking details.' (Site from DM).	(b) (4), (b) (6)	01 Oct 2020 16:48:51
User entered '30 Jul 2020'	amy sheets (b) (4) (b) (4)	18 Aug 2020 14:39:59

US3052005

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 15:00:53

Collection time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:41:16
User signature succeeded.	Judith Borger (b) (4)	23 Feb 2021 07:32:26
User entered '10:38'	(b) (4) amy sheets (b) (4) (b) (4)	18 Aug 2020 14:39:59

US3052005

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 15:00:53

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:41:16
User entered '30 Jul 2020 10:38'	System	18 Aug 2020 14:39:59

US3052005

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab

Generated On: 09 Jun 2021 15:00:53

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:41:16
User signature succeeded.	Judith Borger (b) (4)	23 Feb 2021 07:32:26
User entered '30 Jul 2020'	(b) (4) amy sheets (b) (4) (b) (4)	18 Aug 2020 14:40:31

US3052005

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 15:00:53

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:41:16
User accepted default value 'Nasopharyngeal Swab 1 (NASAL1)'	amy sheets (b) (4) (b) (4)	18 Aug 2020 14:40:31

US3052005

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 15:00:53

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:41:16
User signature succeeded.	Judith Borger (b) (4)	23 Feb 2021 07:32:26
User entered 'Yes (Y)'	(b) (4) amy sheets (b) (4) (b) (4)	18 Aug 2020 14:40:31

US3052005

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 15:00:53

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:41:16
User signature succeeded.	Judith Borger (b) (4)	23 Feb 2021 07:32:26
User entered '10:34'	(b) (4) amy sheets (b) (4) (b) (4)	18 Aug 2020 14:40:31

US3052005

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 15:00:53

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:41:16
User entered '30 Jul 2020 10:34'	System	18 Aug 2020 14:40:31

US3052005

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 15:00:53

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:41:16
User accepted default value 'Nasopharyngeal Swab 2 (NASAL2)'	amy sheets (b) (4) (b) (4)	18 Aug 2020 14:40:31

US3052005

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 15:00:53

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:41:16
User signature succeeded.	Judith Borger (b) (4)	23 Feb 2021 07:32:26
User closed query 'Data is required. Please complete.' (Site from System).	(b) (4)	07 Oct 2020 15:41:10
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	07 Oct 2020 15:41:10
User entered 'No (N)' reason for change: Data Entry Error	Avia McClain-Stocker (b) (4)	07 Oct 2020 15:41:10
User opened query 'Data is required. Please complete.' (Site from System).	System	18 Aug 2020 14:40:31
User entered empty.	amy sheets (b) (4)	18 Aug 2020 14:40:31

US3052005

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 15:00:53

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:41:16
User signature succeeded.	Judith Borger (b) (4)	23 Feb 2021 07:32:26
User entered empty.	(b) (4) amy sheets (b) (4) (b) (4)	18 Aug 2020 14:40:31

US3052005

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 15:00:53

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:41:16
User entered empty.	System	18 Aug 2020 14:40:31

US3052005

Folder: Visit 1 Day 1

Form: Continuing

Generated On: 09 Jun 2021 15:00:53

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:41:16
User signature succeeded.	Judith Borger (b) (4)	23 Feb 2021 07:32:26
User entered 'Yes (Y)'	(b) (4) amy sheets (b) (4) (b) (4)	18 Aug 2020 14:40:47

US3052005

Folder: Visit 1 Day 1

Form: Continuing

Generated On: 09 Jun 2021 15:00:53

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:41:16
User entered 'I'	System	18 Aug 2020 14:40:47

US3052005

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 15:00:53

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:58:03
Data hard unlocked.		25 Feb 2021 15:15:57
Data hard locked.		25 Feb 2021 06:48:14
Data entry locked.	System	30 Jul 2020 16:00:02
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	30 Jul 2020 16:00:02

US3052005

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 15:00:53

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:58:03
Data hard unlocked.		25 Feb 2021 15:15:57
Data hard locked.		25 Feb 2021 06:48:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9EADD593-414F-498C-AC00-8AAC8D311A10)', Time: '2020-07-30T12:01:32', User OID: 'PatientReportedOutcome (US3052005)', ODM File OID: 'd0e2a5df-b0d7-4f02-a3d3-65e87ae0cb9f' User entered 'Yes (Y)'	System	30 Jul 2020 16:02:06
	System	30 Jul 2020 16:02:06

US3052005

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 15:00:53

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:58:03
Data hard unlocked.		25 Feb 2021 15:15:57
Data hard locked.		25 Feb 2021 06:48:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9EADD593-414F-498C-AC00-8AAC8D311A10)', Time: '2020-07-30T12:01:45', User OID: 'PatientReportedOutcome (US3052005)', ODM File OID: 'd0e2a5df-b0d7-4f02-a3d3-65e87ae0cb9f' User entered '96.4'	System	30 Jul 2020 16:02:06
	System	30 Jul 2020 16:02:06

US3052005

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 15:00:53

Was any **MEDICATION TAKEN** today for pain or fever?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:58:03
Data hard unlocked.	(b) (4), (b) (6)	25 Feb 2021 15:15:57
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:48:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9EADD593-414F-498C-AC00-8AAC8D311A10)', Time: '2020-07-30T12:01:53', User OID: 'PatientReportedOutcome (US3052005)', ODM File OID: 'd0e2a5df-b0d7-4f02-a3d3-65e87ae0cb9f'	System	30 Jul 2020 16:02:06
User entered 'No (N)'	System	30 Jul 2020 16:02:06

US3052005

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 15:00:53

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:58:03
Data hard unlocked.		25 Feb 2021 15:15:57
Data hard locked.		25 Feb 2021 06:48:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9EADD593-414F-498C-AC00-8AAC8D311A10)', Time: '2020-07-30T12:02:01', User OID: 'PatientReportedOutcome (US3052005)', ODM File OID: 'd0e2a5df-b0d7-4f02-a3d3-65e87ae0cb9f' User entered '30 Jul 2020 12:02'	System	30 Jul 2020 16:02:06
	System	30 Jul 2020 16:02:06

US3052005

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 15:00:53

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:58:03
Data hard unlocked.		25 Feb 2021 15:15:57
Data hard locked.		25 Feb 2021 06:48:14
User entered '30 Jul 2020 11:42'	System	30 Jul 2020 16:00:02

US3052005

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 15:00:53

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:58:03
Data hard unlocked.		25 Feb 2021 15:15:57
Data hard locked.		25 Feb 2021 06:48:14
User entered '30 Jul 2020 14:12'	System	30 Jul 2020 16:00:02

US3052005

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 15:00:53

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:58:03
Data hard unlocked.		25 Feb 2021 15:15:57
Data hard locked.		25 Feb 2021 06:48:14
Data entry locked.	System	30 Jul 2020 16:00:02
User entered 'Day 1, after vaccination (at home)'	System	30 Jul 2020 16:00:02

US3052005

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 15:00:53

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:58:03
Data hard unlocked.		25 Feb 2021 15:15:57
Data hard locked.		25 Feb 2021 06:48:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9EADD593-414F-498C-AC00-8AAC8D311A10)', Time: '2020-07-30T21:18:52', User OID: 'PatientReportedOutcome (US3052005)', ODM File OID: 'b71f18a4-db3f-41eb-af57-070b33ce3cf9' User entered 'Yes (Y)'	System	31 Jul 2020 01:19:49
	System	31 Jul 2020 01:19:49

US3052005

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 15:00:53

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:58:03
Data hard unlocked.		25 Feb 2021 15:15:57
Data hard locked.		25 Feb 2021 06:48:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9EADD593-414F-498C-AC00-8AAC8D311A10)', Time: '2020-07-30T21:19:26', User OID: 'PatientReportedOutcome (US3052005)', ODM File OID: 'b71f18a4-db3f-41eb-af57-070b33ce3cf9' User entered '96.0'	System	31 Jul 2020 01:19:49
	System	31 Jul 2020 01:19:49

US3052005

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 15:00:53

Was any **MEDICATION TAKEN** today for pain or fever?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:58:03
Data hard unlocked.		25 Feb 2021 15:15:57
Data hard locked.		25 Feb 2021 06:48:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9EADD593-414F-498C-AC00-8AAC8D311A10)', Time: '2020-07-30T21:19:35', User OID: 'PatientReportedOutcome (US3052005)', ODM File OID: 'b71f18a4-db3f-41eb-af57-070b33ce3cf9'	System	31 Jul 2020 01:19:49
User entered 'No (N)'	System	31 Jul 2020 01:19:49

US3052005

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 15:00:53

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:58:03
Data hard unlocked.		25 Feb 2021 15:15:57
Data hard locked.		25 Feb 2021 06:48:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9EADD593-414F-498C-AC00-8AAC8D311A10)', Time: '2020-07-30T21:19:47', User OID: 'PatientReportedOutcome (US3052005)', ODM File OID: 'b71f18a4-db3f-41eb-af57-070b33ce3cf9' User entered '30 Jul 2020 21:19'	System	31 Jul 2020 01:19:49
	System	31 Jul 2020 01:19:49

US3052005

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 15:00:53

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:58:03
Data hard unlocked.		25 Feb 2021 15:15:57
Data hard locked.		25 Feb 2021 06:48:14
User entered '30 Jul 2020 15:07'	System	30 Jul 2020 16:00:02

US3052005

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 15:00:53

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:58:03
Data hard unlocked.		25 Feb 2021 15:15:57
Data hard locked.		25 Feb 2021 06:48:14
User entered '31 Jul 2020 11:59'	System	30 Jul 2020 16:00:02

US3052005

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 15:00:53

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:58:03
Data hard unlocked.		25 Feb 2021 15:15:57
Data hard locked.		25 Feb 2021 06:48:14
Data entry locked.	System	30 Jul 2020 16:00:02
User entered 'Day 2'	System	30 Jul 2020 16:00:02

US3052005

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 15:00:53

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:58:03
Data hard unlocked.		25 Feb 2021 15:15:57
Data hard locked.		25 Feb 2021 06:48:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9EADD593-414F-498C-AC00-8AAC8D311A10)', Time: '2020-07-31T20:31:51', User OID: 'PatientReportedOutcome (US3052005)', ODM File OID: '2608d6aa-f2b3-402f-8902-df606d9ab92a'	System	01 Aug 2020 00:33:11
User entered 'Yes (Y)'	System	01 Aug 2020 00:33:11

US3052005

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 15:00:53

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:58:03
Data hard unlocked.		25 Feb 2021 15:15:57
Data hard locked.		25 Feb 2021 06:48:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9EADD593-414F-498C-AC00-8AAC8D311A10)', Time: '2020-07-31T20:32:57', User OID: 'PatientReportedOutcome (US3052005)', ODM File OID: '2608d6aa-f2b3-402f-8902-df606d9ab92a'	System	01 Aug 2020 00:33:11
User entered '97.7'	System	01 Aug 2020 00:33:11

US3052005

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 15:00:53

Was any **MEDICATION TAKEN** today for pain or fever?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:58:03
Data hard unlocked.		25 Feb 2021 15:15:57
Data hard locked.		25 Feb 2021 06:48:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9EADD593-414F-498C-AC00-8AAC8D311A10)', Time: '2020-07-31T20:33:01', User OID: 'PatientReportedOutcome (US3052005)', ODM File OID: '2608d6aa-f2b3-402f-8902-df606d9ab92a'	System	01 Aug 2020 00:33:11
User entered 'No (N)'	System	01 Aug 2020 00:33:11

US3052005

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 15:00:53

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:58:03
Data hard unlocked.		25 Feb 2021 15:15:57
Data hard locked.		25 Feb 2021 06:48:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9EADD593-414F-498C-AC00-8AAC8D311A10)', Time: '2020-07-31T20:33:07', User OID: 'PatientReportedOutcome (US3052005)', ODM File OID: '2608d6aa-f2b3-402f-8902-df606d9ab92a' User entered '31 Jul 2020 20:33'	System	01 Aug 2020 00:33:11
	System	01 Aug 2020 00:33:11

US3052005

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 15:00:53

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:58:03
Data hard unlocked.		25 Feb 2021 15:15:57
Data hard locked.		25 Feb 2021 06:48:14
User entered '31 Jul 2020 12:00'	System	30 Jul 2020 16:00:02

US3052005

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 15:00:53

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:58:03
Data hard unlocked.		25 Feb 2021 15:15:57
Data hard locked.		25 Feb 2021 06:48:14
User entered '01 Aug 2020 11:59'	System	30 Jul 2020 16:00:02

US3052005

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 15:00:53

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:58:03
Data hard unlocked.		25 Feb 2021 15:15:57
Data hard locked.		25 Feb 2021 06:48:14
Data entry locked.	System	30 Jul 2020 16:00:02
User entered 'Day 3'	System	30 Jul 2020 16:00:02

US3052005

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 15:00:53

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:58:03
Data hard unlocked.		25 Feb 2021 15:15:57
Data hard locked.		25 Feb 2021 06:48:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9EADD593-414F-498C-AC00-8AAC8D311A10)', Time: '2020-08-01T22:39:44', User OID: 'PatientReportedOutcome (US3052005)', ODM File OID: 'cf7ab742-c54b-4ab9-8f8b-69f2afcaf577'	System	02 Aug 2020 02:40:11
User entered 'Yes (Y)'	System	02 Aug 2020 02:40:11

US3052005

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 15:00:53

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:58:03
Data hard unlocked.		25 Feb 2021 15:15:57
Data hard locked.		25 Feb 2021 06:48:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9EADD593-414F-498C-AC00-8AAC8D311A10)', Time: '2020-08-01T22:39:54', User OID: 'PatientReportedOutcome (US3052005)', ODM File OID: 'cf7ab742-c54b-4ab9-8f8b-69f2afcaf577'	System	02 Aug 2020 02:40:11
User entered '97.4'	System	02 Aug 2020 02:40:11

US3052005

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 15:00:53

Was any **MEDICATION TAKEN** today for pain or fever?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:58:03
Data hard unlocked.		25 Feb 2021 15:15:57
Data hard locked.		25 Feb 2021 06:48:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9EADD593-414F-498C-AC00-8AAC8D311A10)', Time: '2020-08-01T22:39:58', User OID: 'PatientReportedOutcome (US3052005)', ODM File OID: 'cf7ab742-c54b-4ab9-8f8b-69f2afcaf577'	System	02 Aug 2020 02:40:11
User entered 'No (N)'	System	02 Aug 2020 02:40:11

US3052005

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 15:00:53

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:58:03
Data hard unlocked.		25 Feb 2021 15:15:57
Data hard locked.		25 Feb 2021 06:48:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9EADD593-414F-498C-AC00-8AAC8D311A10)', Time: '2020-08-01T22:40:03', User OID: 'PatientReportedOutcome (US3052005)', ODM File OID: 'cf7ab742-c54b-4ab9-8f8b-69f2afcaf577'	System	02 Aug 2020 02:40:11
User entered '01 Aug 2020 22:40'	System	02 Aug 2020 02:40:11

US3052005

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 15:00:53

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:58:03
Data hard unlocked.		25 Feb 2021 15:15:57
Data hard locked.		25 Feb 2021 06:48:14
User entered '01 Aug 2020 12:00'	System	30 Jul 2020 16:00:02

US3052005

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 15:00:53

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:58:03
Data hard unlocked.		25 Feb 2021 15:15:57
Data hard locked.		25 Feb 2021 06:48:14
User entered '02 Aug 2020 11:59'	System	30 Jul 2020 16:00:02

US3052005

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 15:00:53

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:58:03
Data hard unlocked.		25 Feb 2021 15:15:57
Data hard locked.		25 Feb 2021 06:48:14
Data entry locked.	System	30 Jul 2020 16:00:02
User entered 'Day 4'	System	30 Jul 2020 16:00:02

US3052005

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 15:00:53

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:58:03
Data hard unlocked.		25 Feb 2021 15:15:57
Data hard locked.		25 Feb 2021 06:48:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9EADD593-414F-498C-AC00-8AAC8D311A10)', Time: '2020-08-02T19:07:51', User OID: 'PatientReportedOutcome (US3052005)', ODM File OID: 'ea8c9a42-b486-4f08-aeca-cadded6d8d70'	System	02 Aug 2020 23:08:12
User entered 'Yes (Y)'	System	02 Aug 2020 23:08:12

US3052005

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 15:00:53

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:58:03
Data hard unlocked.		25 Feb 2021 15:15:57
Data hard locked.		25 Feb 2021 06:48:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9EADD593-414F-498C-AC00-8AAC8D311A10)', Time: '2020-08-02T19:08:00', User OID: 'PatientReportedOutcome (US3052005)', ODM File OID: 'ea8c9a42-b486-4f08-aeca-cadded6d8d70'	System	02 Aug 2020 23:08:12
User entered '97.4'	System	02 Aug 2020 23:08:12

US3052005

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 15:00:53

Was any **MEDICATION TAKEN** today for pain or fever?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:58:03
Data hard unlocked.		25 Feb 2021 15:15:57
Data hard locked.		25 Feb 2021 06:48:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9EADD593-414F-498C-AC00-8AAC8D311A10)', Time: '2020-08-02T19:08:06', User OID: 'PatientReportedOutcome (US3052005)', ODM File OID: 'ea8c9a42-b486-4f08-aeca-cadded6d8d70'	System	02 Aug 2020 23:08:12
User entered 'No (N)'	System	02 Aug 2020 23:08:12

US3052005

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 15:00:53

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:58:03
Data hard unlocked.		25 Feb 2021 15:15:57
Data hard locked.		25 Feb 2021 06:48:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9EADD593-414F-498C-AC00-8AAC8D311A10)', Time: '2020-08-02T19:08:09', User OID: 'PatientReportedOutcome (US3052005)', ODM File OID: 'ea8c9a42-b486-4f08-aeca-cadded6d8d70'	System	02 Aug 2020 23:08:12
User entered '02 Aug 2020 19:08'	System	02 Aug 2020 23:08:12

US3052005

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 15:00:53

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:58:03
Data hard unlocked.		25 Feb 2021 15:15:57
Data hard locked.		25 Feb 2021 06:48:14
User entered '02 Aug 2020 12:00'	System	30 Jul 2020 16:00:02

US3052005

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 15:00:53

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:58:03
Data hard unlocked.		25 Feb 2021 15:15:57
Data hard locked.		25 Feb 2021 06:48:14
User entered '03 Aug 2020 11:59'	System	30 Jul 2020 16:00:02

US3052005

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 15:00:53

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:58:03
Data hard unlocked.		25 Feb 2021 15:15:57
Data hard locked.		25 Feb 2021 06:48:14
Data entry locked.	System	30 Jul 2020 16:00:02
User entered 'Day 5'	System	30 Jul 2020 16:00:02

US3052005

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 15:00:53

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:58:03
Data hard unlocked.		25 Feb 2021 15:15:57
Data hard locked.		25 Feb 2021 06:48:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9EADD593-414F-498C-AC00-8AAC8D311A10)', Time: '2020-08-04T06:03:15', User OID: 'PatientReportedOutcome (US3052005)', ODM File OID: 'd84bb754-e761-4545-9498-7c3252a7f0e7'		04 Aug 2020 10:03:33
User entered 'Yes (Y)'	System	04 Aug 2020 10:03:33

US3052005

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 15:00:53

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:58:03
Data hard unlocked.		25 Feb 2021 15:15:57
Data hard locked.		25 Feb 2021 06:48:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9EADD593-414F-498C-AC00-8AAC8D311A10)', Time: '2020-08-04T06:03:22', User OID: 'PatientReportedOutcome (US3052005)', ODM File OID: 'd84bb754-e761-4545-9498-7c3252a7f0e7'	System	04 Aug 2020 10:03:33
User entered '97.2'	System	04 Aug 2020 10:03:33

US3052005

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 15:00:53

Was any **MEDICATION TAKEN** today for pain or fever?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:58:03
Data hard unlocked.		25 Feb 2021 15:15:57
Data hard locked.		25 Feb 2021 06:48:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9EADD593-414F-498C-AC00-8AAC8D311A10)', Time: '2020-08-04T06:03:27', User OID: 'PatientReportedOutcome (US3052005)', ODM File OID: 'd84bb754-e761-4545-9498-7c3252a7f0e7'		04 Aug 2020 10:03:33
User entered 'No (N)'	System	04 Aug 2020 10:03:33

US3052005

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 15:00:53

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:58:03
Data hard unlocked.		25 Feb 2021 15:15:57
Data hard locked.		25 Feb 2021 06:48:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9EADD593-414F-498C-AC00-8AAC8D311A10)', Time: '2020-08-04T06:03:30', User OID: 'PatientReportedOutcome (US3052005)', ODM File OID: 'd84bb754-e761-4545-9498-7c3252a7f0e7'	System	04 Aug 2020 10:03:33
User entered '04 Aug 2020 06:03'	System	04 Aug 2020 10:03:33

US3052005

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 15:00:53

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:58:03
Data hard unlocked.		25 Feb 2021 15:15:57
Data hard locked.		25 Feb 2021 06:48:14
User entered '03 Aug 2020 12:00'	System	30 Jul 2020 16:00:02

US3052005

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 15:00:53

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:58:03
Data hard unlocked.		25 Feb 2021 15:15:57
Data hard locked.		25 Feb 2021 06:48:14
User entered '04 Aug 2020 11:59'	System	30 Jul 2020 16:00:02

US3052005

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 15:00:53

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:58:03
Data hard unlocked.		25 Feb 2021 15:15:57
Data hard locked.		25 Feb 2021 06:48:14
Data entry locked.	System	30 Jul 2020 16:00:02
User entered 'Day 6'	System	30 Jul 2020 16:00:02

US3052005

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 15:00:53

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:58:03
Data hard unlocked.		25 Feb 2021 15:15:57
Data hard locked.		25 Feb 2021 06:48:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9EADD593-414F-498C-AC00-8AAC8D311A10)', Time: '2020-08-04T23:34:46', User OID: 'PatientReportedOutcome (US3052005)', ODM File OID: '7c1f25b7-091d-4dd8-9858-db8f6c752c81'	System	05 Aug 2020 03:35:07
User entered 'Yes (Y)'	System	05 Aug 2020 03:35:07

US3052005

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 15:00:53

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:58:03
Data hard unlocked.		25 Feb 2021 15:15:57
Data hard locked.		25 Feb 2021 06:48:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9EADD593-414F-498C-AC00-8AAC8D311A10)', Time: '2020-08-04T23:34:56', User OID: 'PatientReportedOutcome (US3052005)', ODM File OID: '7c1f25b7-091d-4dd8-9858-db8f6c752c81'	System	05 Aug 2020 03:35:07
User entered '97.2'	System	05 Aug 2020 03:35:07

US3052005

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 15:00:53

Was any **MEDICATION TAKEN** today for pain or fever?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:58:03
Data hard unlocked.		25 Feb 2021 15:15:57
Data hard locked.		25 Feb 2021 06:48:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9EADD593-414F-498C-AC00-8AAC8D311A10)', Time: '2020-08-04T23:35:02', User OID: 'PatientReportedOutcome (US3052005)', ODM File OID: '7c1f25b7-091d-4dd8-9858-db8f6c752c81'	System	05 Aug 2020 03:35:07
User entered 'No (N)'	System	05 Aug 2020 03:35:07

US3052005

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 15:00:53

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:58:03
Data hard unlocked.		25 Feb 2021 15:15:57
Data hard locked.		25 Feb 2021 06:48:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9EADD593-414F-498C-AC00-8AAC8D311A10)', Time: '2020-08-04T23:35:05', User OID: 'PatientReportedOutcome (US3052005)', ODM File OID: '7c1f25b7-091d-4dd8-9858-db8f6c752c81'	System	05 Aug 2020 03:35:07
User entered '04 Aug 2020 23:35'	System	05 Aug 2020 03:35:07

US3052005

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 15:00:53

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:58:03
Data hard unlocked.		25 Feb 2021 15:15:57
Data hard locked.		25 Feb 2021 06:48:14
User entered '04 Aug 2020 12:00'	System	30 Jul 2020 16:00:02

US3052005

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 15:00:53

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:58:03
Data hard unlocked.		25 Feb 2021 15:15:57
Data hard locked.		25 Feb 2021 06:48:14
User entered '05 Aug 2020 11:59'	System	30 Jul 2020 16:00:02

US3052005

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 15:00:53

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:58:03
Data hard unlocked.		25 Feb 2021 15:15:57
Data hard locked.		25 Feb 2021 06:48:14
Data entry locked.	System	30 Jul 2020 16:00:02
User entered 'Day 7'	System	30 Jul 2020 16:00:02

US3052005

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 15:00:53

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:58:03
Data hard unlocked.		25 Feb 2021 15:15:57
Data hard locked.		25 Feb 2021 06:48:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9EADD593-414F-498C-AC00-8AAC8D311A10)', Time: '2020-08-05T21:46:11', User OID: 'PatientReportedOutcome (US3052005)', ODM File OID: '6c22d9a0-4026-480a-9026-61840827052f'	System	06 Aug 2020 01:46:39
User entered 'Yes (Y)'	System	06 Aug 2020 01:46:39

US3052005

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 15:00:53

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:58:03
Data hard unlocked.		25 Feb 2021 15:15:57
Data hard locked.		25 Feb 2021 06:48:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9EADD593-414F-498C-AC00-8AAC8D311A10)', Time: '2020-08-05T21:46:26', User OID: 'PatientReportedOutcome (US3052005)', ODM File OID: '6c22d9a0-4026-480a-9026-61840827052f'	System	06 Aug 2020 01:46:39
User entered '97.8'	System	06 Aug 2020 01:46:39

US3052005

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 15:00:53

Was any **MEDICATION TAKEN** today for pain or fever?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:58:03
Data hard unlocked.		25 Feb 2021 15:15:57
Data hard locked.		25 Feb 2021 06:48:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9EADD593-414F-498C-AC00-8AAC8D311A10)', Time: '2020-08-05T21:46:32', User OID: 'PatientReportedOutcome (US3052005)', ODM File OID: '6c22d9a0-4026-480a-9026-61840827052f'	System	06 Aug 2020 01:46:39
User entered 'No (N)'	System	06 Aug 2020 01:46:39

US3052005

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 15:00:53

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:58:03
Data hard unlocked.		25 Feb 2021 15:15:57
Data hard locked.		25 Feb 2021 06:48:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9EADD593-414F-498C-AC00-8AAC8D311A10)', Time: '2020-08-05T21:46:36', User OID: 'PatientReportedOutcome (US3052005)', ODM File OID: '6c22d9a0-4026-480a-9026-61840827052f' User entered '05 Aug 2020 21:46'	System	06 Aug 2020 01:46:39
	System	06 Aug 2020 01:46:39

US3052005

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 15:00:53

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:58:03
Data hard unlocked.		25 Feb 2021 15:15:57
Data hard locked.		25 Feb 2021 06:48:14
User entered '05 Aug 2020 12:00'		30 Jul 2020 16:00:02

US3052005

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 15:00:53

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:58:03
Data hard unlocked.		25 Feb 2021 15:15:57
Data hard locked.		25 Feb 2021 06:48:14
User entered '06 Aug 2020 11:59'	System	30 Jul 2020 16:00:02

US3052005

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 15:00:53

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:58:03
Data hard unlocked.		25 Feb 2021 15:16:06
Data hard locked.		25 Feb 2021 06:48:14
Data entry locked.	System	30 Jul 2020 16:00:02
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	30 Jul 2020 16:00:02

US3052005

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 15:00:53

Please record - **PAIN AT INJECTION SITE.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:58:03
Data hard unlocked.		25 Feb 2021 15:16:06
Data hard locked.		25 Feb 2021 06:48:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9EADD593-414F-498C-AC00-8AAC8D311A10)', Time: '2020-07-30T12:02:09', User OID: 'PatientReportedOutcome (US3052005)', ODM File OID: '21a75983-eb27-4949-bff5-3fee75021242'	System	30 Jul 2020 16:02:46
User entered 'None (1)'	System	30 Jul 2020 16:02:46

US3052005

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 15:00:53

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:58:03
Data hard unlocked.		25 Feb 2021 15:16:06
Data hard locked.		25 Feb 2021 06:48:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9EADD593-414F-498C-AC00-8AAC8D311A10)', Time: '2020-07-30T12:02:32', User OID: 'PatientReportedOutcome (US3052005)', ODM File OID: '21a75983-eb27-4949-bff5-3fee75021242'	System	30 Jul 2020 16:02:46
User entered 'No (N)'	System	30 Jul 2020 16:02:46

US3052005

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 15:00:53

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:58:03
Data hard unlocked.		25 Feb 2021 15:16:06
Data hard locked.		25 Feb 2021 06:48:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9EADD593-414F-498C-AC00-8AAC8D311A10)', Time: '2020-07-30T12:02:35', User OID: 'PatientReportedOutcome (US3052005)', ODM File OID: '21a75983-eb27-4949-bff5-3fee75021242'	System	30 Jul 2020 16:02:46
User entered 'No (N)'	System	30 Jul 2020 16:02:46

US3052005

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 15:00:53

Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:58:03
Data hard unlocked.		25 Feb 2021 15:16:06
Data hard locked.		25 Feb 2021 06:48:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9EADD593-414F-498C-AC00-8AAC8D311A10)', Time: '2020-07-30T12:02:40', User OID: 'PatientReportedOutcome (US3052005)', ODM File OID: '21a75983-eb27-4949-bff5-3fee75021242'	System	30 Jul 2020 16:02:46
User entered 'None (1)'	System	30 Jul 2020 16:02:46

US3052005

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 15:00:53

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:58:03
Data hard unlocked.		25 Feb 2021 15:16:06
Data hard locked.		25 Feb 2021 06:48:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9EADD593-414F-498C-AC00-8AAC8D311A10)', Time: '2020-07-30T12:02:44', User OID: 'PatientReportedOutcome (US3052005)', ODM File OID: '21a75983-eb27-4949-bff5-3fee75021242'	System	30 Jul 2020 16:02:46
User entered '30 Jul 2020 12:02'	System	30 Jul 2020 16:02:46

US3052005

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 15:00:53

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:58:03
Data hard unlocked.		25 Feb 2021 15:16:06
Data hard locked.		25 Feb 2021 06:48:14
User entered '30 Jul 2020 11:42'	System	30 Jul 2020 16:00:02

US3052005

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 15:00:53

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:58:03
Data hard unlocked.		25 Feb 2021 15:16:06
Data hard locked.		25 Feb 2021 06:48:14
User entered '30 Jul 2020 14:12'	System	30 Jul 2020 16:00:02

US3052005

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 15:00:53

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:58:03
Data hard unlocked.		25 Feb 2021 15:16:06
Data hard locked.		25 Feb 2021 06:48:14
Data entry locked.	System	30 Jul 2020 16:00:02
User entered 'Day 1, after vaccination (at home)'	System	30 Jul 2020 16:00:02

US3052005

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 15:00:53

Please record - **PAIN AT INJECTION SITE.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:58:03
Data hard unlocked.		25 Feb 2021 15:16:06
Data hard locked.		25 Feb 2021 06:48:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9EADD593-414F-498C-AC00-8AAC8D311A10)', Time: '2020-07-30T21:19:54', User OID: 'PatientReportedOutcome (US3052005)', ODM File OID: 'f857f025-b4f6-412d-98d3-a98fd24e4bee'	System	31 Jul 2020 01:20:15
User entered 'None (1)'	System	31 Jul 2020 01:20:15

US3052005

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 15:00:53

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:58:03
Data hard unlocked.		25 Feb 2021 15:16:06
Data hard locked.		25 Feb 2021 06:48:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9EADD593-414F-498C-AC00-8AAC8D311A10)', Time: '2020-07-30T21:19:59', User OID: 'PatientReportedOutcome (US3052005)', ODM File OID: 'f857f025-b4f6-412d-98d3-a98fd24e4bee'	System	31 Jul 2020 01:20:15
User entered 'No (N)'	System	31 Jul 2020 01:20:15

US3052005

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 15:00:53

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:58:03
Data hard unlocked.		25 Feb 2021 15:16:06
Data hard locked.		25 Feb 2021 06:48:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9EADD593-414F-498C-AC00-8AAC8D311A10)', Time: '2020-07-30T21:20:03', User OID: 'PatientReportedOutcome (US3052005)', ODM File OID: 'f857f025-b4f6-412d-98d3-a98fd24e4bee'	System	31 Jul 2020 01:20:15
User entered 'No (N)'	System	31 Jul 2020 01:20:15

US3052005

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 15:00:53

Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:58:03
Data hard unlocked.		25 Feb 2021 15:16:06
Data hard locked.		25 Feb 2021 06:48:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9EADD593-414F-498C-AC00-8AAC8D311A10)', Time: '2020-07-30T21:20:07', User OID: 'PatientReportedOutcome (US3052005)', ODM File OID: 'f857f025-b4f6-412d-98d3-a98fd24e4bee'	System	31 Jul 2020 01:20:15
User entered 'None (1)'	System	31 Jul 2020 01:20:15

US3052005

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 15:00:53

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:58:03
Data hard unlocked.		25 Feb 2021 15:16:06
Data hard locked.		25 Feb 2021 06:48:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9EADD593-414F-498C-AC00-8AAC8D311A10)', Time: '2020-07-30T21:20:13', User OID: 'PatientReportedOutcome (US3052005)', ODM File OID: 'f857f025-b4f6-412d-98d3-a98fd24e4bee' User entered '30 Jul 2020 21:20'	System	31 Jul 2020 01:20:15
	System	31 Jul 2020 01:20:15

US3052005

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 15:00:53

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:58:03
Data hard unlocked.		25 Feb 2021 15:16:06
Data hard locked.		25 Feb 2021 06:48:14
User entered '30 Jul 2020 15:07'	System	30 Jul 2020 16:00:02

US3052005

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 15:00:53

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:58:03
Data hard unlocked.		25 Feb 2021 15:16:06
Data hard locked.		25 Feb 2021 06:48:14
User entered '31 Jul 2020 11:59'	System	30 Jul 2020 16:00:02

US3052005

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 15:00:53

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:58:03
Data hard unlocked.		25 Feb 2021 15:16:06
Data hard locked.		25 Feb 2021 06:48:14
Data entry locked.	System	30 Jul 2020 16:00:02
User entered 'Day 2'	System	30 Jul 2020 16:00:02

US3052005

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 15:00:53

Please record - **PAIN AT INJECTION SITE.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:58:03
Data hard unlocked.		25 Feb 2021 15:16:06
Data hard locked.		25 Feb 2021 06:48:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9EADD593-414F-498C-AC00-8AAC8D311A10)', Time: '2020-07-31T20:33:13', User OID: 'PatientReportedOutcome (US3052005)', ODM File OID: '22ef23ac-faf3-4d40-a70e-d47d8b573e4b'	System	01 Aug 2020 00:33:32
User entered 'None (1)'	System	01 Aug 2020 00:33:32

US3052005

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 15:00:53

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:58:03
Data hard unlocked.		25 Feb 2021 15:16:06
Data hard locked.		25 Feb 2021 06:48:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9EADD593-414F-498C-AC00-8AAC8D311A10)', Time: '2020-07-31T20:33:16', User OID: 'PatientReportedOutcome (US3052005)', ODM File OID: '22ef23ac-faf3-4d40-a70e-d47d8b573e4b'	System	01 Aug 2020 00:33:32
User entered 'No (N)'	System	01 Aug 2020 00:33:32

US3052005

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 15:00:53

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:58:03
Data hard unlocked.		25 Feb 2021 15:16:06
Data hard locked.		25 Feb 2021 06:48:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9EADD593-414F-498C-AC00-8AAC8D311A10)', Time: '2020-07-31T20:33:20', User OID: 'PatientReportedOutcome (US3052005)', ODM File OID: '22ef23ac-faf3-4d40-a70e-d47d8b573e4b'	System	01 Aug 2020 00:33:32
User entered 'No (N)'	System	01 Aug 2020 00:33:32

US3052005

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 15:00:53

Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:58:03
Data hard unlocked.		25 Feb 2021 15:16:06
Data hard locked.		25 Feb 2021 06:48:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9EADD593-414F-498C-AC00-8AAC8D311A10)', Time: '2020-07-31T20:33:25', User OID: 'PatientReportedOutcome (US3052005)', ODM File OID: '22ef23ac-faf3-4d40-a70e-d47d8b573e4b'	System	01 Aug 2020 00:33:32
User entered 'None (1)'	System	01 Aug 2020 00:33:32

US3052005

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 15:00:53

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:58:03
Data hard unlocked.		25 Feb 2021 15:16:06
Data hard locked.		25 Feb 2021 06:48:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9EADD593-414F-498C-AC00-8AAC8D311A10)', Time: '2020-07-31T20:33:28', User OID: 'PatientReportedOutcome (US3052005)', ODM File OID: '22ef23ac-faf3-4d40-a70e-d47d8b573e4b' User entered '31 Jul 2020 20:33'	System	01 Aug 2020 00:33:32
	System	01 Aug 2020 00:33:32

US3052005

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 15:00:53

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:58:03
Data hard unlocked.		25 Feb 2021 15:16:06
Data hard locked.		25 Feb 2021 06:48:14
User entered '31 Jul 2020 12:00'	System	30 Jul 2020 16:00:02

US3052005

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 15:00:53

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:58:03
Data hard unlocked.		25 Feb 2021 15:16:06
Data hard locked.		25 Feb 2021 06:48:14
User entered '01 Aug 2020 11:59'	System	30 Jul 2020 16:00:02

US3052005

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 15:00:53

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:58:03
Data hard unlocked.		25 Feb 2021 15:16:06
Data hard locked.		25 Feb 2021 06:48:14
Data entry locked.	System	30 Jul 2020 16:00:02
User entered 'Day 3'	System	30 Jul 2020 16:00:02

US3052005

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 15:00:53

Please record - **PAIN AT INJECTION SITE.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:58:03
Data hard unlocked.		25 Feb 2021 15:16:06
Data hard locked.		25 Feb 2021 06:48:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9EADD593-414F-498C-AC00-8AAC8D311A10)', Time: '2020-08-01T22:40:12', User OID: 'PatientReportedOutcome (US3052005)', ODM File OID: 'e8cd5f03-b1eb-4d49-94ef-3861d4851455'	System	02 Aug 2020 02:40:30
User entered 'None (1)'	System	02 Aug 2020 02:40:30

US3052005

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 15:00:53

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:58:03
Data hard unlocked.		25 Feb 2021 15:16:06
Data hard locked.		25 Feb 2021 06:48:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9EADD593-414F-498C-AC00-8AAC8D311A10)', Time: '2020-08-01T22:40:14', User OID: 'PatientReportedOutcome (US3052005)', ODM File OID: 'e8cd5f03-b1eb-4d49-94ef-3861d4851455'	System	02 Aug 2020 02:40:30
User entered 'No (N)'	System	02 Aug 2020 02:40:30

US3052005

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 15:00:53

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:58:03
Data hard unlocked.		25 Feb 2021 15:16:06
Data hard locked.		25 Feb 2021 06:48:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9EADD593-414F-498C-AC00-8AAC8D311A10)', Time: '2020-08-01T22:40:17', User OID: 'PatientReportedOutcome (US3052005)', ODM File OID: 'e8cd5f03-b1eb-4d49-94ef-3861d4851455'	System	02 Aug 2020 02:40:30
User entered 'No (N)'	System	02 Aug 2020 02:40:30

US3052005

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 15:00:53

Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:58:03
Data hard unlocked.		25 Feb 2021 15:16:06
Data hard locked.		25 Feb 2021 06:48:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9EADD593-414F-498C-AC00-8AAC8D311A10)', Time: '2020-08-01T22:40:22', User OID: 'PatientReportedOutcome (US3052005)', ODM File OID: 'e8cd5f03-b1eb-4d49-94ef-3861d4851455'	System	02 Aug 2020 02:40:30
User entered 'None (1)'	System	02 Aug 2020 02:40:30

US3052005

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 15:00:53

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:58:03
Data hard unlocked.		25 Feb 2021 15:16:06
Data hard locked.		25 Feb 2021 06:48:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9EADD593-414F-498C-AC00-8AAC8D311A10)', Time: '2020-08-01T22:40:25', User OID: 'PatientReportedOutcome (US3052005)', ODM File OID: 'e8cd5f03-b1eb-4d49-94ef-3861d4851455'	System	02 Aug 2020 02:40:30
User entered '01 Aug 2020 22:40'	System	02 Aug 2020 02:40:30

US3052005

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 15:00:53

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:58:03
Data hard unlocked.		25 Feb 2021 15:16:06
Data hard locked.		25 Feb 2021 06:48:14
User entered '01 Aug 2020 12:00'	System	30 Jul 2020 16:00:02

US3052005

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 15:00:53

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:58:03
Data hard unlocked.		25 Feb 2021 15:16:06
Data hard locked.		25 Feb 2021 06:48:14
User entered '02 Aug 2020 11:59'	System	30 Jul 2020 16:00:02

US3052005

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 15:00:53

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:58:03
Data hard unlocked.		25 Feb 2021 15:16:06
Data hard locked.		25 Feb 2021 06:48:14
Data entry locked.	System	30 Jul 2020 16:00:02
User entered 'Day 4'	System	30 Jul 2020 16:00:02

US3052005

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 15:00:53

Please record - **PAIN AT INJECTION SITE.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:58:03
Data hard unlocked.		25 Feb 2021 15:16:06
Data hard locked.		25 Feb 2021 06:48:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9EADD593-414F-498C-AC00-8AAC8D311A10)', Time: '2020-08-02T19:08:38', User OID: 'PatientReportedOutcome (US3052005)', ODM File OID: '69ad0d46-ac61-4e64-a864-759c164ba07d'	System	02 Aug 2020 23:08:58
User entered 'None (1)'	System	02 Aug 2020 23:08:58

US3052005

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 15:00:53

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:58:03
Data hard unlocked.		25 Feb 2021 15:16:06
Data hard locked.		25 Feb 2021 06:48:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9EADD593-414F-498C-AC00-8AAC8D311A10)', Time: '2020-08-02T19:08:44', User OID: 'PatientReportedOutcome (US3052005)', ODM File OID: '69ad0d46-ac61-4e64-a864-759c164ba07d'	System	02 Aug 2020 23:08:58
User entered 'No (N)'	System	02 Aug 2020 23:08:58

US3052005

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 15:00:53

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:58:03
Data hard unlocked.		25 Feb 2021 15:16:06
Data hard locked.		25 Feb 2021 06:48:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9EADD593-414F-498C-AC00-8AAC8D311A10)', Time: '2020-08-02T19:08:47', User OID: 'PatientReportedOutcome (US3052005)', ODM File OID: '69ad0d46-ac61-4e64-a864-759c164ba07d'	System	02 Aug 2020 23:08:58
User entered 'No (N)'	System	02 Aug 2020 23:08:58

US3052005

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 15:00:53

Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:58:03
Data hard unlocked.		25 Feb 2021 15:16:06
Data hard locked.		25 Feb 2021 06:48:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9EADD593-414F-498C-AC00-8AAC8D311A10)', Time: '2020-08-02T19:08:53', User OID: 'PatientReportedOutcome (US3052005)', ODM File OID: '69ad0d46-ac61-4e64-a864-759c164ba07d'	System	02 Aug 2020 23:08:58
User entered 'None (1)'	System	02 Aug 2020 23:08:58

US3052005

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 15:00:53

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:58:03
Data hard unlocked.		25 Feb 2021 15:16:06
Data hard locked.		25 Feb 2021 06:48:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9EADD593-414F-498C-AC00-8AAC8D311A10)', Time: '2020-08-02T19:08:56', User OID: 'PatientReportedOutcome (US3052005)', ODM File OID: '69ad0d46-ac61-4e64-a864-759c164ba07d' User entered '02 Aug 2020 19:08'	System	02 Aug 2020 23:08:58
	System	02 Aug 2020 23:08:58

US3052005

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 15:00:53

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:58:03
Data hard unlocked.		25 Feb 2021 15:16:06
Data hard locked.		25 Feb 2021 06:48:14
User entered '02 Aug 2020 12:00'	System	30 Jul 2020 16:00:02

US3052005

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 15:00:53

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:58:03
Data hard unlocked.		25 Feb 2021 15:16:06
Data hard locked.		25 Feb 2021 06:48:14
User entered '03 Aug 2020 11:59'	System	30 Jul 2020 16:00:02

US3052005

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 15:00:53

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:58:03
Data hard unlocked.		25 Feb 2021 15:16:06
Data hard locked.		25 Feb 2021 06:48:14
Data entry locked.	System	30 Jul 2020 16:00:02
User entered 'Day 5'	System	30 Jul 2020 16:00:02

US3052005

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 15:00:53

Please record - **PAIN AT INJECTION SITE.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:58:03
Data hard unlocked.		25 Feb 2021 15:16:06
Data hard locked.		25 Feb 2021 06:48:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9EADD593-414F-498C-AC00-8AAC8D311A10)', Time: '2020-08-04T06:03:39', User OID: 'PatientReportedOutcome (US3052005)', ODM File OID: 'dd0c031a-4361-4178-ab30-052bffb9ecb2'	System	04 Aug 2020 10:03:59
User entered 'None (1)'	System	04 Aug 2020 10:03:59

US3052005

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 15:00:53

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:58:03
Data hard unlocked.		25 Feb 2021 15:16:06
Data hard locked.		25 Feb 2021 06:48:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9EADD593-414F-498C-AC00-8AAC8D311A10)', Time: '2020-08-04T06:03:43', User OID: 'PatientReportedOutcome (US3052005)', ODM File OID: 'dd0c031a-4361-4178-ab30-052bffb9ecb2'	System	04 Aug 2020 10:03:59
User entered 'No (N)'	System	04 Aug 2020 10:03:59

US3052005

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 15:00:53

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:58:03
Data hard unlocked.		25 Feb 2021 15:16:06
Data hard locked.		25 Feb 2021 06:48:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9EADD593-414F-498C-AC00-8AAC8D311A10)', Time: '2020-08-04T06:03:49', User OID: 'PatientReportedOutcome (US3052005)', ODM File OID: 'dd0c031a-4361-4178-ab30-052bffb9ecb2'	System	04 Aug 2020 10:03:59
User entered 'No (N)'	System	04 Aug 2020 10:03:59

US3052005

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 15:00:53

Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:58:03
Data hard unlocked.		25 Feb 2021 15:16:06
Data hard locked.		25 Feb 2021 06:48:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9EADD593-414F-498C-AC00-8AAC8D311A10)', Time: '2020-08-04T06:03:54', User OID: 'PatientReportedOutcome (US3052005)', ODM File OID: 'dd0c031a-4361-4178-ab30-052bffb9ecb2'	System	04 Aug 2020 10:03:59
User entered 'None (1)'	System	04 Aug 2020 10:03:59

US3052005

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 15:00:53

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:58:03
Data hard unlocked.		25 Feb 2021 15:16:06
Data hard locked.		25 Feb 2021 06:48:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9EADD593-414F-498C-AC00-8AAC8D311A10)', Time: '2020-08-04T06:03:57', User OID: 'PatientReportedOutcome (US3052005)', ODM File OID: 'dd0c031a-4361-4178-ab30-052bffb9ecb2'	System	04 Aug 2020 10:03:59
User entered '04 Aug 2020 06:03'	System	04 Aug 2020 10:03:59

US3052005

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 15:00:53

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:58:03
Data hard unlocked.		25 Feb 2021 15:16:06
Data hard locked.		25 Feb 2021 06:48:14
User entered '03 Aug 2020 12:00'	System	30 Jul 2020 16:00:02

US3052005

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 15:00:53

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:58:03
Data hard unlocked.		25 Feb 2021 15:16:06
Data hard locked.		25 Feb 2021 06:48:14
User entered '04 Aug 2020 11:59'	System	30 Jul 2020 16:00:02

US3052005

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 15:00:53

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:58:03
Data hard unlocked.		25 Feb 2021 15:16:06
Data hard locked.		25 Feb 2021 06:48:14
Data entry locked.	System	30 Jul 2020 16:00:02
User entered 'Day 6'	System	30 Jul 2020 16:00:02

US3052005

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 15:00:53

Please record - **PAIN AT INJECTION SITE.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:58:03
Data hard unlocked.		25 Feb 2021 15:16:06
Data hard locked.		25 Feb 2021 06:48:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9EADD593-414F-498C-AC00-8AAC8D311A10)', Time: '2020-08-04T23:35:09', User OID: 'PatientReportedOutcome (US3052005)', ODM File OID: 'b9a1e443-468d-4989-9d0c-bcbba79d341a'	System	05 Aug 2020 03:35:28
User entered 'None (1)'	System	05 Aug 2020 03:35:28

US3052005

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 15:00:53

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:58:03
Data hard unlocked.		25 Feb 2021 15:16:06
Data hard locked.		25 Feb 2021 06:48:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9EADD593-414F-498C-AC00-8AAC8D311A10)', Time: '2020-08-04T23:35:14', User OID: 'PatientReportedOutcome (US3052005)', ODM File OID: 'b9a1e443-468d-4989-9d0c-bcbba79d341a'	System	05 Aug 2020 03:35:28
User entered 'No (N)'	System	05 Aug 2020 03:35:28

US3052005

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 15:00:53

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:58:03
Data hard unlocked.		25 Feb 2021 15:16:06
Data hard locked.		25 Feb 2021 06:48:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9EADD593-414F-498C-AC00-8AAC8D311A10)', Time: '2020-08-04T23:35:18', User OID: 'PatientReportedOutcome (US3052005)', ODM File OID: 'b9a1e443-468d-4989-9d0c-bcbba79d341a'	System	05 Aug 2020 03:35:28
User entered 'No (N)'	System	05 Aug 2020 03:35:28

US3052005

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 15:00:53

Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:58:03
Data hard unlocked.		25 Feb 2021 15:16:06
Data hard locked.		25 Feb 2021 06:48:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9EADD593-414F-498C-AC00-8AAC8D311A10)', Time: '2020-08-04T23:35:21', User OID: 'PatientReportedOutcome (US3052005)', ODM File OID: 'b9a1e443-468d-4989-9d0c-bcbba79d341a'	System	05 Aug 2020 03:35:28
User entered 'None (1)'	System	05 Aug 2020 03:35:28

US3052005

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 15:00:53

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:58:03
Data hard unlocked.		25 Feb 2021 15:16:06
Data hard locked.		25 Feb 2021 06:48:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9EADD593-414F-498C-AC00-8AAC8D311A10)', Time: '2020-08-04T23:35:24', User OID: 'PatientReportedOutcome (US3052005)', ODM File OID: 'b9a1e443-468d-4989-9d0c-bcbba79d341a' User entered '04 Aug 2020 23:35'	System	05 Aug 2020 03:35:28
	System	05 Aug 2020 03:35:28

US3052005

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 15:00:53

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:58:03
Data hard unlocked.		25 Feb 2021 15:16:06
Data hard locked.		25 Feb 2021 06:48:14
User entered '04 Aug 2020 12:00'	System	30 Jul 2020 16:00:02

US3052005

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 15:00:53

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:58:03
Data hard unlocked.		25 Feb 2021 15:16:06
Data hard locked.		25 Feb 2021 06:48:14
User entered '05 Aug 2020 11:59'	System	30 Jul 2020 16:00:02

US3052005

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 15:00:53

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:58:03
Data hard unlocked.		25 Feb 2021 15:16:06
Data hard locked.		25 Feb 2021 06:48:14
Data entry locked.	System	30 Jul 2020 16:00:02
User entered 'Day 7'	System	30 Jul 2020 16:00:02

US3052005

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 15:00:53

Please record - **PAIN AT INJECTION SITE.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:58:03
Data hard unlocked.		25 Feb 2021 15:16:06
Data hard locked.		25 Feb 2021 06:48:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9EADD593-414F-498C-AC00-8AAC8D311A10)', Time: '2020-08-05T21:46:42', User OID: 'PatientReportedOutcome (US3052005)', ODM File OID: 'c94baece-ed2d-4113-8d7c-303038b9714f'	System	06 Aug 2020 01:46:56
User entered 'None (1)'	System	06 Aug 2020 01:46:56

US3052005

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 15:00:53

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:58:03
Data hard unlocked.		25 Feb 2021 15:16:06
Data hard locked.		25 Feb 2021 06:48:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9EADD593-414F-498C-AC00-8AAC8D311A10)', Time: '2020-08-05T21:46:45', User OID: 'PatientReportedOutcome (US3052005)', ODM File OID: 'c94baece-ed2d-4113-8d7c-303038b9714f' User entered 'No (N)'	System	06 Aug 2020 01:46:56
	System	06 Aug 2020 01:46:56

US3052005

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 15:00:53

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:58:03
Data hard unlocked.		25 Feb 2021 15:16:06
Data hard locked.		25 Feb 2021 06:48:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9EADD593-414F-498C-AC00-8AAC8D311A10)', Time: '2020-08-05T21:46:48', User OID: 'PatientReportedOutcome (US3052005)', ODM File OID: 'c94baece-ed2d-4113-8d7c-303038b9714f'	System	06 Aug 2020 01:46:56
User entered 'No (N)'	System	06 Aug 2020 01:46:56

US3052005

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 15:00:53

Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:58:03
Data hard unlocked.		25 Feb 2021 15:16:06
Data hard locked.		25 Feb 2021 06:48:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9EADD593-414F-498C-AC00-8AAC8D311A10)', Time: '2020-08-05T21:46:51', User OID: 'PatientReportedOutcome (US3052005)', ODM File OID: 'c94baece-ed2d-4113-8d7c-303038b9714f'	System	06 Aug 2020 01:46:56
User entered 'None (1)'	System	06 Aug 2020 01:46:56

US3052005

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 15:00:53

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:58:03
Data hard unlocked.		25 Feb 2021 15:16:06
Data hard locked.		25 Feb 2021 06:48:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9EADD593-414F-498C-AC00-8AAC8D311A10)', Time: '2020-08-05T21:46:53', User OID: 'PatientReportedOutcome (US3052005)', ODM File OID: 'c94baece-ed2d-4113-8d7c-303038b9714f' User entered '05 Aug 2020 21:46'	System	06 Aug 2020 01:46:56
	System	06 Aug 2020 01:46:56

US3052005

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 15:00:53

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:58:03
Data hard unlocked.		25 Feb 2021 15:16:06
Data hard locked.		25 Feb 2021 06:48:14
User entered '05 Aug 2020 12:00'	System	30 Jul 2020 16:00:02

US3052005

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 15:00:53

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:58:03
Data hard unlocked.		25 Feb 2021 15:16:06
Data hard locked.		25 Feb 2021 06:48:14
User entered '06 Aug 2020 11:59'	System	30 Jul 2020 16:00:02

US3052005

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 15:00:53

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:58:03
Data hard unlocked.		25 Feb 2021 15:16:45
Data hard locked.		25 Feb 2021 06:48:14
Data entry locked.	System	30 Jul 2020 16:00:02
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	30 Jul 2020 16:00:02

US3052005

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 15:00:53

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:58:03
Data hard unlocked.		25 Feb 2021 15:16:45
Data hard locked.		25 Feb 2021 06:48:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9EADD593-414F-498C-AC00-8AAC8D311A10)', Time: '2020-07-30T12:02:51', User OID: 'PatientReportedOutcome (US3052005)', ODM File OID: '24ae7259-f991-49bf-8058-43fca2262c93'	System	30 Jul 2020 16:03:19
User entered 'None (0)'	System	30 Jul 2020 16:03:19

US3052005

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 15:00:53

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:58:03
Data hard unlocked.		25 Feb 2021 15:16:45
Data hard locked.		25 Feb 2021 06:48:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9EADD593-414F-498C-AC00-8AAC8D311A10)', Time: '2020-07-30T12:02:54', User OID: 'PatientReportedOutcome (US3052005)', ODM File OID: '24ae7259-f991-49bf-8058-43fca2262c93'	System	30 Jul 2020 16:03:19
User entered 'None (0)'	System	30 Jul 2020 16:03:19

US3052005

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 15:00:53

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:58:03
Data hard unlocked.		25 Feb 2021 15:16:45
Data hard locked.		25 Feb 2021 06:48:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9EADD593-414F-498C-AC00-8AAC8D311A10)', Time: '2020-07-30T12:02:57', User OID: 'PatientReportedOutcome (US3052005)', ODM File OID: '24ae7259-f991-49bf-8058-43fca2262c93'	System	30 Jul 2020 16:03:19
User entered 'None (0)'	System	30 Jul 2020 16:03:19

US3052005

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 15:00:53

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:58:03
Data hard unlocked.		25 Feb 2021 15:16:45
Data hard locked.		25 Feb 2021 06:48:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9EADD593-414F-498C-AC00-8AAC8D311A10)', Time: '2020-07-30T12:03:01', User OID: 'PatientReportedOutcome (US3052005)', ODM File OID: '24ae7259-f991-49bf-8058-43fca2262c93'	System	30 Jul 2020 16:03:19
User entered 'None (0)'	System	30 Jul 2020 16:03:19

US3052005

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 15:00:53

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:58:03
Data hard unlocked.		25 Feb 2021 15:16:45
Data hard locked.		25 Feb 2021 06:48:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9EADD593-414F-498C-AC00-8AAC8D311A10)', Time: '2020-07-30T12:03:04', User OID: 'PatientReportedOutcome (US3052005)', ODM File OID: '24ae7259-f991-49bf-8058-43fca2262c93'	System	30 Jul 2020 16:03:19
User entered 'None (0)'	System	30 Jul 2020 16:03:19

US3052005

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 15:00:53

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:58:03
Data hard unlocked.		25 Feb 2021 15:16:45
Data hard locked.		25 Feb 2021 06:48:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9EADD593-414F-498C-AC00-8AAC8D311A10)', Time: '2020-07-30T12:03:08', User OID: 'PatientReportedOutcome (US3052005)', ODM File OID: '24ae7259-f991-49bf-8058-43fca2262c93'	System	30 Jul 2020 16:03:19
User entered 'None (0)'	System	30 Jul 2020 16:03:19

US3052005

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 15:00:53

Did you receive any **MEDICAL ATTENTION** (doctor visit, other) for any illness or symptoms?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:58:03
Data hard unlocked.		25 Feb 2021 15:16:45
Data hard locked.		25 Feb 2021 06:48:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9EADD593-414F-498C-AC00-8AAC8D311A10)', Time: '2020-07-30T12:03:14', User OID: 'PatientReportedOutcome (US3052005)', ODM File OID: '24ae7259-f991-49bf-8058-43fca2262c93'	System	30 Jul 2020 16:03:19
User entered 'No (N)'	System	30 Jul 2020 16:03:19

US3052005

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 15:00:53

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:58:03
Data hard unlocked.		25 Feb 2021 15:16:45
Data hard locked.		25 Feb 2021 06:48:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9EADD593-414F-498C-AC00-8AAC8D311A10)', Time: '2020-07-30T12:03:17', User OID: 'PatientReportedOutcome (US3052005)', ODM File OID: '24ae7259-f991-49bf-8058-43fca2262c93'	System	30 Jul 2020 16:03:19
User entered '30 Jul 2020 12:03'	System	30 Jul 2020 16:03:19

US3052005

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 15:00:53

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:58:03
Data hard unlocked.		25 Feb 2021 15:16:45
Data hard locked.		25 Feb 2021 06:48:14
User entered '30 Jul 2020 11:42'	System	30 Jul 2020 16:00:02

US3052005

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 15:00:53

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:58:03
Data hard unlocked.		25 Feb 2021 15:16:45
Data hard locked.		25 Feb 2021 06:48:14
User entered '30 Jul 2020 14:12'	System	30 Jul 2020 16:00:02

US3052005

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 15:00:53

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:58:03
Data hard unlocked.		25 Feb 2021 15:16:45
Data hard locked.		25 Feb 2021 06:48:14
Data entry locked.	System	30 Jul 2020 16:00:02
User entered 'Day 1, after vaccination (at home)'	System	30 Jul 2020 16:00:02

US3052005

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 15:00:53

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:58:03
Data hard unlocked.		25 Feb 2021 15:16:45
Data hard locked.		25 Feb 2021 06:48:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9EADD593-414F-498C-AC00-8AAC8D311A10)', Time: '2020-07-30T21:20:20', User OID: 'PatientReportedOutcome (US3052005)', ODM File OID: 'd7563a18-3ebc-4a4a-b5c8-0629dea2d8cb' User entered 'None (0)'	System	31 Jul 2020 01:20:48
	System	31 Jul 2020 01:20:48

US3052005

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 15:00:53

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:58:03
Data hard unlocked.		25 Feb 2021 15:16:45
Data hard locked.		25 Feb 2021 06:48:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9EADD593-414F-498C-AC00-8AAC8D311A10)', Time: '2020-07-30T21:20:23', User OID: 'PatientReportedOutcome (US3052005)', ODM File OID: 'd7563a18-3ebc-4a4a-b5c8-0629dea2d8cb' User entered 'None (0)'	System	31 Jul 2020 01:20:48
	System	31 Jul 2020 01:20:48

US3052005

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 15:00:53

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:58:03
Data hard unlocked.		25 Feb 2021 15:16:45
Data hard locked.		25 Feb 2021 06:48:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9EADD593-414F-498C-AC00-8AAC8D311A10)', Time: '2020-07-30T21:20:25', User OID: 'PatientReportedOutcome (US3052005)', ODM File OID: 'd7563a18-3ebc-4a4a-b5c8-0629dea2d8cb'	System	31 Jul 2020 01:20:48
User entered 'None (0)'	System	31 Jul 2020 01:20:48

US3052005

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 15:00:53

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:58:03
Data hard unlocked.		25 Feb 2021 15:16:45
Data hard locked.		25 Feb 2021 06:48:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9EADD593-414F-498C-AC00-8AAC8D311A10)', Time: '2020-07-30T21:20:28', User OID: 'PatientReportedOutcome (US3052005)', ODM File OID: 'd7563a18-3ebc-4a4a-b5c8-0629dea2d8cb' User entered 'None (0)'	System	31 Jul 2020 01:20:48
	System	31 Jul 2020 01:20:48

US3052005

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 15:00:53

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:58:03
Data hard unlocked.		25 Feb 2021 15:16:45
Data hard locked.		25 Feb 2021 06:48:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9EADD593-414F-498C-AC00-8AAC8D311A10)', Time: '2020-07-30T21:20:30', User OID: 'PatientReportedOutcome (US3052005)', ODM File OID: 'd7563a18-3ebc-4a4a-b5c8-0629dea2d8cb' User entered 'None (0)'	System	31 Jul 2020 01:20:48
	System	31 Jul 2020 01:20:48

US3052005

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 15:00:53

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:58:03
Data hard unlocked.		25 Feb 2021 15:16:45
Data hard locked.		25 Feb 2021 06:48:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9EADD593-414F-498C-AC00-8AAC8D311A10)', Time: '2020-07-30T21:20:33', User OID: 'PatientReportedOutcome (US3052005)', ODM File OID: 'd7563a18-3ebc-4a4a-b5c8-0629dea2d8cb' User entered 'None (0)'	System	31 Jul 2020 01:20:48
	System	31 Jul 2020 01:20:48

US3052005

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 15:00:53

Did you receive any **MEDICAL ATTENTION** (doctor visit, other) for any illness or symptoms?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:58:03
Data hard unlocked.		25 Feb 2021 15:16:45
Data hard locked.		25 Feb 2021 06:48:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9EADD593-414F-498C-AC00-8AAC8D311A10)', Time: '2020-07-30T21:20:39', User OID: 'PatientReportedOutcome (US3052005)', ODM File OID: 'd7563a18-3ebc-4a4a-b5c8-0629dea2d8cb'	System	31 Jul 2020 01:20:48
User entered 'No (N)'	System	31 Jul 2020 01:20:48

US3052005

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 15:00:53

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:58:03
Data hard unlocked.		25 Feb 2021 15:16:45
Data hard locked.		25 Feb 2021 06:48:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9EADD593-414F-498C-AC00-8AAC8D311A10)', Time: '2020-07-30T21:20:44', User OID: 'PatientReportedOutcome (US3052005)', ODM File OID: 'd7563a18-3ebc-4a4a-b5c8-0629dea2d8cb' User entered '30 Jul 2020 21:20'	System	31 Jul 2020 01:20:48
	System	31 Jul 2020 01:20:48

US3052005

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 15:00:53

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:58:03
Data hard unlocked.		25 Feb 2021 15:16:45
Data hard locked.		25 Feb 2021 06:48:14
User entered '30 Jul 2020 15:07'	System	30 Jul 2020 16:00:02

US3052005

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 15:00:53

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:58:03
Data hard unlocked.		25 Feb 2021 15:16:45
Data hard locked.		25 Feb 2021 06:48:14
User entered '31 Jul 2020 11:59'	System	30 Jul 2020 16:00:02

US3052005

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 15:00:53

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:58:03
Data hard unlocked.		25 Feb 2021 15:16:45
Data hard locked.		25 Feb 2021 06:48:14
Data entry locked.	System	30 Jul 2020 16:00:02
User entered 'Day 2'	System	30 Jul 2020 16:00:02

US3052005

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 15:00:53

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:58:03
Data hard unlocked.		25 Feb 2021 15:16:45
Data hard locked.		25 Feb 2021 06:48:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9EADD593-414F-498C-AC00-8AAC8D311A10)', Time: '2020-07-31T20:33:34', User OID: 'PatientReportedOutcome (US3052005)', ODM File OID: '8e937f4c-f4e0-45b3-86d6-9729255365ab'	System	01 Aug 2020 00:33:59
User entered 'None (0)'	System	01 Aug 2020 00:33:59

US3052005

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 15:00:53

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:58:03
Data hard unlocked.		25 Feb 2021 15:16:45
Data hard locked.		25 Feb 2021 06:48:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9EADD593-414F-498C-AC00-8AAC8D311A10)', Time: '2020-07-31T20:33:37', User OID: 'PatientReportedOutcome (US3052005)', ODM File OID: '8e937f4c-f4e0-45b3-86d6-9729255365ab'	System	01 Aug 2020 00:33:59
User entered 'None (0)'	System	01 Aug 2020 00:33:59

US3052005

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 15:00:53

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:58:03
Data hard unlocked.		25 Feb 2021 15:16:45
Data hard locked.		25 Feb 2021 06:48:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9EADD593-414F-498C-AC00-8AAC8D311A10)', Time: '2020-07-31T20:33:40', User OID: 'PatientReportedOutcome (US3052005)', ODM File OID: '8e937f4c-f4e0-45b3-86d6-9729255365ab'	System	01 Aug 2020 00:33:59
User entered 'None (0)'	System	01 Aug 2020 00:33:59

US3052005

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 15:00:53

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:58:03
Data hard unlocked.		25 Feb 2021 15:16:45
Data hard locked.		25 Feb 2021 06:48:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9EADD593-414F-498C-AC00-8AAC8D311A10)', Time: '2020-07-31T20:33:43', User OID: 'PatientReportedOutcome (US3052005)', ODM File OID: '8e937f4c-f4e0-45b3-86d6-9729255365ab'	System	01 Aug 2020 00:33:59
User entered 'None (0)'	System	01 Aug 2020 00:33:59

US3052005

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 15:00:53

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:58:03
Data hard unlocked.		25 Feb 2021 15:16:45
Data hard locked.		25 Feb 2021 06:48:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9EADD593-414F-498C-AC00-8AAC8D311A10)', Time: '2020-07-31T20:33:45', User OID: 'PatientReportedOutcome (US3052005)', ODM File OID: '8e937f4c-f4e0-45b3-86d6-9729255365ab'	System	01 Aug 2020 00:33:59
User entered 'None (0)'	System	01 Aug 2020 00:33:59

US3052005

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 15:00:53

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:58:03
Data hard unlocked.		25 Feb 2021 15:16:45
Data hard locked.		25 Feb 2021 06:48:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9EADD593-414F-498C-AC00-8AAC8D311A10)', Time: '2020-07-31T20:33:48', User OID: 'PatientReportedOutcome (US3052005)', ODM File OID: '8e937f4c-f4e0-45b3-86d6-9729255365ab'	System	01 Aug 2020 00:33:59
User entered 'None (0)'	System	01 Aug 2020 00:33:59

US3052005

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 15:00:53

Did you receive any **MEDICAL ATTENTION** (doctor visit, other) for any illness or symptoms?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:58:03
Data hard unlocked.		25 Feb 2021 15:16:45
Data hard locked.		25 Feb 2021 06:48:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9EADD593-414F-498C-AC00-8AAC8D311A10)', Time: '2020-07-31T20:33:53', User OID: 'PatientReportedOutcome (US3052005)', ODM File OID: '8e937f4c-f4e0-45b3-86d6-9729255365ab'	System	01 Aug 2020 00:33:59
User entered 'No (N)'	System	01 Aug 2020 00:33:59

US3052005

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 15:00:53

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:58:03
Data hard unlocked.		25 Feb 2021 15:16:45
Data hard locked.		25 Feb 2021 06:48:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9EADD593-414F-498C-AC00-8AAC8D311A10)', Time: '2020-07-31T20:33:56', User OID: 'PatientReportedOutcome (US3052005)', ODM File OID: '8e937f4c-f4e0-45b3-86d6-9729255365ab' User entered '31 Jul 2020 20:33'	System	01 Aug 2020 00:33:59
	System	01 Aug 2020 00:33:59

US3052005

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 15:00:53

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:58:03
Data hard unlocked.		25 Feb 2021 15:16:45
Data hard locked.		25 Feb 2021 06:48:14
User entered '31 Jul 2020 12:00'		30 Jul 2020 16:00:02

US3052005

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 15:00:53

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:58:03
Data hard unlocked.		25 Feb 2021 15:16:45
Data hard locked.		25 Feb 2021 06:48:14
User entered '01 Aug 2020 11:59'	System	30 Jul 2020 16:00:02

US3052005

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 15:00:53

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:58:03
Data hard unlocked.		25 Feb 2021 15:16:45
Data hard locked.		25 Feb 2021 06:48:14
Data entry locked.	System	30 Jul 2020 16:00:02
User entered 'Day 3'	System	30 Jul 2020 16:00:02

US3052005

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 15:00:53

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:58:03
Data hard unlocked.		25 Feb 2021 15:16:45
Data hard locked.		25 Feb 2021 06:48:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9EADD593-414F-498C-AC00-8AAC8D311A10)', Time: '2020-08-01T22:40:31', User OID: 'PatientReportedOutcome (US3052005)', ODM File OID: '7af22443-de8f-42f5-adc5-f42df26cf6df'	System	02 Aug 2020 02:41:02
User entered 'None (0)'	System	02 Aug 2020 02:41:02

US3052005

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 15:00:53

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:58:03
Data hard unlocked.		25 Feb 2021 15:16:45
Data hard locked.		25 Feb 2021 06:48:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9EADD593-414F-498C-AC00-8AAC8D311A10)', Time: '2020-08-01T22:40:34', User OID: 'PatientReportedOutcome (US3052005)', ODM File OID: '7af22443-de8f-42f5-adc5-f42df26cf6df'	System	02 Aug 2020 02:41:02
User entered 'None (0)'	System	02 Aug 2020 02:41:02

US3052005

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 15:00:53

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:58:03
Data hard unlocked.		25 Feb 2021 15:16:45
Data hard locked.		25 Feb 2021 06:48:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9EADD593-414F-498C-AC00-8AAC8D311A10)', Time: '2020-08-01T22:40:38', User OID: 'PatientReportedOutcome (US3052005)', ODM File OID: '7af22443-de8f-42f5-adc5-f42df26cf6df'	System	02 Aug 2020 02:41:02
User entered 'None (0)'	System	02 Aug 2020 02:41:02

US3052005

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 15:00:53

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:58:03
Data hard unlocked.		25 Feb 2021 15:16:45
Data hard locked.		25 Feb 2021 06:48:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9EADD593-414F-498C-AC00-8AAC8D311A10)', Time: '2020-08-01T22:40:42', User OID: 'PatientReportedOutcome (US3052005)', ODM File OID: '7af22443-de8f-42f5-adc5-f42df26cf6df'	System	02 Aug 2020 02:41:02
User entered 'None (0)'	System	02 Aug 2020 02:41:02

US3052005

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 15:00:53

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:58:03
Data hard unlocked.		25 Feb 2021 15:16:45
Data hard locked.		25 Feb 2021 06:48:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9EADD593-414F-498C-AC00-8AAC8D311A10)', Time: '2020-08-01T22:40:45', User OID: 'PatientReportedOutcome (US3052005)', ODM File OID: '7af22443-de8f-42f5-adc5-f42df26cf6df'	System	02 Aug 2020 02:41:02
User entered 'None (0)'	System	02 Aug 2020 02:41:02

US3052005

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 15:00:53

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:58:03
Data hard unlocked.		25 Feb 2021 15:16:45
Data hard locked.		25 Feb 2021 06:48:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9EADD593-414F-498C-AC00-8AAC8D311A10)', Time: '2020-08-01T22:40:50', User OID: 'PatientReportedOutcome (US3052005)', ODM File OID: '7af22443-de8f-42f5-adc5-f42df26cf6df'	System	02 Aug 2020 02:41:02
User entered 'None (0)'	System	02 Aug 2020 02:41:02

US3052005

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 15:00:53

Did you receive any **MEDICAL ATTENTION** (doctor visit, other) for any illness or symptoms?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:58:03
Data hard unlocked.		25 Feb 2021 15:16:45
Data hard locked.		25 Feb 2021 06:48:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9EADD593-414F-498C-AC00-8AAC8D311A10)', Time: '2020-08-01T22:40:53', User OID: 'PatientReportedOutcome (US3052005)', ODM File OID: '7af22443-de8f-42f5-adc5-f42df26cf6df'	System	02 Aug 2020 02:41:02
User entered 'No (N)'	System	02 Aug 2020 02:41:02

US3052005

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 15:00:53

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:58:03
Data hard unlocked.		25 Feb 2021 15:16:45
Data hard locked.		25 Feb 2021 06:48:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9EADD593-414F-498C-AC00-8AAC8D311A10)', Time: '2020-08-01T22:40:57', User OID: 'PatientReportedOutcome (US3052005)', ODM File OID: '7af22443-de8f-42f5-adc5-f42df26cf6df'	System	02 Aug 2020 02:41:02
User entered '01 Aug 2020 22:40'	System	02 Aug 2020 02:41:02

US3052005

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 15:00:53

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:58:03
Data hard unlocked.		25 Feb 2021 15:16:45
Data hard locked.		25 Feb 2021 06:48:14
User entered '01 Aug 2020 12:00'	System	30 Jul 2020 16:00:02

US3052005

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 15:00:53

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:58:03
Data hard unlocked.		25 Feb 2021 15:16:45
Data hard locked.		25 Feb 2021 06:48:14
User entered '02 Aug 2020 11:59'	System	30 Jul 2020 16:00:02

US3052005

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 15:00:53

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:58:03
Data hard unlocked.		25 Feb 2021 15:16:45
Data hard locked.		25 Feb 2021 06:48:14
Data entry locked.	System	30 Jul 2020 16:00:02
User entered 'Day 4'	System	30 Jul 2020 16:00:02

US3052005

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 15:00:53

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:58:03
Data hard unlocked.		25 Feb 2021 15:16:45
Data hard locked.		25 Feb 2021 06:48:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9EADD593-414F-498C-AC00-8AAC8D311A10)', Time: '2020-08-02T19:09:01', User OID: 'PatientReportedOutcome (US3052005)', ODM File OID: 'b192cf48-1b90-48ef-9d93-2b8ae3aebd22'	System	02 Aug 2020 23:09:32
User entered 'None (0)'	System	02 Aug 2020 23:09:32

US3052005

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 15:00:53

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:58:03
Data hard unlocked.		25 Feb 2021 15:16:45
Data hard locked.		25 Feb 2021 06:48:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9EADD593-414F-498C-AC00-8AAC8D311A10)', Time: '2020-08-02T19:09:05', User OID: 'PatientReportedOutcome (US3052005)', ODM File OID: 'b192cf48-1b90-48ef-9d93-2b8ae3aebd22'	System	02 Aug 2020 23:09:32
User entered 'None (0)'	System	02 Aug 2020 23:09:32

US3052005

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 15:00:53

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:58:03
Data hard unlocked.		25 Feb 2021 15:16:45
Data hard locked.		25 Feb 2021 06:48:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9EADD593-414F-498C-AC00-8AAC8D311A10)', Time: '2020-08-02T19:09:10', User OID: 'PatientReportedOutcome (US3052005)', ODM File OID: 'b192cf48-1b90-48ef-9d93-2b8ae3aebd22'	System	02 Aug 2020 23:09:32
User entered 'None (0)'	System	02 Aug 2020 23:09:32

US3052005

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 15:00:53

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:58:03
Data hard unlocked.		25 Feb 2021 15:16:45
Data hard locked.		25 Feb 2021 06:48:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9EADD593-414F-498C-AC00-8AAC8D311A10)', Time: '2020-08-02T19:09:15', User OID: 'PatientReportedOutcome (US3052005)', ODM File OID: 'b192cf48-1b90-48ef-9d93-2b8ae3aebd22'	System	02 Aug 2020 23:09:32
User entered 'None (0)'	System	02 Aug 2020 23:09:32

US3052005

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 15:00:53

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:58:03
Data hard unlocked.		25 Feb 2021 15:16:45
Data hard locked.		25 Feb 2021 06:48:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9EADD593-414F-498C-AC00-8AAC8D311A10)', Time: '2020-08-02T19:09:19', User OID: 'PatientReportedOutcome (US3052005)', ODM File OID: 'b192cf48-1b90-48ef-9d93-2b8ae3aebd22'	System	02 Aug 2020 23:09:32
User entered 'None (0)'	System	02 Aug 2020 23:09:32

US3052005

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 15:00:53

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:58:03
Data hard unlocked.		25 Feb 2021 15:16:45
Data hard locked.		25 Feb 2021 06:48:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9EADD593-414F-498C-AC00-8AAC8D311A10)', Time: '2020-08-02T19:09:22', User OID: 'PatientReportedOutcome (US3052005)', ODM File OID: 'b192cf48-1b90-48ef-9d93-2b8ae3aebd22'	System	02 Aug 2020 23:09:32
User entered 'None (0)'	System	02 Aug 2020 23:09:32

US3052005

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 15:00:53

Did you receive any **MEDICAL ATTENTION** (doctor visit, other) for any illness or symptoms?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:58:03
Data hard unlocked.		25 Feb 2021 15:16:45
Data hard locked.		25 Feb 2021 06:48:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9EADD593-414F-498C-AC00-8AAC8D311A10)', Time: '2020-08-02T19:09:26', User OID: 'PatientReportedOutcome (US3052005)', ODM File OID: 'b192cf48-1b90-48ef-9d93-2b8ae3aebd22'	System	02 Aug 2020 23:09:32
User entered 'No (N)'	System	02 Aug 2020 23:09:32

US3052005

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 15:00:53

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:58:03
Data hard unlocked.		25 Feb 2021 15:16:45
Data hard locked.		25 Feb 2021 06:48:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9EADD593-414F-498C-AC00-8AAC8D311A10)', Time: '2020-08-02T19:09:29', User OID: 'PatientReportedOutcome (US3052005)', ODM File OID: 'b192cf48-1b90-48ef-9d93-2b8ae3aebd22'	System	02 Aug 2020 23:09:32
User entered '02 Aug 2020 19:09'	System	02 Aug 2020 23:09:32

US3052005

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 15:00:53

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:58:03
Data hard unlocked.		25 Feb 2021 15:16:45
Data hard locked.		25 Feb 2021 06:48:14
User entered '02 Aug 2020 12:00'	System	30 Jul 2020 16:00:02

US3052005

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 15:00:53

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:58:03
Data hard unlocked.		25 Feb 2021 15:16:45
Data hard locked.		25 Feb 2021 06:48:14
User entered '03 Aug 2020 11:59'	System	30 Jul 2020 16:00:02

US3052005

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 15:00:53

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:58:03
Data hard unlocked.		25 Feb 2021 15:16:45
Data hard locked.		25 Feb 2021 06:48:14
Data entry locked.	System	30 Jul 2020 16:00:02
User entered 'Day 5'	System	30 Jul 2020 16:00:02

US3052005

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 15:00:53

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:58:03
Data hard unlocked.		25 Feb 2021 15:16:45
Data hard locked.		25 Feb 2021 06:48:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9EADD593-414F-498C-AC00-8AAC8D311A10)', Time: '2020-08-04T06:04:03', User OID: 'PatientReportedOutcome (US3052005)', ODM File OID: 'ba75ae08-3366-4d2e-b317-ae7e46e2edbc'	System	04 Aug 2020 10:04:27
User entered 'None (0)'	System	04 Aug 2020 10:04:27

US3052005

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 15:00:53

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:58:03
Data hard unlocked.		25 Feb 2021 15:16:45
Data hard locked.		25 Feb 2021 06:48:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9EADD593-414F-498C-AC00-8AAC8D311A10)', Time: '2020-08-04T06:04:05', User OID: 'PatientReportedOutcome (US3052005)', ODM File OID: 'ba75ae08-3366-4d2e-b317-ae7e46e2edbc' User entered 'None (0)'	System	04 Aug 2020 10:04:27
	System	04 Aug 2020 10:04:27

US3052005

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 15:00:53

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:58:03
Data hard unlocked.		25 Feb 2021 15:16:45
Data hard locked.		25 Feb 2021 06:48:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9EADD593-414F-498C-AC00-8AAC8D311A10)', Time: '2020-08-04T06:04:09', User OID: 'PatientReportedOutcome (US3052005)', ODM File OID: 'ba75ae08-3366-4d2e-b317-ae7e46e2edbc'	System	04 Aug 2020 10:04:27
User entered 'None (0)'	System	04 Aug 2020 10:04:27

US3052005

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 15:00:53

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:58:03
Data hard unlocked.		25 Feb 2021 15:16:45
Data hard locked.		25 Feb 2021 06:48:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9EADD593-414F-498C-AC00-8AAC8D311A10)', Time: '2020-08-04T06:04:13', User OID: 'PatientReportedOutcome (US3052005)', ODM File OID: 'ba75ae08-3366-4d2e-b317-ae7e46e2edbc'	System	04 Aug 2020 10:04:27
User entered 'None (0)'	System	04 Aug 2020 10:04:27

US3052005

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 15:00:53

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:58:03
Data hard unlocked.		25 Feb 2021 15:16:45
Data hard locked.		25 Feb 2021 06:48:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9EADD593-414F-498C-AC00-8AAC8D311A10)', Time: '2020-08-04T06:04:16', User OID: 'PatientReportedOutcome (US3052005)', ODM File OID: 'ba75ae08-3366-4d2e-b317-ae7e46e2edbc' User entered 'None (0)'	System	04 Aug 2020 10:04:27
	System	04 Aug 2020 10:04:27

US3052005

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 15:00:53

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:58:03
Data hard unlocked.		25 Feb 2021 15:16:45
Data hard locked.		25 Feb 2021 06:48:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9EADD593-414F-498C-AC00-8AAC8D311A10)', Time: '2020-08-04T06:04:19', User OID: 'PatientReportedOutcome (US3052005)', ODM File OID: 'ba75ae08-3366-4d2e-b317-ae7e46e2edbc'	System	04 Aug 2020 10:04:27
User entered 'None (0)'	System	04 Aug 2020 10:04:27

US3052005

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 15:00:53

Did you receive any **MEDICAL ATTENTION** (doctor visit, other) for any illness or symptoms?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:58:03
Data hard unlocked.		25 Feb 2021 15:16:45
Data hard locked.		25 Feb 2021 06:48:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9EADD593-414F-498C-AC00-8AAC8D311A10)', Time: '2020-08-04T06:04:22', User OID: 'PatientReportedOutcome (US3052005)', ODM File OID: 'ba75ae08-3366-4d2e-b317-ae7e46e2edbc'	System	04 Aug 2020 10:04:27
User entered 'No (N)'	System	04 Aug 2020 10:04:27

US3052005

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 15:00:53

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:58:03
Data hard unlocked.		25 Feb 2021 15:16:45
Data hard locked.		25 Feb 2021 06:48:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9EADD593-414F-498C-AC00-8AAC8D311A10)', Time: '2020-08-04T06:04:26', User OID: 'PatientReportedOutcome (US3052005)', ODM File OID: 'ba75ae08-3366-4d2e-b317-ae7e46e2edbc'	System	04 Aug 2020 10:04:27
User entered '04 Aug 2020 06:04'	System	04 Aug 2020 10:04:27

US3052005

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 15:00:53

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:58:03
Data hard unlocked.		25 Feb 2021 15:16:45
Data hard locked.		25 Feb 2021 06:48:14
User entered '03 Aug 2020 12:00'	System	30 Jul 2020 16:00:02

US3052005

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 15:00:53

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:58:03
Data hard unlocked.		25 Feb 2021 15:16:45
Data hard locked.		25 Feb 2021 06:48:14
User entered '04 Aug 2020 11:59'	System	30 Jul 2020 16:00:02

US3052005

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 15:00:53

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:58:03
Data hard unlocked.		25 Feb 2021 15:16:45
Data hard locked.		25 Feb 2021 06:48:14
Data entry locked.	System	30 Jul 2020 16:00:02
User entered 'Day 6'	System	30 Jul 2020 16:00:02

US3052005

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 15:00:53

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:58:03
Data hard unlocked.		25 Feb 2021 15:16:45
Data hard locked.		25 Feb 2021 06:48:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9EADD593-414F-498C-AC00-8AAC8D311A10)', Time: '2020-08-04T23:35:29', User OID: 'PatientReportedOutcome (US3052005)', ODM File OID: '671fa276-1301-445d-8802-e7ee12ec8b8f'	System	05 Aug 2020 03:35:53
User entered 'None (0)'	System	05 Aug 2020 03:35:53

US3052005

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 15:00:53

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:58:03
Data hard unlocked.		25 Feb 2021 15:16:45
Data hard locked.		25 Feb 2021 06:48:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9EADD593-414F-498C-AC00-8AAC8D311A10)', Time: '2020-08-04T23:35:31', User OID: 'PatientReportedOutcome (US3052005)', ODM File OID: '671fa276-1301-445d-8802-e7ee12ec8b8f' User entered 'None (0)'	System	05 Aug 2020 03:35:53
	System	05 Aug 2020 03:35:53

US3052005

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 15:00:53

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:58:03
Data hard unlocked.		25 Feb 2021 15:16:45
Data hard locked.		25 Feb 2021 06:48:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9EADD593-414F-498C-AC00-8AAC8D311A10)', Time: '2020-08-04T23:35:34', User OID: 'PatientReportedOutcome (US3052005)', ODM File OID: '671fa276-1301-445d-8802-e7ee12ec8b8f' User entered 'None (0)'	System	05 Aug 2020 03:35:53
	System	05 Aug 2020 03:35:53

US3052005

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 15:00:53

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:58:03
Data hard unlocked.		25 Feb 2021 15:16:45
Data hard locked.		25 Feb 2021 06:48:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9EADD593-414F-498C-AC00-8AAC8D311A10)', Time: '2020-08-04T23:35:38', User OID: 'PatientReportedOutcome (US3052005)', ODM File OID: '671fa276-1301-445d-8802-e7ee12ec8b8f' User entered 'None (0)'	System	05 Aug 2020 03:35:53
	System	05 Aug 2020 03:35:53

US3052005

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 15:00:53

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:58:03
Data hard unlocked.		25 Feb 2021 15:16:45
Data hard locked.		25 Feb 2021 06:48:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9EADD593-414F-498C-AC00-8AAC8D311A10)', Time: '2020-08-04T23:35:41', User OID: 'PatientReportedOutcome (US3052005)', ODM File OID: '671fa276-1301-445d-8802-e7ee12ec8b8f' User entered 'None (0)'	System	05 Aug 2020 03:35:53
	System	05 Aug 2020 03:35:53

US3052005

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 15:00:53

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:58:03
Data hard unlocked.		25 Feb 2021 15:16:45
Data hard locked.		25 Feb 2021 06:48:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9EADD593-414F-498C-AC00-8AAC8D311A10)', Time: '2020-08-04T23:35:44', User OID: 'PatientReportedOutcome (US3052005)', ODM File OID: '671fa276-1301-445d-8802-e7ee12ec8b8f' User entered 'None (0)'	System	05 Aug 2020 03:35:53
	System	05 Aug 2020 03:35:53

US3052005

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 15:00:53

Did you receive any **MEDICAL ATTENTION** (doctor visit, other) for any illness or symptoms?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:58:03
Data hard unlocked.		25 Feb 2021 15:16:45
Data hard locked.		25 Feb 2021 06:48:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9EADD593-414F-498C-AC00-8AAC8D311A10)', Time: '2020-08-04T23:35:48', User OID: 'PatientReportedOutcome (US3052005)', ODM File OID: '671fa276-1301-445d-8802-e7ee12ec8b8f'	System	05 Aug 2020 03:35:53
User entered 'No (N)'	System	05 Aug 2020 03:35:53

US3052005

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 15:00:53

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:58:03
Data hard unlocked.		25 Feb 2021 15:16:45
Data hard locked.		25 Feb 2021 06:48:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9EADD593-414F-498C-AC00-8AAC8D311A10)', Time: '2020-08-04T23:35:50', User OID: 'PatientReportedOutcome (US3052005)', ODM File OID: '671fa276-1301-445d-8802-e7ee12ec8b8f' User entered '04 Aug 2020 23:35'	System	05 Aug 2020 03:35:53
	System	05 Aug 2020 03:35:53

US3052005

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 15:00:53

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:58:03
Data hard unlocked.		25 Feb 2021 15:16:45
Data hard locked.		25 Feb 2021 06:48:14
User entered '04 Aug 2020 12:00'	System	30 Jul 2020 16:00:02

US3052005

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 15:00:53

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:58:03
Data hard unlocked.		25 Feb 2021 15:16:45
Data hard locked.		25 Feb 2021 06:48:14
User entered '05 Aug 2020 11:59'	System	30 Jul 2020 16:00:02

US3052005

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 15:00:53

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:58:03
Data hard unlocked.		25 Feb 2021 15:16:45
Data hard locked.		25 Feb 2021 06:48:14
Data entry locked.	System	30 Jul 2020 16:00:02
User entered 'Day 7'	System	30 Jul 2020 16:00:02

US3052005

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 15:00:53

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:58:03
Data hard unlocked.		25 Feb 2021 15:16:45
Data hard locked.		25 Feb 2021 06:48:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9EADD593-414F-498C-AC00-8AAC8D311A10)', Time: '2020-08-05T21:46:58', User OID: 'PatientReportedOutcome (US3052005)', ODM File OID: '594c5f1e-9d85-4144-b8b4-035929c17d49'	System	06 Aug 2020 01:47:23
User entered 'None (0)'	System	06 Aug 2020 01:47:23

US3052005

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 15:00:53

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:58:03
Data hard unlocked.		25 Feb 2021 15:16:45
Data hard locked.		25 Feb 2021 06:48:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9EADD593-414F-498C-AC00-8AAC8D311A10)', Time: '2020-08-05T21:47:03', User OID: 'PatientReportedOutcome (US3052005)', ODM File OID: '594c5f1e-9d85-4144-b8b4-035929c17d49'	System	06 Aug 2020 01:47:23
User entered 'None (0)'	System	06 Aug 2020 01:47:23

US3052005

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 15:00:53

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:58:03
Data hard unlocked.		25 Feb 2021 15:16:45
Data hard locked.		25 Feb 2021 06:48:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9EADD593-414F-498C-AC00-8AAC8D311A10)', Time: '2020-08-05T21:47:06', User OID: 'PatientReportedOutcome (US3052005)', ODM File OID: '594c5f1e-9d85-4144-b8b4-035929c17d49'	System	06 Aug 2020 01:47:23
User entered 'None (0)'	System	06 Aug 2020 01:47:23

US3052005

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 15:00:53

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:58:03
Data hard unlocked.		25 Feb 2021 15:16:45
Data hard locked.		25 Feb 2021 06:48:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9EADD593-414F-498C-AC00-8AAC8D311A10)', Time: '2020-08-05T21:47:10', User OID: 'PatientReportedOutcome (US3052005)', ODM File OID: '594c5f1e-9d85-4144-b8b4-035929c17d49'	System	06 Aug 2020 01:47:23
User entered 'None (0)'	System	06 Aug 2020 01:47:23

US3052005

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 15:00:53

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:58:03
Data hard unlocked.		25 Feb 2021 15:16:45
Data hard locked.		25 Feb 2021 06:48:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9EADD593-414F-498C-AC00-8AAC8D311A10)', Time: '2020-08-05T21:47:13', User OID: 'PatientReportedOutcome (US3052005)', ODM File OID: '594c5f1e-9d85-4144-b8b4-035929c17d49'	System	06 Aug 2020 01:47:23
User entered 'None (0)'	System	06 Aug 2020 01:47:23

US3052005

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 15:00:53

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:58:03
Data hard unlocked.		25 Feb 2021 15:16:45
Data hard locked.		25 Feb 2021 06:48:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9EADD593-414F-498C-AC00-8AAC8D311A10)', Time: '2020-08-05T21:47:16', User OID: 'PatientReportedOutcome (US3052005)', ODM File OID: '594c5f1e-9d85-4144-b8b4-035929c17d49'	System	06 Aug 2020 01:47:23
User entered 'None (0)'	System	06 Aug 2020 01:47:23

US3052005

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 15:00:53

Did you receive any **MEDICAL ATTENTION** (doctor visit, other) for any illness or symptoms?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:58:03
Data hard unlocked.		25 Feb 2021 15:16:45
Data hard locked.		25 Feb 2021 06:48:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9EADD593-414F-498C-AC00-8AAC8D311A10)', Time: '2020-08-05T21:47:19', User OID: 'PatientReportedOutcome (US3052005)', ODM File OID: '594c5f1e-9d85-4144-b8b4-035929c17d49'	System	06 Aug 2020 01:47:23
User entered 'No (N)'	System	06 Aug 2020 01:47:23

US3052005

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 15:00:53

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:58:03
Data hard unlocked.		25 Feb 2021 15:16:45
Data hard locked.		25 Feb 2021 06:48:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9EADD593-414F-498C-AC00-8AAC8D311A10)', Time: '2020-08-05T21:47:22', User OID: 'PatientReportedOutcome (US3052005)', ODM File OID: '594c5f1e-9d85-4144-b8b4-035929c17d49'	System	06 Aug 2020 01:47:23
User entered '05 Aug 2020 21:47'	System	06 Aug 2020 01:47:23

US3052005

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 15:00:53

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:58:03
Data hard unlocked.		25 Feb 2021 15:16:45
Data hard locked.		25 Feb 2021 06:48:14
User entered '05 Aug 2020 12:00'		30 Jul 2020 16:00:02

US3052005

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 15:00:53

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:58:03
Data hard unlocked.		25 Feb 2021 15:16:45
Data hard locked.		25 Feb 2021 06:48:14
User entered '06 Aug 2020 11:59'	System	30 Jul 2020 16:00:02

US3052005

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:00:53

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:41:16
User signature succeeded.	Judith Borger (b) (4)	23 Feb 2021 07:32:26
User entered 'Yes (Y)'	(b) (4) Stacey Saldua (b) (4)	21 Sep 2020 19:31:34

US3052005

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:00:53

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:41:16
User signature succeeded.	Judith Borger (b) (4)	23 Feb 2021 07:32:26
User entered '09 Aug 2020'	Stacey Saldua (b) (4)	21 Sep 2020 19:31:34

US3052005

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:00:53

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:41:16
User signature succeeded.	Judith Borger (b) (4)	23 Feb 2021 07:32:26
User entered 'Contact Made (CONTACT MADE)'	(b) (4) Stacey Saldua (b) (4)	21 Sep 2020 19:31:34

US3052005

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:00:53

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:41:16
User signature succeeded.	Judith Borger (b) (4)	23 Feb 2021 07:32:26
User entered empty.	(b) (4) Stacey Saldua (b) (4) (b) (4)	21 Sep 2020 19:31:34

US3052005

Folder: Safety Call Day 8 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:00:53

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:41:16
User signature succeeded.	Judith Borger (b) (4)	23 Feb 2021 07:32:26
User entered 'Yes (Y)'	amy sheets (b) (4)	18 Aug 2020 14:46:42

US3052005

Folder: Safety Call Day 8 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:00:53

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:41:16
User entered 'I'	System	18 Aug 2020 14:46:42

US3052005

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:00:53

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:41:16
User signature succeeded.	Judith Borger (b) (4)	23 Feb 2021 07:32:26
User entered 'Yes (Y)'	(b) (4) amy sheets (b) (4) (b) (4)	20 Aug 2020 12:53:21

US3052005

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:00:53

Date of Contact or Contact Attempt (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:41:16
User signature succeeded.	Judith Borger (b) (4)	23 Feb 2021 07:32:26
User closed query 'Safety Call Day 15 'Date of Contact or Contact Attempt' is less than 14 days or greater than 17 days after Visit 1 Treatment Date on the Exposure Form. Please review and reconcile, or clarify.' (Site from System).	(b) (4) (b) (4), (b) (6)	08 Oct 2020 09:00:27
Query 'Safety Call Day 15 'Date of Contact or Contact Attempt' is less than 14 days or greater than 17 days after Visit 1 Treatment Date on the Exposure Form. Please review and reconcile, or clarify.' answered with 'Confirmed 18 AUG call date' (Site from System).	Avia McClain-Stocker (b) (4)	07 Oct 2020 15:43:17
User opened query 'Safety Call Day 15 'Date of Contact or Contact Attempt' is less than 14 days or greater than 17 days after Visit 1 Treatment Date on the Exposure Form. Please review and reconcile, or clarify.' (Site from System).	System	20 Aug 2020 12:53:21
User entered '18 Aug 2020'	amy sheets (b) (4) (b) (4)	20 Aug 2020 12:53:21

US3052005

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:00:53

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:41:16
User signature succeeded.	Judith Borger (b) (4)	23 Feb 2021 07:32:26
User entered 'Contact Made (CONTACT MADE)'	(b) (4) amy sheets (b) (4) (b) (4)	20 Aug 2020 12:53:21

US3052005

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:00:53

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:41:16
User signature succeeded.	Judith Borger (b) (4)	23 Feb 2021 07:32:26
User entered empty.	(b) (4) amy sheets (b) (4) (b) (4)	20 Aug 2020 12:53:21

US3052005

Folder: Safety Call Day 15 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:00:53

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:41:16
User signature succeeded.	Judith Borger (b) (4)	23 Feb 2021 07:32:26
User entered 'Yes (Y)'	(b) (4) amy sheets (b) (4) (b) (4)	20 Aug 2020 12:53:28

US3052005

Folder: Safety Call Day 15 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:00:53

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:41:16
User entered 'I'	System	20 Aug 2020 12:53:28

US3052005

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:00:53

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:41:16
User signature succeeded.	Judith Borger (b) (4)	23 Feb 2021 07:32:26
User entered 'No (N)'	(b) (4) Avia McClain-Stocker (b) (4)	08 Oct 2020 18:42:35

US3052005

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:00:53

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:41:16
User signature succeeded.	Judith Borger (b) (4)	23 Feb 2021 07:32:26
User entered empty.	(b) (4) Avia McClain-Stocker (b) (4)	08 Oct 2020 18:42:35

US3052005

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:00:53

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:41:16
User signature succeeded.	Judith Borger (b) (4)	23 Feb 2021 07:32:26
User entered empty.	(b) (4) Avia McClain-Stocker (b) (4)	08 Oct 2020 18:42:35

US3052005

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:00:53

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:41:16
User signature succeeded.	Judith Borger (b) (4)	23 Feb 2021 07:32:26
User entered empty.	(b) (4) Avia McClain-Stocker (b) (4)	08 Oct 2020 18:42:35

US3052005

Folder: Safety Call Day 22 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:00:53

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:41:16
User signature succeeded.	Judith Borger (b) (4)	23 Feb 2021 07:32:26
User entered 'Yes (Y)'	Nicole Davis (b) (4)	26 Aug 2020 15:02:48

US3052005

Folder: Safety Call Day 22 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:00:53

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:41:16
User entered 'I'	System	26 Aug 2020 15:02:48

US3052005

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 09 Jun 2021 15:00:53

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:41:16
User signature succeeded.	Judith Borger (b) (4)	23 Feb 2021 07:32:26
User entered 'Yes (Y)'	Nicole Davis (b) (4)	26 Aug 2020 15:03:25

US3052005

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 09 Jun 2021 15:00:53

[Visit date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:41:16
User signature succeeded.	Judith Borger (b) (4)	23 Feb 2021 07:32:26
Query 'Visit 2 Date is < 28 days or > 35 days after Visit 1 vaccination. Please reconcile or confirm dates.' canceled (Site from System).	(b) (4) (b) (4), (b) (6)	27 Aug 2020 00:36:44
User opened query 'Visit 2 Date is < 28 days or > 35 days after Visit 1 vaccination. Please reconcile or confirm dates.' (Site from System).	System	26 Aug 2020 15:03:25
User entered '26 Aug 2020'	Nicole Davis (b) (4) (b) (4)	26 Aug 2020 15:03:25

US3052005

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 09 Jun 2021 15:00:53

[Was visit performed at the participant's home or at the clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:41:16
User signature succeeded.	Judith Borger (b) (4)	23 Feb 2021 07:32:26
User entered 'Clinic (Clinic)'	Nicole Davis (b) (4)	26 Aug 2020 15:03:25

US3052005

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 09 Jun 2021 15:00:53

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:41:16
User entered 'VISIT2'	System	26 Aug 2020 15:03:25

US3052005

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:00:53

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:41:16
User accepted default value 'Pre-Dose (PREDOSE)'	Stacey Saldua (b) (4) (b) (4)	01 Oct 2020 18:46:46

US3052005

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:00:53

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:41:16
User signature succeeded.	Judith Borger (b) (4)	23 Feb 2021 07:32:26
User entered 'Yes (Y)'	(b) (4) Stacey Saldua (b) (4)	01 Oct 2020 18:46:46

US3052005

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:00:53

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:41:16
User signature succeeded.	Judith Borger (b) (4)	23 Feb 2021 07:32:26
User entered '26 Aug 2020'	(b) (4) Stacey Saldua (b) (4)	01 Oct 2020 18:46:46

US3052005

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:00:53

Time of assessment (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:41:16
User signature succeeded.	Judith Borger (b) (4)	23 Feb 2021 07:32:26
User entered '10:00'	(b) (4) Stacey Saldua (b) (4) (b) (4)	01 Oct 2020 18:46:46

US3052005

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:00:53

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:41:16
User entered '26 Aug 2020 10:00'	System	01 Oct 2020 18:46:46

US3052005

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:00:53

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:41:16
User signature succeeded.	Judith Borger (b) (4)	23 Feb 2021 07:32:26
User entered '97.8' F	(b) (4) Stacey Saldua (b) (4)	01 Oct 2020 18:46:46

US3052005

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:00:53

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:41:16
User signature succeeded.	Judith Borger (b) (4)	23 Feb 2021 07:32:26
User entered 'Oral (Oral)'	(b) (4) Stacey Saldua (b) (4)	01 Oct 2020 18:46:46
	(b) (4)	

US3052005

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:00:53

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:41:16
User signature succeeded.	Judith Borger (b) (4)	23 Feb 2021 07:32:26
User entered empty.	(b) (4) Stacey Saldua (b) (4)	01 Oct 2020 18:46:46
	(b) (4)	

US3052005

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:00:53

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:41:16
User signature succeeded.	Judith Borger (b) (4)	23 Feb 2021 07:32:26
User entered '58'	(b) (4) Stacey Saldua (b) (4) (b) (4)	01 Oct 2020 18:46:46

US3052005

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:00:53

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:41:16
User entered 'bpm'	System	01 Oct 2020 18:46:46

US3052005

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:00:53

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:41:16
User signature succeeded.	Judith Borger (b) (4)	23 Feb 2021 07:32:26
User entered '18'	(b) (4) Stacey Saldua (b) (4) (b) (4)	01 Oct 2020 18:46:46

US3052005

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:00:53

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:41:16
User entered 'breaths/min'	System	01 Oct 2020 18:46:46

US3052005

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:00:53

[Systolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:41:16
User signature succeeded.	Judith Borger (b) (4)	23 Feb 2021 07:32:26
User entered '112'	(b) (4) Stacey Saldua (b) (4)	01 Oct 2020 18:46:46

US3052005

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:00:53

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:41:16
User entered 'mmHg'	System	01 Oct 2020 18:46:46

US3052005

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:00:53

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:41:16
User signature succeeded.	Judith Borger (b) (4)	23 Feb 2021 07:32:26
User entered '72'	(b) (4) Stacey Saldua (b) (4)	01 Oct 2020 18:46:46

US3052005

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:00:53

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:41:16
User entered 'mmHg'	System	01 Oct 2020 18:46:46

US3052005

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:00:53

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:41:16
User accepted default value 'Post-Dose (POSTDOSE)'	Stacey Saldua (b) (4) (b) (4)	01 Oct 2020 18:46:46

US3052005

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:00:53

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:41:16
User signature succeeded.	Judith Borger (b) (4)	23 Feb 2021 07:32:26
User entered 'Yes (Y)'	(b) (4) Stacey Saldua (b) (4)	01 Oct 2020 18:46:46

US3052005

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:00:53

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:41:16
User signature succeeded.	Judith Borger (b) (4)	23 Feb 2021 07:32:26
User entered '26 Aug 2020'	(b) (4) Stacey Saldua (b) (4)	01 Oct 2020 18:46:46

US3052005

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:00:53

Time of assessment (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:41:16
User signature succeeded.	Judith Borger (b) (4)	23 Feb 2021 07:32:26
User entered '11:57'	(b) (4) Stacey Saldua (b) (4)	01 Oct 2020 18:46:46

US3052005

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:00:53

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:41:16
User entered '26 Aug 2020 11:57'	System	01 Oct 2020 18:46:46

US3052005

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:00:53

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:41:16
User signature succeeded.	Judith Borger (b) (4)	23 Feb 2021 07:32:26
User entered '97.9' F	Stacey Saldua (b) (4)	01 Oct 2020 18:46:46

US3052005

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:00:53

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:41:16
User signature succeeded.	Judith Borger (b) (4)	23 Feb 2021 07:32:26
User entered 'Oral (Oral)'	(b) (4) Stacey Saldua (b) (4)	01 Oct 2020 18:46:46

US3052005

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:00:53

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:41:16
User signature succeeded.	Judith Borger (b) (4)	23 Feb 2021 07:32:26
User entered empty.	(b) (4) Stacey Saldua (b) (4)	01 Oct 2020 18:46:46
	(b) (4)	

US3052005

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:00:53

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:41:16
User signature succeeded.	Judith Borger (b) (4)	23 Feb 2021 07:32:26
User entered '52'	(b) (4) Stacey Saldua (b) (4)	01 Oct 2020 18:46:46

US3052005

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:00:53

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:41:16
User entered 'bpm'	System	01 Oct 2020 18:46:46

US3052005

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:00:53

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:41:16
User signature succeeded.	Judith Borger (b) (4)	23 Feb 2021 07:32:26
User entered '18'	(b) (4) Stacey Saldua (b) (4)	01 Oct 2020 18:46:46

US3052005

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:00:53

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:41:16
User entered 'breaths/min'	System	01 Oct 2020 18:46:46

US3052005

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:00:53

[Systolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:41:16
User signature succeeded.	Judith Borger (b) (4)	23 Feb 2021 07:32:26
User entered '122'	(b) (4) Stacey Saldua (b) (4) (b) (4)	01 Oct 2020 18:46:46

US3052005

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:00:53

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:41:16
User entered 'mmHg'	System	01 Oct 2020 18:46:46

US3052005

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:00:53

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:41:16
User signature succeeded.	Judith Borger (b) (4)	23 Feb 2021 07:32:26
User entered '83'	(b) (4) Stacey Saldua (b) (4)	01 Oct 2020 18:46:46

US3052005

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:00:53

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:41:16
User entered 'mmHg'	System	01 Oct 2020 18:46:46

US3052005

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 15:00:53

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:41:16
User signature succeeded.	Judith Borger (b) (4)	23 Feb 2021 07:32:26
User entered 'Yes (Y)'	Nicole Davis (b) (4)	26 Aug 2020 15:03:34

US3052005

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 15:00:53

Date of examination (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:41:16
User signature succeeded.	Judith Borger (b) (4)	23 Feb 2021 07:32:26
User entered '26 Aug 2020'	Nicole Davis (b) (4)	26 Aug 2020 15:03:34

US3052005

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 15:00:53

[Was study treatment given?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:41:16
User signature succeeded.	Judith Borger (b) (4)	23 Feb 2021 07:32:26
User entered 'Yes (Y)'	(b) (4) Nicole Davis (b) (4)	26 Aug 2020 15:29:38

US3052005

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 15:00:53

If No, reason not given

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:41:16
User signature succeeded.	Judith Borger (b) (4)	23 Feb 2021 07:32:26
User entered empty.	Nicole Davis (b) (4)	26 Aug 2020 15:29:38

US3052005

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 15:00:53

If reason is Physician Decision, Withdrawal of Consent by Participant, Protocol Deviation, or Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:41:16
User signature succeeded.	Judith Borger (b) (4)	23 Feb 2021 07:32:26
User entered empty.	Nicole Davis (b) (4)	26 Aug 2020 15:29:38

US3052005

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 15:00:53

[What was the study treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:41:16
User entered 'MRNA-1273 OR PLACEBO'	System	26 Aug 2020 15:29:38

US3052005

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 15:00:53

What was the treatment date? (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:41:16
User signature succeeded.	Judith Borger (b) (4)	23 Feb 2021 07:32:26
User entered '26 Aug 2020'	Nicole Davis (b) (4)	26 Aug 2020 15:29:38

US3052005

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 15:00:53

[What was the treatment time? \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:41:16
User signature succeeded.	Judith Borger (b) (4)	23 Feb 2021 07:32:26
User entered '11:27'	Nicole Davis (b) (4)	26 Aug 2020 15:29:38

US3052005

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 15:00:53

[Treatment Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:41:16
User entered '26 Aug 2020 11:27'	System	26 Aug 2020 15:29:38

US3052005

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 15:00:53

[Which arm was used to give treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:41:16
User signature succeeded.	Judith Borger (b) (4)	23 Feb 2021 07:32:26
User entered 'Left Arm (LEFT ARM)'	Nicole Davis (b) (4)	26 Aug 2020 15:29:38

US3052005

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 15:00:53

What was the frequency of the study treatment dosing?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:41:16
User entered 'ONCE'	System	26 Aug 2020 15:29:38

US3052005

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 15:00:53

What was the route of administration for the study treatment?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:41:16
User entered 'INTRAMUSCULAR'	System	26 Aug 2020 15:29:38

US3052005

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 15:00:53

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:41:16
User signature succeeded.	Judith Borger (b) (4)	23 Feb 2021 07:32:26
User entered 'Yes (Y)'	Nicole Davis (b) (4)	26 Aug 2020 15:04:05

US3052005

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 15:00:53

Collection date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:41:16
User signature succeeded.	Judith Borger (b) (4)	23 Feb 2021 07:32:26
User closed query 'Per IMMUNO Lab Recon: it appears a sample was collected on 26AUG2020; however, it has not been received by GCL. Please clarify.' (Site from DM).	(b) (4) (b) (4), (b) (6)	04 Nov 2020 15:16:40
Query 'Per IMMUNO Lab Recon: it appears a samplemy sheets was collected on 26AUG2020; however, it has not been received by GCL. Please clarify.' answered with 'the samples were shipped and received at preclarus ' (Site from DM).	(b) (4) (b) (4)	08 Oct 2020 00:23:41
User opened query 'Per IMMUNO Lab Recon: it appears a sample was collected on 26AUG2020; however, it has not been received by GCL. Please clarify.' (Site from DM).	(b) (4), (b) (6)	01 Oct 2020 16:03:11
User entered '26 Aug 2020'	Nicole Davis (b) (4) (b) (4)	26 Aug 2020 15:04:05

US3052005

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 15:00:53

Collection time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:41:16
User signature succeeded.	Judith Borger (b) (4)	23 Feb 2021 07:32:26
User entered '10:04'	Nicole Davis (b) (4)	26 Aug 2020 15:04:05

US3052005

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 15:00:53

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:41:16
User entered '26 Aug 2020 10:04'	System	26 Aug 2020 15:04:05

US3052005

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab

Generated On: 09 Jun 2021 15:00:53

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:41:16
User signature succeeded.	Judith Borger (b) (4)	23 Feb 2021 07:32:26
User entered '26 Aug 2020'	(b) (4) Nicole Davis (b) (4)	26 Aug 2020 15:04:23

US3052005

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 15:00:53

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:41:16
User accepted default value 'Nasopharyngeal Swab 1 (NASAL1)'	Nicole Davis (b) (4) (b) (4)	26 Aug 2020 15:04:23

US3052005

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 15:00:53

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:41:16
User signature succeeded.	Judith Borger (b) (4)	23 Feb 2021 07:32:26
User entered 'Yes (Y)'	(b) (4) Nicole Davis (b) (4)	26 Aug 2020 15:04:23

US3052005

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 15:00:53

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:41:16
User signature succeeded.	Judith Borger (b) (4)	23 Feb 2021 07:32:26
User entered '10:07'	Nicole Davis (b) (4)	26 Aug 2020 15:04:23

US3052005

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 15:00:53

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:41:16
User entered '26 Aug 2020 10:07'	System	26 Aug 2020 15:04:23

US3052005

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 15:00:53

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:41:16
User accepted default value 'Nasopharyngeal Swab 2 (NASAL2)'	Nicole Davis (b) (4) (b) (4)	26 Aug 2020 15:04:23

US3052005

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 15:00:53

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:41:16
User signature succeeded.	Judith Borger (b) (4)	23 Feb 2021 07:32:26
User entered 'No (N)'	(b) (4) Nicole Davis (b) (4)	26 Aug 2020 15:04:23

US3052005

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 15:00:53

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:41:16
User signature succeeded.	Judith Borger (b) (4)	23 Feb 2021 07:32:26
User entered empty.	Nicole Davis (b) (4)	26 Aug 2020 15:04:23

US3052005

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 15:00:53

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:41:16
User entered empty.	System	26 Aug 2020 15:04:23

US3052005

Folder: Visit 2 Day 29 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:00:53

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:41:16
User signature succeeded.	Judith Borger (b) (4)	23 Feb 2021 07:32:26
User entered 'Yes (Y)'	(b) (4) Nicole Davis (b) (4)	26 Aug 2020 15:04:29

US3052005

Folder: Visit 2 Day 29 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:00:53

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:41:16
User entered 'I'	System	26 Aug 2020 15:04:29

US3052005

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 15:00:53

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:58:03
Data hard unlocked.		25 Feb 2021 15:17:11
Data hard locked.		25 Feb 2021 06:48:14
Data entry locked.	System	26 Aug 2020 15:29:38
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	26 Aug 2020 15:29:38

US3052005

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 15:00:53

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:58:03
Data hard unlocked.		25 Feb 2021 15:17:11
Data hard locked.		25 Feb 2021 06:48:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9EADD593-414F-498C-AC00-8AAC8D311A10)', Time: '2020-08-26T11:55:56', User OID: 'PatientReportedOutcome (US3052005)', ODM File OID: '9de277d4-581a-4fba-b13a-36273609efb7'	System	26 Aug 2020 15:57:41
User entered 'Yes (Y)'	System	26 Aug 2020 15:57:41

US3052005

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 15:00:53

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:58:03
Data hard unlocked.		25 Feb 2021 15:17:11
Data hard locked.		25 Feb 2021 06:48:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9EADD593-414F-498C-AC00-8AAC8D311A10)', Time: '2020-08-26T11:56:03', User OID: 'PatientReportedOutcome (US3052005)', ODM File OID: '9de277d4-581a-4fba-b13a-36273609efb7'	System	26 Aug 2020 15:57:41
User entered '97.9'	System	26 Aug 2020 15:57:41

US3052005

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 15:00:53

Was any **MEDICATION TAKEN** today for pain or fever?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:58:03
Data hard unlocked.		25 Feb 2021 15:17:11
Data hard locked.		25 Feb 2021 06:48:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9EADD593-414F-498C-AC00-8AAC8D311A10)', Time: '2020-08-26T11:57:34', User OID: 'PatientReportedOutcome (US3052005)', ODM File OID: '9de277d4-581a-4fba-b13a-36273609efb7'	System	26 Aug 2020 15:57:41
User entered 'No (N)'	System	26 Aug 2020 15:57:41

US3052005

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 15:00:53

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:58:03
Data hard unlocked.		25 Feb 2021 15:17:11
Data hard locked.		25 Feb 2021 06:48:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9EADD593-414F-498C-AC00-8AAC8D311A10)', Time: '2020-08-26T11:57:38', User OID: 'PatientReportedOutcome (US3052005)', ODM File OID: '9de277d4-581a-4fba-b13a-36273609efb7'	System	26 Aug 2020 15:57:41
User entered '26 Aug 2020 11:57'	System	26 Aug 2020 15:57:41

US3052005

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 15:00:53

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:58:03
Data hard unlocked.		25 Feb 2021 15:17:11
Data hard locked.		25 Feb 2021 06:48:14
User entered '26 Aug 2020 11:47'	System	26 Aug 2020 15:29:38

US3052005

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 15:00:53

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:58:03
Data hard unlocked.		25 Feb 2021 15:17:11
Data hard locked.		25 Feb 2021 06:48:14
User entered '26 Aug 2020 14:17'	System	26 Aug 2020 15:29:38

US3052005

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 15:00:53

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:58:03
Data hard unlocked.		25 Feb 2021 15:17:11
Data hard locked.		25 Feb 2021 06:48:14
Data entry locked.	System	26 Aug 2020 15:29:38
User entered 'Day 1, after vaccination (at home)'	System	26 Aug 2020 15:29:38

US3052005

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 15:00:53

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:58:03
Data hard unlocked.		25 Feb 2021 15:17:11
Data hard locked.		25 Feb 2021 06:48:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9EADD593-414F-498C-AC00-8AAC8D311A10)', Time: '2020-08-26T17:44:50', User OID: 'PatientReportedOutcome (US3052005)', ODM File OID: 'e0c1f4b7-a2da-4e5c-9adc-6915e0e63cf5'	System	26 Aug 2020 21:45:15
User entered 'Yes (Y)'	System	26 Aug 2020 21:45:15

US3052005

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 15:00:53

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:58:03
Data hard unlocked.		25 Feb 2021 15:17:11
Data hard locked.		25 Feb 2021 06:48:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9EADD593-414F-498C-AC00-8AAC8D311A10)', Time: '2020-08-26T17:45:00', User OID: 'PatientReportedOutcome (US3052005)', ODM File OID: 'e0c1f4b7-a2da-4e5c-9adc-6915e0e63cf5' User entered '95.7'	System	26 Aug 2020 21:45:15
	System	26 Aug 2020 21:45:15

US3052005

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 15:00:53

Was any **MEDICATION TAKEN** today for pain or fever?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:58:03
Data hard unlocked.		25 Feb 2021 15:17:11
Data hard locked.		25 Feb 2021 06:48:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9EADD593-414F-498C-AC00-8AAC8D311A10)', Time: '2020-08-26T17:45:06', User OID: 'PatientReportedOutcome (US3052005)', ODM File OID: 'e0c1f4b7-a2da-4e5c-9adc-6915e0e63cf5'	System	26 Aug 2020 21:45:15
User entered 'No (N)'	System	26 Aug 2020 21:45:15

US3052005

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 15:00:53

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:58:03
Data hard unlocked.		25 Feb 2021 15:17:11
Data hard locked.		25 Feb 2021 06:48:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9EADD593-414F-498C-AC00-8AAC8D311A10)', Time: '2020-08-26T17:45:12', User OID: 'PatientReportedOutcome (US3052005)', ODM File OID: 'e0c1f4b7-a2da-4e5c-9adc-6915e0e63cf5' User entered '26 Aug 2020 17:45'	System	26 Aug 2020 21:45:15
	System	26 Aug 2020 21:45:15

US3052005

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 15:00:53

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:58:03
Data hard unlocked.		25 Feb 2021 15:17:11
Data hard locked.		25 Feb 2021 06:48:14
User entered '26 Aug 2020 15:12'	System	26 Aug 2020 15:29:38

US3052005

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 15:00:53

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:58:03
Data hard unlocked.		25 Feb 2021 15:17:11
Data hard locked.		25 Feb 2021 06:48:14
User entered '27 Aug 2020 11:59'	System	26 Aug 2020 15:29:38

US3052005

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 15:00:53

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:58:03
Data hard unlocked.		25 Feb 2021 15:17:11
Data hard locked.		25 Feb 2021 06:48:14
Data entry locked.	System	26 Aug 2020 15:29:38
User entered 'Day 2'	System	26 Aug 2020 15:29:38

US3052005

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 15:00:53

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:58:03
Data hard unlocked.		25 Feb 2021 15:17:11
Data hard locked.		25 Feb 2021 06:48:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9EADD593-414F-498C-AC00-8AAC8D311A10)', Time: '2020-08-27T18:23:21', User OID: 'PatientReportedOutcome (US3052005)', ODM File OID: '944f6598-0bcb-40b2-8725-cc99c810fad5'	System	27 Aug 2020 22:23:45
User entered 'Yes (Y)'	System	27 Aug 2020 22:23:45

US3052005

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 15:00:53

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:58:03
Data hard unlocked.		25 Feb 2021 15:17:11
Data hard locked.		25 Feb 2021 06:48:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9EADD593-414F-498C-AC00-8AAC8D311A10)', Time: '2020-08-27T18:23:29', User OID: 'PatientReportedOutcome (US3052005)', ODM File OID: '944f6598-0bcb-40b2-8725-cc99c810fad5'	System	27 Aug 2020 22:23:45
User entered '96.8'	System	27 Aug 2020 22:23:45

US3052005

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 15:00:53

Was any **MEDICATION TAKEN** today for pain or fever?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:58:03
Data hard unlocked.		25 Feb 2021 15:17:11
Data hard locked.		25 Feb 2021 06:48:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9EADD593-414F-498C-AC00-8AAC8D311A10)', Time: '2020-08-27T18:23:34', User OID: 'PatientReportedOutcome (US3052005)', ODM File OID: '944f6598-0bcb-40b2-8725-cc99c810fad5'	System	27 Aug 2020 22:23:45
User entered 'No (N)'	System	27 Aug 2020 22:23:45

US3052005

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 15:00:53

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:58:03
Data hard unlocked.		25 Feb 2021 15:17:11
Data hard locked.		25 Feb 2021 06:48:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9EADD593-414F-498C-AC00-8AAC8D311A10)', Time: '2020-08-27T18:23:39', User OID: 'PatientReportedOutcome (US3052005)', ODM File OID: '944f6598-0bcb-40b2-8725-cc99c810fad5' User entered '27 Aug 2020 18:23'	System	27 Aug 2020 22:23:45
	System	27 Aug 2020 22:23:45

US3052005

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 15:00:53

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:58:03
Data hard unlocked.		25 Feb 2021 15:17:11
Data hard locked.		25 Feb 2021 06:48:14
User entered '27 Aug 2020 12:00'	System	26 Aug 2020 15:29:38

US3052005

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 15:00:53

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:58:03
Data hard unlocked.		25 Feb 2021 15:17:11
Data hard locked.		25 Feb 2021 06:48:14
User entered '28 Aug 2020 11:59'	System	26 Aug 2020 15:29:38

US3052005

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 15:00:53

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:58:03
Data hard unlocked.		25 Feb 2021 15:17:11
Data hard locked.		25 Feb 2021 06:48:14
Data entry locked.	System	26 Aug 2020 15:29:38
User entered 'Day 3'	System	26 Aug 2020 15:29:38

US3052005

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 15:00:53

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:58:03
Data hard unlocked.		25 Feb 2021 15:17:11
Data hard locked.		25 Feb 2021 06:48:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9EADD593-414F-498C-AC00-8AAC8D311A10)', Time: '2020-08-28T20:37:28', User OID: 'PatientReportedOutcome (US3052005)', ODM File OID: '25f1e895-ca16-4a29-9715-90fb3cacc6c1' User entered 'Yes (Y)'	System	29 Aug 2020 00:37:45
	System	29 Aug 2020 00:37:45

US3052005

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 15:00:53

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:58:03
Data hard unlocked.		25 Feb 2021 15:17:11
Data hard locked.		25 Feb 2021 06:48:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9EADD593-414F-498C-AC00-8AAC8D311A10)', Time: '2020-08-28T20:37:34', User OID: 'PatientReportedOutcome (US3052005)', ODM File OID: '25f1e895-ca16-4a29-9715-90fb3cacc6c1' User entered '95.6'	System	29 Aug 2020 00:37:45
	System	29 Aug 2020 00:37:45

US3052005

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 15:00:53

Was any **MEDICATION TAKEN** today for pain or fever?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:58:03
Data hard unlocked.		25 Feb 2021 15:17:11
Data hard locked.		25 Feb 2021 06:48:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9EADD593-414F-498C-AC00-8AAC8D311A10)', Time: '2020-08-28T20:37:39', User OID: 'PatientReportedOutcome (US3052005)', ODM File OID: '25f1e895-ca16-4a29-9715-90fb3cacc6c1'	System	29 Aug 2020 00:37:45
User entered 'No (N)'	System	29 Aug 2020 00:37:45

US3052005

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 15:00:53

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:58:03
Data hard unlocked.		25 Feb 2021 15:17:11
Data hard locked.		25 Feb 2021 06:48:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9EADD593-414F-498C-AC00-8AAC8D311A10)', Time: '2020-08-28T20:37:42', User OID: 'PatientReportedOutcome (US3052005)', ODM File OID: '25f1e895-ca16-4a29-9715-90fb3cacc6c1' User entered '28 Aug 2020 20:37'	System	29 Aug 2020 00:37:45
	System	29 Aug 2020 00:37:45

US3052005

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 15:00:53

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:58:03
Data hard unlocked.		25 Feb 2021 15:17:11
Data hard locked.		25 Feb 2021 06:48:14
User entered '28 Aug 2020 12:00'	System	26 Aug 2020 15:29:38

US3052005

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 15:00:53

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:58:03
Data hard unlocked.		25 Feb 2021 15:17:11
Data hard locked.		25 Feb 2021 06:48:14
User entered '29 Aug 2020 11:59'	System	26 Aug 2020 15:29:38

US3052005

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 15:00:53

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:58:03
Data hard unlocked.		25 Feb 2021 15:17:11
Data hard locked.		25 Feb 2021 06:48:14
Data entry locked.	System	26 Aug 2020 15:29:38
User entered 'Day 4'	System	26 Aug 2020 15:29:38

US3052005

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 15:00:53

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:58:03
Data hard unlocked.		25 Feb 2021 15:17:11
Data hard locked.		25 Feb 2021 06:48:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9EADD593-414F-498C-AC00-8AAC8D311A10)', Time: '2020-08-29T12:33:09', User OID: 'PatientReportedOutcome (US3052005)', ODM File OID: 'aeeb63a1-7034-4c06-a485-26f90d555247'	System	29 Aug 2020 16:33:41
User entered 'Yes (Y)'	System	29 Aug 2020 16:33:41

US3052005

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 15:00:53

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:58:03
Data hard unlocked.		25 Feb 2021 15:17:11
Data hard locked.		25 Feb 2021 06:48:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9EADD593-414F-498C-AC00-8AAC8D311A10)', Time: '2020-08-29T12:33:29', User OID: 'PatientReportedOutcome (US3052005)', ODM File OID: 'aeeb63a1-7034-4c06-a485-26f90d555247'	System	29 Aug 2020 16:33:41
User entered '97.7'	System	29 Aug 2020 16:33:41

US3052005

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 15:00:53

Was any **MEDICATION TAKEN** today for pain or fever?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:58:03
Data hard unlocked.		25 Feb 2021 15:17:11
Data hard locked.		25 Feb 2021 06:48:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9EADD593-414F-498C-AC00-8AAC8D311A10)', Time: '2020-08-29T12:33:36', User OID: 'PatientReportedOutcome (US3052005)', ODM File OID: 'aeeb63a1-7034-4c06-a485-26f90d555247'	System	29 Aug 2020 16:33:41
User entered 'No (N)'	System	29 Aug 2020 16:33:41

US3052005

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 15:00:53

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:58:03
Data hard unlocked.		25 Feb 2021 15:17:11
Data hard locked.		25 Feb 2021 06:48:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9EADD593-414F-498C-AC00-8AAC8D311A10)', Time: '2020-08-29T12:33:39', User OID: 'PatientReportedOutcome (US3052005)', ODM File OID: 'aeeb63a1-7034-4c06-a485-26f90d555247' User entered '29 Aug 2020 12:33'	System	29 Aug 2020 16:33:41
	System	29 Aug 2020 16:33:41

US3052005

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 15:00:53

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:58:03
Data hard unlocked.		25 Feb 2021 15:17:11
Data hard locked.		25 Feb 2021 06:48:14
User entered '29 Aug 2020 12:00'	System	26 Aug 2020 15:29:38

US3052005

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 15:00:53

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:58:03
Data hard unlocked.		25 Feb 2021 15:17:11
Data hard locked.		25 Feb 2021 06:48:14
User entered '30 Aug 2020 11:59'	System	26 Aug 2020 15:29:38

US3052005

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 15:00:53

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:58:03
Data hard unlocked.		25 Feb 2021 15:17:11
Data hard locked.		25 Feb 2021 06:48:14
Data entry locked.	System	26 Aug 2020 15:29:38
User entered 'Day 5'	System	26 Aug 2020 15:29:38

US3052005

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 15:00:53

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:58:03
Data hard unlocked.		25 Feb 2021 15:17:11
Data hard locked.		25 Feb 2021 06:48:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9EADD593-414F-498C-AC00-8AAC8D311A10)', Time: '2020-08-30T19:20:31', User OID: 'PatientReportedOutcome (US3052005)', ODM File OID: 'd78c8df5-6824-48eb-b296-647da229cb0d'	System	30 Aug 2020 23:21:00
User entered 'Yes (Y)'	System	30 Aug 2020 23:21:00

US3052005

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 15:00:53

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:58:03
Data hard unlocked.		25 Feb 2021 15:17:11
Data hard locked.		25 Feb 2021 06:48:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9EADD593-414F-498C-AC00-8AAC8D311A10)', Time: '2020-08-30T19:20:45', User OID: 'PatientReportedOutcome (US3052005)', ODM File OID: 'd78c8df5-6824-48eb-b296-647da229cb0d'	System	30 Aug 2020 23:21:00
User entered '96.6'	System	30 Aug 2020 23:21:00

US3052005

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 15:00:53

Was any **MEDICATION TAKEN** today for pain or fever?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:58:03
Data hard unlocked.		25 Feb 2021 15:17:11
Data hard locked.		25 Feb 2021 06:48:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9EADD593-414F-498C-AC00-8AAC8D311A10)', Time: '2020-08-30T19:20:53', User OID: 'PatientReportedOutcome (US3052005)', ODM File OID: 'd78c8df5-6824-48eb-b296-647da229cb0d'	System	30 Aug 2020 23:21:00
User entered 'No (N)'	System	30 Aug 2020 23:21:00

US3052005

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 15:00:53

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:58:03
Data hard unlocked.		25 Feb 2021 15:17:11
Data hard locked.		25 Feb 2021 06:48:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9EADD593-414F-498C-AC00-8AAC8D311A10)', Time: '2020-08-30T19:20:56', User OID: 'PatientReportedOutcome (US3052005)', ODM File OID: 'd78c8df5-6824-48eb-b296-647da229cb0d'	System	30 Aug 2020 23:21:00
User entered '30 Aug 2020 19:20'	System	30 Aug 2020 23:21:00

US3052005

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 15:00:53

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:58:03
Data hard unlocked.		25 Feb 2021 15:17:11
Data hard locked.		25 Feb 2021 06:48:14
User entered '30 Aug 2020 12:00'	System	26 Aug 2020 15:29:38

US3052005

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 15:00:53

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:58:03
Data hard unlocked.		25 Feb 2021 15:17:11
Data hard locked.		25 Feb 2021 06:48:14
User entered '31 Aug 2020 11:59'	System	26 Aug 2020 15:29:38

US3052005

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 15:00:53

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:58:03
Data hard unlocked.		25 Feb 2021 15:17:11
Data hard locked.		25 Feb 2021 06:48:14
Data entry locked.	System	26 Aug 2020 15:29:38
User entered 'Day 6'	System	26 Aug 2020 15:29:38

US3052005

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 15:00:53

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:58:03
Data hard unlocked.		25 Feb 2021 15:17:11
Data hard locked.		25 Feb 2021 06:48:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9EADD593-414F-498C-AC00-8AAC8D311A10)', Time: '2020-09-01T00:19:05', User OID: 'PatientReportedOutcome (US3052005)', ODM File OID: 'e2c5b16b-793a-4b26-ae3d-286adaf33817'	System	01 Sep 2020 04:19:23
User entered 'Yes (Y)'	System	01 Sep 2020 04:19:23

US3052005

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 15:00:53

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:58:03
Data hard unlocked.		25 Feb 2021 15:17:11
Data hard locked.		25 Feb 2021 06:48:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9EADD593-414F-498C-AC00-8AAC8D311A10)', Time: '2020-09-01T00:19:14', User OID: 'PatientReportedOutcome (US3052005)', ODM File OID: 'e2c5b16b-793a-4b26-ae3d-286adaf33817'	System	01 Sep 2020 04:19:23
User entered '96.6'	System	01 Sep 2020 04:19:23

US3052005

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 15:00:53

Was any **MEDICATION TAKEN** today for pain or fever?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:58:03
Data hard unlocked.		25 Feb 2021 15:17:11
Data hard locked.		25 Feb 2021 06:48:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9EADD593-414F-498C-AC00-8AAC8D311A10)', Time: '2020-09-01T00:19:19', User OID: 'PatientReportedOutcome (US3052005)', ODM File OID: 'e2c5b16b-793a-4b26-ae3d-286adaf33817'	System	01 Sep 2020 04:19:23
User entered 'No (N)'	System	01 Sep 2020 04:19:23

US3052005

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 15:00:53

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:58:03
Data hard unlocked.		25 Feb 2021 15:17:11
Data hard locked.		25 Feb 2021 06:48:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9EADD593-414F-498C-AC00-8AAC8D311A10)', Time: '2020-09-01T00:19:22', User OID: 'PatientReportedOutcome (US3052005)', ODM File OID: 'e2c5b16b-793a-4b26-ae3d-286adaf33817' User entered '01 Sep 2020 00:19'	System	01 Sep 2020 04:19:23
	System	01 Sep 2020 04:19:23

US3052005

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 15:00:53

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:58:03
Data hard unlocked.		25 Feb 2021 15:17:11
Data hard locked.		25 Feb 2021 06:48:14
User entered '31 Aug 2020 12:00'	System	26 Aug 2020 15:29:38

US3052005

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 15:00:53

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:58:03
Data hard unlocked.		25 Feb 2021 15:17:11
Data hard locked.		25 Feb 2021 06:48:14
User entered '01 Sep 2020 11:59'	System	26 Aug 2020 15:29:38

US3052005

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 15:00:53

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:58:03
Data hard unlocked.		25 Feb 2021 15:17:11
Data hard locked.		25 Feb 2021 06:48:14
Data entry locked.	System	26 Aug 2020 15:29:38
User entered 'Day 7'	System	26 Aug 2020 15:29:38

US3052005

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 15:00:53

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:58:03
Data hard unlocked.		25 Feb 2021 15:17:11
Data hard locked.		25 Feb 2021 06:48:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9EADD593-414F-498C-AC00-8AAC8D311A10)', Time: '2020-09-01T18:48:50', User OID: 'PatientReportedOutcome (US3052005)', ODM File OID: '30355746-b94d-4eac-a021-2c91744bff64'	System	01 Sep 2020 22:49:10
User entered 'Yes (Y)'	System	01 Sep 2020 22:49:10

US3052005

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 15:00:53

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:58:03
Data hard unlocked.		25 Feb 2021 15:17:11
Data hard locked.		25 Feb 2021 06:48:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9EADD593-414F-498C-AC00-8AAC8D311A10)', Time: '2020-09-01T18:48:59', User OID: 'PatientReportedOutcome (US3052005)', ODM File OID: '30355746-b94d-4eac-a021-2c91744bff64'	System	01 Sep 2020 22:49:10
User entered '96.6'	System	01 Sep 2020 22:49:10

US3052005

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 15:00:53

Was any **MEDICATION TAKEN** today for pain or fever?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:58:03
Data hard unlocked.		25 Feb 2021 15:17:11
Data hard locked.		25 Feb 2021 06:48:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9EADD593-414F-498C-AC00-8AAC8D311A10)', Time: '2020-09-01T18:49:04', User OID: 'PatientReportedOutcome (US3052005)', ODM File OID: '30355746-b94d-4eac-a021-2c91744bff64'	System	01 Sep 2020 22:49:10
User entered 'No (N)'	System	01 Sep 2020 22:49:10

US3052005

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 15:00:53

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:58:03
Data hard unlocked.		25 Feb 2021 15:17:11
Data hard locked.		25 Feb 2021 06:48:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9EADD593-414F-498C-AC00-8AAC8D311A10)', Time: '2020-09-01T18:49:06', User OID: 'PatientReportedOutcome (US3052005)', ODM File OID: '30355746-b94d-4eac-a021-2c91744bfff64'	System	01 Sep 2020 22:49:10
User entered '01 Sep 2020 18:49'	System	01 Sep 2020 22:49:10

US3052005

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 15:00:53

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:58:03
Data hard unlocked.		25 Feb 2021 15:17:11
Data hard locked.		25 Feb 2021 06:48:14
User entered '01 Sep 2020 12:00'	System	26 Aug 2020 15:29:38

US3052005

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 15:00:53

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:58:03
Data hard unlocked.		25 Feb 2021 15:17:11
Data hard locked.		25 Feb 2021 06:48:14
User entered '02 Sep 2020 11:59'	System	26 Aug 2020 15:29:38

US3052005

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 15:00:53

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:58:03
Data hard unlocked.		25 Feb 2021 15:17:19
Data hard locked.		25 Feb 2021 06:48:14
Data entry locked.	System	26 Aug 2020 15:29:38
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	26 Aug 2020 15:29:38

US3052005

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 15:00:53

Please record - **PAIN AT INJECTION SITE.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:58:03
Data hard unlocked.		25 Feb 2021 15:17:19
Data hard locked.		25 Feb 2021 06:48:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9EADD593-414F-498C-AC00-8AAC8D311A10)', Time: '2020-08-26T11:54:07', User OID: 'PatientReportedOutcome (US3052005)', ODM File OID: 'f672373d-734b-4c1a-8ee4-7b7df5671c73'	System	26 Aug 2020 15:54:42
User entered 'None (1)'	System	26 Aug 2020 15:54:42

US3052005

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 15:00:53

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:58:03
Data hard unlocked.		25 Feb 2021 15:17:19
Data hard locked.		25 Feb 2021 06:48:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9EADD593-414F-498C-AC00-8AAC8D311A10)', Time: '2020-08-26T11:54:13', User OID: 'PatientReportedOutcome (US3052005)', ODM File OID: 'f672373d-734b-4c1a-8ee4-7b7df5671c73'	System	26 Aug 2020 15:54:42
User entered 'No (N)'	System	26 Aug 2020 15:54:42

US3052005

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 15:00:53

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:58:03
Data hard unlocked.		25 Feb 2021 15:17:19
Data hard locked.		25 Feb 2021 06:48:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9EADD593-414F-498C-AC00-8AAC8D311A10)', Time: '2020-08-26T11:54:16', User OID: 'PatientReportedOutcome (US3052005)', ODM File OID: 'f672373d-734b-4c1a-8ee4-7b7df5671c73'	System	26 Aug 2020 15:54:42
User entered 'No (N)'	System	26 Aug 2020 15:54:42

US3052005

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 15:00:53

Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:58:03
Data hard unlocked.		25 Feb 2021 15:17:19
Data hard locked.		25 Feb 2021 06:48:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9EADD593-414F-498C-AC00-8AAC8D311A10)', Time: '2020-08-26T11:54:23', User OID: 'PatientReportedOutcome (US3052005)', ODM File OID: 'f672373d-734b-4c1a-8ee4-7b7df5671c73'	System	26 Aug 2020 15:54:42
User entered 'None (1)'	System	26 Aug 2020 15:54:42

US3052005

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 15:00:53

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:58:03
Data hard unlocked.		25 Feb 2021 15:17:19
Data hard locked.		25 Feb 2021 06:48:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9EADD593-414F-498C-AC00-8AAC8D311A10)', Time: '2020-08-26T11:54:39', User OID: 'PatientReportedOutcome (US3052005)', ODM File OID: 'f672373d-734b-4c1a-8ee4-7b7df5671c73'	System	26 Aug 2020 15:54:42
User entered '26 Aug 2020 11:54'	System	26 Aug 2020 15:54:42

US3052005

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 15:00:53

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:58:03
Data hard unlocked.		25 Feb 2021 15:17:19
Data hard locked.		25 Feb 2021 06:48:14
User entered '26 Aug 2020 11:47'	System	26 Aug 2020 15:29:38

US3052005

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 15:00:53

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:58:03
Data hard unlocked.		25 Feb 2021 15:17:19
Data hard locked.		25 Feb 2021 06:48:14
User entered '26 Aug 2020 14:17'		26 Aug 2020 15:29:38

US3052005

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 15:00:53

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:58:03
Data hard unlocked.		25 Feb 2021 15:17:19
Data hard locked.		25 Feb 2021 06:48:14
Data entry locked.	System	26 Aug 2020 15:29:38
User entered 'Day 1, after vaccination (at home)'	System	26 Aug 2020 15:29:38

US3052005

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 15:00:53

Please record - **PAIN AT INJECTION SITE.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:58:03
Data hard unlocked.		25 Feb 2021 15:17:19
Data hard locked.		25 Feb 2021 06:48:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9EADD593-414F-498C-AC00-8AAC8D311A10)', Time: '2020-08-26T17:45:18', User OID: 'PatientReportedOutcome (US3052005)', ODM File OID: '460967d3-a79b-4853-9f7d-cb0090b34254'	System	26 Aug 2020 21:45:37
User entered 'None (1)'	System	26 Aug 2020 21:45:37

US3052005

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 15:00:53

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:58:03
Data hard unlocked.		25 Feb 2021 15:17:19
Data hard locked.		25 Feb 2021 06:48:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9EADD593-414F-498C-AC00-8AAC8D311A10)', Time: '2020-08-26T17:45:24', User OID: 'PatientReportedOutcome (US3052005)', ODM File OID: '460967d3-a79b-4853-9f7d-cb0090b34254'	System	26 Aug 2020 21:45:37
User entered 'No (N)'	System	26 Aug 2020 21:45:37

US3052005

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 15:00:53

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:58:03
Data hard unlocked.		25 Feb 2021 15:17:19
Data hard locked.		25 Feb 2021 06:48:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9EADD593-414F-498C-AC00-8AAC8D311A10)', Time: '2020-08-26T17:45:28', User OID: 'PatientReportedOutcome (US3052005)', ODM File OID: '460967d3-a79b-4853-9f7d-cb0090b34254'	System	26 Aug 2020 21:45:37
User entered 'No (N)'	System	26 Aug 2020 21:45:37

US3052005

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 15:00:53

Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:58:03
Data hard unlocked.		25 Feb 2021 15:17:19
Data hard locked.		25 Feb 2021 06:48:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9EADD593-414F-498C-AC00-8AAC8D311A10)', Time: '2020-08-26T17:45:31', User OID: 'PatientReportedOutcome (US3052005)', ODM File OID: '460967d3-a79b-4853-9f7d-cb0090b34254'	System	26 Aug 2020 21:45:37
User entered 'None (1)'	System	26 Aug 2020 21:45:37

US3052005

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 15:00:53

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:58:03
Data hard unlocked.		25 Feb 2021 15:17:19
Data hard locked.		25 Feb 2021 06:48:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9EADD593-414F-498C-AC00-8AAC8D311A10)', Time: '2020-08-26T17:45:34', User OID: 'PatientReportedOutcome (US3052005)', ODM File OID: '460967d3-a79b-4853-9f7d-cb0090b34254'	System	26 Aug 2020 21:45:37
User entered '26 Aug 2020 17:45'	System	26 Aug 2020 21:45:37

US3052005

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 15:00:53

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:58:03
Data hard unlocked.		25 Feb 2021 15:17:19
Data hard locked.		25 Feb 2021 06:48:14
User entered '26 Aug 2020 15:12'		26 Aug 2020 15:29:38

US3052005

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 15:00:53

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:58:03
Data hard unlocked.		25 Feb 2021 15:17:19
Data hard locked.		25 Feb 2021 06:48:14
User entered '27 Aug 2020 11:59'	System	26 Aug 2020 15:29:38

US3052005

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 15:00:53

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:58:03
Data hard unlocked.		25 Feb 2021 15:17:19
Data hard locked.		25 Feb 2021 06:48:14
Data entry locked.	System	26 Aug 2020 15:29:38
User entered 'Day 2'	System	26 Aug 2020 15:29:38

US3052005

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 15:00:53

Please record - **PAIN AT INJECTION SITE.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:58:03
Data hard unlocked.		25 Feb 2021 15:17:19
Data hard locked.		25 Feb 2021 06:48:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9EADD593-414F-498C-AC00-8AAC8D311A10)', Time: '2020-08-27T18:23:43', User OID: 'PatientReportedOutcome (US3052005)', ODM File OID: '4a5c1de2-0fb5-4026-9c59-992663cad636'	System	27 Aug 2020 22:24:03
User entered 'None (1)'	System	27 Aug 2020 22:24:03

US3052005

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 15:00:53

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:58:03
Data hard unlocked.		25 Feb 2021 15:17:19
Data hard locked.		25 Feb 2021 06:48:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9EADD593-414F-498C-AC00-8AAC8D311A10)', Time: '2020-08-27T18:23:47', User OID: 'PatientReportedOutcome (US3052005)', ODM File OID: '4a5c1de2-0fb5-4026-9c59-992663cad636'	System	27 Aug 2020 22:24:03
User entered 'No (N)'	System	27 Aug 2020 22:24:03

US3052005

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 15:00:53

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:58:03
Data hard unlocked.		25 Feb 2021 15:17:19
Data hard locked.		25 Feb 2021 06:48:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9EADD593-414F-498C-AC00-8AAC8D311A10)', Time: '2020-08-27T18:23:50', User OID: 'PatientReportedOutcome (US3052005)', ODM File OID: '4a5c1de2-0fb5-4026-9c59-992663cad636'	System	27 Aug 2020 22:24:03
User entered 'No (N)'	System	27 Aug 2020 22:24:03

US3052005

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 15:00:53

Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:58:03
Data hard unlocked.		25 Feb 2021 15:17:19
Data hard locked.		25 Feb 2021 06:48:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9EADD593-414F-498C-AC00-8AAC8D311A10)', Time: '2020-08-27T18:23:53', User OID: 'PatientReportedOutcome (US3052005)', ODM File OID: '4a5c1de2-0fb5-4026-9c59-992663cad636'	System	27 Aug 2020 22:24:03
User entered 'None (1)'	System	27 Aug 2020 22:24:03

US3052005

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 15:00:53

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:58:03
Data hard unlocked.		25 Feb 2021 15:17:19
Data hard locked.		25 Feb 2021 06:48:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9EADD593-414F-498C-AC00-8AAC8D311A10)', Time: '2020-08-27T18:23:56', User OID: 'PatientReportedOutcome (US3052005)', ODM File OID: '4a5c1de2-0fb5-4026-9c59-992663cad636'	System	27 Aug 2020 22:24:03
User entered '27 Aug 2020 18:23'	System	27 Aug 2020 22:24:03

US3052005

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 15:00:53

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:58:03
Data hard unlocked.		25 Feb 2021 15:17:19
Data hard locked.		25 Feb 2021 06:48:14
User entered '27 Aug 2020 12:00'	System	26 Aug 2020 15:29:38

US3052005

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 15:00:53

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:58:03
Data hard unlocked.		25 Feb 2021 15:17:19
Data hard locked.		25 Feb 2021 06:48:14
User entered '28 Aug 2020 11:59'	System	26 Aug 2020 15:29:38

US3052005

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 15:00:53

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:58:03
Data hard unlocked.		25 Feb 2021 15:17:19
Data hard locked.		25 Feb 2021 06:48:14
Data entry locked.	System	26 Aug 2020 15:29:38
User entered 'Day 3'	System	26 Aug 2020 15:29:38

US3052005

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 15:00:53

Please record - **PAIN AT INJECTION SITE.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:58:03
Data hard unlocked.		25 Feb 2021 15:17:19
Data hard locked.		25 Feb 2021 06:48:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9EADD593-414F-498C-AC00-8AAC8D311A10)', Time: '2020-08-28T20:37:48', User OID: 'PatientReportedOutcome (US3052005)', ODM File OID: 'a2ce0699-a026-4360-b165-b130645116ac'	System	29 Aug 2020 00:38:04
User entered 'None (1)'	System	29 Aug 2020 00:38:04

US3052005

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 15:00:53

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:58:03
Data hard unlocked.		25 Feb 2021 15:17:19
Data hard locked.		25 Feb 2021 06:48:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9EADD593-414F-498C-AC00-8AAC8D311A10)', Time: '2020-08-28T20:37:51', User OID: 'PatientReportedOutcome (US3052005)', ODM File OID: 'a2ce0699-a026-4360-b165-b130645116ac'	System	29 Aug 2020 00:38:04
User entered 'No (N)'	System	29 Aug 2020 00:38:04

US3052005

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 15:00:53

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:58:03
Data hard unlocked.		25 Feb 2021 15:17:19
Data hard locked.		25 Feb 2021 06:48:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9EADD593-414F-498C-AC00-8AAC8D311A10)', Time: '2020-08-28T20:37:55', User OID: 'PatientReportedOutcome (US3052005)', ODM File OID: 'a2ce0699-a026-4360-b165-b130645116ac'	System	29 Aug 2020 00:38:04
User entered 'No (N)'	System	29 Aug 2020 00:38:04

US3052005

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 15:00:53

Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:58:03
Data hard unlocked.		25 Feb 2021 15:17:19
Data hard locked.		25 Feb 2021 06:48:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9EADD593-414F-498C-AC00-8AAC8D311A10)', Time: '2020-08-28T20:37:58', User OID: 'PatientReportedOutcome (US3052005)', ODM File OID: 'a2ce0699-a026-4360-b165-b130645116ac'	System	29 Aug 2020 00:38:04
User entered 'None (1)'	System	29 Aug 2020 00:38:04

US3052005

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 15:00:53

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:58:03
Data hard unlocked.		25 Feb 2021 15:17:19
Data hard locked.		25 Feb 2021 06:48:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9EADD593-414F-498C-AC00-8AAC8D311A10)', Time: '2020-08-28T20:38:01', User OID: 'PatientReportedOutcome (US3052005)', ODM File OID: 'a2ce0699-a026-4360-b165-b130645116ac'	System	29 Aug 2020 00:38:04
User entered '28 Aug 2020 20:38'	System	29 Aug 2020 00:38:04

US3052005

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 15:00:53

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:58:03
Data hard unlocked.		25 Feb 2021 15:17:19
Data hard locked.		25 Feb 2021 06:48:14
User entered '28 Aug 2020 12:00'	System	26 Aug 2020 15:29:38

US3052005

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 15:00:53

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:58:03
Data hard unlocked.		25 Feb 2021 15:17:19
Data hard locked.		25 Feb 2021 06:48:14
User entered '29 Aug 2020 11:59'	System	26 Aug 2020 15:29:38

US3052005

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 15:00:53

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:58:03
Data hard unlocked.		25 Feb 2021 15:17:19
Data hard locked.		25 Feb 2021 06:48:14
Data entry locked.	System	26 Aug 2020 15:29:38
User entered 'Day 4'	System	26 Aug 2020 15:29:38

US3052005

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 15:00:53

Please record - **PAIN AT INJECTION SITE.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:58:03
Data hard unlocked.		25 Feb 2021 15:17:19
Data hard locked.		25 Feb 2021 06:48:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9EADD593-414F-498C-AC00-8AAC8D311A10)', Time: '2020-08-29T12:33:44', User OID: 'PatientReportedOutcome (US3052005)', ODM File OID: 'ff2ed744-28c8-4297-b332-3ffab369b7c7'	System	29 Aug 2020 16:34:04
User entered 'None (1)'	System	29 Aug 2020 16:34:04

US3052005

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 15:00:53

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:58:03
Data hard unlocked.		25 Feb 2021 15:17:19
Data hard locked.		25 Feb 2021 06:48:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9EADD593-414F-498C-AC00-8AAC8D311A10)', Time: '2020-08-29T12:33:48', User OID: 'PatientReportedOutcome (US3052005)', ODM File OID: 'ff2ed744-28c8-4297-b332-3ffab369b7c7'	System	29 Aug 2020 16:34:04
User entered 'No (N)'	System	29 Aug 2020 16:34:04

US3052005

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 15:00:53

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:58:03
Data hard unlocked.		25 Feb 2021 15:17:19
Data hard locked.		25 Feb 2021 06:48:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9EADD593-414F-498C-AC00-8AAC8D311A10)', Time: '2020-08-29T12:33:53', User OID: 'PatientReportedOutcome (US3052005)', ODM File OID: 'ff2ed744-28c8-4297-b332-3ffab369b7c7'	System	29 Aug 2020 16:34:04
User entered 'No (N)'	System	29 Aug 2020 16:34:04

US3052005

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 15:00:53

Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:58:03
Data hard unlocked.		25 Feb 2021 15:17:19
Data hard locked.		25 Feb 2021 06:48:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9EADD593-414F-498C-AC00-8AAC8D311A10)', Time: '2020-08-29T12:33:58', User OID: 'PatientReportedOutcome (US3052005)', ODM File OID: 'ff2ed744-28c8-4297-b332-3ffab369b7c7'	System	29 Aug 2020 16:34:04
User entered 'None (1)'	System	29 Aug 2020 16:34:04

US3052005

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 15:00:53

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:58:03
Data hard unlocked.		25 Feb 2021 15:17:19
Data hard locked.		25 Feb 2021 06:48:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9EADD593-414F-498C-AC00-8AAC8D311A10)', Time: '2020-08-29T12:34:02', User OID: 'PatientReportedOutcome (US3052005)', ODM File OID: 'ff2ed744-28c8-4297-b332-3ffab369b7c7'	System	29 Aug 2020 16:34:04
User entered '29 Aug 2020 12:34'	System	29 Aug 2020 16:34:04

US3052005

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 15:00:53

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:58:03
Data hard unlocked.		25 Feb 2021 15:17:19
Data hard locked.		25 Feb 2021 06:48:14
User entered '29 Aug 2020 12:00'	System	26 Aug 2020 15:29:38

US3052005

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 15:00:53

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:58:03
Data hard unlocked.		25 Feb 2021 15:17:19
Data hard locked.		25 Feb 2021 06:48:14
User entered '30 Aug 2020 11:59'	System	26 Aug 2020 15:29:38

US3052005

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 15:00:53

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:58:03
Data hard unlocked.		25 Feb 2021 15:17:19
Data hard locked.		25 Feb 2021 06:48:14
Data entry locked.	System	26 Aug 2020 15:29:38
User entered 'Day 5'	System	26 Aug 2020 15:29:38

US3052005

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 15:00:53

Please record - **PAIN AT INJECTION SITE.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:58:03
Data hard unlocked.		25 Feb 2021 15:17:19
Data hard locked.		25 Feb 2021 06:48:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9EADD593-414F-498C-AC00-8AAC8D311A10)', Time: '2020-08-30T19:21:01', User OID: 'PatientReportedOutcome (US3052005)', ODM File OID: 'a0e9b723-afd6-4be4-bc1b-8ab71fd48cbc'	System	30 Aug 2020 23:21:17
User entered 'None (1)'	System	30 Aug 2020 23:21:17

US3052005

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 15:00:53

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:58:03
Data hard unlocked.		25 Feb 2021 15:17:19
Data hard locked.		25 Feb 2021 06:48:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9EADD593-414F-498C-AC00-8AAC8D311A10)', Time: '2020-08-30T19:21:05', User OID: 'PatientReportedOutcome (US3052005)', ODM File OID: 'a0e9b723-afd6-4be4-bc1b-8ab71fd48cbc'	System	30 Aug 2020 23:21:17
User entered 'No (N)'	System	30 Aug 2020 23:21:17

US3052005

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 15:00:53

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:58:03
Data hard unlocked.		25 Feb 2021 15:17:19
Data hard locked.		25 Feb 2021 06:48:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9EADD593-414F-498C-AC00-8AAC8D311A10)', Time: '2020-08-30T19:21:08', User OID: 'PatientReportedOutcome (US3052005)', ODM File OID: 'a0e9b723-afd6-4be4-bc1b-8ab71fd48cbc'	System	30 Aug 2020 23:21:17
User entered 'No (N)'	System	30 Aug 2020 23:21:17

US3052005

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 15:00:53

Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:58:03
Data hard unlocked.		25 Feb 2021 15:17:19
Data hard locked.		25 Feb 2021 06:48:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9EADD593-414F-498C-AC00-8AAC8D311A10)', Time: '2020-08-30T19:21:10', User OID: 'PatientReportedOutcome (US3052005)', ODM File OID: 'a0e9b723-afd6-4be4-bc1b-8ab71fd48cbc'	System	30 Aug 2020 23:21:17
User entered 'None (1)'	System	30 Aug 2020 23:21:17

US3052005

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 15:00:53

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:58:03
Data hard unlocked.		25 Feb 2021 15:17:19
Data hard locked.		25 Feb 2021 06:48:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9EADD593-414F-498C-AC00-8AAC8D311A10)', Time: '2020-08-30T19:21:13', User OID: 'PatientReportedOutcome (US3052005)', ODM File OID: 'a0e9b723-afd6-4be4-bc1b-8ab71fd48cbc'	System	30 Aug 2020 23:21:17
User entered '30 Aug 2020 19:21'	System	30 Aug 2020 23:21:17

US3052005

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 15:00:53

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:58:03
Data hard unlocked.		25 Feb 2021 15:17:19
Data hard locked.		25 Feb 2021 06:48:14
User entered '30 Aug 2020 12:00'	System	26 Aug 2020 15:29:38

US3052005

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 15:00:53

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:58:03
Data hard unlocked.		25 Feb 2021 15:17:19
Data hard locked.		25 Feb 2021 06:48:14
User entered '31 Aug 2020 11:59'	System	26 Aug 2020 15:29:38

US3052005

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 15:00:53

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:58:03
Data hard unlocked.		25 Feb 2021 15:17:19
Data hard locked.		25 Feb 2021 06:48:14
Data entry locked.	System	26 Aug 2020 15:29:38
User entered 'Day 6'	System	26 Aug 2020 15:29:38

US3052005

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 15:00:53

Please record - **PAIN AT INJECTION SITE.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:58:03
Data hard unlocked.		25 Feb 2021 15:17:19
Data hard locked.		25 Feb 2021 06:48:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9EADD593-414F-498C-AC00-8AAC8D311A10)', Time: '2020-09-01T00:19:26', User OID: 'PatientReportedOutcome (US3052005)', ODM File OID: '981b24ec-aa5d-4252-a68c-7a8b0c082b24'	System	01 Sep 2020 04:19:40
User entered 'None (1)'	System	01 Sep 2020 04:19:40

US3052005

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 15:00:53

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:58:03
Data hard unlocked.		25 Feb 2021 15:17:19
Data hard locked.		25 Feb 2021 06:48:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9EADD593-414F-498C-AC00-8AAC8D311A10)', Time: '2020-09-01T00:19:29', User OID: 'PatientReportedOutcome (US3052005)', ODM File OID: '981b24ec-aa5d-4252-a68c-7a8b0c082b24'	System	01 Sep 2020 04:19:40
User entered 'No (N)'	System	01 Sep 2020 04:19:40

US3052005

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 15:00:53

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:58:03
Data hard unlocked.		25 Feb 2021 15:17:19
Data hard locked.		25 Feb 2021 06:48:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9EADD593-414F-498C-AC00-8AAC8D311A10)', Time: '2020-09-01T00:19:31', User OID: 'PatientReportedOutcome (US3052005)', ODM File OID: '981b24ec-aa5d-4252-a68c-7a8b0c082b24'	System	01 Sep 2020 04:19:40
User entered 'No (N)'	System	01 Sep 2020 04:19:40

US3052005

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 15:00:53

Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:58:03
Data hard unlocked.		25 Feb 2021 15:17:19
Data hard locked.		25 Feb 2021 06:48:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9EADD593-414F-498C-AC00-8AAC8D311A10)', Time: '2020-09-01T00:19:33', User OID: 'PatientReportedOutcome (US3052005)', ODM File OID: '981b24ec-aa5d-4252-a68c-7a8b0c082b24'	System	01 Sep 2020 04:19:40
User entered 'None (1)'	System	01 Sep 2020 04:19:40

US3052005

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 15:00:53

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:58:03
Data hard unlocked.		25 Feb 2021 15:17:19
Data hard locked.		25 Feb 2021 06:48:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9EADD593-414F-498C-AC00-8AAC8D311A10)', Time: '2020-09-01T00:19:37', User OID: 'PatientReportedOutcome (US3052005)', ODM File OID: '981b24ec-aa5d-4252-a68c-7a8b0c082b24'	System	01 Sep 2020 04:19:40
User entered '01 Sep 2020 00:19'	System	01 Sep 2020 04:19:40

US3052005

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 15:00:53

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:58:03
Data hard unlocked.		25 Feb 2021 15:17:19
Data hard locked.		25 Feb 2021 06:48:14
User entered '31 Aug 2020 12:00'	System	26 Aug 2020 15:29:38

US3052005

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 15:00:53

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:58:03
Data hard unlocked.		25 Feb 2021 15:17:19
Data hard locked.		25 Feb 2021 06:48:14
User entered '01 Sep 2020 11:59'	System	26 Aug 2020 15:29:38

US3052005

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 15:00:53

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:58:03
Data hard unlocked.		25 Feb 2021 15:17:19
Data hard locked.		25 Feb 2021 06:48:14
Data entry locked.	System	26 Aug 2020 15:29:38
User entered 'Day 7'	System	26 Aug 2020 15:29:38

US3052005

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 15:00:53

Please record - **PAIN AT INJECTION SITE.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:58:03
Data hard unlocked.		25 Feb 2021 15:17:19
Data hard locked.		25 Feb 2021 06:48:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9EADD593-414F-498C-AC00-8AAC8D311A10)', Time: '2020-09-01T18:49:10', User OID: 'PatientReportedOutcome (US3052005)', ODM File OID: '7fcc6778-0a22-4a93-be88-9540619473a8'	System	01 Sep 2020 22:49:33
User entered 'None (1)'	System	01 Sep 2020 22:49:33

US3052005

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 15:00:53

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:58:03
Data hard unlocked.		25 Feb 2021 15:17:19
Data hard locked.		25 Feb 2021 06:48:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9EADD593-414F-498C-AC00-8AAC8D311A10)', Time: '2020-09-01T18:49:13', User OID: 'PatientReportedOutcome (US3052005)', ODM File OID: '7fcc6778-0a22-4a93-be88-9540619473a8'	System	01 Sep 2020 22:49:33
User entered 'No (N)'	System	01 Sep 2020 22:49:33

US3052005

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 15:00:53

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:58:03
Data hard unlocked.		25 Feb 2021 15:17:19
Data hard locked.		25 Feb 2021 06:48:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9EADD593-414F-498C-AC00-8AAC8D311A10)', Time: '2020-09-01T18:49:20', User OID: 'PatientReportedOutcome (US3052005)', ODM File OID: '7fcc6778-0a22-4a93-be88-9540619473a8'	System	01 Sep 2020 22:49:33
User entered 'No (N)'	System	01 Sep 2020 22:49:33

US3052005

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 15:00:53

Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:58:03
Data hard unlocked.		25 Feb 2021 15:17:19
Data hard locked.		25 Feb 2021 06:48:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9EADD593-414F-498C-AC00-8AAC8D311A10)', Time: '2020-09-01T18:49:24', User OID: 'PatientReportedOutcome (US3052005)', ODM File OID: '7fcc6778-0a22-4a93-be88-9540619473a8'	System	01 Sep 2020 22:49:33
User entered 'None (1)'	System	01 Sep 2020 22:49:33

US3052005

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 15:00:53

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:58:03
Data hard unlocked.		25 Feb 2021 15:17:19
Data hard locked.		25 Feb 2021 06:48:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9EADD593-414F-498C-AC00-8AAC8D311A10)', Time: '2020-09-01T18:49:26', User OID: 'PatientReportedOutcome (US3052005)', ODM File OID: '7fcc6778-0a22-4a93-be88-9540619473a8'	System	01 Sep 2020 22:49:33
User entered '01 Sep 2020 18:49'	System	01 Sep 2020 22:49:33

US3052005

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 15:00:53

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:58:03
Data hard unlocked.		25 Feb 2021 15:17:19
Data hard locked.		25 Feb 2021 06:48:14
User entered '01 Sep 2020 12:00'	System	26 Aug 2020 15:29:38

US3052005

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 15:00:53

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:58:03
Data hard unlocked.		25 Feb 2021 15:17:19
Data hard locked.		25 Feb 2021 06:48:14
User entered '02 Sep 2020 11:59'	System	26 Aug 2020 15:29:38

US3052005

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 15:00:53

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:58:03
Data hard unlocked.		25 Feb 2021 15:17:32
Data hard locked.		25 Feb 2021 06:48:14
Data entry locked.	System	26 Aug 2020 15:29:38
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	26 Aug 2020 15:29:38

US3052005

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 15:00:53

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:58:03
Data hard unlocked.		25 Feb 2021 15:17:32
Data hard locked.		25 Feb 2021 06:48:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9EADD593-414F-498C-AC00-8AAC8D311A10)', Time: '2020-08-26T11:54:46', User OID: 'PatientReportedOutcome (US3052005)', ODM File OID: 'b1caf041-a3b1-4c13-9dc5-55dcc3163b39'	System	26 Aug 2020 15:55:17
User entered 'None (0)'	System	26 Aug 2020 15:55:17

US3052005

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 15:00:53

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:58:03
Data hard unlocked.		25 Feb 2021 15:17:32
Data hard locked.		25 Feb 2021 06:48:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9EADD593-414F-498C-AC00-8AAC8D311A10)', Time: '2020-08-26T11:54:50', User OID: 'PatientReportedOutcome (US3052005)', ODM File OID: 'b1caf041-a3b1-4c13-9dc5-55dcc3163b39'	System	26 Aug 2020 15:55:17
User entered 'None (0)'	System	26 Aug 2020 15:55:17

US3052005

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 15:00:53

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:58:03
Data hard unlocked.		25 Feb 2021 15:17:32
Data hard locked.		25 Feb 2021 06:48:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9EADD593-414F-498C-AC00-8AAC8D311A10)', Time: '2020-08-26T11:54:54', User OID: 'PatientReportedOutcome (US3052005)', ODM File OID: 'b1caf041-a3b1-4c13-9dc5-55dcc3163b39'	System	26 Aug 2020 15:55:17
User entered 'None (0)'	System	26 Aug 2020 15:55:17

US3052005

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 15:00:53

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:58:03
Data hard unlocked.		25 Feb 2021 15:17:32
Data hard locked.		25 Feb 2021 06:48:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9EADD593-414F-498C-AC00-8AAC8D311A10)', Time: '2020-08-26T11:54:56', User OID: 'PatientReportedOutcome (US3052005)', ODM File OID: 'b1caf041-a3b1-4c13-9dc5-55dcc3163b39'	System	26 Aug 2020 15:55:17
User entered 'None (0)'	System	26 Aug 2020 15:55:17

US3052005

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 15:00:53

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:58:03
Data hard unlocked.		25 Feb 2021 15:17:32
Data hard locked.		25 Feb 2021 06:48:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9EADD593-414F-498C-AC00-8AAC8D311A10)', Time: '2020-08-26T11:55:00', User OID: 'PatientReportedOutcome (US3052005)', ODM File OID: 'b1caf041-a3b1-4c13-9dc5-55dcc3163b39' User entered 'None (0)'	System	26 Aug 2020 15:55:17
	System	26 Aug 2020 15:55:17

US3052005

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 15:00:53

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:58:03
Data hard unlocked.		25 Feb 2021 15:17:32
Data hard locked.		25 Feb 2021 06:48:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9EADD593-414F-498C-AC00-8AAC8D311A10)', Time: '2020-08-26T11:55:03', User OID: 'PatientReportedOutcome (US3052005)', ODM File OID: 'b1caf041-a3b1-4c13-9dc5-55dcc3163b39'	System	26 Aug 2020 15:55:17
User entered 'None (0)'	System	26 Aug 2020 15:55:17

US3052005

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 15:00:53

Did you receive any **MEDICAL ATTENTION** (doctor visit, other) for any illness or symptoms?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:58:03
Data hard unlocked.		25 Feb 2021 15:17:32
Data hard locked.		25 Feb 2021 06:48:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9EADD593-414F-498C-AC00-8AAC8D311A10)', Time: '2020-08-26T11:55:09', User OID: 'PatientReportedOutcome (US3052005)', ODM File OID: 'b1caf041-a3b1-4c13-9dc5-55dcc3163b39'	System	26 Aug 2020 15:55:17
User entered 'No (N)'	System	26 Aug 2020 15:55:17

US3052005

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 15:00:53

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:58:03
Data hard unlocked.		25 Feb 2021 15:17:32
Data hard locked.		25 Feb 2021 06:48:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9EADD593-414F-498C-AC00-8AAC8D311A10)', Time: '2020-08-26T11:55:13', User OID: 'PatientReportedOutcome (US3052005)', ODM File OID: 'b1caf041-a3b1-4c13-9dc5-55dcc3163b39'	System	26 Aug 2020 15:55:17
User entered '26 Aug 2020 11:55'	System	26 Aug 2020 15:55:17

US3052005

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 15:00:53

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:58:03
Data hard unlocked.		25 Feb 2021 15:17:32
Data hard locked.		25 Feb 2021 06:48:14
User entered '26 Aug 2020 11:47'	System	26 Aug 2020 15:29:38

US3052005

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 15:00:53

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:58:03
Data hard unlocked.		25 Feb 2021 15:17:32
Data hard locked.		25 Feb 2021 06:48:14
User entered '26 Aug 2020 14:17'	System	26 Aug 2020 15:29:38

US3052005

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 15:00:53

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:58:03
Data hard unlocked.		25 Feb 2021 15:17:32
Data hard locked.		25 Feb 2021 06:48:14
Data entry locked.	System	26 Aug 2020 15:29:38
User entered 'Day 1, after vaccination (at home)'	System	26 Aug 2020 15:29:38

US3052005

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 15:00:53

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:58:03
Data hard unlocked.		25 Feb 2021 15:17:32
Data hard locked.		25 Feb 2021 06:48:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9EADD593-414F-498C-AC00-8AAC8D311A10)', Time: '2020-08-26T17:45:39', User OID: 'PatientReportedOutcome (US3052005)', ODM File OID: '98ae5bc0-db6a-424a-ba8c-1b79e5786ae8'	System	26 Aug 2020 21:46:10
User entered 'None (0)'	System	26 Aug 2020 21:46:10

US3052005

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 15:00:53

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:58:03
Data hard unlocked.		25 Feb 2021 15:17:32
Data hard locked.		25 Feb 2021 06:48:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9EADD593-414F-498C-AC00-8AAC8D311A10)', Time: '2020-08-26T17:45:43', User OID: 'PatientReportedOutcome (US3052005)', ODM File OID: '98ae5bc0-db6a-424a-ba8c-1b79e5786ae8'	System	26 Aug 2020 21:46:10
User entered 'None (0)'	System	26 Aug 2020 21:46:10

US3052005

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 15:00:53

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:58:03
Data hard unlocked.		25 Feb 2021 15:17:32
Data hard locked.		25 Feb 2021 06:48:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9EADD593-414F-498C-AC00-8AAC8D311A10)', Time: '2020-08-26T17:45:47', User OID: 'PatientReportedOutcome (US3052005)', ODM File OID: '98ae5bc0-db6a-424a-ba8c-1b79e5786ae8'	System	26 Aug 2020 21:46:10
User entered 'None (0)'	System	26 Aug 2020 21:46:10

US3052005

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 15:00:53

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:58:03
Data hard unlocked.		25 Feb 2021 15:17:32
Data hard locked.		25 Feb 2021 06:48:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9EADD593-414F-498C-AC00-8AAC8D311A10)', Time: '2020-08-26T17:45:50', User OID: 'PatientReportedOutcome (US3052005)', ODM File OID: '98ae5bc0-db6a-424a-ba8c-1b79e5786ae8'	System	26 Aug 2020 21:46:10
User entered 'None (0)'	System	26 Aug 2020 21:46:10

US3052005

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 15:00:53

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:58:03
Data hard unlocked.		25 Feb 2021 15:17:32
Data hard locked.		25 Feb 2021 06:48:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9EADD593-414F-498C-AC00-8AAC8D311A10)', Time: '2020-08-26T17:45:53', User OID: 'PatientReportedOutcome (US3052005)', ODM File OID: '98ae5bc0-db6a-424a-ba8c-1b79e5786ae8'	System	26 Aug 2020 21:46:10
User entered 'None (0)'	System	26 Aug 2020 21:46:10

US3052005

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 15:00:53

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:58:03
Data hard unlocked.		25 Feb 2021 15:17:32
Data hard locked.		25 Feb 2021 06:48:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9EADD593-414F-498C-AC00-8AAC8D311A10)', Time: '2020-08-26T17:45:56', User OID: 'PatientReportedOutcome (US3052005)', ODM File OID: '98ae5bc0-db6a-424a-ba8c-1b79e5786ae8'	System	26 Aug 2020 21:46:10
User entered 'None (0)'	System	26 Aug 2020 21:46:10

US3052005

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 15:00:53

Did you receive any **MEDICAL ATTENTION** (doctor visit, other) for any illness or symptoms?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:58:03
Data hard unlocked.		25 Feb 2021 15:17:32
Data hard locked.		25 Feb 2021 06:48:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9EADD593-414F-498C-AC00-8AAC8D311A10)', Time: '2020-08-26T17:45:59', User OID: 'PatientReportedOutcome (US3052005)', ODM File OID: '98ae5bc0-db6a-424a-ba8c-1b79e5786ae8'	System	26 Aug 2020 21:46:10
User entered 'No (N)'	System	26 Aug 2020 21:46:10

US3052005

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 15:00:53

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:58:03
Data hard unlocked.		25 Feb 2021 15:17:32
Data hard locked.		25 Feb 2021 06:48:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9EADD593-414F-498C-AC00-8AAC8D311A10)', Time: '2020-08-26T17:46:07', User OID: 'PatientReportedOutcome (US3052005)', ODM File OID: '98ae5bc0-db6a-424a-ba8c-1b79e5786ae8'	System	26 Aug 2020 21:46:10
User entered '26 Aug 2020 17:46'	System	26 Aug 2020 21:46:10

US3052005

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 15:00:53

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:58:03
Data hard unlocked.		25 Feb 2021 15:17:32
Data hard locked.		25 Feb 2021 06:48:14
User entered '26 Aug 2020 15:12'	System	26 Aug 2020 15:29:38

US3052005

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 15:00:53

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:58:03
Data hard unlocked.		25 Feb 2021 15:17:32
Data hard locked.		25 Feb 2021 06:48:14
User entered '27 Aug 2020 11:59'	System	26 Aug 2020 15:29:38

US3052005

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 15:00:53

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:58:03
Data hard unlocked.		25 Feb 2021 15:17:32
Data hard locked.		25 Feb 2021 06:48:14
Data entry locked.	System	26 Aug 2020 15:29:38
User entered 'Day 2'	System	26 Aug 2020 15:29:38

US3052005

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 15:00:53

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:58:03
Data hard unlocked.		25 Feb 2021 15:17:32
Data hard locked.		25 Feb 2021 06:48:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9EADD593-414F-498C-AC00-8AAC8D311A10)', Time: '2020-08-27T18:24:01', User OID: 'PatientReportedOutcome (US3052005)', ODM File OID: '9546e247-b52f-4616-9c3b-41ee209abed1' User entered 'None (0)'	System	27 Aug 2020 22:24:32
	System	27 Aug 2020 22:24:32

US3052005

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 15:00:53

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:58:03
Data hard unlocked.		25 Feb 2021 15:17:32
Data hard locked.		25 Feb 2021 06:48:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9EADD593-414F-498C-AC00-8AAC8D311A10)', Time: '2020-08-27T18:24:04', User OID: 'PatientReportedOutcome (US3052005)', ODM File OID: '9546e247-b52f-4616-9c3b-41ee209abed1' User entered 'None (0)'	System	27 Aug 2020 22:24:32
	System	27 Aug 2020 22:24:32

US3052005

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 15:00:53

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:58:03
Data hard unlocked.		25 Feb 2021 15:17:32
Data hard locked.		25 Feb 2021 06:48:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9EADD593-414F-498C-AC00-8AAC8D311A10)', Time: '2020-08-27T18:24:13', User OID: 'PatientReportedOutcome (US3052005)', ODM File OID: '9546e247-b52f-4616-9c3b-41ee209abed1' User entered 'None (0)'	System	27 Aug 2020 22:24:32
	System	27 Aug 2020 22:24:32

US3052005

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 15:00:53

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:58:03
Data hard unlocked.	(b) (4), (b) (6)	25 Feb 2021 15:17:32
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:48:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9EADD593-414F-498C-AC00-8AAC8D311A10)', Time: '2020-08-27T18:24:16', User OID: 'PatientReportedOutcome (US3052005)', ODM File OID: '9546e247-b52f-4616-9c3b-41ee209abed1' User entered 'None (0)'	System	27 Aug 2020 22:24:32
	System	27 Aug 2020 22:24:32

US3052005

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 15:00:53

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:58:03
Data hard unlocked.		25 Feb 2021 15:17:32
Data hard locked.		25 Feb 2021 06:48:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9EADD593-414F-498C-AC00-8AAC8D311A10)', Time: '2020-08-27T18:24:18', User OID: 'PatientReportedOutcome (US3052005)', ODM File OID: '9546e247-b52f-4616-9c3b-41ee209abed1' User entered 'None (0)'	System	27 Aug 2020 22:24:32
	System	27 Aug 2020 22:24:32

US3052005

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 15:00:53

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:58:03
Data hard unlocked.		25 Feb 2021 15:17:32
Data hard locked.		25 Feb 2021 06:48:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9EADD593-414F-498C-AC00-8AAC8D311A10)', Time: '2020-08-27T18:24:22', User OID: 'PatientReportedOutcome (US3052005)', ODM File OID: '9546e247-b52f-4616-9c3b-41ee209abed1' User entered 'None (0)'	System	27 Aug 2020 22:24:32
	System	27 Aug 2020 22:24:32

US3052005

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 15:00:53

Did you receive any **MEDICAL ATTENTION** (doctor visit, other) for any illness or symptoms?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:58:03
Data hard unlocked.		25 Feb 2021 15:17:32
Data hard locked.		25 Feb 2021 06:48:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9EADD593-414F-498C-AC00-8AAC8D311A10)', Time: '2020-08-27T18:24:25', User OID: 'PatientReportedOutcome (US3052005)', ODM File OID: '9546e247-b52f-4616-9c3b-41ee209abed1'	System	27 Aug 2020 22:24:32
User entered 'No (N)'	System	27 Aug 2020 22:24:32

US3052005

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 15:00:53

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:58:03
Data hard unlocked.		25 Feb 2021 15:17:32
Data hard locked.		25 Feb 2021 06:48:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9EADD593-414F-498C-AC00-8AAC8D311A10)', Time: '2020-08-27T18:24:28', User OID: 'PatientReportedOutcome (US3052005)', ODM File OID: '9546e247-b52f-4616-9c3b-41ee209abed1' User entered '27 Aug 2020 18:24'	System	27 Aug 2020 22:24:32
	System	27 Aug 2020 22:24:32

US3052005

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 15:00:53

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:58:03
Data hard unlocked.		25 Feb 2021 15:17:32
Data hard locked.		25 Feb 2021 06:48:14
User entered '27 Aug 2020 12:00'	System	26 Aug 2020 15:29:38

US3052005

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 15:00:53

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:58:03
Data hard unlocked.		25 Feb 2021 15:17:32
Data hard locked.		25 Feb 2021 06:48:14
User entered '28 Aug 2020 11:59'	System	26 Aug 2020 15:29:38

US3052005

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 15:00:53

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:58:03
Data hard unlocked.		25 Feb 2021 15:17:32
Data hard locked.		25 Feb 2021 06:48:14
Data entry locked.	System	26 Aug 2020 15:29:38
User entered 'Day 3'	System	26 Aug 2020 15:29:38

US3052005

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 15:00:53

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:58:03
Data hard unlocked.		25 Feb 2021 15:17:32
Data hard locked.		25 Feb 2021 06:48:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9EADD593-414F-498C-AC00-8AAC8D311A10)', Time: '2020-08-28T20:38:06', User OID: 'PatientReportedOutcome (US3052005)', ODM File OID: 'f07bcc7d-780e-4db5-93b9-7503f841c7af'	System	29 Aug 2020 00:38:40
User entered 'None (0)'	System	29 Aug 2020 00:38:40

US3052005

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 15:00:53

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:58:03
Data hard unlocked.		25 Feb 2021 15:17:32
Data hard locked.		25 Feb 2021 06:48:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9EADD593-414F-498C-AC00-8AAC8D311A10)', Time: '2020-08-28T20:38:18', User OID: 'PatientReportedOutcome (US3052005)', ODM File OID: 'f07bcc7d-780e-4db5-93b9-7503f841c7af'	System	29 Aug 2020 00:38:40
User entered 'None (0)'	System	29 Aug 2020 00:38:40

US3052005

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 15:00:53

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:58:03
Data hard unlocked.		25 Feb 2021 15:17:32
Data hard locked.		25 Feb 2021 06:48:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9EADD593-414F-498C-AC00-8AAC8D311A10)', Time: '2020-08-28T20:38:21', User OID: 'PatientReportedOutcome (US3052005)', ODM File OID: 'f07bcc7d-780e-4db5-93b9-7503f841c7af'	System	29 Aug 2020 00:38:40
User entered 'None (0)'	System	29 Aug 2020 00:38:40

US3052005

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 15:00:53

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:58:03
Data hard unlocked.		25 Feb 2021 15:17:32
Data hard locked.		25 Feb 2021 06:48:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9EADD593-414F-498C-AC00-8AAC8D311A10)', Time: '2020-08-28T20:38:25', User OID: 'PatientReportedOutcome (US3052005)', ODM File OID: 'f07bcc7d-780e-4db5-93b9-7503f841c7af'	System	29 Aug 2020 00:38:40
User entered 'None (0)'	System	29 Aug 2020 00:38:40

US3052005

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 15:00:53

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:58:03
Data hard unlocked.		25 Feb 2021 15:17:32
Data hard locked.		25 Feb 2021 06:48:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9EADD593-414F-498C-AC00-8AAC8D311A10)', Time: '2020-08-28T20:38:28', User OID: 'PatientReportedOutcome (US3052005)', ODM File OID: 'f07bcc7d-780e-4db5-93b9-7503f841c7af'	System	29 Aug 2020 00:38:40
User entered 'None (0)'	System	29 Aug 2020 00:38:40

US3052005

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 15:00:53

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:58:03
Data hard unlocked.		25 Feb 2021 15:17:32
Data hard locked.		25 Feb 2021 06:48:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9EADD593-414F-498C-AC00-8AAC8D311A10)', Time: '2020-08-28T20:38:30', User OID: 'PatientReportedOutcome (US3052005)', ODM File OID: 'f07bcc7d-780e-4db5-93b9-7503f841c7af'	System	29 Aug 2020 00:38:40
User entered 'None (0)'	System	29 Aug 2020 00:38:40

US3052005

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 15:00:53

Did you receive any **MEDICAL ATTENTION** (doctor visit, other) for any illness or symptoms?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:58:03
Data hard unlocked.		25 Feb 2021 15:17:32
Data hard locked.		25 Feb 2021 06:48:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9EADD593-414F-498C-AC00-8AAC8D311A10)', Time: '2020-08-28T20:38:33', User OID: 'PatientReportedOutcome (US3052005)', ODM File OID: 'f07bcc7d-780e-4db5-93b9-7503f841c7af'	System	29 Aug 2020 00:38:40
User entered 'No (N)'	System	29 Aug 2020 00:38:40

US3052005

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 15:00:53

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:58:03
Data hard unlocked.		25 Feb 2021 15:17:32
Data hard locked.		25 Feb 2021 06:48:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9EADD593-414F-498C-AC00-8AAC8D311A10)', Time: '2020-08-28T20:38:38', User OID: 'PatientReportedOutcome (US3052005)', ODM File OID: 'f07bcc7d-780e-4db5-93b9-7503f841c7af'	System	29 Aug 2020 00:38:40
User entered '28 Aug 2020 20:38'	System	29 Aug 2020 00:38:40

US3052005

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 15:00:53

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:58:03
Data hard unlocked.		25 Feb 2021 15:17:32
Data hard locked.		25 Feb 2021 06:48:14
User entered '28 Aug 2020 12:00'	System	26 Aug 2020 15:29:38

US3052005

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 15:00:53

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:58:03
Data hard unlocked.		25 Feb 2021 15:17:32
Data hard locked.		25 Feb 2021 06:48:14
User entered '29 Aug 2020 11:59'	System	26 Aug 2020 15:29:38

US3052005

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 15:00:53

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:58:03
Data hard unlocked.		25 Feb 2021 15:17:32
Data hard locked.		25 Feb 2021 06:48:14
Data entry locked.	System	26 Aug 2020 15:29:38
User entered 'Day 4'	System	26 Aug 2020 15:29:38

US3052005

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 15:00:53

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:58:03
Data hard unlocked.		25 Feb 2021 15:17:32
Data hard locked.		25 Feb 2021 06:48:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9EADD593-414F-498C-AC00-8AAC8D311A10)', Time: '2020-08-29T12:34:07', User OID: 'PatientReportedOutcome (US3052005)', ODM File OID: '266dd376-713b-478c-9f3e-1d4fcdcd2ef'	System	29 Aug 2020 16:34:28
User entered 'None (0)'	System	29 Aug 2020 16:34:28

US3052005

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 15:00:53

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:58:03
Data hard unlocked.		25 Feb 2021 15:17:32
Data hard locked.		25 Feb 2021 06:48:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9EADD593-414F-498C-AC00-8AAC8D311A10)', Time: '2020-08-29T12:34:09', User OID: 'PatientReportedOutcome (US3052005)', ODM File OID: '266dd376-713b-478c-9f3e-1d4fcdcd2ef'	System	29 Aug 2020 16:34:28
User entered 'None (0)'	System	29 Aug 2020 16:34:28

US3052005

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 15:00:53

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:58:03
Data hard unlocked.		25 Feb 2021 15:17:32
Data hard locked.		25 Feb 2021 06:48:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9EADD593-414F-498C-AC00-8AAC8D311A10)', Time: '2020-08-29T12:34:12', User OID: 'PatientReportedOutcome (US3052005)', ODM File OID: '266dd376-713b-478c-9f3e-1d4fcdcd2ef'	System	29 Aug 2020 16:34:28
User entered 'None (0)'	System	29 Aug 2020 16:34:28

US3052005

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 15:00:53

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:58:03
Data hard unlocked.		25 Feb 2021 15:17:32
Data hard locked.		25 Feb 2021 06:48:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9EADD593-414F-498C-AC00-8AAC8D311A10)', Time: '2020-08-29T12:34:15', User OID: 'PatientReportedOutcome (US3052005)', ODM File OID: '266dd376-713b-478c-9f3e-1d4fcdcd2ef'	System	29 Aug 2020 16:34:28
User entered 'None (0)'	System	29 Aug 2020 16:34:28

US3052005

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 15:00:53

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:58:03
Data hard unlocked.		25 Feb 2021 15:17:32
Data hard locked.		25 Feb 2021 06:48:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9EADD593-414F-498C-AC00-8AAC8D311A10)', Time: '2020-08-29T12:34:18', User OID: 'PatientReportedOutcome (US3052005)', ODM File OID: '266dd376-713b-478c-9f3e-1d4fcdcd2ef'	System	29 Aug 2020 16:34:28
User entered 'None (0)'	System	29 Aug 2020 16:34:28

US3052005

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 15:00:53

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:58:03
Data hard unlocked.		25 Feb 2021 15:17:32
Data hard locked.		25 Feb 2021 06:48:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9EADD593-414F-498C-AC00-8AAC8D311A10)', Time: '2020-08-29T12:34:20', User OID: 'PatientReportedOutcome (US3052005)', ODM File OID: '266dd376-713b-478c-9f3e-1d4fcdcd2ef'	System	29 Aug 2020 16:34:28
User entered 'None (0)'	System	29 Aug 2020 16:34:28

US3052005

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 15:00:53

Did you receive any **MEDICAL ATTENTION** (doctor visit, other) for any illness or symptoms?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:58:03
Data hard unlocked.		25 Feb 2021 15:17:32
Data hard locked.		25 Feb 2021 06:48:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9EADD593-414F-498C-AC00-8AAC8D311A10)', Time: '2020-08-29T12:34:23', User OID: 'PatientReportedOutcome (US3052005)', ODM File OID: '266dd376-713b-478c-9f3e-1d4fcdcd2ef'	System	29 Aug 2020 16:34:28
User entered 'No (N)'	System	29 Aug 2020 16:34:28

US3052005

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 15:00:53

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:58:03
Data hard unlocked.		25 Feb 2021 15:17:32
Data hard locked.		25 Feb 2021 06:48:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9EADD593-414F-498C-AC00-8AAC8D311A10)', Time: '2020-08-29T12:34:26', User OID: 'PatientReportedOutcome (US3052005)', ODM File OID: '266dd376-713b-478c-9f3e-1d4fcdcd2ef'	System	29 Aug 2020 16:34:28
User entered '29 Aug 2020 12:34'	System	29 Aug 2020 16:34:28

US3052005

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 15:00:53

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:58:03
Data hard unlocked.		25 Feb 2021 15:17:32
Data hard locked.		25 Feb 2021 06:48:14
User entered '29 Aug 2020 12:00'	System	26 Aug 2020 15:29:38

US3052005

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 15:00:53

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:58:03
Data hard unlocked.		25 Feb 2021 15:17:32
Data hard locked.		25 Feb 2021 06:48:14
User entered '30 Aug 2020 11:59'	System	26 Aug 2020 15:29:38

US3052005

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 15:00:53

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:58:03
Data hard unlocked.		25 Feb 2021 15:17:32
Data hard locked.		25 Feb 2021 06:48:14
Data entry locked.	System	26 Aug 2020 15:29:38
User entered 'Day 5'	System	26 Aug 2020 15:29:38

US3052005

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 15:00:53

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:58:03
Data hard unlocked.		25 Feb 2021 15:17:32
Data hard locked.		25 Feb 2021 06:48:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9EADD593-414F-498C-AC00-8AAC8D311A10)', Time: '2020-08-30T19:21:18', User OID: 'PatientReportedOutcome (US3052005)', ODM File OID: '25c868d1-1960-4dc4-a031-e6452b9a89b6'	System	30 Aug 2020 23:21:41
User entered 'None (0)'	System	30 Aug 2020 23:21:41

US3052005

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 15:00:53

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:58:03
Data hard unlocked.		25 Feb 2021 15:17:32
Data hard locked.		25 Feb 2021 06:48:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9EADD593-414F-498C-AC00-8AAC8D311A10)', Time: '2020-08-30T19:21:21', User OID: 'PatientReportedOutcome (US3052005)', ODM File OID: '25c868d1-1960-4dc4-a031-e6452b9a89b6'	System	30 Aug 2020 23:21:41
User entered 'None (0)'	System	30 Aug 2020 23:21:41

US3052005

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 15:00:53

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:58:03
Data hard unlocked.		25 Feb 2021 15:17:32
Data hard locked.		25 Feb 2021 06:48:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9EADD593-414F-498C-AC00-8AAC8D311A10)', Time: '2020-08-30T19:21:23', User OID: 'PatientReportedOutcome (US3052005)', ODM File OID: '25c868d1-1960-4dc4-a031-e6452b9a89b6'	System	30 Aug 2020 23:21:41
User entered 'None (0)'	System	30 Aug 2020 23:21:41

US3052005

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 15:00:53

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:58:03
Data hard unlocked.		25 Feb 2021 15:17:32
Data hard locked.		25 Feb 2021 06:48:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9EADD593-414F-498C-AC00-8AAC8D311A10)', Time: '2020-08-30T19:21:26', User OID: 'PatientReportedOutcome (US3052005)', ODM File OID: '25c868d1-1960-4dc4-a031-e6452b9a89b6'	System	30 Aug 2020 23:21:41
User entered 'None (0)'	System	30 Aug 2020 23:21:41

US3052005

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 15:00:53

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:58:03
Data hard unlocked.		25 Feb 2021 15:17:32
Data hard locked.		25 Feb 2021 06:48:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9EADD593-414F-498C-AC00-8AAC8D311A10)', Time: '2020-08-30T19:21:29', User OID: 'PatientReportedOutcome (US3052005)', ODM File OID: '25c868d1-1960-4dc4-a031-e6452b9a89b6'	System	30 Aug 2020 23:21:41
User entered 'None (0)'	System	30 Aug 2020 23:21:41

US3052005

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 15:00:53

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:58:03
Data hard unlocked.		25 Feb 2021 15:17:32
Data hard locked.		25 Feb 2021 06:48:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9EADD593-414F-498C-AC00-8AAC8D311A10)', Time: '2020-08-30T19:21:32', User OID: 'PatientReportedOutcome (US3052005)', ODM File OID: '25c868d1-1960-4dc4-a031-e6452b9a89b6'	System	30 Aug 2020 23:21:41
User entered 'None (0)'	System	30 Aug 2020 23:21:41

US3052005

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 15:00:53

Did you receive any **MEDICAL ATTENTION** (doctor visit, other) for any illness or symptoms?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:58:03
Data hard unlocked.		25 Feb 2021 15:17:32
Data hard locked.		25 Feb 2021 06:48:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9EADD593-414F-498C-AC00-8AAC8D311A10)', Time: '2020-08-30T19:21:35', User OID: 'PatientReportedOutcome (US3052005)', ODM File OID: '25c868d1-1960-4dc4-a031-e6452b9a89b6'	System	30 Aug 2020 23:21:41
User entered 'No (N)'	System	30 Aug 2020 23:21:41

US3052005

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 15:00:53

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:58:03
Data hard unlocked.		25 Feb 2021 15:17:32
Data hard locked.		25 Feb 2021 06:48:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9EADD593-414F-498C-AC00-8AAC8D311A10)', Time: '2020-08-30T19:21:38', User OID: 'PatientReportedOutcome (US3052005)', ODM File OID: '25c868d1-1960-4dc4-a031-e6452b9a89b6'	System	30 Aug 2020 23:21:41
User entered '30 Aug 2020 19:21'	System	30 Aug 2020 23:21:41

US3052005

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 15:00:53

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:58:03
Data hard unlocked.		25 Feb 2021 15:17:32
Data hard locked.		25 Feb 2021 06:48:14
User entered '30 Aug 2020 12:00'	System	26 Aug 2020 15:29:38

US3052005

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 15:00:53

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:58:03
Data hard unlocked.		25 Feb 2021 15:17:32
Data hard locked.		25 Feb 2021 06:48:14
User entered '31 Aug 2020 11:59'	System	26 Aug 2020 15:29:38

US3052005

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 15:00:53

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:58:03
Data hard unlocked.		25 Feb 2021 15:17:32
Data hard locked.		25 Feb 2021 06:48:14
Data entry locked.	System	26 Aug 2020 15:29:38
User entered 'Day 6'	System	26 Aug 2020 15:29:38

US3052005

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 15:00:53

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:58:03
Data hard unlocked.		25 Feb 2021 15:17:32
Data hard locked.		25 Feb 2021 06:48:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9EADD593-414F-498C-AC00-8AAC8D311A10)', Time: '2020-09-01T00:19:44', User OID: 'PatientReportedOutcome (US3052005)', ODM File OID: '57c49ac0-b0d1-4521-9fbe-f21dc7380239'	System	01 Sep 2020 04:20:04
User entered 'None (0)'	System	01 Sep 2020 04:20:04

US3052005

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 15:00:53

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:58:03
Data hard unlocked.		25 Feb 2021 15:17:32
Data hard locked.		25 Feb 2021 06:48:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9EADD593-414F-498C-AC00-8AAC8D311A10)', Time: '2020-09-01T00:19:46', User OID: 'PatientReportedOutcome (US3052005)', ODM File OID: '57c49ac0-b0d1-4521-9fbe-f21dc7380239'	System	01 Sep 2020 04:20:04
User entered 'None (0)'	System	01 Sep 2020 04:20:04

US3052005

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 15:00:53

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:58:03
Data hard unlocked.		25 Feb 2021 15:17:32
Data hard locked.		25 Feb 2021 06:48:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9EADD593-414F-498C-AC00-8AAC8D311A10)', Time: '2020-09-01T00:19:48', User OID: 'PatientReportedOutcome (US3052005)', ODM File OID: '57c49ac0-b0d1-4521-9fbe-f21dc7380239'	System	01 Sep 2020 04:20:04
User entered 'None (0)'	System	01 Sep 2020 04:20:04

US3052005

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 15:00:53

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:58:03
Data hard unlocked.		25 Feb 2021 15:17:32
Data hard locked.		25 Feb 2021 06:48:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9EADD593-414F-498C-AC00-8AAC8D311A10)', Time: '2020-09-01T00:19:51', User OID: 'PatientReportedOutcome (US3052005)', ODM File OID: '57c49ac0-b0d1-4521-9fbe-f21dc7380239'	System	01 Sep 2020 04:20:04
User entered 'None (0)'	System	01 Sep 2020 04:20:04

US3052005

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 15:00:53

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:58:03
Data hard unlocked.		25 Feb 2021 15:17:32
Data hard locked.		25 Feb 2021 06:48:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9EADD593-414F-498C-AC00-8AAC8D311A10)', Time: '2020-09-01T00:19:54', User OID: 'PatientReportedOutcome (US3052005)', ODM File OID: '57c49ac0-b0d1-4521-9fbe-f21dc7380239'	System	01 Sep 2020 04:20:04
User entered 'None (0)'	System	01 Sep 2020 04:20:04

US3052005

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 15:00:53

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:58:03
Data hard unlocked.		25 Feb 2021 15:17:32
Data hard locked.		25 Feb 2021 06:48:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9EADD593-414F-498C-AC00-8AAC8D311A10)', Time: '2020-09-01T00:19:57', User OID: 'PatientReportedOutcome (US3052005)', ODM File OID: '57c49ac0-b0d1-4521-9fbe-f21dc7380239'	System	01 Sep 2020 04:20:04
User entered 'None (0)'	System	01 Sep 2020 04:20:04

US3052005

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 15:00:53

Did you receive any **MEDICAL ATTENTION** (doctor visit, other) for any illness or symptoms?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:58:03
Data hard unlocked.		25 Feb 2021 15:17:32
Data hard locked.		25 Feb 2021 06:48:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9EADD593-414F-498C-AC00-8AAC8D311A10)', Time: '2020-09-01T00:19:59', User OID: 'PatientReportedOutcome (US3052005)', ODM File OID: '57c49ac0-b0d1-4521-9fbe-f21dc7380239'	System	01 Sep 2020 04:20:04
User entered 'No (N)'	System	01 Sep 2020 04:20:04

US3052005

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 15:00:53

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:58:03
Data hard unlocked.		25 Feb 2021 15:17:32
Data hard locked.		25 Feb 2021 06:48:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9EADD593-414F-498C-AC00-8AAC8D311A10)', Time: '2020-09-01T00:20:02', User OID: 'PatientReportedOutcome (US3052005)', ODM File OID: '57c49ac0-b0d1-4521-9fbe-f21dc7380239'	System	01 Sep 2020 04:20:04
User entered '01 Sep 2020 00:20'	System	01 Sep 2020 04:20:04

US3052005

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 15:00:53

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:58:03
Data hard unlocked.		25 Feb 2021 15:17:32
Data hard locked.		25 Feb 2021 06:48:14
User entered '31 Aug 2020 12:00'	System	26 Aug 2020 15:29:38

US3052005

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 15:00:53

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:58:03
Data hard unlocked.		25 Feb 2021 15:17:32
Data hard locked.		25 Feb 2021 06:48:14
User entered '01 Sep 2020 11:59'	System	26 Aug 2020 15:29:38

US3052005

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 15:00:53

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:58:03
Data hard unlocked.		25 Feb 2021 15:17:32
Data hard locked.		25 Feb 2021 06:48:14
Data entry locked.	System	26 Aug 2020 15:29:38
User entered 'Day 7'	System	26 Aug 2020 15:29:38

US3052005

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 15:00:53

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:58:03
Data hard unlocked.		25 Feb 2021 15:17:32
Data hard locked.		25 Feb 2021 06:48:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9EADD593-414F-498C-AC00-8AAC8D311A10)', Time: '2020-09-01T18:49:33', User OID: 'PatientReportedOutcome (US3052005)', ODM File OID: 'f62f148d-c22a-4db7-b4eb-528c3044c088'	System	01 Sep 2020 22:50:04
User entered 'None (0)'	System	01 Sep 2020 22:50:04

US3052005

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 15:00:53

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:58:03
Data hard unlocked.		25 Feb 2021 15:17:32
Data hard locked.		25 Feb 2021 06:48:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9EADD593-414F-498C-AC00-8AAC8D311A10)', Time: '2020-09-01T18:49:36', User OID: 'PatientReportedOutcome (US3052005)', ODM File OID: 'f62f148d-c22a-4db7-b4eb-528c3044c088'	System	01 Sep 2020 22:50:04
User entered 'None (0)'	System	01 Sep 2020 22:50:04

US3052005

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 15:00:53

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:58:03
Data hard unlocked.		25 Feb 2021 15:17:32
Data hard locked.		25 Feb 2021 06:48:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9EADD593-414F-498C-AC00-8AAC8D311A10)', Time: '2020-09-01T18:49:38', User OID: 'PatientReportedOutcome (US3052005)', ODM File OID: 'f62f148d-c22a-4db7-b4eb-528c3044c088'	System	01 Sep 2020 22:50:04
User entered 'None (0)'	System	01 Sep 2020 22:50:04

US3052005

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 15:00:53

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:58:03
Data hard unlocked.		25 Feb 2021 15:17:32
Data hard locked.		25 Feb 2021 06:48:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9EADD593-414F-498C-AC00-8AAC8D311A10)', Time: '2020-09-01T18:49:40', User OID: 'PatientReportedOutcome (US3052005)', ODM File OID: 'f62f148d-c22a-4db7-b4eb-528c3044c088'	System	01 Sep 2020 22:50:04
User entered 'None (0)'	System	01 Sep 2020 22:50:04

US3052005

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 15:00:53

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:58:03
Data hard unlocked.		25 Feb 2021 15:17:32
Data hard locked.		25 Feb 2021 06:48:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9EADD593-414F-498C-AC00-8AAC8D311A10)', Time: '2020-09-01T18:49:48', User OID: 'PatientReportedOutcome (US3052005)', ODM File OID: 'f62f148d-c22a-4db7-b4eb-528c3044c088'	System	01 Sep 2020 22:50:04
User entered 'None (0)'	System	01 Sep 2020 22:50:04

US3052005

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 15:00:53

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:58:03
Data hard unlocked.		25 Feb 2021 15:17:32
Data hard locked.		25 Feb 2021 06:48:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9EADD593-414F-498C-AC00-8AAC8D311A10)', Time: '2020-09-01T18:49:52', User OID: 'PatientReportedOutcome (US3052005)', ODM File OID: 'f62f148d-c22a-4db7-b4eb-528c3044c088'	System	01 Sep 2020 22:50:04
User entered 'None (0)'	System	01 Sep 2020 22:50:04

US3052005

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 15:00:53

Did you receive any **MEDICAL ATTENTION** (doctor visit, other) for any illness or symptoms?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:58:03
Data hard unlocked.		25 Feb 2021 15:17:32
Data hard locked.		25 Feb 2021 06:48:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9EADD593-414F-498C-AC00-8AAC8D311A10)', Time: '2020-09-01T18:49:56', User OID: 'PatientReportedOutcome (US3052005)', ODM File OID: 'f62f148d-c22a-4db7-b4eb-528c3044c088'	System	01 Sep 2020 22:50:04
User entered 'No (N)'	System	01 Sep 2020 22:50:04

US3052005

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 15:00:53

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:58:03
Data hard unlocked.		25 Feb 2021 15:17:32
Data hard locked.		25 Feb 2021 06:48:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9EADD593-414F-498C-AC00-8AAC8D311A10)', Time: '2020-09-01T18:49:59', User OID: 'PatientReportedOutcome (US3052005)', ODM File OID: 'f62f148d-c22a-4db7-b4eb-528c3044c088'	System	01 Sep 2020 22:50:04
User entered '01 Sep 2020 18:49'	System	01 Sep 2020 22:50:04

US3052005

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 15:00:53

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:58:03
Data hard unlocked.		25 Feb 2021 15:17:32
Data hard locked.		25 Feb 2021 06:48:14
User entered '01 Sep 2020 12:00'	System	26 Aug 2020 15:29:38

US3052005

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 15:00:53

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:58:03
Data hard unlocked.		25 Feb 2021 15:17:32
Data hard locked.		25 Feb 2021 06:48:14
User entered '02 Sep 2020 11:59'	System	26 Aug 2020 15:29:38

US3052005

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:00:53

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:41:16
User signature succeeded.	Judith Borger (b) (4)	23 Feb 2021 07:32:26
User entered 'Yes (Y)'	(b) (4) Stacey Saldua (b) (4) (b) (4)	21 Sep 2020 19:26:52

US3052005

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:00:53

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:41:16
User signature succeeded.	Judith Borger (b) (4)	23 Feb 2021 07:32:26
User entered '04 Sep 2020'	(b) (4) Stacey Saldua (b) (4) (b) (4)	21 Sep 2020 19:26:52

US3052005

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:00:53

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:41:16
User signature succeeded.	Judith Borger (b) (4)	23 Feb 2021 07:32:26
User entered 'Contact Not Made (CONTACT NOT MADE)'	(b) (4) Stacey Saldua (b) (4)	21 Sep 2020 19:26:52

US3052005

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:00:53

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:41:16
User signature succeeded.	Judith Borger (b) (4)	23 Feb 2021 07:32:26
User entered 'LEFT MESSAGE @2:13PM'	(b) (4) Stacey Saldua (b) (4)	21 Sep 2020 19:26:52

US3052005

Folder: Safety Call Day 36 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:00:53

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:41:16
User signature succeeded.	Judith Borger (b) (4)	23 Feb 2021 07:32:26
User entered 'Yes (Y)'	(b) (4) Stacey Saldua (b) (4)	30 Sep 2020 15:21:25

US3052005

Folder: Safety Call Day 36 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:00:53

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:41:16
User entered 'I'	System	30 Sep 2020 15:21:25

US3052005

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:00:53

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:41:16
User signature succeeded.	Judith Borger (b) (4)	23 Feb 2021 07:32:26
User entered 'No (N)'	(b) (4) Avia McClain-Stocker (b) (4)	08 Oct 2020 18:45:05

US3052005

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:00:53

Date of Contact or Contact Attempt (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:41:16
User signature succeeded.	Judith Borger (b) (4)	23 Feb 2021 07:32:26
User entered empty.	(b) (4) Avia McClain-Stocker (b) (4)	08 Oct 2020 18:45:05

US3052005

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:00:53

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:41:16
User signature succeeded.	Judith Borger (b) (4)	23 Feb 2021 07:32:26
User entered empty.	(b) (4) Avia McClain-Stocker (b) (4)	08 Oct 2020 18:45:05

US3052005

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:00:53

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:41:16
User signature succeeded.	Judith Borger (b) (4)	23 Feb 2021 07:32:26
User entered empty.	(b) (4) Avia McClain-Stocker (b) (4)	08 Oct 2020 18:45:05

US3052005

Folder: Safety Call Day 43 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:00:53

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:41:16
User signature succeeded.	Judith Borger (b) (4)	23 Feb 2021 07:32:26
User entered 'Yes (Y)'	(b) (4) Stacey Saldua (b) (4)	30 Sep 2020 15:21:39

US3052005

Folder: Safety Call Day 43 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:00:53

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:41:16
User entered 'I'	System	30 Sep 2020 15:21:39

US3052005

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:00:53

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:41:16
User signature succeeded.	Judith Borger (b) (4)	23 Feb 2021 07:32:26
User entered 'No (N)'	(b) (4) Avia McClain-Stocker (b) (4)	09 Nov 2020 16:18:41

US3052005

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:00:53

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:41:16
User signature succeeded.	Judith Borger (b) (4)	23 Feb 2021 07:32:26
User entered empty.	(b) (4) Avia McClain-Stocker (b) (4)	09 Nov 2020 16:18:41

US3052005

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:00:53

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:41:16
User signature succeeded.	Judith Borger (b) (4)	23 Feb 2021 07:32:26
User entered empty.	(b) (4) Avia McClain-Stocker (b) (4)	09 Nov 2020 16:18:41

US3052005

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:00:53

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:41:16
User signature succeeded.	Judith Borger (b) (4)	23 Feb 2021 07:32:26
User entered empty.	(b) (4) Avia McClain-Stocker (b) (4)	09 Nov 2020 16:18:41

US3052005

Folder: Safety Call Day 50 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:00:53

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:41:16
User signature succeeded.	Judith Borger (b) (4)	23 Feb 2021 07:32:26
User entered 'Yes (Y)'	(b) (4) Stacey Saldua (b) (4)	30 Sep 2020 15:21:57

US3052005

Folder: Safety Call Day 50 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:00:53

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:41:16
User entered 'I'	System	30 Sep 2020 15:21:57

US3052005

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 09 Jun 2021 15:00:53

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:41:16
User signature succeeded.	Judith Borger (b) (4)	23 Feb 2021 07:32:26
User entered 'Yes (Y)'	(b) (4) Stacey Saldua (b) (4)	30 Sep 2020 15:23:21

US3052005

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 09 Jun 2021 15:00:53

[Visit date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:41:16
User signature succeeded.	Judith Borger (b) (4)	23 Feb 2021 07:32:26
User entered '29 Sep 2020'	(b) (4) Stacey Saldua (b) (4)	30 Sep 2020 15:23:21

US3052005

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 09 Jun 2021 15:00:53

[Was visit performed at the participant's home or at the clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:41:16
User signature succeeded.	Judith Borger (b) (4)	23 Feb 2021 07:32:26
User entered 'Clinic (Clinic)'	(b) (4) Stacey Saldua (b) (4) (b) (4)	30 Sep 2020 15:23:21

US3052005

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 09 Jun 2021 15:00:53

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:41:16
User entered 'VISIT3'	System	30 Sep 2020 15:23:21

US3052005

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:00:53

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:41:16
User signature succeeded.	Judith Borger (b) (4)	23 Feb 2021 07:32:26
User entered 'Yes (Y)'	(b) (4) Stacey Saldua (b) (4)	30 Sep 2020 15:25:47

US3052005

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:00:53

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:41:16
User signature succeeded.	Judith Borger (b) (4)	23 Feb 2021 07:32:26
User entered '29 Sep 2020'	(b) (4) Stacey Saldua (b) (4) (b) (4)	30 Sep 2020 15:25:47

US3052005

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:00:53

Time of assessment (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:41:16
User signature succeeded.	Judith Borger (b) (4)	23 Feb 2021 07:32:26
User entered '11:36'	(b) (4) Stacey Saldua (b) (4) (b) (4)	30 Sep 2020 15:25:47

US3052005

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:00:53

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:41:16
User entered '29 Sep 2020 11:36'	System	30 Sep 2020 15:25:47

US3052005

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:00:53

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:41:16
User signature succeeded.	Judith Borger (b) (4)	23 Feb 2021 07:32:26
User entered '97.7' F	(b) (4) Stacey Saldua (b) (4)	30 Sep 2020 15:25:47

US3052005

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:00:53

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:41:16
User signature succeeded.	Judith Borger (b) (4)	23 Feb 2021 07:32:26
User entered 'Oral (Oral)'	(b) (4) Stacey Saldua (b) (4)	30 Sep 2020 15:25:47

US3052005

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:00:53

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:41:16
User signature succeeded.	Judith Borger (b) (4)	23 Feb 2021 07:32:26
User entered empty.	(b) (4) Stacey Saldua (b) (4) (b) (4)	30 Sep 2020 15:25:47

US3052005

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:00:53

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:41:16
User signature succeeded.	Judith Borger (b) (4)	23 Feb 2021 07:32:26
User entered '62'	(b) (4) Stacey Saldua (b) (4)	30 Sep 2020 15:25:47

US3052005

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:00:53

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:41:16
User entered 'bpm'	System	30 Sep 2020 15:25:47

US3052005

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:00:53

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:41:16
User signature succeeded.	Judith Borger (b) (4)	23 Feb 2021 07:32:26
User entered '15'	(b) (4) Stacey Saldua (b) (4)	30 Sep 2020 15:25:47

US3052005

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:00:53

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:41:16
User entered 'breaths/min'	System	30 Sep 2020 15:25:47

US3052005

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:00:53

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:41:16
User signature succeeded.	Judith Borger (b) (4)	23 Feb 2021 07:32:26
User entered '117'	(b) (4) Stacey Saldua (b) (4)	30 Sep 2020 15:25:47

US3052005

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:00:53

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:41:16
User entered 'mmHg'	System	30 Sep 2020 15:25:47

US3052005

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:00:53

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:41:16
User signature succeeded.	Judith Borger (b) (4)	23 Feb 2021 07:32:26
User entered '78'	(b) (4) Stacey Saldua (b) (4)	30 Sep 2020 15:25:47

US3052005

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:00:53

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:41:16
User entered 'mmHg'	System	30 Sep 2020 15:25:47

US3052005

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:00:53

[Height \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:41:16

US3052005

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:00:53

[Weight \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:41:16

US3052005

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 15:00:53

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:41:16
User signature succeeded.	Judith Borger (b) (4)	23 Feb 2021 07:32:26
User entered 'Yes (Y)'	(b) (4) Stacey Saldua (b) (4)	30 Sep 2020 15:26:18

US3052005

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 15:00:53

Date of examination (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:41:16
User signature succeeded.	Judith Borger (b) (4)	23 Feb 2021 07:32:26
User entered '29 Sep 2020'	(b) (4) Stacey Saldua (b) (4)	30 Sep 2020 15:26:18

US3052005

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 15:00:53

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:41:16
User signature succeeded.	Judith Borger (b) (4)	23 Feb 2021 07:32:26
User entered 'Yes (Y)'	(b) (4) Stacey Saldua (b) (4)	30 Sep 2020 15:27:07

US3052005

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 15:00:53

Collection date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:41:16
User signature succeeded.	Judith Borger (b) (4)	23 Feb 2021 07:32:26
User entered '29 Sep 2020'	(b) (4) Stacey Saldua (b) (4)	30 Sep 2020 15:27:07

US3052005

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 15:00:53

Collection time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:41:16
User signature succeeded.	Judith Borger (b) (4)	23 Feb 2021 07:32:26
User entered '12:00'	(b) (4) Stacey Saldua (b) (4)	30 Sep 2020 15:27:07

US3052005

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 15:00:53

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:41:16
User entered '29 Sep 2020 12:00'	System	30 Sep 2020 15:27:07

US3052005

Folder: Visit 3 Day 57 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:00:53

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:41:16
User signature succeeded.	Judith Borger (b) (4)	23 Feb 2021 07:32:26
User entered 'Yes (Y)'	(b) (4) Stacey Saldua (b) (4)	30 Sep 2020 15:27:17

US3052005

Folder: Visit 3 Day 57 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:00:53

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:41:16
User entered '1'	System	30 Sep 2020 15:27:17

US3052005

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:00:53

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:58:03
Data hard unlocked.		25 Feb 2021 15:17:45
Data hard locked.		25 Feb 2021 06:48:14
Data entry locked.	System	30 Jul 2020 16:00:02
User entered 'Day 64'	System	30 Jul 2020 16:00:02

US3052005

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:00:53

Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:58:03
Data hard unlocked.		25 Feb 2021 15:17:45
Data hard locked.		25 Feb 2021 06:48:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9EADD593-414F-498C-AC00-8AAC8D311A10)', Time: '2020-10-01T13:56:08', User OID: 'PatientReportedOutcome (US3052005)', ODM File OID: 'b2d474b5-8f82-4f66-b1fe-b1fdf3f20ad9'	System	01 Oct 2020 17:56:22
User entered 'No (N)'	System	01 Oct 2020 17:56:22

US3052005

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:00:53

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:58:03
Data hard unlocked.		25 Feb 2021 15:17:45
Data hard locked.		25 Feb 2021 06:48:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9EADD593-414F-498C-AC00-8AAC8D311A10)', Time: '2020-10-01T13:56:12', User OID: 'PatientReportedOutcome (US3052005)', ODM File OID: 'b2d474b5-8f82-4f66-b1fe-b1fdf3f20ad9'	System	01 Oct 2020 17:56:22
User entered 'No (N)'	System	01 Oct 2020 17:56:22

US3052005

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:00:53

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:58:03
Data hard unlocked.		25 Feb 2021 15:17:45
Data hard locked.		25 Feb 2021 06:48:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9EADD593-414F-498C-AC00-8AAC8D311A10)', Time: '2020-10-01T13:56:18', User OID: 'PatientReportedOutcome (US3052005)', ODM File OID: 'b2d474b5-8f82-4f66-b1fe-b1fdf3f20ad9' User entered '01 Oct 2020 13:56:18'	System	01 Oct 2020 17:56:22
	System	01 Oct 2020 17:56:22

US3052005

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:00:53

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:58:03
Data hard unlocked.		25 Feb 2021 15:17:45
Data hard locked.		25 Feb 2021 06:48:14
Data entry locked.	System	30 Jul 2020 16:00:02
User entered '29 Sep 2020 00:01'	System	30 Jul 2020 16:00:02

US3052005

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:00:53

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:58:03
Data hard unlocked.		25 Feb 2021 15:17:45
Data hard locked.		25 Feb 2021 06:48:14
Data entry locked.	System	30 Jul 2020 16:00:02
User entered '03 Oct 2020 23:59'	System	30 Jul 2020 16:00:02

US3052005

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:00:53

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:58:03
Data hard unlocked.		25 Feb 2021 15:17:45
Data hard locked.		25 Feb 2021 06:48:14
Data entry locked.	System	30 Jul 2020 16:00:02
User entered 'Day 71'	System	30 Jul 2020 16:00:02

US3052005

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:00:53

Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:58:03
Data hard unlocked.		25 Feb 2021 15:17:45
Data hard locked.		25 Feb 2021 06:48:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9EADD593-414F-498C-AC00-8AAC8D311A10)', Time: '2020-10-06T20:21:36', User OID: 'PatientReportedOutcome (US3052005)', ODM File OID: '96c4da47-1aa1-46d0-b1b3-4f1a6d38ac48'	System	07 Oct 2020 00:21:54
User entered 'No (N)'	System	07 Oct 2020 00:21:54

US3052005

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:00:53

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:58:03
Data hard unlocked.		25 Feb 2021 15:17:45
Data hard locked.		25 Feb 2021 06:48:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9EADD593-414F-498C-AC00-8AAC8D311A10)', Time: '2020-10-06T20:21:43', User OID: 'PatientReportedOutcome (US3052005)', ODM File OID: '96c4da47-1aa1-46d0-b1b3-4f1a6d38ac48'	System	07 Oct 2020 00:21:54
User entered 'No (N)'	System	07 Oct 2020 00:21:54

US3052005

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:00:53

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:58:03
Data hard unlocked.		25 Feb 2021 15:17:45
Data hard locked.		25 Feb 2021 06:48:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9EADD593-414F-498C-AC00-8AAC8D311A10)', Time: '2020-10-06T20:21:49', User OID: 'PatientReportedOutcome (US3052005)', ODM File OID: '96c4da47-1aa1-46d0-b1b3-4f1a6d38ac48'	System	07 Oct 2020 00:21:54
User entered '06 Oct 2020 20:21:49'	System	07 Oct 2020 00:21:54

US3052005

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:00:53

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:58:03
Data hard unlocked.		25 Feb 2021 15:17:45
Data hard locked.		25 Feb 2021 06:48:14
Data entry locked.	System	30 Jul 2020 16:00:02
User entered '06 Oct 2020 00:01'	System	30 Jul 2020 16:00:02

US3052005

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:00:53

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:58:03
Data hard unlocked.		25 Feb 2021 15:17:45
Data hard locked.		25 Feb 2021 06:48:14
Data entry locked.	System	30 Jul 2020 16:00:02
User entered '10 Oct 2020 23:59'	System	30 Jul 2020 16:00:02

US3052005

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:00:53

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:58:03
Data hard unlocked.		25 Feb 2021 15:17:45
Data hard locked.		25 Feb 2021 06:48:14
Data entry locked.	System	30 Jul 2020 16:00:02
User entered 'Day 78'	System	30 Jul 2020 16:00:02

US3052005

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:00:53

Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:58:03
Data hard unlocked.	(b) (4), (b) (6)	25 Feb 2021 15:17:45
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:48:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9EADD593-414F-498C-AC00-8AAC8D311A10)', Time: '2020-10-16T18:47:25', User OID: 'PatientReportedOutcome (US3052005)', ODM File OID: '7d0a3611-4d4b-4e23-b5a0-246ef153aa58'	System	16 Oct 2020 22:47:44
User entered 'No (N)'	System	16 Oct 2020 22:47:44

US3052005

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:00:53

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:58:03
Data hard unlocked.		25 Feb 2021 15:17:45
Data hard locked.		25 Feb 2021 06:48:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9EADD593-414F-498C-AC00-8AAC8D311A10)', Time: '2020-10-16T18:47:31', User OID: 'PatientReportedOutcome (US3052005)', ODM File OID: '7d0a3611-4d4b-4e23-b5a0-246ef153aa58'	System	16 Oct 2020 22:47:44
User entered 'No (N)'	System	16 Oct 2020 22:47:44

US3052005

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:00:53

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:58:03
Data hard unlocked.		25 Feb 2021 15:17:45
Data hard locked.		25 Feb 2021 06:48:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9EADD593-414F-498C-AC00-8AAC8D311A10)', Time: '2020-10-16T18:47:35', User OID: 'PatientReportedOutcome (US3052005)', ODM File OID: '7d0a3611-4d4b-4e23-b5a0-246ef153aa58'	System	16 Oct 2020 22:47:44
User entered '16 Oct 2020 18:47:35'	System	16 Oct 2020 22:47:44

US3052005

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:00:53

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:58:03
Data hard unlocked.		25 Feb 2021 15:17:45
Data hard locked.		25 Feb 2021 06:48:14
Data entry locked.	System	30 Jul 2020 16:00:02
User entered '13 Oct 2020 00:01'	System	30 Jul 2020 16:00:02

US3052005

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:00:53

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:58:03
Data hard unlocked.		25 Feb 2021 15:17:45
Data hard locked.		25 Feb 2021 06:48:14
Data entry locked.	System	30 Jul 2020 16:00:02
User entered '17 Oct 2020 23:59'	System	30 Jul 2020 16:00:02

US3052005

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:00:53

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 22:40:04
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 10:27:51
Data entry locked.	System	30 Jul 2020 16:00:02
User entered 'Day 92'	System	30 Jul 2020 16:00:02

US3052005

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:00:53

[Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 22:40:04
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 10:27:51

US3052005

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:00:53

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 22:40:04
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 10:27:51

US3052005

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:00:53

[Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 22:40:04
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 10:27:51

US3052005

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:00:53

[Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 22:40:04
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 10:27:51

US3052005

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:00:53

Fever (Temperature \geq 100.4°F/38°C)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 22:40:04
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 10:27:51

US3052005

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:00:53

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 22:40:04
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 10:27:51

US3052005

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:00:53

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 22:40:04
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 10:27:51

US3052005

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:00:53

[Shortness of breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 22:40:04
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 10:27:51

US3052005

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:00:53

[Difficulty breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 22:40:04
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 10:27:51

US3052005

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:00:53

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 22:40:04
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 10:27:51

US3052005

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:00:53

[Muscle aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 22:40:04
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 10:27:51

US3052005

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:00:53

[Body aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 22:40:04
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 10:27:51

US3052005

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:00:53

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 22:40:04
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 10:27:51

US3052005

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:00:53

[New loss of taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 22:40:04
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 10:27:51

US3052005

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:00:53

[New loss of smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 22:40:04
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 10:27:51

US3052005

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:00:53

[Sore throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 22:40:04
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 10:27:51

US3052005

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:00:53

[Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 22:40:04
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 10:27:51

US3052005

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:00:53

[Runny nose](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 22:40:04
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 10:27:51

US3052005

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:00:53

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 22:40:04
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 10:27:51

US3052005

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:00:53

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 22:40:04
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 10:27:51

US3052005

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:00:53

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 22:40:04
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 10:27:51

US3052005

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:00:53

[Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 22:40:04
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 10:27:51

US3052005

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:00:53

[Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 22:40:04
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 10:27:51

US3052005

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:00:53

[Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 22:40:04
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 10:27:51

US3052005

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:00:53

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 22:40:04
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 10:27:51

US3052005

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:00:53

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 22:40:04
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 10:27:51
Data entry locked.	System	30 Jul 2020 16:00:02
User entered '27 Oct 2020 00:01'	System	30 Jul 2020 16:00:02

US3052005

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:00:53

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 22:40:04
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 10:27:51
Data entry locked.	System	30 Jul 2020 16:00:02
User entered '31 Oct 2020 23:59'	System	30 Jul 2020 16:00:02

US3052005

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:00:53

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:58:03
Data hard unlocked.		25 Feb 2021 15:17:45
Data hard locked.		25 Feb 2021 06:48:14
Data entry locked.	System	30 Jul 2020 16:00:02
User entered 'Day 99'	System	30 Jul 2020 16:00:02

US3052005

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:00:53

Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:58:03
Data hard unlocked.		25 Feb 2021 15:17:45
Data hard locked.		25 Feb 2021 06:48:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9EADD593-414F-498C-AC00-8AAC8D311A10)', Time: '2020-11-05T14:12:00', User OID: 'PatientReportedOutcome (US3052005)', ODM File OID: '9246e32d-d907-40d2-a19e-2cc2349b8055'	System	05 Nov 2020 19:15:05
User entered 'No (N)'	System	05 Nov 2020 19:15:05

US3052005

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:00:53

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:58:03
Data hard unlocked.		25 Feb 2021 15:17:45
Data hard locked.		25 Feb 2021 06:48:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9EADD593-414F-498C-AC00-8AAC8D311A10)', Time: '2020-11-05T14:14:08', User OID: 'PatientReportedOutcome (US3052005)', ODM File OID: '9246e32d-d907-40d2-a19e-2cc2349b8055'	System	05 Nov 2020 19:15:05
User entered 'Yes (Y)'	System	05 Nov 2020 19:15:05

US3052005

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:00:53

[Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:58:03
Data hard unlocked.		25 Feb 2021 15:17:45
Data hard locked.		25 Feb 2021 06:48:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9EADD593-414F-498C-AC00-8AAC8D311A10)', Time: '2020-11-05T14:14:36', User OID: 'PatientReportedOutcome (US3052005)', ODM File OID: '9246e32d-d907-40d2-a19e-2cc2349b8055'	System	05 Nov 2020 19:15:05
User entered 'I confirm I have read this message and will call the study clinic immediately (9)'	System	05 Nov 2020 19:15:05

US3052005

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:00:53

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:58:03
Data hard unlocked.		25 Feb 2021 15:17:45
Data hard locked.		25 Feb 2021 06:48:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9EADD593-414F-498C-AC00-8AAC8D311A10)', Time: '2020-11-05T14:14:51', User OID: 'PatientReportedOutcome (US3052005)', ODM File OID: '9246e32d-d907-40d2-a19e-2cc2349b8055'	System	05 Nov 2020 19:15:05
User entered '05 Nov 2020 14:14:51'	System	05 Nov 2020 19:15:05

US3052005

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:00:53

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:58:03
Data hard unlocked.		25 Feb 2021 15:17:45
Data hard locked.		25 Feb 2021 06:48:14
Data entry locked.	System	30 Jul 2020 16:00:02
User entered '03 Nov 2020 00:01'	System	30 Jul 2020 16:00:02

US3052005

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:00:53

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:58:03
Data hard unlocked.	(b) (4), (b) (6)	25 Feb 2021 15:17:45
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:48:14
Data entry locked.	System	30 Jul 2020 16:00:02
User entered '07 Nov 2020 23:59'	System	30 Jul 2020 16:00:02

US3052005

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:00:53

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:58:03
Data hard unlocked.		25 Feb 2021 15:17:45
Data hard locked.		25 Feb 2021 06:48:14
Data entry locked.	System	30 Jul 2020 16:00:02
User entered 'Day 106'	System	30 Jul 2020 16:00:02

US3052005

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:00:53

Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:58:03
Data hard unlocked.		25 Feb 2021 15:17:45
Data hard locked.		25 Feb 2021 06:48:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9EADD593-414F-498C-AC00-8AAC8D311A10)', Time: '2020-11-14T12:00:06', User OID: 'PatientReportedOutcome (US3052005)', ODM File OID: '2b67694a-4104-4ab4-87d4-c369c1e81b50'	System	14 Nov 2020 17:00:24
User entered 'No (N)'	System	14 Nov 2020 17:00:24

US3052005

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:00:53

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:58:03
Data hard unlocked.		25 Feb 2021 15:17:45
Data hard locked.		25 Feb 2021 06:48:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9EADD593-414F-498C-AC00-8AAC8D311A10)', Time: '2020-11-14T12:00:12', User OID: 'PatientReportedOutcome (US3052005)', ODM File OID: '2b67694a-4104-4ab4-87d4-c369c1e81b50'	System	14 Nov 2020 17:00:24
User entered 'No (N)'	System	14 Nov 2020 17:00:24

US3052005

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:00:53

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:58:03
Data hard unlocked.		25 Feb 2021 15:17:45
Data hard locked.		25 Feb 2021 06:48:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9EADD593-414F-498C-AC00-8AAC8D311A10)', Time: '2020-11-14T12:00:17', User OID: 'PatientReportedOutcome (US3052005)', ODM File OID: '2b67694a-4104-4ab4-87d4-c369c1e81b50'	System	14 Nov 2020 17:00:24
User entered '14 Nov 2020 12:00:17'	System	14 Nov 2020 17:00:24

US3052005

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:00:53

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:58:03
Data hard unlocked.		25 Feb 2021 15:17:45
Data hard locked.		25 Feb 2021 06:48:14
Data entry locked.	System	30 Jul 2020 16:00:02
User entered '10 Nov 2020 00:01'	System	30 Jul 2020 16:00:02

US3052005

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:00:53

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:58:03
Data hard unlocked.		25 Feb 2021 15:17:45
Data hard locked.		25 Feb 2021 06:48:14
Data entry locked.	System	30 Jul 2020 16:00:02
User entered '14 Nov 2020 23:59'	System	30 Jul 2020 16:00:02

US3052005

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:00:53

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:58:03
Data hard unlocked.		25 Feb 2021 15:17:45
Data hard locked.		25 Feb 2021 06:48:14
Data entry locked.	System	30 Jul 2020 16:00:02
User entered 'Day 113'	System	30 Jul 2020 16:00:02

US3052005

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:00:53

Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:58:03
Data hard unlocked.		25 Feb 2021 15:17:45
Data hard locked.		25 Feb 2021 06:48:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9EADD593-414F-498C-AC00-8AAC8D311A10)', Time: '2020-11-17T07:59:33', User OID: 'PatientReportedOutcome (US3052005)', ODM File OID: 'ed23b752-fcfe-4f86-bc6c-c3142e312f0a'	System	17 Nov 2020 12:59:51
User entered 'No (N)'	System	17 Nov 2020 12:59:51

US3052005

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:00:53

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:58:03
Data hard unlocked.		25 Feb 2021 15:17:45
Data hard locked.		25 Feb 2021 06:48:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9EADD593-414F-498C-AC00-8AAC8D311A10)', Time: '2020-11-17T07:59:42', User OID: 'PatientReportedOutcome (US3052005)', ODM File OID: 'ed23b752-fcfe-4f86-bc6c-c3142e312f0a'	System	17 Nov 2020 12:59:51
User entered 'No (N)'	System	17 Nov 2020 12:59:51

US3052005

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:00:53

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:58:03
Data hard unlocked.		25 Feb 2021 15:17:45
Data hard locked.		25 Feb 2021 06:48:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9EADD593-414F-498C-AC00-8AAC8D311A10)', Time: '2020-11-17T07:59:46', User OID: 'PatientReportedOutcome (US3052005)', ODM File OID: 'ed23b752-fcfe-4f86-bc6c-c3142e312f0a' User entered '17 Nov 2020 07:59:46'	System	17 Nov 2020 12:59:51
	System	17 Nov 2020 12:59:51

US3052005

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:00:53

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:58:03
Data hard unlocked.		25 Feb 2021 15:17:45
Data hard locked.		25 Feb 2021 06:48:14
Data entry locked.	System	30 Jul 2020 16:00:02
User entered '17 Nov 2020 00:01'	System	30 Jul 2020 16:00:02

US3052005

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:00:53

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:58:03
Data hard unlocked.		25 Feb 2021 15:17:45
Data hard locked.		25 Feb 2021 06:48:14
Data entry locked.	System	30 Jul 2020 16:00:02
User entered '21 Nov 2020 23:59'	System	30 Jul 2020 16:00:02

US3052005

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:00:53

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:27:51
Amendment Manager: User entered 'Day 117'	System	19 Nov 2020 10:27:51

US3052005

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:00:53

[Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9EADD593-414F-498C-AC00-8AAC8D311A10)', Time: '2020-11-21T03:28:23', User OID: 'PatientReportedOutcome (US3052005)', ODM File OID: '84868a0d-f442-4cb3-8e16-42d3163b3029'	System	21 Nov 2020 08:28:43
User entered 'No (N)'	System	21 Nov 2020 08:28:43

US3052005

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:00:53

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9EADD593-414F-498C-AC00-8AAC8D311A10)', Time: '2020-11-21T03:28:30', User OID: 'PatientReportedOutcome (US3052005)', ODM File OID: '84868a0d-f442-4cb3-8e16-42d3163b3029'	System	21 Nov 2020 08:28:43
User entered 'No (N)'	System	21 Nov 2020 08:28:43

US3052005

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:00:53

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9EADD593-414F-498C-AC00-8AAC8D311A10)', Time: '2020-11-21T03:28:39', User OID: 'PatientReportedOutcome (US3052005)', ODM File OID: '84868a0d-f442-4cb3-8e16-42d3163b3029' User entered '21 Nov 2020 03:28:39'	System	21 Nov 2020 08:28:43
	System	21 Nov 2020 08:28:43

US3052005

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:00:53

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:27:51
Amendment Manager: User entered '21 Nov 2020 00:01'	System	19 Nov 2020 10:27:51

US3052005

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:00:53

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:27:51
Amendment Manager: User entered '25 Nov 2020 23:59'	System	19 Nov 2020 10:27:51

US3052005

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:00:53

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:27:51
Amendment Manager: User entered 'Day 124'	System	19 Nov 2020 10:27:51

US3052005

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:00:53

[Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9EADD593-414F-498C-AC00-8AAC8D311A10)', Time: '2020-12-01T18:01:56', User OID: 'PatientReportedOutcome (US3052005)', ODM File OID: 'acb4992e-fe1e-4b47-b85e-b049e1ffab25'	System	01 Dec 2020 23:02:09
User entered 'No (N)'	System	01 Dec 2020 23:02:09

US3052005

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:00:53

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9EADD593-414F-498C-AC00-8AAC8D311A10)', Time: '2020-12-01T18:02:00', User OID: 'PatientReportedOutcome (US3052005)', ODM File OID: 'acb4992e-fe1e-4b47-b85e-b049e1ffab25'	System	01 Dec 2020 23:02:09
User entered 'No (N)'	System	01 Dec 2020 23:02:09

US3052005

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:00:53

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9EADD593-414F-498C-AC00-8AAC8D311A10)', Time: '2020-12-01T18:02:04', User OID: 'PatientReportedOutcome (US3052005)', ODM File OID: 'acb4992e-fe1e-4b47-b85e-b049e1ffab25' User entered '01 Dec 2020 18:02:04'	System	01 Dec 2020 23:02:09
	System	01 Dec 2020 23:02:09

US3052005

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:00:53

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:27:51
Amendment Manager: User entered '28 Nov 2020 00:01'	System	19 Nov 2020 10:27:51

US3052005

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:00:53

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:27:51
Amendment Manager: User entered '02 Dec 2020 23:59'	System	19 Nov 2020 10:27:51

US3052005

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:00:53

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:27:51
Amendment Manager: User entered 'Day 131'	System	19 Nov 2020 10:27:51

US3052005

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:00:53

[Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9EADD593-414F-498C-AC00-8AAC8D311A10)', Time: '2020-12-08T19:23:17', User OID: 'PatientReportedOutcome (US3052005)', ODM File OID: '5de3ba42-6307-46c6-a4ac-9c82e47c0582'	System	09 Dec 2020 00:23:35
User entered 'No (N)'	System	09 Dec 2020 00:23:35

US3052005

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:00:53

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9EADD593-414F-498C-AC00-8AAC8D311A10)', Time: '2020-12-08T19:23:25', User OID: 'PatientReportedOutcome (US3052005)', ODM File OID: '5de3ba42-6307-46c6-a4ac-9c82e47c0582'	System	09 Dec 2020 00:23:35
User entered 'No (N)'	System	09 Dec 2020 00:23:35

US3052005

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:00:53

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9EADD593-414F-498C-AC00-8AAC8D311A10)', Time: '2020-12-08T19:23:30', User OID: 'PatientReportedOutcome (US3052005)', ODM File OID: '5de3ba42-6307-46c6-a4ac-9c82e47c0582' User entered '08 Dec 2020 19:23:30'	System	09 Dec 2020 00:23:35
	System	09 Dec 2020 00:23:35

US3052005

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:00:53

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:27:51
Amendment Manager: User entered '05 Dec 2020 00:01'	System	19 Nov 2020 10:27:51

US3052005

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:00:53

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:27:51
Amendment Manager: User entered '09 Dec 2020 23:59'	System	19 Nov 2020 10:27:51

US3052005

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:00:53

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:27:51
Amendment Manager: User entered 'Day 138'	System	19 Nov 2020 10:27:51

US3052005

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:00:53

[Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9EADD593-414F-498C-AC00-8AAC8D311A10)', Time: '2020-12-15T20:13:38', User OID: 'PatientReportedOutcome (US3052005)', ODM File OID: '575d0028-ff6f-486f-8ccb-9e396382193f' User entered 'No (N)'	System	16 Dec 2020 01:13:49
	System	16 Dec 2020 01:13:49

US3052005

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:00:53

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9EADD593-414F-498C-AC00-8AAC8D311A10)', Time: '2020-12-15T20:13:42', User OID: 'PatientReportedOutcome (US3052005)', ODM File OID: '575d0028-ff6f-486f-8ccb-9e396382193f' User entered 'No (N)'	System	16 Dec 2020 01:13:49

US3052005

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:00:53

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9EADD593-414F-498C-AC00-8AAC8D311A10)', Time: '2020-12-15T20:13:46', User OID: 'PatientReportedOutcome (US3052005)', ODM File OID: '575d0028-ff6f-486f-8ccb-9e396382193f' User entered '15 Dec 2020 20:13:46'	System	16 Dec 2020 01:13:49
	System	16 Dec 2020 01:13:49

US3052005

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:00:53

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:27:51
Amendment Manager: User entered '12 Dec 2020 00:01'	System	19 Nov 2020 10:27:51

US3052005

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:00:53

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:27:51
Amendment Manager: User entered '16 Dec 2020 23:59'	System	19 Nov 2020 10:27:51

US3052005

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:00:53

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:27:51
Amendment Manager: User entered 'Day 145'	System	19 Nov 2020 10:27:51

US3052005

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:00:53

[Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9EADD593-414F-498C-AC00-8AAC8D311A10)', Time: '2020-12-23T10:47:51', User OID: 'PatientReportedOutcome (US3052005)', ODM File OID: 'e92e4641-7408-4b5d-938d-eded12193169' User entered 'No (N)'	System	23 Dec 2020 15:54:55
	System	23 Dec 2020 15:54:55

US3052005

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:00:53

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9EADD593-414F-498C-AC00-8AAC8D311A10)', Time: '2020-12-23T10:48:00', User OID: 'PatientReportedOutcome (US3052005)', ODM File OID: 'e92e4641-7408-4b5d-938d-eded12193169'	System	23 Dec 2020 15:54:55
User entered 'Yes (Y)'	System	23 Dec 2020 15:54:55

US3052005

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:00:53

[Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9EADD593-414F-498C-AC00-8AAC8D311A10)', Time: '2020-12-23T10:54:36', User OID: 'PatientReportedOutcome (US3052005)', ODM File OID: 'e92e4641-7408-4b5d-938d-eded12193169'	System	23 Dec 2020 15:54:55
User entered 'I confirm I have read this message and will call the study clinic immediately (9)'	System	23 Dec 2020 15:54:55

US3052005

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:00:53

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9EADD593-414F-498C-AC00-8AAC8D311A10)', Time: '2020-12-23T10:54:43', User OID: 'PatientReportedOutcome (US3052005)', ODM File OID: 'e92e4641-7408-4b5d-938d-eded12193169' User entered '23 Dec 2020 10:54:43'	System	23 Dec 2020 15:54:55
	System	23 Dec 2020 15:54:55

US3052005

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:00:53

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:27:51
Amendment Manager: User entered '19 Dec 2020 00:01'	System	19 Nov 2020 10:27:51

US3052005

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:00:53

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:27:51
Amendment Manager: User entered '23 Dec 2020 23:59'	System	19 Nov 2020 10:27:51

US3052005

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:00:53

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:27:51
Amendment Manager: User entered 'Day 152'	System	19 Nov 2020 10:27:51

US3052005

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:00:53

[Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9EADD593-414F-498C-AC00-8AAC8D311A10)', Time: '2020-12-28T13:00:35', User OID: 'PatientReportedOutcome (US3052005)', ODM File OID: '62a8d144-d02a-4676-92ca-1f805d87c89c'	System	28 Dec 2020 18:01:28
User entered 'No (N)'	System	28 Dec 2020 18:01:28

US3052005

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:00:53

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9EADD593-414F-498C-AC00-8AAC8D311A10)', Time: '2020-12-28T13:01:07', User OID: 'PatientReportedOutcome (US3052005)', ODM File OID: '62a8d144-d02a-4676-92ca-1f805d87c89c'	System	28 Dec 2020 18:01:28
User entered 'No (N)'	System	28 Dec 2020 18:01:28

US3052005

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:00:53

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9EADD593-414F-498C-AC00-8AAC8D311A10)', Time: '2020-12-28T13:01:11', User OID: 'PatientReportedOutcome (US3052005)', ODM File OID: '62a8d144-d02a-4676-92ca-1f805d87c89c' User entered '28 Dec 2020 13:01:11'	System	28 Dec 2020 18:01:28
	System	28 Dec 2020 18:01:28

US3052005

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:00:53

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:27:51
Amendment Manager: User entered '26 Dec 2020 00:01'	System	19 Nov 2020 10:27:51

US3052005

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:00:53

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:27:51
Amendment Manager: User entered '30 Dec 2020 23:59'	System	19 Nov 2020 10:27:51

US3052005

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:00:53

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:27:51
Amendment Manager: User entered 'Day 159'	System	19 Nov 2020 10:27:51

US3052005

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:00:53

[Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9EADD593-414F-498C-AC00-8AAC8D311A10)', Time: '2021-01-05T18:33:04', User OID: 'PatientReportedOutcome (US3052005)', ODM File OID: '6ae958cf-58ff-4fae-ad5b-facf658a77e4'	System	05 Jan 2021 23:33:18
User entered 'No (N)'	System	05 Jan 2021 23:33:18

US3052005

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:00:53

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9EADD593-414F-498C-AC00-8AAC8D311A10)', Time: '2021-01-05T18:33:08', User OID: 'PatientReportedOutcome (US3052005)', ODM File OID: '6ae958cf-58ff-4fae-ad5b-facf658a77e4'	System	05 Jan 2021 23:33:18
User entered 'No (N)'	System	05 Jan 2021 23:33:18

US3052005

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:00:53

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9EADD593-414F-498C-AC00-8AAC8D311A10)', Time: '2021-01-05T18:33:12', User OID: 'PatientReportedOutcome (US3052005)', ODM File OID: '6ae958cf-58ff-4fae-ad5b-facf658a77e4' User entered '05 Jan 2021 18:33:12'	System	05 Jan 2021 23:33:18
	System	05 Jan 2021 23:33:18

US3052005

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:00:53

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:27:51
Amendment Manager: User entered '02 Jan 2021 00:01'	System	19 Nov 2020 10:27:51

US3052005

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:00:53

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:27:51
Amendment Manager: User entered '06 Jan 2021 23:59'	System	19 Nov 2020 10:27:51

US3052005

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:00:53

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:27:51
Amendment Manager: User entered 'Day 166'	System	19 Nov 2020 10:27:51

US3052005

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:00:53

[Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9EADD593-414F-498C-AC00-8AAC8D311A10)', Time: '2021-01-11T12:36:26', User OID: 'PatientReportedOutcome (US3052005)', ODM File OID: '99aa6f7d-0169-4d48-bb5e-9b92bbfca486'	System	11 Jan 2021 17:36:38
User entered 'No (N)'	System	11 Jan 2021 17:36:38

US3052005

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:00:53

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9EADD593-414F-498C-AC00-8AAC8D311A10)', Time: '2021-01-11T12:36:30', User OID: 'PatientReportedOutcome (US3052005)', ODM File OID: '99aa6f7d-0169-4d48-bb5e-9b92bbfca486'	System	11 Jan 2021 17:36:38
User entered 'No (N)'	System	11 Jan 2021 17:36:38

US3052005

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:00:53

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9EADD593-414F-498C-AC00-8AAC8D311A10)', Time: '2021-01-11T12:36:34', User OID: 'PatientReportedOutcome (US3052005)', ODM File OID: '99aa6f7d-0169-4d48-bb5e-9b92bbfca486' User entered '11 Jan 2021 12:36:34'	System	11 Jan 2021 17:36:38
	System	11 Jan 2021 17:36:38

US3052005

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:00:53

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:27:51
Amendment Manager: User entered '09 Jan 2021 00:01'	System	19 Nov 2020 10:27:51

US3052005

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:00:53

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:27:51
Amendment Manager: User entered '13 Jan 2021 23:59'	System	19 Nov 2020 10:27:51

US3052005

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:00:53

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:27:51
Amendment Manager: User entered 'Day 173'	System	19 Nov 2020 10:27:51

US3052005

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:00:53

[Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9EADD593-414F-498C-AC00-8AAC8D311A10)', Time: '2021-01-16T07:50:45', User OID: 'PatientReportedOutcome (US3052005)', ODM File OID: 'bc27638f-4b7a-45fa-9d29-c83fdbddfdaf' User entered 'No (N)'	System	16 Jan 2021 12:50:57
	System	16 Jan 2021 12:50:57

US3052005

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:00:53

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9EADD593-414F-498C-AC00-8AAC8D311A10)', Time: '2021-01-16T07:50:52', User OID: 'PatientReportedOutcome (US3052005)', ODM File OID: 'bc27638f-4b7a-45fa-9d29-c83fdbddfdaf' User entered 'No (N)'	System	16 Jan 2021 12:50:57
	System	16 Jan 2021 12:50:57

US3052005

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:00:53

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9EADD593-414F-498C-AC00-8AAC8D311A10)', Time: '2021-01-16T07:50:55', User OID: 'PatientReportedOutcome (US3052005)', ODM File OID: 'bc27638f-4b7a-45fa-9d29-c83fdbddfdaf' User entered '16 Jan 2021 07:50:55'	System	16 Jan 2021 12:50:57
	System	16 Jan 2021 12:50:57

US3052005

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:00:53

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:27:51
Amendment Manager: User entered '16 Jan 2021 00:01'	System	19 Nov 2020 10:27:51

US3052005

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:00:53

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:27:51
Amendment Manager: User entered '20 Jan 2021 23:59'	System	19 Nov 2020 10:27:51

US3052005

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:00:53

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:27:51
Amendment Manager: User entered 'Day 180'	System	19 Nov 2020 10:27:51

US3052005

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:00:53

[Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9EADD593-414F-498C-AC00-8AAC8D311A10)', Time: '2021-01-23T07:52:25', User OID: 'PatientReportedOutcome (US3052005)', ODM File OID: 'e8461d60-91e1-4a71-8811-04a2aedd92cc' User entered 'No (N)'	System	23 Jan 2021 13:52:39
	System	23 Jan 2021 13:52:39

US3052005

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:00:53

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9EADD593-414F-498C-AC00-8AAC8D311A10)', Time: '2021-01-23T07:52:29', User OID: 'PatientReportedOutcome (US3052005)', ODM File OID: 'e8461d60-91e1-4a71-8811-04a2aedd92cc'	System	23 Jan 2021 13:52:39
User entered 'No (N)'	System	23 Jan 2021 13:52:39

US3052005

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:00:53

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9EADD593-414F-498C-AC00-8AAC8D311A10)', Time: '2021-01-23T07:52:37', User OID: 'PatientReportedOutcome (US3052005)', ODM File OID: 'e8461d60-91e1-4a71-8811-04a2aedd92cc' User entered '23 Jan 2021 07:52:37'	System	23 Jan 2021 13:52:39

US3052005

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:00:53

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:27:51
Amendment Manager: User entered '23 Jan 2021 00:01'	System	19 Nov 2020 10:27:51

US3052005

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:00:53

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:27:51
Amendment Manager: User entered '27 Jan 2021 23:59'	System	19 Nov 2020 10:27:51

US3052005

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:00:53

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:27:51
Amendment Manager: User entered 'Day 187'	System	19 Nov 2020 10:27:51

US3052005

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:00:53

[Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9EADD593-414F-498C-AC00-8AAC8D311A10)', Time: '2021-01-30T08:51:15', User OID: 'PatientReportedOutcome (US3052005)', ODM File OID: '39d53ab9-4bde-4c66-b62f-b52e10db44b8'	System	30 Jan 2021 13:51:27
User entered 'No (N)'	System	30 Jan 2021 13:51:27

US3052005

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:00:53

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9EADD593-414F-498C-AC00-8AAC8D311A10)', Time: '2021-01-30T08:51:19', User OID: 'PatientReportedOutcome (US3052005)', ODM File OID: '39d53ab9-4bde-4c66-b62f-b52e10db44b8'	System	30 Jan 2021 13:51:27
User entered 'No (N)'	System	30 Jan 2021 13:51:27

US3052005

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:00:53

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9EADD593-414F-498C-AC00-8AAC8D311A10)', Time: '2021-01-30T08:51:22', User OID: 'PatientReportedOutcome (US3052005)', ODM File OID: '39d53ab9-4bde-4c66-b62f-b52e10db44b8' User entered '30 Jan 2021 08:51:22'	System	30 Jan 2021 13:51:27
	System	30 Jan 2021 13:51:27

US3052005

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:00:53

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:27:51
Amendment Manager: User entered '30 Jan 2021 00:01'	System	19 Nov 2020 10:27:51

US3052005

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:00:53

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:27:51
Amendment Manager: User entered '03 Feb 2021 23:59'	System	19 Nov 2020 10:27:51

US3052005

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:00:53

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:27:51
Amendment Manager: User entered 'Day 194'	System	19 Nov 2020 10:27:51

US3052005

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:00:53

[Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9EADD593-414F-498C-AC00-8AAC8D311A10)', Time: '2021-02-09T18:41:19', User OID: 'PatientReportedOutcome (US3052005)', ODM File OID: 'c5bcbe4f-721d-449b-a691-417c71775ec7'	System	09 Feb 2021 23:41:30
User entered 'No (N)'	System	09 Feb 2021 23:41:30

US3052005

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:00:53

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9EADD593-414F-498C-AC00-8AAC8D311A10)', Time: '2021-02-09T18:41:22', User OID: 'PatientReportedOutcome (US3052005)', ODM File OID: 'c5bcbe4f-721d-449b-a691-417c71775ec7'	System	09 Feb 2021 23:41:30
User entered 'No (N)'	System	09 Feb 2021 23:41:30

US3052005

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:00:53

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9EADD593-414F-498C-AC00-8AAC8D311A10)', Time: '2021-02-09T18:41:25', User OID: 'PatientReportedOutcome (US3052005)', ODM File OID: 'c5bcbe4f-721d-449b-a691-417c71775ec7' User entered '09 Feb 2021 18:41:25'	System	09 Feb 2021 23:41:30
	System	09 Feb 2021 23:41:30

US3052005

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:00:53

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:27:51
Amendment Manager: User entered '06 Feb 2021 00:01'	System	19 Nov 2020 10:27:51

US3052005

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:00:53

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:27:51
Amendment Manager: User entered '10 Feb 2021 23:59'	System	19 Nov 2020 10:27:51

US3052005

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:00:53

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:27:51
Amendment Manager: User entered 'Day 201'	System	19 Nov 2020 10:27:51

US3052005

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:00:53

[Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9EADD593-414F-498C-AC00-8AAC8D311A10)', Time: '2021-02-15T12:00:35', User OID: 'PatientReportedOutcome (US3052005)', ODM File OID: '4be88aba-fec7-455e-be82-cafdf3610ab7'	System	15 Feb 2021 17:03:25
User entered 'No (N)'	System	15 Feb 2021 17:03:25

US3052005

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:00:53

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9EADD593-414F-498C-AC00-8AAC8D311A10)', Time: '2021-02-15T12:00:38', User OID: 'PatientReportedOutcome (US3052005)', ODM File OID: '4be88aba-fec7-455e-be82-cafdf3610ab7'	System	15 Feb 2021 17:03:25
User entered 'No (N)'	System	15 Feb 2021 17:03:25

US3052005

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:00:53

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9EADD593-414F-498C-AC00-8AAC8D311A10)', Time: '2021-02-15T12:00:41', User OID: 'PatientReportedOutcome (US3052005)', ODM File OID: '4be88aba-fec7-455e-be82-cafdf3610ab7' User entered '15 Feb 2021 12:00:41'	System	15 Feb 2021 17:03:25
	System	15 Feb 2021 17:03:25

US3052005

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:00:53

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:27:51
Amendment Manager: User entered '13 Feb 2021 00:01'	System	19 Nov 2020 10:27:51

US3052005

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:00:53

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:27:51
Amendment Manager: User entered '17 Feb 2021 23:59'	System	19 Nov 2020 10:27:51

US3052005

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:00:53

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:27:51
Amendment Manager: User entered 'Day 208'	System	19 Nov 2020 10:27:51

US3052005

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:00:53

[Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9EADD593-414F-498C-AC00-8AAC8D311A10)', Time: '2021-02-21T08:30:39', User OID: 'PatientReportedOutcome (US3052005)', ODM File OID: 'a65750d4-2a17-4744-8d0e-5d6b30e94010' User entered 'No (N)'	System	21 Feb 2021 13:31:10
	System	21 Feb 2021 13:31:10

US3052005

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:00:53

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9EADD593-414F-498C-AC00-8AAC8D311A10)', Time: '2021-02-21T08:30:46', User OID: 'PatientReportedOutcome (US3052005)', ODM File OID: 'a65750d4-2a17-4744-8d0e-5d6b30e94010'	System	21 Feb 2021 13:31:10
User entered 'Yes (Y)'	System	21 Feb 2021 13:31:10

US3052005

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:00:53

[Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9EADD593-414F-498C-AC00-8AAC8D311A10)', Time: '2021-02-21T08:30:53', User OID: 'PatientReportedOutcome (US3052005)', ODM File OID: 'a65750d4-2a17-4744-8d0e-5d6b30e94010'	System	21 Feb 2021 13:31:10
User entered 'I confirm I have read this message and will call the study clinic immediately (9)'	System	21 Feb 2021 13:31:10

US3052005

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:00:53

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9EADD593-414F-498C-AC00-8AAC8D311A10)', Time: '2021-02-21T08:31:00', User OID: 'PatientReportedOutcome (US3052005)', ODM File OID: 'a65750d4-2a17-4744-8d0e-5d6b30e94010'	System	21 Feb 2021 13:31:10
User entered '21 Feb 2021 08:31:00'	System	21 Feb 2021 13:31:10

US3052005

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:00:53

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:27:51
Amendment Manager: User entered '20 Feb 2021 00:01'	System	19 Nov 2020 10:27:51

US3052005

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:00:53

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:27:51
Amendment Manager: User entered '24 Feb 2021 23:59'	System	19 Nov 2020 10:27:51

US3052005

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:00:53

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:27:51
Amendment Manager: User entered 'Day 215'	System	19 Nov 2020 10:27:51

US3052005

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:00:53

[Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9EADD593-414F-498C-AC00-8AAC8D311A10)', Time: '2021-02-27T19:39:26-05:00', User OID: 'PatientReportedOutcome (US3052005)', ODM File OID: '34abddb1-5d16-4285-b9cc-a6ccbc0603f1' User entered 'No (N)'	System	28 Feb 2021 00:39:47
	System	28 Feb 2021 00:39:47

US3052005

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:00:53

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9EADD593-414F-498C-AC00-8AAC8D311A10)', Time: '2021-02-27T19:39:36-05:00', User OID: 'PatientReportedOutcome (US3052005)', ODM File OID: '34abddb1-5d16-4285-b9cc-a6ccbc0603f1' User entered 'No (N)'	System	28 Feb 2021 00:39:47
	System	28 Feb 2021 00:39:47

US3052005

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:00:53

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9EADD593-414F-498C-AC00-8AAC8D311A10)', Time: '2021-02-27T19:39:42-05:00', User OID: 'PatientReportedOutcome (US3052005)', ODM File OID: '34abddb1-5d16-4285-b9cc-a6ccbc0603f1' User entered '28 Feb 2021 00:39:42'	System	28 Feb 2021 00:39:47
	System	28 Feb 2021 00:39:47

US3052005

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:00:53

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:27:51
Amendment Manager: User entered '27 Feb 2021 00:01'	System	19 Nov 2020 10:27:51

US3052005

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:00:53

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:27:51
Amendment Manager: User entered '03 Mar 2021 23:59'	System	19 Nov 2020 10:27:51

US3052005

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:00:53

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:27:51
Amendment Manager: User entered 'Day 222'	System	19 Nov 2020 10:27:51

US3052005

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:00:53

[Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9EADD593-414F-498C-AC00-8AAC8D311A10)', Time: '2021-03-08T11:56:36-05:00', User OID: 'PatientReportedOutcome (US3052005)', ODM File OID: '8b0e9610-959a-4a70-a685-982d23032910'	System	08 Mar 2021 16:56:49
User entered 'No (N)'	System	08 Mar 2021 16:56:49

US3052005

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:00:53

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9EADD593-414F-498C-AC00-8AAC8D311A10)', Time: '2021-03-08T11:56:42-05:00', User OID: 'PatientReportedOutcome (US3052005)', ODM File OID: '8b0e9610-959a-4a70-a685-982d23032910'	System	08 Mar 2021 16:56:49
User entered 'No (N)'	System	08 Mar 2021 16:56:49

US3052005

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:00:53

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9EADD593-414F-498C-AC00-8AAC8D311A10)', Time: '2021-03-08T11:56:46-05:00', User OID: 'PatientReportedOutcome (US3052005)', ODM File OID: '8b0e9610-959a-4a70-a685-982d23032910'	System	08 Mar 2021 16:56:49
User entered '08 Mar 2021 11:56:46'	System	08 Mar 2021 16:56:49

US3052005

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:00:53

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:27:51
Amendment Manager: User entered '06 Mar 2021 00:01'	System	19 Nov 2020 10:27:51

US3052005

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:00:53

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:27:51
Amendment Manager: User entered '10 Mar 2021 23:59'	System	19 Nov 2020 10:27:51

US3052005

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:00:53

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:27:51
Amendment Manager: User entered 'Day 229'	System	19 Nov 2020 10:27:51

US3052005

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:00:53

[Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9EADD593-414F-498C-AC00-8AAC8D311A10)', Time: '2021-03-15T12:30:39-04:00', User OID: 'PatientReportedOutcome (US3052005)', ODM File OID: '2661b548-5aec-4a9c-b493-3501de8adfa'	System	15 Mar 2021 16:30:55
User entered 'No (N)'	System	15 Mar 2021 16:30:55

US3052005

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:00:53

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9EADD593-414F-498C-AC00-8AAC8D311A10)', Time: '2021-03-15T12:30:43-04:00', User OID: 'PatientReportedOutcome (US3052005)', ODM File OID: '2661b548-5aec-4a9c-b493-3501de8adfda'	System	15 Mar 2021 16:30:55
User entered 'No (N)'	System	15 Mar 2021 16:30:55

US3052005

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:00:53

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9EADD593-414F-498C-AC00-8AAC8D311A10)', Time: '2021-03-15T12:30:46-04:00', User OID: 'PatientReportedOutcome (US3052005)', ODM File OID: '2661b548-5aec-4a9c-b493-3501de8adfa'	System	15 Mar 2021 16:30:55
User entered '15 Mar 2021 12:30:46'	System	15 Mar 2021 16:30:55

US3052005

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:00:53

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:27:51
Amendment Manager: User entered '13 Mar 2021 00:01'	System	19 Nov 2020 10:27:51

US3052005

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:00:53

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:27:51
Amendment Manager: User entered '17 Mar 2021 23:59'	System	19 Nov 2020 10:27:51

US3052005

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:00:53

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:27:51
Amendment Manager: User entered 'Day 236'	System	19 Nov 2020 10:27:51

US3052005

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:00:53

[Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9EADD593-414F-498C-AC00-8AAC8D311A10)', Time: '2021-03-22T13:29:25-04:00', User OID: 'PatientReportedOutcome (US3052005)', ODM File OID: '0196891f-a7c3-4ff2-a046-27e943bdf596'	System	22 Mar 2021 17:31:01
User entered 'No (N)'	System	22 Mar 2021 17:31:01

US3052005

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:00:53

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9EADD593-414F-498C-AC00-8AAC8D311A10)', Time: '2021-03-22T13:29:29-04:00', User OID: 'PatientReportedOutcome (US3052005)', ODM File OID: '0196891f-a7c3-4ff2-a046-27e943bdf596'	System	22 Mar 2021 17:31:01
User entered 'No (N)'	System	22 Mar 2021 17:31:01

US3052005

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:00:53

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9EADD593-414F-498C-AC00-8AAC8D311A10)', Time: '2021-03-22T13:29:35-04:00', User OID: 'PatientReportedOutcome (US3052005)', ODM File OID: '0196891f-a7c3-4ff2-a046-27e943bdf596'	System	22 Mar 2021 17:31:01
User entered '22 Mar 2021 13:29:35'	System	22 Mar 2021 17:31:01

US3052005

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:00:53

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:27:51
Amendment Manager: User entered '20 Mar 2021 00:01'	System	19 Nov 2020 10:27:51

US3052005

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:00:53

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:27:51
Amendment Manager: User entered '24 Mar 2021 23:59'	System	19 Nov 2020 10:27:51

US3052005

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:00:53

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:27:51
Amendment Manager: User entered 'Day 243'	System	19 Nov 2020 10:27:51

US3052005

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:00:53

[Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9EADD593-414F-498C-AC00-8AAC8D311A10)', Time: '2021-03-30T02:58:08-05:00', User OID: 'PatientReportedOutcome (US3052005)', ODM File OID: '1b7a72d5-ef73-42ee-9190-db166a3eaf2f' User entered 'No (N)'	System	30 Mar 2021 07:58:23
	System	30 Mar 2021 07:58:23

US3052005

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:00:53

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9EADD593-414F-498C-AC00-8AAC8D311A10)', Time: '2021-03-30T02:58:15-05:00', User OID: 'PatientReportedOutcome (US3052005)', ODM File OID: '1b7a72d5-ef73-42ee-9190-db166a3eaf2f' User entered 'No (N)'	System	30 Mar 2021 07:58:23

US3052005

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:00:53

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9EADD593-414F-498C-AC00-8AAC8D311A10)', Time: '2021-03-30T02:58:21-05:00', User OID: 'PatientReportedOutcome (US3052005)', ODM File OID: '1b7a72d5-ef73-42ee-9190-db166a3eaf2f' User entered '30 Mar 2021 02:58:21'	System	30 Mar 2021 07:58:23
	System	30 Mar 2021 07:58:23

US3052005

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:00:53

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:27:51
Amendment Manager: User entered '27 Mar 2021 00:01'	System	19 Nov 2020 10:27:51

US3052005

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:00:53

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:27:51
Amendment Manager: User entered '31 Mar 2021 23:59'	System	19 Nov 2020 10:27:51

US3052005

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:00:53

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:27:51
Amendment Manager: User entered 'Day 250'	System	19 Nov 2020 10:27:51

US3052005

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:00:53

[Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9EADD593-414F-498C-AC00-8AAC8D311A10)', Time: '2021-04-05T12:00:40-05:00', User OID: 'PatientReportedOutcome (US3052005)', ODM File OID: '49cfaabf-ae04-41b9-8695-89c1575eb11b' User entered 'No (N)'	System	05 Apr 2021 17:01:42
	System	05 Apr 2021 17:01:42

US3052005

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:00:53

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9EADD593-414F-498C-AC00-8AAC8D311A10)', Time: '2021-04-05T12:00:43-05:00', User OID: 'PatientReportedOutcome (US3052005)', ODM File OID: '49cfaabf-ae04-41b9-8695-89c1575eb11b'	System	05 Apr 2021 17:01:42
User entered 'No (N)'	System	05 Apr 2021 17:01:42

US3052005

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:00:53

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9EADD593-414F-498C-AC00-8AAC8D311A10)', Time: '2021-04-05T12:00:46-05:00', User OID: 'PatientReportedOutcome (US3052005)', ODM File OID: '49cfaabf-ae04-41b9-8695-89c1575eb11b'	System	05 Apr 2021 17:01:42
User entered '05 Apr 2021 12:00:46'	System	05 Apr 2021 17:01:42

US3052005

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:00:53

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:27:51
Amendment Manager: User entered '03 Apr 2021 00:01'	System	19 Nov 2020 10:27:51

US3052005

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:00:53

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:27:51
Amendment Manager: User entered '07 Apr 2021 23:59'	System	19 Nov 2020 10:27:51

US3052005

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:00:53

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:27:51
Amendment Manager: User entered 'Day 257'	System	19 Nov 2020 10:27:51

US3052005

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:00:53

[Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9EADD593-414F-498C-AC00-8AAC8D311A10)', Time: '2021-04-12T12:00:31-04:00', User OID: 'PatientReportedOutcome (US3052005)', ODM File OID: 'a3386570-f034-4e16-9f7a-6e1825afc480'	System	12 Apr 2021 16:02:20
User entered 'No (N)'	System	12 Apr 2021 16:02:20

US3052005

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:00:53

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9EADD593-414F-498C-AC00-8AAC8D311A10)', Time: '2021-04-12T12:00:33-04:00', User OID: 'PatientReportedOutcome (US3052005)', ODM File OID: 'a3386570-f034-4e16-9f7a-6e1825afc480'	System	12 Apr 2021 16:02:20
User entered 'No (N)'	System	12 Apr 2021 16:02:20

US3052005

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:00:53

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9EADD593-414F-498C-AC00-8AAC8D311A10)', Time: '2021-04-12T12:00:36-04:00', User OID: 'PatientReportedOutcome (US3052005)', ODM File OID: 'a3386570-f034-4e16-9f7a-6e1825afc480'	System	12 Apr 2021 16:02:20
User entered '12 Apr 2021 12:00:36'	System	12 Apr 2021 16:02:20

US3052005

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:00:53

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:27:51
Amendment Manager: User entered '10 Apr 2021 00:01'	System	19 Nov 2020 10:27:51

US3052005

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:00:53

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:27:51
Amendment Manager: User entered '14 Apr 2021 23:59'	System	19 Nov 2020 10:27:51

US3052005

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:00:53

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:27:51
Amendment Manager: User entered 'Day 264'	System	19 Nov 2020 10:27:51

US3052005

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:00:53

[Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9EADD593-414F-498C-AC00-8AAC8D311A10)', Time: '2021-04-20T19:02:37-04:00', User OID: 'PatientReportedOutcome (US3052005)', ODM File OID: 'f1c7155a-db56-40bc-8ef4-7ac739eaa313'	System	20 Apr 2021 23:03:46
User entered 'No (N)'	System	20 Apr 2021 23:03:46

US3052005

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:00:53

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9EADD593-414F-498C-AC00-8AAC8D311A10)', Time: '2021-04-20T19:02:39-04:00', User OID: 'PatientReportedOutcome (US3052005)', ODM File OID: 'f1c7155a-db56-40bc-8ef4-7ac739eaa313'	System	20 Apr 2021 23:03:46
User entered 'No (N)'	System	20 Apr 2021 23:03:46

US3052005

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:00:53

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9EADD593-414F-498C-AC00-8AAC8D311A10)', Time: '2021-04-20T19:02:42-04:00', User OID: 'PatientReportedOutcome (US3052005)', ODM File OID: 'f1c7155a-db56-40bc-8ef4-7ac739eaa313'	System	20 Apr 2021 23:03:46
User entered '20 Apr 2021 19:02:42'	System	20 Apr 2021 23:03:46

US3052005

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:00:53

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:27:51
Amendment Manager: User entered '17 Apr 2021 00:01'	System	19 Nov 2020 10:27:51

US3052005

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:00:53

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:27:51
Amendment Manager: User entered '21 Apr 2021 23:59'	System	19 Nov 2020 10:27:51

US3052005

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:00:53

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:27:51
Amendment Manager: User entered 'Day 271'	System	19 Nov 2020 10:27:51

US3052005

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:00:53

[Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9EADD593-414F-498C-AC00-8AAC8D311A10)', Time: '2021-04-26T12:05:39-04:00', User OID: 'PatientReportedOutcome (US3052005)', ODM File OID: '1abecb09-1bd7-40f0-bb67-44494313c592'	System	26 Apr 2021 16:10:44
User entered 'No (N)'	System	26 Apr 2021 16:10:44

US3052005

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:00:53

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9EADD593-414F-498C-AC00-8AAC8D311A10)', Time: '2021-04-26T12:05:42-04:00', User OID: 'PatientReportedOutcome (US3052005)', ODM File OID: '1abecb09-1bd7-40f0-bb67-44494313c592'	System	26 Apr 2021 16:10:44
User entered 'No (N)'	System	26 Apr 2021 16:10:44

US3052005

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:00:53

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9EADD593-414F-498C-AC00-8AAC8D311A10)', Time: '2021-04-26T12:05:45-04:00', User OID: 'PatientReportedOutcome (US3052005)', ODM File OID: '1abecb09-1bd7-40f0-bb67-44494313c592'	System	26 Apr 2021 16:10:44
User entered '26 Apr 2021 12:05:45'	System	26 Apr 2021 16:10:44

US3052005

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:00:53

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:27:51
Amendment Manager: User entered '24 Apr 2021 00:01'	System	19 Nov 2020 10:27:51

US3052005

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:00:53

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:27:51
Amendment Manager: User entered '28 Apr 2021 23:59'	System	19 Nov 2020 10:27:51

US3052005

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:00:53

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:27:51
Amendment Manager: User entered 'Day 278'	System	19 Nov 2020 10:27:51

US3052005

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:00:53

[Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9EADD593-414F-498C-AC00-8AAC8D311A10)', Time: '2021-05-03T12:05:24-04:00', User OID: 'PatientReportedOutcome (US3052005)', ODM File OID: '1c44e088-987d-43c2-a9f1-739487e7430d'	System	03 May 2021 16:13:31
User entered 'No (N)'	System	03 May 2021 16:13:31

US3052005

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:00:53

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9EADD593-414F-498C-AC00-8AAC8D311A10)', Time: '2021-05-03T12:05:40-04:00', User OID: 'PatientReportedOutcome (US3052005)', ODM File OID: '1c44e088-987d-43c2-a9f1-739487e7430d'	System	03 May 2021 16:13:31
User entered 'No (N)'	System	03 May 2021 16:13:31

US3052005

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:00:53

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9EADD593-414F-498C-AC00-8AAC8D311A10)', Time: '2021-05-03T12:05:44-04:00', User OID: 'PatientReportedOutcome (US3052005)', ODM File OID: '1c44e088-987d-43c2-a9f1-739487e7430d' User entered '03 May 2021 12:05:44'	System	03 May 2021 16:13:31
	System	03 May 2021 16:13:31

US3052005

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:00:53

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:27:51
Amendment Manager: User entered '01 May 2021 00:01'	System	19 Nov 2020 10:27:51

US3052005

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:00:53

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:27:51
Amendment Manager: User entered '05 May 2021 23:59'	System	19 Nov 2020 10:27:51

US3052005

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:00:53

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:27:51
Amendment Manager: User entered 'Day 285'	System	19 Nov 2020 10:27:51

US3052005

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:00:53

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:27:51
Amendment Manager: User entered '08 May 2021 00:01'	System	19 Nov 2020 10:27:51

US3052005

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:00:53

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:27:51
Amendment Manager: User entered '12 May 2021 23:59'	System	19 Nov 2020 10:27:51

US3052005

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:00:53

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:27:51
Amendment Manager: User entered 'Day 292'	System	19 Nov 2020 10:27:51

US3052005

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:00:53

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:27:51
Amendment Manager: User entered '15 May 2021 00:01'	System	19 Nov 2020 10:27:51

US3052005

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:00:53

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:27:51
Amendment Manager: User entered '19 May 2021 23:59'	System	19 Nov 2020 10:27:51

US3052005

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:00:53

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:27:51
Amendment Manager: User entered 'Day 299'	System	19 Nov 2020 10:27:51

US3052005

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:00:53

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:27:51
Amendment Manager: User entered '22 May 2021 00:01'	System	19 Nov 2020 10:27:51

US3052005

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:00:53

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:27:51
Amendment Manager: User entered '26 May 2021 23:59'	System	19 Nov 2020 10:27:51

US3052005

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:00:53

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:27:51
Amendment Manager: User entered 'Day 306'	System	19 Nov 2020 10:27:51

US3052005

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:00:53

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:27:51
Amendment Manager: User entered '29 May 2021 00:01'	System	19 Nov 2020 10:27:51

US3052005

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:00:53

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:27:51
Amendment Manager: User entered '02 Jun 2021 23:59'	System	19 Nov 2020 10:27:51

US3052005

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:00:53

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:27:51
Amendment Manager: User entered 'Day 313'	System	19 Nov 2020 10:27:51

US3052005

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:00:53

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:27:51
Amendment Manager: User entered '05 Jun 2021 00:01'	System	19 Nov 2020 10:27:51

US3052005

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:00:53

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:27:51
Amendment Manager: User entered '09 Jun 2021 23:59'	System	19 Nov 2020 10:27:51

US3052005

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:00:53

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:27:51
Amendment Manager: User entered 'Day 320'	System	19 Nov 2020 10:27:51

US3052005

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:00:53

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:27:51
Amendment Manager: User entered '12 Jun 2021 00:01'	System	19 Nov 2020 10:27:51

US3052005

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:00:53

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:27:51
Amendment Manager: User entered '16 Jun 2021 23:59'	System	19 Nov 2020 10:27:51

US3052005

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:00:53

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:27:51
Amendment Manager: User entered 'Day 327'	System	19 Nov 2020 10:27:51

US3052005

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:00:53

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:27:51
Amendment Manager: User entered '19 Jun 2021 00:01'	System	19 Nov 2020 10:27:51

US3052005

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:00:53

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:27:51
Amendment Manager: User entered '23 Jun 2021 23:59'	System	19 Nov 2020 10:27:51

US3052005

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:00:53

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:27:51
Amendment Manager: User entered 'Day 334'	System	19 Nov 2020 10:27:51

US3052005

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:00:53

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:27:51
Amendment Manager: User entered '26 Jun 2021 00:01'	System	19 Nov 2020 10:27:51

US3052005

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:00:53

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:27:51
Amendment Manager: User entered '30 Jun 2021 23:59'	System	19 Nov 2020 10:27:51

US3052005

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:00:53

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:27:51
Amendment Manager: User entered 'Day 341'	System	19 Nov 2020 10:27:51

US3052005

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:00:53

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:27:51
Amendment Manager: User entered '03 Jul 2021 00:01'	System	19 Nov 2020 10:27:51

US3052005

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:00:53

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:27:51
Amendment Manager: User entered '07 Jul 2021 23:59'	System	19 Nov 2020 10:27:51

US3052005

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:00:53

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:27:51
Amendment Manager: User entered 'Day 348'	System	19 Nov 2020 10:27:51

US3052005

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:00:53

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:27:51
Amendment Manager: User entered '10 Jul 2021 00:01'	System	19 Nov 2020 10:27:51

US3052005

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:00:53

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:27:51
Amendment Manager: User entered '14 Jul 2021 23:59'	System	19 Nov 2020 10:27:51

US3052005

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:00:53

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:27:51
Amendment Manager: User entered 'Day 355'	System	19 Nov 2020 10:27:51

US3052005

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:00:53

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:27:51
Amendment Manager: User entered '17 Jul 2021 00:01'	System	19 Nov 2020 10:27:51

US3052005

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:00:53

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:27:51
Amendment Manager: User entered '21 Jul 2021 23:59'	System	19 Nov 2020 10:27:51

US3052005

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:00:53

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:27:51
Amendment Manager: User entered 'Day 362'	System	19 Nov 2020 10:27:51

US3052005

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:00:53

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:27:51
Amendment Manager: User entered '24 Jul 2021 00:01'	System	19 Nov 2020 10:27:51

US3052005

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:00:53

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:27:51
Amendment Manager: User entered '28 Jul 2021 23:59'	System	19 Nov 2020 10:27:51

US3052005

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:00:53

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:27:51
Amendment Manager: User entered 'Day 369'	System	19 Nov 2020 10:27:51

US3052005

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:00:53

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:27:51
Amendment Manager: User entered '31 Jul 2021 00:01'	System	19 Nov 2020 10:27:51

US3052005

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:00:53

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:27:51
Amendment Manager: User entered '04 Aug 2021 23:59'	System	19 Nov 2020 10:27:51

US3052005

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:00:53

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:27:51
Amendment Manager: User entered 'Day 376'	System	19 Nov 2020 10:27:51

US3052005

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:00:53

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:27:51
Amendment Manager: User entered '07 Aug 2021 00:01'	System	19 Nov 2020 10:27:51

US3052005

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:00:53

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:27:51
Amendment Manager: User entered '11 Aug 2021 23:59'	System	19 Nov 2020 10:27:51

US3052005

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:00:53

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:27:51
Amendment Manager: User entered 'Day 383'	System	19 Nov 2020 10:27:51

US3052005

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:00:53

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:27:51
Amendment Manager: User entered '14 Aug 2021 00:01'	System	19 Nov 2020 10:27:51

US3052005

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:00:53

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:27:51
Amendment Manager: User entered '18 Aug 2021 23:59'	System	19 Nov 2020 10:27:51

US3052005

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:00:53

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:27:51
Amendment Manager: User entered 'Day 390'	System	19 Nov 2020 10:27:51

US3052005

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:00:53

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:27:51
Amendment Manager: User entered '21 Aug 2021 00:01'	System	19 Nov 2020 10:27:51

US3052005

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:00:53

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:27:51
Amendment Manager: User entered '25 Aug 2021 23:59'	System	19 Nov 2020 10:27:51

US3052005

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:00:53

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:27:51
Amendment Manager: User entered 'Day 397'	System	19 Nov 2020 10:27:51

US3052005

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:00:53

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:27:51
Amendment Manager: User entered '28 Aug 2021 00:01'	System	19 Nov 2020 10:27:51

US3052005

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:00:53

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:27:51
Amendment Manager: User entered '01 Sep 2021 23:59'	System	19 Nov 2020 10:27:51

US3052005

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:00:53

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:27:51
Amendment Manager: User entered 'Day 404'	System	19 Nov 2020 10:27:51

US3052005

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:00:53

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:27:51
Amendment Manager: User entered '04 Sep 2021 00:01'	System	19 Nov 2020 10:27:51

US3052005

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:00:53

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:27:51
Amendment Manager: User entered '08 Sep 2021 23:59'	System	19 Nov 2020 10:27:51

US3052005

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:00:53

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:27:51
Amendment Manager: User entered 'Day 411'	System	19 Nov 2020 10:27:51

US3052005

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:00:53

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:27:51
Amendment Manager: User entered '11 Sep 2021 00:01'	System	19 Nov 2020 10:27:51

US3052005

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:00:53

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:27:51
Amendment Manager: User entered '15 Sep 2021 23:59'	System	19 Nov 2020 10:27:51

US3052005

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:00:53

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:27:51
Amendment Manager: User entered 'Day 418'	System	19 Nov 2020 10:27:51

US3052005

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:00:53

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:27:51
Amendment Manager: User entered '18 Sep 2021 00:01'	System	19 Nov 2020 10:27:51

US3052005

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:00:53

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:27:51
Amendment Manager: User entered '22 Sep 2021 23:59'	System	19 Nov 2020 10:27:51

US3052005

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:00:53

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:27:51
Amendment Manager: User entered 'Day 425'	System	19 Nov 2020 10:27:51

US3052005

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:00:53

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:27:51
Amendment Manager: User entered '25 Sep 2021 00:01'	System	19 Nov 2020 10:27:51

US3052005

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:00:53

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:27:51
Amendment Manager: User entered '29 Sep 2021 23:59'	System	19 Nov 2020 10:27:51

US3052005

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:00:53

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:27:51
Amendment Manager: User entered 'Day 432'	System	19 Nov 2020 10:27:51

US3052005

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:00:53

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:27:51
Amendment Manager: User entered '02 Oct 2021 00:01'	System	19 Nov 2020 10:27:51

US3052005

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:00:53

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:27:51
Amendment Manager: User entered '06 Oct 2021 23:59'	System	19 Nov 2020 10:27:51

US3052005

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:00:53

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:27:51
Amendment Manager: User entered 'Day 439'	System	19 Nov 2020 10:27:51

US3052005

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:00:53

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:27:51
Amendment Manager: User entered '09 Oct 2021 00:01'	System	19 Nov 2020 10:27:51

US3052005

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:00:53

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:27:51
Amendment Manager: User entered '13 Oct 2021 23:59'	System	19 Nov 2020 10:27:51

US3052005

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:00:53

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:27:51
Amendment Manager: User entered 'Day 446'	System	19 Nov 2020 10:27:51

US3052005

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:00:53

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:27:51
Amendment Manager: User entered '16 Oct 2021 00:01'	System	19 Nov 2020 10:27:51

US3052005

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:00:53

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:27:51
Amendment Manager: User entered '20 Oct 2021 23:59'	System	19 Nov 2020 10:27:51

US3052005

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:00:53

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:27:51
Amendment Manager: User entered 'Day 453'	System	19 Nov 2020 10:27:51

US3052005

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:00:53

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:27:51
Amendment Manager: User entered '23 Oct 2021 00:01'	System	19 Nov 2020 10:27:51

US3052005

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:00:53

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:27:51
Amendment Manager: User entered '27 Oct 2021 23:59'	System	19 Nov 2020 10:27:51

US3052005

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:00:53

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:27:51
Amendment Manager: User entered 'Day 460'	System	19 Nov 2020 10:27:51

US3052005

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:00:53

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:27:51
Amendment Manager: User entered '30 Oct 2021 00:01'	System	19 Nov 2020 10:27:51

US3052005

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:00:53

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:27:51
Amendment Manager: User entered '03 Nov 2021 23:59'	System	19 Nov 2020 10:27:51

US3052005

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:00:53

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:27:51
Amendment Manager: User entered 'Day 467'	System	19 Nov 2020 10:27:51

US3052005

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:00:53

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:27:51
Amendment Manager: User entered '06 Nov 2021 00:01'	System	19 Nov 2020 10:27:51

US3052005

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:00:53

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:27:51
Amendment Manager: User entered '10 Nov 2021 23:59'	System	19 Nov 2020 10:27:51

US3052005

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:00:53

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:27:51
Amendment Manager: User entered 'Day 474'	System	19 Nov 2020 10:27:51

US3052005

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:00:53

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:27:51
Amendment Manager: User entered '13 Nov 2021 00:01'	System	19 Nov 2020 10:27:51

US3052005

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:00:53

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:27:51
Amendment Manager: User entered '17 Nov 2021 23:59'	System	19 Nov 2020 10:27:51

US3052005

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:00:53

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:27:51
Amendment Manager: User entered 'Day 481'	System	19 Nov 2020 10:27:51

US3052005

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:00:53

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:27:51
Amendment Manager: User entered '20 Nov 2021 00:01'	System	19 Nov 2020 10:27:51

US3052005

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:00:53

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:27:51
Amendment Manager: User entered '24 Nov 2021 23:59'	System	19 Nov 2020 10:27:51

US3052005

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:00:53

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:27:51
Amendment Manager: User entered 'Day 488'	System	19 Nov 2020 10:27:51

US3052005

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:00:53

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:27:51
Amendment Manager: User entered '27 Nov 2021 00:01'	System	19 Nov 2020 10:27:51

US3052005

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:00:53

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:27:51
Amendment Manager: User entered '01 Dec 2021 23:59'	System	19 Nov 2020 10:27:51

US3052005

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:00:53

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:27:51
Amendment Manager: User entered 'Day 495'	System	19 Nov 2020 10:27:51

US3052005

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:00:53

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:27:51
Amendment Manager: User entered '04 Dec 2021 00:01'	System	19 Nov 2020 10:27:51

US3052005

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:00:53

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:27:51
Amendment Manager: User entered '08 Dec 2021 23:59'	System	19 Nov 2020 10:27:51

US3052005

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:00:53

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:27:51
Amendment Manager: User entered 'Day 502'	System	19 Nov 2020 10:27:51

US3052005

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:00:53

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:27:51
Amendment Manager: User entered '11 Dec 2021 00:01'	System	19 Nov 2020 10:27:51

US3052005

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:00:53

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:27:51
Amendment Manager: User entered '15 Dec 2021 23:59'	System	19 Nov 2020 10:27:51

US3052005

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:00:53

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:27:51
Amendment Manager: User entered 'Day 509'	System	19 Nov 2020 10:27:51

US3052005

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:00:53

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:27:51
Amendment Manager: User entered '18 Dec 2021 00:01'	System	19 Nov 2020 10:27:51

US3052005

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:00:53

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:27:51
Amendment Manager: User entered '22 Dec 2021 23:59'	System	19 Nov 2020 10:27:51

US3052005

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:00:53

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:27:51
Amendment Manager: User entered 'Day 516'	System	19 Nov 2020 10:27:51

US3052005

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:00:53

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:27:51
Amendment Manager: User entered '25 Dec 2021 00:01'	System	19 Nov 2020 10:27:51

US3052005

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:00:53

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:27:51
Amendment Manager: User entered '29 Dec 2021 23:59'	System	19 Nov 2020 10:27:51

US3052005

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:00:53

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:27:51
Amendment Manager: User entered 'Day 523'	System	19 Nov 2020 10:27:51

US3052005

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:00:53

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:27:51
Amendment Manager: User entered '01 Jan 2022 00:01'	System	19 Nov 2020 10:27:51

US3052005

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:00:53

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:27:51
Amendment Manager: User entered '05 Jan 2022 23:59'	System	19 Nov 2020 10:27:51

US3052005

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:00:53

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:27:51
Amendment Manager: User entered 'Day 530'	System	19 Nov 2020 10:27:51

US3052005

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:00:53

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:27:51
Amendment Manager: User entered '08 Jan 2022 00:01'	System	19 Nov 2020 10:27:51

US3052005

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:00:53

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:27:51
Amendment Manager: User entered '12 Jan 2022 23:59'	System	19 Nov 2020 10:27:51

US3052005

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:00:53

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:27:51
Amendment Manager: User entered 'Day 537'	System	19 Nov 2020 10:27:51

US3052005

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:00:53

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:27:51
Amendment Manager: User entered '15 Jan 2022 00:01'	System	19 Nov 2020 10:27:51

US3052005

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:00:53

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:27:51
Amendment Manager: User entered '19 Jan 2022 23:59'	System	19 Nov 2020 10:27:51

US3052005

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:00:53

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:27:51
Amendment Manager: User entered 'Day 544'	System	19 Nov 2020 10:27:51

US3052005

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:00:53

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:27:51
Amendment Manager: User entered '22 Jan 2022 00:01'	System	19 Nov 2020 10:27:51

US3052005

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:00:53

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:27:51
Amendment Manager: User entered '26 Jan 2022 23:59'	System	19 Nov 2020 10:27:51

US3052005

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:00:53

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:27:51
Amendment Manager: User entered 'Day 551'	System	19 Nov 2020 10:27:51

US3052005

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:00:53

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:27:51
Amendment Manager: User entered '29 Jan 2022 00:01'	System	19 Nov 2020 10:27:51

US3052005

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:00:53

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:27:51
Amendment Manager: User entered '02 Feb 2022 23:59'	System	19 Nov 2020 10:27:51

US3052005

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:00:53

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:27:51
Amendment Manager: User entered 'Day 558'	System	19 Nov 2020 10:27:51

US3052005

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:00:53

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:27:51
Amendment Manager: User entered '05 Feb 2022 00:01'	System	19 Nov 2020 10:27:51

US3052005

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:00:53

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:27:51
Amendment Manager: User entered '09 Feb 2022 23:59'	System	19 Nov 2020 10:27:51

US3052005

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:00:53

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:27:51
Amendment Manager: User entered 'Day 565'	System	19 Nov 2020 10:27:51

US3052005

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:00:53

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:27:51
Amendment Manager: User entered '12 Feb 2022 00:01'	System	19 Nov 2020 10:27:51

US3052005

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:00:53

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:27:51
Amendment Manager: User entered '16 Feb 2022 23:59'	System	19 Nov 2020 10:27:51

US3052005

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:00:53

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:27:51
Amendment Manager: User entered 'Day 572'	System	19 Nov 2020 10:27:51

US3052005

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:00:53

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:27:51
Amendment Manager: User entered '19 Feb 2022 00:01'	System	19 Nov 2020 10:27:51

US3052005

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:00:53

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:27:51
Amendment Manager: User entered '23 Feb 2022 23:59'	System	19 Nov 2020 10:27:51

US3052005

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:00:53

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:27:51
Amendment Manager: User entered 'Day 579'	System	19 Nov 2020 10:27:51

US3052005

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:00:53

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:27:51
Amendment Manager: User entered '26 Feb 2022 00:01'	System	19 Nov 2020 10:27:51

US3052005

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:00:53

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:27:51
Amendment Manager: User entered '02 Mar 2022 23:59'	System	19 Nov 2020 10:27:51

US3052005

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:00:53

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:27:51
Amendment Manager: User entered 'Day 586'	System	19 Nov 2020 10:27:51

US3052005

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:00:53

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:27:51
Amendment Manager: User entered '05 Mar 2022 00:01'	System	19 Nov 2020 10:27:51

US3052005

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:00:53

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:27:51
Amendment Manager: User entered '09 Mar 2022 23:59'	System	19 Nov 2020 10:27:51

US3052005

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:00:53

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:27:51
Amendment Manager: User entered 'Day 593'	System	19 Nov 2020 10:27:51

US3052005

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:00:53

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:27:51
Amendment Manager: User entered '12 Mar 2022 00:01'	System	19 Nov 2020 10:27:51

US3052005

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:00:53

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:27:51
Amendment Manager: User entered '16 Mar 2022 23:59'	System	19 Nov 2020 10:27:51

US3052005

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:00:53

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:27:51
Amendment Manager: User entered 'Day 600'	System	19 Nov 2020 10:27:51

US3052005

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:00:53

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:27:51
Amendment Manager: User entered '19 Mar 2022 00:01'	System	19 Nov 2020 10:27:51

US3052005

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:00:53

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:27:51
Amendment Manager: User entered '23 Mar 2022 23:59'	System	19 Nov 2020 10:27:51

US3052005

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:00:53

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:27:51
Amendment Manager: User entered 'Day 607'	System	19 Nov 2020 10:27:51

US3052005

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:00:53

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:27:51
Amendment Manager: User entered '26 Mar 2022 00:01'	System	19 Nov 2020 10:27:51

US3052005

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:00:53

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:27:51
Amendment Manager: User entered '30 Mar 2022 23:59'	System	19 Nov 2020 10:27:51

US3052005

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:00:53

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:27:51
Amendment Manager: User entered 'Day 614'	System	19 Nov 2020 10:27:51

US3052005

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:00:53

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:27:51
Amendment Manager: User entered '02 Apr 2022 00:01'	System	19 Nov 2020 10:27:51

US3052005

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:00:53

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:27:51
Amendment Manager: User entered '06 Apr 2022 23:59'	System	19 Nov 2020 10:27:51

US3052005

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:00:53

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:27:51
Amendment Manager: User entered 'Day 621'	System	19 Nov 2020 10:27:51

US3052005

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:00:53

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:27:51
Amendment Manager: User entered '09 Apr 2022 00:01'	System	19 Nov 2020 10:27:51

US3052005

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:00:53

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:27:51
Amendment Manager: User entered '13 Apr 2022 23:59'	System	19 Nov 2020 10:27:51

US3052005

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:00:53

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:27:51
Amendment Manager: User entered 'Day 628'	System	19 Nov 2020 10:27:51

US3052005

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:00:53

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:27:51
Amendment Manager: User entered '16 Apr 2022 00:01'	System	19 Nov 2020 10:27:51

US3052005

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:00:53

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:27:51
Amendment Manager: User entered '20 Apr 2022 23:59'	System	19 Nov 2020 10:27:51

US3052005

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:00:53

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:27:51
Amendment Manager: User entered 'Day 635'	System	19 Nov 2020 10:27:51

US3052005

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:00:53

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:27:51
Amendment Manager: User entered '23 Apr 2022 00:01'	System	19 Nov 2020 10:27:51

US3052005

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:00:53

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:27:51
Amendment Manager: User entered '27 Apr 2022 23:59'	System	19 Nov 2020 10:27:51

US3052005

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:00:53

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:27:51
Amendment Manager: User entered 'Day 642'	System	19 Nov 2020 10:27:51

US3052005

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:00:53

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:27:51
Amendment Manager: User entered '30 Apr 2022 00:01'	System	19 Nov 2020 10:27:51

US3052005

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:00:53

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:27:51
Amendment Manager: User entered '04 May 2022 23:59'	System	19 Nov 2020 10:27:51

US3052005

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:00:53

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:27:51
Amendment Manager: User entered 'Day 649'	System	19 Nov 2020 10:27:51

US3052005

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:00:53

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:27:51
Amendment Manager: User entered '07 May 2022 00:01'	System	19 Nov 2020 10:27:51

US3052005

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:00:53

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:27:51
Amendment Manager: User entered '11 May 2022 23:59'	System	19 Nov 2020 10:27:51

US3052005

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:00:53

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:27:51
Amendment Manager: User entered 'Day 656'	System	19 Nov 2020 10:27:51

US3052005

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:00:53

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:27:51
Amendment Manager: User entered '14 May 2022 00:01'	System	19 Nov 2020 10:27:51

US3052005

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:00:53

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:27:51
Amendment Manager: User entered '18 May 2022 23:59'	System	19 Nov 2020 10:27:51

US3052005

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:00:53

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:27:51
Amendment Manager: User entered 'Day 663'	System	19 Nov 2020 10:27:51

US3052005

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:00:53

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:27:51
Amendment Manager: User entered '21 May 2022 00:01'	System	19 Nov 2020 10:27:51

US3052005

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:00:53

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:27:51
Amendment Manager: User entered '25 May 2022 23:59'	System	19 Nov 2020 10:27:51

US3052005

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:00:53

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:27:51
Amendment Manager: User entered 'Day 670'	System	19 Nov 2020 10:27:51

US3052005

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:00:53

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:27:51
Amendment Manager: User entered '28 May 2022 00:01'	System	19 Nov 2020 10:27:51

US3052005

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:00:53

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:27:51
Amendment Manager: User entered '01 Jun 2022 23:59'	System	19 Nov 2020 10:27:51

US3052005

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:00:53

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:27:51
Amendment Manager: User entered 'Day 677'	System	19 Nov 2020 10:27:51

US3052005

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:00:53

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:27:51
Amendment Manager: User entered '04 Jun 2022 00:01'	System	19 Nov 2020 10:27:51

US3052005

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:00:53

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:27:51
Amendment Manager: User entered '08 Jun 2022 23:59'	System	19 Nov 2020 10:27:51

US3052005

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:00:53

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:27:51
Amendment Manager: User entered 'Day 684'	System	19 Nov 2020 10:27:51

US3052005

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:00:53

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:27:51
Amendment Manager: User entered '11 Jun 2022 00:01'	System	19 Nov 2020 10:27:51

US3052005

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:00:53

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:27:51
Amendment Manager: User entered '15 Jun 2022 23:59'	System	19 Nov 2020 10:27:51

US3052005

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:00:53

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:27:51
Amendment Manager: User entered 'Day 691'	System	19 Nov 2020 10:27:51

US3052005

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:00:53

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:27:51
Amendment Manager: User entered '18 Jun 2022 00:01'	System	19 Nov 2020 10:27:51

US3052005

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:00:53

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:27:51
Amendment Manager: User entered '22 Jun 2022 23:59'	System	19 Nov 2020 10:27:51

US3052005

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:00:53

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:27:51
Amendment Manager: User entered 'Day 698'	System	19 Nov 2020 10:27:51

US3052005

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:00:53

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:27:51
Amendment Manager: User entered '25 Jun 2022 00:01'	System	19 Nov 2020 10:27:51

US3052005

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:00:53

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:27:51
Amendment Manager: User entered '29 Jun 2022 23:59'	System	19 Nov 2020 10:27:51

US3052005

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:00:53

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:27:51
Amendment Manager: User entered 'Day 705'	System	19 Nov 2020 10:27:51

US3052005

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:00:53

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:27:51
Amendment Manager: User entered '02 Jul 2022 00:01'	System	19 Nov 2020 10:27:51

US3052005

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:00:53

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:27:51
Amendment Manager: User entered '06 Jul 2022 23:59'	System	19 Nov 2020 10:27:51

US3052005

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:00:53

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:27:51
Amendment Manager: User entered 'Day 712'	System	19 Nov 2020 10:27:51

US3052005

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:00:53

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:27:51
Amendment Manager: User entered '09 Jul 2022 00:01'	System	19 Nov 2020 10:27:51

US3052005

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:00:53

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:27:51
Amendment Manager: User entered '13 Jul 2022 23:59'	System	19 Nov 2020 10:27:51

US3052005

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:00:53

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:27:51
Amendment Manager: User entered 'Day 719'	System	19 Nov 2020 10:27:51

US3052005

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:00:53

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:27:51
Amendment Manager: User entered '16 Jul 2022 00:01'	System	19 Nov 2020 10:27:51

US3052005

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:00:53

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:27:51
Amendment Manager: User entered '20 Jul 2022 23:59'	System	19 Nov 2020 10:27:51

US3052005

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:00:53

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:27:51
Amendment Manager: User entered 'Day 726'	System	19 Nov 2020 10:27:51

US3052005

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:00:53

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:27:51
Amendment Manager: User entered '23 Jul 2022 00:01'	System	19 Nov 2020 10:27:51

US3052005

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:00:53

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:27:51
Amendment Manager: User entered '27 Jul 2022 23:59'	System	19 Nov 2020 10:27:51

US3052005

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:00:53

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:27:51
Amendment Manager: User entered 'Day 733'	System	19 Nov 2020 10:27:51

US3052005

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:00:53

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:27:51
Amendment Manager: User entered '30 Jul 2022 00:01'	System	19 Nov 2020 10:27:51

US3052005

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:00:53

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:27:51
Amendment Manager: User entered '03 Aug 2022 23:59'	System	19 Nov 2020 10:27:51

US3052005

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:00:53

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:27:51
Amendment Manager: User entered 'Day 740'	System	19 Nov 2020 10:27:51

US3052005

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:00:53

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:27:51
Amendment Manager: User entered '06 Aug 2022 00:01'	System	19 Nov 2020 10:27:51

US3052005

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:00:53

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:27:51
Amendment Manager: User entered '10 Aug 2022 23:59'	System	19 Nov 2020 10:27:51

US3052005

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:00:53

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:27:51
Amendment Manager: User entered 'Day 747'	System	19 Nov 2020 10:27:51

US3052005

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:00:53

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:27:51
Amendment Manager: User entered '13 Aug 2022 00:01'	System	19 Nov 2020 10:27:51

US3052005

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:00:53

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:27:51
Amendment Manager: User entered '17 Aug 2022 23:59'	System	19 Nov 2020 10:27:51

US3052005

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:00:53

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:27:51
Amendment Manager: User entered 'Day 754'	System	19 Nov 2020 10:27:51

US3052005

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:00:53

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:27:51
Amendment Manager: User entered '20 Aug 2022 00:01'	System	19 Nov 2020 10:27:51

US3052005

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:00:53

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:27:51
Amendment Manager: User entered '24 Aug 2022 23:59'	System	19 Nov 2020 10:27:51

US3052005

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:00:53

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:27:51
Amendment Manager: User entered 'Day 761'	System	19 Nov 2020 10:27:51

US3052005

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:00:53

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:27:51
Amendment Manager: User entered '27 Aug 2022 00:01'	System	19 Nov 2020 10:27:51

US3052005

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:00:53

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:27:51
Amendment Manager: User entered '31 Aug 2022 23:59'	System	19 Nov 2020 10:27:51

US3052005

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:00:53

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:27:51
Amendment Manager: User entered 'Day 768'	System	19 Nov 2020 10:27:51

US3052005

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:00:53

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:27:51
Amendment Manager: User entered '03 Sep 2022 00:01'	System	19 Nov 2020 10:27:51

US3052005

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:00:53

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:27:51
Amendment Manager: User entered '07 Sep 2022 23:59'	System	19 Nov 2020 10:27:51

US3052005

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:00:53

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:27:51
Amendment Manager: User entered 'Day 775'	System	19 Nov 2020 10:27:51

US3052005

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:00:53

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:27:51
Amendment Manager: User entered '10 Sep 2022 00:01'	System	19 Nov 2020 10:27:51

US3052005

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:00:53

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:27:51
Amendment Manager: User entered '14 Sep 2022 23:59'	System	19 Nov 2020 10:27:51

US3052005

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:00:53

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:27:51
Amendment Manager: User entered 'Day 782'	System	19 Nov 2020 10:27:51

US3052005

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:00:53

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:27:51
Amendment Manager: User entered '17 Sep 2022 00:01'	System	19 Nov 2020 10:27:51

US3052005

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:00:53

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:27:51
Amendment Manager: User entered '21 Sep 2022 23:59'	System	19 Nov 2020 10:27:51

US3052005

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:00:53

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:27:51
Amendment Manager: User entered 'Day 789'	System	19 Nov 2020 10:27:51

US3052005

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:00:53

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:27:51
Amendment Manager: User entered '24 Sep 2022 00:01'	System	19 Nov 2020 10:27:51

US3052005

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:00:53

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:27:51
Amendment Manager: User entered '28 Sep 2022 23:59'	System	19 Nov 2020 10:27:51

US3052005

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:00:53

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:27:51
Amendment Manager: User entered 'Day 796'	System	19 Nov 2020 10:27:51

US3052005

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:00:53

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:27:51
Amendment Manager: User entered '01 Oct 2022 00:01'	System	19 Nov 2020 10:27:51

US3052005

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:00:53

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:27:51
Amendment Manager: User entered '05 Oct 2022 23:59'	System	19 Nov 2020 10:27:51

US3052005

Folder: Cosmetic Injections and Dermal Fillers

Form: Cosmetic Injection_ Dermal Filler eDiary (1)

Generated On: 09 Jun 2021 15:00:53

Have you ever received facial cosmetic injections, such as Juvederm, Voluma, Radiesse, Restylane, Botox or other?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 22:40:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9EADD593-414F-498C-AC00-8AAC8D311A10)', Time: '2021-02-27T19:39:49-05:00', User OID: 'PatientReportedOutcome (US3052005)', ODM File OID: '067683dc-796e-4777-bef3-ba01342581b1'	System	28 Feb 2021 00:39:59
User entered 'No (N)'	System	28 Feb 2021 00:39:59

US3052005

Folder: Cosmetic Injections and Dermal Fillers

Form: Cosmetic Injection_ Dermal Filler eDiary (1)

Generated On: 09 Jun 2021 15:00:53

[Date & Time of Submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 22:40:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9EADD593-414F-498C-AC00-8AAC8D311A10)', Time: '2021-02-27T19:39:57-05:00', User OID: 'PatientReportedOutcome (US3052005)', ODM File OID: '067683dc-796e-4777-bef3-ba01342581b1' User entered '28 Feb 2021 00:39:57'	System	28 Feb 2021 00:39:59
	System	28 Feb 2021 00:39:59

US3052005

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:00:53

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:41:16
User signature succeeded.	Judith Borger (b) (4)	23 Feb 2021 07:32:26
User entered 'Yes (Y)'	(b) (4) Avia McClain-Stocker (b) (4)	20 Oct 2020 20:39:58

US3052005

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:00:53

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:41:16
User signature succeeded.	Judith Borger (b) (4)	23 Feb 2021 07:32:26
User entered '20 Oct 2020'	(b) (4) Avia McClain-Stocker (b) (4)	20 Oct 2020 20:39:58

US3052005

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:00:53

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:41:16
User signature succeeded.	Judith Borger (b) (4)	23 Feb 2021 07:32:26
User entered 'Contact Made (CONTACT MADE)'	(b) (4) Avia McClain-Stocker (b) (4)	20 Oct 2020 20:39:58

US3052005

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:00:53

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:41:16
User signature succeeded.	Judith Borger (b) (4)	23 Feb 2021 07:32:26
User entered empty.	(b) (4) Avia McClain-Stocker (b) (4)	20 Oct 2020 20:39:58

US3052005

Folder: Safety Call Day 85 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:00:53

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:41:16
User signature succeeded.	Judith Borger (b) (4)	23 Feb 2021 07:32:26
User entered 'Yes (Y)'	(b) (4) Avia McClain-Stocker (b) (4)	20 Oct 2020 20:40:01

US3052005

Folder: Safety Call Day 85 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:00:53

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:41:16
User entered 'I'	System	20 Oct 2020 20:40:01

US3052005

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:00:53

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 17:56:38
User signature succeeded.	Judith Borger (b) (4)	23 Feb 2021 07:32:26
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	28 Dec 2020 15:53:20

US3052005

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:00:53

Date of Contact or Contact Attempt (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 17:56:38
User signature succeeded.	Judith Borger (b) (4)	23 Feb 2021 07:32:26
User entered '22 Nov 2020' reason for change: Data Entry Error	(b) (4) (b) (4), (b) (6)	28 Dec 2020 15:55:35
User closed query 'Safety Call Day 119 'Date of Contact or Contact Attempt' is less than 76 days or greater than 104 days after Visit 2 Treatment Date on the Exposure Form. Please review and reconcile or clarify.' (Site from System).	System	28 Dec 2020 15:53:40
Query 'Safety Call Day 119 'Date of Contact or Contact Attempt' is less than 76 days or greater than 104 days after Visit 2 Treatment Date on the Exposure Form. Please review and reconcile or clarify.' answered by data change (Site from System).	System	28 Dec 2020 15:53:40
User entered '23 Nov 2020' reason for change: Data Entry Error	(b) (4), (b) (6)	28 Dec 2020 15:53:40
User opened query 'Safety Call Day 119 'Date of Contact or Contact Attempt' is less than 76 days or greater than 104 days after Visit 2 Treatment Date on the Exposure Form. Please review and reconcile or clarify.' (Site from System).	System	28 Dec 2020 15:53:20
User entered '2 Nov 2020'	(b) (4), (b) (6)	28 Dec 2020 15:53:20

US3052005

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:00:53

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 17:56:38
User signature succeeded.	Judith Borger (b) (4)	23 Feb 2021 07:32:26
User entered 'Contact Made (CONTACT MADE)'	(b) (4) (b) (4), (b) (6)	28 Dec 2020 15:53:20

US3052005

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:00:53

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 17:56:38
User signature succeeded.	Judith Borger (b) (4)	23 Feb 2021 07:32:26
User entered empty.	(b) (4) (b) (4), (b) (6)	28 Dec 2020 15:53:20

US3052005

Folder: Safety Call Day 119 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:00:53

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 17:56:38
User signature succeeded.	Judith Borger (b) (4)	23 Feb 2021 07:32:26
User entered 'Yes (Y)'	(b) (4) Avia McClain-Stocker (b) (4)	11 Dec 2020 20:19:37

US3052005

Folder: Safety Call Day 119 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:00:53

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 17:56:38
User entered 'I'	System	11 Dec 2020 20:19:37

US3052005

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:00:53

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 17:56:38
User signature succeeded.	Judith Borger (b) (4)	23 Feb 2021 07:32:26
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	31 Dec 2020 20:48:48

US3052005

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:00:53

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 17:56:38
User signature succeeded.	Judith Borger (b) (4)	23 Feb 2021 07:32:26
User entered '23 Dec 2020'	(b) (4) (b) (4), (b) (6)	31 Dec 2020 20:48:48

US3052005

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:00:53

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 17:56:38
User signature succeeded.	Judith Borger (b) (4)	23 Feb 2021 07:32:26
User entered 'Contact Not Made (CONTACT NOT MADE)'	(b) (4) (b) (4), (b) (6)	31 Dec 2020 20:48:48

US3052005

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:00:53

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 17:56:38
User signature succeeded.	Judith Borger (b) (4)	23 Feb 2021 07:32:26
User entered 'left voicemail'	(b) (4) (b) (4), (b) (6)	31 Dec 2020 20:48:48

US3052005

Folder: Safety Call Day 149 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:00:53

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 17:56:38
User signature succeeded.	Judith Borger (b) (4)	23 Feb 2021 07:32:26
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	31 Dec 2020 20:48:53

US3052005

Folder: Safety Call Day 149 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:00:53

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 17:56:38
User entered 'I'	System	31 Dec 2020 20:48:53

US3052005

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:00:53

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 17:56:38
User signature succeeded.	Judith Borger (b) (4)	15 Mar 2021 14:45:16
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	12 Mar 2021 13:08:58

US3052005

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:00:53

Date of Contact or Contact Attempt (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 17:56:38
User signature succeeded.	Judith Borger (b) (4)	15 Mar 2021 14:45:16
User closed query 'Safety Call Day 179 'Date of Contact or Contact Attempt' is less than 147 days or greater than 153 days after Visit 2 Treatment Date on the Exposure Form. Please review and reconcile, or clarify.' (Site from System).	(b) (4) (b) (4), (b) (6)	15 Mar 2021 07:40:32
Query 'Safety Call Day 179 'Date of Contact or Contact Attempt' is less than 147 days or greater than 153 days after Visit 2 Treatment Date on the Exposure Form. Please review and reconcile, or clarify.' answered with 'entry correct' (Site from System).	(b) (4), (b) (6)	12 Mar 2021 13:09:09
User opened query 'Safety Call Day 179 'Date of Contact or Contact Attempt' is less than 147 days or greater than 153 days after Visit 2 Treatment Date on the Exposure Form. Please review and reconcile, or clarify.' (Site from System).	System	12 Mar 2021 13:08:58
User entered '28 Jan 2021'	(b) (4), (b) (6)	12 Mar 2021 13:08:58

US3052005

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:00:53

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 17:56:38
User signature succeeded.	Judith Borger (b) (4)	15 Mar 2021 14:45:16
User entered 'Contact Made (CONTACT MADE)'	(b) (4) (b) (4), (b) (6)	12 Mar 2021 13:08:58

US3052005

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:00:53

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 17:56:38
User signature succeeded.	Judith Borger (b) (4)	15 Mar 2021 14:45:16
User entered empty.	(b) (4) (b) (4), (b) (6)	12 Mar 2021 13:08:58

US3052005

Folder: Safety Call Day 179 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:00:53

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 17:56:38
User signature succeeded.	Judith Borger (b) (4)	15 Mar 2021 14:45:16
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	12 Mar 2021 13:09:19

US3052005

Folder: Safety Call Day 179 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:00:53

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 17:56:38
User entered 'I'	System	12 Mar 2021 13:09:19

US3052005

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Generated On: 09 Jun 2021 15:00:53

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 17:56:38
User signature succeeded.	Yaa Oppong (b) (4)	08 Apr 2021 19:45:37
Signature has been broken.	(b) (4) (b) (4), (b) (6)	08 Apr 2021 18:19:26
User entered 'Yes (Y)' reason for change: Data Entry Error		08 Apr 2021 18:19:26
User signature succeeded.	Yaa Oppong (b) (4)	01 Apr 2021 13:22:50
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	31 Mar 2021 14:21:31

US3052005

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Generated On: 09 Jun 2021 15:00:53

Visit date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 17:56:38
User closed query 'Visit 4 Date is < 166 days or > 194 days after Visit 2 vaccination. Please reconcile or confirm dates.' (Site from System).		09 Apr 2021 21:57:12
User signature succeeded.	Yaa Oppong (b) (4)	08 Apr 2021 19:45:37
Query 'Visit 4 Date is < 166 days or > 194 days after Visit 2 vaccination. Please reconcile or confirm dates.' answered with 'CONFIRMED' (Site from System).	(b) (4) (b) (4), (b) (6)	08 Apr 2021 18:19:40
User opened query 'Visit 4 Date is < 166 days or > 194 days after Visit 2 vaccination. Please reconcile or confirm dates.' (Site from System).	System	08 Apr 2021 18:19:26
Signature has been broken.	(b) (4), (b) (6)	08 Apr 2021 18:19:26
User entered '7 Apr 2021' reason for change: Data Entry Error		08 Apr 2021 18:19:26
User signature succeeded.	Yaa Oppong (b) (4)	01 Apr 2021 13:22:50
User entered empty.	(b) (4) (b) (4), (b) (6)	31 Mar 2021 14:21:31

US3052005

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Generated On: 09 Jun 2021 15:00:53

Was visit performed at the participant's home or at the clinic?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 17:56:38
User signature succeeded.	Yaa Oppong (b) (4)	08 Apr 2021 19:45:37
User closed query 'Visit was performed, however, Was visit performed at home or clinic is missing. Please review and reconcile.' (Site from System). Signature has been broken.	(b) (4) System	08 Apr 2021 18:19:44
User entered 'Clinic (Clinic)' reason for change: Data Entry Error	(b) (4), (b) (6)	08 Apr 2021 18:19:44
User opened query 'Visit was performed, however, Was visit performed at home or clinic is missing. Please review and reconcile.' (Site from System). User signature succeeded.	System	08 Apr 2021 18:19:26
User entered empty.	Yaa Oppong (b) (4) (b) (4), (b) (6)	01 Apr 2021 13:22:50 31 Mar 2021 14:21:31

US3052005

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Generated On: 09 Jun 2021 15:00:53

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 17:56:38
User entered 'VISIT4'	System	31 Mar 2021 14:21:31

US3052005

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:00:53

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 17:56:38
User signature succeeded.	Yaa Oppong (b) (4)	08 Apr 2021 19:45:37
Signature has been broken.	(b) (4) (b) (4), (b) (6)	08 Apr 2021 18:20:58
User entered 'Yes (Y)' reason for change: Data Entry Error		08 Apr 2021 18:20:58
User signature succeeded.	Yaa Oppong (b) (4)	01 Apr 2021 13:22:50
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	31 Mar 2021 14:21:41

US3052005

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:00:53

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 17:56:38
User signature succeeded.	Yaa Oppong (b) (4)	08 Apr 2021 19:45:37
Signature has been broken.	(b) (4) (b) (4), (b) (6)	08 Apr 2021 18:20:58
User entered '7 Apr 2021' reason for change: Data Entry Error		08 Apr 2021 18:20:58
User signature succeeded.	Yaa Oppong (b) (4)	01 Apr 2021 13:22:50
User entered empty.	(b) (4) (b) (4), (b) (6)	31 Mar 2021 14:21:41

US3052005

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:00:53

Time of assessment (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 17:56:38
User signature succeeded.	Yaa Oppong (b) (4)	08 Apr 2021 19:45:37
Signature has been broken.	(b) (4), (b) (6)	08 Apr 2021 18:20:58
User entered '10:20' reason for change: Data Entry Error		08 Apr 2021 18:20:58
User signature succeeded.	Yaa Oppong (b) (4)	01 Apr 2021 13:22:50
User entered empty.	(b) (4), (b) (6)	31 Mar 2021 14:21:41

US3052005

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:00:53

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 17:56:38
User entered '7 Apr 2021 10:20'	System	08 Apr 2021 18:20:58
User entered empty.	System	31 Mar 2021 14:21:41

US3052005

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:00:53

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 17:56:38
User signature succeeded.	Yaa Oppong (b) (4)	08 Apr 2021 19:45:37
Signature has been broken.	(b) (4) (b) (4), (b) (6)	08 Apr 2021 18:20:58
User entered '98.1' F reason for change: Data Entry Error		08 Apr 2021 18:20:58
User signature succeeded.	Yaa Oppong (b) (4)	01 Apr 2021 13:22:50
User entered empty.	(b) (4) (b) (4), (b) (6)	31 Mar 2021 14:21:41

US3052005

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:00:53

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 17:56:38
User signature succeeded.	Yaa Oppong (b) (4)	08 Apr 2021 19:45:37
Signature has been broken.	(b) (4) (b) (4), (b) (6)	08 Apr 2021 18:20:58
User entered 'Oral (Oral)' reason for change: Data Entry Error		08 Apr 2021 18:20:58
User signature succeeded.	Yaa Oppong (b) (4)	01 Apr 2021 13:22:50
User entered empty.	(b) (4) (b) (4), (b) (6)	31 Mar 2021 14:21:41

US3052005

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:00:53

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 17:56:38
User signature succeeded.	Yaa Oppong (b) (4)	01 Apr 2021 13:22:50
User entered empty.	(b) (4) (b) (4), (b) (6)	31 Mar 2021 14:21:41

US3052005

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:00:53

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 17:56:38
User signature succeeded.	Yaa Oppong (b) (4)	08 Apr 2021 19:45:37
Signature has been broken.	(b) (4) (b) (4), (b) (6)	08 Apr 2021 18:20:58
User entered '67' reason for change: Data Entry Error		08 Apr 2021 18:20:58
User signature succeeded.	Yaa Oppong (b) (4)	01 Apr 2021 13:22:50
User entered empty.	(b) (4) (b) (4), (b) (6)	31 Mar 2021 14:21:41

US3052005

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:00:53

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 17:56:38
User entered 'bpm'	System	08 Apr 2021 18:20:58
User entered empty.	System	31 Mar 2021 14:21:41

US3052005

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:00:53

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 17:56:38
User signature succeeded.	Yaa Oppong (b) (4)	08 Apr 2021 19:45:37
Signature has been broken.	(b) (4) (b) (4), (b) (6)	08 Apr 2021 18:20:58
User entered '15' reason for change: Data Entry Error		08 Apr 2021 18:20:58
User signature succeeded.	Yaa Oppong (b) (4)	01 Apr 2021 13:22:50
User entered empty.	(b) (4) (b) (4), (b) (6)	31 Mar 2021 14:21:41

US3052005

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:00:53

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 17:56:38
User entered 'breaths/min'	System	08 Apr 2021 18:20:58
User entered empty.	System	31 Mar 2021 14:21:41

US3052005

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:00:53

[Systolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 17:56:38
User signature succeeded.	Yaa Oppong (b) (4)	08 Apr 2021 19:45:37
Signature has been broken.	(b) (4), (b) (6)	08 Apr 2021 18:20:58
User entered '137' reason for change: Data Entry Error		08 Apr 2021 18:20:58
User signature succeeded.	Yaa Oppong (b) (4)	01 Apr 2021 13:22:50
User entered empty.	(b) (4), (b) (6)	31 Mar 2021 14:21:41

US3052005

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:00:53

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 17:56:38
User entered 'mmHg'	System	08 Apr 2021 18:20:58
User entered empty.	System	31 Mar 2021 14:21:41

US3052005

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:00:53

[Diastolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 17:56:38
User signature succeeded.	Yaa Oppong (b) (4)	08 Apr 2021 19:45:37
Signature has been broken.	(b) (4) (b) (4), (b) (6)	08 Apr 2021 18:20:58
User entered '85' reason for change: Data Entry Error		08 Apr 2021 18:20:58
User signature succeeded.	Yaa Oppong (b) (4)	01 Apr 2021 13:22:50
User entered empty.	(b) (4) (b) (4), (b) (6)	31 Mar 2021 14:21:41

US3052005

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:00:53

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 17:56:38
User entered 'mmHg'	System	08 Apr 2021 18:20:58
User entered empty.	System	31 Mar 2021 14:21:41

US3052005

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:00:53

Height (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 17:56:38

US3052005

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:00:53

Weight (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 17:56:38

US3052005

Folder: Visit 4 Day 209 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 15:00:53

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 17:56:38
User signature succeeded.	Yaa Oppong (b) (4)	08 Apr 2021 19:45:37
Signature has been broken.	(b) (4) (b) (4), (b) (6)	08 Apr 2021 18:21:15
User entered 'Yes (Y)' reason for change: Data Entry Error		08 Apr 2021 18:21:15
User signature succeeded.	Yaa Oppong (b) (4)	01 Apr 2021 13:22:50
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	31 Mar 2021 14:21:47

US3052005

Folder: Visit 4 Day 209 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 15:00:53

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 17:56:38
User signature succeeded.	Yaa Oppong (b) (4)	08 Apr 2021 19:45:37
Signature has been broken.	(b) (4) (b) (4), (b) (6)	08 Apr 2021 18:21:15
User entered '7 Apr 2021' reason for change: Data Entry Error		08 Apr 2021 18:21:15
User signature succeeded.	Yaa Oppong (b) (4)	01 Apr 2021 13:22:50
User entered empty.	(b) (4) (b) (4), (b) (6)	31 Mar 2021 14:21:47

US3052005

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 15:00:53

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 17:56:38
User signature succeeded.	Yaa Oppong (b) (4)	08 Apr 2021 19:45:37
Signature has been broken.	(b) (4) (b) (4), (b) (6)	08 Apr 2021 18:21:31
User entered 'Yes (Y)' reason for change: Data Entry Error		08 Apr 2021 18:21:31
User signature succeeded.	Yaa Oppong (b) (4)	01 Apr 2021 13:22:50
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	31 Mar 2021 14:21:52

US3052005

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 15:00:53

Collection date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 17:56:38
User signature succeeded.	Yaa Oppong (b) (4)	08 Apr 2021 19:45:37
User closed query 'The Collection Date is not equal to Visit Date. Please review and reconcile.' (Site from System).	(b) (4)	08 Apr 2021 18:21:38
Query 'The Collection Date is not equal to Visit Date. System Please review and reconcile.' answered by data change (Site from System).	System	08 Apr 2021 18:21:38
User entered '7 Apr 2021' reason for change: Data Entry Error	(b) (4), (b) (6)	08 Apr 2021 18:21:38
User opened query 'The Collection Date is not equal to Visit Date. Please review and reconcile.' (Site from System).	System	08 Apr 2021 18:21:31
Signature has been broken.	(b) (4), (b) (6)	08 Apr 2021 18:21:31
User entered '4 Apr 2021' reason for change: Data Entry Error		08 Apr 2021 18:21:31
User signature succeeded.	Yaa Oppong (b) (4)	01 Apr 2021 13:22:50
User entered empty.	(b) (4) (b) (4), (b) (6)	31 Mar 2021 14:21:52

US3052005

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 15:00:53

[Collection time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 17:56:38
User signature succeeded.	Yaa Oppong (b) (4)	08 Apr 2021 19:45:37
Signature has been broken.	(b) (4) (b) (4), (b) (6)	08 Apr 2021 18:21:31
User entered '10:55' reason for change: Data Entry Error		08 Apr 2021 18:21:31
User signature succeeded.	Yaa Oppong (b) (4)	01 Apr 2021 13:22:50
User entered empty.	(b) (4) (b) (4), (b) (6)	31 Mar 2021 14:21:52

US3052005

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 15:00:53

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 17:56:38
User entered '7 Apr 2021 10:55'	System	08 Apr 2021 18:21:38
User entered '4 Apr 2021 10:55'	System	08 Apr 2021 18:21:31
User entered empty.	System	31 Mar 2021 14:21:52

US3052005

Folder: Visit 4 Day 209 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:00:53

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 17:56:38
User signature succeeded.	Yaa Oppong (b) (4)	01 Apr 2021 13:22:50
User entered 'Yes (Y)'	(b) (4), (b) (6)	26 Mar 2021 20:48:55

US3052005

Folder: Visit 4 Day 209 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:00:53

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 17:56:38
User entered 'I'	System	26 Mar 2021 20:48:55

US3052005

Folder: Safety Call Day 239 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:00:53

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 13:35:29
User signature succeeded.	Yaa Oppong (b) (4)	01 Apr 2021 13:22:50
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	26 Mar 2021 20:49:10

US3052005

Folder: Safety Call Day 239 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:00:53

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 13:35:29
User signature succeeded.	Yaa Oppong (b) (4)	01 Apr 2021 13:22:50
User entered '23 Mar 2021'	(b) (4) (b) (4), (b) (6)	26 Mar 2021 20:49:10

US3052005

Folder: Safety Call Day 239 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:00:53

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 13:35:29
User signature succeeded.	Yaa Oppong (b) (4)	01 Apr 2021 13:22:50
User entered 'Contact Made (CONTACT MADE)'	(b) (4) (b) (4), (b) (6)	26 Mar 2021 20:49:10

US3052005

Folder: Safety Call Day 239 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:00:53

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 13:35:29
User signature succeeded.	Yaa Oppong (b) (4)	01 Apr 2021 13:22:50
User entered empty.	(b) (4), (b) (6)	26 Mar 2021 20:49:10

US3052005

Folder: Safety Call Day 239 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:00:53

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 13:35:29
User signature succeeded.	Yaa Oppong (b) (4)	01 Apr 2021 13:22:50
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	26 Mar 2021 20:49:44

US3052005

Folder: Safety Call Day 239 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:00:53

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 13:35:29
User entered 'I'	System	26 Mar 2021 20:49:44

US3052005

Folder: Safety Call Day 269 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:00:53

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
User signature succeeded.	Yaa Oppong (b) (4)	26 Apr 2021 20:34:31
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	26 Apr 2021 17:01:08

US3052005

Folder: Safety Call Day 269 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:00:53

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Yaa Oppong (b) (4)	26 Apr 2021 20:34:31
User entered '26 Apr 2021'	(b) (4) (b) (4), (b) (6)	26 Apr 2021 17:01:08

US3052005

Folder: Safety Call Day 269 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:00:53

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
User signature succeeded.	Yaa Oppong (b) (4)	26 Apr 2021 20:34:31
User entered 'Contact Made (CONTACT MADE)'	(b) (4) (b) (4), (b) (6)	26 Apr 2021 17:01:08

US3052005

Folder: Safety Call Day 269 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:00:53

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
User signature succeeded.	Yaa Oppong (b) (4)	26 Apr 2021 20:34:31
User entered empty.	(b) (4) (b) (4), (b) (6)	26 Apr 2021 17:01:08

US3052005

Folder: Safety Call Day 269 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:00:53

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
User signature succeeded.	Yaa Oppong (b) (4)	26 Apr 2021 20:34:31
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	26 Apr 2021 17:00:56

US3052005

Folder: Safety Call Day 269 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:00:53

[Continuing Flag](#)

Audit	User	Time (GMT)
User entered 'I'	System	26 Apr 2021 17:00:56

US3052005

Folder: Participant Decision Visit / OL-D1 (1)

Form: Visit Date

Generated On: 09 Jun 2021 15:00:53

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 13:35:29
User signature succeeded.	Judith Borger (b) (4)	23 Feb 2021 07:32:26
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	12 Jan 2021 20:03:06

US3052005

Folder: Participant Decision Visit / OL-D1 (1)

Form: Visit Date

Generated On: 09 Jun 2021 15:00:53

[Visit date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 13:35:29
User signature succeeded.	Judith Borger (b) (4)	23 Feb 2021 07:32:26
User entered '11 Jan 2021'	(b) (4) (b) (4), (b) (6)	12 Jan 2021 20:03:06

US3052005

Folder: Participant Decision Visit / OL-D1 (1)

Form: Visit Date

Generated On: 09 Jun 2021 15:00:53

[Was visit performed at the participant's home or at the clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 13:35:29
User signature succeeded.	Judith Borger (b) (4)	23 Feb 2021 07:32:26
User entered 'Clinic (Clinic)'	(b) (4) (b) (4), (b) (6)	12 Jan 2021 20:03:06

US3052005

Folder: Participant Decision Visit / OL-D1 (1)

Form: Visit Date

Generated On: 09 Jun 2021 15:00:53

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 13:35:29
User entered 'UNBLND_DECIDE'	System	12 Jan 2021 20:03:06

US3052005

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 09 Jun 2021 15:00:53

Date of updated informed consent (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 13:35:29
User signature succeeded.	Judith Borger (b) (4)	23 Feb 2021 07:32:26
User entered '11 Jan 2021'	(b) (4) (b) (4), (b) (6)	12 Jan 2021 20:03:31

US3052005

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 09 Jun 2021 15:00:53

[N/A - Subject Unblinded under Amendment 5 and Discontinued from Study](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 13:35:29
User signature succeeded.	Judith Borger (b) (4)	15 Mar 2021 14:45:16
User entered '0'	(b) (4) (b) (4), (b) (6)	06 Mar 2021 20:14:21
Amendment Manager inserted this DataPoint.	System	06 Mar 2021 02:05:34

US3052005

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 09 Jun 2021 15:00:53

[Was the participant unblinded?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 13:35:29
User signature succeeded.	Judith Borger (b) (4)	23 Feb 2021 07:32:26
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	12 Jan 2021 20:03:31

US3052005

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 09 Jun 2021 15:00:53

[Under what version of the Protocol was the Participant unblinded?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 13:35:29
User signature succeeded.	Judith Borger (b) (4)	15 Mar 2021 14:45:16
User entered 'Amendment 6 or later (Amendment 6 or later)'	(b) (4) (b) (4), (b) (6)	06 Mar 2021 20:14:21
Amendment Manager inserted this DataPoint.	System	06 Mar 2021 02:05:34

US3052005

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 09 Jun 2021 15:00:53

Date of unblinding (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 13:35:29
User signature succeeded.	Judith Borger (b) (4)	23 Feb 2021 07:32:26
User entered '11 Jan 2021'	(b) (4) (b) (4), (b) (6)	12 Jan 2021 20:03:31

US3052005

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 09 Jun 2021 15:00:53

[Participant randomization assignment](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 13:35:29
User signature succeeded.	Judith Borger (b) (4)	23 Feb 2021 07:32:26
User entered 'mRNA-1273 (mRNA-1273)'	(b) (4) (b) (4), (b) (6)	12 Jan 2021 20:03:31

US3052005

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 09 Jun 2021 15:00:53

[Actual Dose 1](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 13:35:29
User signature succeeded.	Judith Borger (b) (4)	23 Feb 2021 07:32:26
Amendment Manager: User entered 'mRNA-1273 (mRNA-1273)'	(b) (4) System	20 Jan 2021 00:57:39
User entered 'mRNA-1273 (mRNA-1273)'	(b) (4), (b) (6)	12 Jan 2021 20:03:31

US3052005

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 09 Jun 2021 15:00:53

[Actual Dose 2](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 13:35:29
User signature succeeded.	Judith Borger (b) (4)	23 Feb 2021 07:32:26
Amendment Manager: User entered 'mRNA-1273 (mRNA-1273)'	(b) (4) System	20 Jan 2021 00:57:39
User entered 'mRNA-1273 (mRNA-1273)'	(b) (4), (b) (6)	12 Jan 2021 20:03:31

US3052005

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 09 Jun 2021 15:00:53

[Will participant receive mRNA-1273?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 13:35:29
User signature succeeded.	Judith Borger (b) (4)	23 Feb 2021 07:32:26
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	12 Jan 2021 20:03:31

US3052005

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 09 Jun 2021 15:00:53

[Placebo Only Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 13:35:29
User entered empty.	System	12 Jan 2021 20:03:31

US3052005

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 09 Jun 2021 15:00:53

[Continuing with mRNA-1273](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 13:35:29
User entered empty.	System	12 Jan 2021 20:03:31

US3052005

Folder: Participant Decision Visit / OL-D1 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 15:00:53

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 13:35:29
User signature succeeded.	Judith Borger (b) (4)	23 Feb 2021 07:32:26
User entered 'Yes (Y)' reason for change: Data Entry Error	(b) (4) (b) (4), (b) (6)	27 Jan 2021 18:44:46
User entered 'No (N)'		12 Jan 2021 20:02:49

US3052005

Folder: Participant Decision Visit / OL-D1 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 15:00:53

Collection date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 13:35:29
User signature succeeded.	Judith Borger (b) (4)	23 Feb 2021 07:32:26
User closed query 'The Collection Date is not equal to Visit Date. Please review and reconcile.' (Site from System).	(b) (4)	27 Jan 2021 18:45:28
Query 'The Collection Date is not equal to Visit Date. System Please review and reconcile.' answered by data change (Site from System).	System	27 Jan 2021 18:45:28
User entered '11 Jan 2021' reason for change: Data Entry Error	(b) (4), (b) (6)	27 Jan 2021 18:45:28
User opened query 'The Collection Date is not equal to Visit Date. Please review and reconcile.' (Site from System).	System	27 Jan 2021 18:44:46
User entered '12 Jan 2021' reason for change: Data Entry Error	(b) (4), (b) (6)	27 Jan 2021 18:44:46
User entered empty.		12 Jan 2021 20:02:49

US3052005

Folder: Participant Decision Visit / OL-D1 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 15:00:53

[Collection time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 13:35:29
User signature succeeded.	Judith Borger (b) (4)	23 Feb 2021 07:32:26
User entered '09:37' reason for change: Data Entry Error	(b) (4), (b) (6)	27 Jan 2021 18:46:14
User entered '09:39' reason for change: Data Entry Error		27 Jan 2021 18:44:46
User entered empty.		12 Jan 2021 20:02:49

US3052005

Folder: Participant Decision Visit / OL-D1 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 15:00:53

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 13:35:29
User entered '11 Jan 2021 09:37'	System	27 Jan 2021 18:46:14
User entered '11 Jan 2021 09:39'	System	27 Jan 2021 18:45:28
User entered '12 Jan 2021 09:39'	System	27 Jan 2021 18:44:46
User entered empty.	System	12 Jan 2021 20:02:49

US3052005

Folder: Participant Decision Visit / OL-D1 (1)

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 09 Jun 2021 15:00:53

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 13:35:29
User signature succeeded.	Judith Borger (b) (4)	23 Feb 2021 07:32:26
User entered 'Yes (Y)' reason for change: Data Entry Error	(b) (4) (b) (4), (b) (6)	27 Jan 2021 18:45:59
User entered 'No (N)'		12 Jan 2021 20:02:24

US3052005

Folder: Participant Decision Visit / OL-D1 (1)

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 09 Jun 2021 15:00:53

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 13:35:29
User signature succeeded.	Judith Borger (b) (4)	23 Feb 2021 07:32:26
User entered '11 Jan 2021' reason for change: Data Entry Error	(b) (4)	27 Jan 2021 18:45:59
User entered empty.	(b) (4), (b) (6)	12 Jan 2021 20:02:24

US3052005

Folder: Participant Decision Visit / OL-D1 (1)

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 09 Jun 2021 15:00:53

[Collection time \(00:00 - 23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 13:35:29
User signature succeeded.	Judith Borger (b) (4)	23 Feb 2021 07:32:26
User entered '09:39' reason for change: Data Entry Error	(b) (4), (b) (6)	27 Jan 2021 18:45:59
User entered empty.		12 Jan 2021 20:02:24

US3052005

Folder: Participant Decision Visit / OL-D1 (1)

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 09 Jun 2021 15:00:53

[Collection Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 13:35:29
User entered '11 Jan 2021 09:39'	System	27 Jan 2021 18:45:59
User entered empty.	System	12 Jan 2021 20:02:24

US3052005

Folder: Adverse Events

Form: Adverse Events Summary

Generated On: 09 Jun 2021 15:00:53

[Did the participant experience any adverse events?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 07:10:36
User signature succeeded.	Yaa Oppong (b) (4)	08 Apr 2021 19:45:37
Signature has been broken.	(b) (4) (b) (4), (b) (6)	08 Apr 2021 18:17:17
User entered 'Yes (Y)' reason for change: Data Entry Error		08 Apr 2021 18:17:17
User signature succeeded.	Judith Borger (b) (4)	23 Feb 2021 07:32:26
User entered 'No (N)'	(b) (4) amy sheets (b) (4) (b) (4)	18 Aug 2020 14:47:40

US3052005

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:00:53

[AEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Yaa Oppong (b) (4)	09 Apr 2021 18:54:14
Reviewed for Safety.	(b) (4)	
	(b) (4), (b) (6)	08 Apr 2021 23:30:59
User entered	System	08 Apr 2021 23:30:38
'USA-US117-2021-mRNA-1273-P301000007'		
User entered 'New'	(b) (4), (b) (6)	08 Apr 2021 23:30:38

US3052005

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:00:53

[Adverse event](#)

Audit	User	Time (GMT)
User coded data point as SOC: Musculoskeletal and connective tissue disorders, HLGT: Joint disorders, HLT: Osteoarthropathies, PT: Osteoarthritis, LLT: Hips osteoarthritis - version MedDRA\\23.0.	Coder Import (b) (4)	19 Apr 2021 19:59:49
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4)	19 Apr 2021 19:59:49
User signature succeeded.	Yaa Oppong (b) (4)	16 Apr 2021 15:23:47
User closed query 'PV Query: Please consider the reason for the reported surgery (i.e. worsening of osteoarthritis), and if appropriate please update the event to the condition being treated by surgery instead of the surgery itself.' (Site from Safety).	(b) (4), (b) (6)	15 Apr 2021 21:09:42
User closed query 'PV Query: Please consider updating the event term to the underlying cause/etiology of the event. if not so, please clarify.' (Site from Safety).	(b) (4), (b) (6)	15 Apr 2021 21:09:34
Query 'PV Query: Please consider the reason for the reported surgery (i.e. worsening of osteoarthritis), and if appropriate please update the event to the condition being treated by surgery instead of the surgery itself.' answered with 'updated' (Site from Safety).	amy sheets (b) (4)	15 Apr 2021 19:04:16
Query 'PV Query: Please consider updating the event term to the underlying cause/etiology of the event. if not so, please clarify.' answered with 'updated ' (Site from Safety).	amy sheets (b) (4)	15 Apr 2021 19:04:00
Data point term sent to Coder	System	15 Apr 2021 19:03:52
Coding entries removed.	amy sheets (b) (4)	15 Apr 2021 19:03:39
User entered 'RIGHT HIP JOINT REPLACEMENT (worsening of osteoarthritis)' reason for change:	amy sheets (b) (4)	15 Apr 2021 19:03:39
Data Entry Error		
User coded data point as SOC: Surgical and medical procedures, HLGT: Bone and joint therapeutic procedures, HLT: Joint therapeutic procedures, PT: Hip arthroplasty, LLT: Hip replacement - version MedDRA\\23.0.	Coder Import (b) (4)	14 Apr 2021 20:32:55
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	14 Apr 2021 20:32:55
Data point term sent to Coder	System	14 Apr 2021 20:31:22

US3052005

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:00:53

[Adverse event](#)

Audit	User	Time (GMT)
Coding entries removed.	Jeanette Mangual-Coughlin (b) (4)	14 Apr 2021 20:31:06
Signature has been broken.	Jeanette Mangual-Coughlin (b) (4)	14 Apr 2021 20:31:06
User entered 'RIGHT HIP JOINT REPLACEMENT' reason for change: Data Entry Error	Jeanette Mangual-Coughlin (b) (4)	14 Apr 2021 20:31:06
User opened query 'PV Query: Please consider the reason for the reported surgery (i.e. worsening of osteoarthritis), and if appropriate please update the event to the condition being treated by surgery instead of the surgery itself.' (Site from Safety). Query 'IQVIA Medical query: Please consider the reason for the reported surgery (i.e. worsening of osteoarthritis), and if appropriate please update the event to the condition being treated by surgery instead of the surgery itself.' canceled (Site from Safety).	(b) (4), (b) (6)	14 Apr 2021 18:14:02
User opened query 'IQVIA Medical query: Please consider the reason for the reported surgery (i.e. worsening of osteoarthritis), and if appropriate please update the event to the condition being treated by surgery instead of the surgery itself.' (Site from Safety).	(b) (4), (b) (6)	14 Apr 2021 18:13:08
User opened query 'IQVIA Medical query: Please consider the reason for the reported surgery (i.e. worsening of osteoarthritis), and if appropriate please update the event to the condition being treated by surgery instead of the surgery itself.' (Site from Safety).	(b) (4), (b) (6)	14 Apr 2021 18:12:59
User opened query 'PV Query: Please consider updating the event term to the underlying cause/etiology of the event. if not so, please clarify.' (Site from Safety).	(b) (4), (b) (6)	14 Apr 2021 18:11:44
User coded data point as SOC: Surgical and medical procedures, HLGT: Bone and joint therapeutic procedures, HLT: Joint therapeutic procedures, PT: Joint resurfacing surgery, LLT: Joint resurfacing surgery - version MedDRA\23.0.	Coder Import (b) (4)	11 Apr 2021 19:30:36
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\23.0.	Coder Import (b) (4)	11 Apr 2021 19:30:36
User signature succeeded.	Yaa Oppong (b) (4)	08 Apr 2021 19:45:37

US3052005

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:00:53

[Adverse event](#)

Audit	User	Time (GMT)
User coded data point as SOC: Surgical and medical procedures, HLGT: Bone and joint therapeutic procedures, HLT: Joint therapeutic procedures, PT: Joint resurfacing surgery, LLT: Joint resurfacing surgery - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	08 Apr 2021 18:33:58
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	08 Apr 2021 18:33:58
Data point term sent to Coder	System	08 Apr 2021 18:32:16
User entered 'RIGHT HIP RESURFACING'	(b) (4), (b) (6) (b) (4), (b) (6)	08 Apr 2021 18:32:06

US3052005

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:00:53

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
User signature succeeded.	Yaa Oppong (b) (4)	08 Apr 2021 19:45:37
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	08 Apr 2021 18:32:06

US3052005

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:00:53

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
User signature succeeded.	Yaa Oppong (b) (4)	08 Apr 2021 19:45:37
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	08 Apr 2021 18:32:06

US3052005

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:00:53

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
User signature succeeded.	Yaa Oppong (b) (4)	08 Apr 2021 19:45:37
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	08 Apr 2021 18:32:06

US3052005

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:00:53

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Yaa Oppong (b) (4)	08 Apr 2021 19:45:37
User entered '24 Feb 2021'	(b) (4) (b) (4), (b) (6)	08 Apr 2021 18:32:06

US3052005

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:00:53

[Start time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Yaa Oppong (b) (4)	08 Apr 2021 19:45:37
User entered empty.	(b) (4) (b) (4), (b) (6)	08 Apr 2021 18:32:06

US3052005

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:00:53

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	08 Apr 2021 18:32:06

US3052005

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:00:53

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Yaa Oppong (b) (4)	08 Apr 2021 19:45:37
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	08 Apr 2021 18:32:06

US3052005

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:00:53

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Yaa Oppong (b) (4)	08 Apr 2021 19:45:37
User entered '25 Feb 2021'	(b) (4) (b) (4), (b) (6)	08 Apr 2021 18:32:06

US3052005

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:00:53

End time (00:00-23:59)

Audit	User	Time (GMT)
User signature succeeded.	Yaa Oppong (b) (4)	08 Apr 2021 19:45:37
User entered empty.	(b) (4) (b) (4), (b) (6)	08 Apr 2021 18:32:06

US3052005

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:00:53

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	08 Apr 2021 18:32:06

US3052005

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:00:53

[Severity](#)

Audit	User	Time (GMT)
User signature succeeded.	Yaa Oppong (b) (4)	08 Apr 2021 19:45:37
User entered 'Grade 3/Severe (Grade 3/Severe)'	(b) (4) (b) (4), (b) (6)	08 Apr 2021 18:32:06

US3052005

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:00:53

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
User signature succeeded.	Yaa Oppong (b) (4)	08 Apr 2021 19:45:37
User closed query 'Is the adverse event serious is Yes, but seriousness criteria is missing. Please check at least one criteria from the options below.' (Site from System).	(b) (4) System	08 Apr 2021 18:32:56
User opened query 'Is the adverse event serious is Yes, but seriousness criteria is missing. Please check at least one criteria from the options below.' (Site from System).	System	08 Apr 2021 18:32:06
User entered 'Yes (Y)'	(b) (4), (b) (6) (b) (4)	08 Apr 2021 18:32:06

US3052005

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:00:53

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Yaa Oppong (b) (4)	08 Apr 2021 19:45:37
User entered '0'	(b) (4) (b) (4), (b) (6)	08 Apr 2021 18:32:06

US3052005

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:00:53

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Yaa Oppong (b) (4)	08 Apr 2021 19:45:37
User entered '0'	(b) (4) (b) (4), (b) (6)	08 Apr 2021 18:32:06

US3052005

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:00:53

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Yaa Oppong (b) (4)	08 Apr 2021 19:45:37
User closed query 'Requires inpatient or prolongation of existing Hospitalization is not checked, but hospitalization data has been provided. Please correct.' (Site from System).	(b) (4)	08 Apr 2021 18:32:56
Query 'Requires inpatient or prolongation of existing Hospitalization is not checked, but hospitalization data has been provided. Please correct.' answered by data change (Site from System).	System	08 Apr 2021 18:32:56
User entered '1' reason for change: Data Entry Error	(b) (4), (b) (6)	08 Apr 2021 18:32:56
User opened query 'Requires inpatient or prolongation of existing Hospitalization is not checked, but hospitalization data has been provided. Please correct.' (Site from System).	System	08 Apr 2021 18:32:06
User entered '0'	(b) (4), (b) (6)	08 Apr 2021 18:32:06

US3052005

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:00:53

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Yaa Oppong (b) (4)	08 Apr 2021 19:45:37
User entered '24 Feb 2021'	(b) (4) (b) (4), (b) (6)	08 Apr 2021 18:32:06

US3052005

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:00:53

Hospital Discharge Date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Yaa Oppong (b) (4)	08 Apr 2021 19:45:37
User entered '25 Feb 2021'	(b) (4) (b) (4), (b) (6)	08 Apr 2021 18:32:06

US3052005

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:00:53

[Admitted to ICU?](#)

Audit	User	Time (GMT)
User signature succeeded.	Yaa Oppong (b) (4)	08 Apr 2021 19:45:37
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	08 Apr 2021 18:32:06

US3052005

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:00:53

[Number of Days in ICU](#)

Audit	User	Time (GMT)
User signature succeeded.	Yaa Oppong (b) (4)	08 Apr 2021 19:45:37
User entered empty.	(b) (4) (b) (4), (b) (6)	08 Apr 2021 18:32:06

US3052005

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:00:53

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Yaa Oppong (b) (4)	08 Apr 2021 19:45:37
User entered '0'	(b) (4) (b) (4), (b) (6)	08 Apr 2021 18:32:06

US3052005

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:00:53

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Yaa Oppong (b) (4)	08 Apr 2021 19:45:37
User entered '0'	(b) (4) (b) (4), (b) (6)	08 Apr 2021 18:32:06

US3052005

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:00:53

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Yaa Oppong (b) (4)	08 Apr 2021 19:45:37
User entered '0'	(b) (4) (b) (4), (b) (6)	08 Apr 2021 18:32:06

US3052005

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:00:53

[Relationship to investigational product](#)

Audit	User	Time (GMT)
User signature succeeded.	Yaa Oppong (b) (4)	08 Apr 2021 19:45:37
User entered 'Not Related (NOT RELATED)'	(b) (4) (b) (4), (b) (6)	08 Apr 2021 18:32:06

US3052005

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:00:53

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
User signature succeeded.	Yaa Oppong (b) (4)	08 Apr 2021 19:45:37
User entered 'Not Related (NOT RELATED)'	(b) (4) (b) (4), (b) (6)	08 Apr 2021 18:32:06

US3052005

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:00:53

[Action taken with investigational product](#)

Audit	User	Time (GMT)
User signature succeeded.	Yaa Oppong (b) (4)	08 Apr 2021 19:45:37
User entered 'Not Applicable (NOT APPLICABLE)'	(b) (4) (b) (4), (b) (6)	08 Apr 2021 18:32:06

US3052005

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:00:53

[None](#)

Audit	User	Time (GMT)
User signature succeeded.	Yaa Oppong (b) (4)	08 Apr 2021 19:45:37
User entered '0'	(b) (4) (b) (4), (b) (6)	08 Apr 2021 18:32:06

US3052005

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:00:53

[Concomitant Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Yaa Oppong (b) (4)	08 Apr 2021 19:45:37
User entered '0'	(b) (4) (b) (4), (b) (6)	08 Apr 2021 18:32:06

US3052005

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:00:53

[Concomitant Procedure](#)

Audit	User	Time (GMT)
User signature succeeded.	Yaa Oppong (b) (4)	08 Apr 2021 19:45:37
User entered '1'	(b) (4) (b) (4), (b) (6)	08 Apr 2021 18:32:06

US3052005

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:00:53

[Outcome](#)

Audit	User	Time (GMT)
User signature succeeded.	Yaa Oppong (b) (4)	08 Apr 2021 19:45:37
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)'	(b) (4) (b) (4), (b) (6)	08 Apr 2021 18:32:06

US3052005

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:00:53

[If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:](#)

Audit	User	Time (GMT)
User signature succeeded.	Yaa Oppong (b) (4)	08 Apr 2021 19:45:37
User entered empty.	(b) (4) (b) (4), (b) (6)	08 Apr 2021 18:32:06

US3052005

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:00:53

[Narrative](#)

Audit	User	Time (GMT)
User closed query 'PV Query: Please provide the results of any COVID-19 testing performed during hospital admission, including date of collection and type of testing.? If not done, please state so.' (Site from Safety).	(b) (4), (b) (6)	26 Apr 2021 16:24:06
Query 'PV Query: Please provide the results of any COVID-19 testing performed during hospital admission, including date of collection and type of testing.? If not done, please state so.' answered with 'medical records have been requested. subject stated he was not covid tested while admitted to the hospital. ' (Site from Safety).		23 Apr 2021 17:52:49
User opened query 'PV Query: Please provide the results of any COVID-19 testing performed during hospital admission, including date of collection and type of testing.? If not done, please state so.' (Site from Safety).		22 Apr 2021 14:42:19
User signature succeeded.	Yaa Oppong (b) (4)	16 Apr 2021 15:23:47
User closed query 'PV Query: Please provide treatment given for the event including medical intervention and/or surgical treatments. Please add any additional treatment medications to the concomitant medication eCRF (including dates of administration, dose, units, frequency, route and indication). If no additional treatment was provided, please state so.' (Site from Safety).	(b) (4) (b) (4), (b) (6)	15 Apr 2021 21:10:09
User closed query 'PV Query: Please provide any relevant laboratory and diagnostic test results. Please include units and reference ranges if applicable. If needed, results with patient identifiers redacted and subject ID added can be sent to Safety_Moderna@iqvia.com or fax to 866.599.1342. If no results are available, please confirm in your response.' (Site from Safety).	(b) (4), (b) (6)	15 Apr 2021 21:10:00
User closed query 'PV Query: Please provide the results of any COVID-19 testing performed during hospital admission, including date of collection and type of testing.? If not done, please state so.' (Site from Safety).		15 Apr 2021 21:09:51

US3052005

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:00:53

[Narrative](#)

Audit	User	Time (GMT)
Query 'PV Query: Please provide treatment given for amy sheets the event including medical intervention and/or surgical treatments. Please add any additional treatment medications to the concomitant medication eCRF (including dates of administration, dose, units, frequency, route and indication). If no additional treatment was provided, please state so.' answered with 'medical records requested will update once received.' (Site from Safety).	(b) (4)	15 Apr 2021 19:07:32
Query 'PV Query: Please provide any relevant laboratory and diagnostic test results. Please include units and reference ranges if applicable. If needed, results with patient identifiers redacted and subject ID added can be sent to Safety_Moderna@iqvia.com or fax to 866.599.1342. If no results are available, please confirm in your response.' answered with 'medical records requested will update once received.' (Site from Safety).	amy sheets (b) (4)	15 Apr 2021 19:07:13
Query 'PV Query: Please provide the results of any COVID-19 testing performed during hospital admission, including date of collection and type of testing.? If not done, please state so.' answered with 'medical records requested will update once received.' (Site from Safety).	amy sheets (b) (4)	15 Apr 2021 19:06:54
Signature has been broken.	Jeanette Mangual-Coughlin (b) (4)	14 Apr 2021 20:32:10
User entered 'SUBJECT HAD RIGHT HIP JOINT REPLACEMENT (RESURFACING) SURGERY ON 24 FEB 2021. HE WAS ADMITTED TO THE HOSPITAL POST SURGERY FOR OBSERVATION AND DISCHARGED 25 FEB 2021' reason for change: Data Entry Error	Jeanette Mangual-Coughlin (b) (4)	14 Apr 2021 20:32:10
User opened query 'PV Query: Please provide treatment given for the event including medical intervention and/or surgical treatments. Please add any additional treatment medications to the concomitant medication eCRF (including dates of administration, dose, units, frequency, route and indication). If no additional treatment was provided, please state so.' (Site from Safety).	(b) (4), (b) (6)	14 Apr 2021 18:12:14

PRODUCTION RELEASE (v12.003
EAB) (1725)

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US3052005

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:00:53

[Narrative](#)

Audit	User	Time (GMT)
User opened query 'PV Query: Please provide any relevant laboratory and diagnostic test results. Please include units and reference ranges if applicable. If needed, results with patient identifiers redacted and subject ID added can be sent to Safety_Moderna@iqvia.com or fax to 866.599.1342. If no results are available, please confirm in your response.' (Site from Safety).	(b) (4), (b) (6)	14 Apr 2021 18:12:00
User opened query 'PV Query: Please provide the results of any COVID-19 testing performed during hospital admission, including date of collection and type of testing.? If not done, please state so.' (Site from Safety).	(b) (4), (b) (6)	14 Apr 2021 18:11:22
User signature succeeded.	Yaa Oppong (b) (4)	08 Apr 2021 19:45:37
User entered 'SUBJECT HAD RIGHT HIP RESURFACING SURGERY ON 24 FEB 2021. HE WAS ADMITTED TO THE HOSPITAL POST SURGERY FOR OBSERVATION AND DISCHARGED 25 FEB 2021'	(b) (4), (b) (6)	08 Apr 2021 18:32:06

US3052005

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:00:53

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered 'I'	System	08 Apr 2021 18:32:06

US3052005

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:00:53

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '1'	System	08 Apr 2021 18:32:06

US3052005

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:00:53

[Admitted to ICU Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '0'	System	08 Apr 2021 18:32:06

US3052005

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination Summary

Generated On: 09 Jun 2021 15:00:53

[Were any prior/concomitant medications and/or vaccinations taken?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 07:10:36
User signature succeeded.	Judith Borger (b) (4)	23 Feb 2021 07:32:26
User entered 'Yes (Y)'	amy sheets (b) (4)	18 Aug 2020 14:48:06

US3052005

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 15:00:53

Name of Medication

Audit	User	Time (GMT)
User signature succeeded.	Judith Borger (b) (4)	15 Mar 2021 14:45:16
User coded data point as ATC: CARDIOVASCULAR SYSTEM, ATC: BETA BLOCKING AGENTS, ATC: BETA BLOCKING AGENTS, ATC: BETA BLOCKING AGENTS, SELECTIVE, PRODUCT: METOPROLOL - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4) (b) (4)	18 Aug 2020 15:43:07
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	18 Aug 2020 15:43:07
Data point term sent to Coder	System	18 Aug 2020 14:56:21
User entered 'Metoprolol'	amy sheets (b) (4) (b) (4)	18 Aug 2020 14:55:38

US3052005

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 15:00:53

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Borger (b) (4)	15 Mar 2021 14:45:16
User closed query 'Per DM CLR: Prophylaxis = Yes, however there is a corresponding entry on the Medical History CRF. It is unexpected for a medication to be given to prevent a condition the patient already has a diagnosis for. Please review and update the Con Med CRF if applicable. ' (Site from DM).	(b) (4) (b) (4), (b) (6)	15 Oct 2020 15:50:43
Query 'Per DM CLR: Prophylaxis = Yes, however there is a corresponding entry on the Medical History CRF. It is unexpected for a medication to be given to prevent a condition the patient already has a diagnosis for. Please review and update the Con Med CRF if applicable. ' answered with 'updated' (Site from DM).	amy sheets (b) (4) (b) (4)	07 Oct 2020 19:34:11
User entered 'No (N)' reason for change: Data Entry Error	amy sheets (b) (4) (b) (4)	07 Oct 2020 19:33:52
User opened query 'Per DM CLR: Prophylaxis = Yes, however there is a corresponding entry on the Medical History CRF. It is unexpected for a medication to be given to prevent a condition the patient already has a diagnosis for. Please review and update the Con Med CRF if applicable. ' (Site from DM).	(b) (4), (b) (6)	10 Sep 2020 11:59:44
User entered 'Yes (Y)'	amy sheets (b) (4) (b) (4)	18 Aug 2020 14:55:38

US3052005

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 15:00:53

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Borger (b) (4)	15 Mar 2021 14:45:16
User entered 'A-fib/HTN'	(b) (4) amy sheets (b) (4) (b) (4)	18 Aug 2020 14:55:38

US3052005

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 15:00:53

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Borger (b) (4)	15 Mar 2021 14:45:16
User entered '50'	(b) (4) amy sheets (b) (4) (b) (4)	18 Aug 2020 14:55:38

US3052005

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 15:00:53

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Borger (b) (4)	15 Mar 2021 14:45:16
User entered 'mg (mg)'	(b) (4) amy sheets (b) (4) (b) (4)	18 Aug 2020 14:55:38

US3052005

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 15:00:53

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Judith Borger (b) (4)	15 Mar 2021 14:45:16
User entered empty.	(b) (4) amy sheets (b) (4) (b) (4)	18 Aug 2020 14:55:38

US3052005

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 15:00:53

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Borger (b) (4)	15 Mar 2021 14:45:16
User entered 'once daily (QD)'	(b) (4) amy sheets (b) (4) (b) (4)	18 Aug 2020 14:55:38

US3052005

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 15:00:53

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Borger (b) (4)	15 Mar 2021 14:45:16
User entered empty.	(b) (4) amy sheets (b) (4) (b) (4)	18 Aug 2020 14:55:38

US3052005

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 15:00:53

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Borger (b) (4)	15 Mar 2021 14:45:16
User entered 'Oral (ORAL)'	(b) (4) amy sheets (b) (4) (b) (4)	18 Aug 2020 14:55:38

US3052005

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 15:00:53

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Judith Borger (b) (4)	15 Mar 2021 14:45:16
User entered empty.	(b) (4) amy sheets (b) (4) (b) (4)	18 Aug 2020 14:55:38

US3052005

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 15:00:53

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Judith Borger (b) (4)	15 Mar 2021 14:45:16
Amendment Manager: Query closed during migration process because the edit check no longer exists in target version.	(b) (4)	21 Aug 2020 01:21:13
User entered 'un Dec 2018' reason for change: Data Entry Error	amy sheets (b) (4)	18 Aug 2020 15:01:16
User opened query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' (Site from System).	System	18 Aug 2020 14:55:38
User entered '30 Jul 2018'	amy sheets (b) (4)	18 Aug 2020 14:55:38

US3052005

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 15:00:53

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Borger (b) (4)	15 Mar 2021 14:45:16
User entered '0'	(b) (4) amy sheets (b) (4) (b) (4)	18 Aug 2020 14:55:38

US3052005

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 15:00:53

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Borger (b) (4)	15 Mar 2021 14:45:16
User entered 'Yes (Y)'	(b) (4) amy sheets (b) (4) (b) (4)	18 Aug 2020 14:55:38

US3052005

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 15:00:53

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Judith Borger (b) (4)	15 Mar 2021 14:45:16
User entered empty.	(b) (4) amy sheets (b) (4) (b) (4)	18 Aug 2020 14:55:38

US3052005

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 15:00:53

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Borger (b) (4)	15 Mar 2021 14:45:16
User entered 'No (N)'	(b) (4) amy sheets (b) (4) (b) (4)	18 Aug 2020 14:55:38

US3052005

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 15:00:53

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	18 Aug 2020 14:55:38

US3052005

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 15:00:53

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	18 Aug 2020 14:55:38

US3052005

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 15:00:53

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	18 Aug 2020 14:55:38

US3052005

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 15:00:53

Name of Medication

Audit	User	Time (GMT)
User signature succeeded.	Judith Borger (b) (4)	15 Mar 2021 14:45:16
User coded data point as ATC: CARDIOVASCULAR SYSTEM, ATC: AGENTS ACTING ON THE RENIN-ANGIOTENSIN SYSTEM, ATC: ANGIOTENSIN II RECEPTOR BLOCKERS (ARBS), PLAIN, ATC: ANGIOTENSIN II RECEPTOR BLOCKERS (ARBS), PLAIN, PRODUCT: LOSARTAN - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4) (b) (4)	18 Aug 2020 15:52:12
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	18 Aug 2020 15:52:12
Data point term sent to Coder	System	18 Aug 2020 15:00:36
User entered 'Losartan'	amy sheets (b) (4) (b) (4)	18 Aug 2020 15:00:35

US3052005

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 15:00:53

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Borger (b) (4)	15 Mar 2021 14:45:16
User closed query 'Per DM CLR: Prophylaxis = Yes, however there is a corresponding entry on the Medical History CRF. It is unexpected for a medication to be given to prevent a condition the patient already has a diagnosis for. Please review and update the Con Med CRF if applicable. ' (Site from DM).	(b) (4) (b) (4), (b) (6)	19 Oct 2020 11:42:38
Query 'Per DM CLR: Prophylaxis = Yes, however there is a corresponding entry on the Medical History CRF. It is unexpected for a medication to be given to prevent a condition the patient already has a diagnosis for. Please review and update the Con Med CRF if applicable. ' answered with 'updated' (Site from DM).	amy sheets (b) (4) (b) (4)	07 Oct 2020 19:35:31
User entered 'No (N)' reason for change: Data Entry Error	amy sheets (b) (4) (b) (4)	07 Oct 2020 19:35:20
User opened query 'Per DM CLR: Prophylaxis = Yes, however there is a corresponding entry on the Medical History CRF. It is unexpected for a medication to be given to prevent a condition the patient already has a diagnosis for. Please review and update the Con Med CRF if applicable. ' (Site from DM).	(b) (4), (b) (6)	10 Sep 2020 11:59:09
User entered 'Yes (Y)'	amy sheets (b) (4) (b) (4)	18 Aug 2020 15:00:35

US3052005

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 15:00:53

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Borger (b) (4)	15 Mar 2021 14:45:16
User entered 'A-fib/HTN'	(b) (4) amy sheets (b) (4) (b) (4)	18 Aug 2020 15:00:35

US3052005

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 15:00:53

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Borger (b) (4)	15 Mar 2021 14:45:16
User entered '25'	(b) (4) amy sheets (b) (4) (b) (4)	18 Aug 2020 15:00:35

US3052005

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 15:00:53

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Borger (b) (4)	15 Mar 2021 14:45:16
User entered 'mg (mg)'	(b) (4) amy sheets (b) (4) (b) (4)	18 Aug 2020 15:00:35

US3052005

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 15:00:53

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Judith Borger (b) (4)	15 Mar 2021 14:45:16
User entered empty.	(b) (4) amy sheets (b) (4) (b) (4)	18 Aug 2020 15:00:35

US3052005

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 15:00:53

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Borger (b) (4)	15 Mar 2021 14:45:16
User entered 'once daily (QD)'	(b) (4) amy sheets (b) (4) (b) (4)	18 Aug 2020 15:00:35

US3052005

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 15:00:53

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Judith Borger (b) (4)	15 Mar 2021 14:45:16
User entered empty.	(b) (4) amy sheets (b) (4) (b) (4)	18 Aug 2020 15:00:35

US3052005

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 15:00:53

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Borger (b) (4)	15 Mar 2021 14:45:16
User entered 'Oral (ORAL)'	(b) (4) amy sheets (b) (4) (b) (4)	18 Aug 2020 15:00:35

US3052005

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 15:00:53

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Judith Borger (b) (4)	15 Mar 2021 14:45:16
User entered empty.	(b) (4) amy sheets (b) (4) (b) (4)	18 Aug 2020 15:00:35

US3052005

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 15:00:53

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Judith Borger (b) (4)	15 Mar 2021 14:45:16
Amendment Manager: Query closed during migration process because the edit check no longer exists in target version.	(b) (4)	21 Aug 2020 01:21:13
User opened query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' (Site from System).	System	18 Aug 2020 15:00:35
User entered 'un Dec 2018'	amy sheets (b) (4)	18 Aug 2020 15:00:35
	(b) (4)	

US3052005

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 15:00:53

Start date completely unknown

Audit	User	Time (GMT)
User signature succeeded.	Judith Borger (b) (4)	15 Mar 2021 14:45:16
User entered '0'	(b) (4) amy sheets (b) (4) (b) (4)	18 Aug 2020 15:00:35

US3052005

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 15:00:53

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Borger (b) (4)	15 Mar 2021 14:45:16
User entered 'Yes (Y)'	(b) (4) amy sheets (b) (4) (b) (4)	18 Aug 2020 15:00:35

US3052005

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 15:00:53

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Judith Borger (b) (4)	15 Mar 2021 14:45:16
User entered empty.	(b) (4) amy sheets (b) (4) (b) (4)	18 Aug 2020 15:00:35

US3052005

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 15:00:53

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Borger (b) (4)	15 Mar 2021 14:45:16
User entered 'No (N)'	(b) (4) amy sheets (b) (4) (b) (4)	18 Aug 2020 15:00:35

US3052005

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 15:00:53

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	18 Aug 2020 15:00:35

US3052005

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 15:00:53

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	18 Aug 2020 15:00:35

US3052005

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 15:00:53

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	18 Aug 2020 15:00:35

US3052005

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 15:00:53

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Borger (b) (4)	15 Mar 2021 14:45:16
User coded data point as ATC: BLOOD AND BLOOD FORMING ORGANS, ATC: ANTITHROMBOTIC AGENTS, ATC: ANTITHROMBOTIC AGENTS, ATC: DIRECT FACTOR XA INHIBITORS, PRODUCT: APIXABAN, PRODUCTSYNONYM: ELIQUIS - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4)	18 Aug 2020 15:07:24
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	18 Aug 2020 15:07:24
Data point term sent to Coder	System	18 Aug 2020 15:06:59
User entered 'Eliquis'	amy sheets (b) (4) (b) (4)	18 Aug 2020 15:06:40

US3052005

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 15:00:53

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Borger (b) (4)	15 Mar 2021 14:45:16
User closed query 'Per DM CLR: Prophylaxis = Yes, however there is a corresponding entry on the Medical History CRF. It is unexpected for a medication to be given to prevent a condition the patient already has a diagnosis for. Please review and update the Con Med CRF if applicable. ' (Site from DM).	(b) (4) (b) (4), (b) (6)	19 Oct 2020 11:42:23
Query 'Per DM CLR: Prophylaxis = Yes, however there is a corresponding entry on the Medical History CRF. It is unexpected for a medication to be given to prevent a condition the patient already has a diagnosis for. Please review and update the Con Med CRF if applicable. ' answered with 'updated' (Site from DM).	amy sheets (b) (4) (b) (4)	07 Oct 2020 19:36:31
User entered 'No (N)' reason for change: Data Entry Error	amy sheets (b) (4) (b) (4)	07 Oct 2020 19:36:19
User opened query 'Per DM CLR: Prophylaxis = Yes, however there is a corresponding entry on the Medical History CRF. It is unexpected for a medication to be given to prevent a condition the patient already has a diagnosis for. Please review and update the Con Med CRF if applicable. ' (Site from DM).	(b) (4), (b) (6)	10 Sep 2020 11:58:27
User entered 'Yes (Y)'	amy sheets (b) (4) (b) (4)	18 Aug 2020 15:06:40

US3052005

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 15:00:53

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Borger (b) (4)	15 Mar 2021 14:45:16
User entered 'A-fib'	(b) (4) amy sheets (b) (4) (b) (4)	18 Aug 2020 15:06:40

US3052005

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 15:00:53

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Borger (b) (4)	15 Mar 2021 14:45:16
User entered '5'	(b) (4) amy sheets (b) (4) (b) (4)	18 Aug 2020 15:06:40

US3052005

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 15:00:53

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Borger (b) (4)	15 Mar 2021 14:45:16
User entered 'mg (mg)'	(b) (4) amy sheets (b) (4) (b) (4)	18 Aug 2020 15:06:40

US3052005

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 15:00:53

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Judith Borger (b) (4)	15 Mar 2021 14:45:16
User entered empty.	(b) (4) amy sheets (b) (4) (b) (4)	18 Aug 2020 15:06:40

US3052005

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 15:00:53

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Borger (b) (4)	15 Mar 2021 14:45:16
User entered 'once daily (QD)'	(b) (4) amy sheets (b) (4) (b) (4)	18 Aug 2020 15:06:40

US3052005

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 15:00:53

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Judith Borger (b) (4)	15 Mar 2021 14:45:16
User entered empty.	(b) (4) amy sheets (b) (4) (b) (4)	18 Aug 2020 15:06:40

US3052005

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 15:00:53

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Borger (b) (4)	15 Mar 2021 14:45:16
User entered 'Oral (ORAL)'	(b) (4) amy sheets (b) (4) (b) (4)	18 Aug 2020 15:06:40

US3052005

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 15:00:53

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Judith Borger (b) (4)	15 Mar 2021 14:45:16
User entered empty.	(b) (4) amy sheets (b) (4) (b) (4)	18 Aug 2020 15:06:40

US3052005

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 15:00:53

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Judith Borger (b) (4)	15 Mar 2021 14:45:16
Amendment Manager: Query closed during migration process because the edit check no longer exists in target version.	(b) (4)	21 Aug 2020 01:21:13
User opened query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' (Site from System).	System	18 Aug 2020 15:06:40
User entered 'un Dec 2018'	amy sheets (b) (4)	18 Aug 2020 15:06:40
	(b) (4)	

US3052005

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 15:00:53

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Borger (b) (4)	15 Mar 2021 14:45:16
User entered '0'	(b) (4) amy sheets (b) (4) (b) (4)	18 Aug 2020 15:06:40

US3052005

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 15:00:53

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Borger (b) (4)	15 Mar 2021 14:45:16
User entered 'Yes (Y)'	(b) (4) amy sheets (b) (4) (b) (4)	18 Aug 2020 15:06:40

US3052005

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 15:00:53

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Judith Borger (b) (4)	15 Mar 2021 14:45:16
User entered empty.	(b) (4) amy sheets (b) (4) (b) (4)	18 Aug 2020 15:06:40

US3052005

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 15:00:53

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Borger (b) (4)	15 Mar 2021 14:45:16
User entered 'No (N)'	(b) (4) amy sheets (b) (4) (b) (4)	18 Aug 2020 15:06:40

US3052005

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 15:00:53

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	18 Aug 2020 15:06:40

US3052005

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 15:00:53

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	18 Aug 2020 15:06:40

US3052005

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 15:00:53

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	18 Aug 2020 15:06:40

US3052005

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 15:00:53

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Borger (b) (4)	15 Mar 2021 14:45:16
User coded data point as ATC: CARDIOVASCULAR SYSTEM, ATC: LIPID MODIFYING AGENTS, ATC: LIPID MODIFYING AGENTS, PLAIN, ATC: OTHER LIPID MODIFYING AGENTS, PRODUCT: EVOLOCUMAB, PRODUCTSYNONYM: REPATHA - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4) (b) (4)	18 Aug 2020 15:17:08
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	18 Aug 2020 15:17:08
Data point term sent to Coder	System	18 Aug 2020 15:16:31
User entered 'Repatha'	amy sheets (b) (4) (b) (4)	18 Aug 2020 15:16:13

US3052005

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 15:00:53

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Borger (b) (4) (b) (4)	15 Mar 2021 14:45:16
User closed query 'Per DM CLR: Prophylaxis = Yes, however there is a corresponding entry on the Medical History CRF. It is unexpected for a medication to be given to prevent a condition the patient already has a diagnosis for. Please review and update the Con Med CRF if applicable. ' (Site from DM).	(b) (4), (b) (6) (b) (4)	19 Oct 2020 11:43:00
Query 'Per DM CLR: Prophylaxis = Yes, however there is a corresponding entry on the Medical History CRF. It is unexpected for a medication to be given to prevent a condition the patient already has a diagnosis for. Please review and update the Con Med CRF if applicable. ' answered with 'updated' (Site from DM).	amy sheets (b) (4) (b) (4)	07 Oct 2020 19:37:38
User entered 'No (N)' reason for change: Data Entry Error	amy sheets (b) (4) (b) (4)	07 Oct 2020 19:37:22
User opened query 'Per DM CLR: Prophylaxis = Yes, however there is a corresponding entry on the Medical History CRF. It is unexpected for a medication to be given to prevent a condition the patient already has a diagnosis for. Please review and update the Con Med CRF if applicable. ' (Site from DM).	(b) (4), (b) (6) (b) (4)	10 Sep 2020 12:00:20
User entered 'Yes (Y)'	amy sheets (b) (4) (b) (4)	18 Aug 2020 15:16:13

US3052005

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 15:00:53

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Borger (b) (4)	15 Mar 2021 14:45:16
User entered 'High Cholesterol'	(b) (4) amy sheets (b) (4) (b) (4)	18 Aug 2020 15:16:13

US3052005

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 15:00:53

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Borger (b) (4) (b) (4)	15 Mar 2021 14:45:16
User closed query 'Per CDM: Please review "Dose per administration" and update with either a number or "UNK" if unknown. Thank you. ' (Site from DM).	(b) (4), (b) (6) (b) (4)	16 Nov 2020 20:35:32
Query 'Per CDM: Please review "Dose per administration" and update with either a number or "UNK" if unknown. Thank you. ' answered with 'Reviewed and update' (Site from DM).	Stacey Saldua (b) (4) (b) (4)	12 Nov 2020 20:28:39
User entered 'unknown' reason for change: Data Entry Error	Stacey Saldua (b) (4) (b) (4)	12 Nov 2020 20:27:53
User opened query 'Per CDM: Please review "Dose per administration" and update with either a number or "UNK" if unknown. Thank you. ' (Site from DM).	(b) (4), (b) (6) (b) (4)	10 Nov 2020 15:45:11
User entered 'Not listed'	amy sheets (b) (4) (b) (4)	18 Aug 2020 15:16:13

US3052005

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 15:00:53

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Borger (b) (4)	15 Mar 2021 14:45:16
User entered 'Other (OTHER)'	(b) (4) amy sheets (b) (4) (b) (4)	18 Aug 2020 15:16:13

US3052005

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 15:00:53

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Judith Borger (b) (4)	15 Mar 2021 14:45:16
User entered 'Dosage not listed'	(b) (4) amy sheets (b) (4) (b) (4)	18 Aug 2020 15:16:13

US3052005

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 15:00:53

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Borger (b) (4)	15 Mar 2021 14:45:16
User entered 'other (OTHER)'	(b) (4) amy sheets (b) (4) (b) (4)	18 Aug 2020 15:16:13

US3052005

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 15:00:53

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Judith Borger (b) (4)	15 Mar 2021 14:45:16
User entered 'Twice a month'	(b) (4) amy sheets (b) (4) (b) (4)	18 Aug 2020 15:16:13

US3052005

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 15:00:53

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Borger (b) (4)	15 Mar 2021 14:45:16
User entered 'Subcutaneous (SUBCUTANEOUS)'	(b) (4) amy sheets (b) (4) (b) (4)	18 Aug 2020 15:16:13

US3052005

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 15:00:53

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Judith Borger (b) (4)	15 Mar 2021 14:45:16
User entered empty.	(b) (4) amy sheets (b) (4) (b) (4)	18 Aug 2020 15:16:13

US3052005

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 15:00:53

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Judith Borger (b) (4)	15 Mar 2021 14:45:16
Amendment Manager: Query closed during migration process because the edit check no longer exists in target version.	(b) (4)	21 Aug 2020 01:21:13
User entered 'UN Nov 2018' reason for change: Data Entry Error	amy sheets (b) (4)	18 Aug 2020 15:16:50
User opened query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' (Site from System).	System	18 Aug 2020 15:16:13
User entered 'un Dec 2018'	amy sheets (b) (4)	18 Aug 2020 15:16:13

US3052005

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 15:00:53

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Borger (b) (4)	15 Mar 2021 14:45:16
User entered '0'	(b) (4) amy sheets (b) (4) (b) (4)	18 Aug 2020 15:16:13

US3052005

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 15:00:53

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Borger (b) (4)	15 Mar 2021 14:45:16
User entered 'Yes (Y)'	(b) (4) amy sheets (b) (4) (b) (4)	18 Aug 2020 15:16:13

US3052005

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 15:00:53

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Judith Borger (b) (4)	15 Mar 2021 14:45:16
User entered empty.	(b) (4) amy sheets (b) (4) (b) (4)	18 Aug 2020 15:16:13

US3052005

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 15:00:53

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Borger (b) (4)	15 Mar 2021 14:45:16
User entered 'No (N)'	(b) (4) amy sheets (b) (4) (b) (4)	18 Aug 2020 15:16:13

US3052005

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 15:00:53

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	18 Aug 2020 15:16:13

US3052005

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 15:00:53

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	18 Aug 2020 15:16:13

US3052005

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 15:00:53

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	18 Aug 2020 15:16:13

US3052005

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 15:00:53

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Borger (b) (4)	15 Mar 2021 14:45:16
User coded data point as ATC: GENITO URINARY SYSTEM AND SEX HORMONES, ATC: UROLOGICALS, ATC: UROLOGICALS, ATC: DRUGS USED IN ERECTILE DYSFUNCTION, PRODUCT: SILDENAFIL - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4)	18 Aug 2020 15:30:05
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	18 Aug 2020 15:30:05
Data point term sent to Coder	System	18 Aug 2020 15:24:09
User entered 'Sildeafil'	amy sheets (b) (4) (b) (4)	18 Aug 2020 15:23:49

US3052005

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 15:00:53

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Borger (b) (4)	15 Mar 2021 14:45:16
User entered 'No (N)'	(b) (4) amy sheets (b) (4) (b) (4)	18 Aug 2020 15:23:49

US3052005

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 15:00:53

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Borger (b) (4)	15 Mar 2021 14:45:16
User entered 'Erectile Dysfunction'	(b) (4) amy sheets (b) (4) (b) (4)	18 Aug 2020 15:23:49

US3052005

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 15:00:53

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Borger (b) (4)	15 Mar 2021 14:45:16
User entered '80'	(b) (4) amy sheets (b) (4) (b) (4)	18 Aug 2020 15:23:49

US3052005

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 15:00:53

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Borger (b) (4)	15 Mar 2021 14:45:16
User entered 'mg (mg)'	(b) (4) amy sheets (b) (4) (b) (4)	18 Aug 2020 15:23:49

US3052005

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 15:00:53

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Judith Borger (b) (4)	15 Mar 2021 14:45:16
User entered empty.	(b) (4) amy sheets (b) (4) (b) (4)	18 Aug 2020 15:23:49

US3052005

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 15:00:53

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Borger (b) (4)	15 Mar 2021 14:45:16
	(b) (4)	
User entered 'every week (QS)'	amy sheets (b) (4)	18 Aug 2020 15:23:49
	(b) (4)	

US3052005

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 15:00:53

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Judith Borger (b) (4)	15 Mar 2021 14:45:16
User entered empty.	(b) (4) amy sheets (b) (4) (b) (4)	18 Aug 2020 15:23:49

US3052005

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 15:00:53

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Borger (b) (4)	15 Mar 2021 14:45:16
User entered 'Oral (ORAL)'	(b) (4) amy sheets (b) (4) (b) (4)	18 Aug 2020 15:23:49

US3052005

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 15:00:53

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Judith Borger (b) (4)	15 Mar 2021 14:45:16
User entered empty.	(b) (4) amy sheets (b) (4) (b) (4)	18 Aug 2020 15:23:49

US3052005

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 15:00:53

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Judith Borger (b) (4)	15 Mar 2021 14:45:16
Amendment Manager: Query closed during migration process because the edit check no longer exists in target version.	(b) (4)	21 Aug 2020 01:21:13
User opened query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' (Site from System).	System	18 Aug 2020 15:23:49
User entered 'un UNK 2018'	amy sheets (b) (4)	18 Aug 2020 15:23:49
	(b) (4)	

US3052005

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 15:00:53

Start date completely unknown

Audit	User	Time (GMT)
User signature succeeded.	Judith Borger (b) (4)	15 Mar 2021 14:45:16
User entered '0'	(b) (4) amy sheets (b) (4) (b) (4)	18 Aug 2020 15:23:49

US3052005

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 15:00:53

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Borger (b) (4)	15 Mar 2021 14:45:16
User entered 'Yes (Y)'	(b) (4) amy sheets (b) (4) (b) (4)	18 Aug 2020 15:23:49

US3052005

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 15:00:53

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Judith Borger (b) (4)	15 Mar 2021 14:45:16
User entered empty.	(b) (4) amy sheets (b) (4) (b) (4)	18 Aug 2020 15:23:49

US3052005

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 15:00:53

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Borger (b) (4)	15 Mar 2021 14:45:16
User entered 'No (N)'	(b) (4) amy sheets (b) (4) (b) (4)	18 Aug 2020 15:23:49

US3052005

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 15:00:53

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	18 Aug 2020 15:23:49

US3052005

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 15:00:53

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	18 Aug 2020 15:23:49

US3052005

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 15:00:53

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '803 (803)'	System	18 Aug 2020 15:23:49

US3052005

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 15:00:53

Name of Medication

Audit	User	Time (GMT)
User signature succeeded.	Judith Borger (b) (4)	15 Mar 2021 14:45:16
User coded data point as ATC: MUSCULO-SKELETAL SYSTEM, ATC: ANTIINFLAMMATORY AND ANTIRHEUMATIC PRODUCTS, ATC: ANTIINFLAMMATORY AND ANTIRHEUMATIC PRODUCTS, NON-STEROIDS, ATC: OTHER ANTIINFLAMMATORY AND ANTIRHEUMATIC AGENTS, NON-STEROIDS, PRODUCT: GLUCOSAMINE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	02 Feb 2021 16:05:31
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	02 Feb 2021 16:05:31
Data point term sent to Coder Coding entries removed.	System (b) (4), (b) (6)	02 Feb 2021 16:03:47 02 Feb 2021 16:03:16
User coded data point as ATC: MUSCULO-SKELETAL SYSTEM, ATC: ANTIINFLAMMATORY AND ANTIRHEUMATIC PRODUCTS, ATC: ANTIINFLAMMATORY AND ANTIRHEUMATIC PRODUCTS, NON-STEROIDS, ATC: OTHER ANTIINFLAMMATORY AND ANTIRHEUMATIC AGENTS, NON-STEROIDS, PRODUCT: GLUCOSAMINE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	09 Nov 2020 16:22:34
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	09 Nov 2020 16:22:34
Data point term sent to Coder Coding entries removed.	System Avia McClain-Stocker (b) (4)	09 Nov 2020 16:21:47 09 Nov 2020 16:21:08

US3052005

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 15:00:53

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: OTHER ANTIINFLAMMATORY AND ANTIRHEUMATIC AGENTS, NON-STEROIDS, PRODUCT: GLUCOSAMINE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	19 Aug 2020 00:43:15
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	19 Aug 2020 00:43:15
Data point term sent to Coder	System	18 Aug 2020 15:27:16
User entered 'Glucosamine'	amy sheets (b) (4) (b) (4)	18 Aug 2020 15:26:40

US3052005

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 15:00:53

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Borger (b) (4)	15 Mar 2021 14:45:16
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) (4), (b) (6)	08 Mar 2021 07:16:50
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).	(b) (4), (b) (6)	06 Mar 2021 20:13:21
User entered 'Yes (Y)' reason for change: Data Entry Error	(b) (4), (b) (6)	06 Mar 2021 20:13:03
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).		10 Feb 2021 12:19:38
User entered 'No (N)'	amy sheets (b) (4) (b) (4)	18 Aug 2020 15:26:40

US3052005

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 15:00:53

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Borger (b) (4)	15 Mar 2021 14:45:16
User entered 'Supplement' reason for change: Data Entry Error	(b) (4)	02 Feb 2021 16:03:16
User closed query 'Per DM CLR: Please specify the location and/or type of ARTHRITIS. Review and update Indication and ensure to reconcile with AE/MH entries so there is an appropriate match' (Site from DM).	(b) (4), (b) (6)	10 Nov 2020 06:39:32
Query 'Per DM CLR: Please specify the location and/or type of ARTHRITIS. Review and update Indication and ensure to reconcile with AE/MH entries so there is an appropriate match' answered with 'updated to match MH' (Site from DM).	Avia McClain-Stocker (b) (4)	09 Nov 2020 16:21:17
User entered 'osteoarthritis' reason for change: Data Entry Error	Avia McClain-Stocker (b) (4)	09 Nov 2020 16:21:08
User opened query 'Per DM CLR: Please specify the location and/or type of ARTHRITIS. Review and update Indication and ensure to reconcile with AE/MH entries so there is an appropriate match' (Site from DM).	(b) (4), (b) (6)	02 Nov 2020 09:38:30
Query 'Per DM CLR: Please specify the type of ARTHRITIS (Rheumatoid versus Osteoarthritis) and the location. Review and update indication and ensure to update MH/Adverse event eCRF as appropriate.' canceled (Site from DM).		30 Sep 2020 10:13:49
User opened query 'Per DM CLR: Please specify the type of ARTHRITIS (Rheumatoid versus Osteoarthritis) and the location. Review and update indication and ensure to update MH/Adverse event eCRF as appropriate.' (Site from DM).		09 Sep 2020 04:07:08
User entered 'Arthritis'	amy sheets (b) (4) (b) (4)	18 Aug 2020 15:26:40

US3052005

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 15:00:53

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Borger (b) (4)	15 Mar 2021 14:45:16
User closed query 'Per DM CLR: Please remove extraneous data (TABLET) from the dose field as it is already recorded in their respective field. Remove as appropriate.' (Site from DM).	(b) (4) (b) (4), (b) (6)	20 Oct 2020 11:48:56
Query 'Per DM CLR: Please remove extraneous data (TABLET) from the dose field as it is already recorded in their respective field. Remove as appropriate.' answered with 'updated' (Site from DM).	amy sheets (b) (4) (b) (4)	07 Oct 2020 19:38:55
User entered '1' reason for change: Data Entry Error	amy sheets (b) (4) (b) (4)	07 Oct 2020 19:38:38
User opened query 'Per DM CLR: Please remove extraneous data (TABLET) from the dose field as it is already recorded in their respective field. Remove as appropriate.' (Site from DM).	(b) (4), (b) (6)	09 Sep 2020 04:08:14
User entered '1 Tablet'	amy sheets (b) (4) (b) (4)	18 Aug 2020 15:26:40

US3052005

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 15:00:53

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Borger (b) (4)	15 Mar 2021 14:45:16
User closed query 'Per DM CLR: Please review ""Other Unit"" as there is an available option for ""tablet"" in the listed choices for unit. Please review and select an appropriate option from the list provided in the CRF and amend as appropriate.' (Site from DM).	(b) (4) (b) (4), (b) (6)	20 Oct 2020 11:48:55
Query 'Per DM CLR: Please review ""Other Unit"" as there is an available option for ""tablet"" in the listed choices for unit. Please review and select an appropriate option from the list provided in the CRF and amend as appropriate.' answered with 'updated' (Site from DM).	amy sheets (b) (4) (b) (4)	07 Oct 2020 19:39:06
User entered 'tablet (TABLET)' reason for change: Data Entry Error	amy sheets (b) (4) (b) (4)	07 Oct 2020 19:38:38
User opened query 'Per DM CLR: Please review ""Other Unit"" as there is an available option for ""tablet"" in the listed choices for unit. Please review and select an appropriate option from the list provided in the CRF and amend as appropriate.' (Site from DM).	(b) (4), (b) (6)	09 Sep 2020 04:09:14
User entered 'Other (OTHER)'	amy sheets (b) (4) (b) (4)	18 Aug 2020 15:26:40

US3052005

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 15:00:53

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Judith Borger (b) (4)	15 Mar 2021 14:45:16
User closed query 'Per DM CLR: Please remove extraneous data (1) from the If dose unit is Other, specify field as it is already recorded in their respective field. Remove as appropriate.' ' (Site from DM).	(b) (4) (b) (4), (b) (6)	20 Oct 2020 11:48:53
Query 'Per DM CLR: Please remove extraneous data (1) from the If dose unit is Other, specify field as it is already recorded in their respective field. Remove as appropriate.' ' answered with 'updated' (Site from DM).	amy sheets (b) (4) (b) (4)	07 Oct 2020 19:39:20
User entered empty; reason for change Data Entry Error	amy sheets (b) (4) (b) (4)	07 Oct 2020 19:38:38
User opened query 'Per DM CLR: Please remove extraneous data (1) from the If dose unit is Other, specify field as it is already recorded in their respective field. Remove as appropriate.' ' (Site from DM).	(b) (4), (b) (6)	09 Sep 2020 04:10:11
User entered '1 Tablet'	amy sheets (b) (4) (b) (4)	18 Aug 2020 15:26:40

US3052005

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 15:00:53

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Borger (b) (4)	15 Mar 2021 14:45:16
User entered 'once daily (QD)'	(b) (4) amy sheets (b) (4) (b) (4)	18 Aug 2020 15:26:40

US3052005

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 15:00:53

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Judith Borger (b) (4)	15 Mar 2021 14:45:16
User entered empty.	(b) (4) amy sheets (b) (4) (b) (4)	18 Aug 2020 15:26:40

US3052005

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 15:00:53

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Borger (b) (4)	15 Mar 2021 14:45:16
	(b) (4)	
User entered 'Oral (ORAL)'	amy sheets (b) (4)	18 Aug 2020 15:26:40
	(b) (4)	

US3052005

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 15:00:53

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Judith Borger (b) (4)	15 Mar 2021 14:45:16
User entered empty.	(b) (4) amy sheets (b) (4) (b) (4)	18 Aug 2020 15:26:40

US3052005

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 15:00:53

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Judith Borger (b) (4)	15 Mar 2021 14:45:16
User closed query 'Per DM CLR: Con Med start date is prior to the start date of the corresponding MH condition. Please review and reconcile Con Med and MH start dates as appropriate. Otherwise, clarify. ' (Site from DM).	(b) (4) (b) (4), (b) (6)	10 Feb 2021 12:19:31
Query 'Per DM CLR: Con Med start date is prior to the start date of the corresponding MH condition. Please review and reconcile Con Med and MH start dates as appropriate. Otherwise, clarify. ' answered with 'Reviewed and update' (Site from DM).	(b) (4), (b) (6)	02 Feb 2021 16:03:34
User opened query 'Per DM CLR: Con Med start date is prior to the start date of the corresponding MH condition. Please review and reconcile Con Med and MH start dates as appropriate. Otherwise, clarify. ' (Site from DM).	(b) (4), (b) (6)	16 Dec 2020 08:21:34
Amendment Manager: Query closed during migrationSystem process because the edit check no longer exists in target version.		21 Aug 2020 01:21:13
User opened query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' (Site from System).	System	18 Aug 2020 15:26:40
User entered 'un UNK 2005'	amy sheets (b) (4) (b) (4)	18 Aug 2020 15:26:40

US3052005

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 15:00:53

Start date completely unknown

Audit	User	Time (GMT)
User signature succeeded.	Judith Borger (b) (4)	15 Mar 2021 14:45:16
	(b) (4)	
User entered '0'	amy sheets (b) (4)	18 Aug 2020 15:26:40
	(b) (4)	

US3052005

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 15:00:53

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Borger (b) (4)	15 Mar 2021 14:45:16
User entered 'Yes (Y)'	(b) (4) amy sheets (b) (4) (b) (4)	18 Aug 2020 15:26:40

US3052005

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 15:00:53

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Judith Borger (b) (4)	15 Mar 2021 14:45:16
User entered empty.	(b) (4) amy sheets (b) (4) (b) (4)	18 Aug 2020 15:26:40

US3052005

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 15:00:53

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Borger (b) (4)	15 Mar 2021 14:45:16
User entered 'No (N)'	(b) (4) amy sheets (b) (4) (b) (4)	18 Aug 2020 15:26:40

US3052005

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 15:00:53

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	18 Aug 2020 15:26:40

US3052005

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 15:00:53

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	18 Aug 2020 15:26:40

US3052005

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 15:00:53

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	18 Aug 2020 15:26:40

US3052005

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 15:00:53

Name of Medication

Audit	User	Time (GMT)
User signature succeeded.	Judith Borger (b) (4)	15 Mar 2021 14:45:16
User coded data point as ATC: CARDIOVASCULAR SYSTEM, ATC: LIPID MODIFYING AGENTS, ATC: LIPID MODIFYING AGENTS, PLAIN, ATC: OTHER LIPID MODIFYING AGENTS, PRODUCT: FISH OIL - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	07 Oct 2020 20:14:36
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	07 Oct 2020 20:14:36
Data point term sent to Coder Coding entries removed.	System amy sheets (b) (4)	07 Oct 2020 19:41:13 07 Oct 2020 19:40:54
User coded data point as ATC: CARDIOVASCULAR SYSTEM, ATC: LIPID MODIFYING AGENTS, ATC: LIPID MODIFYING AGENTS, PLAIN, ATC: OTHER LIPID MODIFYING AGENTS, PRODUCT: FISH OIL - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	18 Aug 2020 15:40:36
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	18 Aug 2020 15:40:36
Data point term sent to Coder Coding entries removed.	System amy sheets (b) (4)	18 Aug 2020 15:38:46 18 Aug 2020 15:38:18
User coded data point as ATC: VARIOUS, ATC: GENERAL NUTRIENTS, ATC: OTHER NUTRIENTS, ATC: OTHER COMBINATIONS OF NUTRIENTS, PRODUCT: FISH OIL - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	18 Aug 2020 15:31:06
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	18 Aug 2020 15:31:06
Data point term sent to Coder User entered 'Fish Oil'	System amy sheets (b) (4)	18 Aug 2020 15:30:27 18 Aug 2020 15:29:54

US3052005

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 15:00:53

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Borger (b) (4)	15 Mar 2021 14:45:16
User entered 'No (N)'	(b) (4) amy sheets (b) (4) (b) (4)	18 Aug 2020 15:29:54

US3052005

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 15:00:53

Indication

Audit	User	Time (GMT)
User signature succeeded.	Judith Borger (b) (4)	15 Mar 2021 14:45:16
User closed query 'Per DM CLR: Please update the indication to reflect the underlying medical condition that this medication is being used to prevent/treat. Please reconcile with AE or Med History eCRF so there is an appropriate match. Update eCRF as appropriate. (if indication is a mechanism of Action, Drug class, etc.)' (Site from DM).	(b) (4) (b) (4), (b) (6)	20 Oct 2020 11:51:43
Query 'Per DM CLR: Please update the indication to reflect the underlying medical condition that this medication is being used to prevent/treat. Please reconcile with AE or Med History eCRF so there is an appropriate match. Update eCRF as appropriate. (if indication is a mechanism of Action, Drug class, etc.)' ' answered with 'updated' (Site from DM).	amy sheets (b) (4) (b) (4)	07 Oct 2020 19:41:11
User entered 'high CHOLESTEROL' reason for change: Data Entry Error	amy sheets (b) (4) (b) (4)	07 Oct 2020 19:40:54
User opened query 'Per DM CLR: Please update the indication to reflect the underlying medical condition that this medication is being used to prevent/treat. Please reconcile with AE or Med History eCRF so there is an appropriate match. Update eCRF as appropriate. (if indication is a mechanism of Action, Drug class, etc.)' (Site from DM).	(b) (4), (b) (6)	09 Sep 2020 04:32:03
User entered 'Cholesterol' reason for change: Data Entry Error	amy sheets (b) (4) (b) (4)	18 Aug 2020 15:38:18
User entered 'Health Maintenance'	amy sheets (b) (4) (b) (4)	18 Aug 2020 15:29:54

US3052005

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 15:00:53

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Borger (b) (4)	15 Mar 2021 14:45:16
User entered '1200'	(b) (4) amy sheets (b) (4) (b) (4)	18 Aug 2020 15:29:54

US3052005

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 15:00:53

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Borger (b) (4)	15 Mar 2021 14:45:16
User entered 'mg (mg)'	(b) (4) amy sheets (b) (4) (b) (4)	18 Aug 2020 15:29:54

US3052005

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 15:00:53

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Judith Borger (b) (4)	15 Mar 2021 14:45:16
User entered empty.	(b) (4) amy sheets (b) (4) (b) (4)	18 Aug 2020 15:29:54

US3052005

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 15:00:53

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Borger (b) (4)	15 Mar 2021 14:45:16
User entered 'twice daily (BID)'	(b) (4) amy sheets (b) (4) (b) (4)	18 Aug 2020 15:29:54

US3052005

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 15:00:53

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Judith Borger (b) (4)	15 Mar 2021 14:45:16
User entered empty.	(b) (4) amy sheets (b) (4) (b) (4)	18 Aug 2020 15:29:54

US3052005

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 15:00:53

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Borger (b) (4)	15 Mar 2021 14:45:16
User entered 'Oral (ORAL)'	(b) (4) amy sheets (b) (4) (b) (4)	18 Aug 2020 15:29:54

US3052005

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 15:00:53

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Judith Borger (b) (4)	15 Mar 2021 14:45:16
User entered empty.	(b) (4) amy sheets (b) (4) (b) (4)	18 Aug 2020 15:29:54

US3052005

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 15:00:53

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Judith Borger (b) (4)	15 Mar 2021 14:45:16
Amendment Manager: Query closed during migration process because the edit check no longer exists in target version.	(b) (4)	21 Aug 2020 01:21:13
User opened query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' (Site from System).	System	18 Aug 2020 15:29:54
User entered 'un UNK 2005'	amy sheets (b) (4)	18 Aug 2020 15:29:54
	(b) (4)	

US3052005

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 15:00:53

Start date completely unknown

Audit	User	Time (GMT)
User signature succeeded.	Judith Borger (b) (4)	15 Mar 2021 14:45:16
User entered '0'	(b) (4) amy sheets (b) (4) (b) (4)	18 Aug 2020 15:29:54

US3052005

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 15:00:53

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Borger (b) (4)	15 Mar 2021 14:45:16
User entered 'Yes (Y)'	(b) (4) amy sheets (b) (4) (b) (4)	18 Aug 2020 15:29:54

US3052005

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 15:00:53

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Judith Borger (b) (4)	15 Mar 2021 14:45:16
User entered empty.	(b) (4) amy sheets (b) (4) (b) (4)	18 Aug 2020 15:29:54

US3052005

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 15:00:53

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Borger (b) (4)	15 Mar 2021 14:45:16
User entered 'No (N)'	(b) (4) amy sheets (b) (4) (b) (4)	18 Aug 2020 15:29:54

US3052005

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 15:00:53

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '2'	System	18 Aug 2020 15:29:54

US3052005

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 15:00:53

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	18 Aug 2020 15:29:54

US3052005

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 15:00:53

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	18 Aug 2020 15:29:54

US3052005

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 15:00:53

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Borger (b) (4)	15 Mar 2021 14:45:16
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: VITAMINS, ATC: ASCORBIC ACID (VITAMIN C), INCL. COMBINATIONS, ATC: ASCORBIC ACID (VITAMIN C), PLAIN, PRODUCT: ASCORBIC ACID, PRODUCTSYNONYM: VITAMIN C [ASCORBIC ACID] - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4)	18 Aug 2020 15:35:08
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	18 Aug 2020 15:35:08
Data point term sent to Coder	System	18 Aug 2020 15:34:33
User entered 'Vitamin C'	amy sheets (b) (4) (b) (4)	18 Aug 2020 15:33:56

US3052005

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 15:00:53

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Borger (b) (4)	15 Mar 2021 14:45:16
User entered 'No (N)'	(b) (4) amy sheets (b) (4) (b) (4)	18 Aug 2020 15:33:56

US3052005

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 15:00:53

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Borger (b) (4)	15 Mar 2021 14:45:16
User entered 'Health Maintenance'	(b) (4) amy sheets (b) (4) (b) (4)	18 Aug 2020 15:33:56

US3052005

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 15:00:53

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Borger (b) (4)	15 Mar 2021 14:45:16
User entered '500'	(b) (4) amy sheets (b) (4) (b) (4)	18 Aug 2020 15:33:56

US3052005

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 15:00:53

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Borger (b) (4)	15 Mar 2021 14:45:16
User entered 'mg (mg)'	(b) (4) amy sheets (b) (4) (b) (4)	18 Aug 2020 15:33:56

US3052005

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 15:00:53

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Judith Borger (b) (4)	15 Mar 2021 14:45:16
User entered empty.	(b) (4) amy sheets (b) (4) (b) (4)	18 Aug 2020 15:33:56

US3052005

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 15:00:53

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Borger (b) (4)	15 Mar 2021 14:45:16
User entered 'once daily (QD)'	(b) (4) amy sheets (b) (4) (b) (4)	18 Aug 2020 15:33:56

US3052005

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 15:00:53

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Judith Borger (b) (4)	15 Mar 2021 14:45:16
User entered empty.	(b) (4) amy sheets (b) (4) (b) (4)	18 Aug 2020 15:33:56

US3052005

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 15:00:53

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Borger (b) (4)	15 Mar 2021 14:45:16
User entered 'Oral (ORAL)'	(b) (4) amy sheets (b) (4) (b) (4)	18 Aug 2020 15:33:56

US3052005

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 15:00:53

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Judith Borger (b) (4)	15 Mar 2021 14:45:16
User entered empty.	(b) (4) amy sheets (b) (4) (b) (4)	18 Aug 2020 15:33:56

US3052005

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 15:00:53

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Judith Borger (b) (4)	15 Mar 2021 14:45:16
Amendment Manager: Query closed during migration process because the edit check no longer exists in target version.	(b) (4)	21 Aug 2020 01:21:13
User opened query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' (Site from System).	System	18 Aug 2020 15:33:56
User entered 'un UNK 2010'	amy sheets (b) (4)	18 Aug 2020 15:33:56
	(b) (4)	

US3052005

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 15:00:53

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Borger (b) (4)	15 Mar 2021 14:45:16
User entered '0'	(b) (4) amy sheets (b) (4) (b) (4)	18 Aug 2020 15:33:56

US3052005

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 15:00:53

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Borger (b) (4)	15 Mar 2021 14:45:16
User entered 'Yes (Y)'	(b) (4) amy sheets (b) (4) (b) (4)	18 Aug 2020 15:33:56

US3052005

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 15:00:53

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Judith Borger (b) (4)	15 Mar 2021 14:45:16
User entered empty.	(b) (4) amy sheets (b) (4) (b) (4)	18 Aug 2020 15:33:56

US3052005

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 15:00:53

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Borger (b) (4)	15 Mar 2021 14:45:16
User entered 'No (N)'	(b) (4) amy sheets (b) (4) (b) (4)	18 Aug 2020 15:33:56

US3052005

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 15:00:53

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	18 Aug 2020 15:33:56

US3052005

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 15:00:53

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	18 Aug 2020 15:33:56

US3052005

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 15:00:53

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	18 Aug 2020 15:33:56

US3052005

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 15:00:53

Name of Medication

Audit	User	Time (GMT)
User signature succeeded.	Judith Borger (b) (4)	15 Mar 2021 14:45:16
User closed query 'Per DM CLR: Please provide brand name if known. ' (Site from DM).	(b) (4) (b) (4), (b) (6)	17 Nov 2020 17:55:43
Query 'Per DM CLR: Please provide brand name if known. ' answered with 'Unknown' (Site from DM).	Stacey Saldua (b) (4) (b) (4)	12 Nov 2020 20:29:45
User opened query 'Per DM CLR: Please provide brand name if known. ' (Site from DM).	(b) (4), (b) (6)	02 Nov 2020 09:38:53
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)	04 Sep 2020 17:24:39
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	04 Sep 2020 17:24:39
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: VITAMINS, ATC: OTHER VITAMIN PRODUCTS, COMBINATIONS, ATC: COMBINATIONS OF VITAMINS, PRODUCT: VITAMINS NOS, PRODUCTSYNONYM: MULTIVITAMIN [VITAMINS NOS] - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	18 Aug 2020 15:38:23
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	18 Aug 2020 15:38:23
Data point term sent to Coder	System	18 Aug 2020 15:37:44
User entered 'Multi Vitamin'	amy sheets (b) (4) (b) (4)	18 Aug 2020 15:37:09

US3052005

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 15:00:53

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Borger (b) (4)	15 Mar 2021 14:45:16
User entered 'Yes (Y)' reason for change: Data Entry Error	(b) (4) amy sheets (b) (4)	07 Oct 2020 20:37:11
User entered 'No (N)'	(b) (4) amy sheets (b) (4) (b) (4)	18 Aug 2020 15:37:09

US3052005

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 15:00:53

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Borger (b) (4)	15 Mar 2021 14:45:16
User entered 'Health Maintenance'	(b) (4) amy sheets (b) (4) (b) (4)	18 Aug 2020 15:37:09

US3052005

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 15:00:53

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Borger (b) (4)	15 Mar 2021 14:45:16
User closed query 'Per DM CLR: Please remove extraneous data (TABLET) from the dose field as it is already recorded in their respective field. Remove as appropriate.' (Site from DM).	(b) (4) (b) (4), (b) (6)	20 Oct 2020 11:51:58
Query 'Per DM CLR: Please remove extraneous data (TABLET) from the dose field as it is already recorded in their respective field. Remove as appropriate.' answered with 'updated' (Site from DM).	amy sheets (b) (4) (b) (4)	07 Oct 2020 20:37:26
User entered '1' reason for change: Data Entry Error	amy sheets (b) (4) (b) (4)	07 Oct 2020 20:37:11
User opened query 'Per DM CLR: Please remove extraneous data (TABLET) from the dose field as it is already recorded in their respective field. Remove as appropriate.' (Site from DM).	(b) (4), (b) (6)	09 Sep 2020 04:38:36
User entered '1 Tablet'	amy sheets (b) (4) (b) (4)	18 Aug 2020 15:37:09

US3052005

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 15:00:53

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Borger (b) (4)	15 Mar 2021 14:45:16
User entered 'tablet (TABLET)' reason for change:	(b) (4)	
Data Entry Error	amy sheets (b) (4)	07 Oct 2020 20:37:11
User entered 'Other (OTHER)'	(b) (4)	
	amy sheets (b) (4)	18 Aug 2020 15:37:09
	(b) (4)	

US3052005

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 15:00:53

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Judith Borger (b) (4)	15 Mar 2021 14:45:16
User closed query 'Per DM CLR: Please remove extraneous data (1) from the If dose unit is Other, specify field as it is already recorded in their respective field. Remove as appropriate.' ' (Site from DM).	(b) (4) (b) (4), (b) (6)	20 Oct 2020 11:51:59
Query 'Per DM CLR: Please remove extraneous data (1) from the If dose unit is Other, specify field as it is already recorded in their respective field. Remove as appropriate.' ' answered with 'updated' (Site from DM).	amy sheets (b) (4) (b) (4)	07 Oct 2020 20:37:40
User entered empty; reason for change Data Entry Error	amy sheets (b) (4) (b) (4)	07 Oct 2020 20:37:11
User opened query 'Per DM CLR: Please remove extraneous data (1) from the If dose unit is Other, specify field as it is already recorded in their respective field. Remove as appropriate.' ' (Site from DM).	(b) (4), (b) (6)	09 Sep 2020 04:39:23
User entered '1 Tablet'	amy sheets (b) (4) (b) (4)	18 Aug 2020 15:37:09

US3052005

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 15:00:53

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Borger (b) (4)	15 Mar 2021 14:45:16
User entered 'once daily (QD)'	(b) (4) amy sheets (b) (4) (b) (4)	18 Aug 2020 15:37:09

US3052005

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 15:00:53

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Borger (b) (4)	15 Mar 2021 14:45:16
User entered empty.	(b) (4) amy sheets (b) (4) (b) (4)	18 Aug 2020 15:37:09

US3052005

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 15:00:53

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Borger (b) (4)	15 Mar 2021 14:45:16
User entered 'Oral (ORAL)'	(b) (4) amy sheets (b) (4) (b) (4)	18 Aug 2020 15:37:09

US3052005

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 15:00:53

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Judith Borger (b) (4)	15 Mar 2021 14:45:16
User entered empty.	(b) (4) amy sheets (b) (4) (b) (4)	18 Aug 2020 15:37:09

US3052005

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 15:00:53

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Judith Borger (b) (4)	15 Mar 2021 14:45:16
Amendment Manager: Query closed during migration process because the edit check no longer exists in target version.	(b) (4)	21 Aug 2020 01:21:13
User opened query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' (Site from System).	System	18 Aug 2020 15:37:09
User entered 'un UNK 2010'	amy sheets (b) (4)	18 Aug 2020 15:37:09
	(b) (4)	

US3052005

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 15:00:53

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Borger (b) (4)	15 Mar 2021 14:45:16
User entered '0'	(b) (4) amy sheets (b) (4) (b) (4)	18 Aug 2020 15:37:09

US3052005

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 15:00:53

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Borger (b) (4)	15 Mar 2021 14:45:16
User entered 'Yes (Y)'	(b) (4) amy sheets (b) (4) (b) (4)	18 Aug 2020 15:37:09

US3052005

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 15:00:53

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Judith Borger (b) (4)	15 Mar 2021 14:45:16
User entered empty.	(b) (4) amy sheets (b) (4) (b) (4)	18 Aug 2020 15:37:09

US3052005

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 15:00:53

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Borger (b) (4)	15 Mar 2021 14:45:16
User entered 'No (N)'	(b) (4) amy sheets (b) (4) (b) (4)	18 Aug 2020 15:37:09

US3052005

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 15:00:53

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	18 Aug 2020 15:37:09

US3052005

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 15:00:53

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	18 Aug 2020 15:37:09

US3052005

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 15:00:53

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	18 Aug 2020 15:37:09

US3052005

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 15:00:53

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 08:13:12
User signature succeeded.	Judith Borger (b) (4)	15 Mar 2021 14:45:16
User coded data point as ATC: ANTIINFECTIVES FOR SYSTEMIC USE, ATC: VACCINES, ATC: VIRAL VACCINES, ATC: INFLUENZA VACCINES, PRODUCT: INFLUENZA VACCINE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	12 Oct 2020 12:23:19
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	12 Oct 2020 12:23:19
Data point term sent to Coder	System	12 Oct 2020 12:22:38
User entered 'Influenza Vaccine'	Avia McClain-Stocker	12 Oct 2020 12:22:00
	(b) (4)	

US3052005

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 15:00:53

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 08:13:12
User signature succeeded.	Judith Borger (b) (4)	15 Mar 2021 14:45:16
User entered 'Yes (Y)'	(b) (4) Avia McClain-Stocker (b) (4)	12 Oct 2020 12:22:00

US3052005

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 15:00:53

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 08:13:12
User signature succeeded.	Judith Borger (b) (4)	15 Mar 2021 14:45:16
User entered 'Vaccination'	(b) (4) Avia McClain-Stocker (b) (4)	12 Oct 2020 12:22:00

US3052005

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 15:00:53

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 08:13:12
User signature succeeded.	Judith Borger (b) (4)	15 Mar 2021 14:45:16
User entered 'I'	(b) (4) Avia McClain-Stocker (b) (4)	12 Oct 2020 12:22:00

US3052005

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 15:00:53

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 08:13:12
User signature succeeded.	Judith Borger (b) (4)	15 Mar 2021 14:45:16
User entered 'Other (OTHER)'	(b) (4) Avia McClain-Stocker (b) (4)	12 Oct 2020 12:22:00

US3052005

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 15:00:53

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 08:13:12
User signature succeeded.	Judith Borger (b) (4)	15 Mar 2021 14:45:16
User entered 'injection'	(b) (4) Avia McClain-Stocker (b) (4)	12 Oct 2020 12:22:00

US3052005

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 15:00:53

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 08:13:12
User signature succeeded.	Judith Borger (b) (4)	15 Mar 2021 14:45:16
User entered 'once (ONCE)'	(b) (4) Avia McClain-Stocker (b) (4)	12 Oct 2020 12:22:00

US3052005

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 15:00:53

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 08:13:12
User signature succeeded.	Judith Borger (b) (4)	15 Mar 2021 14:45:16
User entered empty.	(b) (4) Avia McClain-Stocker (b) (4)	12 Oct 2020 12:22:00

US3052005

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 15:00:53

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 08:13:12
User signature succeeded.	Judith Borger (b) (4)	15 Mar 2021 14:45:16
User entered 'Intramuscular (INTRAMUSCULAR)'	(b) (4) Avia McClain-Stocker (b) (4)	12 Oct 2020 12:22:00

US3052005

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 15:00:53

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 08:13:12
User signature succeeded.	Judith Borger (b) (4)	15 Mar 2021 14:45:16
User entered empty.	(b) (4) Avia McClain-Stocker (b) (4)	12 Oct 2020 12:22:00

US3052005

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 15:00:53

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 08:13:12
User signature succeeded.	Judith Borger (b) (4)	15 Mar 2021 14:45:16
User entered '25 Sep 2020'	(b) (4) Avia McClain-Stocker (b) (4)	12 Oct 2020 12:22:00

US3052005

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 15:00:53

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 08:13:12
User signature succeeded.	Judith Borger (b) (4)	15 Mar 2021 14:45:16
User entered '0'	(b) (4) Avia McClain-Stocker (b) (4)	12 Oct 2020 12:22:00

US3052005

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 15:00:53

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 08:13:12
User signature succeeded.	Judith Borger (b) (4)	15 Mar 2021 14:45:16
User entered 'No (N)'	(b) (4) Avia McClain-Stocker (b) (4)	12 Oct 2020 12:22:00

US3052005

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 15:00:53

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 08:13:12
User signature succeeded.	Judith Borger (b) (4)	15 Mar 2021 14:45:16
User entered '25 Sep 2020'	(b) (4) Avia McClain-Stocker (b) (4)	12 Oct 2020 12:22:00

US3052005

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 15:00:53

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 08:13:12
User signature succeeded.	Judith Borger (b) (4)	15 Mar 2021 14:45:16
User entered 'No (N)'	(b) (4) Avia McClain-Stocker (b) (4)	12 Oct 2020 12:22:00

US3052005

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 15:00:53

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 08:13:12
User entered empty.	System	12 Oct 2020 12:22:00

US3052005

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 15:00:53

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 08:13:12
User entered empty.	System	12 Oct 2020 12:22:00

US3052005

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 15:00:53

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 08:13:12
User entered empty.	System	12 Oct 2020 12:22:00

US3052005

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 15:00:53

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:55:20
User signature succeeded.	Yaa Oppong (b) (4)	26 Apr 2021 20:34:31
User coded data point as ATC: NERVOUS SYSTEM, ATC: ANALGESICS, ATC: OPIOIDS, ATC: NATURAL OPIUM ALKALOIDS, PRODUCT: OXYCODONE - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4) (b) (4)	24 Apr 2021 13:44:10
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	24 Apr 2021 13:44:10
Data point term sent to Coder	System	23 Apr 2021 18:13:45
User entered 'oxycodone'	(b) (4), (b) (6)	23 Apr 2021 18:12:46

US3052005

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 15:00:53

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:55:20
User signature succeeded.	Yaa Oppong (b) (4)	26 Apr 2021 20:34:31
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	23 Apr 2021 18:12:46

US3052005

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 15:00:53

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:55:20
User signature succeeded.	Yaa Oppong (b) (4)	26 Apr 2021 20:34:31
User entered 'right hip resurfacing surgery'	(b) (4) (b) (4), (b) (6)	23 Apr 2021 18:12:46

US3052005

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 15:00:53

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:55:20
User signature succeeded.	Yaa Oppong (b) (4)	26 Apr 2021 20:34:31
User entered '5-325'	(b) (4), (b) (6)	23 Apr 2021 18:12:46

US3052005

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 15:00:53

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:55:20
User signature succeeded.	Yaa Oppong (b) (4)	26 Apr 2021 20:34:31
User entered 'mg (mg)'	(b) (4) (b) (4), (b) (6)	23 Apr 2021 18:12:46

US3052005

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 15:00:53

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:55:20
User signature succeeded.	Yaa Oppong (b) (4)	26 Apr 2021 20:34:31
User entered empty.	(b) (4) (b) (4), (b) (6)	23 Apr 2021 18:12:46

US3052005

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 15:00:53

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:55:20
User signature succeeded.	Yaa Oppong (b) (4)	26 Apr 2021 20:34:31
User closed query 'Frequency is reported as Once, however the Medication Start and Stop dates are not equal. Please update or clarify.' (Site from System).	(b) (4)	
Query 'Frequency is reported as Once, however the Medication Start and Stop dates are not equal. Please update or clarify.' answered by data change (Site from System).	System	23 Apr 2021 18:12:58
User entered 'once daily (QD)' reason for change: Data Entry Error	System	23 Apr 2021 18:12:58
User opened query 'Frequency is reported as Once, however the Medication Start and Stop dates are not equal. Please update or clarify.' (Site from System).		
User entered 'once (ONCE)'	(b) (4), (b) (6)	23 Apr 2021 18:12:46

US3052005

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 15:00:53

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:55:20
User signature succeeded.	Yaa Oppong (b) (4)	26 Apr 2021 20:34:31
User entered empty.	(b) (4) (b) (4), (b) (6)	23 Apr 2021 18:12:46

US3052005

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 15:00:53

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:55:20
User signature succeeded.	Yaa Oppong (b) (4)	26 Apr 2021 20:34:31
User entered 'Oral (ORAL)'	(b) (4) (b) (4), (b) (6)	23 Apr 2021 18:12:46

US3052005

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 15:00:53

[If route of administration is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:55:20
User signature succeeded.	Yaa Oppong (b) (4)	26 Apr 2021 20:34:31
User entered empty.	(b) (4), (b) (6)	23 Apr 2021 18:12:46

US3052005

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 15:00:53

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:55:20
User signature succeeded.	Yaa Oppong (b) (4)	26 Apr 2021 20:34:31
User entered '25 Feb 2021'	(b) (4) (b) (4), (b) (6)	23 Apr 2021 18:12:46

US3052005

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 15:00:53

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:55:20
User signature succeeded.	Yaa Oppong (b) (4)	26 Apr 2021 20:34:31
User entered '0'	(b) (4), (b) (6)	23 Apr 2021 18:12:46

US3052005

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 15:00:53

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:55:20
User signature succeeded.	Yaa Oppong (b) (4)	26 Apr 2021 20:34:31
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	23 Apr 2021 18:12:46

US3052005

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 15:00:53

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:55:20
User signature succeeded.	Yaa Oppong (b) (4)	26 Apr 2021 20:34:31
User entered '26 Feb 2021'	(b) (4) (b) (4), (b) (6)	23 Apr 2021 18:12:46

US3052005

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 15:00:53

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:55:20
User signature succeeded.	Yaa Oppong (b) (4)	26 Apr 2021 20:34:31
User entered 'Yes (Y)'	(b) (4), (b) (6)	23 Apr 2021 18:12:46

US3052005

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 15:00:53

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:55:20
User entered '1'	System	23 Apr 2021 18:12:58
User entered empty.	System	23 Apr 2021 18:12:46

US3052005

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 15:00:53

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:55:20
User entered '1'	System	23 Apr 2021 18:12:58
User entered empty.	System	23 Apr 2021 18:12:46

US3052005

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 15:00:53

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:55:20
User entered '804 (804)'	System	23 Apr 2021 18:12:58
User entered empty.	System	23 Apr 2021 18:12:46

US3052005

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 15:00:53

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Yaa Oppong (b) (4)	26 Apr 2021 20:34:31
User coded data point as ATC: NERVOUS SYSTEM, ATC: ANALGESICS, ATC: OTHER ANALGESICS AND ANTIPYRETICS, ATC: ANILIDES, PRODUCT: PARACETAMOL, PRODUCTSYNONYM: TYLENOL - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4)	23 Apr 2021 18:16:07
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	23 Apr 2021 18:16:07
Data point term sent to Coder	System	23 Apr 2021 18:14:45
User entered 'tylenol'	(b) (4), (b) (6)	23 Apr 2021 18:14:34

US3052005

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 15:00:53

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Yaa Oppong (b) (4)	26 Apr 2021 20:34:31
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	23 Apr 2021 18:14:34

US3052005

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 15:00:53

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Yaa Oppong (b) (4)	26 Apr 2021 20:34:31
User entered 'right hip resurfacing surgery'	(b) (4) (b) (4), (b) (6)	23 Apr 2021 18:14:34

US3052005

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 15:00:53

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Yaa Oppong (b) (4)	26 Apr 2021 20:34:31
User entered '1,000'	(b) (4) (b) (4), (b) (6)	23 Apr 2021 18:14:34

US3052005

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 15:00:53

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Yaa Oppong (b) (4)	26 Apr 2021 20:34:31
User entered 'mg (mg)'	(b) (4) (b) (4), (b) (6)	23 Apr 2021 18:14:34

US3052005

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 15:00:53

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Yaa Oppong (b) (4)	26 Apr 2021 20:34:31
User entered empty.	(b) (4) (b) (4), (b) (6)	23 Apr 2021 18:14:34

US3052005

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 15:00:53

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Yaa Oppong (b) (4)	26 Apr 2021 20:34:31
User entered 'three times daily (TID)'	(b) (4) (b) (4), (b) (6)	23 Apr 2021 18:14:34

US3052005

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 15:00:53

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Yaa Oppong (b) (4)	26 Apr 2021 20:34:31
User entered empty.	(b) (4) (b) (4), (b) (6)	23 Apr 2021 18:14:34

US3052005

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 15:00:53

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Yaa Oppong (b) (4)	26 Apr 2021 20:34:31
User entered 'Oral (ORAL)'	(b) (4) (b) (4), (b) (6)	23 Apr 2021 18:14:34

US3052005

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 15:00:53

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Yaa Oppong (b) (4)	26 Apr 2021 20:34:31
User entered empty.	(b) (4) (b) (4), (b) (6)	23 Apr 2021 18:14:34

US3052005

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 15:00:53

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Yaa Oppong (b) (4)	26 Apr 2021 20:34:31
User entered '25 Feb 2021'	(b) (4) (b) (4), (b) (6)	23 Apr 2021 18:14:34

US3052005

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 15:00:53

Start date completely unknown

Audit	User	Time (GMT)
User signature succeeded.	Yaa Oppong (b) (4)	26 Apr 2021 20:34:31
User entered '0'	(b) (4) (b) (4), (b) (6)	23 Apr 2021 18:14:34

US3052005

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 15:00:53

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Yaa Oppong (b) (4)	26 Apr 2021 20:34:31
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	23 Apr 2021 18:14:34

US3052005

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 15:00:53

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Yaa Oppong (b) (4)	26 Apr 2021 20:34:31
User entered '11 Apr 2021'	(b) (4) (b) (4), (b) (6)	23 Apr 2021 18:14:34

US3052005

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 15:00:53

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Yaa Oppong (b) (4)	26 Apr 2021 20:34:31
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	23 Apr 2021 18:14:34

US3052005

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 15:00:53

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '3'	System	23 Apr 2021 18:14:34

US3052005

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 15:00:53

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	23 Apr 2021 18:14:34

US3052005

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 15:00:53

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	23 Apr 2021 18:14:34

US3052005

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 15:00:53

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Yaa Oppong (b) (4)	26 Apr 2021 20:34:31
User coded data point as ATC: MUSCULO-SKELETAL SYSTEM, ATC: ANTIINFLAMMATORY AND ANTIRHEUMATIC PRODUCTS, ATC: ANTIINFLAMMATORY AND ANTIRHEUMATIC PRODUCTS, NON-STEROIDS, ATC: OXICAMS, PRODUCT: MELOXICAM - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4) (b) (4)	24 Apr 2021 12:27:48
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	24 Apr 2021 12:27:48
Data point term sent to Coder	System	23 Apr 2021 18:15:47
User entered 'meloxicam'	(b) (4), (b) (6)	23 Apr 2021 18:15:07

US3052005

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 15:00:53

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Yaa Oppong (b) (4)	26 Apr 2021 20:34:31
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	23 Apr 2021 18:15:07

US3052005

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 15:00:53

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Yaa Oppong (b) (4)	26 Apr 2021 20:34:31
User entered 'right hip resurfacing surgery'	(b) (4) (b) (4), (b) (6)	23 Apr 2021 18:15:07

US3052005

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 15:00:53

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Yaa Oppong (b) (4)	26 Apr 2021 20:34:31
User entered '7.5'	(b) (4) (b) (4), (b) (6)	23 Apr 2021 18:15:07

US3052005

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 15:00:53

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Yaa Oppong (b) (4)	26 Apr 2021 20:34:31
User entered 'mg (mg)'	(b) (4) (b) (4), (b) (6)	23 Apr 2021 18:15:07

US3052005

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 15:00:53

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Yaa Oppong (b) (4)	26 Apr 2021 20:34:31
User entered empty.	(b) (4) (b) (4), (b) (6)	23 Apr 2021 18:15:07

US3052005

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 15:00:53

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Yaa Oppong (b) (4)	26 Apr 2021 20:34:31
User entered 'once daily (QD)'	(b) (4) (b) (4), (b) (6)	23 Apr 2021 18:15:07

US3052005

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 15:00:53

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Yaa Oppong (b) (4)	26 Apr 2021 20:34:31
User entered empty.	(b) (4) (b) (4), (b) (6)	23 Apr 2021 18:15:07

US3052005

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 15:00:53

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Yaa Oppong (b) (4)	26 Apr 2021 20:34:31
User entered 'Oral (ORAL)'	(b) (4) (b) (4), (b) (6)	23 Apr 2021 18:15:07

US3052005

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 15:00:53

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Yaa Oppong (b) (4)	26 Apr 2021 20:34:31
User entered empty.	(b) (4) (b) (4), (b) (6)	23 Apr 2021 18:15:07

US3052005

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 15:00:53

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Yaa Oppong (b) (4)	26 Apr 2021 20:34:31
User entered '25 Feb 2021'	(b) (4) (b) (4), (b) (6)	23 Apr 2021 18:15:07

US3052005

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 15:00:53

Start date completely unknown

Audit	User	Time (GMT)
User signature succeeded.	Yaa Oppong (b) (4)	26 Apr 2021 20:34:31
User entered '0'	(b) (4) (b) (4), (b) (6)	23 Apr 2021 18:15:07

US3052005

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 15:00:53

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Yaa Oppong (b) (4)	26 Apr 2021 20:34:31
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	23 Apr 2021 18:15:07

US3052005

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 15:00:53

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Yaa Oppong (b) (4)	26 Apr 2021 20:34:31
User entered '11 Apr 2021'	(b) (4) (b) (4), (b) (6)	23 Apr 2021 18:15:07

US3052005

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 15:00:53

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Yaa Oppong (b) (4)	26 Apr 2021 20:34:31
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	23 Apr 2021 18:15:07

US3052005

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 15:00:53

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	23 Apr 2021 18:15:07

US3052005

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 15:00:53

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	23 Apr 2021 18:15:07

US3052005

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 15:00:53

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	23 Apr 2021 18:15:07

US3052005

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures Summary

Generated On: 09 Jun 2021 15:00:53

[Were any concomitant procedures performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 07:10:36
User signature succeeded.	Yaa Oppong (b) (4)	08 Apr 2021 19:45:37
Signature has been broken.	(b) (4), (b) (6)	08 Apr 2021 18:17:59
User entered 'Yes (Y)' reason for change: Data Entry Error		08 Apr 2021 18:17:59
User signature succeeded.	Judith Borger (b) (4)	23 Feb 2021 07:32:26
User entered 'No (N)'	(b) (4) amy sheets (b) (4) (b) (4)	18 Aug 2020 15:38:48

US3052005

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (1)

Generated On: 09 Jun 2021 15:00:53

Procedure/Surgery date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Yaa Oppong (b) (4)	08 Apr 2021 19:45:37
User entered '24 Feb 2021'	(b) (4) (b) (4), (b) (6)	08 Apr 2021 18:18:48

US3052005

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (1)

Generated On: 09 Jun 2021 15:00:53

[Procedure/Surgery](#)

Audit	User	Time (GMT)
User signature succeeded.	Yaa Oppong (b) (4)	08 Apr 2021 19:45:37
User entered 'RIGHT HIP RESURFACING SURGERY'	(b) (4) (b) (4), (b) (6)	08 Apr 2021 18:18:48

US3052005

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (1)

Generated On: 09 Jun 2021 15:00:53

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Yaa Oppong (b) (4)	08 Apr 2021 19:45:37
User entered 'Medical History (MH)'	(b) (4) (b) (4), (b) (6)	08 Apr 2021 18:18:48

US3052005

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (1)

Generated On: 09 Jun 2021 15:00:53

If indication is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Yaa Oppong (b) (4)	08 Apr 2021 19:45:37
User entered empty.	(b) (4) (b) (4), (b) (6)	08 Apr 2021 18:18:48

US3052005

Folder: SAE USA-US117-2021-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 09 Jun 2021 15:00:53

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Yaa Oppong (b) (4)	09 Apr 2021 18:54:14
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	08 Apr 2021 23:31:12
User entered 'USA-US117-2021-MRNA-1273-P301000007'	System	08 Apr 2021 23:30:38

US3052005

Folder: SAE USA-US117-2021-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 09 Jun 2021 15:00:53

Serious

Audit	User	Time (GMT)
User signature succeeded.	Yaa Oppong (b) (4)	09 Apr 2021 18:54:14
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	08 Apr 2021 23:31:12
User entered 'Yes (Y)'	System	08 Apr 2021 23:30:38

US3052005

Folder: SAE USA-US117-2021-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 09 Jun 2021 15:00:53

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Yaa Oppong (b) (4)	09 Apr 2021 18:54:14
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	08 Apr 2021 23:31:12
User entered 'No (N)'	System	08 Apr 2021 23:30:38

US3052005

Folder: SAE USA-US117-2021-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 09 Jun 2021 15:00:53

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Yaa Oppong (b) (4)	09 Apr 2021 18:54:14
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	08 Apr 2021 23:31:12
User entered 'No (N)'	System	08 Apr 2021 23:30:38

US3052005

Folder: SAE USA-US117-2021-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 09 Jun 2021 15:00:53

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Yaa Oppong (b) (4)	09 Apr 2021 18:54:14
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	08 Apr 2021 23:31:12
User entered 'Yes (Y)'	System	08 Apr 2021 23:30:38

US3052005

Folder: SAE USA-US117-2021-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 09 Jun 2021 15:00:53

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Yaa Oppong (b) (4)	09 Apr 2021 18:54:14
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	08 Apr 2021 23:31:12
User entered 'No (N)'	System	08 Apr 2021 23:30:38

US3052005

Folder: SAE USA-US117-2021-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 09 Jun 2021 15:00:53

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Yaa Oppong (b) (4)	09 Apr 2021 18:54:14
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	08 Apr 2021 23:31:12
User entered 'No (N)'	System	08 Apr 2021 23:30:38

US3052005

Folder: SAE USA-US117-2021-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 09 Jun 2021 15:00:53

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Yaa Oppong (b) (4)	09 Apr 2021 18:54:14
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	08 Apr 2021 23:31:12
User entered 'No (N)'	System	08 Apr 2021 23:30:38

US3052005

Folder: SAE USA-US117-2021-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 09 Jun 2021 15:00:53

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Yaa Oppong (b) (4)	09 Apr 2021 18:54:14
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	08 Apr 2021 23:31:12
User entered 'Yaa'	System	08 Apr 2021 23:30:38

US3052005

Folder: SAE USA-US117-2021-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 09 Jun 2021 15:00:53

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Yaa Oppong (b) (4)	09 Apr 2021 18:54:14
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	08 Apr 2021 23:31:12
User entered 'Oppong'	System	08 Apr 2021 23:30:38

US3052005

Folder: SAE USA-US117-2021-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 09 Jun 2021 15:00:53

[Site Address: Street](#)

Audit	User	Time (GMT)
User signature succeeded.	Yaa Oppong (b) (4)	09 Apr 2021 18:54:14
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	08 Apr 2021 23:31:12
User entered '1565 Purdue Drive'	System	08 Apr 2021 23:30:38

US3052005

Folder: SAE USA-US117-2021-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 09 Jun 2021 15:00:53

[Site Address: City](#)

Audit	User	Time (GMT)
User signature succeeded.	Yaa Oppong (b) (4)	09 Apr 2021 18:54:14
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	08 Apr 2021 23:31:12
User entered 'Fayetteville'	System	08 Apr 2021 23:30:38

US3052005

Folder: SAE USA-US117-2021-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 09 Jun 2021 15:00:53

[Site Address: State](#)

Audit	User	Time (GMT)
User signature succeeded.	Yaa Oppong (b) (4)	09 Apr 2021 18:54:14
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	08 Apr 2021 23:31:12
User entered 'NC'	System	08 Apr 2021 23:30:38

US3052005

Folder: SAE USA-US117-2021-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 09 Jun 2021 15:00:53

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
User signature succeeded.	Yaa Oppong (b) (4)	09 Apr 2021 18:54:14
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	08 Apr 2021 23:31:12
User entered '28314'	System	08 Apr 2021 23:30:38

US3052005

Folder: SAE USA-US117-2021-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 09 Jun 2021 15:00:53

[Investigator Country](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	15 Apr 2021 14:03:11
User signature succeeded.	Yaa Oppong (b) (4)	09 Apr 2021 18:54:14
User entered 'US'	(b) (4) System	08 Apr 2021 23:31:18

US3052005

Folder: SAE USA-US117-2021-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 09 Jun 2021 15:00:53

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '4'	System	26 Apr 2021 16:25:40
User entered '3'	System	15 Apr 2021 21:11:24
User entered '2'	System	15 Apr 2021 14:03:23
User entered '1'	System	08 Apr 2021 23:31:18

US3052005

Folder: SAE USA-US117-2021-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 09 Jun 2021 15:00:53

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Yaa Oppong (b) (4)	09 Apr 2021 18:54:14
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	08 Apr 2021 23:31:12
User entered 'USA-US117-2021-MRNA-1273-P301000007'	System	08 Apr 2021 23:30:38

US3052005

Folder: SAE USA-US117-2021-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 09 Jun 2021 15:00:53

Serious

Audit	User	Time (GMT)
User signature succeeded.	Yaa Oppong (b) (4)	09 Apr 2021 18:54:14
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	08 Apr 2021 23:31:12
User entered 'Yes (Y)'	System	08 Apr 2021 23:30:38

US3052005

Folder: SAE USA-US117-2021-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 09 Jun 2021 15:00:53

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Yaa Oppong (b) (4)	09 Apr 2021 18:54:14
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	08 Apr 2021 23:31:12
User entered 'No (N)'	System	08 Apr 2021 23:30:38

US3052005

Folder: SAE USA-US117-2021-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 09 Jun 2021 15:00:53

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Yaa Oppong (b) (4)	09 Apr 2021 18:54:14
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	08 Apr 2021 23:31:12
User entered 'No (N)'	System	08 Apr 2021 23:30:38

US3052005

Folder: SAE USA-US117-2021-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 09 Jun 2021 15:00:53

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Yaa Oppong (b) (4)	09 Apr 2021 18:54:14
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	08 Apr 2021 23:31:12
User entered 'Yes (Y)'	System	08 Apr 2021 23:30:38

US3052005

Folder: SAE USA-US117-2021-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 09 Jun 2021 15:00:53

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Yaa Oppong (b) (4)	09 Apr 2021 18:54:14
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	08 Apr 2021 23:31:12
User entered 'No (N)'	System	08 Apr 2021 23:30:38

US3052005

Folder: SAE USA-US117-2021-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 09 Jun 2021 15:00:53

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Yaa Oppong (b) (4)	09 Apr 2021 18:54:14
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	08 Apr 2021 23:31:12
User entered 'No (N)'	System	08 Apr 2021 23:30:38

US3052005

Folder: SAE USA-US117-2021-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 09 Jun 2021 15:00:53

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Yaa Oppong (b) (4)	09 Apr 2021 18:54:14
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	08 Apr 2021 23:31:12
User entered 'No (N)'	System	08 Apr 2021 23:30:38

US3052005

Folder: SAE USA-US117-2021-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 09 Jun 2021 15:00:53

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Yaa Oppong (b) (4)	09 Apr 2021 18:54:14
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	08 Apr 2021 23:31:12
User entered 'Yaa'	System	08 Apr 2021 23:30:38

US3052005

Folder: SAE USA-US117-2021-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 09 Jun 2021 15:00:53

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Yaa Oppong (b) (4)	09 Apr 2021 18:54:14
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	08 Apr 2021 23:31:12
User entered 'Oppong'	System	08 Apr 2021 23:30:38

US3052005

Folder: SAE USA-US117-2021-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 09 Jun 2021 15:00:53

[Site Address: Street](#)

Audit	User	Time (GMT)
User signature succeeded.	Yaa Oppong (b) (4)	09 Apr 2021 18:54:14
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	08 Apr 2021 23:31:12
User entered '1565 Purdue Drive'	System	08 Apr 2021 23:30:38

US3052005

Folder: SAE USA-US117-2021-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 09 Jun 2021 15:00:53

[Site Address: City](#)

Audit	User	Time (GMT)
User signature succeeded.	Yaa Oppong (b) (4)	09 Apr 2021 18:54:14
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	08 Apr 2021 23:31:12
User entered 'Fayetteville'	System	08 Apr 2021 23:30:38

US3052005

Folder: SAE USA-US117-2021-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 09 Jun 2021 15:00:53

[Site Address: State](#)

Audit	User	Time (GMT)
User signature succeeded.	Yaa Oppong (b) (4)	09 Apr 2021 18:54:14
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	08 Apr 2021 23:31:12
User entered 'NC'	System	08 Apr 2021 23:30:38

US3052005

Folder: SAE USA-US117-2021-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 09 Jun 2021 15:00:53

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
User signature succeeded.	Yaa Oppong (b) (4)	09 Apr 2021 18:54:14
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	08 Apr 2021 23:31:12
User entered '28314'	System	08 Apr 2021 23:30:38

US3052005

Folder: SAE USA-US117-2021-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 09 Jun 2021 15:00:53

[Investigator Country](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	15 Apr 2021 14:03:11
User signature succeeded.	Yaa Oppong (b) (4)	09 Apr 2021 18:54:14
User entered 'US'	(b) (4) System	08 Apr 2021 23:31:18

US3052005

Folder: SAE USA-US117-2021-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 09 Jun 2021 15:00:53

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '4'	System	26 Apr 2021 16:25:40
User entered '3'	System	15 Apr 2021 21:11:24
User entered '2'	System	15 Apr 2021 14:03:23
User entered '1'	System	08 Apr 2021 23:31:18

US3052005

Folder: SAE USA-US117-2021-MRNA-1273-P301000007

Form: Safety Report Form (1)

Generated On: 09 Jun 2021 15:00:53

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Yaa Oppong (b) (4)	09 Apr 2021 18:54:14
User entered '08/Apr/2021 19:31'	(b) (4) System	08 Apr 2021 23:31:18

US3052005

Folder: SAE USA-US117-2021-MRNA-1273-P301000007

Form: Safety Report Form (1)

Generated On: 09 Jun 2021 15:00:53

Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	15 Apr 2021 14:03:11
User signature succeeded.	Yaa Oppong (b) (4)	09 Apr 2021 18:54:14
User entered 'I'	(b) (4), (b) (6)	08 Apr 2021 23:31:18

US3052005

Folder: SAE USA-US117-2021-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 09 Jun 2021 15:00:53

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Yaa Oppong (b) (4)	09 Apr 2021 18:54:14
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	08 Apr 2021 23:31:12
User entered 'USA-US117-2021-MRNA-1273-P301000007'	System	08 Apr 2021 23:30:38

US3052005

Folder: SAE USA-US117-2021-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 09 Jun 2021 15:00:53

Serious

Audit	User	Time (GMT)
User signature succeeded.	Yaa Oppong (b) (4)	09 Apr 2021 18:54:14
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	08 Apr 2021 23:31:12
User entered 'Yes (Y)'	System	08 Apr 2021 23:30:38

US3052005

Folder: SAE USA-US117-2021-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 09 Jun 2021 15:00:53

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Yaa Oppong (b) (4)	09 Apr 2021 18:54:14
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	08 Apr 2021 23:31:12
User entered 'No (N)'	System	08 Apr 2021 23:30:38

US3052005

Folder: SAE USA-US117-2021-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 09 Jun 2021 15:00:53

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Yaa Oppong (b) (4)	09 Apr 2021 18:54:14
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	08 Apr 2021 23:31:12
User entered 'No (N)'	System	08 Apr 2021 23:30:38

US3052005

Folder: SAE USA-US117-2021-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 09 Jun 2021 15:00:53

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Yaa Oppong (b) (4)	09 Apr 2021 18:54:14
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	08 Apr 2021 23:31:12
User entered 'Yes (Y)'	System	08 Apr 2021 23:30:38

US3052005

Folder: SAE USA-US117-2021-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 09 Jun 2021 15:00:53

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Yaa Oppong (b) (4)	09 Apr 2021 18:54:14
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	08 Apr 2021 23:31:12
User entered 'No (N)'	System	08 Apr 2021 23:30:38

US3052005

Folder: SAE USA-US117-2021-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 09 Jun 2021 15:00:53

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Yaa Oppong (b) (4)	09 Apr 2021 18:54:14
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	08 Apr 2021 23:31:12
User entered 'No (N)'	System	08 Apr 2021 23:30:38

US3052005

Folder: SAE USA-US117-2021-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 09 Jun 2021 15:00:53

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Yaa Oppong (b) (4)	09 Apr 2021 18:54:14
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	08 Apr 2021 23:31:12
User entered 'No (N)'	System	08 Apr 2021 23:30:38

US3052005

Folder: SAE USA-US117-2021-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 09 Jun 2021 15:00:53

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Yaa Oppong (b) (4)	09 Apr 2021 18:54:14
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	08 Apr 2021 23:31:12
User entered 'Yaa'	System	08 Apr 2021 23:30:38

US3052005

Folder: SAE USA-US117-2021-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 09 Jun 2021 15:00:53

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Yaa Oppong (b) (4)	09 Apr 2021 18:54:14
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	08 Apr 2021 23:31:12
User entered 'Oppong'	System	08 Apr 2021 23:30:38

US3052005

Folder: SAE USA-US117-2021-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 09 Jun 2021 15:00:53

[Site Address: Street](#)

Audit	User	Time (GMT)
User signature succeeded.	Yaa Oppong (b) (4)	09 Apr 2021 18:54:14
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	08 Apr 2021 23:31:12
User entered '1565 Purdue Drive'	System	08 Apr 2021 23:30:38

US3052005

Folder: SAE USA-US117-2021-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 09 Jun 2021 15:00:53

[Site Address: City](#)

Audit	User	Time (GMT)
User signature succeeded.	Yaa Oppong (b) (4)	09 Apr 2021 18:54:14
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	08 Apr 2021 23:31:12
User entered 'Fayetteville'	System	08 Apr 2021 23:30:38

US3052005

Folder: SAE USA-US117-2021-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 09 Jun 2021 15:00:53

[Site Address: State](#)

Audit	User	Time (GMT)
User signature succeeded.	Yaa Oppong (b) (4)	09 Apr 2021 18:54:14
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	08 Apr 2021 23:31:12
User entered 'NC'	System	08 Apr 2021 23:30:38

US3052005

Folder: SAE USA-US117-2021-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 09 Jun 2021 15:00:53

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
User signature succeeded.	Yaa Oppong (b) (4)	09 Apr 2021 18:54:14
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	08 Apr 2021 23:31:12
User entered '28314'	System	08 Apr 2021 23:30:38

US3052005

Folder: SAE USA-US117-2021-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 09 Jun 2021 15:00:53

[Investigator Country](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	15 Apr 2021 14:03:11
User signature succeeded.	Yaa Oppong (b) (4)	09 Apr 2021 18:54:14
User entered 'US'	(b) (4) System	08 Apr 2021 23:31:18

US3052005

Folder: SAE USA-US117-2021-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 09 Jun 2021 15:00:53

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '4'	System	26 Apr 2021 16:25:40
User entered '3'	System	15 Apr 2021 21:11:24
User entered '2'	System	15 Apr 2021 14:03:23
User entered '1'	System	08 Apr 2021 23:31:18

US3052005

Folder: SAE USA-US117-2021-MRNA-1273-P301000007

Form: Safety Report Form (2)

Generated On: 09 Jun 2021 15:00:53

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Yaa Oppong (b) (4)	15 Apr 2021 16:21:47
User entered '15/Apr/2021 09:03'	(b) (4) System	15 Apr 2021 14:03:23

US3052005

Folder: SAE USA-US117-2021-MRNA-1273-P301000007

Form: Safety Report Form (2)

Generated On: 09 Jun 2021 15:00:53

Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.

Audit	User	Time (GMT)
User signature succeeded.	Yaa Oppong (b) (4)	15 Apr 2021 16:21:47
User entered 'I'	(b) (4) (b) (4), (b) (6)	15 Apr 2021 14:03:23

US3052005

Folder: SAE USA-US117-2021-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 09 Jun 2021 15:00:53

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Yaa Oppong (b) (4)	09 Apr 2021 18:54:14
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	08 Apr 2021 23:31:12
User entered 'USA-US117-2021-MRNA-1273-P301000007'	System	08 Apr 2021 23:30:38

US3052005

Folder: SAE USA-US117-2021-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 09 Jun 2021 15:00:53

Serious

Audit	User	Time (GMT)
User signature succeeded.	Yaa Oppong (b) (4)	09 Apr 2021 18:54:14
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	08 Apr 2021 23:31:12
User entered 'Yes (Y)'	System	08 Apr 2021 23:30:38

US3052005

Folder: SAE USA-US117-2021-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 09 Jun 2021 15:00:53

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Yaa Oppong (b) (4)	09 Apr 2021 18:54:14
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	08 Apr 2021 23:31:12
User entered 'No (N)'	System	08 Apr 2021 23:30:38

US3052005

Folder: SAE USA-US117-2021-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 09 Jun 2021 15:00:53

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Yaa Oppong (b) (4)	09 Apr 2021 18:54:14
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	08 Apr 2021 23:31:12
User entered 'No (N)'	System	08 Apr 2021 23:30:38

US3052005

Folder: SAE USA-US117-2021-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 09 Jun 2021 15:00:53

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Yaa Oppong (b) (4)	09 Apr 2021 18:54:14
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	08 Apr 2021 23:31:12
User entered 'Yes (Y)'	System	08 Apr 2021 23:30:38

US3052005

Folder: SAE USA-US117-2021-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 09 Jun 2021 15:00:53

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Yaa Oppong (b) (4)	09 Apr 2021 18:54:14
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	08 Apr 2021 23:31:12
User entered 'No (N)'	System	08 Apr 2021 23:30:38

US3052005

Folder: SAE USA-US117-2021-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 09 Jun 2021 15:00:53

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Yaa Oppong (b) (4)	09 Apr 2021 18:54:14
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	08 Apr 2021 23:31:12
User entered 'No (N)'	System	08 Apr 2021 23:30:38

US3052005

Folder: SAE USA-US117-2021-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 09 Jun 2021 15:00:53

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Yaa Oppong (b) (4)	09 Apr 2021 18:54:14
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	08 Apr 2021 23:31:12
User entered 'No (N)'	System	08 Apr 2021 23:30:38

US3052005

Folder: SAE USA-US117-2021-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 09 Jun 2021 15:00:53

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Yaa Oppong (b) (4)	09 Apr 2021 18:54:14
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	08 Apr 2021 23:31:12
User entered 'Yaa'	System	08 Apr 2021 23:30:38

US3052005

Folder: SAE USA-US117-2021-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 09 Jun 2021 15:00:53

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Yaa Oppong (b) (4)	09 Apr 2021 18:54:14
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	08 Apr 2021 23:31:12
User entered 'Oppong'	System	08 Apr 2021 23:30:38

US3052005

Folder: SAE USA-US117-2021-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 09 Jun 2021 15:00:53

[Site Address: Street](#)

Audit	User	Time (GMT)
User signature succeeded.	Yaa Oppong (b) (4)	09 Apr 2021 18:54:14
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	08 Apr 2021 23:31:12
User entered '1565 Purdue Drive'	System	08 Apr 2021 23:30:38

US3052005

Folder: SAE USA-US117-2021-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 09 Jun 2021 15:00:53

[Site Address: City](#)

Audit	User	Time (GMT)
User signature succeeded.	Yaa Oppong (b) (4)	09 Apr 2021 18:54:14
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	08 Apr 2021 23:31:12
User entered 'Fayetteville'	System	08 Apr 2021 23:30:38

US3052005

Folder: SAE USA-US117-2021-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 09 Jun 2021 15:00:53

[Site Address: State](#)

Audit	User	Time (GMT)
User signature succeeded.	Yaa Oppong (b) (4)	09 Apr 2021 18:54:14
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	08 Apr 2021 23:31:12
User entered 'NC'	System	08 Apr 2021 23:30:38

US3052005

Folder: SAE USA-US117-2021-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 09 Jun 2021 15:00:53

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
User signature succeeded.	Yaa Oppong (b) (4)	09 Apr 2021 18:54:14
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	08 Apr 2021 23:31:12
User entered '28314'	System	08 Apr 2021 23:30:38

US3052005

Folder: SAE USA-US117-2021-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 09 Jun 2021 15:00:53

[Investigator Country](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	15 Apr 2021 14:03:11
User signature succeeded.	Yaa Oppong (b) (4)	09 Apr 2021 18:54:14
User entered 'US'	(b) (4) System	08 Apr 2021 23:31:18

US3052005

Folder: SAE USA-US117-2021-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 09 Jun 2021 15:00:53

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '4'	System	26 Apr 2021 16:25:40
User entered '3'	System	15 Apr 2021 21:11:24
User entered '2'	System	15 Apr 2021 14:03:23
User entered '1'	System	08 Apr 2021 23:31:18

US3052005

Folder: SAE USA-US117-2021-MRNA-1273-P301000007

Form: Safety Report Form (3)

Generated On: 09 Jun 2021 15:00:53

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Yaa Oppong (b) (4)	16 Apr 2021 15:23:47
User entered '15/Apr/2021 14:11'	(b) (4) System	15 Apr 2021 21:11:24

US3052005

Folder: SAE USA-US117-2021-MRNA-1273-P301000007

Form: Safety Report Form (3)

Generated On: 09 Jun 2021 15:00:53

Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.

Audit	User	Time (GMT)
User signature succeeded.	Yaa Oppong (b) (4)	16 Apr 2021 15:23:47
User entered 'I'	(b) (4) (b) (4), (b) (6)	15 Apr 2021 21:11:24

US3052005

Folder: SAE USA-US117-2021-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 09 Jun 2021 15:00:53

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Yaa Oppong (b) (4)	09 Apr 2021 18:54:14
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	08 Apr 2021 23:31:12
User entered 'USA-US117-2021-MRNA-1273-P301000007'	System	08 Apr 2021 23:30:38

US3052005

Folder: SAE USA-US117-2021-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 09 Jun 2021 15:00:53

Serious

Audit	User	Time (GMT)
User signature succeeded.	Yaa Oppong (b) (4)	09 Apr 2021 18:54:14
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	08 Apr 2021 23:31:12
User entered 'Yes (Y)'	System	08 Apr 2021 23:30:38

US3052005

Folder: SAE USA-US117-2021-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 09 Jun 2021 15:00:53

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Yaa Oppong (b) (4)	09 Apr 2021 18:54:14
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	08 Apr 2021 23:31:12
User entered 'No (N)'	System	08 Apr 2021 23:30:38

US3052005

Folder: SAE USA-US117-2021-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 09 Jun 2021 15:00:53

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Yaa Oppong (b) (4)	09 Apr 2021 18:54:14
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	08 Apr 2021 23:31:12
User entered 'No (N)'	System	08 Apr 2021 23:30:38

US3052005

Folder: SAE USA-US117-2021-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 09 Jun 2021 15:00:53

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Yaa Oppong (b) (4)	09 Apr 2021 18:54:14
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	08 Apr 2021 23:31:12
User entered 'Yes (Y)'	System	08 Apr 2021 23:30:38

US3052005

Folder: SAE USA-US117-2021-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 09 Jun 2021 15:00:53

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Yaa Oppong (b) (4)	09 Apr 2021 18:54:14
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	08 Apr 2021 23:31:12
User entered 'No (N)'	System	08 Apr 2021 23:30:38

US3052005

Folder: SAE USA-US117-2021-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 09 Jun 2021 15:00:53

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Yaa Oppong (b) (4)	09 Apr 2021 18:54:14
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	08 Apr 2021 23:31:12
User entered 'No (N)'	System	08 Apr 2021 23:30:38

US3052005

Folder: SAE USA-US117-2021-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 09 Jun 2021 15:00:53

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Yaa Oppong (b) (4)	09 Apr 2021 18:54:14
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	08 Apr 2021 23:31:12
User entered 'No (N)'	System	08 Apr 2021 23:30:38

US3052005

Folder: SAE USA-US117-2021-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 09 Jun 2021 15:00:53

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Yaa Oppong (b) (4)	09 Apr 2021 18:54:14
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	08 Apr 2021 23:31:12
User entered 'Yaa'	System	08 Apr 2021 23:30:38

US3052005

Folder: SAE USA-US117-2021-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 09 Jun 2021 15:00:53

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Yaa Oppong (b) (4)	09 Apr 2021 18:54:14
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	08 Apr 2021 23:31:12
User entered 'Oppong'	System	08 Apr 2021 23:30:38

US3052005

Folder: SAE USA-US117-2021-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 09 Jun 2021 15:00:53

[Site Address: Street](#)

Audit	User	Time (GMT)
User signature succeeded.	Yaa Oppong (b) (4)	09 Apr 2021 18:54:14
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	08 Apr 2021 23:31:12
User entered '1565 Purdue Drive'	System	08 Apr 2021 23:30:38

US3052005

Folder: SAE USA-US117-2021-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 09 Jun 2021 15:00:53

[Site Address: City](#)

Audit	User	Time (GMT)
User signature succeeded.	Yaa Oppong (b) (4)	09 Apr 2021 18:54:14
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	08 Apr 2021 23:31:12
User entered 'Fayetteville'	System	08 Apr 2021 23:30:38

US3052005

Folder: SAE USA-US117-2021-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 09 Jun 2021 15:00:53

[Site Address: State](#)

Audit	User	Time (GMT)
User signature succeeded.	Yaa Oppong (b) (4)	09 Apr 2021 18:54:14
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	08 Apr 2021 23:31:12
User entered 'NC'	System	08 Apr 2021 23:30:38

US3052005

Folder: SAE USA-US117-2021-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 09 Jun 2021 15:00:53

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
User signature succeeded.	Yaa Oppong (b) (4)	09 Apr 2021 18:54:14
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	08 Apr 2021 23:31:12
User entered '28314'	System	08 Apr 2021 23:30:38

US3052005

Folder: SAE USA-US117-2021-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 09 Jun 2021 15:00:53

[Investigator Country](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	15 Apr 2021 14:03:11
User signature succeeded.	Yaa Oppong (b) (4)	09 Apr 2021 18:54:14
User entered 'US'	(b) (4) System	08 Apr 2021 23:31:18

US3052005

Folder: SAE USA-US117-2021-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 09 Jun 2021 15:00:53

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '4'	System	26 Apr 2021 16:25:40
User entered '3'	System	15 Apr 2021 21:11:24
User entered '2'	System	15 Apr 2021 14:03:23
User entered '1'	System	08 Apr 2021 23:31:18

US3052005

Folder: SAE USA-US117-2021-MRNA-1273-P301000007

Form: Safety Report Form (4)

Generated On: 09 Jun 2021 15:00:53

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Yaa Oppong (b) (4)	26 Apr 2021 20:34:31
User entered '26/Apr/2021 09:25'	(b) (4) System	26 Apr 2021 16:25:40

US3052005

Folder: SAE USA-US117-2021-MRNA-1273-P301000007

Form: Safety Report Form (4)

Generated On: 09 Jun 2021 15:00:53

Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.

Audit	User	Time (GMT)
User signature succeeded.	Yaa Oppong (b) (4)	26 Apr 2021 20:34:31
User entered 'I'	(b) (4) (b) (4), (b) (6)	26 Apr 2021 16:25:40