

US3032242 (Prod: Meridian Clinical Research (Norfolk-Nebraska))

Generated By: KC Joubran

Generated On: 09 Jun 2021 14:52:51

All time stamps listed in this document are displayed in GMT

US3032242

Form: Participant Creation

Data signed: (b) (4) 28 Sep 2020 17:47:47

Generated On: 09 Jun 2021 14:52:51

[Participant ID](#)

US3032242

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

US3032242

Folder: Screening

Form: Visit Date

Data signed: (b) (4) 28 Sep 2020 17:47:48

Generated On: 09 Jun 2021 14:52:51

Was this visit performed? Yes
No

Visit date (dd MMM yyyy) 19 AUG 2020

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

Folder OID SCRN

US3032242

Folder: Screening

Form: Demographics

Data signed: (b) (4) 28 Sep 2020 17:47:48

Generated On: 09 Jun 2021 14:52:51

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

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Folder: Screening

Form: Enrollment

Data signed: (b) (4) 28 Sep 2020 17:47:48

Generated On: 09 Jun 2021 14:52:51

Date of Informed Consent (*dd MMM yyyy*) 19 AUG 2020

Month and Year of Informed Consent (derived) AUG 2020

Year of Informed Consent (derived) 2020

Protocol Version

Amendment 1

Amendment 2

Amendment 3

Amendment 4

Amendment 5

Was participant enrolled in the study? Yes
No

If No, indicate reason for screen fail

Withdrew Consent

Inclusion/Exclusion

Cohort Full

Other

If reason for screen fail is Other, specify _____

Was this participant screened previously? Yes
No

If Yes, previous participant number _____

Enrollment Trigger 1

US3032242

Folder: Screening

Form: Inclusion/Exclusion Criteria Summary

Data signed: (b) (4) 28 Sep 2020 17:47:48

Generated On: 09 Jun 2021 14:52:51

Did the participant meet all eligibility criteria?

Yes

No

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Folder: Screening

Form: Medical History Summary

Data signed: (b) (4) 28 Sep 2020 17:47:48

Generated On: 09 Jun 2021 14:52:51

Were any significant conditions reported?

Yes

No

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Folder: Screening

Form: Medical History (1)

Data signed: (b) (4) 24 Nov 2020 20:29:22

Generated On: 09 Jun 2021 14:52:51

Condition	POSTMENOPAUSAL
Start date (dd MMM yyyy)	UN UNK 1995
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 1995
Start Year (derived)	1995
Stop Month and Year (derived)	_____
Stop Year (derived)	_____

US3032242

Folder: Screening

Form: Medical History (2)

Data signed: (b) (4) 24 Nov 2020 20:29:22

Generated On: 09 Jun 2021 14:52:51

Condition	HYPERTENSION
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)	_____

US3032242

Folder: Screening

Form: Medical History (3)

Data signed: (b) (4) 24 Nov 2020 20:29:22

Generated On: 09 Jun 2021 14:52:51

Condition	ACID REFLUX
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)	_____

US3032242

Folder: Screening

Form: Medical History (4)

Data signed: (b) (4) 24 Nov 2020 20:29:22

Generated On: 09 Jun 2021 14:52:51

Condition	RIGHT KNEE PAIN
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)	_____

US3032242

Folder: Screening

Form: Medical History (5)

Data signed: (b) (4) 24 Nov 2020 20:29:22

Generated On: 09 Jun 2021 14:52:51

Condition	OSTERARTHRTIS RIGHT KNEE
Start date (dd MMM yyyy)	UN UNK 2016
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 2016
Start Year (derived)	2016
Stop Month and Year (derived)	_____
Stop Year (derived)	_____

US3032242

Folder: Screening

Form: Medical History (6)

Data signed: (b) (4) 24 Nov 2020 20:29:22

Generated On: 09 Jun 2021 14:52:51

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

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Folder: Screening

Form: Vital Signs

Data signed: (b) (4) 08 Oct 2020 15:42:03

Generated On: 09 Jun 2021 14:52:51

Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (<i>dd MMM yyyy</i>)	19 AUG 2020
Time of assessment (<i>00:00-23:59</i>)	15:10 (24 HR)
Vital Signs Date and Time (derived)	19 AUG 2020 15:10
Height (<i>xxx.x</i>)	170.1 cm
Weight (<i>xxx.x</i>)	121.1 kg
BMI (<i>xxx.x</i>)	41.85386 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) 28 Sep 2020 17:47:48

Generated On: 09 Jun 2021 14:52:51

Was the physical examination performed?

Yes

No

Date of examination (dd MMM yyyy)

19 AUG 2020

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

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Folder: Screening

Form: Childbearing Potential

Data signed: (b) (4) 28 Sep 2020 17:47:48

Generated On: 09 Jun 2021 14:52:51

Date of assessment (*dd MMM yyyy*) 19 AUG 2020

Is the participant of childbearing potential? Yes
No

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

If Partner medically sterile or Other, specify _____

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

Date of surgery unknown False

If Post-menopausal, date of last menstruation (*dd MMM yyyy*) UN UNK 1995

Date of last menstruation unknown False

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Folder: Screening

Form: Risk of Exposure

Data signed: (b) (4) 28 Sep 2020 17:47:48

Generated On: 09 Jun 2021 14:52:51

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) 28 Sep 2020 17:47:48

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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) 28 Sep 2020 17:47:48

Generated On: 09 Jun 2021 14:52:51

Was this visit performed? Yes
No

Visit date (dd MMM yyyy) 19 AUG 2020

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

Folder OID VISIT1

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Folder: Visit 1 Day 1

Form: Randomization

Data signed: (b) (4) 02 Nov 2020 22:15:50

Generated On: 09 Jun 2021 14:52:51

What was the date of randomization? (dd MMM yyyy) 19 AUG 2020

What was the participant's randomization number? 187111

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

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

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

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

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

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

Liver Disease Yes No

Human Immunodeficiency Virus (HIV) infection Yes No

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Data signed: (b) (4) 14 Oct 2020 19:36:42

Generated On: 09 Jun 2021 14:52:51

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) 14 Oct 2020 19:36:42

Generated On: 09 Jun 2021 14:52:51

Height	ND - Not Done
Weight	ND - Not Done
Timepoint	Pre-Dose <input checked="" type="radio"/> Post-Dose <input type="radio"/>
Were vital signs assessed?	Yes <input checked="" type="radio"/> No <input type="radio"/>
Date of assessment (<i>dd MMM yyyy</i>)	19 AUG 2020
Time of assessment (<i>00:00-23:59</i>)	15:10 (24 HR)
Vital Signs Date and Time (derived)	19 AUG 2020 15:10
Temperature (<i>xxx.x</i>)	36.7 C
Route of measurement	Oral <input checked="" type="radio"/> Axillary <input type="radio"/> Other <input type="radio"/>
If Other, specify	_____
Pulse (<i>xxx</i>)	71 beats/min
Pulse units	BPM
Respiratory Rate (<i>xxx</i>)	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (<i>xxx</i>)	124 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (<i>xxx</i>)	79 mmHg
Diastolic Blood Pressure units	MMHG

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Data signed: (b) (4) 14 Oct 2020 19:36:42

Generated On: 09 Jun 2021 14:52:51

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 (<i>dd MMM yyyy</i>)	19 AUG 2020
Time of assessment (<i>00:00-23:59</i>)	16:47 (24 HR)
Vital Signs Date and Time (derived)	19 AUG 2020 16:47
Temperature (<i>xxx.x</i>)	36.3 C
Route of measurement	Oral <input checked="" type="radio"/> Axillary <input type="radio"/> Other <input type="radio"/>
If Other, specify	_____
Pulse (<i>xxx</i>)	54 beats/min
Pulse units	BPM
Respiratory Rate (<i>xxx</i>)	17 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (<i>xxx</i>)	120 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (<i>xxx</i>)	60 mmHg
Diastolic Blood Pressure units	MMHG

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Folder: Visit 1 Day 1

Form: Physical Examination

Data signed: (b) (4) 28 Sep 2020 17:47:48

Generated On: 09 Jun 2021 14:52:51

Was the physical examination performed?

Yes

No

Date of examination (dd MMM yyyy)

19 AUG 2020

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

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Folder: Visit 1 Day 1

Form: Exposure

Data signed: (b) (4) 28 Sep 2020 17:47:48

Generated On: 09 Jun 2021 14:52:51

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) 19 AUG 2020

What was the treatment time? (00:00-23:59) 16:16 (24 HR)

Treatment Date and Time (derived) 19 AUG 2020 16:16

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) 24 Nov 2020 20:29:22

Generated On: 09 Jun 2021 14:52:51

Was the sample collected?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Collection date (<i>dd MMM yyyy</i>)	19 AUG 2020
Collection time (<i>00:00-23:59</i>)	14:50 (24 HR)
Collection date and time (derived)	19 AUG 2020 14:50

US3032242

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab

Data signed: (b) (4) 24 Nov 2020 20:29:22

Generated On: 09 Jun 2021 14:52:51

Collection date (<i>dd MMM yyyy</i>)			19 AUG 2020
Lab Test	Was the sample collected?	Collection time (<i>00:00 - 23:59</i>)	Collection date and time (derived)
Nasopharyngeal Swab 1	Yes	15:29	19 AUG 2020 15:29
Nasopharyngeal Swab 2	No		

US3032242

Folder: Visit 1 Day 1

Form: Continuing

Data signed: (b) (4) 28 Sep 2020 17:47:48

Generated On: 09 Jun 2021 14:52:51

Is the participant continuing to the next visit?

Yes

No

Continuing Flag

1

US3032242

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 14:52:51

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 97.4 °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 19 AUG 2020 16:51

PC Open Date & Time 19 AUG 2020 16:36

PC Close Date & Time 19 AUG 2020 19:06

US3032242

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 14:52:51

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 95.9 °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 20 AUG 2020 07:23
PC Open Date & Time 19 AUG 2020 20:01
PC Close Date & Time 20 AUG 2020 11:59

US3032242

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 14:52:51

TIMEPOINT

DAY 2

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

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

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

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

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

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

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

Was TEMPERATURE taken?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Please record your TEMPERATURE in °F	98.2 °F
Was any MEDICATION TAKEN today for pain or fever?	Yes <input type="radio"/>
	No <input checked="" type="radio"/>

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

PC Time Stamp	20 AUG 2020 15:54
PC Open Date & Time	20 AUG 2020 12:00
PC Close Date & Time	21 AUG 2020 11:59

US3032242

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 14:52:51

TIMEPOINT

DAY 3

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

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

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

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

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

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

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

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

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

PC Time Stamp	21 AUG 2020 17:36
PC Open Date & Time	21 AUG 2020 12:00
PC Close Date & Time	22 AUG 2020 11:59

US3032242

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 14:52:51

TIMEPOINT

DAY 4

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

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

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

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

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

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

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

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

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

PC Time Stamp	22 AUG 2020 12:08
PC Open Date & Time	22 AUG 2020 12:00
PC Close Date & Time	23 AUG 2020 11:59

US3032242

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 14:52:51

TIMEPOINT

DAY 5

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

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

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

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

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

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

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

Was TEMPERATURE taken?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Please record your TEMPERATURE in °F	97.2 °F
Was any MEDICATION TAKEN today for pain or fever?	Yes <input type="radio"/>
	No <input checked="" type="radio"/>

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

PC Time Stamp	23 AUG 2020 13:25
PC Open Date & Time	23 AUG 2020 12:00
PC Close Date & Time	24 AUG 2020 11:59

US3032242

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 14:52:51

TIMEPOINT

DAY 6

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

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

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

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

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

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

Was TEMPERATURE taken?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Please record your TEMPERATURE in °F	96.5 °F
Was any MEDICATION TAKEN today for pain or fever?	Yes <input type="radio"/>
	No <input checked="" type="radio"/>

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

PC Time Stamp	24 AUG 2020 14:05
PC Open Date & Time	24 AUG 2020 12:00
PC Close Date & Time	25 AUG 2020 11:59

US3032242

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 14:52:51

TIMEPOINT

DAY 7

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

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

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

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

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

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

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

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

PC Time Stamp	25 AUG 2020 12:34
PC Open Date & Time	25 AUG 2020 12:00
PC Close Date & Time	26 AUG 2020 11:59

US3032242

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 14:52:51

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	19 AUG 2020 16:52
PC Open Date & Time	19 AUG 2020 16:36
PC Close Date & Time	19 AUG 2020 19:06

US3032242

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 14:52:51

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

20 AUG 2020 08:42

PC Open Date & Time

19 AUG 2020 20:01

PC Close Date & Time

20 AUG 2020 11:59

US3032242

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 14:52:51

TIMEPOINT

DAY 2

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

Please select one response below

None

Does not interfere with activity

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

Any use of prescription pain
reliever or prevents daily activity

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

Yes

No

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

Yes

No

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

Please select one response below

None

Does not interfere with activity

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

Any use of prescription pain
reliever or prevents daily activity

PC Time Stamp

20 AUG 2020 15:55

PC Open Date & Time

20 AUG 2020 12:00

PC Close Date & Time

21 AUG 2020 11:59

US3032242

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 14:52:51

TIMEPOINT

DAY 3

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

Please select one response below

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

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

- Yes
- No

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

- Yes
- No

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

Please select one response below

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

PC Time Stamp	21 AUG 2020 17:36
PC Open Date & Time	21 AUG 2020 12:00
PC Close Date & Time	22 AUG 2020 11:59

US3032242

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 14:52:51

TIMEPOINT

DAY 4

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

Please select one response below

None

Does not interfere with activity

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

Any use of prescription pain
reliever or prevents daily activity

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

Yes

No

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

Yes

No

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

Please select one response below

None

Does not interfere with activity

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

Any use of prescription pain
reliever or prevents daily activity

PC Time Stamp

22 AUG 2020 12:09

PC Open Date & Time

22 AUG 2020 12:00

PC Close Date & Time

23 AUG 2020 11:59

US3032242

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 14:52:51

TIMEPOINT

DAY 5

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

Please select one response below

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

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

- Yes
- No

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

- Yes
- No

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

Please select one response below

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

PC Time Stamp	23 AUG 2020 13:26
PC Open Date & Time	23 AUG 2020 12:00
PC Close Date & Time	24 AUG 2020 11:59

US3032242

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 14:52:51

TIMEPOINT

DAY 6

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

Please select one response below

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

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

- Yes
- No

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

- Yes
- No

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

Please select one response below

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

PC Time Stamp	24 AUG 2020 14:05
PC Open Date & Time	24 AUG 2020 12:00
PC Close Date & Time	25 AUG 2020 11:59

US3032242

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 14:52:51

TIMEPOINT

DAY 7

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

Please select one response below

None

Does not interfere with activity

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

Any use of prescription pain
reliever or prevents daily activity

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

Yes

No

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

Yes

No

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

Please select one response below

None

Does not interfere with activity

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

Any use of prescription pain
reliever or prevents daily activity

PC Time Stamp

25 AUG 2020 12:35

PC Open Date & Time

25 AUG 2020 12:00

PC Close Date & Time

26 AUG 2020 11:59

US3032242

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 14:52:51

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

US3032242

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 14:52:51

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

No
Yes

PC Time stamp	19 AUG 2020 16:53
PC Open Date & Time	19 AUG 2020 16:36
PC Close Date & Time	19 AUG 2020 19:06

US3032242

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 14:52:51

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

US3032242

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 14:52:51

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

No

Yes

PC Time stamp	20 AUG 2020 08:43
PC Open Date & Time	19 AUG 2020 20:01
PC Close Date & Time	20 AUG 2020 11:59

US3032242

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 14:52:51

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

US3032242

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 14:52:51

	Yes <input type="checkbox"/>
PC Time stamp	20 AUG 2020 15:56
PC Open Date & Time	20 AUG 2020 12:00
PC Close Date & Time	21 AUG 2020 11:59

US3032242

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 14:52:51

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

US3032242

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 14:52:51

	Yes <input type="checkbox"/>
PC Time stamp	21 AUG 2020 17:37
PC Open Date & Time	21 AUG 2020 12:00
PC Close Date & Time	22 AUG 2020 11:59

US3032242

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 14:52:51

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

US3032242

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 14:52:51

	Yes <input type="checkbox"/>
PC Time stamp	22 AUG 2020 12:10
PC Open Date & Time	22 AUG 2020 12:00
PC Close Date & Time	23 AUG 2020 11:59

US3032242

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 14:52:51

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

US3032242

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 14:52:51

	Yes <input type="checkbox"/>
PC Time stamp	23 AUG 2020 13:27
PC Open Date & Time	23 AUG 2020 12:00
PC Close Date & Time	24 AUG 2020 11:59

US3032242

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 14:52:51

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

US3032242

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 14:52:51

	Yes <input type="checkbox"/>
PC Time stamp	24 AUG 2020 14:06
PC Open Date & Time	24 AUG 2020 12:00
PC Close Date & Time	25 AUG 2020 11:59

US3032242

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 14:52:51

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

US3032242

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 14:52:51

	Yes <input type="checkbox"/>
PC Time stamp	25 AUG 2020 12:35
PC Open Date & Time	25 AUG 2020 12:00
PC Close Date & Time	26 AUG 2020 11:59

US3032242

Folder: Safety Call Day 8 (1)

Form: Safety Call

Data signed: (b) (4) 28 Sep 2020 17:47:48

Generated On: 09 Jun 2021 14:52:51

Was Contact Attempted? Yes
No

Date of Contact or Contact Attempt (dd MMM yyyy) 26 AUG 2020

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

Comments

If Contact Not Made, please provide Comments

US3032242

Folder: Safety Call Day 8 (1)

Form: Continuing

Data signed: (b) (4) 28 Sep 2020 17:47:47

Generated On: 09 Jun 2021 14:52:51

Is the participant continuing to the next visit?

Yes

No

Continuing Flag

1

US3032242

Folder: Safety Call Day 15 (1)

Form: Safety Call

Data signed: (b) (4) 28 Sep 2020 17:47:47

Generated On: 09 Jun 2021 14:52:51

Was Contact Attempted? Yes
No

Date of Contact or Contact Attempt (*dd MMM yyyy*) 02 SEP 2020

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

Comments

If Contact Not Made, please provide Comments

US3032242

Folder: Safety Call Day 15 (1)

Form: Continuing

Data signed: (b) (4) 28 Sep 2020 17:47:47

Generated On: 09 Jun 2021 14:52:51

Is the participant continuing to the next visit?

Yes

No

Continuing Flag

1

US3032242

Folder: Safety Call Day 22 (1)

Form: Safety Call

Data signed: (b) (4) 28 Sep 2020 17:47:47

Generated On: 09 Jun 2021 14:52:51

Was Contact Attempted? Yes
No

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

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

Comments

If Contact Not Made, please provide Comments

US3032242

Folder: Safety Call Day 22 (1)

Form: Continuing

Data signed: (b) (4) 28 Sep 2020 17:47:47

Generated On: 09 Jun 2021 14:52:51

Is the participant continuing to the next visit?

Yes

No

Continuing Flag

1

US3032242

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Data signed: (b) (4) 28 Sep 2020 17:47:48

Generated On: 09 Jun 2021 14:52:51

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	18 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	VISIT2

US3032242

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Data signed: (b) (4) 28 Sep 2020 17:47:48

Generated On: 09 Jun 2021 14:52:51

Timepoint	Pre-Dose <input checked="" type="radio"/>
	Post-Dose <input type="radio"/>
Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (<i>dd MMM yyyy</i>)	18 SEP 2020
Time of assessment (<i>00:00-23:59</i>)	08:16 (24 HR)
Vital Signs Date and Time (derived)	18 SEP 2020 08:16
Temperature (<i>xxx.x</i>)	36.4 C
Route of measurement	Oral <input checked="" type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify _____	
Pulse (<i>xxx</i>)	80 beats/min
Pulse units	BPM
Respiratory Rate (<i>xxx</i>)	15 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (<i>xxx</i>)	108 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (<i>xxx</i>)	79 mmHg
Diastolic Blood Pressure units	MMHG

US3032242

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Data signed: (b) (4) 28 Sep 2020 17:47:48

Generated On: 09 Jun 2021 14:52:51

Timepoint	Pre-Dose <input type="radio"/>
	Post-Dose <input checked="" type="radio"/>
Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (<i>dd MMM yyyy</i>)	18 SEP 2020
Time of assessment (<i>00:00-23:59</i>)	09:49 (24 HR)
Vital Signs Date and Time (derived)	18 SEP 2020 09:49
Temperature (<i>xxx.x</i>)	36.8 C
Route of measurement	Oral <input checked="" type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify _____	
Pulse (<i>xxx</i>)	84 beats/min
Pulse units	BPM
Respiratory Rate (<i>xxx</i>)	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (<i>xxx</i>)	102 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (<i>xxx</i>)	78 mmHg
Diastolic Blood Pressure units	MMHG

US3032242

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Data signed: (b) (4) 28 Sep 2020 17:47:48

Generated On: 09 Jun 2021 14:52:51

Was the physical examination performed?

Yes

No

Date of examination (dd MMM yyyy)

18 SEP 2020

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

US3032242

Folder: Visit 2 Day 29 (1)

Form: Exposure

Data signed: (b) (4) 28 Sep 2020 17:47:48

Generated On: 09 Jun 2021 14:52:51

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) 18 SEP 2020

What was the treatment time? (00:00-23:59) 09:17 (24 HR)

Treatment Date and Time (derived) 18 SEP 2020 09:17

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

US3032242

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 28 Sep 2020 17:47:48

Generated On: 09 Jun 2021 14:52:51

Was the sample collected? Yes No

Collection date (*dd MMM yyyy*) 18 SEP 2020

Collection time (*00:00-23:59*) 08:40 (24 HR)

Collection date and time (derived) 18 SEP 2020 08:40

US3032242

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab

Data signed: (b) (4) 28 Sep 2020 17:47:48

Generated On: 09 Jun 2021 14:52:51

Collection date (<i>dd MMM yyyy</i>)			18 SEP 2020
Lab Test	Was the sample collected?	Collection time (<i>00:00 - 23:59</i>)	Collection date and time (derived)
Nasopharyngeal Swab 1	Yes	08:29	18 SEP 2020 08:29
Nasopharyngeal Swab 2	No		

US3032242

Folder: Visit 2 Day 29 (1)

Form: Continuing

Data signed: (b) (4) 28 Sep 2020 17:47:48

Generated On: 09 Jun 2021 14:52:51

Is the participant continuing to the next visit?

Yes

No

Continuing Flag

1

US3032242

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 14:52:51

TIMEPOINT

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

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

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

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

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

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

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

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

Was **TEMPERATURE** taken? Yes No

Please record your **TEMPERATURE** in °F 98.2 °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 18 SEP 2020 09:51

PC Open Date & Time 18 SEP 2020 09:37

PC Close Date & Time 18 SEP 2020 12:07

US3032242

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 14:52:51

TIMEPOINT

DAY 1, AFTER VACCINATION
(AT HOME)

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

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

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

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

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

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

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

Was **TEMPERATURE** taken? Yes No

Please record your **TEMPERATURE** in °F 97.5 °F

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

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

PC Time Stamp 18 SEP 2020 17:02
PC Open Date & Time 18 SEP 2020 13:02
PC Close Date & Time 19 SEP 2020 11:59

US3032242

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 14:52:51

TIMEPOINT

DAY 2

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

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

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

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

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

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

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

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

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

PC Time Stamp	19 SEP 2020 15:49
PC Open Date & Time	19 SEP 2020 12:00
PC Close Date & Time	20 SEP 2020 11:59

US3032242

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 14:52:51

TIMEPOINT

DAY 3

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

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

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

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

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

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

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

Was TEMPERATURE taken?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Please record your TEMPERATURE in °F	97.2 °F
Was any MEDICATION TAKEN today for pain or fever?	Yes <input type="radio"/>
	No <input checked="" type="radio"/>

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

PC Time Stamp	20 SEP 2020 12:14
PC Open Date & Time	20 SEP 2020 12:00
PC Close Date & Time	21 SEP 2020 11:59

US3032242

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 14:52:51

TIMEPOINT

DAY 4

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

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

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

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

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

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

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

Was **TEMPERATURE** taken? Yes No

Please record your **TEMPERATURE** in °F 98.0 °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 21 SEP 2020 12:04

PC Open Date & Time 21 SEP 2020 12:00

PC Close Date & Time 22 SEP 2020 11:59

US3032242

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 14:52:51

TIMEPOINT

DAY 5

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

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

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

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

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

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

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

Was TEMPERATURE taken?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Please record your TEMPERATURE in °F	96.8 °F
Was any MEDICATION TAKEN today for pain or fever?	Yes <input type="radio"/>
	No <input checked="" type="radio"/>

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

PC Time Stamp	22 SEP 2020 12:14
PC Open Date & Time	22 SEP 2020 12:00
PC Close Date & Time	23 SEP 2020 11:59

US3032242

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 14:52:51

TIMEPOINT

DAY 6

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

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

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

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

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

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

Was TEMPERATURE taken?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Please record your TEMPERATURE in °F	97.7 °F
Was any MEDICATION TAKEN today for pain or fever?	Yes <input type="radio"/>
	No <input checked="" type="radio"/>

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

PC Time Stamp	23 SEP 2020 12:04
PC Open Date & Time	23 SEP 2020 12:00
PC Close Date & Time	24 SEP 2020 11:59

US3032242

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 14:52:51

TIMEPOINT

DAY 7

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

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

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

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

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

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

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

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

PC Time Stamp	24 SEP 2020 15:59
PC Open Date & Time	24 SEP 2020 12:00
PC Close Date & Time	25 SEP 2020 11:59

US3032242

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 14:52:51

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	18 SEP 2020 09:52
PC Open Date & Time	18 SEP 2020 09:37
PC Close Date & Time	18 SEP 2020 12:07

US3032242

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 14:52:51

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

18 SEP 2020 17:02

PC Open Date & Time

18 SEP 2020 13:02

PC Close Date & Time

19 SEP 2020 11:59

US3032242

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 14:52:51

TIMEPOINT

DAY 2

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

Please select one response below

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

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

- Yes
- No

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

- Yes
- No

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

Please select one response below

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

PC Time Stamp	19 SEP 2020 15:50
PC Open Date & Time	19 SEP 2020 12:00
PC Close Date & Time	20 SEP 2020 11:59

US3032242

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 14:52:51

TIMEPOINT

DAY 3

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

Please select one response below

None

Does not interfere with activity

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

Any use of prescription pain
reliever or prevents daily activity

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

Yes

No

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

Yes

No

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

Please select one response below

None

Does not interfere with activity

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

Any use of prescription pain
reliever or prevents daily activity

PC Time Stamp

20 SEP 2020 12:14

PC Open Date & Time

20 SEP 2020 12:00

PC Close Date & Time

21 SEP 2020 11:59

US3032242

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 14:52:51

TIMEPOINT

DAY 4

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

Please select one response below

None

Does not interfere with activity

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

Any use of prescription pain
reliever or prevents daily activity

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

Yes

No

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

Yes

No

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

Please select one response below

None

Does not interfere with activity

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

Any use of prescription pain
reliever or prevents daily activity

PC Time Stamp

21 SEP 2020 12:05

PC Open Date & Time

21 SEP 2020 12:00

PC Close Date & Time

22 SEP 2020 11:59

US3032242

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 14:52:51

TIMEPOINT

DAY 5

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

Please select one response below

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

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

- Yes
- No

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

- Yes
- No

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

Please select one response below

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

PC Time Stamp	22 SEP 2020 12:14
PC Open Date & Time	22 SEP 2020 12:00
PC Close Date & Time	23 SEP 2020 11:59

US3032242

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 14:52:51

TIMEPOINT

DAY 6

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

Please select one response below

None

Does not interfere with activity

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

Any use of prescription pain
reliever or prevents daily activity

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

Yes

No

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

Yes

No

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

Please select one response below

None

Does not interfere with activity

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

Any use of prescription pain
reliever or prevents daily activity

PC Time Stamp

23 SEP 2020 12:04

PC Open Date & Time

23 SEP 2020 12:00

PC Close Date & Time

24 SEP 2020 11:59

US3032242

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 14:52:51

TIMEPOINT

DAY 7

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

Please select one response below

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

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

- Yes
- No

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

- Yes
- No

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

Please select one response below

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

PC Time Stamp	24 SEP 2020 15:59
PC Open Date & Time	24 SEP 2020 12:00
PC Close Date & Time	25 SEP 2020 11:59

US3032242

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 14:52:51

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

US3032242

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 14:52:51

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

No
Yes

PC Time stamp	18 SEP 2020 09:53
PC Open Date & Time	18 SEP 2020 09:37
PC Close Date & Time	18 SEP 2020 12:07

US3032242

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 14:52:51

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

US3032242

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 14:52:51

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

No

Yes

PC Time stamp	18 SEP 2020 17:03
PC Open Date & Time	18 SEP 2020 13:02
PC Close Date & Time	19 SEP 2020 11:59

US3032242

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 14:52:51

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

US3032242

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 14:52:51

	Yes <input type="checkbox"/>
PC Time stamp	19 SEP 2020 15:50
PC Open Date & Time	19 SEP 2020 12:00
PC Close Date & Time	20 SEP 2020 11:59

US3032242

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 14:52:51

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

US3032242

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 14:52:51

	Yes <input type="checkbox"/>
PC Time stamp	20 SEP 2020 12:15
PC Open Date & Time	20 SEP 2020 12:00
PC Close Date & Time	21 SEP 2020 11:59

US3032242

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 14:52:51

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

US3032242

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 14:52:51

	Yes <input type="checkbox"/>
PC Time stamp	21 SEP 2020 12:05
PC Open Date & Time	21 SEP 2020 12:00
PC Close Date & Time	22 SEP 2020 11:59

US3032242

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 14:52:51

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

US3032242

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 14:52:51

	Yes <input type="checkbox"/>
PC Time stamp	22 SEP 2020 12:15
PC Open Date & Time	22 SEP 2020 12:00
PC Close Date & Time	23 SEP 2020 11:59

US3032242

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 14:52:51

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

US3032242

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 14:52:51

	Yes <input type="checkbox"/>
PC Time stamp	23 SEP 2020 12:05
PC Open Date & Time	23 SEP 2020 12:00
PC Close Date & Time	24 SEP 2020 11:59

US3032242

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 14:52:51

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

US3032242

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 14:52:51

	Yes <input type="checkbox"/>
PC Time stamp	24 SEP 2020 16:00
PC Open Date & Time	24 SEP 2020 12:00
PC Close Date & Time	25 SEP 2020 11:59

US3032242

Folder: Safety Call Day 36 (1)

Form: Safety Call

Data signed: (b) (4) 28 Sep 2020 17:47:47

Generated On: 09 Jun 2021 14:52:51

Was Contact Attempted? Yes
No

Date of Contact or Contact Attempt (*dd MMM yyyy*) 25 SEP 2020

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

Comments

If Contact Not Made, please provide Comments

US3032242

Folder: Safety Call Day 36 (1)

Form: Continuing

Data signed: (b) (4) 28 Sep 2020 17:47:47

Generated On: 09 Jun 2021 14:52:51

Is the participant continuing to the next visit?

Yes

No

Continuing Flag

1

US3032242

Folder: Safety Call Day 43 (1)

Form: Safety Call

Data signed: (b) (4) 08 Oct 2020 15:42:03

Generated On: 09 Jun 2021 14:52:51

Was Contact Attempted? Yes
No

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

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

Comments

If Contact Not Made, please provide Comments

US3032242

Folder: Safety Call Day 43 (1)

Form: Continuing

Data signed: (b) (4) 08 Oct 2020 15:42:03

Generated On: 09 Jun 2021 14:52:51

Is the participant continuing to the next visit?

Yes

No

Continuing Flag

1

US3032242

Folder: Safety Call Day 50 (1)

Form: Safety Call

Data signed: (b) (4) 22 Oct 2020 14:54:53

Generated On: 09 Jun 2021 14:52:51

Was Contact Attempted? Yes
No

Date of Contact or Contact Attempt (*dd MMM yyyy*) 09 OCT 2020

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

Comments

If Contact Not Made, please provide Comments

US3032242

Folder: Safety Call Day 50 (1)

Form: Continuing

Data signed: (b) (4) 22 Oct 2020 14:54:53

Generated On: 09 Jun 2021 14:52:51

Is the participant continuing to the next visit?

Yes

No

Continuing Flag

1

US3032242

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Data signed: (b) (4) 22 Oct 2020 14:54:53

Generated On: 09 Jun 2021 14:52:51

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	15 OCT 2020
Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>
Folder OID	VISIT3

US3032242

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Data signed: (b) (4) 22 Oct 2020 14:54:53

Generated On: 09 Jun 2021 14:52:51

Were vital signs assessed? Yes
No

Date of assessment (dd MMM yyyy) 15 OCT 2020

Time of assessment (00:00-23:59) 14:52 (24 HR)

Vital Signs Date and Time (derived) 15 OCT 2020 14:52

Temperature (xxx.x) 36.6 C

Route of measurement Oral
Axillary
Other

If Other, specify _____

Pulse (xxx) 81 beats/min

Pulse units BPM

Respiratory Rate (xxx) 14 breaths/min

Respiratory Rate units BREATHS/MIN

Systolic Blood Pressure (xxx) 134 mmHg

Systolic Blood Pressure units MMHG

Diastolic Blood Pressure (xxx) 90 mmHg

Diastolic Blood Pressure units MMHG

Height (derived) _____

Weight (derived) _____

US3032242

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Data signed: (b) (4) 22 Oct 2020 14:54:53

Generated On: 09 Jun 2021 14:52:51

Was the physical examination performed?

Yes

No

Date of examination (dd MMM yyyy)

15 OCT 2020

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

US3032242

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 22 Oct 2020 14:54:53

Generated On: 09 Jun 2021 14:52:51

Was the sample collected? Yes No

Collection date (*dd MMM yyyy*) 15 OCT 2020

Collection time (*00:00-23:59*) 15:06 (24 HR)

Collection date and time (derived) 15 OCT 2020 15:06

US3032242

Folder: Visit 3 Day 57 (1)

Form: Continuing

Data signed: (b) (4) 22 Oct 2020 14:54:53

Generated On: 09 Jun 2021 14:52:51

Is the participant continuing to the next visit?

Yes

No

Continuing Flag

1

US3032242

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:52:51

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 19 OCT 2020 18:12:50

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

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

US3032242

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:52:51

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 26 OCT 2020 17:26:34

Patient Cloud Open Date & Time 26 OCT 2020 00:01

Patient Cloud Close Date & Time 30 OCT 2020 23:59

US3032242

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:52:51

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 <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	02 NOV 2020 14:40:29
Patient Cloud Open Date & Time	02 NOV 2020 00:01
Patient Cloud Close Date & Time	06 NOV 2020 23:59

US3032242

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:52:51

TIMEPOINT

DAY 92

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

No

Yes

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

No

Yes

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

Date and time of submission 17 NOV 2020 00:04:25

Patient Cloud Open Date & Time 16 NOV 2020 00:01

Patient Cloud Close Date & Time 20 NOV 2020 23:59

US3032242

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:52:51

TIMEPOINT	DAY 96
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	23 NOV 2020 12:21:27
Patient Cloud Open Date & Time	20 NOV 2020 00:01
Patient Cloud Close Date & Time	24 NOV 2020 23:59

US3032242

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:52:51

TIMEPOINT

DAY 103

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

No

Yes

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

No

Yes

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

Date and time of submission 30 NOV 2020 12:45:56

Patient Cloud Open Date & Time 27 NOV 2020 00:01

Patient Cloud Close Date & Time 01 DEC 2020 23:59

US3032242

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:52:51

TIMEPOINT	DAY 110
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	08 DEC 2020 00:14:35
Patient Cloud Open Date & Time	04 DEC 2020 00:01
Patient Cloud Close Date & Time	08 DEC 2020 23:59

US3032242

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:52:51

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 <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	11 DEC 2020 09:49:54
Patient Cloud Open Date & Time	11 DEC 2020 00:01
Patient Cloud Close Date & Time	15 DEC 2020 23:59

US3032242

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:52:51

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	18 DEC 2020 04:20:52
Patient Cloud Open Date & Time	18 DEC 2020 00:01
Patient Cloud Close Date & Time	22 DEC 2020 23:59

US3032242

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:52:51

TIMEPOINT	DAY 131
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	25 DEC 2020 07:23:50
Patient Cloud Open Date & Time	25 DEC 2020 00:01
Patient Cloud Close Date & Time	29 DEC 2020 23:59

US3032242

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:52:51

TIMEPOINT	DAY 138
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	01 JAN 2021 05:32:32
Patient Cloud Open Date & Time	01 JAN 2021 00:01
Patient Cloud Close Date & Time	05 JAN 2021 23:59

US3032242

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:52:51

TIMEPOINT

DAY 145

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

No

Yes

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

No

Yes

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

Date and time of submission 08 JAN 2021 08:53:08

Patient Cloud Open Date & Time 08 JAN 2021 00:01

Patient Cloud Close Date & Time 12 JAN 2021 23:59

US3032242

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:52:51

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 15 JAN 2021 09:25:39

Patient Cloud Open Date & Time 15 JAN 2021 00:01

Patient Cloud Close Date & Time 19 JAN 2021 23:59

US3032242

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:52:51

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	22 JAN 2021 15:32:35
Patient Cloud Open Date & Time	22 JAN 2021 00:01
Patient Cloud Close Date & Time	26 JAN 2021 23:59

US3032242

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:52:51

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 <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	29 JAN 2021 08:39:07
Patient Cloud Open Date & Time	29 JAN 2021 00:01
Patient Cloud Close Date & Time	02 FEB 2021 23:59

US3032242

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:52:51

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 <input type="radio"/> Yes <input checked="" 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"/>
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 checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <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"/>
Date and time of submission	05 FEB 2021 08:37:00
Patient Cloud Open Date & Time	05 FEB 2021 00:01
Patient Cloud Close Date & Time	09 FEB 2021 23:59

US3032242

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:52:51

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 <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	12 FEB 2021 09:05:34
Patient Cloud Open Date & Time	12 FEB 2021 00:01
Patient Cloud Close Date & Time	16 FEB 2021 23:59

US3032242

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:52:51

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	19 FEB 2021 09:20:56
Patient Cloud Open Date & Time	19 FEB 2021 00:01
Patient Cloud Close Date & Time	23 FEB 2021 23:59

US3032242

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:52:51

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 <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	26 FEB 2021 08:58:06
Patient Cloud Open Date & Time	26 FEB 2021 00:01
Patient Cloud Close Date & Time	02 MAR 2021 23:59

US3032242

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:52:51

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 05 MAR 2021 02:49:28

Patient Cloud Open Date & Time 05 MAR 2021 00:01

Patient Cloud Close Date & Time 09 MAR 2021 23:59

US3032242

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:52:51

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

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 MAR 2021 15:17:18

Patient Cloud Open Date & Time 12 MAR 2021 00:01

Patient Cloud Close Date & Time 16 MAR 2021 23:59

US3032242

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:52:51

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 <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	19 MAR 2021 02:44:54
Patient Cloud Open Date & Time	19 MAR 2021 00:01
Patient Cloud Close Date & Time	23 MAR 2021 23:59

US3032242

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:52:51

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 <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	26 MAR 2021 02:35:16
Patient Cloud Open Date & Time	26 MAR 2021 00:01
Patient Cloud Close Date & Time	30 MAR 2021 23:59

US3032242

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:52:51

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 <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	02 APR 2021 02:43:00
Patient Cloud Open Date & Time	02 APR 2021 00:01
Patient Cloud Close Date & Time	06 APR 2021 23:59

US3032242

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:52:51

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 <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	09 APR 2021 02:34:22
Patient Cloud Open Date & Time	09 APR 2021 00:01
Patient Cloud Close Date & Time	13 APR 2021 23:59

US3032242

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:52:51

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 <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	16 APR 2021 02:40:25
Patient Cloud Open Date & Time	16 APR 2021 00:01
Patient Cloud Close Date & Time	20 APR 2021 23:59

US3032242

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:52:51

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 <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	23 APR 2021 03:09:38
Patient Cloud Open Date & Time	23 APR 2021 00:01
Patient Cloud Close Date & Time	27 APR 2021 23:59

US3032242

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:52:51

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 <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 APR 2021 02:59:37
Patient Cloud Open Date & Time	30 APR 2021 00:01
Patient Cloud Close Date & Time	04 MAY 2021 23:59

US3032242

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:52:51

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 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

US3032242

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:52:51

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

07 MAY 2021 00:01

[Patient Cloud Close Date & Time](#)

11 MAY 2021 23:59

US3032242

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:52:51

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 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

US3032242

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:52:51

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

Date and time of submission	
Patient Cloud Open Date & Time	14 MAY 2021 00:01
Patient Cloud Close Date & Time	18 MAY 2021 23:59

US3032242

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:52:51

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 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

US3032242

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:52:51

Please 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	21 MAY 2021 00:01
Patient Cloud Close Date & Time	25 MAY 2021 23:59

US3032242

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:52:51

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
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

US3032242

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:52:51

Please 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 MAY 2021 00:01

[Patient Cloud Close Date & Time](#)

01 JUN 2021 23:59

US3032242

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:52:51

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°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

US3032242

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:52:51

Please 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	04 JUN 2021 00:01
Patient Cloud Close Date & Time	08 JUN 2021 23:59

US3032242

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:52:51

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
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

US3032242

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:52:51

Please 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	11 JUN 2021 00:01
Patient Cloud Close Date & Time	15 JUN 2021 23:59

US3032242

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:52:51

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°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

US3032242

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:52:51

Please 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	18 JUN 2021 00:01
Patient Cloud Close Date & Time	22 JUN 2021 23:59

US3032242

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:52:51

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

US3032242

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:52:51

Please 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	25 JUN 2021 00:01
Patient Cloud Close Date & Time	29 JUN 2021 23:59

US3032242

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:52:51

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
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

US3032242

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:52:51

Please 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 JUL 2021 00:01

[Patient Cloud Close Date & Time](#)

06 JUL 2021 23:59

US3032242

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:52:51

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°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

US3032242

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:52:51

Please 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 JUL 2021 00:01

[Patient Cloud Close Date & Time](#)

13 JUL 2021 23:59

US3032242

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:52:51

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°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

US3032242

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:52:51

Please 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 JUL 2021 00:01
Patient Cloud Close Date & Time	20 JUL 2021 23:59

US3032242

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:52:51

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 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

US3032242

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:52:51

Please 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](#)

23 JUL 2021 00:01

[Patient Cloud Close Date & Time](#)

27 JUL 2021 23:59

US3032242

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:52:51

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
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

US3032242

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:52:51

Please 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 JUL 2021 00:01

[Patient Cloud Close Date & Time](#)

03 AUG 2021 23:59

US3032242

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:52:51

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°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

US3032242

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:52:51

Please 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](#)

06 AUG 2021 00:01

[Patient Cloud Close Date & Time](#)

10 AUG 2021 23:59

US3032242

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:52:51

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°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

US3032242

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:52:51

Please 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](#)

13 AUG 2021 00:01

[Patient Cloud Close Date & Time](#)

17 AUG 2021 23:59

US3032242

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:52:51

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°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

US3032242

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:52:51

Please 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	20 AUG 2021 00:01
Patient Cloud Close Date & Time	24 AUG 2021 23:59

US3032242

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:52:51

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°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

US3032242

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:52:51

Please 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 AUG 2021 00:01
Patient Cloud Close Date & Time	31 AUG 2021 23:59

US3032242

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:52:51

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°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

US3032242

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:52:51

Please 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	03 SEP 2021 00:01
Patient Cloud Close Date & Time	07 SEP 2021 23:59

US3032242

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:52:51

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°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

US3032242

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:52:51

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

10 SEP 2021 00:01

[Patient Cloud Close Date & Time](#)

14 SEP 2021 23:59

US3032242

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:52:51

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°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

US3032242

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:52:51

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

Date and time of submission	
Patient Cloud Open Date & Time	17 SEP 2021 00:01
Patient Cloud Close Date & Time	21 SEP 2021 23:59

US3032242

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:52:51

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 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

US3032242

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:52:51

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

Date and time of submission	
Patient Cloud Open Date & Time	24 SEP 2021 00:01
Patient Cloud Close Date & Time	28 SEP 2021 23:59

US3032242

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:52:51

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
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

US3032242

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:52:51

Please 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	01 OCT 2021 00:01
Patient Cloud Close Date & Time	05 OCT 2021 23:59

US3032242

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:52:51

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°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

US3032242

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:52:51

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

Date and time of submission	
Patient Cloud Open Date & Time	08 OCT 2021 00:01
Patient Cloud Close Date & Time	12 OCT 2021 23:59

US3032242

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:52:51

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°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

US3032242

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:52:51

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

15 OCT 2021 00:01

[Patient Cloud Close Date & Time](#)

19 OCT 2021 23:59

US3032242

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:52:51

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°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

US3032242

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:52:51

Please 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	22 OCT 2021 00:01
Patient Cloud Close Date & Time	26 OCT 2021 23:59

US3032242

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:52:51

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

US3032242

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:52:51

Please 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](#)

29 OCT 2021 00:01

[Patient Cloud Close Date & Time](#)

02 NOV 2021 23:59

US3032242

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:52:51

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°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

US3032242

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:52:51

Please 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	05 NOV 2021 00:01
Patient Cloud Close Date & Time	09 NOV 2021 23:59

US3032242

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:52:51

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°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

US3032242

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:52:51

Please 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 NOV 2021 00:01

[Patient Cloud Close Date & Time](#)

16 NOV 2021 23:59

US3032242

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:52:51

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

US3032242

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:52:51

Please 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](#)

19 NOV 2021 00:01

[Patient Cloud Close Date & Time](#)

23 NOV 2021 23:59

US3032242

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:52:51

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°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

US3032242

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:52:51

Please 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](#)

26 NOV 2021 00:01

[Patient Cloud Close Date & Time](#)

30 NOV 2021 23:59

US3032242

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:52:51

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

US3032242

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:52:51

Please 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](#) 03 DEC 2021 00:01

[Patient Cloud Close Date & Time](#) 07 DEC 2021 23:59

US3032242

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:52:51

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°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

US3032242

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:52:51

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

Date and time of submission	
Patient Cloud Open Date & Time	10 DEC 2021 00:01
Patient Cloud Close Date & Time	14 DEC 2021 23:59

US3032242

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:52:51

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 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

US3032242

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:52:51

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

Date and time of submission	
Patient Cloud Open Date & Time	17 DEC 2021 00:01
Patient Cloud Close Date & Time	21 DEC 2021 23:59

US3032242

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:52:51

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°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

US3032242

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:52:51

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

24 DEC 2021 00:01

[Patient Cloud Close Date & Time](#)

28 DEC 2021 23:59

US3032242

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:52:51

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°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

US3032242

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:52:51

Please 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	31 DEC 2021 00:01
Patient Cloud Close Date & Time	04 JAN 2022 23:59

US3032242

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:52:51

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°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

US3032242

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:52:51

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

Date and time of submission	
Patient Cloud Open Date & Time	07 JAN 2022 00:01
Patient Cloud Close Date & Time	11 JAN 2022 23:59

US3032242

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:52:51

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

US3032242

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:52:51

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

14 JAN 2022 00:01

[Patient Cloud Close Date & Time](#)

18 JAN 2022 23:59

US3032242

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:52:51

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 $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$) _____
- 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

US3032242

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:52:51

Please 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	21 JAN 2022 00:01
Patient Cloud Close Date & Time	25 JAN 2022 23:59

US3032242

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:52:51

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
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

US3032242

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:52:51

Please 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 JAN 2022 00:01
Patient Cloud Close Date & Time	01 FEB 2022 23:59

US3032242

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:52:51

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°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

US3032242

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:52:51

Please 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	04 FEB 2022 00:01
Patient Cloud Close Date & Time	08 FEB 2022 23:59

US3032242

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:52:51

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
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

US3032242

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:52:51

Please 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	11 FEB 2022 00:01
Patient Cloud Close Date & Time	15 FEB 2022 23:59

US3032242

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:52:51

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

US3032242

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:52:51

Please 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	18 FEB 2022 00:01
Patient Cloud Close Date & Time	22 FEB 2022 23:59

US3032242

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:52:51

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°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

US3032242

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:52:51

Please 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	25 FEB 2022 00:01
Patient Cloud Close Date & Time	01 MAR 2022 23:59

US3032242

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:52:51

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°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

US3032242

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:52:51

Please 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](#)

04 MAR 2022 00:01

[Patient Cloud Close Date & Time](#)

08 MAR 2022 23:59

US3032242

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:52:51

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°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

US3032242

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:52:51

Please 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](#)

11 MAR 2022 00:01

[Patient Cloud Close Date & Time](#)

15 MAR 2022 23:59

US3032242

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:52:51

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°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

US3032242

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:52:51

Please 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](#)

18 MAR 2022 00:01

[Patient Cloud Close Date & Time](#)

22 MAR 2022 23:59

US3032242

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:52:51

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°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

US3032242

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:52:51

Please 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](#)

25 MAR 2022 00:01

[Patient Cloud Close Date & Time](#)

29 MAR 2022 23:59

US3032242

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:52:51

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°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

US3032242

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:52:51

Please 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	01 APR 2022 00:01
Patient Cloud Close Date & Time	05 APR 2022 23:59

US3032242

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:52:51

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
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

US3032242

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:52:51

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

Date and time of submission	
Patient Cloud Open Date & Time	08 APR 2022 00:01
Patient Cloud Close Date & Time	12 APR 2022 23:59

US3032242

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:52:51

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
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

US3032242

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:52:51

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

15 APR 2022 00:01

[Patient Cloud Close Date & Time](#)

19 APR 2022 23:59

US3032242

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:52:51

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
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

US3032242

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:52:51

Please 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](#)

22 APR 2022 00:01

[Patient Cloud Close Date & Time](#)

26 APR 2022 23:59

US3032242

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:52:51

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
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

US3032242

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:52:51

Please 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](#)

29 APR 2022 00:01

[Patient Cloud Close Date & Time](#)

03 MAY 2022 23:59

US3032242

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:52:51

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 $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$) _____

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

US3032242

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:52:51

Please 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](#)

06 MAY 2022 00:01

[Patient Cloud Close Date & Time](#)

10 MAY 2022 23:59

US3032242

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:52:51

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°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

US3032242

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:52:51

Please 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	13 MAY 2022 00:01
Patient Cloud Close Date & Time	17 MAY 2022 23:59

US3032242

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:52:51

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°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

US3032242

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:52:51

Please 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](#)

20 MAY 2022 00:01

[Patient Cloud Close Date & Time](#)

24 MAY 2022 23:59

US3032242

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:52:51

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 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

US3032242

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:52:51

Please 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 MAY 2022 00:01
Patient Cloud Close Date & Time	31 MAY 2022 23:59

US3032242

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:52:51

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°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

US3032242

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:52:51

Please 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](#) 03 JUN 2022 00:01

[Patient Cloud Close Date & Time](#) 07 JUN 2022 23:59

US3032242

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:52:51

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°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

US3032242

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:52:51

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

Date and time of submission	
Patient Cloud Open Date & Time	10 JUN 2022 00:01
Patient Cloud Close Date & Time	14 JUN 2022 23:59

US3032242

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:52:51

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
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

US3032242

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:52:51

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

17 JUN 2022 00:01

[Patient Cloud Close Date & Time](#)

21 JUN 2022 23:59

US3032242

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:52:51

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°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

US3032242

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:52:51

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

24 JUN 2022 00:01

[Patient Cloud Close Date & Time](#)

28 JUN 2022 23:59

US3032242

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:52:51

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°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

US3032242

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:52:51

Please 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	01 JUL 2022 00:01
Patient Cloud Close Date & Time	05 JUL 2022 23:59

US3032242

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:52:51

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 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

US3032242

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:52:51

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

Date and time of submission	
Patient Cloud Open Date & Time	08 JUL 2022 00:01
Patient Cloud Close Date & Time	12 JUL 2022 23:59

US3032242

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:52:51

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
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

US3032242

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:52:51

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

15 JUL 2022 00:01

[Patient Cloud Close Date & Time](#)

19 JUL 2022 23:59

US3032242

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:52:51

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 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

US3032242

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:52:51

Please 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](#)

22 JUL 2022 00:01

[Patient Cloud Close Date & Time](#)

26 JUL 2022 23:59

US3032242

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:52:51

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
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

US3032242

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:52:51

Please 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	29 JUL 2022 00:01
Patient Cloud Close Date & Time	02 AUG 2022 23:59

US3032242

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:52:51

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

US3032242

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:52:51

Please 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](#)

05 AUG 2022 00:01

[Patient Cloud Close Date & Time](#)

09 AUG 2022 23:59

US3032242

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:52:51

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°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

US3032242

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:52:51

Please 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 AUG 2022 00:01
Patient Cloud Close Date & Time	16 AUG 2022 23:59

US3032242

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:52:51

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°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

US3032242

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:52:51

Please 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	19 AUG 2022 00:01
Patient Cloud Close Date & Time	23 AUG 2022 23:59

US3032242

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:52:51

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
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

US3032242

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:52:51

Please 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	26 AUG 2022 00:01
Patient Cloud Close Date & Time	30 AUG 2022 23:59

US3032242

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:52:51

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 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

US3032242

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:52:51

Please 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 SEP 2022 00:01

[Patient Cloud Close Date & Time](#)

06 SEP 2022 23:59

US3032242

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:52:51

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
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

US3032242

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:52:51

Please 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 SEP 2022 00:01

[Patient Cloud Close Date & Time](#)

13 SEP 2022 23:59

US3032242

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:52:51

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

US3032242

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:52:51

Please 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 SEP 2022 00:01

[Patient Cloud Close Date & Time](#)

20 SEP 2022 23:59

US3032242

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:52:51

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°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

US3032242

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:52:51

Please 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	23 SEP 2022 00:01
Patient Cloud Close Date & Time	27 SEP 2022 23:59

US3032242

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:52:51

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

US3032242

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:52:51

Please 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 SEP 2022 00:01

[Patient Cloud Close Date & Time](#)

04 OCT 2022 23:59

US3032242

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:52:51

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°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

US3032242

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:52:51

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

Date and time of submission	
Patient Cloud Open Date & Time	07 OCT 2022 00:01
Patient Cloud Close Date & Time	11 OCT 2022 23:59

US3032242

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:52:51

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°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

US3032242

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:52:51

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

Date and time of submission	
Patient Cloud Open Date & Time	14 OCT 2022 00:01
Patient Cloud Close Date & Time	18 OCT 2022 23:59

US3032242

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:52:51

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
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

US3032242

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:52:51

Please 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](#)

21 OCT 2022 00:01

[Patient Cloud Close Date & Time](#)

25 OCT 2022 23:59

US3032242

Folder: Cosmetic Injections and Dermal Fillers

Form: Cosmetic Injection_ Dermal Filler eDiary

Generated On: 09 Jun 2021 14:52:51

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		01 MAR 2021 03:25:45

US3032242

Folder: Safety Call Day 85 (1)

Form: Safety Call

Data signed: (b) (4) 10 Nov 2020 21:41:06

Generated On: 09 Jun 2021 14:52:51

Was Contact Attempted? Yes
No

Date of Contact or Contact Attempt (*dd MMM yyyy*) 10 NOV 2020

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

Comments

If Contact Not Made, please provide Comments

US3032242

Folder: Safety Call Day 85 (1)

Form: Continuing

Data signed: (b) (4) 10 Nov 2020 21:41:06

Generated On: 09 Jun 2021 14:52:51

Is the participant continuing to the next visit?

Yes

No

Continuing Flag

1

US3032242

Folder: Safety Call Day 119 (1)

Form: Safety Call

Data signed: (b) (4) 05 Feb 2021 19:41:27

Generated On: 09 Jun 2021 14:52:51

Was Contact Attempted? Yes
No

Date of Contact or Contact Attempt (*dd MMM yyyy*) 14 DEC 2020

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

Comments

If Contact Not Made, please provide Comments

US3032242

Folder: Safety Call Day 119 (1)

Form: Continuing

Data signed: (b) (4) 05 Feb 2021 19:41:27

Generated On: 09 Jun 2021 14:52:51

Is the participant continuing to the next visit?

Yes

No

Continuing Flag

1

US3032242

Folder: Safety Call Day 149 (1)

Form: Safety Call

Data signed: (b) (4) 05 Feb 2021 19:41:27

Generated On: 09 Jun 2021 14:52:51

Was Contact Attempted? Yes
No

Date of Contact or Contact Attempt (*dd MMM yyyy*) 13 JAN 2021

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

Comments

If Contact Not Made, please provide Comments

US3032242

Folder: Safety Call Day 149 (1)

Form: Continuing

Data signed: (b) (4) 05 Feb 2021 19:41:27

Generated On: 09 Jun 2021 14:52:51

Is the participant continuing to the next visit?

Yes

No

Continuing Flag

1

US3032242

Folder: Safety Call Day 179 (1)

Form: Safety Call

Data signed: (b) (4) 18 Mar 2021 21:20:21

Generated On: 09 Jun 2021 14:52:51

Was Contact Attempted? Yes
No

Date of Contact or Contact Attempt (*dd MMM yyyy*) 12 FEB 2021

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

Comments

If Contact Not Made, please provide Comments

US3032242

Folder: Safety Call Day 179 (1)

Form: Continuing

Data signed: (b) (4) 18 Mar 2021 21:20:21

Generated On: 09 Jun 2021 14:52:51

Is the participant continuing to the next visit?

Yes

No

Continuing Flag

1

US3032242

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Data signed: (b) (4) 06 Apr 2021 15:40:49

Generated On: 09 Jun 2021 14:52:51

Was this visit performed? Yes
No

Visit date (dd MMM yyyy) 25 MAR 2021

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

Folder OID VISIT4

US3032242

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Data signed: (b) (4) 06 Apr 2021 15:40:49

Generated On: 09 Jun 2021 14:52:51

Were vital signs assessed? Yes
No

Date of assessment (dd MMM yyyy) _____

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

Vital Signs Date and Time (derived) _____

Temperature (xxx.x) _____

Route of measurement Oral
Axillary
Other

If Other, specify _____

Pulse (xxx) _____

Pulse units _____

Respiratory Rate (xxx) _____

Respiratory Rate units _____

Systolic Blood Pressure (xxx) _____

Systolic Blood Pressure units _____

Diastolic Blood Pressure (xxx) _____

Diastolic Blood Pressure units _____

Height (derived) _____

Weight (derived) _____

US3032242

Folder: Visit 4 Day 209 (1)

Form: Physical Examination

Data signed: (b) (4) 06 Apr 2021 15:40:49

Generated On: 09 Jun 2021 14:52:51

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.

US3032242

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 06 Apr 2021 15:40:49

Generated On: 09 Jun 2021 14:52:51

Was the sample collected? Yes No

Collection date (*dd MMM yyyy*) 25 MAR 2021

Collection time (*00:00-23:59*) 13:11 (24 HR)

Collection date and time (derived) 25 MAR 2021 13:11

US3032242

Folder: Visit 4 Day 209 (1)

Form: Continuing

Data signed: (b) (4) 06 Apr 2021 15:40:49

Generated On: 09 Jun 2021 14:52:51

Is the participant continuing to the next visit?

Yes

No

Continuing Flag

1

US3032242

Folder: Safety Call Day 239 (1)

Form: Safety Call

Generated On: 09 Jun 2021 14:52:51

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 _____

US3032242

Folder: Safety Call Day 239 (1)

Form: Continuing

Generated On: 09 Jun 2021 14:52:51

Is the participant continuing to the next visit?

Yes

No

Continuing Flag

US3032242

Folder: Covid-19 Assessment (1)

Form: COVID-19 Contact

Generated On: 09 Jun 2021 14:52:51

Date of Contact	_____
Time of Contact	_____
Date and Time of Contact (derived)	_____
Type of Contact	Clinic Visit - Scheduled <input type="checkbox"/>
	Clinical Visit - Unscheduled <input type="checkbox"/>
	Safety Call <input type="checkbox"/>
	Convalescent Tele-visit <input type="checkbox"/>
Has the subject reported symptoms of SARS-COV-2?	Yes <input type="checkbox"/>
	No <input type="checkbox"/>

US3032242

Folder: Covid-19 Assessment (1)

Form: Generate Next COVID-19 Assessment

Generated On: 09 Jun 2021 14:52:51

Generate Next COVID-19 Assessment

Yes

No

US3032242

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

Form: Visit Date

Data signed: (b) (4) 12 Feb 2021 19:56:37

Generated On: 09 Jun 2021 14:52:51

Was this visit performed? Yes
No

Visit date (dd MMM yyyy) 9 FEB 2021

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

Folder OID UNBLND_DECIDE

US3032242

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

Form: Unblinding

Data signed: (b) (4) 18 Mar 2021 21:20:21

Generated On: 09 Jun 2021 14:52:51

Date of updated informed consent (<i>dd MMM yyyy</i>)	9 FEB 2021
N/A - Subject Unblinded under Amendment 5 and Discontinued from Study	False
Was the participant unblinded?	Yes <input checked="" type="radio"/> No <input type="radio"/>
Under what version of the Protocol was the Participant unblinded?	Amendment 5 <input type="radio"/> Amendment 6 or later <input checked="" type="radio"/>
Date of unblinding (<i>dd MMM yyyy</i>)	9 FEB 2021
Participant randomization assignment	mRNA-1273 <input type="radio"/> Placebo <input checked="" type="radio"/>
Actual Dose 1	mRNA-1273 <input type="radio"/> Placebo <input checked="" type="radio"/> Not Administered <input type="radio"/>
Actual Dose 2	mRNA-1273 <input type="radio"/> Placebo <input checked="" type="radio"/> Not Administered <input type="radio"/>
Will participant receive mRNA-1273?	Yes <input checked="" type="radio"/> No <input type="radio"/>
Placebo Only Flag	1
Continuing with mRNA-1273	1

US3032242

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

Form: Vital Signs - Dosing

Data signed: (b) (4) 22 Feb 2021 17:26:07

Generated On: 09 Jun 2021 14:52:51

Height	ND - Not Done
Weight	ND - Not Done
BMI (xxx.x)	

US3032242

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

Form: Vital Signs - Dosing (1)

Data signed: (b) (4) 22 Feb 2021 17:26:07

Generated On: 09 Jun 2021 14:52:51

Height	ND - Not Done
Weight	ND - Not Done
BMI (xxx.x)	
Timepoint	Pre-Dose <input checked="" type="radio"/> Post-Dose <input type="radio"/>
Were vital signs assessed?	Yes <input checked="" type="radio"/> No <input type="radio"/>
Date of assessment (dd MMM yyyy)	19 FEB 2021
Time of assessment (00:00-23:59)	10:06 (24 HR)
Vital Signs Date and Time (derived)	19 FEB 2021 10:06
Temperature (xxx.x)	36.9 C
Route of measurement	Oral <input checked="" type="radio"/> Axillary <input type="radio"/> Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	96 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	20 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	104 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	78 mmHg
Diastolic Blood Pressure units	MMHG

US3032242

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

Form: Vital Signs - Dosing (2)

Data signed: (b) (4) 22 Feb 2021 17:26:07

Generated On: 09 Jun 2021 14:52:51

Height	ND - Not Done
Weight	ND - Not Done
BMI (xxx.x)	
Timepoint	Pre-Dose <input type="radio"/> Post-Dose <input checked="" type="radio"/>
Were vital signs assessed?	Yes <input checked="" type="radio"/> No <input type="radio"/>
Date of assessment (dd MMM yyyy)	19 FEB 2021
Time of assessment (00:00-23:59)	11:15 (24 HR)
Vital Signs Date and Time (derived)	19 FEB 2021 11:15
Temperature (xxx.x)	36.7 C
Route of measurement	Oral <input checked="" type="radio"/> Axillary <input type="radio"/> Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	84 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	15 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	95 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	74 mmHg
Diastolic Blood Pressure units	MMHG

US3032242

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

Form: Physical Examination

Data signed: (b) (4) 22 Feb 2021 17:26:07

Generated On: 09 Jun 2021 14:52:51

Was the physical examination performed?

Yes

No

Date of examination (dd MMM yyyy)

19 FEB 2021

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

US3032242

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

Form: Exposure

Data signed: (b) (4) 22 Feb 2021 17:26:07

Generated On: 09 Jun 2021 14:52:51

Was study treatment given? Yes
No

If No, reason not given

Participant declined due to Adverse Event
Physician withheld dose due to Adverse Event
Death
Lost To Follow-Up
Physician Decision
Pregnancy
Protocol Deviation
Study Terminated by Sponsor
Withdrawal of Consent by Participant
Confirmed COVID-19
Other

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

What was the study treatment? (Unblinded) MRNA-1273

What was the treatment date? (dd MMM yyyy) 19 FEB 2021

What was the treatment time? (00:00-23:59) 10:43 (24 HR)

Treatment Date and Time (derived) 19 FEB 2021 10:43

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

US3032242

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

Form: Immunogenicity Assessment

Data signed: (b) (4) 12 Feb 2021 19:56:37

Generated On: 09 Jun 2021 14:52:51

Was the sample collected? Yes No

Collection date (*dd MMM yyyy*) 9 FEB 2021

Collection time (*00:00-23:59*) 12:46 (24 HR)

Collection date and time (derived) 9 FEB 2021 12:46

US3032242

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

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Data signed: (b) (4) 12 Feb 2021 19:56:37

Generated On: 09 Jun 2021 14:52:51

Was the sample collected? Yes No

Collection date (*dd MMM yyyy*) 9 FEB 2021

Collection time (*00:00 - 23:59*) 12:43

Collection Date and Time (derived) 9 FEB 2021 12:43

US3032242

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

Form: Continuing

Data signed: (b) (4) 22 Feb 2021 17:26:07

Generated On: 09 Jun 2021 14:52:51

Is the participant continuing to the next visit?

Yes

No

Continuing Flag

1

US3032242

Folder: Safety Call OL-D8 (1)

Form: Safety Call

Data signed: (b) (4) 18 Mar 2021 21:20:21

Generated On: 09 Jun 2021 14:52:51

Was Contact Attempted? Yes
No

Date of Contact or Contact Attempt (*dd MMM yyyy*) 1 MAR 2021

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

Comments

If Contact Not Made, please provide Comments

US3032242

Folder: Safety Call OL-D8 (1)

Form: Continuing

Data signed: (b) (4) 18 Mar 2021 21:20:21

Generated On: 09 Jun 2021 14:52:51

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

US3032242

Folder: OL-D29 (1)

Form: Visit Date

Data signed: (b) (4) 06 Apr 2021 15:40:49

Generated On: 09 Jun 2021 14:52:51

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	18 MAR 2021
Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>
Folder OID	OLD29

US3032242

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Data signed: (b) (4) 06 Apr 2021 15:40:49

Generated On: 09 Jun 2021 14:52:51

Timepoint	Pre-Dose <input checked="" type="radio"/>
	Post-Dose <input type="radio"/>
Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (<i>dd MMM yyyy</i>)	18 MAR 2021
Time of assessment (<i>00:00-23:59</i>)	11:05 (24 HR)
Vital Signs Date and Time (derived)	18 MAR 2021 11:05
Temperature (<i>xxx.x</i>)	36.8 C
Route of measurement	Oral <input checked="" type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	
Pulse (<i>xxx</i>)	79 beats/min
Pulse units	BPM
Respiratory Rate (<i>xxx</i>)	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (<i>xxx</i>)	108 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (<i>xxx</i>)	77 mmHg
Diastolic Blood Pressure units	MMHG

US3032242

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Data signed: (b) (4) 06 Apr 2021 15:40:49

Generated On: 09 Jun 2021 14:52:51

Timepoint	Pre-Dose <input type="radio"/>
	Post-Dose <input checked="" type="radio"/>
Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (<i>dd MMM yyyy</i>)	18 MAR 2021
Time of assessment (<i>00:00-23:59</i>)	12:29 (24 HR)
Vital Signs Date and Time (derived)	18 MAR 2021 12:29
Temperature (<i>xxx.x</i>)	36.7 C
Route of measurement	Oral <input checked="" type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify _____	
Pulse (<i>xxx</i>)	75 beats/min
Pulse units	BPM
Respiratory Rate (<i>xxx</i>)	15 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (<i>xxx</i>)	118 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (<i>xxx</i>)	76 mmHg
Diastolic Blood Pressure units	MMHG

US3032242

Folder: OL-D29 (1)

Form: Physical Examination

Data signed: (b) (4) 06 Apr 2021 15:40:49

Generated On: 09 Jun 2021 14:52:51

Was the physical examination performed?

Yes

No

Date of examination (dd MMM yyyy)

18 MAR 2021

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

US3032242

Folder: OL-D29 (1)

Form: Exposure

Data signed: (b) (4) 06 Apr 2021 15:40:49

Generated On: 09 Jun 2021 14:52:51

Was study treatment given? Yes
No

If No, reason not given

Participant declined due to Adverse Event
Physician withheld dose due to Adverse Event
Death
Lost To Follow-Up
Physician Decision
Pregnancy
Protocol Deviation
Study Terminated by Sponsor
Withdrawal of Consent by Participant
Confirmed COVID-19
Other

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

What was the study treatment? (Unblinded) MRNA-1273

What was the treatment date? (dd MMM yyyy) 18 MAR 2021

What was the treatment time? (00:00-23:59) 11:57 (24 HR)

Treatment Date and Time (derived) 18 MAR 2021 11:57

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

US3032242

Folder: OL-D29 (1)

Form: Continuing

Data signed: (b) (4) 06 Apr 2021 15:40:49

Generated On: 09 Jun 2021 14:52:51

Is the participant continuing to the next visit?

Yes

No

Continuing Flag

1

US3032242

Folder: Safety Call OL-D36 (1)

Form: Safety Call

Data signed: (b) (4) 06 Apr 2021 15:40:49

Generated On: 09 Jun 2021 14:52:51

Was Contact Attempted? Yes
No

Date of Contact or Contact Attempt (*dd MMM yyyy*) 25 MAR 2021

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

Comments

If Contact Not Made, please provide Comments

US3032242

Folder: Safety Call OL-D36 (1)

Form: Continuing

Data signed: (b) (4) 06 Apr 2021 15:40:49

Generated On: 09 Jun 2021 14:52:51

Is the participant continuing to the next visit?

Yes

No

Continuing Flag

1

US3032242

Folder: OL-D57 (1)

Form: Visit Date

Data signed: (b) (4) 14 Apr 2021 19:22:58

Generated On: 09 Jun 2021 14:52:51

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	13 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	OLD57

US3032242

Folder: OL-D57 (1)

Form: Vital Signs

Data signed: (b) (4) 14 Apr 2021 19:22:59

Generated On: 09 Jun 2021 14:52:51

Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (<i>dd MMM yyyy</i>)	13 APR 2021
Time of assessment (<i>00:00-23:59</i>)	12:55 (24 HR)
Vital Signs Date and Time (derived)	13 APR 2021 12:55
Temperature (<i>xxx.x</i>)	36.7 C
Route of measurement	Oral <input checked="" type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	
Pulse (<i>xxx</i>)	55 beats/min
Pulse units	BPM
Respiratory Rate (<i>xxx</i>)	17 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>)	64 mmHg
Diastolic Blood Pressure units	MMHG
Height (derived)	
Weight (derived)	

US3032242

Folder: OL-D57 (1)

Form: Physical Examination

Data signed: (b) (4) 14 Apr 2021 19:22:58

Generated On: 09 Jun 2021 14:52:51

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.

US3032242

Folder: OL-D57 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 14 Apr 2021 19:22:58

Generated On: 09 Jun 2021 14:52:51

Was the sample collected? Yes No

Collection date (*dd MMM yyyy*) 13 APR 2021

Collection time (*00:00-23:59*) 13:04 (24 HR)

Collection date and time (derived) 13 APR 2021 13:04

US3032242

Folder: Adverse Events

Form: Adverse Events Summary

Data signed: (b) (4) 05 Feb 2021 19:41:27

Generated On: 09 Jun 2021 14:52:51

Did the participant experience any adverse events?

Yes

No

If Yes, enter details on the Adverse Events form.

US3032242

Folder: Adverse Events

Form: Adverse Events (1)

Data signed: (b) (4) 03 May 2021 16:17:39

Generated On: 09 Jun 2021 14:52:51

AEID USA-US032-2021-MRNA-1273-P30
1000006

Adverse event ENDOMETRIAL CANCER

Was this a medically-attended AE? Yes
No

Was this a Solicited Adverse Reaction? Yes
No

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

Start date (dd MMM yyyy) 29 DEC 2020

Start time (00:00-23:59)

AE start date and time (derived)

Ongoing? Yes
No

If not Ongoing, end date (dd MMM yyyy)

End time (00:00-23:59)

AE End Date and Time (derived)

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

Is the adverse event serious? Yes
No

AE is serious due To (check all that apply)

Death False

Life threatening False

Requires inpatient or prolongation of existing Hospitalization False

Hospital Admission Date (dd MMM yyyy)

Hospital Discharge Date (dd MMM yyyy)

Admitted to ICU? Yes
No
Unknown

US3032242

Folder: Adverse Events

Form: Adverse Events (1)

Data signed: (b) (4) 03 May 2021 16:17:39

Generated On: 09 Jun 2021 14:52:51

Number of Days in ICU _____

Persistent or significant disability or incapacity False

Congenital anomaly or birth defect False

Other medically important event True

Relationship to investigational product Not Related
Related
Not Applicable

Relationship to Study Procedure Not Related
Related
Not Applicable

Action taken with investigational product None
Dose Delayed
Investigational Product Withdrawn
Not Applicable

Other action taken (check all that apply)

None False

Concomitant Medication False

Concomitant Procedure True

Outcome Fatal
Not Recovered/Not Resolved
Recovered/Resolved
Recovered/Resolved with Sequelae
Recovering/Resolving
Unknown

If outcome is Recovered/Resolved with Sequelae, please specify the sequelae: _____

Narrative

US3032242

Folder: Adverse Events

Form: Adverse Events (1)

Data signed: (b) (4) 03 May 2021 16:17:39

Generated On: 09 Jun 2021 14:52:51

SUBJECT ENTERED IN HER
EDAIRY 05/FEB/2021 THAT
MEDICAL ATTENTION WAS
NEEDED. SITE THEN CALLED
SUBJECT AND SUBJECT
REPORTED THE CANCER AND
THAT SHE HAD A
HYSTERECTOMY 01FEB2021.
MEDICAL RELEASE HAS BEEN
SENT TO SUBJECT. FOLLOW UP
TREATMENT IS UNKNOWN AT
THIS TIME. AWAITING A
PATHOLOGY REPORT.
UPDATE 17FEB2021: MEDICAL
RECORDS RECEIVED AND
REVIEWED. THE SUBJECT WAS
SEEN 23DEC2020 BY HER
OB/GYN FOR EVALUATION OF
POST-MENOPAUSAL VAGINAL
BLEEDING THAT WORSENE
OVER ONE MONTH.
COPOSCOPY WAS PERFORMED
WHICH RESULTED IN RESULTS
OF ENDOMETRIAL
ADENOCARCINOMA GRADE 2/3.
THE SUBJECT HAD NOT HAD A
PAP SMEAR IN THE LAST 25
YEARS. TREATMENT WILL BE
BASED ON RECOMMENDATION
MADE BY THE ONCOLOGIST.
UPDATE 26APR2021: FINAL
DIAGNOSIS FROM SUBJECTS
23DEC2020 ENDOMETRIAL
BIOPSY AND COLPOSCOPY: A)
ENDOCERVICAL POLYP

US3032242

Folder: Adverse Events

Form: Adverse Events (1)

Data signed: (b) (4) 03 May 2021 16:17:39

Generated On: 09 Jun 2021 14:52:51

EXCISION: BENIGN. B)
ENDOCERVIX CURRETAGE:
SCAN BENIGN ECTOCERVICAL
TISSUE, MUCUS, AND
INFLAMMATORY DEBRIS. C)
ENDOMETRIAL BIOPSY:
ADENOCARCINOMA, GRADE
2/3.
UPDATE 29APR2021:
GYNECOLOGIST ONCOLOGIST
PERFORMED
DAVINCI-ASSISTED TOTAL
LAPAROSCOPIC
HYSTERECTOMY W/
BILATERAL OOPHORECTOMY
AND RIGHT PELVIC SENTINEL
LYMPH NODE BIOPSY.
PATHOLOGY REVEALED
ENDOMETRIAL CANCER FIGO
GRADE 3 WITH A 2.7X2.5X1.0
CM MASS WHICH EXTENDED
DEEP INTO THE MYOMETRIUM
AND LYMPHOVASCULAR
INVASION WAS PRESENT. THE
RIGHT PELVIC SENTINEL
LYMPH NODE WAS BIOPSIED
AND NEGATIVE FOR
CARCINOMA. SHE WAS
TREATED WITH RADIATION
(4500 CGY DELIVERED OM 25
FRACTIONS) FINAL
PATHOLOGY CONSISTENT
WITH GRADE 3 HISTOLOGY,
STAGE 1B WITH >95%
MYOMETRIAL INVASION TLVSI

US3032242

Folder: Adverse Events

Form: Adverse Events (1)

Data signed: (b) (4) 03 May 2021 16:17:39

Generated On: 09 Jun 2021 14:52:51

NEGATIVE RIGHT PELVIC SLN.
SUBJECT HAS COMPLETED
RADIATION TREATMENTS. SHE
WILL BEGIN CHEMOTHERAPY
(TAXOL/CARBOPLATIN) ON
12MAY2021.

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

US3032242

Folder: Adverse Events

Form: Adverse Events (2)

Data signed: (b) (4) 03 May 2021 16:17:39

Generated On: 09 Jun 2021 14:52:51

AEID

Adverse event

POSTMENOPAUSAL VAGINAL
BLEEDING

Was this a medically-attended AE?

Yes
No

Was this a Solicited Adverse Reaction?

Yes
No

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

Yes
No

Start date (dd MMM yyyy)

23 NOV 2020

Start time (00:00-23:59)

AE start date and time (derived)

Ongoing?

Yes
No

If not Ongoing, end date (dd MMM yyyy)

1 FEB 2021

End time (00:00-23:59)

AE End Date and Time (derived)

Severity

Grade 1/Mild
Grade 2/Moderate
Grade 3/Severe
Grade 4

Is the adverse event serious?

Yes
No

AE is serious due To (check all that apply)

Death False

Life threatening False

Requires inpatient or prolongation of existing Hospitalization False

Hospital Admission Date (dd MMM yyyy)

Hospital Discharge Date (dd MMM yyyy)

Admitted to ICU?

Yes
No
Unknown

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EAB) (1725)

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Folder: Adverse Events

Form: Adverse Events (2)

Data signed: (b) (4) 03 May 2021 16:17:39

Generated On: 09 Jun 2021 14:52:51

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

US3032242

Folder: Adverse Events

Form: Adverse Events (3)

Data signed: (b) (4) 03 May 2021 16:17:39

Generated On: 09 Jun 2021 14:52:51

AEID	
Adverse event	CERVICAL POLYP
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)	23 DEC 2020
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)	23 DEC 2020
End time (00:00-23:59)	
AE End Date and Time (derived)	
Severity	Grade 1/Mild <input checked="" type="radio"/> Grade 2/Moderate <input type="radio"/> Grade 3/Severe <input type="radio"/> Grade 4 <input type="radio"/>
Is the adverse event serious?	Yes <input type="radio"/> No <input checked="" type="radio"/>
AE is serious due To (check all that apply)	
Death	False
Life threatening	False
Requires inpatient or prolongation of existing Hospitalization	False
Hospital Admission Date (dd MMM yyyy)	
Hospital Discharge Date (dd MMM yyyy)	
Admitted to ICU?	Yes <input type="radio"/> No <input type="radio"/> Unknown <input type="radio"/>
Number of Days in ICU	

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EAB) (1725)

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Folder: Adverse Events

Form: Adverse Events (3)

Data signed: (b) (4) 03 May 2021 16:17:39

Generated On: 09 Jun 2021 14:52:51

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

US3032242

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination Summary

Data signed: (b) (4) 01 Oct 2020 22:01:36

Generated On: 09 Jun 2021 14:52:51

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

Yes

No

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

US3032242

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Data signed: (b) (4) 03 May 2021 16:17:39

Generated On: 09 Jun 2021 14:52:51

Name of Medication LISINOPRIL

Prophylaxis Yes
No

Indication HYPERTENSION

Dose per administration 20

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 (1)

Data signed: (b) (4) 03 May 2021 16:17:39

Generated On: 09 Jun 2021 14:52:51

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
No

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

Was this medication taken for solicited event? Yes
No

Separate Dosage Number (derived) 1

Interval Dosage Unit Number (derived) 1

Interval Dosage Definition (derived) 802
803
804

US3032242

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Data signed: (b) (4) 03 May 2021 16:17:39

Generated On: 09 Jun 2021 14:52:51

Name of Medication PANTOPRAZOLE

Prophylaxis Yes
No

Indication GASTROESOPHAGEAL REFLUX DISEASE

Dose per administration 40

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

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EAB) (1725)

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Data signed: (b) (4) 03 May 2021 16:17:39

Generated On: 09 Jun 2021 14:52:51

	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)	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"/>

US3032242

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Data signed: (b) (4) 03 May 2021 16:17:39

Generated On: 09 Jun 2021 14:52:51

Name of Medication ASPIRIN

Prophylaxis Yes
No

Indication CARDIAC PROPHYLAXIS

Dose per administration 81

Dose unit mg
ug
mL
g
IU
tablet
capsule
puff
Other

If dose unit is Other, specify

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

If frequency is Other, specify

Route of administration Oral
Topical
Subcutaneous
Transdermal
Intraocular

PRODUCTION RELEASE (v12.003
EAB) (1725)

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Data signed: (b) (4) 03 May 2021 16:17:39

Generated On: 09 Jun 2021 14:52:51

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
No

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

Was this medication taken for solicited event? Yes
No

Separate Dosage Number (derived) 1

Interval Dosage Unit Number (derived) 1

Interval Dosage Definition (derived) 802
803
804

US3032242

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Data signed: (b) (4) 03 May 2021 16:17:39

Generated On: 09 Jun 2021 14:52:51

Name of Medication PEPCID

Prophylaxis Yes
No

Indication GASTROESOPHAGEAL REFLUX
DISEASE

Dose per administration 40

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Data signed: (b) (4) 03 May 2021 16:17:39

Generated On: 09 Jun 2021 14:52:51

	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)	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"/>

US3032242

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Data signed: (b) (4) 03 May 2021 16:17:39

Generated On: 09 Jun 2021 14:52:51

Name of Medication ADVIL

Prophylaxis Yes
No

Indication KNEE PAIN

Dose per administration 400

Dose unit mg
ug
mL
g
IU
tablet
capsule
puff
Other

If dose unit is Other, specify _____

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

If frequency is Other, specify _____

Route of administration Oral
Topical
Subcutaneous
Transdermal
Intraocular

US3032242

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Data signed: (b) (4) 03 May 2021 16:17:39

Generated On: 09 Jun 2021 14:52:51

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 2016

Start date completely unknown False

Ongoing? Yes
No

If not Ongoing, End date (*dd MMM yyyy*) 25 JAN 2021

Was this medication taken for solicited event? Yes
No

Separate Dosage Number (derived) _____

Interval Dosage Unit Number (derived) _____

Interval Dosage Definition (derived) 802
803
804

US3032242

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Data signed: (b) (4) 03 May 2021 16:17:39

Generated On: 09 Jun 2021 14:52:51

Name of Medication INFLUENZA VACCINE

Prophylaxis Yes
No

Indication FLU VACCINE

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

US3032242

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Data signed: (b) (4) 03 May 2021 16:17:39

Generated On: 09 Jun 2021 14:52:51

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*) 02 OCT 2020

Start date completely unknown False

Ongoing? Yes
No

If not Ongoing, End date (*dd MMM yyyy*) 02 OCT 2020

Was this medication taken for solicited event? Yes
No

Separate Dosage Number (derived) _____

Interval Dosage Unit Number (derived) _____

Interval Dosage Definition (derived) 802
803
804

US3032242

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Data signed: (b) (4) 03 May 2021 16:17:39

Generated On: 09 Jun 2021 14:52:51

Name of Medication ACETAMINOPHEN

Prophylaxis Yes
No

Indication KNEE PAIN

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

PRODUCTION RELEASE (v12.003
EAB) (1725)

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US3032242

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Data signed: (b) (4) 03 May 2021 16:17:39

Generated On: 09 Jun 2021 14:52:51

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*) 01 FEB 2021

Start date completely unknown False

Ongoing? Yes
No

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

Was this medication taken for solicited event? Yes
No

Separate Dosage Number (derived) 4

Interval Dosage Unit Number (derived) 1

Interval Dosage Definition (derived) 802
803
804

US3032242

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Data signed: (b) (4) 03 May 2021 16:17:39

Generated On: 09 Jun 2021 14:52:51

Name of Medication HYDROCHLOROTHIAZIDE

Prophylaxis Yes
No

Indication HYPERTENSION

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

PRODUCTION RELEASE (v12.003
EAB) (1725)

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US3032242

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Data signed: (b) (4) 03 May 2021 16:17:39

Generated On: 09 Jun 2021 14:52:51

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
No

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

Was this medication taken for solicited event? Yes
No

Separate Dosage Number (derived) 1

Interval Dosage Unit Number (derived) 1

Interval Dosage Definition (derived) 802
803
804

US3032242

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Data signed: (b) (4) 03 May 2021 16:17:39

Generated On: 09 Jun 2021 14:52:51

Name of Medication MEDROXYPROGESTERONE

Prophylaxis Yes
No

Indication POSTMENOPAUSAL VAGINAL BLEEDING

Dose per administration 10

Dose unit mg
ug
mL
g
IU
tablet
capsule
puff
Other

If dose unit is Other, specify _____

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

If frequency is Other, specify _____

Route of administration Oral
Topical
Subcutaneous
Transdermal

PRODUCTION RELEASE (v12.003
EAB) (1725)

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US3032242

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Data signed: (b) (4) 03 May 2021 16:17:39

Generated On: 09 Jun 2021 14:52:51

	Intraocular	<input type="radio"/>
	Intramuscular	<input 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)	22 DEC 2020
--------------------------	-------------

Start date completely unknown	False
-------------------------------	-------

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

If not Ongoing, End date (dd MMM yyyy)	01 JAN 2021
--	-------------

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"/>

US3032242

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Data signed: (b) (4) 03 May 2021 16:17:39

Generated On: 09 Jun 2021 14:52:51

Name of Medication NORMAL SALINE

Prophylaxis Yes
No

Indication HYSTERECTOMY

Dose per administration 750

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

US3032242

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Data signed: (b) (4) 03 May 2021 16:17:39

Generated On: 09 Jun 2021 14:52:51

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 checked="" 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*) 01 FEB 2021

Start date completely unknown False

Ongoing? Yes
No

If not Ongoing, End date (*dd MMM yyyy*) 01 FEB 2021

Was this medication taken for solicited event? Yes
No

Separate Dosage Number (derived) _____

Interval Dosage Unit Number (derived) _____

Interval Dosage Definition (derived) 802
803
804

US3032242

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Data signed: (b) (4) 03 May 2021 16:17:39

Generated On: 09 Jun 2021 14:52:51

Name of Medication TRAMADOL

Prophylaxis Yes
No

Indication HYSTERECTOMY

Dose per administration 50

Dose unit mg
ug
mL
g
IU
tablet
capsule
puff
Other

If dose unit is Other, specify

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

If frequency is Other, specify

Route of administration Oral
Topical
Subcutaneous
Transdermal
Intraocular

PRODUCTION RELEASE (v12.003
EAB) (1725)

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US3032242

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Data signed: (b) (4) 03 May 2021 16:17:39

Generated On: 09 Jun 2021 14:52:51

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*) 01 FEB 2021

Start date completely unknown False

Ongoing? Yes
No

If not Ongoing, End date (*dd MMM yyyy*) 15 FEB 2021

Was this medication taken for solicited event? Yes
No

Separate Dosage Number (derived) _____

Interval Dosage Unit Number (derived) _____

Interval Dosage Definition (derived) 802
803
804

US3032242

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Data signed: (b) (4) 03 May 2021 16:17:39

Generated On: 09 Jun 2021 14:52:51

Name of Medication VITAMIN D3

Prophylaxis Yes
No

Indication ENDOMETRIAL CANCER

Dose per administration 5000

Dose unit mg
ug
mL
g
IU
tablet
capsule
puff
Other

If dose unit is Other, specify UNITS

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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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Data signed: (b) (4) 03 May 2021 16:17:39

Generated On: 09 Jun 2021 14:52:51

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*) 01 FEB 2021

Start date completely unknown False

Ongoing? Yes
No

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

Was this medication taken for solicited event? Yes
No

Separate Dosage Number (derived) 1

Interval Dosage Unit Number (derived) 1

Interval Dosage Definition (derived) 802
803
804

US3032242

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Data signed: (b) (4) 03 May 2021 16:17:39

Generated On: 09 Jun 2021 14:52:51

Name of Medication DOCUSATE SODIUM

Prophylaxis Yes
No

Indication HYSTERECTOMY

Dose per administration 200

Dose unit mg
ug
mL
g
IU
tablet
capsule
puff
Other

If dose unit is Other, specify _____

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

If frequency is Other, specify _____

Route of administration Oral
Topical
Subcutaneous
Transdermal
Intraocular

PRODUCTION RELEASE (v12.003
EAB) (1725)

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US3032242

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Data signed: (b) (4) 03 May 2021 16:17:39

Generated On: 09 Jun 2021 14:52:51

Intramuscular	<input 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*) 02 FEB 2021

Start date completely unknown False

Ongoing? Yes
No

If not Ongoing, End date (*dd MMM yyyy*) 15 FEB 2021

Was this medication taken for solicited event? Yes
No

Separate Dosage Number (derived) 1

Interval Dosage Unit Number (derived) 1

Interval Dosage Definition (derived) 802
803
804

US3032242

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Data signed: (b) (4) 03 May 2021 16:17:39

Generated On: 09 Jun 2021 14:52:51

Name of Medication 0.5% ROPIVACAINE

Prophylaxis Yes
No

Indication HYSTERECTOMY

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

PRODUCTION RELEASE (v12.003
EAB) (1725)

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US3032242

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Data signed: (b) (4) 03 May 2021 16:17:39

Generated On: 09 Jun 2021 14:52:51

	Intramuscular	<input 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 checked="" type="radio"/>

If route of administration is Other, specify	EPIDURAL
Start date (<i>dd MMM yyyy</i>)	01 FEB 2021
Start date completely unknown	False
Ongoing?	Yes <input type="radio"/> No <input checked="" type="radio"/>
If not Ongoing, End date (<i>dd MMM yyyy</i>)	01 FEB 2021
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"/>

US3032242

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures Summary

Data signed: (b) (4) 05 Feb 2021 19:41:27

Generated On: 09 Jun 2021 14:52:51

Were any concomitant procedures performed?

Yes

No

If yes, please complete Concomitant Procedures form.

US3032242

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures

Data signed: (b) (4) 03 May 2021 16:17:40

Generated On: 09 Jun 2021 14:52:51

Procedure/Surgery date (dd MMM yyyy)	Procedure/Surgery	Indication	If indication is Other, specify
01 FEB 2021	HYSTERECTOMY	Adverse Event	
22 MAR 2021	RADIATION TO PELVIC REGION	Adverse Event	
23 DEC 2020	COLPOSCOPY	Adverse Event	
23 SEP 2020	ENDOMETRIAL BIOPSY	Adverse Event	
23 DEC 2020	LOCAL EXCISION OF CERVICAL POLYP	Adverse Event	
22 DEC 2020	PELVIC ULTRASOUND	Adverse Event	
22 DEC 2020	COMPLETE BLOOD COUNT	Adverse Event	
01 FEB 2021	BILATERAL SALPINGO-OOPHORECTOMY	Adverse Event	
01 FEB 2021	RIGHT PELVIC SENTINEL LYMPH NODE BIOPSY	Adverse Event	
01 FEB 2021	EXCISION OF A LEFT VULVAR INTRADERMAL MELANOCYTIC NEVUS	Adverse Event	
14 JAN 2021	CT OF ABDOMEN	Adverse Event	
01 FEB 2021	FOLEY CATHETER	Adverse Event	
15 FEB 2021	CT OF CHEST	Adverse Event	

US3032242

Folder: End of Study (1)

Form: Dosing Discontinuation

Generated On: 09 Jun 2021 14:52:51

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

US3032242

Folder: End of Study (1)

Form: End of Study / Study Discontinuation

Generated On: 09 Jun 2021 14:52:51

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

US3032242

Folder: SAE USA-US032-2021-MRNA-1273-P301000006

Form: Safety Report Form

Data signed: (b) (4) 03 May 2021 16:17:40

Generated On: 09 Jun 2021 14:52:51

SAEID	USA-US032-2021-MRNA-1273-P30 1000006
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 type="radio"/> No <input checked="" 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 checked="" type="radio"/> No <input type="radio"/>
Investigator's First Name	KEITH
Investigator's Last Name	VRBICKY
Site Address: Street	_____
Site Address: City	_____
Site Address: State	_____
Site Address: Postal Code	_____
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	7

US3032242

Folder: SAE USA-US032-2021-MRNA-1273-P301000006

Form: Safety Report Form (1)

Data signed: (b) (4) 03 May 2021 16:17:40

Generated On: 09 Jun 2021 14:52:51

SAEID	USA-US032-2021-MRNA-1273-P301000006
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 type="radio"/> No <input checked="" 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 checked="" type="radio"/> No <input type="radio"/>
Investigator's First Name	KEITH
Investigator's Last Name	VRBICKY
Site Address: Street	
Site Address: City	
Site Address: State	
Site Address: Postal Code	
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	7
Date of submission (Pre-filled from custom function)	08/FEB/2021 15:49
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.	<input checked="" type="checkbox"/> True

US3032242

Folder: SAE USA-US032-2021-MRNA-1273-P301000006

Form: Safety Report Form (2)

Data signed: (b) (4) 03 May 2021 16:17:40

Generated On: 09 Jun 2021 14:52:51

SAEID	USA-US032-2021-MRNA-1273-P301000006
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 type="radio"/> No <input checked="" 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 checked="" type="radio"/> No <input type="radio"/>
Investigator's First Name	KEITH
Investigator's Last Name	VRBICKY
Site Address: Street	
Site Address: City	
Site Address: State	
Site Address: Postal Code	
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	7
Date of submission (Pre-filled from custom function)	19/FEB/2021 12:44
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.	<input checked="" type="checkbox"/> True

US3032242

Folder: SAE USA-US032-2021-MRNA-1273-P301000006

Form: Safety Report Form (3)

Data signed: (b) (4) 03 May 2021 16:17:40

Generated On: 09 Jun 2021 14:52:51

SAEID	USA-US032-2021-MRNA-1273-P301000006
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 type="radio"/> No <input checked="" 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 checked="" type="radio"/> No <input type="radio"/>
Investigator's First Name	KEITH
Investigator's Last Name	VRBICKY
Site Address: Street	_____
Site Address: City	_____
Site Address: State	_____
Site Address: Postal Code	_____
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	7
Date of submission (Pre-filled from custom function)	24/FEB/2021 07:45
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

US3032242

Folder: SAE USA-US032-2021-MRNA-1273-P301000006

Form: Safety Report Form (4)

Data signed: (b) (4) 03 May 2021 16:17:40

Generated On: 09 Jun 2021 14:52:51

SAEID	USA-US032-2021-MRNA-1273-P301000006
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 type="radio"/> No <input checked="" 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 checked="" type="radio"/> No <input type="radio"/>
Investigator's First Name	KEITH
Investigator's Last Name	VRBICKY
Site Address: Street	
Site Address: City	
Site Address: State	
Site Address: Postal Code	
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	7
Date of submission (Pre-filled from custom function)	06/APR/2021 15:03
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.	<input checked="" type="checkbox"/> True

US3032242

Folder: SAE USA-US032-2021-MRNA-1273-P301000006

Form: Safety Report Form (5)

Data signed: (b) (4) 03 May 2021 16:17:40

Generated On: 09 Jun 2021 14:52:51

SAEID	USA-US032-2021-MRNA-1273-P301000006
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 type="radio"/> No <input checked="" 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 checked="" type="radio"/> No <input type="radio"/>
Investigator's First Name	KEITH
Investigator's Last Name	VRBICKY
Site Address: Street	_____
Site Address: City	_____
Site Address: State	_____
Site Address: Postal Code	_____
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	7
Date of submission (Pre-filled from custom function)	19/APR/2021 10:39
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.	<input checked="" type="checkbox"/> True

US3032242

Folder: SAE USA-US032-2021-MRNA-1273-P301000006

Form: Safety Report Form (6)

Data signed: (b) (4) 03 May 2021 16:17:40

Generated On: 09 Jun 2021 14:52:51

SAEID	USA-US032-2021-MRNA-1273-P301000006
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 type="radio"/> No <input checked="" 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 checked="" type="radio"/> No <input type="radio"/>
Investigator's First Name	KEITH
Investigator's Last Name	VRBICKY
Site Address: Street	
Site Address: City	
Site Address: State	
Site Address: Postal Code	
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	7
Date of submission (Pre-filled from custom function)	26/APR/2021 16:03
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.	<input checked="" type="checkbox"/> True

US3032242

Folder: SAE USA-US032-2021-MRNA-1273-P301000006

Form: Safety Report Form (7)

Data signed: (b) (4) 03 May 2021 16:17:40

Generated On: 09 Jun 2021 14:52:51

SAEID	USA-US032-2021-MRNA-1273-P301000006
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 type="radio"/> No <input checked="" 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 checked="" type="radio"/> No <input type="radio"/>
Investigator's First Name	KEITH
Investigator's Last Name	VRBICKY
Site Address: Street	
Site Address: City	
Site Address: State	
Site Address: Postal Code	
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	7
Date of submission (Pre-filled from custom function)	30/APR/2021 10:33
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

US3032242 (Prod: Meridian Clinical Research (Norfolk-Nebraska))

US3032242

Form: Participant Creation

Generated On: 09 Jun 2021 14:52:51

[Participant ID](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 15:11:08
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 17:47:49
User entered 'US3032242'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	19 Aug 2020 20:19:19

US3032242

Folder: Screening

Form: Visit Date

Generated On: 09 Jun 2021 14:52:51

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:55:39
DataPoint Verified.	(b) (4), (b) (6)	03 Dec 2020 16:33:43
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 17:47:49
User entered 'Yes (Y)'	(b) (4) Linden DeBoer (b) (4)	01 Sep 2020 13:33:07

US3032242

Folder: Screening

Form: Visit Date

Generated On: 09 Jun 2021 14:52:51

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:55:39
DataPoint Verified.		03 Dec 2020 16:33:43
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 17:47:49
User entered '19 AUG 2020'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	19 Aug 2020 20:19:20

US3032242

Folder: Screening

Form: Visit Date

Generated On: 09 Jun 2021 14:52:51

[Was visit performed at the participant's home or at the clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:55:39
DataPoint Verified.		03 Dec 2020 16:33:43
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 17:47:49
User entered 'Clinic (Clinic)'	(b) (4) Linden DeBoer (b) (4) (b) (4)	01 Sep 2020 13:33:07

US3032242

Folder: Screening

Form: Visit Date

Generated On: 09 Jun 2021 14:52:51

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:55:39
User entered 'SCRN'	System	01 Sep 2020 13:33:07

US3032242

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 14:52:51

Date of Birth (MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:55:39
DataPoint Verified.		03 Dec 2020 16:33:52
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 17:47:49
User entered (b) (6) 1947'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	19 Aug 2020 20:19:21

US3032242

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 14:52:51

[Age](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:55:39
DataPoint Verified.		03 Dec 2020 16:33:52
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 17:47:49
User entered '72'	(b) (4) Linden DeBoer (b) (4) (b) (4)	01 Sep 2020 13:33:23

US3032242

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 14:52:51

[Age Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:55:39
User entered 'YEARS'	System	01 Sep 2020 13:33:23

US3032242

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 14:52:51

[Age \(Derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:55:39
User entered '72'	System	19 Aug 2020 21:22:45

US3032242

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 14:52:51

[Sex](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:55:39
DataPoint Verified.		03 Dec 2020 16:33:52
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 17:47:49
User entered 'Female (F)'	(b) (4) Linden DeBoer (b) (4) (b) (4)	01 Sep 2020 13:33:23

US3032242

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 14:52:51

[Ethnicity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:55:39
DataPoint Verified.		03 Dec 2020 16:33:52
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 17:47:49
User entered 'Not Hispanic or Latino (NOT HISPANIC OR LATINO)'	(b) (4) Linden DeBoer (b) (4)	01 Sep 2020 13:33:23
	(b) (4)	

US3032242

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 14:52:51

White

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:55:39
DataPoint Verified.		03 Dec 2020 16:33:52
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 17:47:49
User entered '1'	(b) (4) Linden DeBoer (b) (4)	01 Sep 2020 13:33:23
	(b) (4)	

US3032242

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 14:52:51

[Black](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:55:39
DataPoint Verified.	(b) (4)	03 Dec 2020 16:33:52
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 17:47:49
User entered '0'	(b) (4) Linden DeBoer (b) (4)	01 Sep 2020 13:33:23
	(b) (4)	

US3032242

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 14:52:51

[Asian](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:55:39
DataPoint Verified.		03 Dec 2020 16:33:52
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 17:47:49
User entered '0'	(b) (4) Linden DeBoer (b) (4) (b) (4)	01 Sep 2020 13:33:23

US3032242

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 14:52:51

[American Indian or Alaska Native](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:55:39
DataPoint Verified.		03 Dec 2020 16:33:52
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 17:47:49
User entered '0'	(b) (4) Linden DeBoer (b) (4) (b) (4)	01 Sep 2020 13:33:23

US3032242

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 14:52:51

[Native Hawaiian or other Pacific Islander](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:55:39
DataPoint Verified.		03 Dec 2020 16:33:52
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 17:47:49
User entered '0'	(b) (4) Linden DeBoer (b) (4) (b) (4)	01 Sep 2020 13:33:23

US3032242

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 14:52:51

[Other](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:55:39
DataPoint Verified.		03 Dec 2020 16:33:52
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 17:47:49
User entered '0'	(b) (4) Linden DeBoer (b) (4)	01 Sep 2020 13:33:23
	(b) (4)	

US3032242

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 14:52:51

If race is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:55:39
DataPoint Verified.		03 Dec 2020 16:33:52
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 17:47:49
User entered empty.	(b) (4) Linden DeBoer (b) (4)	01 Sep 2020 13:33:23
	(b) (4)	

US3032242

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 14:52:51

Unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:55:39
DataPoint Verified.		03 Dec 2020 16:33:52
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 17:47:49
User entered '0'	(b) (4) Linden DeBoer (b) (4) (b) (4)	01 Sep 2020 13:33:23

US3032242

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 14:52:51

Not reported

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:55:39
DataPoint Verified.		03 Dec 2020 16:33:52
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 17:47:49
User entered '0'	(b) (4) Linden DeBoer (b) (4) (b) (4)	01 Sep 2020 13:33:23

US3032242

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 14:52:51

Date of Informed Consent (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:55:39
DataPoint Verified.		03 Dec 2020 16:33:56
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 17:47:49
User entered '19 Aug 2020'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	19 Aug 2020 21:22:45

US3032242

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 14:52:51

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:55:39
User entered 'Aug 2020'	System	19 Aug 2020 21:22:45

US3032242

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 14:52:51

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:55:39
User entered '2020'	System	19 Aug 2020 21:22:45

US3032242

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 14:52:51

[Protocol Version](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:55:39
DataPoint Verified.		03 Dec 2020 16:33:56
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 17:47:49
User entered 'Amendment 2 (2)'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	19 Aug 2020 21:22:45

US3032242

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 14:52:51

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:55:39
DataPoint Verified.		03 Dec 2020 16:33:56
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 17:47:49
User entered 'Yes (Y)'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	19 Aug 2020 21:22:45

US3032242

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 14:52:51

If No, indicate reason for screen fail

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:55:39
DataPoint Verified.		03 Dec 2020 16:33:56
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 17:47:49
User entered empty.	(b) (4) Kelsey Kelley (b) (4) (b) (4)	19 Aug 2020 21:22:45

US3032242

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 14:52:51

If reason for screen fail is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:55:39
DataPoint Verified.		03 Dec 2020 16:33:56
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 17:47:49
User entered empty.	(b) (4) Kelsey Kelley (b) (4) (b) (4)	19 Aug 2020 21:22:45

US3032242

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 14:52:51

[Was this participant screened previously?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:55:39
DataPoint Verified.		03 Dec 2020 16:33:56
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 17:47:49
User entered 'No (N)'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	19 Aug 2020 21:22:45

US3032242

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 14:52:51

[If Yes, previous participant number](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:55:39
DataPoint Verified.		03 Dec 2020 16:33:56
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 17:47:49
User entered empty.	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	19 Aug 2020 20:19:20

US3032242

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 14:52:51

[Enrollment Trigger](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:55:39
User entered '1'	System	19 Aug 2020 21:22:45

US3032242

Folder: Screening

Form: Inclusion/Exclusion Criteria Summary

Generated On: 09 Jun 2021 14:52:51

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:55:39
DataPoint Verified.	(b) (4)	03 Dec 2020 16:34:07
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 17:47:49
User entered 'Yes (Y)'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	19 Aug 2020 21:22:33

US3032242

Folder: Screening

Form: Medical History Summary

Generated On: 09 Jun 2021 14:52:51

[Were any significant conditions reported?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:55:39
User signature succeeded.	Keith Vrbicky (b) (4) (b) (4)	28 Sep 2020 17:47:49
User entered 'Yes (Y)'	Linden DeBoer (b) (4) (b) (4)	01 Sep 2020 13:33:59

US3032242

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 14:52:51

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:55:39
DataPoint Verified.	(b) (4)	03 Dec 2020 16:35:40
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 17:47:49
User coded data point as SOC: Social circumstances, HLT: Age related factors, HLT: Age related issues, PT: Postmenopause, LLT: Postmenopause - version MedDRA\\23.0.	(b) (4) Coder Import (b) (4)	01 Sep 2020 13:42:03
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	01 Sep 2020 13:42:03
Data point term sent to Coder	System	01 Sep 2020 13:35:06
User entered 'postmenopausal'	Linden DeBoer (b) (4) (b) (4)	01 Sep 2020 13:34:39

US3032242

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 14:52:51

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:55:39
DataPoint Verified.	(b) (4)	03 Dec 2020 16:35:40
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 17:47:49
User entered 'un UNK 1995'	(b) (4) Linden DeBoer (b) (4) (b) (4)	01 Sep 2020 13:34:39

US3032242

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 14:52:51

Start date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:55:39
DataPoint Verified.		03 Dec 2020 16:35:40
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 17:47:49
User entered '0'	(b) (4) Linden DeBoer (b) (4)	01 Sep 2020 13:34:39
	(b) (4)	

US3032242

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 14:52:51

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:55:39
DataPoint Verified.		03 Dec 2020 16:35:40
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 17:47:49
User entered 'Yes (Y)'	(b) (4) Linden DeBoer (b) (4)	01 Sep 2020 13:34:39
	(b) (4)	

US3032242

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 14:52:51

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:55:39
DataPoint Verified.		03 Dec 2020 16:35:40
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 17:47:49
User entered empty.	(b) (4) Linden DeBoer (b) (4)	01 Sep 2020 13:34:39
	(b) (4)	

US3032242

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 14:52:51

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:55:39
DataPoint Verified.		03 Dec 2020 16:35:40
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 17:47:49
User entered '0'	(b) (4) Linden DeBoer (b) (4) (b) (4)	01 Sep 2020 13:34:39

US3032242

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 14:52:51

Start Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:55:39
User entered 'Jan 1995'	System	01 Sep 2020 13:34:39

US3032242

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 14:52:51

Start Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:55:39
User entered '1995'	System	01 Sep 2020 13:34:39

US3032242

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 14:52:51

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:55:39
User entered empty.	System	01 Sep 2020 13:34:39

US3032242

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 14:52:51

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:55:39
User entered empty.	System	01 Sep 2020 13:34:39

US3032242

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 14:52:51

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:55:39
DataPoint Verified.		03 Dec 2020 16:35:40
User closed query 'Per DM CLR: Please note that there is no Con Med listed for treatment of this condition and treatment would be expected for this condition. Please review and if applicable add a Con Med or provide an explanation for no medical treatment. ' (Site from DM).		01 Oct 2020 07:55:24
Query 'Per DM CLR: Please note that there is no Con Med listed for treatment of this condition and treatment would be expected for this condition. Please review and if applicable add a Con Med or provide an explanation for no medical treatment. ' answered with 'updated' (Site from DM).	Samantha Wieseler (b) (4) (b) (4)	30 Sep 2020 22:03:52
User opened query 'Per DM CLR: Please note that there is no Con Med listed for treatment of this condition and treatment would be expected for this condition. Please review and if applicable add a Con Med or provide an explanation for no medical treatment. ' (Site from DM).	(b) (4), (b) (6)	29 Sep 2020 11:56:12
User signature succeeded.	Keith Vrbicky (b) (4) (b) (4)	28 Sep 2020 17:47:49
User coded data point as SOC: Vascular disorders, HLGT: Vascular hypertensive disorders, HLT: Vascular hypertensive disorders NEC, PT: Hypertension, LLT: Hypertension - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	01 Sep 2020 13:42:04
User coded data point as Term Coded data point by User: Coder System - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	01 Sep 2020 13:42:04
Data point term sent to Coder	System	01 Sep 2020 13:35:06
User entered 'hypertension'	Linden DeBoer (b) (4) (b) (4)	01 Sep 2020 13:34:53

US3032242

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 14:52:51

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:55:39
DataPoint Verified.	(b) (4)	03 Dec 2020 16:35:40
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 17:47:49
User entered 'un UNK 2010'	(b) (4) Linden DeBoer (b) (4)	01 Sep 2020 13:34:53
	(b) (4)	

US3032242

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 14:52:51

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:55:39
DataPoint Verified.		03 Dec 2020 16:35:40
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 17:47:49
User entered '0'	(b) (4) Linden DeBoer (b) (4)	01 Sep 2020 13:34:53
	(b) (4)	

US3032242

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 14:52:51

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:55:39
DataPoint Verified.	(b) (4)	03 Dec 2020 16:35:40
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 17:47:49
User entered 'Yes (Y)'	(b) (4) Linden DeBoer (b) (4)	01 Sep 2020 13:34:53
	(b) (4)	

US3032242

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 14:52:51

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:55:39
DataPoint Verified.		03 Dec 2020 16:35:40
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 17:47:49
User entered empty.	(b) (4) Linden DeBoer (b) (4)	01 Sep 2020 13:34:53
	(b) (4)	

US3032242

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 14:52:51

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:55:39
DataPoint Verified.		03 Dec 2020 16:35:40
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 17:47:49
User entered '0'	(b) (4) Linden DeBoer (b) (4)	01 Sep 2020 13:34:53
	(b) (4)	

US3032242

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 14:52:51

Start Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:55:39
User entered 'Jan 2010'	System	01 Sep 2020 13:34:53

US3032242

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 14:52:51

Start Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:55:39
User entered '2010'	System	01 Sep 2020 13:34:53

US3032242

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 14:52:51

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:55:39
User entered empty.	System	01 Sep 2020 13:34:53

US3032242

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 14:52:51

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:55:39
User entered empty.	System	01 Sep 2020 13:34:53

US3032242

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 14:52:51

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:55:39
DataPoint Verified.	(b) (4)	03 Dec 2020 16:35:40
User signature succeeded.	Keith Vrbicky (b) (4)	24 Nov 2020 20:29:22
User coded data point as SOC: Gastrointestinal disorders, HLG: Gastrointestinal motility and defaecation conditions, HLT: Gastrointestinal atonic and hypomotility disorders NEC, PT: Gastroesophageal reflux disease, LLT: Acid reflux (esophageal) - version MedDRA\\23.0.	(b) (4) (b) (4) Coder Import (b) (4)	24 Nov 2020 19:17:10
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	24 Nov 2020 19:17:10
Data point term sent to Coder	System	24 Nov 2020 19:15:46
Coding entries removed.	Linden DeBoer (b) (4)	24 Nov 2020 19:15:07
Signature has been broken.	(b) (4) Linden DeBoer (b) (4)	24 Nov 2020 19:15:07
User entered 'acid reflux' reason for change: Data Entry Error	(b) (4) Linden DeBoer (b) (4)	24 Nov 2020 19:15:07
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 17:47:49
User coded data point as SOC: Gastrointestinal disorders, HLG: Gastrointestinal motility and defaecation conditions, HLT: Gastrointestinal atonic and hypomotility disorders NEC, PT: Gastroesophageal reflux disease, LLT: Gastroesophageal reflux disease - version MedDRA\\23.0.	(b) (4) Coder Import (b) (4)	01 Sep 2020 13:42:05
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	01 Sep 2020 13:42:05
Data point term sent to Coder	System	01 Sep 2020 13:36:09
User entered 'gastroesophageal reflux disease'	Linden DeBoer (b) (4)	01 Sep 2020 13:36:01

US3032242

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 14:52:51

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:55:39
DataPoint Verified.		03 Dec 2020 16:35:40
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 17:47:49
User entered 'un UNK 2010'	(b) (4) Linden DeBoer (b) (4)	01 Sep 2020 13:36:01
	(b) (4)	

US3032242

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 14:52:51

Start date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:55:39
DataPoint Verified.		03 Dec 2020 16:35:40
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 17:47:49
User entered '0'	(b) (4) Linden DeBoer (b) (4) (b) (4)	01 Sep 2020 13:36:01

US3032242

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 14:52:51

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:55:39
DataPoint Verified.	(b) (4)	03 Dec 2020 16:35:40
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 17:47:49
User entered 'Yes (Y)'	(b) (4) Linden DeBoer (b) (4)	01 Sep 2020 13:36:01
	(b) (4)	

US3032242

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 14:52:51

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:55:39
DataPoint Verified.		03 Dec 2020 16:35:40
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 17:47:49
User entered empty.	(b) (4) Linden DeBoer (b) (4)	01 Sep 2020 13:36:01
	(b) (4)	

US3032242

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 14:52:51

Stop date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:55:39
DataPoint Verified.		03 Dec 2020 16:35:40
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 17:47:49
User entered '0'	(b) (4) Linden DeBoer (b) (4) (b) (4)	01 Sep 2020 13:36:01

US3032242

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 14:52:51

Start Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:55:39
User entered 'Jan 2010'	System	01 Sep 2020 13:36:01

US3032242

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 14:52:51

Start Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:55:39
User entered '2010'	System	01 Sep 2020 13:36:01

US3032242

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 14:52:51

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:55:39
User entered empty.	System	01 Sep 2020 13:36:01

US3032242

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 14:52:51

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:55:39
User entered empty.	System	01 Sep 2020 13:36:01

US3032242

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 14:52:51

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:55:39
DataPoint Verified.	(b) (4)	03 Dec 2020 16:35:40
User signature succeeded.	Keith Vrbicky (b) (4)	20 Nov 2020 16:30:05
User coded data point as SOC: Musculoskeletal and connective tissue disorders, HLGT: Joint disorders, HLT: Joint related signs and symptoms, PT: Arthralgia, LLT: Knee pain - version MedDRA\23.0.	(b) (4) Coder Import (b) (4)	18 Nov 2020 21:57:49
User coded data point as Term Coded data point by User: Coder System - version MedDRA\23.0.	Coder Import (b) (4)	18 Nov 2020 21:57:49
Data point term sent to Coder	System	18 Nov 2020 21:57:28
Coding entries removed.	Russell Herstein (b) (4)	18 Nov 2020 21:56:51
Signature has been broken.	(b) (4) Russell Herstein (b) (4)	18 Nov 2020 21:56:51
User entered 'RIGHT KNEE PAIN' reason for change: Data Entry Error	Russell Herstein (b) (4)	18 Nov 2020 21:56:51
User coded data point as SOC: Musculoskeletal and connective tissue disorders, HLGT: Joint disorders, HLT: Osteoarthropathies, PT: Osteoarthritis, LLT: Knee osteoarthritis - version MedDRA\23.0.	(b) (4) Coder Import (b) (4)	30 Sep 2020 11:44:54
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\23.0.	Coder Import (b) (4)	30 Sep 2020 11:44:54
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 17:47:49
Data point term sent to Coder	System	01 Sep 2020 13:37:10
User entered 'right knee pain due to osteoarthritis'	Linden DeBoer (b) (4)	01 Sep 2020 13:36:34
	(b) (4)	

US3032242

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 14:52:51

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:55:39
DataPoint Verified.		03 Dec 2020 16:35:40
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 17:47:49
User entered 'un UNK 2010'	(b) (4) Linden DeBoer (b) (4)	01 Sep 2020 13:36:34
	(b) (4)	

US3032242

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 14:52:51

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:55:39
DataPoint Verified.		03 Dec 2020 16:35:40
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 17:47:49
User entered '0'	(b) (4) Linden DeBoer (b) (4) (b) (4)	01 Sep 2020 13:36:34

US3032242

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 14:52:51

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:55:39
DataPoint Verified.	(b) (4)	03 Dec 2020 16:35:40
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 17:47:49
User entered 'Yes (Y)'	(b) (4) Linden DeBoer (b) (4)	01 Sep 2020 13:36:34
	(b) (4)	

US3032242

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 14:52:51

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:55:39
DataPoint Verified.		03 Dec 2020 16:35:40
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 17:47:49
User entered empty.	(b) (4) Linden DeBoer (b) (4)	01 Sep 2020 13:36:34
	(b) (4)	

US3032242

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 14:52:51

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:55:39
DataPoint Verified.	(b) (4)	03 Dec 2020 16:35:40
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 17:47:49
User entered '0'	(b) (4) Linden DeBoer (b) (4)	01 Sep 2020 13:36:34
	(b) (4)	

US3032242

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 14:52:51

Start Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:55:39
User entered 'Jan 2010'	System	01 Sep 2020 13:36:34

US3032242

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 14:52:51

Start Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:55:39
User entered '2010'	System	01 Sep 2020 13:36:34

US3032242

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 14:52:51

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:55:39
User entered empty.	System	01 Sep 2020 13:36:34

US3032242

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 14:52:51

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:55:39
User entered empty.	System	01 Sep 2020 13:36:34

US3032242

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 14:52:51

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:55:39
DataPoint Verified.	(b) (4)	03 Dec 2020 16:35:40
User coded data point as SOC: Musculoskeletal and connective tissue disorders, HLG: Joint disorders, HLT: Osteoarthropathies, PT: Osteoarthritis, LLT: Osteoarthritis knee - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	23 Nov 2020 15:28:53
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	23 Nov 2020 15:28:53
User closed query 'Per DM CLR: Please review if this MH should be combined with MH #4 RIGHT KNEE PAIN DUE TO OSTEOARTHRITIS (UN UNK 2010-Ongoing), as these have overlapping start/stop dates. Review if these MHs can be combined into one medical condition rather than separating a symptom. Update eCRF as appropriate. ' (Site from DM).	(b) (4), (b) (6)	19 Nov 2020 05:42:47
Query 'Per DM CLR: Please review if this MH should be combined with MH #4 RIGHT KNEE PAIN DUE TO OSTEOARTHRITIS (UN UNK 2010-Ongoing), as these have overlapping start/stop dates. Review if these MHs can be combined into one medical condition rather than separating a symptom. Update eCRF as appropriate. ' answered with 'Data updated in previous entry for clarity, this entry to serve as reason behind right knee pain' (Site from DM).	Russell Herstein (b) (4) (b) (4)	18 Nov 2020 21:57:29
User opened query 'Per DM CLR: Please review if this MH should be combined with MH #4 RIGHT KNEE PAIN DUE TO OSTEOARTHRITIS (UN UNK 2010-Ongoing), as these have overlapping start/stop dates. Review if these MHs can be combined into one medical condition rather than separating a symptom. Update eCRF as appropriate. ' (Site from DM).	(b) (4), (b) (6)	22 Oct 2020 09:00:12
User signature succeeded.	Keith Vrbicky (b) (4) (b) (4)	01 Oct 2020 22:01:37

US3032242

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 14:52:51

Condition

Audit	User	Time (GMT)
User closed query 'Per DM CLR: Please specify the location of OSTERARTHRTIS. Review and update medical history diagnosis as appropriate and ensure update to MHx is reconciled with any corresponding AE or ConMed entries, if applicable. ' (Site from DM).	(b) (4), (b) (6)	01 Oct 2020 07:55:41
Data point term sent to Coder	System	30 Sep 2020 22:04:58
Query 'Per DM CLR: Please specify the location of OSTERARTHRTIS. Review and update medical history diagnosis as appropriate and ensure update to MHx is reconciled with any corresponding AE or ConMed entries, if applicable.	Samantha Wieseler (b) (4)	30 Sep 2020 22:04:13
' answered with 'updated ' (Site from DM).	(b) (4)	
Coding entries removed.	Samantha Wieseler (b) (4)	30 Sep 2020 22:04:07
	(b) (4)	
Signature has been broken.	Samantha Wieseler (b) (4)	30 Sep 2020 22:04:07
	(b) (4)	
User entered 'OSTERARTHRTIS Right knee' reason for change: Data Entry Error	Samantha Wieseler (b) (4)	30 Sep 2020 22:04:07
	(b) (4)	
User opened query 'Per DM CLR: Please specify the location of OSTERARTHRTIS. Review and update medical history diagnosis as appropriate and ensure update to MHx is reconciled with any corresponding AE or ConMed entries, if applicable.	(b) (4), (b) (6)	29 Sep 2020 11:56:22
' (Site from DM).		
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 17:47:49
	(b) (4)	
User coded data point as SOC: Musculoskeletal and connective tissue disorders, HLG: Joint disorders, HLT: Osteoarthropathies, PT: Osteoarthritis, LLT: Osteoarthritis - version MedDRA\23.0.	Coder Import (b) (4)	01 Sep 2020 13:42:06
	(b) (4)	
User coded data point as Term Coded data point by User: Coder System - version MedDRA\23.0.	Coder Import (b) (4)	01 Sep 2020 13:42:06
	(b) (4)	
Data point term sent to Coder	System	01 Sep 2020 13:37:10
User entered 'osterarthrtis'	Linden DeBoer (b) (4)	01 Sep 2020 13:36:53
	(b) (4)	

US3032242

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 14:52:51

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:55:39
DataPoint Verified.		03 Dec 2020 16:35:40
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 17:47:49
User entered 'un UNK 2016'	(b) (4) Linden DeBoer (b) (4) (b) (4)	01 Sep 2020 13:36:53

US3032242

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 14:52:51

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:55:39
DataPoint Verified.		03 Dec 2020 16:35:40
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 17:47:49
User entered '0'	(b) (4) Linden DeBoer (b) (4) (b) (4)	01 Sep 2020 13:36:53

US3032242

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 14:52:51

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:55:39
DataPoint Verified.	(b) (4)	03 Dec 2020 16:35:40
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 17:47:49
User entered 'Yes (Y)'	(b) (4) Linden DeBoer (b) (4) (b) (4)	01 Sep 2020 13:36:53

US3032242

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 14:52:51

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:55:39
DataPoint Verified.		03 Dec 2020 16:35:40
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 17:47:49
User entered empty.	(b) (4) Linden DeBoer (b) (4) (b) (4)	01 Sep 2020 13:36:53

US3032242

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 14:52:51

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:55:39
DataPoint Verified.		03 Dec 2020 16:35:40
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 17:47:49
User entered '0'	(b) (4) Linden DeBoer (b) (4) (b) (4)	01 Sep 2020 13:36:53

US3032242

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 14:52:51

Start Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:55:39
User entered 'Jan 2016'	System	01 Sep 2020 13:36:53

US3032242

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 14:52:51

Start Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:55:39
User entered '2016'	System	01 Sep 2020 13:36:53

US3032242

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 14:52:51

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:55:39
User entered empty.	System	01 Sep 2020 13:36:53

US3032242

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 14:52:51

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:55:39
User entered empty.	System	01 Sep 2020 13:36:53

US3032242

Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 14:52:51

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:55:39
DataPoint Verified.		03 Dec 2020 16:35:40
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 17:47:49
User coded data point as SOC: Metabolism and nutrition disorders, HLG: Appetite and general nutritional disorders, HLT: General nutritional disorders NEC, PT: Obesity, LLT: Obesity - version MedDRA\23.0.	(b) (4) Coder Import (b) (4)	01 Sep 2020 13:42:10
User coded data point as Term Coded data point by User: Coder System - version MedDRA\23.0.	Coder Import (b) (4)	01 Sep 2020 13:42:10
Data point term sent to Coder	System	01 Sep 2020 13:38:12
User entered 'severe obesity'	Linden DeBoer (b) (4)	01 Sep 2020 13:37:20

US3032242

Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 14:52:51

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:55:39
DataPoint Verified.		03 Dec 2020 16:35:40
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 17:47:49
User entered 'un UNK 2000'	(b) (4) Linden DeBoer (b) (4) (b) (4)	01 Sep 2020 13:37:20

US3032242

Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 14:52:51

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:55:39
DataPoint Verified.	(b) (4)	03 Dec 2020 16:35:40
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 17:47:49
User entered '0'	(b) (4) Linden DeBoer (b) (4) (b) (4)	01 Sep 2020 13:37:20

US3032242

Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 14:52:51

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:55:39
DataPoint Verified.	(b) (4), (b) (6)	03 Dec 2020 16:35:40
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 17:47:49
User entered 'Yes (Y)'	(b) (4) Linden DeBoer (b) (4)	01 Sep 2020 13:37:20
	(b) (4)	

US3032242

Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 14:52:51

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:55:39
DataPoint Verified.	(b) (4), (b) (6)	03 Dec 2020 16:35:40
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 17:47:49
User entered empty.	(b) (4) Linden DeBoer (b) (4)	01 Sep 2020 13:37:20

US3032242

Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 14:52:51

Stop date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:55:39
DataPoint Verified.	(b) (4), (b) (6)	03 Dec 2020 16:35:40
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 17:47:49
User entered '0'	(b) (4) Linden DeBoer (b) (4)	01 Sep 2020 13:37:20
	(b) (4)	

US3032242

Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 14:52:51

Start Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:55:39
User entered 'Jan 2000'	System	01 Sep 2020 13:37:20

US3032242

Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 14:52:51

Start Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:55:39
User entered '2000'	System	01 Sep 2020 13:37:20

US3032242

Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 14:52:51

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:55:39
User entered empty.	System	01 Sep 2020 13:37:20

US3032242

Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 14:52:51

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:55:39
User entered empty.	System	01 Sep 2020 13:37:20

US3032242

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 14:52:51

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:55:39
DataPoint Verified.	(b) (4), (b) (6)	03 Dec 2020 16:36:20
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 17:47:49
User entered 'Yes (Y)'	(b) (4) Linden DeBoer (b) (4)	01 Sep 2020 13:38:15
	(b) (4)	

US3032242

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 14:52:51

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:55:39
DataPoint Verified.	(b) (4), (b) (6)	03 Dec 2020 16:36:20
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 17:47:49
User entered '19 Aug 2020'	(b) (4) Linden DeBoer (b) (4)	01 Sep 2020 13:38:15

US3032242

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 14:52:51

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:55:39
DataPoint Verified.	(b) (4), (b) (6)	03 Dec 2020 16:36:20
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 17:47:49
User entered '15:10'	(b) (4) Linden DeBoer (b) (4)	01 Sep 2020 13:38:15

US3032242

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 14:52:51

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:55:39
User entered '19 Aug 2020 15:10'	System	01 Sep 2020 13:38:15

US3032242

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 14:52:51

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:55:39
DataPoint Verified.	(b) (4), (b) (6)	03 Dec 2020 16:36:20
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 17:47:49
User entered '170.1' cm	(b) (4) Linden DeBoer (b) (4)	01 Sep 2020 13:38:15
DataPoint set to visible.	(b) (4) System	19 Aug 2020 21:22:45

US3032242

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 14:52:51

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:55:39
DataPoint Verified.	(b) (4), (b) (6)	03 Dec 2020 16:36:20
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 17:47:49
User entered '121.1' kg	(b) (4) Linden DeBoer (b) (4)	01 Sep 2020 13:38:15
DataPoint set to visible.	(b) (4) System	19 Aug 2020 21:22:45

US3032242

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 14:52:51

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:55:39
User entered '41.85386'	System	01 Sep 2020 13:38:15
DataPoint set to visible.	System	19 Aug 2020 21:22:45

US3032242

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 14:52:51

[BMI units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:55:39
User entered 'kg/m2'	System	01 Sep 2020 13:38:15
DataPoint set to visible.	System	19 Aug 2020 21:22:45

US3032242

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 14:52:51

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:55:39
DataPoint Verified.	(b) (4), (b) (6)	03 Dec 2020 16:36:20
User signature succeeded.	Keith Vrbicky (b) (4)	08 Oct 2020 15:42:03
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)	08 Oct 2020 07:01:33
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 'DATA UPDATED' (Site from DM).	Linden DeBoer (b) (4) (b) (4)	07 Oct 2020 14:58:26
Signature has been broken.	Linden DeBoer (b) (4) (b) (4)	07 Oct 2020 14:58:20
User entered missing code ND - Not Done; reason for change Data Entry Error	Linden DeBoer (b) (4) (b) (4)	07 Oct 2020 14:58:20
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)	07 Oct 2020 11:52:43
User signature succeeded.	Keith Vrbicky (b) (4) (b) (4)	28 Sep 2020 17:47:49
User entered '36.7' C	Linden DeBoer (b) (4) (b) (4)	01 Sep 2020 13:38:15

US3032242

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 14:52:51

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:55:39
DataPoint Verified.	(b) (4), (b) (6)	03 Dec 2020 16:36:20
User signature succeeded.	Keith Vrbicky (b) (4)	08 Oct 2020 15:42:03
Signature has been broken.	(b) (4) Linden DeBoer (b) (4)	07 Oct 2020 14:58:20
User entered empty; reason for change Data Entry Error	(b) (4) Linden DeBoer (b) (4)	07 Oct 2020 14:58:20
User signature succeeded.	(b) (4) Keith Vrbicky (b) (4)	28 Sep 2020 17:47:49
User entered 'Oral (Oral)'	(b) (4) Linden DeBoer (b) (4)	01 Sep 2020 13:38:15

US3032242

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 14:52:51

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:55:39
DataPoint Verified.	(b) (4), (b) (6)	03 Dec 2020 16:36:20
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 17:47:49
User entered empty.	(b) (4) Linden DeBoer (b) (4)	01 Sep 2020 13:38:15

US3032242

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 14:52:51

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:55:39
DataPoint Verified.	(b) (4), (b) (6)	03 Dec 2020 16:36:20
User signature succeeded.	Keith Vrbicky (b) (4)	08 Oct 2020 15:42:03
Signature has been broken.	(b) (4) Linden DeBoer (b) (4)	07 Oct 2020 14:58:20
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4) Linden DeBoer (b) (4)	07 Oct 2020 14:58:20
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 17:47:49
User entered '71'	(b) (4) Linden DeBoer (b) (4)	01 Sep 2020 13:38:15

US3032242

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 14:52:51

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:55:39
User entered 'bpm'	System	01 Sep 2020 13:38:15

US3032242

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 14:52:51

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:55:39
DataPoint Verified.	(b) (4), (b) (6)	03 Dec 2020 16:36:20
User signature succeeded.	Keith Vrbicky (b) (4)	08 Oct 2020 15:42:03
Signature has been broken.	(b) (4) Linden DeBoer (b) (4)	07 Oct 2020 14:58:20
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4) Linden DeBoer (b) (4)	07 Oct 2020 14:58:20
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 17:47:49
User entered '16'	(b) (4) Linden DeBoer (b) (4)	01 Sep 2020 13:38:15

US3032242

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 14:52:51

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:55:39
User entered 'breaths/min'	System	01 Sep 2020 13:38:15

US3032242

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 14:52:51

Systolic Blood Pressure (.xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:55:39
DataPoint Verified.	(b) (4), (b) (6)	03 Dec 2020 16:36:20
User signature succeeded.	Keith Vrbicky (b) (4)	08 Oct 2020 15:42:03
Signature has been broken.	(b) (4) Linden DeBoer (b) (4)	07 Oct 2020 14:58:20
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4) Linden DeBoer (b) (4)	07 Oct 2020 14:58:20
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 17:47:49
User entered '124'	(b) (4) Linden DeBoer (b) (4)	01 Sep 2020 13:38:15

US3032242

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 14:52:51

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:55:39
User entered 'mmHg'	System	01 Sep 2020 13:38:15

US3032242

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 14:52:51

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:55:39
DataPoint Verified.	(b) (4), (b) (6)	03 Dec 2020 16:36:20
User signature succeeded.	Keith Vrbicky (b) (4)	08 Oct 2020 15:42:03
Signature has been broken.	(b) (4) Linden DeBoer (b) (4)	07 Oct 2020 14:58:20
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4) Linden DeBoer (b) (4)	07 Oct 2020 14:58:20
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 17:47:49
User entered '79'	(b) (4) Linden DeBoer (b) (4)	01 Sep 2020 13:38:15

US3032242

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 14:52:51

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:55:39
User entered 'mmHg'	System	01 Sep 2020 13:38:15

US3032242

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 14:52:51

[Height \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:55:39

US3032242

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 14:52:51

[Weight \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:55:39

US3032242

Folder: Screening

Form: Physical Examination

Generated On: 09 Jun 2021 14:52:51

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:55:39
DataPoint Verified.	(b) (4), (b) (6)	03 Dec 2020 16:36:29
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 17:47:49
User entered 'Yes (Y)'	(b) (4) Linden DeBoer (b) (4)	01 Sep 2020 13:38:23
	(b) (4)	

US3032242

Folder: Screening

Form: Physical Examination

Generated On: 09 Jun 2021 14:52:51

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:55:39
DataPoint Verified.	(b) (4), (b) (6)	03 Dec 2020 16:36:29
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 17:47:49
User entered '19 Aug 2020'	(b) (4) Linden DeBoer (b) (4)	01 Sep 2020 13:38:23

US3032242

Folder: Screening

Form: Childbearing Potential

Generated On: 09 Jun 2021 14:52:51

Date of assessment (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:55:39
DataPoint Verified.	(b) (4), (b) (6)	03 Dec 2020 16:36:34
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 17:47:49
User entered '19 Aug 2020'	(b) (4) Linden DeBoer (b) (4)	01 Sep 2020 13:38:41

US3032242

Folder: Screening

Form: Childbearing Potential

Generated On: 09 Jun 2021 14:52:51

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:55:39
DataPoint Verified.	(b) (4), (b) (6)	03 Dec 2020 16:36:34
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 17:47:49
User entered 'No (N)'	(b) (4) Linden DeBoer (b) (4)	01 Sep 2020 13:38:41

US3032242

Folder: Screening

Form: Childbearing Potential

Generated On: 09 Jun 2021 14:52:51

[If No, what is the reason?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:55:39
DataPoint Verified.	(b) (4), (b) (6)	03 Dec 2020 16:36:34
User signature succeeded.	Keith Vrbicky (b) (4) (b) (4)	28 Sep 2020 17:47:49
User entered 'Post-menopausal (POST-MENOPAUSAL)'	Linden DeBoer (b) (4) (b) (4)	01 Sep 2020 13:38:41

US3032242

Folder: Screening

Form: Childbearing Potential

Generated On: 09 Jun 2021 14:52:51

If Partner medically sterile or Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:55:39
DataPoint Verified.	(b) (4), (b) (6)	03 Dec 2020 16:36:34
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 17:47:49
User entered empty.	(b) (4) Linden DeBoer (b) (4)	01 Sep 2020 13:38:41

US3032242

Folder: Screening

Form: Childbearing Potential

Generated On: 09 Jun 2021 14:52:51

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:55:39
DataPoint Verified.	(b) (4), (b) (6)	03 Dec 2020 16:36:34
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 17:47:49
User entered empty.	(b) (4) Linden DeBoer (b) (4)	01 Sep 2020 13:38:41

US3032242

Folder: Screening

Form: Childbearing Potential

Generated On: 09 Jun 2021 14:52:51

Date of surgery unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:55:39
DataPoint Verified.		03 Dec 2020 16:36:34
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 17:47:49
User entered '0'	(b) (4) Linden DeBoer (b) (4)	01 Sep 2020 13:38:41
	(b) (4)	

US3032242

Folder: Screening

Form: Childbearing Potential

Generated On: 09 Jun 2021 14:52:51

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:55:39
DataPoint Verified.		03 Dec 2020 16:36:34
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 17:47:49
User entered 'un UNK 1995'	(b) (4) Linden DeBoer (b) (4)	01 Sep 2020 13:38:41
	(b) (4)	

US3032242

Folder: Screening

Form: Childbearing Potential

Generated On: 09 Jun 2021 14:52:51

Date of last menstruation unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:55:39
DataPoint Verified.		03 Dec 2020 16:36:34
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 17:47:49
User entered '0'	(b) (4) Linden DeBoer (b) (4) (b) (4)	01 Sep 2020 13:38:41

US3032242

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 14:52:51

[Healthcare workers](#) (e.g., doctors, nurses, dentists, hospital support staff, morgue/mortuary workers)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:55:39
DataPoint Verified.		03 Dec 2020 16:37:08
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 17:47:49
User entered 'No (N)'	(b) (4) Linden DeBoer (b) (4)	01 Sep 2020 13:39:38
	(b) (4)	

US3032242

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 14:52:51

[Emergency Response](#) (e.g., Law enforcement officers, Firefighters, emergency medical service workers)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:55:39
DataPoint Verified.		03 Dec 2020 16:37:08
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 17:47:49
User entered 'No (N)'	(b) (4) Linden DeBoer (b) (4)	01 Sep 2020 13:39:38
	(b) (4)	

US3032242

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 14:52:51

Retail or Restaurant Operations, particularly those in critical and/high-customer volume (e.g., grocery, convenience, hardware, big-box stores)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:55:39
DataPoint Verified.		03 Dec 2020 16:37:08
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 17:47:49
User entered 'No (N)'	(b) (4) Linden DeBoer (b) (4) (b) (4)	01 Sep 2020 13:39:38

US3032242

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 14:52:51

Manufacturing & Production Operations with inherent overcrowding (e.g., factory workers, meat/food processing plants)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:55:39
DataPoint Verified.		03 Dec 2020 16:37:08
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 17:47:49
User entered 'No (N)'	(b) (4) Linden DeBoer (b) (4) (b) (4)	01 Sep 2020 13:39:38

US3032242

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 14:52:51

[Warehouse shipping and fulfillment centers and jobs \(e.g., Amazon facilities\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:55:39
DataPoint Verified.	(b) (4)	03 Dec 2020 16:37:08
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 17:47:49
User entered 'No (N)'	(b) (4) Linden DeBoer (b) (4)	01 Sep 2020 13:39:38
	(b) (4)	

US3032242

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 14:52:51

[Transportation and delivery services](#) (e.g., airlines, public transit, taxi/UBER, fed ex/UPS, postal workers)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:55:39
DataPoint Verified.		03 Dec 2020 16:37:08
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 17:47:49
User entered 'Yes (Y)'	(b) (4) Linden DeBoer (b) (4) (b) (4)	01 Sep 2020 13:39:38

US3032242

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 14:52:51

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)	8 Apr 2021 18:55:39
DataPoint Verified.		3 Dec 2020 16:37:08
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 17:47:49
User entered 'No (N)'	(b) (4) Linden DeBoer (b) (4)	01 Sep 2020 13:39:38
	(b) (4)	

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Folder: Screening

Form: Risk of Exposure

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[Personal Care and in-home services](#) (e.g., barber/salon/spa, in-home repair services, electricians, plumbers, janitorial services)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:55:39
DataPoint Verified.	(b) (4)	03 Dec 2020 16:37:08
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 17:47:49
User entered 'No (N)'	(b) (4) Linden DeBoer (b) (4) (b) (4)	01 Sep 2020 13:39:38

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Folder: Screening

Form: Risk of Exposure

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[Hospitality and Tourism Workers](#) (e.g., hotel, casino, amusement/theme park, entertainment, ski resorts)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:55:39
DataPoint Verified.		03 Dec 2020 16:37:08
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 17:47:49
User entered 'No (N)'	(b) (4) Linden DeBoer (b) (4) (b) (4)	01 Sep 2020 13:39:38

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Folder: Screening

Form: Risk of Exposure

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Pastoral, Social or Public Health Workers requiring frequent contact with community members (e.g., social workers, volunteers, religious clergy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:55:39
DataPoint Verified.		03 Dec 2020 16:37:08
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 17:47:49
User entered 'No (N)'	(b) (4) Linden DeBoer (b) (4) (b) (4)	01 Sep 2020 13:39:38

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Folder: Screening

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[Educators and Students](#) (e.g., teachers, administrators, support staff, and students interacting in face-to-face school setting)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:55:39
DataPoint Verified.		03 Dec 2020 16:37:08
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 17:47:49
User entered 'No (N)'	(b) (4) Linden DeBoer (b) (4) (b) (4)	01 Sep 2020 13:39:38

US3032242

Folder: Screening

Form: Risk of Exposure

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[Other](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:55:39
DataPoint Verified.		03 Dec 2020 16:37:08
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 17:47:49
User entered 'No (N)'	(b) (4) Linden DeBoer (b) (4) (b) (4)	01 Sep 2020 13:39:38

US3032242

Folder: Screening

Form: Risk of Exposure

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[Specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:55:39
DataPoint Verified.		03 Dec 2020 16:37:08
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 17:47:49
User entered empty.	(b) (4) Linden DeBoer (b) (4) (b) (4)	01 Sep 2020 13:39:38

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No Risk Identified

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:55:39
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 17:47:49
User entered '0'	(b) (4) Linden DeBoer (b) (4)	01 Sep 2020 13:39:38
	(b) (4)	

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Folder: Screening

Form: Risk of Exposure

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:55:39
DataPoint Verified.		03 Dec 2020 16:37:08
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 17:47:49
User entered '0'	(b) (4) Linden DeBoer (b) (4) (b) (4)	01 Sep 2020 13:39:38

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Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 14:52:51

Resides in Multi-family dwelling (e.g., cohabitation in dwelling with > 5 people, includes grandparents living with children < 18yrs)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:55:39
DataPoint Verified.	(b) (4)	03 Dec 2020 16:37:08
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 17:47:49
User entered '0'	(b) (4) Linden DeBoer (b) (4) (b) (4)	01 Sep 2020 13:39:38

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Folder: Screening

Form: Risk of Exposure

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[Resides in high density housing](#) (e.g., high rise apartments with shared entrances or elevators)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:55:39
DataPoint Verified.	(b) (4)	03 Dec 2020 16:37:08
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 17:47:49
User entered '0'	(b) (4) Linden DeBoer (b) (4)	01 Sep 2020 13:39:38
	(b) (4)	

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Folder: Screening

Form: Risk of Exposure

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Resides in low density, multi-family setting without (e.g., apartments complex without shared entrances or elevators, duplexes)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:55:39
DataPoint Verified.		03 Dec 2020 16:37:08
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 17:47:49
User entered '0'	(b) (4) Linden DeBoer (b) (4) (b) (4)	01 Sep 2020 13:39:38

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Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 14:52:51

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:55:39
DataPoint Verified.		03 Dec 2020 16:37:08
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 17:47:49
User entered '1'	(b) (4) Linden DeBoer (b) (4) (b) (4)	01 Sep 2020 13:39:38

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Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 14:52:51

[Other](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:55:39
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 17:47:49
User entered '0'	(b) (4) Linden DeBoer (b) (4)	01 Sep 2020 13:39:38
	(b) (4)	

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Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 14:52:51

[Specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:55:39
DataPoint Verified.	(b) (4)	03 Dec 2020 16:37:08
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 17:47:49
User entered empty.	(b) (4) Linden DeBoer (b) (4) (b) (4)	01 Sep 2020 13:39:38

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Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 09 Jun 2021 14:52:51

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:25:04
DataPoint Verified.	(b) (4)	03 Dec 2020 16:37:17
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 17:47:49
User entered 'Yes (Y)'	(b) (4) Linden DeBoer (b) (4) (b) (4)	01 Sep 2020 13:26:40

US3032242

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 09 Jun 2021 14:52:51

Visit date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:25:04
DataPoint Verified.		03 Dec 2020 16:37:17
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 17:47:49
User entered '19 Aug 2020'	(b) (4) Linden DeBoer (b) (4) (b) (4)	01 Sep 2020 13:26:40

US3032242

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 09 Jun 2021 14:52:51

[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 19:25:04
DataPoint Verified.		03 Dec 2020 16:37:17
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 17:47:49
User entered 'Clinic (Clinic)'	(b) (4) Linden DeBoer (b) (4) (b) (4)	01 Sep 2020 13:26:40

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Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 09 Jun 2021 14:52:51

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:25:04
User entered 'VISIT1'	System	01 Sep 2020 13:26:40

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Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 14:52:51

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:25:04
DataPoint Verified.		03 Dec 2020 16:37:20
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 17:47:49
User entered '19 AUG 2020'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	19 Aug 2020 20:59:25

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Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 14:52:51

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:25:04
DataPoint Verified.		03 Dec 2020 16:37:20
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 17:47:49
Amendment Manager: User closed query 'Data entered is non-conformant. Please correct.' (Site from System).	(b) (4) System	21 Aug 2020 05:42:47
Amendment Manager: Data point set to conformant.	System	21 Aug 2020 05:42:47
User opened query 'Data entered is non-conformant. Please correct.' (Site from System).	System	19 Aug 2020 20:59:25
User entered '187111' (non-conformant).	RWS_ENDPOINT ENDPOINT (b) (4)	19 Aug 2020 20:59:25

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Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 14:52:51

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:25:04
DataPoint Verified.		03 Dec 2020 16:37:20
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 17:47:49
User entered '>=65 years (3)'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	19 Aug 2020 20:59:25

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Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 14:52:51

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 19:25:04
DataPoint Verified.	(b) (4), (b) (6)	03 Dec 2020 16:37:20
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 17:47:49
User closed query 'Per CDM: Please complete this section of the form (a required response (Yes or No) is needed for each), otherwise explain.' (Site from DM).	(b) (4) (b) (4), (b) (6)	03 Sep 2020 06:40:44
Query 'Per CDM: Please complete this section of the form (a required response (Yes or No) is needed for each), otherwise explain.' answered with 'data has been entered' (Site from DM).	Linden DeBoer (b) (4) (b) (4)	01 Sep 2020 13:28:16
User entered 'No (N)'	Linden DeBoer (b) (4) (b) (4)	01 Sep 2020 13:28:06
User opened query 'Per CDM: Please complete this section of the form (a required response (Yes or No) is needed for each), otherwise explain.' (Site from DM).	(b) (4) (b) (4), (b) (6)	31 Aug 2020 12:46:09

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Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 14:52:51

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 19:25:04
DataPoint Verified.		03 Dec 2020 16:37:20
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 17:47:49
User entered 'No (N)'	(b) (4) Linden DeBoer (b) (4) (b) (4)	01 Sep 2020 13:28:06

US3032242

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 14:52:51

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:25:04
DataPoint Verified.		03 Dec 2020 16:37:20
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 17:47:49
User entered 'Yes (Y)'	(b) (4) Linden DeBoer (b) (4)	01 Sep 2020 13:28:06
	(b) (4)	

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Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 14:52:51

Diabetes (Type I, Type 2, or gestational)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:25:04
DataPoint Verified.		03 Dec 2020 16:37:20
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 17:47:49
User entered 'No (N)'	(b) (4) Linden DeBoer (b) (4) (b) (4)	01 Sep 2020 13:28:06

US3032242

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 14:52:51

[Liver Disease](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:25:04
DataPoint Verified.	(b) (4)	03 Dec 2020 16:37:20
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 17:47:49
User entered 'No (N)'	(b) (4) Linden DeBoer (b) (4)	01 Sep 2020 13:28:06
	(b) (4)	

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Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 14:52:51

Human Immunodeficiency Virus (HIV) infection

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:25:04
DataPoint Verified.		03 Dec 2020 16:37:20
User signature succeeded.	Keith Vrbicky (b) (4)	02 Nov 2020 22:15:50
User closed query 'Per CDM: This field requires yes or no. Please complete. ' (Site from DM).	(b) (4) (b) (4), (b) (6)	02 Nov 2020 08:32:14
Query 'Per CDM: This field requires yes or no. Please complete. ' answered with 'data updated' (Site from DM).	Linden DeBoer (b) (4)	29 Oct 2020 21:26:02
User entered 'No (N)'	(b) (4)	29 Oct 2020 21:25:57
User opened query 'Per CDM: This field requires yes or no. Please complete. ' (Site from DM).	(b) (4), (b) (6)	29 Oct 2020 11:57:28
Amendment Manager: DataPoint set to visible.	System	19 Sep 2020 10:36:18
Amendment Manager inserted this DataPoint.	System	19 Sep 2020 01:37:40

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 14:52:51

Height

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:25:04
DataPoint Verified.	(b) (4)	03 Dec 2020 16:37:24
User signature succeeded.	Keith Vrbicky (b) (4)	14 Oct 2020 19:36:42
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.' (Site from DM).	(b) (4) (b) (4), (b) (6)	14 Oct 2020 03:38:48
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.' answered with 'data updated' (Site from DM).	Linden DeBoer (b) (4) (b) (4)	13 Oct 2020 13:43:25
Signature has been broken.	Linden DeBoer (b) (4) (b) (4)	13 Oct 2020 13:43:18
User entered missing code ND - Not Done; reason for change Data Entry Error	Linden DeBoer (b) (4) (b) (4)	13 Oct 2020 13:43:18
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.' (Site from DM).	(b) (4), (b) (6)	13 Oct 2020 09:05:28
User signature succeeded.	Keith Vrbicky (b) (4) (b) (4)	28 Sep 2020 17:47:49
User entered '170.1' cm	Linden DeBoer (b) (4) (b) (4)	01 Sep 2020 13:31:11

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 14:52:51

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:25:04
DataPoint Verified.		03 Dec 2020 16:37:24
User signature succeeded.	Keith Vrbicky (b) (4)	14 Oct 2020 19:36:42
Signature has been broken.	(b) (4) Linden DeBoer (b) (4)	13 Oct 2020 13:43:18
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4) Linden DeBoer (b) (4)	13 Oct 2020 13:43:18
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 17:47:49
User entered '121.1' kg	(b) (4) Linden DeBoer (b) (4)	01 Sep 2020 13:31:11
	(b) (4)	

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 14:52:51

Height

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:25:04
DataPoint Verified.	(b) (4)	03 Dec 2020 16:37:24
User signature succeeded.	Keith Vrbicky (b) (4)	14 Oct 2020 19:36:42
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.' (Site from DM).	(b) (4) (b) (4), (b) (6)	14 Oct 2020 03:38:48
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.' answered with 'data updated' (Site from DM).	Linden DeBoer (b) (4) (b) (4)	13 Oct 2020 13:43:25
Signature has been broken.	Linden DeBoer (b) (4) (b) (4)	13 Oct 2020 13:43:18
User entered missing code ND - Not Done; reason for change Data Entry Error	Linden DeBoer (b) (4) (b) (4)	13 Oct 2020 13:43:18
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.' (Site from DM).	(b) (4), (b) (6)	13 Oct 2020 09:05:28
User signature succeeded.	Keith Vrbicky (b) (4) (b) (4)	28 Sep 2020 17:47:49
User entered '170.1' cm	Linden DeBoer (b) (4) (b) (4)	01 Sep 2020 13:31:11

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 14:52:51

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:25:04
DataPoint Verified.	(b) (4)	03 Dec 2020 16:37:24
User signature succeeded.	Keith Vrbicky (b) (4)	14 Oct 2020 19:36:42
Signature has been broken.	(b) (4) Linden DeBoer (b) (4)	13 Oct 2020 13:43:18
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4) Linden DeBoer (b) (4)	13 Oct 2020 13:43:18
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 17:47:49
User entered '121.1' kg	(b) (4) Linden DeBoer (b) (4)	01 Sep 2020 13:31:11
	(b) (4)	

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 14:52:51

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:25:04
User accepted default value 'Pre-Dose (PREDOSE)'	Linden DeBoer (b) (4) (b) (4)	01 Sep 2020 13:31:11

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 14:52:51

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:25:04
DataPoint Verified.		03 Dec 2020 16:37:24
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 17:47:49
User entered 'Yes (Y)'	(b) (4) Linden DeBoer (b) (4)	01 Sep 2020 13:31:11
	(b) (4)	

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 14:52:51

Date of assessment (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:25:04
DataPoint Verified.		03 Dec 2020 16:37:24
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 17:47:49
User entered '19 Aug 2020'	(b) (4) Linden DeBoer (b) (4)	01 Sep 2020 13:31:11
	(b) (4)	

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 14:52:51

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:25:04
DataPoint Verified.		03 Dec 2020 16:37:24
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 17:47:49
User entered '15:10'	(b) (4) Linden DeBoer (b) (4) (b) (4)	01 Sep 2020 13:31:11

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 14:52:51

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:25:04
User entered '19 Aug 2020 15:10'	System	01 Sep 2020 13:31:11

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 14:52:51

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:25:04
DataPoint Verified.		03 Dec 2020 16:37:24
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 17:47:49
User entered '36.7' C	(b) (4) Linden DeBoer (b) (4) (b) (4)	01 Sep 2020 13:31:11

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 14:52:51

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:25:04
DataPoint Verified.		03 Dec 2020 16:37:24
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 17:47:49
User entered 'Oral (Oral)'	(b) (4) Linden DeBoer (b) (4) (b) (4)	01 Sep 2020 13:31:11

US3032242

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 14:52:51

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:25:04
DataPoint Verified.		03 Dec 2020 16:37:24
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 17:47:49
User entered empty.	(b) (4) Linden DeBoer (b) (4)	01 Sep 2020 13:31:11
	(b) (4)	

US3032242

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 14:52:51

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:25:04
DataPoint Verified.		03 Dec 2020 16:37:24
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 17:47:49
User entered '71'	(b) (4) Linden DeBoer (b) (4)	01 Sep 2020 13:31:11
	(b) (4)	

US3032242

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 14:52:51

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:25:04
User entered 'bpm'	System	01 Sep 2020 13:31:11

US3032242

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 14:52:51

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:25:04
DataPoint Verified.		03 Dec 2020 16:37:24
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 17:47:49
User entered '16'	(b) (4) Linden DeBoer (b) (4) (b) (4)	01 Sep 2020 13:31:11

US3032242

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 14:52:51

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:25:04
User entered 'breaths/min'	System	01 Sep 2020 13:31:11

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 14:52:51

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:25:04
DataPoint Verified.		03 Dec 2020 16:37:24
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 17:47:49
User entered '124'	(b) (4) Linden DeBoer (b) (4) (b) (4)	01 Sep 2020 13:31:11

US3032242

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 14:52:51

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:25:04
User entered 'mmHg'	System	01 Sep 2020 13:31:11

US3032242

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 14:52:51

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:25:04
DataPoint Verified.		03 Dec 2020 16:37:24
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 17:47:49
User entered '79'	(b) (4) Linden DeBoer (b) (4)	01 Sep 2020 13:31:11
	(b) (4)	

US3032242

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 14:52:51

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:25:04
User entered 'mmHg'	System	01 Sep 2020 13:31:11

US3032242

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 14:52:51

Height

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:25:04
DataPoint Verified.	(b) (4)	03 Dec 2020 16:37:24
User signature succeeded.	Keith Vrbicky (b) (4)	14 Oct 2020 19:36:42
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.' (Site from DM).	(b) (4) (b) (4), (b) (6)	14 Oct 2020 03:38:48
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.' answered with 'data updated' (Site from DM).	Linden DeBoer (b) (4) (b) (4)	13 Oct 2020 13:43:25
Signature has been broken.	Linden DeBoer (b) (4) (b) (4)	13 Oct 2020 13:43:18
User entered missing code ND - Not Done; reason for change Data Entry Error	Linden DeBoer (b) (4) (b) (4)	13 Oct 2020 13:43:18
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.' (Site from DM).	(b) (4), (b) (6)	13 Oct 2020 09:05:28
User signature succeeded.	Keith Vrbicky (b) (4) (b) (4)	28 Sep 2020 17:47:49
User entered '170.1' cm	Linden DeBoer (b) (4) (b) (4)	01 Sep 2020 13:31:11

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 14:52:51

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:25:04
DataPoint Verified.	(b) (4)	03 Dec 2020 16:37:24
User signature succeeded.	Keith Vrbicky (b) (4)	14 Oct 2020 19:36:42
Signature has been broken.	(b) (4) Linden DeBoer (b) (4)	13 Oct 2020 13:43:18
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4) Linden DeBoer (b) (4)	13 Oct 2020 13:43:18
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 17:47:49
User entered '121.1' kg	(b) (4) Linden DeBoer (b) (4)	01 Sep 2020 13:31:11
	(b) (4)	

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 14:52:51

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:25:04
User accepted default value 'Post-Dose (POSTDOSE)'	Linden DeBoer (b) (4) (b) (4)	01 Sep 2020 13:31:11

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 14:52:51

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:25:04
DataPoint Verified.		03 Dec 2020 16:37:24
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 17:47:49
User entered 'Yes (Y)'	(b) (4) Linden DeBoer (b) (4)	01 Sep 2020 13:31:11
	(b) (4)	

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 14:52:51

Date of assessment (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:25:04
DataPoint Verified.		03 Dec 2020 16:37:24
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 17:47:49
User entered '19 Aug 2020'	(b) (4) Linden DeBoer (b) (4) (b) (4)	01 Sep 2020 13:31:11

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 14:52:51

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:25:04
DataPoint Verified.		03 Dec 2020 16:37:24
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 17:47:49
User entered '16:47'	(b) (4) Linden DeBoer (b) (4) (b) (4)	01 Sep 2020 13:31:11

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 14:52:51

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:25:04
User entered '19 Aug 2020 16:47'	System	01 Sep 2020 13:31:11

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 14:52:51

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:25:04
DataPoint Verified.		03 Dec 2020 16:37:24
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 17:47:49
User entered '36.3' C	(b) (4) Linden DeBoer (b) (4) (b) (4)	01 Sep 2020 13:31:11

US3032242

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 14:52:51

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:25:04
DataPoint Verified.		03 Dec 2020 16:37:24
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 17:47:49
User entered 'Oral (Oral)'	(b) (4) Linden DeBoer (b) (4)	01 Sep 2020 13:31:11
	(b) (4)	

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 14:52:51

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:25:04
DataPoint Verified.		03 Dec 2020 16:37:24
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 17:47:49
User entered empty.	(b) (4) Linden DeBoer (b) (4) (b) (4)	01 Sep 2020 13:31:11

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 14:52:51

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:25:04
DataPoint Verified.		03 Dec 2020 16:37:24
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 17:47:49
User entered '54'	(b) (4) Linden DeBoer (b) (4) (b) (4)	01 Sep 2020 13:31:11

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 14:52:51

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:25:04
User entered 'bpm'	System	01 Sep 2020 13:31:11

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 14:52:51

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:25:04
DataPoint Verified.	(b) (4)	03 Dec 2020 16:37:24
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 17:47:49
User entered '17'	(b) (4) Linden DeBoer (b) (4) (b) (4)	01 Sep 2020 13:31:11

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 14:52:51

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:25:04
User entered 'breaths/min'	System	01 Sep 2020 13:31:11

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 14:52:51

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:25:04
DataPoint Verified.		03 Dec 2020 16:37:24
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 17:47:49
User entered '120'	(b) (4) Linden DeBoer (b) (4) (b) (4)	01 Sep 2020 13:31:11

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 14:52:51

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:25:04
User entered 'mmHg'	System	01 Sep 2020 13:31:11

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 14:52:51

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:25:04
DataPoint Verified.		03 Dec 2020 16:37:24
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 17:47:49
User entered '60'	(b) (4) Linden DeBoer (b) (4) (b) (4)	01 Sep 2020 13:31:11

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 14:52:51

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:25:04
User entered 'mmHg'	System	01 Sep 2020 13:31:11

US3032242

Folder: Visit 1 Day 1

Form: Physical Examination

Generated On: 09 Jun 2021 14:52:51

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:25:04
DataPoint Verified.		03 Dec 2020 16:38:28
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 17:47:49
User entered 'Yes (Y)'	(b) (4) Linden DeBoer (b) (4)	01 Sep 2020 13:31:23
	(b) (4)	

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Folder: Visit 1 Day 1

Form: Physical Examination

Generated On: 09 Jun 2021 14:52:51

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:25:04
DataPoint Verified.		03 Dec 2020 16:38:28
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 17:47:49
User entered '19 Aug 2020'	(b) (4) Linden DeBoer (b) (4) (b) (4)	01 Sep 2020 13:31:23

US3032242

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 14:52:51

[Was study treatment given?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:25:04
User signature succeeded.	Keith Vrbicky (b) (4) (b) (4)	28 Sep 2020 17:47:49
User entered 'Yes (Y)'	Kelsey Kelley (b) (4) (b) (4)	19 Aug 2020 21:23:04

US3032242

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 14:52:51

[If No, reason not given](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:25:04
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 17:47:49
User entered empty.	(b) (4) Kelsey Kelley (b) (4)	19 Aug 2020 21:23:04

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Folder: Visit 1 Day 1

Form: Exposure

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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 19:25:04
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 17:47:49
User entered empty.	(b) (4) Kelsey Kelley (b) (4)	19 Aug 2020 21:23:04
	(b) (4)	

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Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 14:52:51

[What was the study treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:25:04
User entered 'MRNA-1273 OR PLACEBO'	System	19 Aug 2020 21:23:04

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Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 14:52:51

What was the treatment date? (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:25:04
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 17:47:49
User entered '19 Aug 2020'	(b) (4) Kelsey Kelley (b) (4)	19 Aug 2020 21:23:04

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Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 14:52:51

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:25:04
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 17:47:49
User entered '16:16'	(b) (4) Kelsey Kelley (b) (4)	19 Aug 2020 21:23:04

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Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 14:52:51

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:25:04
User entered '19 Aug 2020 16:16'	System	19 Aug 2020 21:23:04

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Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 14:52:51

Which arm was used to give treatment?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:25:04
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 17:47:49
User entered 'Left Arm (LEFT ARM)'	(b) (4) Kelsey Kelley (b) (4)	19 Aug 2020 21:23:04

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Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 14:52:51

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:25:04
User entered 'ONCE'	System	19 Aug 2020 21:23:04

US3032242

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 14:52:51

[What was the route of administration for the study treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:25:04
User entered 'INTRAMUSCULAR'	System	19 Aug 2020 21:23:04

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Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 14:52:51

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:25:04
DataPoint Verified.		03 Dec 2020 16:38:54
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 17:47:49
User entered 'Yes (Y)'	(b) (4) Linden DeBoer (b) (4)	01 Sep 2020 13:31:53
	(b) (4)	

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Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 14:52:51

Collection date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:25:04
DataPoint Verified.		03 Dec 2020 16:38:54
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 17:47:49
User entered '19 Aug 2020'	(b) (4) Linden DeBoer (b) (4)	01 Sep 2020 13:31:53
	(b) (4)	

US3032242

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 14:52:51

Collection time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:25:04
DataPoint Verified.	(b) (4)	03 Dec 2020 16:38:54
User signature succeeded.	Keith Vrbicky (b) (4)	24 Nov 2020 20:29:22
Signature has been broken.	(b) (4) Linden DeBoer (b) (4)	24 Nov 2020 19:13:59
User entered '14:50' reason for change: Data Entry Error	(b) (4) Linden DeBoer (b) (4)	24 Nov 2020 19:13:59
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 17:47:49
User entered '13:50'	(b) (4) Linden DeBoer (b) (4)	01 Sep 2020 13:31:53
	(b) (4)	

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Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 14:52:51

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:25:04
User entered '19 Aug 2020 14:50'	System	24 Nov 2020 19:13:59
User entered '19 Aug 2020 13:50'	System	01 Sep 2020 13:31:53

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Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab

Generated On: 09 Jun 2021 14:52:51

Collection date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:25:04
DataPoint Verified.		03 Dec 2020 16:39:05
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 17:47:49
User entered '19 Aug 2020'	(b) (4) Linden DeBoer (b) (4) (b) (4)	01 Sep 2020 13:32:55

US3032242

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 14:52:51

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:25:04
User accepted default value 'Nasopharyngeal Swab 1 (NASAL1)'	Linden DeBoer (b) (4) (b) (4)	01 Sep 2020 13:32:55

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Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 14:52:51

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:25:04
DataPoint Verified.		03 Dec 2020 16:39:05
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 17:47:49
User entered 'Yes (Y)'	(b) (4) Linden DeBoer (b) (4) (b) (4)	01 Sep 2020 13:32:55

US3032242

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 14:52:51

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:25:04
DataPoint Verified.		03 Dec 2020 16:39:05
User signature succeeded.	Keith Vrbicky (b) (4)	24 Nov 2020 20:29:22
Signature has been broken.	(b) (4) Linden DeBoer (b) (4)	24 Nov 2020 19:14:16
User entered '15:29' reason for change: Data Entry Error	(b) (4) Linden DeBoer (b) (4)	24 Nov 2020 19:14:16
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 17:47:49
User entered '14:50'	(b) (4) Linden DeBoer (b) (4)	01 Sep 2020 13:32:55

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Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 14:52:51

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:25:04
User entered '19 Aug 2020 15:29'	System	24 Nov 2020 19:14:16
User entered '19 Aug 2020 14:50'	System	01 Sep 2020 13:32:55

US3032242

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 14:52:51

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:25:04
User accepted default value 'Nasopharyngeal Swab 2 (NASAL2)'	Linden DeBoer (b) (4) (b) (4)	01 Sep 2020 13:32:55

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Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 14:52:51

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:25:04
DataPoint Verified.		03 Dec 2020 16:39:05
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 17:47:49
User entered 'No (N)'	(b) (4) Linden DeBoer (b) (4) (b) (4)	01 Sep 2020 13:32:55

US3032242

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 14:52:51

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:25:04
DataPoint Verified.		03 Dec 2020 16:39:05
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 17:47:49
User entered empty.	(b) (4) Linden DeBoer (b) (4)	01 Sep 2020 13:32:55
	(b) (4)	

US3032242

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 14:52:51

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:25:04
User entered empty.	System	01 Sep 2020 13:32:55

US3032242

Folder: Visit 1 Day 1

Form: Continuing

Generated On: 09 Jun 2021 14:52:51

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:25:04
DataPoint Verified.		03 Dec 2020 16:39:10
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 17:47:49
User entered 'Yes (Y)'	(b) (4) Linden DeBoer (b) (4)	01 Sep 2020 13:32:58
	(b) (4)	

US3032242

Folder: Visit 1 Day 1

Form: Continuing

Generated On: 09 Jun 2021 14:52:51

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:25:04
User entered '1'	System	01 Sep 2020 13:32:58

US3032242

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 14:52:51

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:43:06
Data entry locked.	System	19 Aug 2020 21:23:04
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	19 Aug 2020 21:23:04

US3032242

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 14:52:51

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:43:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6C42AABB-C8BC-44AC-B3C0-D8720CCF0DD6)', Time: '2020-08-19T16:50:49', User OID: 'PatientReportedOutcome (US3032242)', ODM File OID: '024467ee-9cc5-4911-8c63-4994f0f4ec14'	System	19 Aug 2020 21:51:33
User entered 'Yes (Y)'	System	19 Aug 2020 21:51:33

US3032242

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 14:52:51

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:43:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6C42AABB-C8BC-44AC-B3C0-D8720CCF0DD6)', Time: '2020-08-19T16:51:05', User OID: 'PatientReportedOutcome (US3032242)', ODM File OID: '024467ee-9cc5-4911-8c63-4994f0f4ec14' User entered '97.4'	System	19 Aug 2020 21:51:33
	System	19 Aug 2020 21:51:33

US3032242

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 14:52:51

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:43:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6C42AABB-C8BC-44AC-B3C0-D8720CCF0DD6)', Time: '2020-08-19T16:51:16', User OID: 'PatientReportedOutcome (US3032242)', ODM File OID: '024467ee-9cc5-4911-8c63-4994f0f4ec14'	System	19 Aug 2020 21:51:33
User entered 'No (N)'	System	19 Aug 2020 21:51:33

US3032242

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 14:52:51

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:43:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6C42AABB-C8BC-44AC-B3C0-D8720CCF0DD6)', Time: '2020-08-19T16:51:29', User OID: 'PatientReportedOutcome (US3032242)', ODM File OID: '024467ee-9cc5-4911-8c63-4994f0f4ec14'	System	19 Aug 2020 21:51:33
User entered '19 Aug 2020 16:51'	System	19 Aug 2020 21:51:33

US3032242

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 14:52:51

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:43:06
User entered '19 Aug 2020 16:36'	System	19 Aug 2020 21:23:04

US3032242

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 14:52:51

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:43:06
User entered '19 Aug 2020 19:06'	System	19 Aug 2020 21:23:04

US3032242

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 14:52:51

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:43:06
Data entry locked.	System	19 Aug 2020 21:23:04
User entered 'Day 1, after vaccination (at home)'	System	19 Aug 2020 21:23:04

US3032242

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 14:52:51

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:43:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6C42AABB-C8BC-44AC-B3C0-D8720CCF0DD6)', Time: '2020-08-20T07:22:51', User OID: 'PatientReportedOutcome (US3032242)', ODM File OID: 'cb0cacb6-06bd-426d-b346-6bd3a636fea2' User entered 'Yes (Y)'	System	20 Aug 2020 12:23:48
	System	20 Aug 2020 12:23:48

US3032242

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 14:52:51

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:43:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6C42AABB-C8BC-44AC-B3C0-D8720CCF0DD6)', Time: '2020-08-20T07:23:05', User OID: 'PatientReportedOutcome (US3032242)', ODM File OID: 'cb0cacb6-06bd-426d-b346-6bd3a636fea2' User entered '95.9'	System	20 Aug 2020 12:23:48
	System	20 Aug 2020 12:23:48

US3032242

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 14:52:51

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:43:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6C42AABB-C8BC-44AC-B3C0-D8720CCF0DD6)', Time: '2020-08-20T07:23:31', User OID: 'PatientReportedOutcome (US3032242)', ODM File OID: 'cb0cacb6-06bd-426d-b346-6bd3a636fea2'	System	20 Aug 2020 12:23:48
User entered 'No (N)'	System	20 Aug 2020 12:23:48

US3032242

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 14:52:51

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:43:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6C42AABB-C8BC-44AC-B3C0-D8720CCF0DD6)', Time: '2020-08-20T07:23:45', User OID: 'PatientReportedOutcome (US3032242)', ODM File OID: 'cb0cacb6-06bd-426d-b346-6bd3a636fea2' User entered '20 Aug 2020 07:23'	System	20 Aug 2020 12:23:48
	System	20 Aug 2020 12:23:48

US3032242

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 14:52:51

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:43:06
User entered '19 Aug 2020 20:01'	System	19 Aug 2020 21:23:04

US3032242

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 14:52:51

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:43:06
User entered '20 Aug 2020 11:59'	System	19 Aug 2020 21:23:04

US3032242

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 14:52:51

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:43:06
Data entry locked.	System	19 Aug 2020 21:23:04
User entered 'Day 2'	System	19 Aug 2020 21:23:04

US3032242

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 14:52:51

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:43:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6C42AABB-C8BC-44AC-B3C0-D8720CCF0DD6)', Time: '2020-08-20T15:54:32', User OID: 'PatientReportedOutcome (US3032242)', ODM File OID: '70e13bb9-d9f8-4ca6-965a-e43b53b69472'	System	20 Aug 2020 20:54:56
User entered 'Yes (Y)'	System	20 Aug 2020 20:54:56

US3032242

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 14:52:51

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:43:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6C42AABB-C8BC-44AC-B3C0-D8720CCF0DD6)', Time: '2020-08-20T15:54:39', User OID: 'PatientReportedOutcome (US3032242)', ODM File OID: '70e13bb9-d9f8-4ca6-965a-e43b53b69472' User entered '98.2'	System	20 Aug 2020 20:54:56
	System	20 Aug 2020 20:54:56

US3032242

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 14:52:51

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:43:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6C42AABB-C8BC-44AC-B3C0-D8720CCF0DD6)', Time: '2020-08-20T15:54:45', User OID: 'PatientReportedOutcome (US3032242)', ODM File OID: '70e13bb9-d9f8-4ca6-965a-e43b53b69472'	System	20 Aug 2020 20:54:56
User entered 'No (N)'	System	20 Aug 2020 20:54:56

US3032242

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 14:52:51

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:43:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6C42AABB-C8BC-44AC-B3C0-D8720CCF0DD6)', Time: '2020-08-20T15:54:54', User OID: 'PatientReportedOutcome (US3032242)', ODM File OID: '70e13bb9-d9f8-4ca6-965a-e43b53b69472'	System	20 Aug 2020 20:54:56
User entered '20 Aug 2020 15:54'	System	20 Aug 2020 20:54:56

US3032242

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 14:52:51

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:43:06
User entered '20 Aug 2020 12:00'	System	19 Aug 2020 21:23:04

US3032242

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 14:52:51

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:43:06
User entered '21 Aug 2020 11:59'	System	19 Aug 2020 21:23:04

US3032242

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 14:52:51

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:43:06
Data entry locked.	System	19 Aug 2020 21:23:04
User entered 'Day 3'	System	19 Aug 2020 21:23:04

US3032242

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 14:52:51

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:43:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6C42AABB-C8BC-44AC-B3C0-D8720CCF0DD6)', Time: '2020-08-21T17:35:35', User OID: 'PatientReportedOutcome (US3032242)', ODM File OID: '4b676214-12f6-4fc2-8463-60c9d7060d14'	System	21 Aug 2020 22:36:04
User entered 'Yes (Y)'	System	21 Aug 2020 22:36:04

US3032242

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 14:52:51

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:43:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6C42AABB-C8BC-44AC-B3C0-D8720CCF0DD6)', Time: '2020-08-21T17:35:43', User OID: 'PatientReportedOutcome (US3032242)', ODM File OID: '4b676214-12f6-4fc2-8463-60c9d7060d14' User entered '97.6'	System	21 Aug 2020 22:36:04
	System	21 Aug 2020 22:36:04

US3032242

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 14:52:51

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:43:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6C42AABB-C8BC-44AC-B3C0-D8720CCF0DD6)', Time: '2020-08-21T17:35:48', User OID: 'PatientReportedOutcome (US3032242)', ODM File OID: '4b676214-12f6-4fc2-8463-60c9d7060d14'	System	21 Aug 2020 22:36:04
User entered 'No (N)'	System	21 Aug 2020 22:36:04

US3032242

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 14:52:51

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:43:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6C42AABB-C8BC-44AC-B3C0-D8720CCF0DD6)', Time: '2020-08-21T17:36:02', User OID: 'PatientReportedOutcome (US3032242)', ODM File OID: '4b676214-12f6-4fc2-8463-60c9d7060d14'	System	21 Aug 2020 22:36:04
User entered '21 Aug 2020 17:36'	System	21 Aug 2020 22:36:04

US3032242

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 14:52:51

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:43:06
User entered '21 Aug 2020 12:00'	System	19 Aug 2020 21:23:04

US3032242

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 14:52:51

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:43:06
User entered '22 Aug 2020 11:59'	System	19 Aug 2020 21:23:04

US3032242

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 14:52:51

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:43:06
Data entry locked.	System	19 Aug 2020 21:23:04
User entered 'Day 4'	System	19 Aug 2020 21:23:04

US3032242

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 14:52:51

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:43:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6C42AABB-C8BC-44AC-B3C0-D8720CCF0DD6)', Time: '2020-08-22T12:08:34', User OID: 'PatientReportedOutcome (US3032242)', ODM File OID: '8559505c-d2cc-493f-b244-468b6cac1f6a'	System	22 Aug 2020 17:09:04
User entered 'Yes (Y)'	System	22 Aug 2020 17:09:04

US3032242

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 14:52:51

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:43:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6C42AABB-C8BC-44AC-B3C0-D8720CCF0DD6)', Time: '2020-08-22T12:08:44', User OID: 'PatientReportedOutcome (US3032242)', ODM File OID: '8559505c-d2cc-493f-b244-468b6cac1f6a'	System	22 Aug 2020 17:09:04
User entered '98.0'	System	22 Aug 2020 17:09:04

US3032242

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 14:52:51

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:43:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6C42AABB-C8BC-44AC-B3C0-D8720CCF0DD6)', Time: '2020-08-22T12:08:49', User OID: 'PatientReportedOutcome (US3032242)', ODM File OID: '8559505c-d2cc-493f-b244-468b6cac1f6a'	System	22 Aug 2020 17:09:04
User entered 'No (N)'	System	22 Aug 2020 17:09:04

US3032242

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 14:52:51

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:43:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6C42AABB-C8BC-44AC-B3C0-D8720CCF0DD6)', Time: '2020-08-22T12:08:57', User OID: 'PatientReportedOutcome (US3032242)', ODM File OID: '8559505c-d2cc-493f-b244-468b6cac1f6a'	System	22 Aug 2020 17:09:04
User entered '22 Aug 2020 12:08'	System	22 Aug 2020 17:09:04

US3032242

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 14:52:51

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:43:06
User entered '22 Aug 2020 12:00'	System	19 Aug 2020 21:23:04

US3032242

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 14:52:51

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:43:06
User entered '23 Aug 2020 11:59'	System	19 Aug 2020 21:23:04

US3032242

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 14:52:51

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:43:06
Data entry locked.	System	19 Aug 2020 21:23:04
User entered 'Day 5'	System	19 Aug 2020 21:23:04

US3032242

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 14:52:51

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:43:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6C42AABB-C8BC-44AC-B3C0-D8720CCF0DD6)', Time: '2020-08-23T13:25:21', User OID: 'PatientReportedOutcome (US3032242)', ODM File OID: 'bb79efc9-e973-4fe3-903c-0cf4161ea17b' User entered 'Yes (Y)'	System	23 Aug 2020 18:25:44
	System	23 Aug 2020 18:25:44

US3032242

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 14:52:51

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:43:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6C42AABB-C8BC-44AC-B3C0-D8720CCF0DD6)', Time: '2020-08-23T13:25:28', User OID: 'PatientReportedOutcome (US3032242)', ODM File OID: 'bb79efc9-e973-4fe3-903c-0cf4161ea17b' User entered '97.2'	System	23 Aug 2020 18:25:44
	System	23 Aug 2020 18:25:44

US3032242

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 14:52:51

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:43:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6C42AABB-C8BC-44AC-B3C0-D8720CCF0DD6)', Time: '2020-08-23T13:25:34', User OID: 'PatientReportedOutcome (US3032242)', ODM File OID: 'bb79efc9-e973-4fe3-903c-0cf4161ea17b'	System	23 Aug 2020 18:25:44
User entered 'No (N)'	System	23 Aug 2020 18:25:44

US3032242

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 14:52:51

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:43:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6C42AABB-C8BC-44AC-B3C0-D8720CCF0DD6)', Time: '2020-08-23T13:25:40', User OID: 'PatientReportedOutcome (US3032242)', ODM File OID: 'bb79efc9-e973-4fe3-903c-0cf4161ea17b' User entered '23 Aug 2020 13:25'	System	23 Aug 2020 18:25:44
	System	23 Aug 2020 18:25:44

US3032242

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 14:52:51

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:43:06
User entered '23 Aug 2020 12:00'	System	19 Aug 2020 21:23:04

US3032242

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 14:52:51

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:43:06
User entered '24 Aug 2020 11:59'	System	19 Aug 2020 21:23:04

US3032242

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 14:52:51

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:43:06
Data entry locked.	System	19 Aug 2020 21:23:04
User entered 'Day 6'	System	19 Aug 2020 21:23:04

US3032242

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 14:52:51

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:43:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6C42AABB-C8BC-44AC-B3C0-D8720CCF0DD6)', Time: '2020-08-24T14:04:46', User OID: 'PatientReportedOutcome (US3032242)', ODM File OID: '798d23d0-79ce-41f4-9049-ca8a5729f1d7'	System	24 Aug 2020 19:05:13
User entered 'Yes (Y)'	System	24 Aug 2020 19:05:13

US3032242

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 14:52:51

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:43:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6C42AABB-C8BC-44AC-B3C0-D8720CCF0DD6)', Time: '2020-08-24T14:04:57', User OID: 'PatientReportedOutcome (US3032242)', ODM File OID: '798d23d0-79ce-41f4-9049-ca8a5729f1d7'	System	24 Aug 2020 19:05:13
User entered '96.5'	System	24 Aug 2020 19:05:13

US3032242

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 14:52:51

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:43:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6C42AABB-C8BC-44AC-B3C0-D8720CCF0DD6)', Time: '2020-08-24T14:05:02', User OID: 'PatientReportedOutcome (US3032242)', ODM File OID: '798d23d0-79ce-41f4-9049-ca8a5729f1d7'	System	24 Aug 2020 19:05:13
User entered 'No (N)'	System	24 Aug 2020 19:05:13

US3032242

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 14:52:51

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:43:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6C42AABB-C8BC-44AC-B3C0-D8720CCF0DD6)', Time: '2020-08-24T14:05:10', User OID: 'PatientReportedOutcome (US3032242)', ODM File OID: '798d23d0-79ce-41f4-9049-ca8a5729f1d7'	System	24 Aug 2020 19:05:13
User entered '24 Aug 2020 14:05'	System	24 Aug 2020 19:05:13

US3032242

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 14:52:51

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:43:06
User entered '24 Aug 2020 12:00'	System	19 Aug 2020 21:23:04

US3032242

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 14:52:51

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:43:06
User entered '25 Aug 2020 11:59'	System	19 Aug 2020 21:23:04

US3032242

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 14:52:51

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:43:06
Data entry locked.	System	19 Aug 2020 21:23:04
User entered 'Day 7'	System	19 Aug 2020 21:23:04

US3032242

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 14:52:51

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:43:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6C42AABB-C8BC-44AC-B3C0-D8720CCF0DD6)', Time: '2020-08-25T12:34:02', User OID: 'PatientReportedOutcome (US3032242)', ODM File OID: '21319c1e-289e-4d28-8323-4b2333434957'	System	25 Aug 2020 17:34:32
User entered 'Yes (Y)'	System	25 Aug 2020 17:34:32

US3032242

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 14:52:51

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:43:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6C42AABB-C8BC-44AC-B3C0-D8720CCF0DD6)', Time: '2020-08-25T12:34:11', User OID: 'PatientReportedOutcome (US3032242)', ODM File OID: '21319c1e-289e-4d28-8323-4b2333434957'	System	25 Aug 2020 17:34:32
User entered '97.6'	System	25 Aug 2020 17:34:32

US3032242

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 14:52:51

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:43:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6C42AABB-C8BC-44AC-B3C0-D8720CCF0DD6)', Time: '2020-08-25T12:34:16', User OID: 'PatientReportedOutcome (US3032242)', ODM File OID: '21319c1e-289e-4d28-8323-4b2333434957'	System	25 Aug 2020 17:34:32
User entered 'No (N)'	System	25 Aug 2020 17:34:32

US3032242

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 14:52:51

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:43:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6C42AABB-C8BC-44AC-B3C0-D8720CCF0DD6)', Time: '2020-08-25T12:34:28', User OID: 'PatientReportedOutcome (US3032242)', ODM File OID: '21319c1e-289e-4d28-8323-4b2333434957'	System	25 Aug 2020 17:34:32
User entered '25 Aug 2020 12:34'	System	25 Aug 2020 17:34:32

US3032242

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 14:52:51

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:43:06
User entered '25 Aug 2020 12:00'	System	19 Aug 2020 21:23:04

(

US3032242

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 14:52:51

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:43:06
User entered '26 Aug 2020 11:59'	System	19 Aug 2020 21:23:04

US3032242

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 14:52:51

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:43:06
Data entry locked.	System	19 Aug 2020 21:23:04
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	19 Aug 2020 21:23:04

US3032242

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 14:52:51

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:43:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6C42AABB-C8BC-44AC-B3C0-D8720CCF0DD6)', Time: '2020-08-19T16:52:01', User OID: 'PatientReportedOutcome (US3032242)', ODM File OID: 'b6dce8dd-d4ff-45bc-becd-d50271757e21'	System	19 Aug 2020 21:52:24
User entered 'None (1)'	System	19 Aug 2020 21:52:24

US3032242

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 14:52:51

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:43:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6C42AABB-C8BC-44AC-B3C0-D8720CCF0DD6)', Time: '2020-08-19T16:52:05', User OID: 'PatientReportedOutcome (US3032242)', ODM File OID: 'b6dce8dd-d4ff-45bc-becd-d50271757e21'	System	19 Aug 2020 21:52:24
User entered 'No (N)'	System	19 Aug 2020 21:52:24

US3032242

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 14:52:51

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:43:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6C42AABB-C8BC-44AC-B3C0-D8720CCF0DD6)', Time: '2020-08-19T16:52:10', User OID: 'PatientReportedOutcome (US3032242)', ODM File OID: 'b6dce8dd-d4ff-45bc-becd-d50271757e21'	System	19 Aug 2020 21:52:24
User entered 'No (N)'	System	19 Aug 2020 21:52:24

US3032242

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 14:52:51

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:43:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6C42AABB-C8BC-44AC-B3C0-D8720CCF0DD6)', Time: '2020-08-19T16:52:15', User OID: 'PatientReportedOutcome (US3032242)', ODM File OID: 'b6dce8dd-d4ff-45bc-becd-d50271757e21'	System	19 Aug 2020 21:52:24
User entered 'None (1)'	System	19 Aug 2020 21:52:24

US3032242

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 14:52:51

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:43:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6C42AABB-C8BC-44AC-B3C0-D8720CCF0DD6)', Time: '2020-08-19T16:52:22', User OID: 'PatientReportedOutcome (US3032242)', ODM File OID: 'b6dce8dd-d4ff-45bc-becd-d50271757e21' User entered '19 Aug 2020 16:52'	System	19 Aug 2020 21:52:24
	System	19 Aug 2020 21:52:24

US3032242

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 14:52:51

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:43:06
User entered '19 Aug 2020 16:36'	System	19 Aug 2020 21:23:04

US3032242

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 14:52:51

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:43:06
User entered '19 Aug 2020 19:06'	System	19 Aug 2020 21:23:04

US3032242

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 14:52:51

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:43:06
Data entry locked.	System	19 Aug 2020 21:23:04
User entered 'Day 1, after vaccination (at home)'	System	19 Aug 2020 21:23:04

US3032242

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 14:52:51

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:43:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6C42AABB-C8BC-44AC-B3C0-D8720CCF0DD6)', Time: '2020-08-20T08:42:20', User OID: 'PatientReportedOutcome (US3032242)', ODM File OID: 'c55dbabb-a482-4e9f-aa33-5eb25735275e' User entered 'None (1)'	System	20 Aug 2020 13:43:01
	System	20 Aug 2020 13:43:01

US3032242

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 14:52:51

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:43:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6C42AABB-C8BC-44AC-B3C0-D8720CCF0DD6)', Time: '2020-08-20T08:42:24', User OID: 'PatientReportedOutcome (US3032242)', ODM File OID: 'c55dbabb-a482-4e9f-aa33-5eb25735275e' User entered 'No (N)'	System	20 Aug 2020 13:43:01
	System	20 Aug 2020 13:43:01

US3032242

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 14:52:51

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:43:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6C42AABB-C8BC-44AC-B3C0-D8720CCF0DD6)', Time: '2020-08-20T08:42:28', User OID: 'PatientReportedOutcome (US3032242)', ODM File OID: 'c55dbabb-a482-4e9f-aa33-5eb25735275e' User entered 'No (N)'	System	20 Aug 2020 13:43:01
	System	20 Aug 2020 13:43:01

US3032242

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 14:52:51

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:43:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6C42AABB-C8BC-44AC-B3C0-D8720CCF0DD6)', Time: '2020-08-20T08:42:36', User OID: 'PatientReportedOutcome (US3032242)', ODM File OID: 'c55dbabb-a482-4e9f-aa33-5eb25735275e' User entered 'None (1)'	System	20 Aug 2020 13:43:01
	System	20 Aug 2020 13:43:01

US3032242

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 14:52:51

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:43:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6C42AABB-C8BC-44AC-B3C0-D8720CCF0DD6)', Time: '2020-08-20T08:42:56', User OID: 'PatientReportedOutcome (US3032242)', ODM File OID: 'c55dbabb-a482-4e9f-aa33-5eb25735275e' User entered '20 Aug 2020 08:42'	System	20 Aug 2020 13:43:01
	System	20 Aug 2020 13:43:01

US3032242

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 14:52:51

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:43:06
User entered '19 Aug 2020 20:01'	System	19 Aug 2020 21:23:04

US3032242

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 14:52:51

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:43:06
User entered '20 Aug 2020 11:59'	System	19 Aug 2020 21:23:04

US3032242

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 14:52:51

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:43:06
Data entry locked.	System	19 Aug 2020 21:23:04
User entered 'Day 2'	System	19 Aug 2020 21:23:04

US3032242

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 14:52:51

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:43:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6C42AABB-C8BC-44AC-B3C0-D8720CCF0DD6)', Time: '2020-08-20T15:55:04', User OID: 'PatientReportedOutcome (US3032242)', ODM File OID: 'dfa3be7d-6956-4f63-813e-c84573a87887'	System	20 Aug 2020 20:55:30
User entered 'None (1)'	System	20 Aug 2020 20:55:30

US3032242

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 14:52:51

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:43:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6C42AABB-C8BC-44AC-B3C0-D8720CCF0DD6)', Time: '2020-08-20T15:55:08', User OID: 'PatientReportedOutcome (US3032242)', ODM File OID: 'dfa3be7d-6956-4f63-813e-c84573a87887' User entered 'No (N)'	System	20 Aug 2020 20:55:30
	System	20 Aug 2020 20:55:30

US3032242

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 14:52:51

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:43:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6C42AABB-C8BC-44AC-B3C0-D8720CCF0DD6)', Time: '2020-08-20T15:55:15', User OID: 'PatientReportedOutcome (US3032242)', ODM File OID: 'dfa3be7d-6956-4f63-813e-c84573a87887'	System	20 Aug 2020 20:55:30
User entered 'No (N)'	System	20 Aug 2020 20:55:30

US3032242

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 14:52:51

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:43:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6C42AABB-C8BC-44AC-B3C0-D8720CCF0DD6)', Time: '2020-08-20T15:55:21', User OID: 'PatientReportedOutcome (US3032242)', ODM File OID: 'dfa3be7d-6956-4f63-813e-c84573a87887'	System	20 Aug 2020 20:55:30
User entered 'None (1)'	System	20 Aug 2020 20:55:30

US3032242

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 14:52:51

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:43:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6C42AABB-C8BC-44AC-B3C0-D8720CCF0DD6)', Time: '2020-08-20T15:55:28', User OID: 'PatientReportedOutcome (US3032242)', ODM File OID: 'dfa3be7d-6956-4f63-813e-c84573a87887' User entered '20 Aug 2020 15:55'	System	20 Aug 2020 20:55:30
	System	20 Aug 2020 20:55:30

US3032242

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 14:52:51

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:43:06
User entered '20 Aug 2020 12:00'	System	19 Aug 2020 21:23:04

US3032242

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 14:52:51

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:43:06
User entered '21 Aug 2020 11:59'	System	19 Aug 2020 21:23:04

US3032242

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 14:52:51

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:43:06
Data entry locked.	System	19 Aug 2020 21:23:04
User entered 'Day 3'	System	19 Aug 2020 21:23:04

US3032242

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 14:52:51

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:43:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6C42AABB-C8BC-44AC-B3C0-D8720CCF0DD6)', Time: '2020-08-21T17:36:18', User OID: 'PatientReportedOutcome (US3032242)', ODM File OID: 'c31e1d89-b34c-4eb0-a1ba-187a9d3a3e1c' User entered 'None (1)'	System	21 Aug 2020 22:36:52
	System	21 Aug 2020 22:36:52

US3032242

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 14:52:51

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:43:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6C42AABB-C8BC-44AC-B3C0-D8720CCF0DD6)', Time: '2020-08-21T17:36:23', User OID: 'PatientReportedOutcome (US3032242)', ODM File OID: 'c31e1d89-b34c-4eb0-a1ba-187a9d3a3e1c' User entered 'No (N)'	System	21 Aug 2020 22:36:52
	System	21 Aug 2020 22:36:52

US3032242

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 14:52:51

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:43:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6C42AABB-C8BC-44AC-B3C0-D8720CCF0DD6)', Time: '2020-08-21T17:36:30', User OID: 'PatientReportedOutcome (US3032242)', ODM File OID: 'c31e1d89-b34c-4eb0-a1ba-187a9d3a3e1c' User entered 'No (N)'	System	21 Aug 2020 22:36:52
	System	21 Aug 2020 22:36:52

US3032242

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 14:52:51

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:43:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6C42AABB-C8BC-44AC-B3C0-D8720CCF0DD6)', Time: '2020-08-21T17:36:38', User OID: 'PatientReportedOutcome (US3032242)', ODM File OID: 'c31e1d89-b34c-4eb0-a1ba-187a9d3a3e1c' User entered 'None (1)'	System	21 Aug 2020 22:36:52
	System	21 Aug 2020 22:36:52

US3032242

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 14:52:51

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:43:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6C42AABB-C8BC-44AC-B3C0-D8720CCF0DD6)', Time: '2020-08-21T17:36:47', User OID: 'PatientReportedOutcome (US3032242)', ODM File OID: 'c31e1d89-b34c-4eb0-a1ba-187a9d3a3e1c' User entered '21 Aug 2020 17:36'	System	21 Aug 2020 22:36:52
	System	21 Aug 2020 22:36:52

US3032242

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 14:52:51

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:43:06
User entered '21 Aug 2020 12:00'	System	19 Aug 2020 21:23:04

US3032242

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 14:52:51

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:43:06
User entered '22 Aug 2020 11:59'	System	19 Aug 2020 21:23:04

US3032242

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 14:52:51

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:43:06
Data entry locked.	System	19 Aug 2020 21:23:04
User entered 'Day 4'	System	19 Aug 2020 21:23:04

US3032242

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 14:52:51

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:43:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6C42AABB-C8BC-44AC-B3C0-D8720CCF0DD6)', Time: '2020-08-22T12:09:20', User OID: 'PatientReportedOutcome (US3032242)', ODM File OID: '45404478-322a-432e-8784-ff1ac1c24a35'	System	22 Aug 2020 17:09:47
User entered 'None (1)'	System	22 Aug 2020 17:09:47

US3032242

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 14:52:51

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:43:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6C42AABB-C8BC-44AC-B3C0-D8720CCF0DD6)', Time: '2020-08-22T12:09:26', User OID: 'PatientReportedOutcome (US3032242)', ODM File OID: '45404478-322a-432e-8784-ff1ac1c24a35'	System	22 Aug 2020 17:09:47
User entered 'No (N)'	System	22 Aug 2020 17:09:47

US3032242

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 14:52:51

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:43:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6C42AABB-C8BC-44AC-B3C0-D8720CCF0DD6)', Time: '2020-08-22T12:09:30', User OID: 'PatientReportedOutcome (US3032242)', ODM File OID: '45404478-322a-432e-8784-ff1ac1c24a35'	System	22 Aug 2020 17:09:47
User entered 'No (N)'	System	22 Aug 2020 17:09:47

US3032242

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 14:52:51

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:43:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6C42AABB-C8BC-44AC-B3C0-D8720CCF0DD6)', Time: '2020-08-22T12:09:37', User OID: 'PatientReportedOutcome (US3032242)', ODM File OID: '45404478-322a-432e-8784-ff1ac1c24a35'	System	22 Aug 2020 17:09:47
User entered 'None (1)'	System	22 Aug 2020 17:09:47

US3032242

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 14:52:51

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:43:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6C42AABB-C8BC-44AC-B3C0-D8720CCF0DD6)', Time: '2020-08-22T12:09:46', User OID: 'PatientReportedOutcome (US3032242)', ODM File OID: '45404478-322a-432e-8784-ff1ac1c24a35'	System	22 Aug 2020 17:09:47
User entered '22 Aug 2020 12:09'	System	22 Aug 2020 17:09:47

US3032242

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 14:52:51

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:43:06
User entered '22 Aug 2020 12:00'	System	19 Aug 2020 21:23:04

US3032242

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 14:52:51

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:43:06
User entered '23 Aug 2020 11:59'	System	19 Aug 2020 21:23:04

US3032242

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 14:52:51

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:43:06
Data entry locked.	System	19 Aug 2020 21:23:04
User entered 'Day 5'	System	19 Aug 2020 21:23:04

US3032242

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 14:52:51

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:43:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6C42AABB-C8BC-44AC-B3C0-D8720CCF0DD6)', Time: '2020-08-23T13:25:51', User OID: 'PatientReportedOutcome (US3032242)', ODM File OID: '998d609c-aa90-4c5b-bf8c-402e85c62017'	System	23 Aug 2020 18:26:24
User entered 'None (1)'	System	23 Aug 2020 18:26:24

US3032242

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 14:52:51

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:43:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6C42AABB-C8BC-44AC-B3C0-D8720CCF0DD6)', Time: '2020-08-23T13:25:57', User OID: 'PatientReportedOutcome (US3032242)', ODM File OID: '998d609c-aa90-4c5b-bf8c-402e85c62017'	System	23 Aug 2020 18:26:24
User entered 'No (N)'	System	23 Aug 2020 18:26:24

US3032242

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 14:52:51

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:43:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6C42AABB-C8BC-44AC-B3C0-D8720CCF0DD6)', Time: '2020-08-23T13:26:03', User OID: 'PatientReportedOutcome (US3032242)', ODM File OID: '998d609c-aa90-4c5b-bf8c-402e85c62017'	System	23 Aug 2020 18:26:24
User entered 'No (N)'	System	23 Aug 2020 18:26:24

US3032242

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 14:52:51

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:43:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6C42AABB-C8BC-44AC-B3C0-D8720CCF0DD6)', Time: '2020-08-23T13:26:11', User OID: 'PatientReportedOutcome (US3032242)', ODM File OID: '998d609c-aa90-4c5b-bf8c-402e85c62017'	System	23 Aug 2020 18:26:24
User entered 'None (1)'	System	23 Aug 2020 18:26:24

US3032242

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 14:52:51

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:43:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6C42AABB-C8BC-44AC-B3C0-D8720CCF0DD6)', Time: '2020-08-23T13:26:21', User OID: 'PatientReportedOutcome (US3032242)', ODM File OID: '998d609c-aa90-4c5b-bf8c-402e85c62017' User entered '23 Aug 2020 13:26'	System	23 Aug 2020 18:26:24
	System	23 Aug 2020 18:26:24

US3032242

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 14:52:51

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:43:06
User entered '23 Aug 2020 12:00'	System	19 Aug 2020 21:23:04

US3032242

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 14:52:51

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:43:06
User entered '24 Aug 2020 11:59'	System	19 Aug 2020 21:23:04

US3032242

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 14:52:51

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:43:06
Data entry locked.	System	19 Aug 2020 21:23:04
User entered 'Day 6'	System	19 Aug 2020 21:23:04

US3032242

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 14:52:51

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:43:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6C42AABB-C8BC-44AC-B3C0-D8720CCF0DD6)', Time: '2020-08-24T14:05:33', User OID: 'PatientReportedOutcome (US3032242)', ODM File OID: '8e7524ac-309b-44de-8273-96139bf48115'	System	24 Aug 2020 19:06:01
User entered 'None (1)'	System	24 Aug 2020 19:06:01

US3032242

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 14:52:51

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:43:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6C42AABB-C8BC-44AC-B3C0-D8720CCF0DD6)', Time: '2020-08-24T14:05:30', User OID: 'PatientReportedOutcome (US3032242)', ODM File OID: '8e7524ac-309b-44de-8273-96139bf48115'	System	24 Aug 2020 19:06:01
User entered 'No (N)'	System	24 Aug 2020 19:06:01

US3032242

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 14:52:51

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:43:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6C42AABB-C8BC-44AC-B3C0-D8720CCF0DD6)', Time: '2020-08-24T14:05:36', User OID: 'PatientReportedOutcome (US3032242)', ODM File OID: '8e7524ac-309b-44de-8273-96139bf48115'	System	24 Aug 2020 19:06:01
User entered 'No (N)'	System	24 Aug 2020 19:06:01

US3032242

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 14:52:51

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:43:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6C42AABB-C8BC-44AC-B3C0-D8720CCF0DD6)', Time: '2020-08-24T14:05:44', User OID: 'PatientReportedOutcome (US3032242)', ODM File OID: '8e7524ac-309b-44de-8273-96139bf48115'	System	24 Aug 2020 19:06:01
User entered 'None (1)'	System	24 Aug 2020 19:06:01

US3032242

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 14:52:51

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:43:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6C42AABB-C8BC-44AC-B3C0-D8720CCF0DD6)', Time: '2020-08-24T14:05:57', User OID: 'PatientReportedOutcome (US3032242)', ODM File OID: '8e7524ac-309b-44de-8273-96139bf48115' User entered '24 Aug 2020 14:05'	System	24 Aug 2020 19:06:01
	System	24 Aug 2020 19:06:01

US3032242

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 14:52:51

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:43:06
User entered '24 Aug 2020 12:00'	System	19 Aug 2020 21:23:04

US3032242

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 14:52:51

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:43:06
User entered '25 Aug 2020 11:59'	System	19 Aug 2020 21:23:04

US3032242

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 14:52:51

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:43:06
Data entry locked.	System	19 Aug 2020 21:23:04
User entered 'Day 7'	System	19 Aug 2020 21:23:04

US3032242

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 14:52:51

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:43:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6C42AABB-C8BC-44AC-B3C0-D8720CCF0DD6)', Time: '2020-08-25T12:34:48', User OID: 'PatientReportedOutcome (US3032242)', ODM File OID: 'b1d53c05-1bab-4000-8483-245a3b763655'	System	25 Aug 2020 17:35:19
User entered 'None (1)'	System	25 Aug 2020 17:35:19

US3032242

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 14:52:51

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:43:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6C42AABB-C8BC-44AC-B3C0-D8720CCF0DD6)', Time: '2020-08-25T12:34:46', User OID: 'PatientReportedOutcome (US3032242)', ODM File OID: 'b1d53c05-1bab-4000-8483-245a3b763655'	System	25 Aug 2020 17:35:19
User entered 'No (N)'	System	25 Aug 2020 17:35:19

US3032242

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 14:52:51

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:43:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6C42AABB-C8BC-44AC-B3C0-D8720CCF0DD6)', Time: '2020-08-25T12:34:54', User OID: 'PatientReportedOutcome (US3032242)', ODM File OID: 'b1d53c05-1bab-4000-8483-245a3b763655'	System	25 Aug 2020 17:35:19
User entered 'No (N)'	System	25 Aug 2020 17:35:19

US3032242

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 14:52:51

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:43:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6C42AABB-C8BC-44AC-B3C0-D8720CCF0DD6)', Time: '2020-08-25T12:35:02', User OID: 'PatientReportedOutcome (US3032242)', ODM File OID: 'b1d53c05-1bab-4000-8483-245a3b763655'	System	25 Aug 2020 17:35:19
User entered 'None (1)'	System	25 Aug 2020 17:35:19

US3032242

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 14:52:51

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:43:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6C42AABB-C8BC-44AC-B3C0-D8720CCF0DD6)', Time: '2020-08-25T12:35:13', User OID: 'PatientReportedOutcome (US3032242)', ODM File OID: 'b1d53c05-1bab-4000-8483-245a3b763655'	System	25 Aug 2020 17:35:19
User entered '25 Aug 2020 12:35'	System	25 Aug 2020 17:35:19

US3032242

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 14:52:51

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:43:06
User entered '25 Aug 2020 12:00'	System	19 Aug 2020 21:23:04

US3032242

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 14:52:51

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:43:06
User entered '26 Aug 2020 11:59'	System	19 Aug 2020 21:23:04

US3032242

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 14:52:51

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:43:06
Data entry locked.	System	19 Aug 2020 21:23:04
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	19 Aug 2020 21:23:04

US3032242

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 14:52:51

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:43:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6C42AABB-C8BC-44AC-B3C0-D8720CCF0DD6)', Time: '2020-08-19T16:52:31', User OID: 'PatientReportedOutcome (US3032242)', ODM File OID: 'f3ad85e2-549d-4453-be65-2d6d46b6bedd' User entered 'None (0)'	System	19 Aug 2020 21:53:08
	System	19 Aug 2020 21:53:08

US3032242

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 14:52:51

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:43:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6C42AABB-C8BC-44AC-B3C0-D8720CCF0DD6)', Time: '2020-08-19T16:52:36', User OID: 'PatientReportedOutcome (US3032242)', ODM File OID: 'f3ad85e2-549d-4453-be65-2d6d46b6bedd' User entered 'None (0)'	System	19 Aug 2020 21:53:08
	System	19 Aug 2020 21:53:08

US3032242

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 14:52:51

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:43:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6C42AABB-C8BC-44AC-B3C0-D8720CCF0DD6)', Time: '2020-08-19T16:52:40', User OID: 'PatientReportedOutcome (US3032242)', ODM File OID: 'f3ad85e2-549d-4453-be65-2d6d46b6bedd' User entered 'None (0)'	System	19 Aug 2020 21:53:08
	System	19 Aug 2020 21:53:08

US3032242

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 14:52:51

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:43:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6C42AABB-C8BC-44AC-B3C0-D8720CCF0DD6)', Time: '2020-08-19T16:52:46', User OID: 'PatientReportedOutcome (US3032242)', ODM File OID: 'f3ad85e2-549d-4453-be65-2d6d46b6bedd' User entered 'None (0)'	System	19 Aug 2020 21:53:08
	System	19 Aug 2020 21:53:08

US3032242

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 14:52:51

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:43:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6C42AABB-C8BC-44AC-B3C0-D8720CCF0DD6)', Time: '2020-08-19T16:52:50', User OID: 'PatientReportedOutcome (US3032242)', ODM File OID: 'f3ad85e2-549d-4453-be65-2d6d46b6bedd' User entered 'None (0)'	System	19 Aug 2020 21:53:08
	System	19 Aug 2020 21:53:08

US3032242

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 14:52:51

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:43:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6C42AABB-C8BC-44AC-B3C0-D8720CCF0DD6)', Time: '2020-08-19T16:52:53', User OID: 'PatientReportedOutcome (US3032242)', ODM File OID: 'f3ad85e2-549d-4453-be65-2d6d46b6bedd' User entered 'None (0)'	System	19 Aug 2020 21:53:08
	System	19 Aug 2020 21:53:08

US3032242

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 14:52:51

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)	27 Mar 2021 20:43:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6C42AABB-C8BC-44AC-B3C0-D8720CCF0DD6)', Time: '2020-08-19T16:52:58', User OID: 'PatientReportedOutcome (US3032242)', ODM File OID: 'f3ad85e2-549d-4453-be65-2d6d46b6bedd'	System	19 Aug 2020 21:53:08
User entered 'No (N)'	System	19 Aug 2020 21:53:08

US3032242

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 14:52:51

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:43:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6C42AABB-C8BC-44AC-B3C0-D8720CCF0DD6)', Time: '2020-08-19T16:53:04', User OID: 'PatientReportedOutcome (US3032242)', ODM File OID: 'f3ad85e2-549d-4453-be65-2d6d46b6bedd' User entered '19 Aug 2020 16:53'	System	19 Aug 2020 21:53:08
	System	19 Aug 2020 21:53:08

US3032242

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 14:52:51

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:43:06
User entered '19 Aug 2020 16:36'	System	19 Aug 2020 21:23:04

US3032242

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 14:52:51

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:43:06
User entered '19 Aug 2020 19:06'	System	19 Aug 2020 21:23:04

US3032242

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 14:52:51

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:43:06
Data entry locked.	System	19 Aug 2020 21:23:04
User entered 'Day 1, after vaccination (at home)'	System	19 Aug 2020 21:23:04

US3032242

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 14:52:51

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:43:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6C42AABB-C8BC-44AC-B3C0-D8720CCF0DD6)', Time: '2020-08-20T08:43:15', User OID: 'PatientReportedOutcome (US3032242)', ODM File OID: 'fa531d50-61ae-432c-8652-5af1f8631683'	System	20 Aug 2020 13:43:54
User entered 'None (0)'	System	20 Aug 2020 13:43:54

US3032242

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 14:52:51

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:43:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6C42AABB-C8BC-44AC-B3C0-D8720CCF0DD6)', Time: '2020-08-20T08:43:23', User OID: 'PatientReportedOutcome (US3032242)', ODM File OID: 'fa531d50-61ae-432c-8652-5af1f8631683'	System	20 Aug 2020 13:43:54
User entered 'None (0)'	System	20 Aug 2020 13:43:54

US3032242

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 14:52:51

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:43:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6C42AABB-C8BC-44AC-B3C0-D8720CCF0DD6)', Time: '2020-08-20T08:43:27', User OID: 'PatientReportedOutcome (US3032242)', ODM File OID: 'fa531d50-61ae-432c-8652-5af1f8631683'	System	20 Aug 2020 13:43:54
User entered 'None (0)'	System	20 Aug 2020 13:43:54

US3032242

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 14:52:51

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:43:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6C42AABB-C8BC-44AC-B3C0-D8720CCF0DD6)', Time: '2020-08-20T08:43:31', User OID: 'PatientReportedOutcome (US3032242)', ODM File OID: 'fa531d50-61ae-432c-8652-5af1f8631683'	System	20 Aug 2020 13:43:54
User entered 'None (0)'	System	20 Aug 2020 13:43:54

US3032242

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 14:52:51

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:43:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6C42AABB-C8BC-44AC-B3C0-D8720CCF0DD6)', Time: '2020-08-20T08:43:35', User OID: 'PatientReportedOutcome (US3032242)', ODM File OID: 'fa531d50-61ae-432c-8652-5af1f8631683'	System	20 Aug 2020 13:43:54
User entered 'None (0)'	System	20 Aug 2020 13:43:54

US3032242

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 14:52:51

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:43:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6C42AABB-C8BC-44AC-B3C0-D8720CCF0DD6)', Time: '2020-08-20T08:43:38', User OID: 'PatientReportedOutcome (US3032242)', ODM File OID: 'fa531d50-61ae-432c-8652-5af1f8631683'	System	20 Aug 2020 13:43:54
User entered 'None (0)'	System	20 Aug 2020 13:43:54

US3032242

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 14:52:51

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)	27 Mar 2021 20:43:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6C42AABB-C8BC-44AC-B3C0-D8720CCF0DD6)', Time: '2020-08-20T08:43:44', User OID: 'PatientReportedOutcome (US3032242)', ODM File OID: 'fa531d50-61ae-432c-8652-5af1f8631683'	System	20 Aug 2020 13:43:54
User entered 'No (N)'	System	20 Aug 2020 13:43:54

US3032242

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 14:52:51

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:43:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6C42AABB-C8BC-44AC-B3C0-D8720CCF0DD6)', Time: '2020-08-20T08:43:52', User OID: 'PatientReportedOutcome (US3032242)', ODM File OID: 'fa531d50-61ae-432c-8652-5af1f8631683'	System	20 Aug 2020 13:43:54
User entered '20 Aug 2020 08:43'	System	20 Aug 2020 13:43:54

US3032242

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 14:52:51

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:43:06
User entered '19 Aug 2020 20:01'	System	19 Aug 2020 21:23:04

US3032242

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 14:52:51

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:43:06
User entered '20 Aug 2020 11:59'	System	19 Aug 2020 21:23:04

US3032242

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 14:52:51

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:43:06
Data entry locked.	System	19 Aug 2020 21:23:04
User entered 'Day 2'	System	19 Aug 2020 21:23:04

US3032242

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 14:52:51

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:43:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6C42AABB-C8BC-44AC-B3C0-D8720CCF0DD6)', Time: '2020-08-20T15:55:41', User OID: 'PatientReportedOutcome (US3032242)', ODM File OID: '083f614f-a2f5-4cae-941e-e2a2ae2ff353'	System	20 Aug 2020 20:56:14
User entered 'None (0)'	System	20 Aug 2020 20:56:14

US3032242

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 14:52:51

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:43:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6C42AABB-C8BC-44AC-B3C0-D8720CCF0DD6)', Time: '2020-08-20T15:55:45', User OID: 'PatientReportedOutcome (US3032242)', ODM File OID: '083f614f-a2f5-4cae-941e-e2a2ae2ff353'	System	20 Aug 2020 20:56:14
User entered 'None (0)'	System	20 Aug 2020 20:56:14

US3032242

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 14:52:51

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:43:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6C42AABB-C8BC-44AC-B3C0-D8720CCF0DD6)', Time: '2020-08-20T15:55:49', User OID: 'PatientReportedOutcome (US3032242)', ODM File OID: '083f614f-a2f5-4cae-941e-e2a2ae2ff353'	System	20 Aug 2020 20:56:14
User entered 'None (0)'	System	20 Aug 2020 20:56:14

US3032242

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 14:52:51

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:43:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6C42AABB-C8BC-44AC-B3C0-D8720CCF0DD6)', Time: '2020-08-20T15:55:53', User OID: 'PatientReportedOutcome (US3032242)', ODM File OID: '083f614f-a2f5-4cae-941e-e2a2ae2ff353'	System	20 Aug 2020 20:56:14
User entered 'None (0)'	System	20 Aug 2020 20:56:14

US3032242

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 14:52:51

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:43:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6C42AABB-C8BC-44AC-B3C0-D8720CCF0DD6)', Time: '2020-08-20T15:55:56', User OID: 'PatientReportedOutcome (US3032242)', ODM File OID: '083f614f-a2f5-4cae-941e-e2a2ae2ff353'	System	20 Aug 2020 20:56:14
User entered 'None (0)'	System	20 Aug 2020 20:56:14

US3032242

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 14:52:51

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:43:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6C42AABB-C8BC-44AC-B3C0-D8720CCF0DD6)', Time: '2020-08-20T15:55:59', User OID: 'PatientReportedOutcome (US3032242)', ODM File OID: '083f614f-a2f5-4cae-941e-e2a2ae2ff353'	System	20 Aug 2020 20:56:14
User entered 'None (0)'	System	20 Aug 2020 20:56:14

US3032242

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 14:52:51

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)	27 Mar 2021 20:43:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6C42AABB-C8BC-44AC-B3C0-D8720CCF0DD6)', Time: '2020-08-20T15:56:04', User OID: 'PatientReportedOutcome (US3032242)', ODM File OID: '083f614f-a2f5-4cae-941e-e2a2ae2ff353'	System	20 Aug 2020 20:56:14
User entered 'No (N)'	System	20 Aug 2020 20:56:14

US3032242

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 14:52:51

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:43:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6C42AABB-C8BC-44AC-B3C0-D8720CCF0DD6)', Time: '2020-08-20T15:56:13', User OID: 'PatientReportedOutcome (US3032242)', ODM File OID: '083f614f-a2f5-4cae-941e-e2a2ae2ff353'	System	20 Aug 2020 20:56:14
User entered '20 Aug 2020 15:56'	System	20 Aug 2020 20:56:14

US3032242

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 14:52:51

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:43:06
User entered '20 Aug 2020 12:00'	System	19 Aug 2020 21:23:04

US3032242

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 14:52:51

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:43:06
User entered '21 Aug 2020 11:59'	System	19 Aug 2020 21:23:04

US3032242

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 14:52:51

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:43:06
Data entry locked.	System	19 Aug 2020 21:23:04
User entered 'Day 3'	System	19 Aug 2020 21:23:04

US3032242

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 14:52:51

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:43:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6C42AABB-C8BC-44AC-B3C0-D8720CCF0DD6)', Time: '2020-08-21T17:37:04', User OID: 'PatientReportedOutcome (US3032242)', ODM File OID: '0343211c-c9d9-4582-95d6-42c2dde19191'	System	21 Aug 2020 22:37:55
User entered 'None (0)'	System	21 Aug 2020 22:37:55

US3032242

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 14:52:51

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:43:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6C42AABB-C8BC-44AC-B3C0-D8720CCF0DD6)', Time: '2020-08-21T17:37:13', User OID: 'PatientReportedOutcome (US3032242)', ODM File OID: '0343211c-c9d9-4582-95d6-42c2dde19191'	System	21 Aug 2020 22:37:55
User entered 'None (0)'	System	21 Aug 2020 22:37:55

US3032242

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 14:52:51

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:43:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6C42AABB-C8BC-44AC-B3C0-D8720CCF0DD6)', Time: '2020-08-21T17:37:19', User OID: 'PatientReportedOutcome (US3032242)', ODM File OID: '0343211c-c9d9-4582-95d6-42c2dde19191'	System	21 Aug 2020 22:37:55
User entered 'None (0)'	System	21 Aug 2020 22:37:55

US3032242

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 14:52:51

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:43:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6C42AABB-C8BC-44AC-B3C0-D8720CCF0DD6)', Time: '2020-08-21T17:37:25', User OID: 'PatientReportedOutcome (US3032242)', ODM File OID: '0343211c-c9d9-4582-95d6-42c2dde19191'	System	21 Aug 2020 22:37:55
User entered 'None (0)'	System	21 Aug 2020 22:37:55

US3032242

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 14:52:51

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:43:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6C42AABB-C8BC-44AC-B3C0-D8720CCF0DD6)', Time: '2020-08-21T17:37:32', User OID: 'PatientReportedOutcome (US3032242)', ODM File OID: '0343211c-c9d9-4582-95d6-42c2dde19191'	System	21 Aug 2020 22:37:55
User entered 'None (0)'	System	21 Aug 2020 22:37:55

US3032242

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 14:52:51

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:43:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6C42AABB-C8BC-44AC-B3C0-D8720CCF0DD6)', Time: '2020-08-21T17:37:37', User OID: 'PatientReportedOutcome (US3032242)', ODM File OID: '0343211c-c9d9-4582-95d6-42c2dde19191'	System	21 Aug 2020 22:37:55
User entered 'None (0)'	System	21 Aug 2020 22:37:55

US3032242

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 14:52:51

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)	27 Mar 2021 20:43:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6C42AABB-C8BC-44AC-B3C0-D8720CCF0DD6)', Time: '2020-08-21T17:37:44', User OID: 'PatientReportedOutcome (US3032242)', ODM File OID: '0343211c-c9d9-4582-95d6-42c2dde19191'	System	21 Aug 2020 22:37:55
User entered 'No (N)'	System	21 Aug 2020 22:37:55

US3032242

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 14:52:51

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:43:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6C42AABB-C8BC-44AC-B3C0-D8720CCF0DD6)', Time: '2020-08-21T17:37:53', User OID: 'PatientReportedOutcome (US3032242)', ODM File OID: '0343211c-c9d9-4582-95d6-42c2dde19191'	System	21 Aug 2020 22:37:55
User entered '21 Aug 2020 17:37'	System	21 Aug 2020 22:37:55

US3032242

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 14:52:51

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:43:06
User entered '21 Aug 2020 12:00'	System	19 Aug 2020 21:23:04

US3032242

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 14:52:51

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:43:06
User entered '22 Aug 2020 11:59'	System	19 Aug 2020 21:23:04

US3032242

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 14:52:51

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:43:06
Data entry locked.	System	19 Aug 2020 21:23:04
User entered 'Day 4'	System	19 Aug 2020 21:23:04

US3032242

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 14:52:51

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:43:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6C42AABB-C8BC-44AC-B3C0-D8720CCF0DD6)', Time: '2020-08-22T12:09:59', User OID: 'PatientReportedOutcome (US3032242)', ODM File OID: 'deab7e6b-53f6-4802-b362-a5d514e89cd9' User entered 'None (0)'	System	22 Aug 2020 17:11:04
	System	22 Aug 2020 17:11:04

US3032242

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 14:52:51

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:43:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6C42AABB-C8BC-44AC-B3C0-D8720CCF0DD6)', Time: '2020-08-22T12:10:06', User OID: 'PatientReportedOutcome (US3032242)', ODM File OID: 'deab7e6b-53f6-4802-b362-a5d514e89cd9' User entered 'None (0)'	System	22 Aug 2020 17:11:04
	System	22 Aug 2020 17:11:04

US3032242

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 14:52:51

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:43:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6C42AABB-C8BC-44AC-B3C0-D8720CCF0DD6)', Time: '2020-08-22T12:10:14', User OID: 'PatientReportedOutcome (US3032242)', ODM File OID: 'deab7e6b-53f6-4802-b362-a5d514e89cd9' User entered 'None (0)'	System	22 Aug 2020 17:11:04
	System	22 Aug 2020 17:11:04

US3032242

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 14:52:51

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:43:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6C42AABB-C8BC-44AC-B3C0-D8720CCF0DD6)', Time: '2020-08-22T12:10:22', User OID: 'PatientReportedOutcome (US3032242)', ODM File OID: 'deab7e6b-53f6-4802-b362-a5d514e89cd9' User entered 'None (0)'	System	22 Aug 2020 17:11:04
	System	22 Aug 2020 17:11:04

US3032242

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 14:52:51

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:43:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6C42AABB-C8BC-44AC-B3C0-D8720CCF0DD6)', Time: '2020-08-22T12:10:25', User OID: 'PatientReportedOutcome (US3032242)', ODM File OID: 'deab7e6b-53f6-4802-b362-a5d514e89cd9' User entered 'None (0)'	System	22 Aug 2020 17:11:04
	System	22 Aug 2020 17:11:04

US3032242

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 14:52:51

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:43:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6C42AABB-C8BC-44AC-B3C0-D8720CCF0DD6)', Time: '2020-08-22T12:10:30', User OID: 'PatientReportedOutcome (US3032242)', ODM File OID: 'deab7e6b-53f6-4802-b362-a5d514e89cd9' User entered 'None (0)'	System	22 Aug 2020 17:11:04
	System	22 Aug 2020 17:11:04

US3032242

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 14:52:51

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)	27 Mar 2021 20:43:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6C42AABB-C8BC-44AC-B3C0-D8720CCF0DD6)', Time: '2020-08-22T12:10:35', User OID: 'PatientReportedOutcome (US3032242)', ODM File OID: 'deab7e6b-53f6-4802-b362-a5d514e89cd9' User entered 'No (N)'	System	22 Aug 2020 17:11:04
	System	22 Aug 2020 17:11:04

US3032242

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 14:52:51

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:43:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6C42AABB-C8BC-44AC-B3C0-D8720CCF0DD6)', Time: '2020-08-22T12:10:58', User OID: 'PatientReportedOutcome (US3032242)', ODM File OID: 'deab7e6b-53f6-4802-b362-a5d514e89cd9' User entered '22 Aug 2020 12:10'	System	22 Aug 2020 17:11:04
	System	22 Aug 2020 17:11:04

US3032242

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 14:52:51

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:43:06
User entered '22 Aug 2020 12:00'	System	19 Aug 2020 21:23:04

US3032242

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 14:52:51

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:43:06
User entered '23 Aug 2020 11:59'	System	19 Aug 2020 21:23:04

US3032242

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 14:52:51

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:43:06
Data entry locked.	System	19 Aug 2020 21:23:04
User entered 'Day 5'	System	19 Aug 2020 21:23:04

US3032242

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 14:52:51

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:43:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6C42AABB-C8BC-44AC-B3C0-D8720CCF0DD6)', Time: '2020-08-23T13:26:30', User OID: 'PatientReportedOutcome (US3032242)', ODM File OID: '4eeec19a-ff4f-45df-8af4-432ce78ef594'	System	23 Aug 2020 18:27:15
User entered 'None (0)'	System	23 Aug 2020 18:27:15

US3032242

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 14:52:51

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:43:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6C42AABB-C8BC-44AC-B3C0-D8720CCF0DD6)', Time: '2020-08-23T13:26:42', User OID: 'PatientReportedOutcome (US3032242)', ODM File OID: '4eeec19a-ff4f-45df-8af4-432ce78ef594'	System	23 Aug 2020 18:27:15
User entered 'None (0)'	System	23 Aug 2020 18:27:15

US3032242

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 14:52:51

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:43:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6C42AABB-C8BC-44AC-B3C0-D8720CCF0DD6)', Time: '2020-08-23T13:26:47', User OID: 'PatientReportedOutcome (US3032242)', ODM File OID: '4eeec19a-ff4f-45df-8af4-432ce78ef594'	System	23 Aug 2020 18:27:15
User entered 'None (0)'	System	23 Aug 2020 18:27:15

US3032242

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 14:52:51

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:43:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6C42AABB-C8BC-44AC-B3C0-D8720CCF0DD6)', Time: '2020-08-23T13:26:52', User OID: 'PatientReportedOutcome (US3032242)', ODM File OID: '4eeec19a-ff4f-45df-8af4-432ce78ef594'	System	23 Aug 2020 18:27:15
User entered 'None (0)'	System	23 Aug 2020 18:27:15

US3032242

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 14:52:51

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:43:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6C42AABB-C8BC-44AC-B3C0-D8720CCF0DD6)', Time: '2020-08-23T13:26:57', User OID: 'PatientReportedOutcome (US3032242)', ODM File OID: '4eeec19a-ff4f-45df-8af4-432ce78ef594'	System	23 Aug 2020 18:27:15
User entered 'None (0)'	System	23 Aug 2020 18:27:15

US3032242

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 14:52:51

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:43:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6C42AABB-C8BC-44AC-B3C0-D8720CCF0DD6)', Time: '2020-08-23T13:27:00', User OID: 'PatientReportedOutcome (US3032242)', ODM File OID: '4eeec19a-ff4f-45df-8af4-432ce78ef594'	System	23 Aug 2020 18:27:15
User entered 'None (0)'	System	23 Aug 2020 18:27:15

US3032242

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 14:52:51

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)	27 Mar 2021 20:43:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6C42AABB-C8BC-44AC-B3C0-D8720CCF0DD6)', Time: '2020-08-23T13:27:05', User OID: 'PatientReportedOutcome (US3032242)', ODM File OID: '4eeec19a-ff4f-45df-8af4-432ce78ef594'	System	23 Aug 2020 18:27:15
User entered 'No (N)'	System	23 Aug 2020 18:27:15

US3032242

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 14:52:51

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:43:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6C42AABB-C8BC-44AC-B3C0-D8720CCF0DD6)', Time: '2020-08-23T13:27:12', User OID: 'PatientReportedOutcome (US3032242)', ODM File OID: '4eeec19a-ff4f-45df-8af4-432ce78ef594' User entered '23 Aug 2020 13:27'	System	23 Aug 2020 18:27:15
	System	23 Aug 2020 18:27:15

US3032242

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 14:52:51

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:43:06
User entered '23 Aug 2020 12:00'	System	19 Aug 2020 21:23:04

US3032242

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 14:52:51

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:43:06
User entered '24 Aug 2020 11:59'	System	19 Aug 2020 21:23:04

US3032242

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 14:52:51

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:43:06
Data entry locked.	System	19 Aug 2020 21:23:04
User entered 'Day 6'	System	19 Aug 2020 21:23:04

US3032242

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 14:52:51

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:43:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6C42AABB-C8BC-44AC-B3C0-D8720CCF0DD6)', Time: '2020-08-24T14:06:04', User OID: 'PatientReportedOutcome (US3032242)', ODM File OID: '4f6ecc89-b124-44e5-9854-6eea949a9765'	System	24 Aug 2020 19:06:35
User entered 'None (0)'	System	24 Aug 2020 19:06:35

US3032242

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 14:52:51

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:43:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6C42AABB-C8BC-44AC-B3C0-D8720CCF0DD6)', Time: '2020-08-24T14:06:07', User OID: 'PatientReportedOutcome (US3032242)', ODM File OID: '4f6ecc89-b124-44e5-9854-6eea949a9765'	System	24 Aug 2020 19:06:35
User entered 'None (0)'	System	24 Aug 2020 19:06:35

US3032242

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 14:52:51

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:43:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6C42AABB-C8BC-44AC-B3C0-D8720CCF0DD6)', Time: '2020-08-24T14:06:11', User OID: 'PatientReportedOutcome (US3032242)', ODM File OID: '4f6ecc89-b124-44e5-9854-6eea949a9765'	System	24 Aug 2020 19:06:35
User entered 'None (0)'	System	24 Aug 2020 19:06:35

US3032242

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 14:52:51

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:43:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6C42AABB-C8BC-44AC-B3C0-D8720CCF0DD6)', Time: '2020-08-24T14:06:14', User OID: 'PatientReportedOutcome (US3032242)', ODM File OID: '4f6ecc89-b124-44e5-9854-6eea949a9765' User entered 'None (0)'	System	24 Aug 2020 19:06:35
	System	24 Aug 2020 19:06:35

US3032242

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 14:52:51

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:43:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6C42AABB-C8BC-44AC-B3C0-D8720CCF0DD6)', Time: '2020-08-24T14:06:17', User OID: 'PatientReportedOutcome (US3032242)', ODM File OID: '4f6ecc89-b124-44e5-9854-6eea949a9765'	System	24 Aug 2020 19:06:35
User entered 'None (0)'	System	24 Aug 2020 19:06:35

US3032242

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 14:52:51

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:43:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6C42AABB-C8BC-44AC-B3C0-D8720CCF0DD6)', Time: '2020-08-24T14:06:20', User OID: 'PatientReportedOutcome (US3032242)', ODM File OID: '4f6ecc89-b124-44e5-9854-6eea949a9765'	System	24 Aug 2020 19:06:35
User entered 'None (0)'	System	24 Aug 2020 19:06:35

US3032242

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 14:52:51

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)	27 Mar 2021 20:43:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6C42AABB-C8BC-44AC-B3C0-D8720CCF0DD6)', Time: '2020-08-24T14:06:23', User OID: 'PatientReportedOutcome (US3032242)', ODM File OID: '4f6ecc89-b124-44e5-9854-6eea949a9765'	System	24 Aug 2020 19:06:35
User entered 'No (N)'	System	24 Aug 2020 19:06:35

US3032242

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 14:52:51

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:43:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6C42AABB-C8BC-44AC-B3C0-D8720CCF0DD6)', Time: '2020-08-24T14:06:31', User OID: 'PatientReportedOutcome (US3032242)', ODM File OID: '4f6ecc89-b124-44e5-9854-6eea949a9765'	System	24 Aug 2020 19:06:35
User entered '24 Aug 2020 14:06'	System	24 Aug 2020 19:06:35

US3032242

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 14:52:51

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:43:06
User entered '24 Aug 2020 12:00'	System	19 Aug 2020 21:23:04

US3032242

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 14:52:51

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:43:06
User entered '25 Aug 2020 11:59'	System	19 Aug 2020 21:23:04

US3032242

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 14:52:51

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:43:06
Data entry locked.	System	19 Aug 2020 21:23:04
User entered 'Day 7'	System	19 Aug 2020 21:23:04

US3032242

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 14:52:51

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:43:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6C42AABB-C8BC-44AC-B3C0-D8720CCF0DD6)', Time: '2020-08-25T12:35:20', User OID: 'PatientReportedOutcome (US3032242)', ODM File OID: '1ebcdcb3-236d-45b3-9df6-ee7ffd857d50'	System	25 Aug 2020 17:36:00
User entered 'None (0)'	System	25 Aug 2020 17:36:00

US3032242

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 14:52:51

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:43:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6C42AABB-C8BC-44AC-B3C0-D8720CCF0DD6)', Time: '2020-08-25T12:35:26', User OID: 'PatientReportedOutcome (US3032242)', ODM File OID: '1ebcdcb3-236d-45b3-9df6-ee7ffd857d50'	System	25 Aug 2020 17:36:00
User entered 'None (0)'	System	25 Aug 2020 17:36:00

US3032242

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 14:52:51

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:43:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6C42AABB-C8BC-44AC-B3C0-D8720CCF0DD6)', Time: '2020-08-25T12:35:32', User OID: 'PatientReportedOutcome (US3032242)', ODM File OID: '1ebcdcb3-236d-45b3-9df6-ee7ffd857d50'	System	25 Aug 2020 17:36:00
User entered 'None (0)'	System	25 Aug 2020 17:36:00

US3032242

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 14:52:51

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:43:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6C42AABB-C8BC-44AC-B3C0-D8720CCF0DD6)', Time: '2020-08-25T12:35:37', User OID: 'PatientReportedOutcome (US3032242)', ODM File OID: '1ebcdcb3-236d-45b3-9df6-ee7ffd857d50'	System	25 Aug 2020 17:36:00
User entered 'None (0)'	System	25 Aug 2020 17:36:00

US3032242

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 14:52:51

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:43:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6C42AABB-C8BC-44AC-B3C0-D8720CCF0DD6)', Time: '2020-08-25T12:35:40', User OID: 'PatientReportedOutcome (US3032242)', ODM File OID: '1ebcdcb3-236d-45b3-9df6-ee7ffd857d50'	System	25 Aug 2020 17:36:00
User entered 'None (0)'	System	25 Aug 2020 17:36:00

US3032242

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 14:52:51

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:43:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6C42AABB-C8BC-44AC-B3C0-D8720CCF0DD6)', Time: '2020-08-25T12:35:43', User OID: 'PatientReportedOutcome (US3032242)', ODM File OID: '1ebcdcb3-236d-45b3-9df6-ee7ffd857d50' User entered 'None (0)'	System	25 Aug 2020 17:36:00
	System	25 Aug 2020 17:36:00

US3032242

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 14:52:51

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)	27 Mar 2021 20:43:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6C42AABB-C8BC-44AC-B3C0-D8720CCF0DD6)', Time: '2020-08-25T12:35:48', User OID: 'PatientReportedOutcome (US3032242)', ODM File OID: '1ebcdcb3-236d-45b3-9df6-ee7ffd857d50'	System	25 Aug 2020 17:36:00
User entered 'No (N)'	System	25 Aug 2020 17:36:00

US3032242

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 14:52:51

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:43:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6C42AABB-C8BC-44AC-B3C0-D8720CCF0DD6)', Time: '2020-08-25T12:35:58', User OID: 'PatientReportedOutcome (US3032242)', ODM File OID: '1ebcdcb3-236d-45b3-9df6-ee7ffd857d50' User entered '25 Aug 2020 12:35'	System	25 Aug 2020 17:36:00
	System	25 Aug 2020 17:36:00

US3032242

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 14:52:51

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:43:06
User entered '25 Aug 2020 12:00'	System	19 Aug 2020 21:23:04

US3032242

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 14:52:51

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:43:06
User entered '26 Aug 2020 11:59'	System	19 Aug 2020 21:23:04

US3032242

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 09 Jun 2021 14:52:51

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:25:04
DataPoint Verified.		03 Dec 2020 16:39:38
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 17:47:49
User entered 'Yes (Y)'	(b) (4) Linden DeBoer (b) (4)	01 Sep 2020 13:41:50
	(b) (4)	

US3032242

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 09 Jun 2021 14:52:51

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:25:04
DataPoint Verified.		03 Dec 2020 16:39:38
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 17:47:49
User entered '26 Aug 2020'	(b) (4) Linden DeBoer (b) (4) (b) (4)	01 Sep 2020 13:41:50

US3032242

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 09 Jun 2021 14:52:51

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:25:04
DataPoint Verified.		03 Dec 2020 16:39:38
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 17:47:49
User entered 'Contact Made (CONTACT MADE)'	(b) (4) Linden DeBoer (b) (4) (b) (4)	01 Sep 2020 13:41:50

US3032242

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 09 Jun 2021 14:52:51

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:25:04
DataPoint Verified.	(b) (4)	03 Dec 2020 16:39:38
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 17:47:49
User entered empty.	(b) (4) Linden DeBoer (b) (4)	01 Sep 2020 13:41:50
	(b) (4)	

US3032242

Folder: Safety Call Day 8 (1)

Form: Continuing

Generated On: 09 Jun 2021 14:52:51

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:25:04
DataPoint Verified.	(b) (4)	03 Dec 2020 16:39:43
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 17:47:49
User entered 'Yes (Y)'	(b) (4) Linden DeBoer (b) (4)	01 Sep 2020 13:41:56
	(b) (4)	

US3032242

Folder: Safety Call Day 8 (1)

Form: Continuing

Generated On: 09 Jun 2021 14:52:51

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:25:04
User entered '1'	System	01 Sep 2020 13:41:56

US3032242

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 09 Jun 2021 14:52:51

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:25:04
DataPoint Verified.		03 Dec 2020 16:40:10
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 17:47:49
User entered 'Yes (Y)'	(b) (4) Samantha Wieseler (b) (4)	02 Sep 2020 23:51:01
	(b) (4)	

US3032242

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 09 Jun 2021 14:52:51

Date of Contact or Contact Attempt (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:25:04
DataPoint Verified.		03 Dec 2020 16:40:10
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 17:47:49
User entered '02 Sep 2020'	(b) (4) Samantha Wieseler (b) (4) (b) (4)	02 Sep 2020 23:51:01

US3032242

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 09 Jun 2021 14:52:51

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:25:04
DataPoint Verified.		03 Dec 2020 16:40:10
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 17:47:49
User entered 'Contact Made (CONTACT MADE)'	(b) (4) Samantha Wieseler (b) (4) (b) (4)	02 Sep 2020 23:51:01

US3032242

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 09 Jun 2021 14:52:51

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:25:04
DataPoint Verified.	(b) (4)	03 Dec 2020 16:40:10
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 17:47:49
User entered empty.	(b) (4) Samantha Wieseler (b) (4)	02 Sep 2020 23:51:01
	(b) (4)	

US3032242

Folder: Safety Call Day 15 (1)

Form: Continuing

Generated On: 09 Jun 2021 14:52:51

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:25:04
DataPoint Verified.		03 Dec 2020 16:40:17
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 17:47:49
User entered 'Yes (Y)'	(b) (4) Samantha Wieseler (b) (4)	02 Sep 2020 23:51:05
	(b) (4)	

US3032242

Folder: Safety Call Day 15 (1)

Form: Continuing

Generated On: 09 Jun 2021 14:52:51

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:25:04
User entered '1'	System	02 Sep 2020 23:51:05

US3032242

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 09 Jun 2021 14:52:51

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:25:04
DataPoint Verified.		03 Dec 2020 16:40:53
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 17:47:49
User entered 'Yes (Y)'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	15 Sep 2020 13:50:01

US3032242

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 09 Jun 2021 14:52:51

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:25:04
DataPoint Verified.		03 Dec 2020 16:40:53
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 17:47:49
User entered '9 Sep 2020'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	15 Sep 2020 13:50:01

US3032242

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 09 Jun 2021 14:52:51

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:25:04
DataPoint Verified.		03 Dec 2020 16:40:53
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 17:47:49
User entered 'Contact Made (CONTACT MADE)'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	15 Sep 2020 13:50:01

US3032242

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 09 Jun 2021 14:52:51

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:25:04
DataPoint Verified.		03 Dec 2020 16:40:53
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 17:47:49
User entered empty.	(b) (4) Kelsey Kelley (b) (4) (b) (4)	15 Sep 2020 13:50:01

US3032242

Folder: Safety Call Day 22 (1)

Form: Continuing

Generated On: 09 Jun 2021 14:52:51

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:25:04
DataPoint Verified.		03 Dec 2020 16:40:56
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 17:47:49
User entered 'Yes (Y)'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	15 Sep 2020 13:50:03

US3032242

Folder: Safety Call Day 22 (1)

Form: Continuing

Generated On: 09 Jun 2021 14:52:51

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:25:04
User entered '1'	System	15 Sep 2020 13:50:03

US3032242

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 09 Jun 2021 14:52:51

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:25:04
DataPoint Verified.	(b) (4)	03 Dec 2020 16:41:13
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 17:47:49
User entered 'Yes (Y)'	(b) (4) Linden DeBoer (b) (4)	18 Sep 2020 14:37:58
	(b) (4)	

US3032242

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 09 Jun 2021 14:52:51

Visit date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:25:04
DataPoint Verified.		03 Dec 2020 16:41:13
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 17:47:49
User entered '18 Sep 2020'	(b) (4) Linden DeBoer (b) (4) (b) (4)	18 Sep 2020 14:37:58

US3032242

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 09 Jun 2021 14:52:51

[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 19:25:04
DataPoint Verified.		03 Dec 2020 16:41:13
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 17:47:49
User entered 'Clinic (Clinic)'	(b) (4) Linden DeBoer (b) (4) (b) (4)	18 Sep 2020 14:37:58

US3032242

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 09 Jun 2021 14:52:51

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:25:04
User entered 'VISIT2'	System	18 Sep 2020 14:37:58

US3032242

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 14:52:51

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:25:04
User accepted default value 'Pre-Dose (PREDOSE)'	Linden DeBoer (b) (4) (b) (4)	18 Sep 2020 15:09:23

US3032242

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 14:52:51

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:25:04
DataPoint Verified.		03 Dec 2020 16:42:24
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 17:47:49
User entered 'Yes (Y)'	(b) (4) Linden DeBoer (b) (4) (b) (4)	18 Sep 2020 15:09:23

US3032242

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 14:52:51

Date of assessment (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:25:04
DataPoint Verified.		03 Dec 2020 16:42:24
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 17:47:49
User entered '18 Sep 2020'	(b) (4) Linden DeBoer (b) (4) (b) (4)	18 Sep 2020 15:09:23

US3032242

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 14:52:51

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:25:04
DataPoint Verified.		03 Dec 2020 16:42:24
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 17:47:49
User entered '08:16'	(b) (4) Linden DeBoer (b) (4) (b) (4)	18 Sep 2020 15:09:23

US3032242

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 14:52:51

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:25:04
User entered '18 Sep 2020 08:16'	System	18 Sep 2020 15:09:23

US3032242

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 14:52:51

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:25:04
DataPoint Verified.		03 Dec 2020 16:42:24
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 17:47:49
User entered '36.4' C	(b) (4) Linden DeBoer (b) (4) (b) (4)	18 Sep 2020 15:09:23

US3032242

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 14:52:51

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:25:04
DataPoint Verified.		03 Dec 2020 16:42:24
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 17:47:49
User entered 'Oral (Oral)'	(b) (4) Linden DeBoer (b) (4) (b) (4)	18 Sep 2020 15:09:23

US3032242

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 14:52:51

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:25:04
DataPoint Verified.		03 Dec 2020 16:42:24
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 17:47:49
User entered empty.	(b) (4) Linden DeBoer (b) (4) (b) (4)	18 Sep 2020 15:09:23

US3032242

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 14:52:51

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:25:04
DataPoint Verified.		03 Dec 2020 16:42:24
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 17:47:49
User entered '80'	(b) (4) Linden DeBoer (b) (4)	18 Sep 2020 15:09:23
	(b) (4)	

US3032242

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 14:52:51

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:25:04
User entered 'bpm'	System	18 Sep 2020 15:09:23

US3032242

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 14:52:51

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:25:04
DataPoint Verified.		03 Dec 2020 16:42:24
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 17:47:49
User entered '15'	(b) (4) Linden DeBoer (b) (4)	18 Sep 2020 15:09:23
	(b) (4)	

US3032242

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 14:52:51

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:25:04
User entered 'breaths/min'	System	18 Sep 2020 15:09:23

US3032242

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 14:52:51

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:25:04
DataPoint Verified.		03 Dec 2020 16:42:24
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 17:47:49
User entered '108'	(b) (4) Linden DeBoer (b) (4)	18 Sep 2020 15:09:23
	(b) (4)	

US3032242

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 14:52:51

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:25:04
User entered 'mmHg'	System	18 Sep 2020 15:09:23

US3032242

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 14:52:51

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:25:04
DataPoint Verified.		03 Dec 2020 16:42:24
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 17:47:49
User entered '79'	(b) (4) Linden DeBoer (b) (4) (b) (4)	18 Sep 2020 15:09:23

US3032242

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 14:52:51

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:25:04
User entered 'mmHg'	System	18 Sep 2020 15:09:23

US3032242

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 14:52:51

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:25:04
User accepted default value 'Post-Dose (POSTDOSE)'	Linden DeBoer (b) (4) (b) (4)	18 Sep 2020 15:09:23

US3032242

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 14:52:51

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:25:04
DataPoint Verified.		03 Dec 2020 16:42:24
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 17:47:49
User entered 'Yes (Y)'	(b) (4) Linden DeBoer (b) (4) (b) (4)	18 Sep 2020 15:09:23

US3032242

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 14:52:51

Date of assessment (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:25:04
DataPoint Verified.		03 Dec 2020 16:42:24
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 17:47:49
User entered '18 Sep 2020'	(b) (4) Linden DeBoer (b) (4) (b) (4)	18 Sep 2020 15:09:23

US3032242

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 14:52:51

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:25:04
DataPoint Verified.	(b) (4)	03 Dec 2020 16:42:24
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 17:47:49
User entered '09:49'	(b) (4) Linden DeBoer (b) (4) (b) (4)	18 Sep 2020 15:09:23

US3032242

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 14:52:51

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:25:04
User entered '18 Sep 2020 09:49'	System	18 Sep 2020 15:09:23

US3032242

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 14:52:51

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:25:04
DataPoint Verified.		03 Dec 2020 16:42:24
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 17:47:49
User entered '36.8' C	(b) (4) Linden DeBoer (b) (4)	18 Sep 2020 15:09:23
	(b) (4)	

US3032242

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 14:52:51

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:25:04
DataPoint Verified.		03 Dec 2020 16:42:24
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 17:47:49
User entered 'Oral (Oral)'	(b) (4) Linden DeBoer (b) (4)	18 Sep 2020 15:09:23
	(b) (4)	

US3032242

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 14:52:51

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:25:04
DataPoint Verified.		03 Dec 2020 16:42:24
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 17:47:49
User entered empty.	(b) (4) Linden DeBoer (b) (4)	18 Sep 2020 15:09:23
	(b) (4)	

US3032242

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 14:52:51

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:25:04
DataPoint Verified.		03 Dec 2020 16:42:24
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 17:47:49
User entered '84'	(b) (4) Linden DeBoer (b) (4) (b) (4)	18 Sep 2020 15:09:23

US3032242

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 14:52:51

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:25:04
User entered 'bpm'	System	18 Sep 2020 15:09:23

US3032242

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 14:52:51

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:25:04
DataPoint Verified.		03 Dec 2020 16:42:24
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 17:47:49
User entered '16'	(b) (4) Linden DeBoer (b) (4) (b) (4)	18 Sep 2020 15:09:23

US3032242

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 14:52:51

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:25:04
User entered 'breaths/min'	System	18 Sep 2020 15:09:23

US3032242

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 14:52:51

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:25:04
DataPoint Verified.		03 Dec 2020 16:42:24
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 17:47:49
User entered '102'	(b) (4) Linden DeBoer (b) (4)	18 Sep 2020 15:09:23
	(b) (4)	

US3032242

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 14:52:51

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:25:04
User entered 'mmHg'	System	18 Sep 2020 15:09:23

US3032242

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 14:52:51

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:25:04
DataPoint Verified.		03 Dec 2020 16:42:24
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 17:47:49
User entered '78'	(b) (4) Linden DeBoer (b) (4) (b) (4)	18 Sep 2020 15:09:23

US3032242

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 14:52:51

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:25:04
User entered 'mmHg'	System	18 Sep 2020 15:09:23

US3032242

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 14:52:51

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:25:04
DataPoint Verified.		03 Dec 2020 16:42:26
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 17:47:49
User entered 'Yes (Y)'	(b) (4) Linden DeBoer (b) (4) (b) (4)	18 Sep 2020 14:38:25

US3032242

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 14:52:51

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:25:04
DataPoint Verified.		03 Dec 2020 16:42:26
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 17:47:49
User entered '18 Sep 2020'	(b) (4) Linden DeBoer (b) (4) (b) (4)	18 Sep 2020 14:38:25

US3032242

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 14:52:51

[Was study treatment given?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:25:04
DataPoint Verified.		03 Dec 2020 16:42:48
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 17:47:49
User entered 'Yes (Y)'	(b) (4) Linden DeBoer (b) (4)	18 Sep 2020 14:39:06
	(b) (4)	

US3032242

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 14:52:51

[If No, reason not given](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:25:04
DataPoint Verified.		03 Dec 2020 16:42:48
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 17:47:49
User entered empty.	(b) (4) Linden DeBoer (b) (4)	18 Sep 2020 14:39:06
	(b) (4)	

US3032242

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 14:52:51

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 19:25:04
DataPoint Verified.		03 Dec 2020 16:42:48
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 17:47:49
User entered empty.	(b) (4) Linden DeBoer (b) (4)	18 Sep 2020 14:39:06
	(b) (4)	

US3032242

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 14:52:51

[What was the study treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:25:04
User entered 'MRNA-1273 OR PLACEBO'	System	18 Sep 2020 14:39:06

US3032242

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 14:52:51

[What was the treatment date? \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:25:04
DataPoint Verified.		03 Dec 2020 16:42:48
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 17:47:49
User entered '18 Sep 2020'	(b) (4) Linden DeBoer (b) (4)	18 Sep 2020 14:39:06
	(b) (4)	

US3032242

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 14:52:51

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:25:04
DataPoint Verified.		03 Dec 2020 16:42:48
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 17:47:49
User entered '09:17'	(b) (4) Linden DeBoer (b) (4)	18 Sep 2020 14:39:06
	(b) (4)	

US3032242

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 14:52:51

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:25:04
User entered '18 Sep 2020 09:17'	System	18 Sep 2020 14:39:06

US3032242

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 14:52:51

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:25:04
DataPoint Verified.		03 Dec 2020 16:42:48
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 17:47:49
User entered 'Left Arm (LEFT ARM)'	(b) (4) Linden DeBoer (b) (4) (b) (4)	18 Sep 2020 14:39:06

US3032242

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 14:52:51

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:25:04
DataPoint Verified.		03 Dec 2020 16:42:48
User entered 'ONCE'	System	18 Sep 2020 14:39:06

US3032242

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 14:52:51

What was the route of administration for the study treatment?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:25:04
User entered 'INTRAMUSCULAR'	System	18 Sep 2020 14:39:06

US3032242

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 14:52:51

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:25:04
DataPoint Verified.	(b) (4)	03 Dec 2020 16:43:05
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 17:47:49
User entered 'Yes (Y)'	(b) (4) Linden DeBoer (b) (4)	18 Sep 2020 14:39:22
	(b) (4)	

US3032242

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 14:52:51

Collection date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:25:04
DataPoint Verified.		03 Dec 2020 16:43:05
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 17:47:49
User entered '18 Sep 2020'	(b) (4) Linden DeBoer (b) (4)	18 Sep 2020 14:39:22
	(b) (4)	

US3032242

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 14:52:51

Collection time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:25:04
DataPoint Verified.		03 Dec 2020 16:43:05
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 17:47:49
User entered '08:40'	(b) (4) Linden DeBoer (b) (4)	18 Sep 2020 14:39:22
	(b) (4)	

US3032242

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 14:52:51

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:25:04
User entered '18 Sep 2020 08:40'	System	18 Sep 2020 14:39:22

US3032242

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab

Generated On: 09 Jun 2021 14:52:51

Collection date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:25:04
DataPoint Verified.		03 Dec 2020 16:43:10
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 17:47:49
User entered '18 Sep 2020'	(b) (4) Linden DeBoer (b) (4) (b) (4)	18 Sep 2020 14:39:38

US3032242

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 14:52:51

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:25:04
User accepted default value 'Nasopharyngeal Swab 1 (NASAL1)'	Linden DeBoer (b) (4) (b) (4)	18 Sep 2020 14:39:38

US3032242

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 14:52:51

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:25:04
DataPoint Verified.		03 Dec 2020 16:43:10
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 17:47:49
User entered 'Yes (Y)'	(b) (4) Linden DeBoer (b) (4)	18 Sep 2020 14:39:38
	(b) (4)	

US3032242

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 14:52:51

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:25:04
DataPoint Verified.		03 Dec 2020 16:43:10
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 17:47:49
User entered '08:29'	(b) (4) Linden DeBoer (b) (4) (b) (4)	18 Sep 2020 14:39:38

US3032242

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 14:52:51

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:25:04
User entered '18 Sep 2020 08:29'	System	18 Sep 2020 14:39:38

US3032242

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 14:52:51

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:25:04
User accepted default value 'Nasopharyngeal Swab 2 (NASAL2)'	Linden DeBoer (b) (4) (b) (4)	18 Sep 2020 14:39:38

US3032242

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 14:52:51

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:25:04
DataPoint Verified.		03 Dec 2020 16:43:10
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 17:47:49
User entered 'No (N)'	(b) (4) Linden DeBoer (b) (4) (b) (4)	18 Sep 2020 14:39:38

US3032242

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 14:52:51

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:25:04
DataPoint Verified.		03 Dec 2020 16:43:10
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 17:47:49
User entered empty.	(b) (4) Linden DeBoer (b) (4)	18 Sep 2020 14:39:38
	(b) (4)	

US3032242

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 14:52:51

Collection date and time (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:25:04
User entered empty.	System	18 Sep 2020 14:39:38

US3032242

Folder: Visit 2 Day 29 (1)

Form: Continuing

Generated On: 09 Jun 2021 14:52:51

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:25:04
DataPoint Verified.	(b) (4)	03 Dec 2020 16:43:13
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 17:47:49
User entered 'Yes (Y)'	(b) (4) Linden DeBoer (b) (4)	18 Sep 2020 14:39:42
	(b) (4)	

US3032242

Folder: Visit 2 Day 29 (1)

Form: Continuing

Generated On: 09 Jun 2021 14:52:51

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:25:04
User entered '1'	System	18 Sep 2020 14:39:42

US3032242

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 14:52:51

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:43:06
Data entry locked.	System	18 Sep 2020 14:39:06
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	18 Sep 2020 14:39:06

US3032242

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 14:52:51

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:43:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6C42AABB-C8BC-44AC-B3C0-D8720CCF0DD6)', Time: '2020-09-18T09:51:23', User OID: 'PatientReportedOutcome (US3032242)', ODM File OID: 'c8fb97be-6248-49f9-96d2-0daee2bbcd4e' User entered 'Yes (Y)'	System	18 Sep 2020 14:51:48
	System	18 Sep 2020 14:51:48

US3032242

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 14:52:51

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:43:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6C42AABB-C8BC-44AC-B3C0-D8720CCF0DD6)', Time: '2020-09-18T09:51:32', User OID: 'PatientReportedOutcome (US3032242)', ODM File OID: 'c8fb97be-6248-49f9-96d2-0daee2bbcd4e' User entered '98.2'	System	18 Sep 2020 14:51:48
	System	18 Sep 2020 14:51:48

US3032242

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 14:52:51

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:43:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6C42AABB-C8BC-44AC-B3C0-D8720CCF0DD6)', Time: '2020-09-18T09:51:39', User OID: 'PatientReportedOutcome (US3032242)', ODM File OID: 'c8fb97be-6248-49f9-96d2-0daee2bbcd4e' User entered 'No (N)'	System	18 Sep 2020 14:51:48
	System	18 Sep 2020 14:51:48

US3032242

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 14:52:51

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:43:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6C42AABB-C8BC-44AC-B3C0-D8720CCF0DD6)', Time: '2020-09-18T09:51:45', User OID: 'PatientReportedOutcome (US3032242)', ODM File OID: 'c8fb97be-6248-49f9-96d2-0daee2bbcd4e' User entered '18 Sep 2020 09:51'	System	18 Sep 2020 14:51:48
	System	18 Sep 2020 14:51:48

US3032242

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 14:52:51

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:43:06
User entered '18 Sep 2020 09:37'	System	18 Sep 2020 14:39:06

US3032242

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 14:52:51

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:43:06
User entered '18 Sep 2020 12:07'	System	18 Sep 2020 14:39:06

US3032242

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 14:52:51

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:43:06
Data entry locked.	System	18 Sep 2020 14:39:06
User entered 'Day 1, after vaccination (at home)'	System	18 Sep 2020 14:39:06

US3032242

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 14:52:51

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:43:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6C42AABB-C8BC-44AC-B3C0-D8720CCF0DD6)', Time: '2020-09-18T17:01:54', User OID: 'PatientReportedOutcome (US3032242)', ODM File OID: '9311f046-35e3-4ad1-b7fa-0e7b92eb54fc' User entered 'Yes (Y)'	System	18 Sep 2020 22:03:15
	System	18 Sep 2020 22:03:15

US3032242

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 14:52:51

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:43:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6C42AABB-C8BC-44AC-B3C0-D8720CCF0DD6)', Time: '2020-09-18T17:02:01', User OID: 'PatientReportedOutcome (US3032242)', ODM File OID: '9311f046-35e3-4ad1-b7fa-0e7b92eb54fc' User entered '97.5'	System	18 Sep 2020 22:03:15
	System	18 Sep 2020 22:03:15

US3032242

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 14:52:51

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:43:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6C42AABB-C8BC-44AC-B3C0-D8720CCF0DD6)', Time: '2020-09-18T17:02:06', User OID: 'PatientReportedOutcome (US3032242)', ODM File OID: '9311f046-35e3-4ad1-b7fa-0e7b92eb54fc'	System	18 Sep 2020 22:03:15
User entered 'No (N)'	System	18 Sep 2020 22:03:15

US3032242

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 14:52:51

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:43:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6C42AABB-C8BC-44AC-B3C0-D8720CCF0DD6)', Time: '2020-09-18T17:02:14', User OID: 'PatientReportedOutcome (US3032242)', ODM File OID: '9311f046-35e3-4ad1-b7fa-0e7b92eb54fc' User entered '18 Sep 2020 17:02'	System	18 Sep 2020 22:03:15
	System	18 Sep 2020 22:03:15

US3032242

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 14:52:51

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:43:06
User entered '18 Sep 2020 13:02'	System	18 Sep 2020 14:39:06

US3032242

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 14:52:51

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:43:06
User entered '19 Sep 2020 11:59'	System	18 Sep 2020 14:39:06

US3032242

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 14:52:51

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:43:06
Data entry locked.	System	18 Sep 2020 14:39:06
User entered 'Day 2'	System	18 Sep 2020 14:39:06

US3032242

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 14:52:51

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:43:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6C42AABB-C8BC-44AC-B3C0-D8720CCF0DD6)', Time: '2020-09-19T15:49:40', User OID: 'PatientReportedOutcome (US3032242)', ODM File OID: '8b72e5da-057c-4cc7-a345-2da083d293f2'	System	19 Sep 2020 20:49:59
User entered 'Yes (Y)'	System	19 Sep 2020 20:49:59

US3032242

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 14:52:51

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:43:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6C42AABB-C8BC-44AC-B3C0-D8720CCF0DD6)', Time: '2020-09-19T15:49:46', User OID: 'PatientReportedOutcome (US3032242)', ODM File OID: '8b72e5da-057c-4cc7-a345-2da083d293f2'	System	19 Sep 2020 20:49:59
User entered '97.3'	System	19 Sep 2020 20:49:59

US3032242

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 14:52:51

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:43:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6C42AABB-C8BC-44AC-B3C0-D8720CCF0DD6)', Time: '2020-09-19T15:49:50', User OID: 'PatientReportedOutcome (US3032242)', ODM File OID: '8b72e5da-057c-4cc7-a345-2da083d293f2'	System	19 Sep 2020 20:49:59
User entered 'No (N)'	System	19 Sep 2020 20:49:59

US3032242

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 14:52:51

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:43:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6C42AABB-C8BC-44AC-B3C0-D8720CCF0DD6)', Time: '2020-09-19T15:49:58', User OID: 'PatientReportedOutcome (US3032242)', ODM File OID: '8b72e5da-057c-4cc7-a345-2da083d293f2'	System	19 Sep 2020 20:49:59
User entered '19 Sep 2020 15:49'	System	19 Sep 2020 20:49:59

US3032242

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 14:52:51

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:43:06
User entered '19 Sep 2020 12:00'	System	18 Sep 2020 14:39:06

US3032242

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 14:52:51

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:43:06
User entered '20 Sep 2020 11:59'	System	18 Sep 2020 14:39:06

US3032242

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 14:52:51

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:43:06
Data entry locked.	System	18 Sep 2020 14:39:06
User entered 'Day 3'	System	18 Sep 2020 14:39:06

US3032242

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 14:52:51

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:43:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6C42AABB-C8BC-44AC-B3C0-D8720CCF0DD6)', Time: '2020-09-20T12:13:48', User OID: 'PatientReportedOutcome (US3032242)', ODM File OID: '60768dd6-bad6-44c7-9e30-cb1afce3ca4a' User entered 'Yes (Y)'	System	20 Sep 2020 17:14:10
	System	20 Sep 2020 17:14:10

US3032242

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 14:52:51

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:43:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6C42AABB-C8BC-44AC-B3C0-D8720CCF0DD6)', Time: '2020-09-20T12:13:55', User OID: 'PatientReportedOutcome (US3032242)', ODM File OID: '60768dd6-bad6-44c7-9e30-cb1afce3ca4a' User entered '97.2'	System	20 Sep 2020 17:14:10
	System	20 Sep 2020 17:14:10

US3032242

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 14:52:51

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:43:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6C42AABB-C8BC-44AC-B3C0-D8720CCF0DD6)', Time: '2020-09-20T12:14:00', User OID: 'PatientReportedOutcome (US3032242)', ODM File OID: '60768dd6-bad6-44c7-9e30-cb1afce3ca4a'	System	20 Sep 2020 17:14:10
User entered 'No (N)'	System	20 Sep 2020 17:14:10

US3032242

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 14:52:51

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:43:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6C42AABB-C8BC-44AC-B3C0-D8720CCF0DD6)', Time: '2020-09-20T12:14:06', User OID: 'PatientReportedOutcome (US3032242)', ODM File OID: '60768dd6-bad6-44c7-9e30-cb1afce3ca4a' User entered '20 Sep 2020 12:14'	System	20 Sep 2020 17:14:10
	System	20 Sep 2020 17:14:10

US3032242

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 14:52:51

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:43:06
User entered '20 Sep 2020 12:00'	System	18 Sep 2020 14:39:06

US3032242

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 14:52:51

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:43:06
User entered '21 Sep 2020 11:59'	System	18 Sep 2020 14:39:06

US3032242

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 14:52:51

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:43:06
Data entry locked.	System	18 Sep 2020 14:39:06
User entered 'Day 4'	System	18 Sep 2020 14:39:06

US3032242

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 14:52:51

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:43:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6C42AABB-C8BC-44AC-B3C0-D8720CCF0DD6)', Time: '2020-09-21T12:04:24', User OID: 'PatientReportedOutcome (US3032242)', ODM File OID: '218763da-b863-4614-9627-fbfed066710e' User entered 'Yes (Y)'	System	21 Sep 2020 17:07:22
	System	21 Sep 2020 17:07:22

US3032242

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 14:52:51

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:43:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6C42AABB-C8BC-44AC-B3C0-D8720CCF0DD6)', Time: '2020-09-21T12:04:33', User OID: 'PatientReportedOutcome (US3032242)', ODM File OID: '218763da-b863-4614-9627-fbfed066710e' User entered '98.0'	System	21 Sep 2020 17:07:22
	System	21 Sep 2020 17:07:22

US3032242

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 14:52:51

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:43:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6C42AABB-C8BC-44AC-B3C0-D8720CCF0DD6)', Time: '2020-09-21T12:04:38', User OID: 'PatientReportedOutcome (US3032242)', ODM File OID: '218763da-b863-4614-9627-fbfed066710e'	System	21 Sep 2020 17:07:22
User entered 'No (N)'	System	21 Sep 2020 17:07:22

US3032242

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 14:52:51

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:43:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6C42AABB-C8BC-44AC-B3C0-D8720CCF0DD6)', Time: '2020-09-21T12:04:42', User OID: 'PatientReportedOutcome (US3032242)', ODM File OID: '218763da-b863-4614-9627-fbfed066710e' User entered '21 Sep 2020 12:04'	System	21 Sep 2020 17:07:22
	System	21 Sep 2020 17:07:22

US3032242

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 14:52:51

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:43:06
User entered '21 Sep 2020 12:00'	System	18 Sep 2020 14:39:06

US3032242

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 14:52:51

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:43:06
User entered '22 Sep 2020 11:59'	System	18 Sep 2020 14:39:06

US3032242

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 14:52:51

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:43:06
Data entry locked.	System	18 Sep 2020 14:39:06
User entered 'Day 5'	System	18 Sep 2020 14:39:06

US3032242

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 14:52:51

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:43:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6C42AABB-C8BC-44AC-B3C0-D8720CCF0DD6)', Time: '2020-09-22T12:13:41', User OID: 'PatientReportedOutcome (US3032242)', ODM File OID: 'cbed1059-5316-40d8-8286-d2f066381a23'	System	22 Sep 2020 17:14:06
User entered 'Yes (Y)'	System	22 Sep 2020 17:14:06

US3032242

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 14:52:51

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:43:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6C42AABB-C8BC-44AC-B3C0-D8720CCF0DD6)', Time: '2020-09-22T12:13:49', User OID: 'PatientReportedOutcome (US3032242)', ODM File OID: 'cbcd1059-5316-40d8-8286-d2f066381a23'	System	22 Sep 2020 17:14:06
User entered '96.8'	System	22 Sep 2020 17:14:06

US3032242

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 14:52:51

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:43:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6C42AABB-C8BC-44AC-B3C0-D8720CCF0DD6)', Time: '2020-09-22T12:13:54', User OID: 'PatientReportedOutcome (US3032242)', ODM File OID: 'cbed1059-5316-40d8-8286-d2f066381a23'	System	22 Sep 2020 17:14:06
User entered 'No (N)'	System	22 Sep 2020 17:14:06

US3032242

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 14:52:51

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:43:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6C42AABB-C8BC-44AC-B3C0-D8720CCF0DD6)', Time: '2020-09-22T12:14:00', User OID: 'PatientReportedOutcome (US3032242)', ODM File OID: 'cbcd1059-5316-40d8-8286-d2f066381a23'	System	22 Sep 2020 17:14:06
User entered '22 Sep 2020 12:14'	System	22 Sep 2020 17:14:06

US3032242

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 14:52:51

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:43:06
User entered '22 Sep 2020 12:00'	System	18 Sep 2020 14:39:06

US3032242

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 14:52:51

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:43:06
User entered '23 Sep 2020 11:59'	System	18 Sep 2020 14:39:06

US3032242

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 14:52:51

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:43:06
Data entry locked.	System	18 Sep 2020 14:39:06
User entered 'Day 6'	System	18 Sep 2020 14:39:06

US3032242

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 14:52:51

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:43:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6C42AABB-C8BC-44AC-B3C0-D8720CCF0DD6)', Time: '2020-09-23T12:04:03', User OID: 'PatientReportedOutcome (US3032242)', ODM File OID: 'bcb18a56-16a6-4f46-bf62-0dc9d91c5d40' User entered 'Yes (Y)'	System	23 Sep 2020 17:08:02
	System	23 Sep 2020 17:08:02

US3032242

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 14:52:51

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:43:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6C42AABB-C8BC-44AC-B3C0-D8720CCF0DD6)', Time: '2020-09-23T12:04:11', User OID: 'PatientReportedOutcome (US3032242)', ODM File OID: 'bcb18a56-16a6-4f46-bf62-0dc9d91c5d40' User entered '97.7'	System	23 Sep 2020 17:08:02
	System	23 Sep 2020 17:08:02

US3032242

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 14:52:51

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:43:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6C42AABB-C8BC-44AC-B3C0-D8720CCF0DD6)', Time: '2020-09-23T12:04:15', User OID: 'PatientReportedOutcome (US3032242)', ODM File OID: 'bcb18a56-16a6-4f46-bf62-0dc9d91c5d40'	System	23 Sep 2020 17:08:02
User entered 'No (N)'	System	23 Sep 2020 17:08:02

US3032242

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 14:52:51

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:43:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6C42AABB-C8BC-44AC-B3C0-D8720CCF0DD6)', Time: '2020-09-23T12:04:22', User OID: 'PatientReportedOutcome (US3032242)', ODM File OID: 'bcb18a56-16a6-4f46-bf62-0dc9d91c5d40'	System	23 Sep 2020 17:08:02
User entered '23 Sep 2020 12:04'	System	23 Sep 2020 17:08:02

US3032242

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 14:52:51

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:43:06
User entered '23 Sep 2020 12:00'	System	18 Sep 2020 14:39:06

US3032242

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 14:52:51

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:43:06
User entered '24 Sep 2020 11:59'	System	18 Sep 2020 14:39:06

US3032242

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 14:52:51

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:43:06
Data entry locked.	System	18 Sep 2020 14:39:06
User entered 'Day 7'	System	18 Sep 2020 14:39:06

US3032242

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 14:52:51

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:43:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6C42AABB-C8BC-44AC-B3C0-D8720CCF0DD6)', Time: '2020-09-24T15:58:52', User OID: 'PatientReportedOutcome (US3032242)', ODM File OID: 'a0d241fe-822f-4190-8ad4-0c9c06993528' User entered 'Yes (Y)'	System	24 Sep 2020 20:59:19
	System	24 Sep 2020 20:59:19

US3032242

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 14:52:51

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:43:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6C42AABB-C8BC-44AC-B3C0-D8720CCF0DD6)', Time: '2020-09-24T15:59:03', User OID: 'PatientReportedOutcome (US3032242)', ODM File OID: 'a0d241fe-822f-4190-8ad4-0c9c06993528' User entered '97.5'	System	24 Sep 2020 20:59:19
	System	24 Sep 2020 20:59:19

US3032242

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 14:52:51

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:43:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6C42AABB-C8BC-44AC-B3C0-D8720CCF0DD6)', Time: '2020-09-24T15:59:08', User OID: 'PatientReportedOutcome (US3032242)', ODM File OID: 'a0d241fe-822f-4190-8ad4-0c9c06993528'	System	24 Sep 2020 20:59:19
User entered 'No (N)'	System	24 Sep 2020 20:59:19

US3032242

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 14:52:51

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:43:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6C42AABB-C8BC-44AC-B3C0-D8720CCF0DD6)', Time: '2020-09-24T15:59:15', User OID: 'PatientReportedOutcome (US3032242)', ODM File OID: 'a0d241fe-822f-4190-8ad4-0c9c06993528'	System	24 Sep 2020 20:59:19
User entered '24 Sep 2020 15:59'	System	24 Sep 2020 20:59:19

US3032242

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 14:52:51

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:43:06
User entered '24 Sep 2020 12:00'	System	18 Sep 2020 14:39:06

US3032242

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 14:52:51

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:43:06
User entered '25 Sep 2020 11:59'	System	18 Sep 2020 14:39:06

US3032242

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 14:52:51

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:43:06
Data entry locked.	System	18 Sep 2020 14:39:06
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	18 Sep 2020 14:39:06

US3032242

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 14:52:51

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:43:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6C42AABB-C8BC-44AC-B3C0-D8720CCF0DD6)', Time: '2020-09-18T09:52:14', User OID: 'PatientReportedOutcome (US3032242)', ODM File OID: '17460e0f-9cce-43db-aeef-ce00b14305b6'	System	18 Sep 2020 14:52:47
User entered 'None (1)'	System	18 Sep 2020 14:52:47

US3032242

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 14:52:51

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:43:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6C42AABB-C8BC-44AC-B3C0-D8720CCF0DD6)', Time: '2020-09-18T09:52:34', User OID: 'PatientReportedOutcome (US3032242)', ODM File OID: '17460e0f-9cce-43db-aeef-ce00b14305b6'	System	18 Sep 2020 14:52:47
User entered 'No (N)'	System	18 Sep 2020 14:52:47

US3032242

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 14:52:51

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:43:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6C42AABB-C8BC-44AC-B3C0-D8720CCF0DD6)', Time: '2020-09-18T09:52:37', User OID: 'PatientReportedOutcome (US3032242)', ODM File OID: '17460e0f-9cce-43db-aeef-ce00b14305b6'	System	18 Sep 2020 14:52:47
User entered 'No (N)'	System	18 Sep 2020 14:52:47

US3032242

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 14:52:51

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:43:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6C42AABB-C8BC-44AC-B3C0-D8720CCF0DD6)', Time: '2020-09-18T09:52:39', User OID: 'PatientReportedOutcome (US3032242)', ODM File OID: '17460e0f-9cce-43db-aeef-ce00b14305b6'	System	18 Sep 2020 14:52:47
User entered 'None (1)'	System	18 Sep 2020 14:52:47

US3032242

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 14:52:51

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:43:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6C42AABB-C8BC-44AC-B3C0-D8720CCF0DD6)', Time: '2020-09-18T09:52:42', User OID: 'PatientReportedOutcome (US3032242)', ODM File OID: '17460e0f-9cce-43db-aeef-ce00b14305b6'	System	18 Sep 2020 14:52:47
User entered '18 Sep 2020 09:52'	System	18 Sep 2020 14:52:47

US3032242

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 14:52:51

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:43:06
User entered '18 Sep 2020 09:37'	System	18 Sep 2020 14:39:06

US3032242

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 14:52:51

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:43:06
User entered '18 Sep 2020 12:07'	System	18 Sep 2020 14:39:06

US3032242

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 14:52:51

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:43:06
Data entry locked.	System	18 Sep 2020 14:39:06
User entered 'Day 1, after vaccination (at home)'	System	18 Sep 2020 14:39:06

US3032242

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 14:52:51

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:43:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6C42AABB-C8BC-44AC-B3C0-D8720CCF0DD6)', Time: '2020-09-18T17:02:21', User OID: 'PatientReportedOutcome (US3032242)', ODM File OID: 'cace576c-3c41-421b-9c98-d6c5a4df9606'	System	18 Sep 2020 22:03:25
User entered 'None (1)'	System	18 Sep 2020 22:03:25

US3032242

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 14:52:51

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:43:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6C42AABB-C8BC-44AC-B3C0-D8720CCF0DD6)', Time: '2020-09-18T17:02:25', User OID: 'PatientReportedOutcome (US3032242)', ODM File OID: 'cace576c-3c41-421b-9c98-d6c5a4df9606'	System	18 Sep 2020 22:03:25
User entered 'No (N)'	System	18 Sep 2020 22:03:25

US3032242

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 14:52:51

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:43:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6C42AABB-C8BC-44AC-B3C0-D8720CCF0DD6)', Time: '2020-09-18T17:02:30', User OID: 'PatientReportedOutcome (US3032242)', ODM File OID: 'cace576c-3c41-421b-9c98-d6c5a4df9606'	System	18 Sep 2020 22:03:25
User entered 'No (N)'	System	18 Sep 2020 22:03:25

US3032242

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 14:52:51

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:43:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6C42AABB-C8BC-44AC-B3C0-D8720CCF0DD6)', Time: '2020-09-18T17:02:36', User OID: 'PatientReportedOutcome (US3032242)', ODM File OID: 'cace576c-3c41-421b-9c98-d6c5a4df9606'	System	18 Sep 2020 22:03:25
User entered 'None (1)'	System	18 Sep 2020 22:03:25

US3032242

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 14:52:51

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:43:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6C42AABB-C8BC-44AC-B3C0-D8720CCF0DD6)', Time: '2020-09-18T17:02:44', User OID: 'PatientReportedOutcome (US3032242)', ODM File OID: 'cace576c-3c41-421b-9c98-d6c5a4df9606' User entered '18 Sep 2020 17:02'	System	18 Sep 2020 22:03:25
	System	18 Sep 2020 22:03:25

US3032242

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 14:52:51

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:43:06
User entered '18 Sep 2020 13:02'	System	18 Sep 2020 14:39:06

US3032242

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 14:52:51

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:43:06
User entered '19 Sep 2020 11:59'	System	18 Sep 2020 14:39:06

US3032242

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 14:52:51

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:43:06
Data entry locked.	System	18 Sep 2020 14:39:06
User entered 'Day 2'	System	18 Sep 2020 14:39:06

US3032242

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 14:52:51

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:43:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6C42AABB-C8BC-44AC-B3C0-D8720CCF0DD6)', Time: '2020-09-19T15:50:05', User OID: 'PatientReportedOutcome (US3032242)', ODM File OID: 'af80dad5-6231-4670-b434-88b9a067bdfd' User entered 'None (1)'	System	19 Sep 2020 20:50:30
	System	19 Sep 2020 20:50:30

US3032242

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 14:52:51

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:43:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6C42AABB-C8BC-44AC-B3C0-D8720CCF0DD6)', Time: '2020-09-19T15:50:08', User OID: 'PatientReportedOutcome (US3032242)', ODM File OID: 'af80dad5-6231-4670-b434-88b9a067bdfd'	System	19 Sep 2020 20:50:30
User entered 'No (N)'	System	19 Sep 2020 20:50:30

US3032242

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 14:52:51

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:43:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6C42AABB-C8BC-44AC-B3C0-D8720CCF0DD6)', Time: '2020-09-19T15:50:14', User OID: 'PatientReportedOutcome (US3032242)', ODM File OID: 'af80dad5-6231-4670-b434-88b9a067bdfd'	System	19 Sep 2020 20:50:30
User entered 'No (N)'	System	19 Sep 2020 20:50:30

US3032242

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 14:52:51

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:43:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6C42AABB-C8BC-44AC-B3C0-D8720CCF0DD6)', Time: '2020-09-19T15:50:20', User OID: 'PatientReportedOutcome (US3032242)', ODM File OID: 'af80dad5-6231-4670-b434-88b9a067bdfd'	System	19 Sep 2020 20:50:30
User entered 'None (1)'	System	19 Sep 2020 20:50:30

US3032242

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 14:52:51

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:43:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6C42AABB-C8BC-44AC-B3C0-D8720CCF0DD6)', Time: '2020-09-19T15:50:27', User OID: 'PatientReportedOutcome (US3032242)', ODM File OID: 'af80dad5-6231-4670-b434-88b9a067bdfd' User entered '19 Sep 2020 15:50'	System	19 Sep 2020 20:50:30
	System	19 Sep 2020 20:50:30

US3032242

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 14:52:51

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:43:06
User entered '19 Sep 2020 12:00'	System	18 Sep 2020 14:39:06

US3032242

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 14:52:51

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:43:06
User entered '20 Sep 2020 11:59'	System	18 Sep 2020 14:39:06

US3032242

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 14:52:51

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:43:06
Data entry locked.	System	18 Sep 2020 14:39:06
User entered 'Day 3'	System	18 Sep 2020 14:39:06

US3032242

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 14:52:51

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:43:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6C42AABB-C8BC-44AC-B3C0-D8720CCF0DD6)', Time: '2020-09-20T12:14:34', User OID: 'PatientReportedOutcome (US3032242)', ODM File OID: '1884defa-75ba-45bd-83e8-b02a0cac7c0d'	System	20 Sep 2020 17:14:57
User entered 'None (1)'	System	20 Sep 2020 17:14:57

US3032242

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 14:52:51

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:43:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6C42AABB-C8BC-44AC-B3C0-D8720CCF0DD6)', Time: '2020-09-20T12:14:39', User OID: 'PatientReportedOutcome (US3032242)', ODM File OID: '1884defa-75ba-45bd-83e8-b02a0cac7c0d' User entered 'No (N)'	System	20 Sep 2020 17:14:57
	System	20 Sep 2020 17:14:57

US3032242

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 14:52:51

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:43:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6C42AABB-C8BC-44AC-B3C0-D8720CCF0DD6)', Time: '2020-09-20T12:14:43', User OID: 'PatientReportedOutcome (US3032242)', ODM File OID: '1884defa-75ba-45bd-83e8-b02a0cac7c0d' User entered 'No (N)'	System	20 Sep 2020 17:14:57
	System	20 Sep 2020 17:14:57

US3032242

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 14:52:51

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:43:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6C42AABB-C8BC-44AC-B3C0-D8720CCF0DD6)', Time: '2020-09-20T12:14:47', User OID: 'PatientReportedOutcome (US3032242)', ODM File OID: '1884defa-75ba-45bd-83e8-b02a0cac7c0d'	System	20 Sep 2020 17:14:57
User entered 'None (1)'	System	20 Sep 2020 17:14:57

US3032242

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 14:52:51

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:43:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6C42AABB-C8BC-44AC-B3C0-D8720CCF0DD6)', Time: '2020-09-20T12:14:55', User OID: 'PatientReportedOutcome (US3032242)', ODM File OID: '1884defa-75ba-45bd-83e8-b02a0cac7c0d' User entered '20 Sep 2020 12:14'	System	20 Sep 2020 17:14:57
	System	20 Sep 2020 17:14:57

US3032242

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 14:52:51

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:43:06
User entered '20 Sep 2020 12:00'	System	18 Sep 2020 14:39:06

US3032242

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 14:52:51

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:43:06
User entered '21 Sep 2020 11:59'	System	18 Sep 2020 14:39:06

US3032242

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 14:52:51

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:43:06
Data entry locked.	System	18 Sep 2020 14:39:06
User entered 'Day 4'	System	18 Sep 2020 14:39:06

US3032242

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 14:52:51

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:43:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6C42AABB-C8BC-44AC-B3C0-D8720CCF0DD6)', Time: '2020-09-21T12:04:52', User OID: 'PatientReportedOutcome (US3032242)', ODM File OID: '959d2b77-ddcb-4f7f-9fec-d5a5679eb719'	System	21 Sep 2020 17:07:30
User entered 'None (1)'	System	21 Sep 2020 17:07:30

US3032242

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 14:52:51

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:43:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6C42AABB-C8BC-44AC-B3C0-D8720CCF0DD6)', Time: '2020-09-21T12:04:55', User OID: 'PatientReportedOutcome (US3032242)', ODM File OID: '959d2b77-ddcb-4f7f-9fec-d5a5679eb719'	System	21 Sep 2020 17:07:30
User entered 'No (N)'	System	21 Sep 2020 17:07:30

US3032242

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 14:52:51

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:43:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6C42AABB-C8BC-44AC-B3C0-D8720CCF0DD6)', Time: '2020-09-21T12:04:59', User OID: 'PatientReportedOutcome (US3032242)', ODM File OID: '959d2b77-ddcb-4f7f-9fec-d5a5679eb719'	System	21 Sep 2020 17:07:30
User entered 'No (N)'	System	21 Sep 2020 17:07:30

US3032242

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 14:52:51

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:43:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6C42AABB-C8BC-44AC-B3C0-D8720CCF0DD6)', Time: '2020-09-21T12:05:04', User OID: 'PatientReportedOutcome (US3032242)', ODM File OID: '959d2b77-ddcb-4f7f-9fec-d5a5679eb719'	System	21 Sep 2020 17:07:30
User entered 'None (1)'	System	21 Sep 2020 17:07:30

US3032242

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 14:52:51

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:43:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6C42AABB-C8BC-44AC-B3C0-D8720CCF0DD6)', Time: '2020-09-21T12:05:09', User OID: 'PatientReportedOutcome (US3032242)', ODM File OID: '959d2b77-ddcb-4f7f-9fec-d5a5679eb719'	System	21 Sep 2020 17:07:30
User entered '21 Sep 2020 12:05'	System	21 Sep 2020 17:07:30

US3032242

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 14:52:51

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:43:06
User entered '21 Sep 2020 12:00'	System	18 Sep 2020 14:39:06

US3032242

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 14:52:51

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:43:06
User entered '22 Sep 2020 11:59'	System	18 Sep 2020 14:39:06

US3032242

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 14:52:51

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:43:06
Data entry locked.	System	18 Sep 2020 14:39:06
User entered 'Day 5'	System	18 Sep 2020 14:39:06

US3032242

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 14:52:51

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:43:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6C42AABB-C8BC-44AC-B3C0-D8720CCF0DD6)', Time: '2020-09-22T12:14:08', User OID: 'PatientReportedOutcome (US3032242)', ODM File OID: '44a2f546-69e2-4d84-8bed-4930987cc875'	System	22 Sep 2020 17:14:37
User entered 'None (1)'	System	22 Sep 2020 17:14:37

US3032242

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 14:52:51

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:43:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6C42AABB-C8BC-44AC-B3C0-D8720CCF0DD6)', Time: '2020-09-22T12:14:11', User OID: 'PatientReportedOutcome (US3032242)', ODM File OID: '44a2f546-69e2-4d84-8bed-4930987cc875'	System	22 Sep 2020 17:14:37
User entered 'No (N)'	System	22 Sep 2020 17:14:37

US3032242

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 14:52:51

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:43:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6C42AABB-C8BC-44AC-B3C0-D8720CCF0DD6)', Time: '2020-09-22T12:14:20', User OID: 'PatientReportedOutcome (US3032242)', ODM File OID: '44a2f546-69e2-4d84-8bed-4930987cc875'	System	22 Sep 2020 17:14:37
User entered 'No (N)'	System	22 Sep 2020 17:14:37

US3032242

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 14:52:51

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:43:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6C42AABB-C8BC-44AC-B3C0-D8720CCF0DD6)', Time: '2020-09-22T12:14:27', User OID: 'PatientReportedOutcome (US3032242)', ODM File OID: '44a2f546-69e2-4d84-8bed-4930987cc875'	System	22 Sep 2020 17:14:37
User entered 'None (1)'	System	22 Sep 2020 17:14:37

US3032242

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 14:52:51

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:43:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6C42AABB-C8BC-44AC-B3C0-D8720CCF0DD6)', Time: '2020-09-22T12:14:35', User OID: 'PatientReportedOutcome (US3032242)', ODM File OID: '44a2f546-69e2-4d84-8bed-4930987cc875'	System	22 Sep 2020 17:14:37
User entered '22 Sep 2020 12:14'	System	22 Sep 2020 17:14:37

US3032242

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 14:52:51

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:43:06
User entered '22 Sep 2020 12:00'	System	18 Sep 2020 14:39:06

US3032242

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 14:52:51

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:43:06
User entered '23 Sep 2020 11:59'	System	18 Sep 2020 14:39:06

US3032242

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 14:52:51

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:43:06
Data entry locked.	System	18 Sep 2020 14:39:06
User entered 'Day 6'	System	18 Sep 2020 14:39:06

US3032242

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 14:52:51

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:43:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6C42AABB-C8BC-44AC-B3C0-D8720CCF0DD6)', Time: '2020-09-23T12:04:28', User OID: 'PatientReportedOutcome (US3032242)', ODM File OID: 'edc9225b-4334-46d7-9b44-1513a5468a7d'	System	23 Sep 2020 17:08:17
User entered 'None (1)'	System	23 Sep 2020 17:08:17

US3032242

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 14:52:51

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:43:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6C42AABB-C8BC-44AC-B3C0-D8720CCF0DD6)', Time: '2020-09-23T12:04:32', User OID: 'PatientReportedOutcome (US3032242)', ODM File OID: 'edc9225b-4334-46d7-9b44-1513a5468a7d'	System	23 Sep 2020 17:08:17
User entered 'No (N)'	System	23 Sep 2020 17:08:17

US3032242

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 14:52:51

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:43:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6C42AABB-C8BC-44AC-B3C0-D8720CCF0DD6)', Time: '2020-09-23T12:04:36', User OID: 'PatientReportedOutcome (US3032242)', ODM File OID: 'edc9225b-4334-46d7-9b44-1513a5468a7d'	System	23 Sep 2020 17:08:17
User entered 'No (N)'	System	23 Sep 2020 17:08:17

US3032242

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 14:52:51

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:43:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6C42AABB-C8BC-44AC-B3C0-D8720CCF0DD6)', Time: '2020-09-23T12:04:42', User OID: 'PatientReportedOutcome (US3032242)', ODM File OID: 'edc9225b-4334-46d7-9b44-1513a5468a7d'	System	23 Sep 2020 17:08:17
User entered 'None (1)'	System	23 Sep 2020 17:08:17

US3032242

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 14:52:51

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:43:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6C42AABB-C8BC-44AC-B3C0-D8720CCF0DD6)', Time: '2020-09-23T12:04:50', User OID: 'PatientReportedOutcome (US3032242)', ODM File OID: 'edc9225b-4334-46d7-9b44-1513a5468a7d' User entered '23 Sep 2020 12:04'	System	23 Sep 2020 17:08:17
	System	23 Sep 2020 17:08:17

US3032242

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 14:52:51

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:43:06
User entered '23 Sep 2020 12:00'	System	18 Sep 2020 14:39:06

US3032242

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 14:52:51

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:43:06
User entered '24 Sep 2020 11:59'	System	18 Sep 2020 14:39:06

US3032242

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 14:52:51

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:43:06
Data entry locked.	System	18 Sep 2020 14:39:06
User entered 'Day 7'	System	18 Sep 2020 14:39:06

US3032242

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 14:52:51

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:43:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6C42AABB-C8BC-44AC-B3C0-D8720CCF0DD6)', Time: '2020-09-24T15:59:25', User OID: 'PatientReportedOutcome (US3032242)', ODM File OID: '5328461f-a7d7-4cff-a1f3-d9e0d070153e' User entered 'None (1)'	System	24 Sep 2020 20:59:53
	System	24 Sep 2020 20:59:53

US3032242

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 14:52:51

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:43:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6C42AABB-C8BC-44AC-B3C0-D8720CCF0DD6)', Time: '2020-09-24T15:59:43', User OID: 'PatientReportedOutcome (US3032242)', ODM File OID: '5328461f-a7d7-4cff-a1f3-d9e0d070153e'	System	24 Sep 2020 20:59:53
User entered 'No (N)'	System	24 Sep 2020 20:59:53

US3032242

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 14:52:51

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:43:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6C42AABB-C8BC-44AC-B3C0-D8720CCF0DD6)', Time: '2020-09-24T15:59:33', User OID: 'PatientReportedOutcome (US3032242)', ODM File OID: '5328461f-a7d7-4cff-a1f3-d9e0d070153e' User entered 'No (N)'	System	24 Sep 2020 20:59:53
	System	24 Sep 2020 20:59:53

US3032242

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 14:52:51

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:43:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6C42AABB-C8BC-44AC-B3C0-D8720CCF0DD6)', Time: '2020-09-24T15:59:37', User OID: 'PatientReportedOutcome (US3032242)', ODM File OID: '5328461f-a7d7-4cff-a1f3-d9e0d070153e' User entered 'None (1)'	System	24 Sep 2020 20:59:53
	System	24 Sep 2020 20:59:53

US3032242

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 14:52:51

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:43:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6C42AABB-C8BC-44AC-B3C0-D8720CCF0DD6)', Time: '2020-09-24T15:59:50', User OID: 'PatientReportedOutcome (US3032242)', ODM File OID: '5328461f-a7d7-4cff-a1f3-d9e0d070153e' User entered '24 Sep 2020 15:59'	System	24 Sep 2020 20:59:53
	System	24 Sep 2020 20:59:53

US3032242

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 14:52:51

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:43:06
User entered '24 Sep 2020 12:00'	System	18 Sep 2020 14:39:06

US3032242

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 14:52:51

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:43:06
User entered '25 Sep 2020 11:59'	System	18 Sep 2020 14:39:06

US3032242

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 14:52:51

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:43:06
Data entry locked.	System	18 Sep 2020 14:39:06
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	18 Sep 2020 14:39:06

US3032242

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 14:52:51

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:43:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6C42AABB-C8BC-44AC-B3C0-D8720CCF0DD6)', Time: '2020-09-18T09:53:00', User OID: 'PatientReportedOutcome (US3032242)', ODM File OID: '6743801f-9cbd-4b36-b34d-0db75f1214f0' User entered 'None (0)'	System	18 Sep 2020 14:53:30
	System	18 Sep 2020 14:53:30

US3032242

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 14:52:51

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:43:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6C42AABB-C8BC-44AC-B3C0-D8720CCF0DD6)', Time: '2020-09-18T09:53:03', User OID: 'PatientReportedOutcome (US3032242)', ODM File OID: '6743801f-9cbd-4b36-b34d-0db75f1214f0' User entered 'None (0)'	System	18 Sep 2020 14:53:30
	System	18 Sep 2020 14:53:30

US3032242

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 14:52:51

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:43:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6C42AABB-C8BC-44AC-B3C0-D8720CCF0DD6)', Time: '2020-09-18T09:53:06', User OID: 'PatientReportedOutcome (US3032242)', ODM File OID: '6743801f-9cbd-4b36-b34d-0db75f1214f0' User entered 'None (0)'	System	18 Sep 2020 14:53:30
	System	18 Sep 2020 14:53:30

US3032242

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 14:52:51

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:43:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6C42AABB-C8BC-44AC-B3C0-D8720CCF0DD6)', Time: '2020-09-18T09:53:09', User OID: 'PatientReportedOutcome (US3032242)', ODM File OID: '6743801f-9cbd-4b36-b34d-0db75f1214f0' User entered 'None (0)'	System	18 Sep 2020 14:53:30
	System	18 Sep 2020 14:53:30

US3032242

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 14:52:51

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:43:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6C42AABB-C8BC-44AC-B3C0-D8720CCF0DD6)', Time: '2020-09-18T09:53:12', User OID: 'PatientReportedOutcome (US3032242)', ODM File OID: '6743801f-9cbd-4b36-b34d-0db75f1214f0' User entered 'None (0)'	System	18 Sep 2020 14:53:30
	System	18 Sep 2020 14:53:30

US3032242

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 14:52:51

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:43:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6C42AABB-C8BC-44AC-B3C0-D8720CCF0DD6)', Time: '2020-09-18T09:53:15', User OID: 'PatientReportedOutcome (US3032242)', ODM File OID: '6743801f-9cbd-4b36-b34d-0db75f1214f0' User entered 'None (0)'	System	18 Sep 2020 14:53:30
	System	18 Sep 2020 14:53:30

US3032242

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 14:52:51

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)	27 Mar 2021 20:43:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6C42AABB-C8BC-44AC-B3C0-D8720CCF0DD6)', Time: '2020-09-18T09:53:20', User OID: 'PatientReportedOutcome (US3032242)', ODM File OID: '6743801f-9cbd-4b36-b34d-0db75f1214f0' User entered 'No (N)'	System	18 Sep 2020 14:53:30
	System	18 Sep 2020 14:53:30

US3032242

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 14:52:51

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:43:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6C42AABB-C8BC-44AC-B3C0-D8720CCF0DD6)', Time: '2020-09-18T09:53:28', User OID: 'PatientReportedOutcome (US3032242)', ODM File OID: '6743801f-9cbd-4b36-b34d-0db75f1214f0' User entered '18 Sep 2020 09:53'	System	18 Sep 2020 14:53:30
	System	18 Sep 2020 14:53:30

US3032242

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 14:52:51

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:43:06
User entered '18 Sep 2020 09:37'	System	18 Sep 2020 14:39:06

US3032242

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 14:52:51

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:43:06
User entered '18 Sep 2020 12:07'	System	18 Sep 2020 14:39:06

US3032242

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 14:52:51

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:43:06
Data entry locked.	System	18 Sep 2020 14:39:06
User entered 'Day 1, after vaccination (at home)'	System	18 Sep 2020 14:39:06

US3032242

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 14:52:51

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:43:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6C42AABB-C8BC-44AC-B3C0-D8720CCF0DD6)', Time: '2020-09-18T17:02:51', User OID: 'PatientReportedOutcome (US3032242)', ODM File OID: 'f48fecfc-9903-46b2-81de-0a0bfb941423'	System	18 Sep 2020 22:03:34
User entered 'None (0)'	System	18 Sep 2020 22:03:34

US3032242

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 14:52:51

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:43:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6C42AABB-C8BC-44AC-B3C0-D8720CCF0DD6)', Time: '2020-09-18T17:02:58', User OID: 'PatientReportedOutcome (US3032242)', ODM File OID: 'f48fecfc-9903-46b2-81de-0a0bfb941423'	System	18 Sep 2020 22:03:34
User entered 'None (0)'	System	18 Sep 2020 22:03:34

US3032242

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 14:52:51

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:43:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6C42AABB-C8BC-44AC-B3C0-D8720CCF0DD6)', Time: '2020-09-18T17:03:02', User OID: 'PatientReportedOutcome (US3032242)', ODM File OID: 'f48fecfc-9903-46b2-81de-0a0bfb941423'	System	18 Sep 2020 22:03:34
User entered 'None (0)'	System	18 Sep 2020 22:03:34

US3032242

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 14:52:51

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:43:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6C42AABB-C8BC-44AC-B3C0-D8720CCF0DD6)', Time: '2020-09-18T17:03:06', User OID: 'PatientReportedOutcome (US3032242)', ODM File OID: 'f48fecfc-9903-46b2-81de-0a0bfb941423' User entered 'None (0)'	System	18 Sep 2020 22:03:34
	System	18 Sep 2020 22:03:34

US3032242

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 14:52:51

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:43:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6C42AABB-C8BC-44AC-B3C0-D8720CCF0DD6)', Time: '2020-09-18T17:03:09', User OID: 'PatientReportedOutcome (US3032242)', ODM File OID: 'f48fecfc-9903-46b2-81de-0a0bfb941423' User entered 'None (0)'	System	18 Sep 2020 22:03:34
	System	18 Sep 2020 22:03:34

US3032242

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 14:52:51

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:43:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6C42AABB-C8BC-44AC-B3C0-D8720CCF0DD6)', Time: '2020-09-18T17:03:12', User OID: 'PatientReportedOutcome (US3032242)', ODM File OID: 'f48fecfc-9903-46b2-81de-0a0bfb941423'	System	18 Sep 2020 22:03:34
User entered 'None (0)'	System	18 Sep 2020 22:03:34

US3032242

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 14:52:51

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)	27 Mar 2021 20:43:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6C42AABB-C8BC-44AC-B3C0-D8720CCF0DD6)', Time: '2020-09-18T17:03:18', User OID: 'PatientReportedOutcome (US3032242)', ODM File OID: 'f48fecfc-9903-46b2-81de-0a0bfb941423'	System	18 Sep 2020 22:03:34
User entered 'No (N)'	System	18 Sep 2020 22:03:34

US3032242

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 14:52:51

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:43:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6C42AABB-C8BC-44AC-B3C0-D8720CCF0DD6)', Time: '2020-09-18T17:03:26', User OID: 'PatientReportedOutcome (US3032242)', ODM File OID: 'f48fecfc-9903-46b2-81de-0a0bfb941423' User entered '18 Sep 2020 17:03'	System	18 Sep 2020 22:03:34
	System	18 Sep 2020 22:03:34

US3032242

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 14:52:51

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:43:06
User entered '18 Sep 2020 13:02'	System	18 Sep 2020 14:39:06

US3032242

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 14:52:51

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:43:06
User entered '19 Sep 2020 11:59'	System	18 Sep 2020 14:39:06

US3032242

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 14:52:51

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:43:06
Data entry locked.	System	18 Sep 2020 14:39:06
User entered 'Day 2'	System	18 Sep 2020 14:39:06

US3032242

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 14:52:51

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:43:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6C42AABB-C8BC-44AC-B3C0-D8720CCF0DD6)', Time: '2020-09-19T15:50:33', User OID: 'PatientReportedOutcome (US3032242)', ODM File OID: '6552ad27-df6c-4530-ad85-3b36605cf166'	System	19 Sep 2020 20:51:01
User entered 'None (0)'	System	19 Sep 2020 20:51:01

US3032242

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 14:52:51

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:43:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6C42AABB-C8BC-44AC-B3C0-D8720CCF0DD6)', Time: '2020-09-19T15:50:36', User OID: 'PatientReportedOutcome (US3032242)', ODM File OID: '6552ad27-df6c-4530-ad85-3b36605cf166'	System	19 Sep 2020 20:51:01
User entered 'None (0)'	System	19 Sep 2020 20:51:01

US3032242

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 14:52:51

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:43:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6C42AABB-C8BC-44AC-B3C0-D8720CCF0DD6)', Time: '2020-09-19T15:50:39', User OID: 'PatientReportedOutcome (US3032242)', ODM File OID: '6552ad27-df6c-4530-ad85-3b36605cf166'	System	19 Sep 2020 20:51:01
User entered 'None (0)'	System	19 Sep 2020 20:51:01

US3032242

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 14:52:51

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:43:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6C42AABB-C8BC-44AC-B3C0-D8720CCF0DD6)', Time: '2020-09-19T15:50:41', User OID: 'PatientReportedOutcome (US3032242)', ODM File OID: '6552ad27-df6c-4530-ad85-3b36605cf166'	System	19 Sep 2020 20:51:01
User entered 'None (0)'	System	19 Sep 2020 20:51:01

US3032242

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 14:52:51

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:43:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6C42AABB-C8BC-44AC-B3C0-D8720CCF0DD6)', Time: '2020-09-19T15:50:44', User OID: 'PatientReportedOutcome (US3032242)', ODM File OID: '6552ad27-df6c-4530-ad85-3b36605cf166'	System	19 Sep 2020 20:51:01
User entered 'None (0)'	System	19 Sep 2020 20:51:01

US3032242

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 14:52:51

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:43:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6C42AABB-C8BC-44AC-B3C0-D8720CCF0DD6)', Time: '2020-09-19T15:50:47', User OID: 'PatientReportedOutcome (US3032242)', ODM File OID: '6552ad27-df6c-4530-ad85-3b36605cf166'	System	19 Sep 2020 20:51:01
User entered 'None (0)'	System	19 Sep 2020 20:51:01

US3032242

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 14:52:51

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)	27 Mar 2021 20:43:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6C42AABB-C8BC-44AC-B3C0-D8720CCF0DD6)', Time: '2020-09-19T15:50:51', User OID: 'PatientReportedOutcome (US3032242)', ODM File OID: '6552ad27-df6c-4530-ad85-3b36605cf166'	System	19 Sep 2020 20:51:01
User entered 'No (N)'	System	19 Sep 2020 20:51:01

US3032242

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 14:52:51

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:43:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6C42AABB-C8BC-44AC-B3C0-D8720CCF0DD6)', Time: '2020-09-19T15:50:58', User OID: 'PatientReportedOutcome (US3032242)', ODM File OID: '6552ad27-df6c-4530-ad85-3b36605cf166'	System	19 Sep 2020 20:51:01
User entered '19 Sep 2020 15:50'	System	19 Sep 2020 20:51:01

US3032242

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 14:52:51

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:43:06
User entered '19 Sep 2020 12:00'	System	18 Sep 2020 14:39:06

US3032242

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 14:52:51

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:43:06
User entered '20 Sep 2020 11:59'	System	18 Sep 2020 14:39:06

US3032242

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 14:52:51

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:43:06
Data entry locked.	System	18 Sep 2020 14:39:06
User entered 'Day 3'	System	18 Sep 2020 14:39:06

US3032242

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 14:52:51

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:43:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6C42AABB-C8BC-44AC-B3C0-D8720CCF0DD6)', Time: '2020-09-20T12:15:01', User OID: 'PatientReportedOutcome (US3032242)', ODM File OID: '2720b847-1eea-4b5b-8c1e-c03b4f593850'	System	20 Sep 2020 17:15:34
User entered 'None (0)'	System	20 Sep 2020 17:15:34

US3032242

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 14:52:51

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:43:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6C42AABB-C8BC-44AC-B3C0-D8720CCF0DD6)', Time: '2020-09-20T12:15:05', User OID: 'PatientReportedOutcome (US3032242)', ODM File OID: '2720b847-1eea-4b5b-8c1e-c03b4f593850' User entered 'None (0)'	System	20 Sep 2020 17:15:34
	System	20 Sep 2020 17:15:34

US3032242

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 14:52:51

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:43:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6C42AABB-C8BC-44AC-B3C0-D8720CCF0DD6)', Time: '2020-09-20T12:15:10', User OID: 'PatientReportedOutcome (US3032242)', ODM File OID: '2720b847-1eea-4b5b-8c1e-c03b4f593850' User entered 'None (0)'	System	20 Sep 2020 17:15:34
	System	20 Sep 2020 17:15:34

US3032242

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 14:52:51

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:43:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6C42AABB-C8BC-44AC-B3C0-D8720CCF0DD6)', Time: '2020-09-20T12:15:13', User OID: 'PatientReportedOutcome (US3032242)', ODM File OID: '2720b847-1eea-4b5b-8c1e-c03b4f593850' User entered 'None (0)'	System	20 Sep 2020 17:15:34
	System	20 Sep 2020 17:15:34

US3032242

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 14:52:51

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:43:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6C42AABB-C8BC-44AC-B3C0-D8720CCF0DD6)', Time: '2020-09-20T12:15:16', User OID: 'PatientReportedOutcome (US3032242)', ODM File OID: '2720b847-1eea-4b5b-8c1e-c03b4f593850' User entered 'None (0)'	System	20 Sep 2020 17:15:34
	System	20 Sep 2020 17:15:34

US3032242

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 14:52:51

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:43:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6C42AABB-C8BC-44AC-B3C0-D8720CCF0DD6)', Time: '2020-09-20T12:15:19', User OID: 'PatientReportedOutcome (US3032242)', ODM File OID: '2720b847-1eea-4b5b-8c1e-c03b4f593850' User entered 'None (0)'	System	20 Sep 2020 17:15:34
	System	20 Sep 2020 17:15:34

US3032242

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 14:52:51

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)	27 Mar 2021 20:43:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6C42AABB-C8BC-44AC-B3C0-D8720CCF0DD6)', Time: '2020-09-20T12:15:23', User OID: 'PatientReportedOutcome (US3032242)', ODM File OID: '2720b847-1eea-4b5b-8c1e-c03b4f593850'	System	20 Sep 2020 17:15:34
User entered 'No (N)'	System	20 Sep 2020 17:15:34

US3032242

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 14:52:51

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:43:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6C42AABB-C8BC-44AC-B3C0-D8720CCF0DD6)', Time: '2020-09-20T12:15:32', User OID: 'PatientReportedOutcome (US3032242)', ODM File OID: '2720b847-1eea-4b5b-8c1e-c03b4f593850'	System	20 Sep 2020 17:15:34
User entered '20 Sep 2020 12:15'	System	20 Sep 2020 17:15:34

US3032242

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 14:52:51

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:43:06
User entered '20 Sep 2020 12:00'	System	18 Sep 2020 14:39:06

US3032242

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 14:52:51

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:43:06
User entered '21 Sep 2020 11:59'	System	18 Sep 2020 14:39:06

US3032242

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 14:52:51

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:43:06
Data entry locked.	System	18 Sep 2020 14:39:06
User entered 'Day 4'	System	18 Sep 2020 14:39:06

US3032242

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 14:52:51

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:43:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6C42AABB-C8BC-44AC-B3C0-D8720CCF0DD6)', Time: '2020-09-21T12:05:14', User OID: 'PatientReportedOutcome (US3032242)', ODM File OID: '6801ef27-241c-4c68-a247-559014af033a' User entered 'None (0)'	System	21 Sep 2020 17:07:43
	System	21 Sep 2020 17:07:43

US3032242

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 14:52:51

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:43:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6C42AABB-C8BC-44AC-B3C0-D8720CCF0DD6)', Time: '2020-09-21T12:05:19', User OID: 'PatientReportedOutcome (US3032242)', ODM File OID: '6801ef27-241c-4c68-a247-559014af033a' User entered 'None (0)'	System	21 Sep 2020 17:07:43
	System	21 Sep 2020 17:07:43

US3032242

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 14:52:51

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:43:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6C42AABB-C8BC-44AC-B3C0-D8720CCF0DD6)', Time: '2020-09-21T12:05:23', User OID: 'PatientReportedOutcome (US3032242)', ODM File OID: '6801ef27-241c-4c68-a247-559014af033a' User entered 'None (0)'	System	21 Sep 2020 17:07:43
	System	21 Sep 2020 17:07:43

US3032242

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 14:52:51

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:43:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6C42AABB-C8BC-44AC-B3C0-D8720CCF0DD6)', Time: '2020-09-21T12:05:26', User OID: 'PatientReportedOutcome (US3032242)', ODM File OID: '6801ef27-241c-4c68-a247-559014af033a' User entered 'None (0)'	System	21 Sep 2020 17:07:43
	System	21 Sep 2020 17:07:43

US3032242

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 14:52:51

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:43:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6C42AABB-C8BC-44AC-B3C0-D8720CCF0DD6)', Time: '2020-09-21T12:05:29', User OID: 'PatientReportedOutcome (US3032242)', ODM File OID: '6801ef27-241c-4c68-a247-559014af033a' User entered 'None (0)'	System	21 Sep 2020 17:07:43
	System	21 Sep 2020 17:07:43

US3032242

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 14:52:51

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:43:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6C42AABB-C8BC-44AC-B3C0-D8720CCF0DD6)', Time: '2020-09-21T12:05:32', User OID: 'PatientReportedOutcome (US3032242)', ODM File OID: '6801ef27-241c-4c68-a247-559014af033a' User entered 'None (0)'	System	21 Sep 2020 17:07:43
	System	21 Sep 2020 17:07:43

US3032242

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 14:52:51

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)	27 Mar 2021 20:43:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6C42AABB-C8BC-44AC-B3C0-D8720CCF0DD6)', Time: '2020-09-21T12:05:36', User OID: 'PatientReportedOutcome (US3032242)', ODM File OID: '6801ef27-241c-4c68-a247-559014af033a'	System	21 Sep 2020 17:07:43
User entered 'No (N)'	System	21 Sep 2020 17:07:43

US3032242

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 14:52:51

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:43:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6C42AABB-C8BC-44AC-B3C0-D8720CCF0DD6)', Time: '2020-09-21T12:05:45', User OID: 'PatientReportedOutcome (US3032242)', ODM File OID: '6801ef27-241c-4c68-a247-559014af033a' User entered '21 Sep 2020 12:05'	System	21 Sep 2020 17:07:43
	System	21 Sep 2020 17:07:43

US3032242

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 14:52:51

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:43:06
User entered '21 Sep 2020 12:00'	System	18 Sep 2020 14:39:06

US3032242

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 14:52:51

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:43:06
User entered '22 Sep 2020 11:59'	System	18 Sep 2020 14:39:06

US3032242

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 14:52:51

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:43:06
Data entry locked.	System	18 Sep 2020 14:39:06
User entered 'Day 5'	System	18 Sep 2020 14:39:06

US3032242

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 14:52:51

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:43:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6C42AABB-C8BC-44AC-B3C0-D8720CCF0DD6)', Time: '2020-09-22T12:14:43', User OID: 'PatientReportedOutcome (US3032242)', ODM File OID: '008197a8-d87c-40af-83b2-c987bdca858e' User entered 'None (0)'	System	22 Sep 2020 17:15:19
	System	22 Sep 2020 17:15:19

US3032242

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 14:52:51

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:43:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6C42AABB-C8BC-44AC-B3C0-D8720CCF0DD6)', Time: '2020-09-22T12:14:47', User OID: 'PatientReportedOutcome (US3032242)', ODM File OID: '008197a8-d87c-40af-83b2-c987bdca858e' User entered 'None (0)'	System	22 Sep 2020 17:15:19
	System	22 Sep 2020 17:15:19

US3032242

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 14:52:51

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:43:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6C42AABB-C8BC-44AC-B3C0-D8720CCF0DD6)', Time: '2020-09-22T12:14:51', User OID: 'PatientReportedOutcome (US3032242)', ODM File OID: '008197a8-d87c-40af-83b2-c987bdca858e' User entered 'None (0)'	System	22 Sep 2020 17:15:19
	System	22 Sep 2020 17:15:19

US3032242

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 14:52:51

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:43:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6C42AABB-C8BC-44AC-B3C0-D8720CCF0DD6)', Time: '2020-09-22T12:14:56', User OID: 'PatientReportedOutcome (US3032242)', ODM File OID: '008197a8-d87c-40af-83b2-c987bdca858e' User entered 'None (0)'	System	22 Sep 2020 17:15:19
	System	22 Sep 2020 17:15:19

US3032242

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 14:52:51

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:43:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6C42AABB-C8BC-44AC-B3C0-D8720CCF0DD6)', Time: '2020-09-22T12:14:59', User OID: 'PatientReportedOutcome (US3032242)', ODM File OID: '008197a8-d87c-40af-83b2-c987bdca858e' User entered 'None (0)'	System	22 Sep 2020 17:15:19
	System	22 Sep 2020 17:15:19

US3032242

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 14:52:51

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:43:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6C42AABB-C8BC-44AC-B3C0-D8720CCF0DD6)', Time: '2020-09-22T12:15:02', User OID: 'PatientReportedOutcome (US3032242)', ODM File OID: '008197a8-d87c-40af-83b2-c987bdca858e' User entered 'None (0)'	System	22 Sep 2020 17:15:19
	System	22 Sep 2020 17:15:19

US3032242

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 14:52:51

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)	27 Mar 2021 20:43:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6C42AABB-C8BC-44AC-B3C0-D8720CCF0DD6)', Time: '2020-09-22T12:15:07', User OID: 'PatientReportedOutcome (US3032242)', ODM File OID: '008197a8-d87c-40af-83b2-c987bdca858e' User entered 'No (N)'	System	22 Sep 2020 17:15:19
	System	22 Sep 2020 17:15:19

US3032242

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 14:52:51

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:43:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6C42AABB-C8BC-44AC-B3C0-D8720CCF0DD6)', Time: '2020-09-22T12:15:14', User OID: 'PatientReportedOutcome (US3032242)', ODM File OID: '008197a8-d87c-40af-83b2-c987bdca858e' User entered '22 Sep 2020 12:15'	System	22 Sep 2020 17:15:19
	System	22 Sep 2020 17:15:19

US3032242

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 14:52:51

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:43:06
User entered '22 Sep 2020 12:00'	System	18 Sep 2020 14:39:06

US3032242

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 14:52:51

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:43:06
User entered '23 Sep 2020 11:59'	System	18 Sep 2020 14:39:06

US3032242

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 14:52:51

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:43:06
Data entry locked.	System	18 Sep 2020 14:39:06
User entered 'Day 6'	System	18 Sep 2020 14:39:06

US3032242

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 14:52:51

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:43:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6C42AABB-C8BC-44AC-B3C0-D8720CCF0DD6)', Time: '2020-09-23T12:04:57', User OID: 'PatientReportedOutcome (US3032242)', ODM File OID: '12c18c3c-5c94-4eca-99c5-02fd94bccb10'	System	23 Sep 2020 17:08:39
User entered 'None (0)'	System	23 Sep 2020 17:08:39

US3032242

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 14:52:51

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:43:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6C42AABB-C8BC-44AC-B3C0-D8720CCF0DD6)', Time: '2020-09-23T12:05:00', User OID: 'PatientReportedOutcome (US3032242)', ODM File OID: '12c18c3c-5c94-4eca-99c5-02fd94bccb10'	System	23 Sep 2020 17:08:39
User entered 'None (0)'	System	23 Sep 2020 17:08:39

US3032242

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 14:52:51

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:43:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6C42AABB-C8BC-44AC-B3C0-D8720CCF0DD6)', Time: '2020-09-23T12:05:03', User OID: 'PatientReportedOutcome (US3032242)', ODM File OID: '12c18c3c-5c94-4eca-99c5-02fd94bccb10'	System	23 Sep 2020 17:08:39
User entered 'None (0)'	System	23 Sep 2020 17:08:39

US3032242

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 14:52:51

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:43:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6C42AABB-C8BC-44AC-B3C0-D8720CCF0DD6)', Time: '2020-09-23T12:05:06', User OID: 'PatientReportedOutcome (US3032242)', ODM File OID: '12c18c3c-5c94-4eca-99c5-02fd94bccb10'	System	23 Sep 2020 17:08:39
User entered 'None (0)'	System	23 Sep 2020 17:08:39

US3032242

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 14:52:51

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:43:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6C42AABB-C8BC-44AC-B3C0-D8720CCF0DD6)', Time: '2020-09-23T12:05:09', User OID: 'PatientReportedOutcome (US3032242)', ODM File OID: '12c18c3c-5c94-4eca-99c5-02fd94bccb10'	System	23 Sep 2020 17:08:39
User entered 'None (0)'	System	23 Sep 2020 17:08:39

US3032242

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 14:52:51

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:43:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6C42AABB-C8BC-44AC-B3C0-D8720CCF0DD6)', Time: '2020-09-23T12:05:11', User OID: 'PatientReportedOutcome (US3032242)', ODM File OID: '12c18c3c-5c94-4eca-99c5-02fd94bccb10'	System	23 Sep 2020 17:08:39
User entered 'None (0)'	System	23 Sep 2020 17:08:39

US3032242

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 14:52:51

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)	27 Mar 2021 20:43:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6C42AABB-C8BC-44AC-B3C0-D8720CCF0DD6)', Time: '2020-09-23T12:05:15', User OID: 'PatientReportedOutcome (US3032242)', ODM File OID: '12c18c3c-5c94-4eca-99c5-02fd94bccb10'	System	23 Sep 2020 17:08:39
User entered 'No (N)'	System	23 Sep 2020 17:08:39

US3032242

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 14:52:51

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:43:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6C42AABB-C8BC-44AC-B3C0-D8720CCF0DD6)', Time: '2020-09-23T12:05:21', User OID: 'PatientReportedOutcome (US3032242)', ODM File OID: '12c18c3c-5c94-4eca-99c5-02fd94bccb10'	System	23 Sep 2020 17:08:39
User entered '23 Sep 2020 12:05'	System	23 Sep 2020 17:08:39

US3032242

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 14:52:51

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:43:06
User entered '23 Sep 2020 12:00'	System	18 Sep 2020 14:39:06

US3032242

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 14:52:51

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:43:06
User entered '24 Sep 2020 11:59'	System	18 Sep 2020 14:39:06

US3032242

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 14:52:51

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:43:06
Data entry locked.	System	18 Sep 2020 14:39:06
User entered 'Day 7'	System	18 Sep 2020 14:39:06

US3032242

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 14:52:51

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:43:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6C42AABB-C8BC-44AC-B3C0-D8720CCF0DD6)', Time: '2020-09-24T15:59:56', User OID: 'PatientReportedOutcome (US3032242)', ODM File OID: 'a97e1818-1b13-4d27-b662-1371bc61bbdc' User entered 'None (0)'	System	24 Sep 2020 21:00:25
	System	24 Sep 2020 21:00:25

US3032242

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 14:52:51

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:43:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6C42AABB-C8BC-44AC-B3C0-D8720CCF0DD6)', Time: '2020-09-24T15:59:59', User OID: 'PatientReportedOutcome (US3032242)', ODM File OID: 'a97e1818-1b13-4d27-b662-1371bc61bbdc' User entered 'None (0)'	System	24 Sep 2020 21:00:25
	System	24 Sep 2020 21:00:25

US3032242

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 14:52:51

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:43:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6C42AABB-C8BC-44AC-B3C0-D8720CCF0DD6)', Time: '2020-09-24T16:00:02', User OID: 'PatientReportedOutcome (US3032242)', ODM File OID: 'a97e1818-1b13-4d27-b662-1371bc61bbdc' User entered 'None (0)'	System	24 Sep 2020 21:00:25
	System	24 Sep 2020 21:00:25

US3032242

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 14:52:51

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:43:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6C42AABB-C8BC-44AC-B3C0-D8720CCF0DD6)', Time: '2020-09-24T16:00:05', User OID: 'PatientReportedOutcome (US3032242)', ODM File OID: 'a97e1818-1b13-4d27-b662-1371bc61bbdc' User entered 'None (0)'	System	24 Sep 2020 21:00:25
	System	24 Sep 2020 21:00:25

US3032242

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 14:52:51

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:43:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6C42AABB-C8BC-44AC-B3C0-D8720CCF0DD6)', Time: '2020-09-24T16:00:08', User OID: 'PatientReportedOutcome (US3032242)', ODM File OID: 'a97e1818-1b13-4d27-b662-1371bc61bbdc' User entered 'None (0)'	System	24 Sep 2020 21:00:25
	System	24 Sep 2020 21:00:25

US3032242

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 14:52:51

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:43:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6C42AABB-C8BC-44AC-B3C0-D8720CCF0DD6)', Time: '2020-09-24T16:00:10', User OID: 'PatientReportedOutcome (US3032242)', ODM File OID: 'a97e1818-1b13-4d27-b662-1371bc61bbdc' User entered 'None (0)'	System	24 Sep 2020 21:00:25
	System	24 Sep 2020 21:00:25

US3032242

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 14:52:51

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)	27 Mar 2021 20:43:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6C42AABB-C8BC-44AC-B3C0-D8720CCF0DD6)', Time: '2020-09-24T16:00:14', User OID: 'PatientReportedOutcome (US3032242)', ODM File OID: 'a97e1818-1b13-4d27-b662-1371bc61bbdc'	System	24 Sep 2020 21:00:25
User entered 'No (N)'	System	24 Sep 2020 21:00:25

US3032242

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 14:52:51

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:43:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6C42AABB-C8BC-44AC-B3C0-D8720CCF0DD6)', Time: '2020-09-24T16:00:21', User OID: 'PatientReportedOutcome (US3032242)', ODM File OID: 'a97e1818-1b13-4d27-b662-1371bc61bbdc' User entered '24 Sep 2020 16:00'	System	24 Sep 2020 21:00:25
	System	24 Sep 2020 21:00:25

US3032242

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 14:52:51

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:43:06
User entered '24 Sep 2020 12:00'	System	18 Sep 2020 14:39:06

US3032242

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 14:52:51

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:43:06
User entered '25 Sep 2020 11:59'	System	18 Sep 2020 14:39:06

US3032242

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 09 Jun 2021 14:52:51

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:25:04
DataPoint Verified.		03 Dec 2020 16:43:35
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 17:47:49
User entered 'Yes (Y)'	(b) (4) Samantha Wieseler (b) (4)	25 Sep 2020 14:50:41
	(b) (4)	

US3032242

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 09 Jun 2021 14:52:51

Date of Contact or Contact Attempt (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:25:04
DataPoint Verified.		03 Dec 2020 16:43:35
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 17:47:49
User entered '25 Sep 2020'	(b) (4) Samantha Wieseler (b) (4)	25 Sep 2020 14:50:41
	(b) (4)	

US3032242

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 09 Jun 2021 14:52:51

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:25:04
DataPoint Verified.		03 Dec 2020 16:43:35
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 17:47:49
User entered 'Contact Made (CONTACT MADE)'	(b) (4) Samantha Wieseler (b) (4) (b) (4)	25 Sep 2020 14:50:41

US3032242

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 09 Jun 2021 14:52:51

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:25:04
DataPoint Verified.		03 Dec 2020 16:43:35
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 17:47:49
User entered empty.	(b) (4) Samantha Wieseler (b) (4)	25 Sep 2020 14:50:41
	(b) (4)	

US3032242

Folder: Safety Call Day 36 (1)

Form: Continuing

Generated On: 09 Jun 2021 14:52:51

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:25:04
DataPoint Verified.		03 Dec 2020 16:43:37
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 17:47:49
User entered 'Yes (Y)'	(b) (4) Samantha Wieseler (b) (4)	25 Sep 2020 14:50:46
	(b) (4)	

US3032242

Folder: Safety Call Day 36 (1)

Form: Continuing

Generated On: 09 Jun 2021 14:52:51

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:25:04
User entered '1'	System	25 Sep 2020 14:50:46

US3032242

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 09 Jun 2021 14:52:51

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:25:04
DataPoint Verified.		03 Dec 2020 16:43:53
User signature succeeded.	Keith Vrbicky (b) (4)	08 Oct 2020 15:42:03
User entered 'Yes (Y)'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	06 Oct 2020 22:47:26

US3032242

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 09 Jun 2021 14:52:51

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:25:04
DataPoint Verified.		03 Dec 2020 16:43:53
User signature succeeded.	Keith Vrbicky (b) (4)	08 Oct 2020 15:42:03
User entered '2 Oct 2020'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	06 Oct 2020 22:47:26

US3032242

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 09 Jun 2021 14:52:51

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:25:04
DataPoint Verified.	(b) (4)	03 Dec 2020 16:43:53
User signature succeeded.	Keith Vrbicky (b) (4)	08 Oct 2020 15:42:03
User entered 'Contact Made (CONTACT MADE)'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	06 Oct 2020 22:47:26

US3032242

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 09 Jun 2021 14:52:51

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:25:04
DataPoint Verified.		03 Dec 2020 16:43:53
User signature succeeded.	Keith Vrbicky (b) (4)	08 Oct 2020 15:42:03
User entered empty.	(b) (4) Kelsey Kelley (b) (4) (b) (4)	06 Oct 2020 22:47:26

US3032242

Folder: Safety Call Day 43 (1)

Form: Continuing

Generated On: 09 Jun 2021 14:52:51

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:25:04
DataPoint Verified.		03 Dec 2020 16:43:56
User signature succeeded.	Keith Vrbicky (b) (4)	08 Oct 2020 15:42:03
User entered 'Yes (Y)'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	06 Oct 2020 22:47:31

US3032242

Folder: Safety Call Day 43 (1)

Form: Continuing

Generated On: 09 Jun 2021 14:52:51

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:25:04
User entered '1'	System	06 Oct 2020 22:47:31

US3032242

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 09 Jun 2021 14:52:51

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:25:04
DataPoint Verified.		03 Dec 2020 16:44:00
User signature succeeded.	Keith Vrbicky (b) (4)	22 Oct 2020 14:54:53
User entered 'Yes (Y)'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	16 Oct 2020 15:51:26

US3032242

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 09 Jun 2021 14:52:51

Date of Contact or Contact Attempt (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:25:04
DataPoint Verified.		03 Dec 2020 16:44:00
User signature succeeded.	Keith Vrbicky (b) (4)	22 Oct 2020 14:54:53
User closed query 'Safety Call Day 50 'Date of Contact or Contact Attempt' is less than 21 days or greater than 24 days after Visit 2 Treatment Date on the Exposure Form. Please review and reconcile, or clarify.' (Site from System).	(b) (4) System	16 Oct 2020 15:51:33
Query 'Safety Call Day 50 'Date of Contact or Contact Attempt' is less than 21 days or greater than 24 days after Visit 2 Treatment Date on the Exposure Form. Please review and reconcile, or clarify.' answered by data change (Site from System).	System	16 Oct 2020 15:51:33
User entered '09 Oct 2020' reason for change: Data Entry Error	Kelsey Kelley (b) (4) (b) (4)	16 Oct 2020 15:51:33
User opened query 'Safety Call Day 50 'Date of Contact or Contact Attempt' is less than 21 days or greater than 24 days after Visit 2 Treatment Date on the Exposure Form. Please review and reconcile, or clarify.' (Site from System).	System	16 Oct 2020 15:51:26
User entered '15 Oct 2020'	Kelsey Kelley (b) (4) (b) (4)	16 Oct 2020 15:51:26

US3032242

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 09 Jun 2021 14:52:51

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:25:04
DataPoint Verified.		03 Dec 2020 16:44:00
User signature succeeded.	Keith Vrbicky (b) (4)	22 Oct 2020 14:54:53
User entered 'Contact Made (CONTACT MADE)'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	16 Oct 2020 15:51:26

US3032242

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 09 Jun 2021 14:52:51

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:25:04
DataPoint Verified.		03 Dec 2020 16:44:00
User signature succeeded.	Keith Vrbicky (b) (4)	22 Oct 2020 14:54:53
User entered empty.	(b) (4) Kelsey Kelley (b) (4) (b) (4)	16 Oct 2020 15:51:26

US3032242

Folder: Safety Call Day 50 (1)

Form: Continuing

Generated On: 09 Jun 2021 14:52:51

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:25:04
DataPoint Verified.		03 Dec 2020 16:44:16
User signature succeeded.	Keith Vrbicky (b) (4)	22 Oct 2020 14:54:53
User entered 'Yes (Y)'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	16 Oct 2020 15:51:36

US3032242

Folder: Safety Call Day 50 (1)

Form: Continuing

Generated On: 09 Jun 2021 14:52:51

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:25:04
User entered '1'	System	16 Oct 2020 15:51:36

US3032242

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 09 Jun 2021 14:52:51

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:25:04
DataPoint Verified.		03 Dec 2020 16:44:28
User signature succeeded.	Keith Vrbicky (b) (4)	22 Oct 2020 14:54:53
User entered 'Yes (Y)'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	16 Oct 2020 15:52:53

US3032242

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 09 Jun 2021 14:52:51

Visit date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:25:04
DataPoint Verified.		03 Dec 2020 16:44:28
User signature succeeded.	Keith Vrbicky (b) (4)	22 Oct 2020 14:54:53
User entered '15 Oct 2020'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	16 Oct 2020 15:52:53

US3032242

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 09 Jun 2021 14:52:51

[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 19:25:04
DataPoint Verified.		03 Dec 2020 16:44:28
User signature succeeded.	Keith Vrbicky (b) (4)	22 Oct 2020 14:54:53
User entered 'Clinic (Clinic)'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	16 Oct 2020 15:52:53

US3032242

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 09 Jun 2021 14:52:51

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:25:04
User entered 'VISIT3'	System	16 Oct 2020 15:52:53

US3032242

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 14:52:51

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:25:04
DataPoint Verified.		03 Dec 2020 16:45:03
User signature succeeded.	Keith Vrbicky (b) (4)	22 Oct 2020 14:54:53
User entered 'Yes (Y)'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	16 Oct 2020 15:53:24

US3032242

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 14:52:51

Date of assessment (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:25:04
DataPoint Verified.		03 Dec 2020 16:45:03
User signature succeeded.	Keith Vrbicky (b) (4)	22 Oct 2020 14:54:53
User entered '15 Oct 2020'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	16 Oct 2020 15:53:24

US3032242

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 14:52:51

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:25:04
DataPoint Verified.		03 Dec 2020 16:45:03
User signature succeeded.	Keith Vrbicky (b) (4)	22 Oct 2020 14:54:53
User entered '14:52'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	16 Oct 2020 15:53:24

US3032242

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 14:52:51

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:25:04
User entered '15 Oct 2020 14:52'	System	16 Oct 2020 15:53:24

US3032242

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 14:52:51

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:25:04
DataPoint Verified.		03 Dec 2020 16:45:03
User signature succeeded.	Keith Vrbicky (b) (4)	22 Oct 2020 14:54:53
User entered '36.6' C	(b) (4) Kelsey Kelley (b) (4) (b) (4)	16 Oct 2020 15:53:24

US3032242

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 14:52:51

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:25:04
DataPoint Verified.		03 Dec 2020 16:45:03
User signature succeeded.	Keith Vrbicky (b) (4)	22 Oct 2020 14:54:53
User entered 'Oral (Oral)'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	16 Oct 2020 15:53:24

US3032242

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 14:52:51

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:25:04
DataPoint Verified.		03 Dec 2020 16:45:03
User signature succeeded.	Keith Vrbicky (b) (4)	22 Oct 2020 14:54:53
User entered empty.	(b) (4) Kelsey Kelley (b) (4) (b) (4)	16 Oct 2020 15:53:24

US3032242

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 14:52:51

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:25:04
DataPoint Verified.		03 Dec 2020 16:45:03
User signature succeeded.	Keith Vrbicky (b) (4)	22 Oct 2020 14:54:53
User entered '81'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	16 Oct 2020 15:53:24

US3032242

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 14:52:51

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:25:04
User entered 'bpm'	System	16 Oct 2020 15:53:24

US3032242

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 14:52:51

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:25:04
DataPoint Verified.		03 Dec 2020 16:45:03
User signature succeeded.	Keith Vrbicky (b) (4)	22 Oct 2020 14:54:53
User entered '14'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	16 Oct 2020 15:53:24

US3032242

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 14:52:51

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:25:04
User entered 'breaths/min'	System	16 Oct 2020 15:53:24

US3032242

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 14:52:51

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:25:04
DataPoint Verified.		03 Dec 2020 16:45:03
User signature succeeded.	Keith Vrbicky (b) (4)	22 Oct 2020 14:54:53
User entered '134'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	16 Oct 2020 15:53:24

US3032242

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 14:52:51

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:25:04
User entered 'mmHg'	System	16 Oct 2020 15:53:24

US3032242

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 14:52:51

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:25:04
DataPoint Verified.		03 Dec 2020 16:45:03
User signature succeeded.	Keith Vrbicky (b) (4)	22 Oct 2020 14:54:53
User entered '90'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	16 Oct 2020 15:53:24

US3032242

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 14:52:51

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:25:04
User entered 'mmHg'	System	16 Oct 2020 15:53:24

US3032242

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 14:52:51

[Height \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:25:04

US3032242

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 14:52:51

[Weight \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:25:04

US3032242

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 14:52:51

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:25:04
DataPoint Verified.		03 Dec 2020 16:45:12
User signature succeeded.	Keith Vrbicky (b) (4)	22 Oct 2020 14:54:53
User entered 'Yes (Y)'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	16 Oct 2020 15:54:00

US3032242

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 14:52:51

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:25:04
DataPoint Verified.		03 Dec 2020 16:45:12
User signature succeeded.	Keith Vrbicky (b) (4)	22 Oct 2020 14:54:53
User entered '15 Oct 2020'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	16 Oct 2020 15:54:00

US3032242

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 14:52:51

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:25:04
DataPoint Verified.		03 Dec 2020 16:45:23
User signature succeeded.	Keith Vrbicky (b) (4)	22 Oct 2020 14:54:53
User entered 'Yes (Y)'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	16 Oct 2020 15:54:10

US3032242

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 14:52:51

Collection date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:25:04
DataPoint Verified.		03 Dec 2020 16:45:23
User signature succeeded.	Keith Vrbicky (b) (4)	22 Oct 2020 14:54:53
User entered '15 Oct 2020'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	16 Oct 2020 15:54:10

US3032242

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 14:52:51

Collection time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:25:04
DataPoint Verified.		03 Dec 2020 16:45:23
User signature succeeded.	Keith Vrbicky (b) (4)	22 Oct 2020 14:54:53
User entered '15:06'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	16 Oct 2020 15:54:10

US3032242

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 14:52:51

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:25:04
User entered '15 Oct 2020 15:06'	System	16 Oct 2020 15:54:10

US3032242

Folder: Visit 3 Day 57 (1)

Form: Continuing

Generated On: 09 Jun 2021 14:52:51

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:25:04
DataPoint Verified.		03 Dec 2020 16:45:27
User signature succeeded.	Keith Vrbicky (b) (4)	22 Oct 2020 14:54:53
User entered 'Yes (Y)'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	16 Oct 2020 15:54:14

US3032242

Folder: Visit 3 Day 57 (1)

Form: Continuing

Generated On: 09 Jun 2021 14:52:51

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:25:04
User entered '1'	System	16 Oct 2020 15:54:14

US3032242

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:52:51

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:43:06
Data entry locked.	System	19 Aug 2020 21:23:04
User entered 'Day 64'	System	19 Aug 2020 21:23:04

US3032242

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:52:51

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)	27 Mar 2021 20:43:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6C42AABB-C8BC-44AC-B3C0-D8720CCF0DD6)', Time: '2020-10-19T18:12:31', User OID: 'PatientReportedOutcome (US3032242)', ODM File OID: '1d76866c-d63b-4a1a-834c-05c1d5d8cc5d' User entered 'No (N)'	System	19 Oct 2020 23:12:54
	System	19 Oct 2020 23:12:54

US3032242

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:52:51

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)	27 Mar 2021 20:43:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6C42AABB-C8BC-44AC-B3C0-D8720CCF0DD6)', Time: '2020-10-19T18:12:41', User OID: 'PatientReportedOutcome (US3032242)', ODM File OID: '1d76866c-d63b-4a1a-834c-05c1d5d8cc5d' User entered 'No (N)'	System	19 Oct 2020 23:12:54
	System	19 Oct 2020 23:12:54

US3032242

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:52:51

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:43:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6C42AABB-C8BC-44AC-B3C0-D8720CCF0DD6)', Time: '2020-10-19T18:12:50', User OID: 'PatientReportedOutcome (US3032242)', ODM File OID: '1d76866c-d63b-4a1a-834c-05c1d5d8cc5d' User entered '19 Oct 2020 18:12:50'	System	19 Oct 2020 23:12:54
	System	19 Oct 2020 23:12:54

US3032242

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:52:51

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:43:06
Data entry locked.	System	19 Aug 2020 21:23:04
User entered '19 Oct 2020 00:01'	System	19 Aug 2020 21:23:04

US3032242

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:52:51

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:43:06
Data entry locked.	System	19 Aug 2020 21:23:04
User entered '23 Oct 2020 23:59'	System	19 Aug 2020 21:23:04

US3032242

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:52:51

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:43:06
Data entry locked.	System	19 Aug 2020 21:23:04
User entered 'Day 71'	System	19 Aug 2020 21:23:04

US3032242

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:52:51

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)	27 Mar 2021 20:43:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6C42AABB-C8BC-44AC-B3C0-D8720CCF0DD6)', Time: '2020-10-26T17:26:14', User OID: 'PatientReportedOutcome (US3032242)', ODM File OID: '5f67187a-8d1e-4e83-9b41-416e2d8a755c'	System	26 Oct 2020 22:26:37
User entered 'No (N)'	System	26 Oct 2020 22:26:37

US3032242

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:52:51

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)	27 Mar 2021 20:43:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6C42AABB-C8BC-44AC-B3C0-D8720CCF0DD6)', Time: '2020-10-26T17:26:26', User OID: 'PatientReportedOutcome (US3032242)', ODM File OID: '5f67187a-8d1e-4e83-9b41-416e2d8a755c'	System	26 Oct 2020 22:26:37
User entered 'No (N)'	System	26 Oct 2020 22:26:37

US3032242

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:52:51

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:43:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6C42AABB-C8BC-44AC-B3C0-D8720CCF0DD6)', Time: '2020-10-26T17:26:34', User OID: 'PatientReportedOutcome (US3032242)', ODM File OID: '5f67187a-8d1e-4e83-9b41-416e2d8a755c' User entered '26 Oct 2020 17:26:34'	System	26 Oct 2020 22:26:37
	System	26 Oct 2020 22:26:37

US3032242

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:52:51

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:43:06
Data entry locked.	System	19 Aug 2020 21:23:04
User entered '26 Oct 2020 00:01'	System	19 Aug 2020 21:23:04

US3032242

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:52:51

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:43:06
Data entry locked.	System	19 Aug 2020 21:23:04
User entered '30 Oct 2020 23:59'	System	19 Aug 2020 21:23:04

US3032242

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:52:51

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:43:06
Data entry locked.	System	19 Aug 2020 21:23:04
User entered 'Day 78'	System	19 Aug 2020 21:23:04

US3032242

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:52:51

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)	27 Mar 2021 20:43:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6C42AABB-C8BC-44AC-B3C0-D8720CCF0DD6)', Time: '2020-11-02T14:40:11', User OID: 'PatientReportedOutcome (US3032242)', ODM File OID: 'c01035a6-6d06-47c7-b19c-6f677d79f2b2'	System	02 Nov 2020 20:40:32
User entered 'No (N)'	System	02 Nov 2020 20:40:32

US3032242

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:52:51

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)	27 Mar 2021 20:43:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6C42AABB-C8BC-44AC-B3C0-D8720CCF0DD6)', Time: '2020-11-02T14:40:20', User OID: 'PatientReportedOutcome (US3032242)', ODM File OID: 'c01035a6-6d06-47c7-b19c-6f677d79f2b2'	System	02 Nov 2020 20:40:32
User entered 'No (N)'	System	02 Nov 2020 20:40:32

US3032242

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:52:51

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:43:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6C42AABB-C8BC-44AC-B3C0-D8720CCF0DD6)', Time: '2020-11-02T14:40:29', User OID: 'PatientReportedOutcome (US3032242)', ODM File OID: 'c01035a6-6d06-47c7-b19c-6f677d79f2b2'	System	02 Nov 2020 20:40:32
User entered '02 Nov 2020 14:40:29'	System	02 Nov 2020 20:40:32

US3032242

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:52:51

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:43:06
Data entry locked.	System	19 Aug 2020 21:23:04
User entered '02 Nov 2020 00:01'	System	19 Aug 2020 21:23:04

US3032242

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:52:51

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:43:06
Data entry locked.	System	19 Aug 2020 21:23:04
User entered '06 Nov 2020 23:59'	System	19 Aug 2020 21:23:04

US3032242

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:52:51

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:43:06
Data entry locked.	System	19 Aug 2020 21:23:04
User entered 'Day 92'	System	19 Aug 2020 21:23:04

US3032242

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:52:51

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)	27 Mar 2021 20:43:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6C42AABB-C8BC-44AC-B3C0-D8720CCF0DD6)', Time: '2020-11-17T00:04:13', User OID: 'PatientReportedOutcome (US3032242)', ODM File OID: 'b2de2c30-d027-4543-8515-5c71daf20a96'	System	17 Nov 2020 06:04:29
User entered 'No (N)'	System	17 Nov 2020 06:04:29

US3032242

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:52:51

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)	27 Mar 2021 20:43:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6C42AABB-C8BC-44AC-B3C0-D8720CCF0DD6)', Time: '2020-11-17T00:04:18', User OID: 'PatientReportedOutcome (US3032242)', ODM File OID: 'b2de2c30-d027-4543-8515-5c71daf20a96'	System	17 Nov 2020 06:04:29
User entered 'No (N)'	System	17 Nov 2020 06:04:29

US3032242

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:52:51

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:43:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6C42AABB-C8BC-44AC-B3C0-D8720CCF0DD6)', Time: '2020-11-17T00:04:25', User OID: 'PatientReportedOutcome (US3032242)', ODM File OID: 'b2de2c30-d027-4543-8515-5c71daf20a96'	System	17 Nov 2020 06:04:29
User entered '17 Nov 2020 00:04:25'	System	17 Nov 2020 06:04:29

US3032242

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:52:51

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:43:06
Data entry locked.	System	19 Aug 2020 21:23:04
User entered '16 Nov 2020 00:01'	System	19 Aug 2020 21:23:04

US3032242

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:52:51

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:43:06
Data entry locked.	System	19 Aug 2020 21:23:04
User entered '20 Nov 2020 23:59'	System	19 Aug 2020 21:23:04

US3032242

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:52:51

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:19:33
Amendment Manager: User entered 'Day 96'	System	19 Nov 2020 23:19:33

US3032242

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:52:51

[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 (6C42AABB-C8BC-44AC-B3C0-D8720CCF0DD6)', Time: '2020-11-23T12:21:11', User OID: 'PatientReportedOutcome (US3032242)', ODM File OID: 'd0cdce20-92cc-436f-839b-ba15d77600db'	System	23 Nov 2020 18:21:30
User entered 'No (N)'	System	23 Nov 2020 18:21:30

US3032242

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:52:51

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 (6C42AABB-C8BC-44AC-B3C0-D8720CCF0DD6)', Time: '2020-11-23T12:21:20', User OID: 'PatientReportedOutcome (US3032242)', ODM File OID: 'd0cdce20-92cc-436f-839b-ba15d77600db'	System	23 Nov 2020 18:21:30
User entered 'No (N)'	System	23 Nov 2020 18:21:30

US3032242

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:52:51

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6C42AABB-C8BC-44AC-B3C0-D8720CCF0DD6)', Time: '2020-11-23T12:21:27', User OID: 'PatientReportedOutcome (US3032242)', ODM File OID: 'd0cdce20-92cc-436f-839b-ba15d77600db' User entered '23 Nov 2020 12:21:27'	System	23 Nov 2020 18:21:30
	System	23 Nov 2020 18:21:30

US3032242

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:52:51

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:19:33
Amendment Manager: User entered '20 Nov 2020 00:01'	System	19 Nov 2020 23:19:33

US3032242

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:52:51

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:19:33
Amendment Manager: User entered '24 Nov 2020 23:59'	System	19 Nov 2020 23:19:33

US3032242

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:52:51

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:19:33
Amendment Manager: User entered 'Day 103'	System	19 Nov 2020 23:19:33

US3032242

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:52:51

[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 (6C42AABB-C8BC-44AC-B3C0-D8720CCF0DD6)', Time: '2020-11-30T12:45:43', User OID: 'PatientReportedOutcome (US3032242)', ODM File OID: '40280607-b60d-4a94-97e8-369c7e82f806'	System	30 Nov 2020 18:45:59
User entered 'No (N)'	System	30 Nov 2020 18:45:59

US3032242

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:52:51

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 (6C42AABB-C8BC-44AC-B3C0-D8720CCF0DD6)', Time: '2020-11-30T12:45:51', User OID: 'PatientReportedOutcome (US3032242)', ODM File OID: '40280607-b60d-4a94-97e8-369c7e82f806'	System	30 Nov 2020 18:45:59
User entered 'No (N)'	System	30 Nov 2020 18:45:59

US3032242

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:52:51

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6C42AABB-C8BC-44AC-B3C0-D8720CCF0DD6)', Time: '2020-11-30T12:45:56', User OID: 'PatientReportedOutcome (US3032242)', ODM File OID: '40280607-b60d-4a94-97e8-369c7e82f806'	System	30 Nov 2020 18:45:59
User entered '30 Nov 2020 12:45:56'	System	30 Nov 2020 18:45:59

US3032242

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:52:51

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:19:33
Amendment Manager: User entered '27 Nov 2020 00:01'	System	19 Nov 2020 23:19:33

US3032242

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:52:51

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:19:33
Amendment Manager: User entered '01 Dec 2020 23:59'	System	19 Nov 2020 23:19:33

US3032242

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:52:51

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:19:33
Amendment Manager: User entered 'Day 110'	System	19 Nov 2020 23:19:33

US3032242

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:52:51

[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 (6C42AABB-C8BC-44AC-B3C0-D8720CCF0DD6)', Time: '2020-12-08T00:14:30', User OID: 'PatientReportedOutcome (US3032242)', ODM File OID: '3453dc84-f7ef-4f9f-a1f1-6f395a2df530'	System	08 Dec 2020 06:14:38
User entered 'No (N)'	System	08 Dec 2020 06:14:38

US3032242

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:52:51

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 (6C42AABB-C8BC-44AC-B3C0-D8720CCF0DD6)', Time: '2020-12-08T00:14:32', User OID: 'PatientReportedOutcome (US3032242)', ODM File OID: '3453dc84-f7ef-4f9f-a1f1-6f395a2df530'	System	08 Dec 2020 06:14:38
User entered 'No (N)'	System	08 Dec 2020 06:14:38

US3032242

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:52:51

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6C42AABB-C8BC-44AC-B3C0-D8720CCF0DD6)', Time: '2020-12-08T00:14:35', User OID: 'PatientReportedOutcome (US3032242)', ODM File OID: '3453dc84-f7ef-4f9f-a1f1-6f395a2df530'	System	08 Dec 2020 06:14:38
User entered '08 Dec 2020 00:14:35'	System	08 Dec 2020 06:14:38

US3032242

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:52:51

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:19:33
Amendment Manager: User entered '04 Dec 2020 00:01'	System	19 Nov 2020 23:19:33

US3032242

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:52:51

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:19:33
Amendment Manager: User entered '08 Dec 2020 23:59'	System	19 Nov 2020 23:19:33

US3032242

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:52:51

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:19:33
Amendment Manager: User entered 'Day 117'	System	19 Nov 2020 23:19:33

US3032242

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:52:51

[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 (6C42AABB-C8BC-44AC-B3C0-D8720CCF0DD6)', Time: '2020-12-11T09:49:40', User OID: 'PatientReportedOutcome (US3032242)', ODM File OID: 'f65af8cc-7a9a-4a9f-a9d5-bbddd305b01'	System	11 Dec 2020 15:49:56
User entered 'No (N)'	System	11 Dec 2020 15:49:56

US3032242

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:52:51

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 (6C42AABB-C8BC-44AC-B3C0-D8720CCF0DD6)', Time: '2020-12-11T09:49:48', User OID: 'PatientReportedOutcome (US3032242)', ODM File OID: 'f65af8cc-7a9a-4a9f-a9d5-bbddd305b01'	System	11 Dec 2020 15:49:56
User entered 'No (N)'	System	11 Dec 2020 15:49:56

US3032242

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:52:51

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6C42AABB-C8BC-44AC-B3C0-D8720CCF0DD6)', Time: '2020-12-11T09:49:54', User OID: 'PatientReportedOutcome (US3032242)', ODM File OID: 'f65af8cc-7a9a-4a9f-a9d5-bbdba305b01'	System	11 Dec 2020 15:49:56
User entered '11 Dec 2020 09:49:54'	System	11 Dec 2020 15:49:56

US3032242

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:52:51

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:19:33
Amendment Manager: User entered '11 Dec 2020 00:01'	System	19 Nov 2020 23:19:33

US3032242

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:52:51

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:19:33
Amendment Manager: User entered '15 Dec 2020 23:59'	System	19 Nov 2020 23:19:33

US3032242

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:52:51

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:19:33
Amendment Manager: User entered 'Day 124'	System	19 Nov 2020 23:19:33

US3032242

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:52:51

[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 (6C42AABB-C8BC-44AC-B3C0-D8720CCF0DD6)', Time: '2020-12-18T04:20:42', User OID: 'PatientReportedOutcome (US3032242)', ODM File OID: '9e6e26c6-8cbf-445c-83dc-f5d211eb58c3'	System	18 Dec 2020 10:20:54
User entered 'No (N)'	System	18 Dec 2020 10:20:54

US3032242

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:52:51

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 (6C42AABB-C8BC-44AC-B3C0-D8720CCF0DD6)', Time: '2020-12-18T04:20:48', User OID: 'PatientReportedOutcome (US3032242)', ODM File OID: '9e6e26c6-8cbf-445c-83dc-f5d211eb58c3'	System	18 Dec 2020 10:20:54
User entered 'No (N)'	System	18 Dec 2020 10:20:54

US3032242

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:52:51

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6C42AABB-C8BC-44AC-B3C0-D8720CCF0DD6)', Time: '2020-12-18T04:20:52', User OID: 'PatientReportedOutcome (US3032242)', ODM File OID: '9e6e26c6-8cbf-445c-83dc-f5d211eb58c3'	System	18 Dec 2020 10:20:54
User entered '18 Dec 2020 04:20:52'	System	18 Dec 2020 10:20:54

US3032242

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:52:51

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:19:33
Amendment Manager: User entered '18 Dec 2020 00:01'	System	19 Nov 2020 23:19:33

US3032242

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:52:51

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:19:33
Amendment Manager: User entered '22 Dec 2020 23:59'	System	19 Nov 2020 23:19:33

US3032242

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:52:51

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:19:33
Amendment Manager: User entered 'Day 131'	System	19 Nov 2020 23:19:33

US3032242

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:52:51

[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 (6C42AABB-C8BC-44AC-B3C0-D8720CCF0DD6)', Time: '2020-12-25T07:23:41', User OID: 'PatientReportedOutcome (US3032242)', ODM File OID: '316ef9d3-aa36-437b-9621-7882f4ddf3'	System	25 Dec 2020 13:23:51
User entered 'No (N)'	System	25 Dec 2020 13:23:51

US3032242

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:52:51

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 (6C42AABB-C8BC-44AC-B3C0-D8720CCF0DD6)', Time: '2020-12-25T07:23:46', User OID: 'PatientReportedOutcome (US3032242)', ODM File OID: '316ef9d3-aa36-437b-9621-7882f4ddf3'	System	25 Dec 2020 13:23:51
User entered 'No (N)'	System	25 Dec 2020 13:23:51

US3032242

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:52:51

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6C42AABB-C8BC-44AC-B3C0-D8720CCF0DD6)', Time: '2020-12-25T07:23:50', User OID: 'PatientReportedOutcome (US3032242)', ODM File OID: '316ef9d3-aa36-437b-9621-7882f4ddf3'	System	25 Dec 2020 13:23:51
User entered '25 Dec 2020 07:23:50'	System	25 Dec 2020 13:23:51

US3032242

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:52:51

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:19:33
Amendment Manager: User entered '25 Dec 2020 00:01'	System	19 Nov 2020 23:19:33

US3032242

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:52:51

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:19:33
Amendment Manager: User entered '29 Dec 2020 23:59'	System	19 Nov 2020 23:19:33

US3032242

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:52:51

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:19:33
Amendment Manager: User entered 'Day 138'	System	19 Nov 2020 23:19:33

US3032242

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:52:51

[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 (6C42AABB-C8BC-44AC-B3C0-D8720CCF0DD6)', Time: '2021-01-01T05:32:24', User OID: 'PatientReportedOutcome (US3032242)', ODM File OID: '875d75b1-ae1d-4eb3-b673-5d93d6ffa48b' User entered 'No (N)'	System	01 Jan 2021 11:32:33
	System	01 Jan 2021 11:32:33

US3032242

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:52:51

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 (6C42AABB-C8BC-44AC-B3C0-D8720CCF0DD6)', Time: '2021-01-01T05:32:28', User OID: 'PatientReportedOutcome (US3032242)', ODM File OID: '875d75b1-ae1d-4eb3-b673-5d93d6ffa48b' User entered 'No (N)'	System	01 Jan 2021 11:32:33
	System	01 Jan 2021 11:32:33

US3032242

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:52:51

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6C42AABB-C8BC-44AC-B3C0-D8720CCF0DD6)', Time: '2021-01-01T05:32:32', User OID: 'PatientReportedOutcome (US3032242)', ODM File OID: '875d75b1-ae1d-4eb3-b673-5d93d6ffa48b' User entered '01 Jan 2021 05:32:32'	System	01 Jan 2021 11:32:33
	System	01 Jan 2021 11:32:33

US3032242

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:52:51

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:19:33
Amendment Manager: User entered '01 Jan 2021 00:01'	System	19 Nov 2020 23:19:33

US3032242

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:52:51

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:19:33
Amendment Manager: User entered '05 Jan 2021 23:59'	System	19 Nov 2020 23:19:33

US3032242

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:52:51

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:19:33
Amendment Manager: User entered 'Day 145'	System	19 Nov 2020 23:19:33

US3032242

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:52:51

[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 (6C42AABB-C8BC-44AC-B3C0-D8720CCF0DD6)', Time: '2021-01-08T08:53:02', User OID: 'PatientReportedOutcome (US3032242)', ODM File OID: '75a9fc2c-400f-4f25-af6b-4ad50ba4d066'	System	08 Jan 2021 14:53:11
User entered 'No (N)'	System	08 Jan 2021 14:53:11

US3032242

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:52:51

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 (6C42AABB-C8BC-44AC-B3C0-D8720CCF0DD6)', Time: '2021-01-08T08:53:04', User OID: 'PatientReportedOutcome (US3032242)', ODM File OID: '75a9fc2c-400f-4f25-af6b-4ad50ba4d066'	System	08 Jan 2021 14:53:11
User entered 'No (N)'	System	08 Jan 2021 14:53:11

US3032242

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:52:51

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6C42AABB-C8BC-44AC-B3C0-D8720CCF0DD6)', Time: '2021-01-08T08:53:08', User OID: 'PatientReportedOutcome (US3032242)', ODM File OID: '75a9fc2c-400f-4f25-af6b-4ad50ba4d066' User entered '08 Jan 2021 08:53:08'	System	08 Jan 2021 14:53:11
	System	08 Jan 2021 14:53:11

US3032242

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:52:51

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:19:33
Amendment Manager: User entered '08 Jan 2021 00:01'	System	19 Nov 2020 23:19:33

US3032242

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:52:51

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:19:33
Amendment Manager: User entered '12 Jan 2021 23:59'	System	19 Nov 2020 23:19:33

US3032242

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:52:51

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:19:33
Amendment Manager: User entered 'Day 152'	System	19 Nov 2020 23:19:33

US3032242

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:52:51

[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 (6C42AABB-C8BC-44AC-B3C0-D8720CCF0DD6)', Time: '2021-01-15T09:25:31', User OID: 'PatientReportedOutcome (US3032242)', ODM File OID: '20a602c5-eb9a-4b6b-bd1b-7977554a7f74'	System	15 Jan 2021 15:25:43
User entered 'No (N)'	System	15 Jan 2021 15:25:43

US3032242

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:52:51

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 (6C42AABB-C8BC-44AC-B3C0-D8720CCF0DD6)', Time: '2021-01-15T09:25:35', User OID: 'PatientReportedOutcome (US3032242)', ODM File OID: '20a602c5-eb9a-4b6b-bd1b-7977554a7f74'	System	15 Jan 2021 15:25:43
User entered 'No (N)'	System	15 Jan 2021 15:25:43

US3032242

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:52:51

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6C42AABB-C8BC-44AC-B3C0-D8720CCF0DD6)', Time: '2021-01-15T09:25:39', User OID: 'PatientReportedOutcome (US3032242)', ODM File OID: '20a602c5-eb9a-4b6b-bd1b-7977554a7f74'	System	15 Jan 2021 15:25:43
User entered '15 Jan 2021 09:25:39'	System	15 Jan 2021 15:25:43

US3032242

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:52:51

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:19:33
Amendment Manager: User entered '15 Jan 2021 00:01'	System	19 Nov 2020 23:19:33

US3032242

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:52:51

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:19:33
Amendment Manager: User entered '19 Jan 2021 23:59'	System	19 Nov 2020 23:19:33

US3032242

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:52:51

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:19:33
Amendment Manager: User entered 'Day 159'	System	19 Nov 2020 23:19:33

US3032242

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:52:51

[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 (6C42AABB-C8BC-44AC-B3C0-D8720CCF0DD6)', Time: '2021-01-22T15:32:29', User OID: 'PatientReportedOutcome (US3032242)', ODM File OID: 'd5e8c1f7-627f-442e-a0f3-b5fa979aa4ac'	System	22 Jan 2021 21:32:38
User entered 'No (N)'	System	22 Jan 2021 21:32:38

US3032242

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:52:51

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 (6C42AABB-C8BC-44AC-B3C0-D8720CCF0DD6)', Time: '2021-01-22T15:32:32', User OID: 'PatientReportedOutcome (US3032242)', ODM File OID: 'd5e8c1f7-627f-442e-a0f3-b5fa979aa4ac'	System	22 Jan 2021 21:32:38
User entered 'No (N)'	System	22 Jan 2021 21:32:38

US3032242

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:52:51

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6C42AABB-C8BC-44AC-B3C0-D8720CCF0DD6)', Time: '2021-01-22T15:32:35', User OID: 'PatientReportedOutcome (US3032242)', ODM File OID: 'd5e8c1f7-627f-442e-a0f3-b5fa979aa4ac'	System	22 Jan 2021 21:32:38
User entered '22 Jan 2021 15:32:35'	System	22 Jan 2021 21:32:38

US3032242

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:52:51

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:19:33
Amendment Manager: User entered '22 Jan 2021 00:01'	System	19 Nov 2020 23:19:33

US3032242

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:52:51

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:19:33
Amendment Manager: User entered '26 Jan 2021 23:59'	System	19 Nov 2020 23:19:33

US3032242

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:52:51

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:19:33
Amendment Manager: User entered 'Day 166'	System	19 Nov 2020 23:19:33

US3032242

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:52:51

[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 (6C42AABB-C8BC-44AC-B3C0-D8720CCF0DD6)', Time: '2021-01-29T08:39:02', User OID: 'PatientReportedOutcome (US3032242)', ODM File OID: '21952da7-4f1f-4c03-b19e-1b796987189e' User entered 'No (N)'	System	29 Jan 2021 14:39:10
	System	29 Jan 2021 14:39:10

US3032242

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:52:51

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 (6C42AABB-C8BC-44AC-B3C0-D8720CCF0DD6)', Time: '2021-01-29T08:39:04', User OID: 'PatientReportedOutcome (US3032242)', ODM File OID: '21952da7-4f1f-4c03-b19e-1b796987189e' User entered 'No (N)'	System	29 Jan 2021 14:39:10
	System	29 Jan 2021 14:39:10

US3032242

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:52:51

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6C42AABB-C8BC-44AC-B3C0-D8720CCF0DD6)', Time: '2021-01-29T08:39:07', User OID: 'PatientReportedOutcome (US3032242)', ODM File OID: '21952da7-4f1f-4c03-b19e-1b796987189e' User entered '29 Jan 2021 08:39:07'	System	29 Jan 2021 14:39:10
	System	29 Jan 2021 14:39:10

US3032242

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:52:51

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:19:33
Amendment Manager: User entered '29 Jan 2021 00:01'	System	19 Nov 2020 23:19:33

US3032242

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:52:51

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:19:33
Amendment Manager: User entered '02 Feb 2021 23:59'	System	19 Nov 2020 23:19:33

US3032242

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:52:51

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:19:33
Amendment Manager: User entered 'Day 173'	System	19 Nov 2020 23:19:33

US3032242

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:52:51

[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 (6C42AABB-C8BC-44AC-B3C0-D8720CCF0DD6)', Time: '2021-02-05T08:35:53', User OID: 'PatientReportedOutcome (US3032242)', ODM File OID: '4d4088b9-0ae1-4640-bdd0-63e490f93f7c'	System	05 Feb 2021 14:37:12
User entered 'Yes (Y)'	System	05 Feb 2021 14:37:12

US3032242

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:52:51

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 (6C42AABB-C8BC-44AC-B3C0-D8720CCF0DD6)', Time: '2021-02-05T08:36:04', User OID: 'PatientReportedOutcome (US3032242)', ODM File OID: '4d4088b9-0ae1-4640-bdd0-63e490f93f7c'	System	05 Feb 2021 14:37:12
User entered 'No (N)'	System	05 Feb 2021 14:37:12

US3032242

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:52:51

[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)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6C42AABB-C8BC-44AC-B3C0-D8720CCF0DD6)', Time: '2021-02-05T08:36:12', User OID: 'PatientReportedOutcome (US3032242)', ODM File OID: '4d4088b9-0ae1-4640-bdd0-63e490f93f7c' User entered 'No (N)'	System	05 Feb 2021 14:37:12
	System	05 Feb 2021 14:37:12

US3032242

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:52:51

[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)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6C42AABB-C8BC-44AC-B3C0-D8720CCF0DD6)', Time: '2021-02-05T08:36:37', User OID: 'PatientReportedOutcome (US3032242)', ODM File OID: '4d4088b9-0ae1-4640-bdd0-63e490f93f7c'	System	05 Feb 2021 14:37:12
User entered 'Yes (Y)'	System	05 Feb 2021 14:37:12

US3032242

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:52:51

[Please 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 (6C42AABB-C8BC-44AC-B3C0-D8720CCF0DD6)', Time: '2021-02-05T08:36:47', User OID: 'PatientReportedOutcome (US3032242)', ODM File OID: '4d4088b9-0ae1-4640-bdd0-63e490f93f7c'	System	05 Feb 2021 14:37:12
User entered 'I confirm I have read this message and will call the study clinic immediately (9)'	System	05 Feb 2021 14:37:12

US3032242

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:52:51

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6C42AABB-C8BC-44AC-B3C0-D8720CCF0DD6)', Time: '2021-02-05T08:37:00', User OID: 'PatientReportedOutcome (US3032242)', ODM File OID: '4d4088b9-0ae1-4640-bdd0-63e490f93f7c' User entered '05 Feb 2021 08:37:00'	System	05 Feb 2021 14:37:12
	System	05 Feb 2021 14:37:12

US3032242

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:52:51

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:19:33
Amendment Manager: User entered '05 Feb 2021 00:01'	System	19 Nov 2020 23:19:33

US3032242

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:52:51

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:19:33
Amendment Manager: User entered '09 Feb 2021 23:59'	System	19 Nov 2020 23:19:33

US3032242

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:52:51

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:19:33
Amendment Manager: User entered 'Day 180'	System	19 Nov 2020 23:19:33

US3032242

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:52:51

[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 (6C42AABB-C8BC-44AC-B3C0-D8720CCF0DD6)', Time: '2021-02-12T09:05:23', User OID: 'PatientReportedOutcome (US3032242)', ODM File OID: '156f5c8e-15bf-4e45-bea7-55631cfb5b8b'	System	12 Feb 2021 15:05:39
User entered 'No (N)'	System	12 Feb 2021 15:05:39

US3032242

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:52:51

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 (6C42AABB-C8BC-44AC-B3C0-D8720CCF0DD6)', Time: '2021-02-12T09:05:29', User OID: 'PatientReportedOutcome (US3032242)', ODM File OID: '156f5c8e-15bf-4e45-bea7-55631cfb5b8b'	System	12 Feb 2021 15:05:39
User entered 'No (N)'	System	12 Feb 2021 15:05:39

US3032242

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:52:51

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6C42AABB-C8BC-44AC-B3C0-D8720CCF0DD6)', Time: '2021-02-12T09:05:34', User OID: 'PatientReportedOutcome (US3032242)', ODM File OID: '156f5c8e-15bf-4e45-bea7-55631cfb5b8b' User entered '12 Feb 2021 09:05:34'	System	12 Feb 2021 15:05:39
	System	12 Feb 2021 15:05:39

US3032242

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:52:51

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:19:33
Amendment Manager: User entered '12 Feb 2021 00:01'	System	19 Nov 2020 23:19:33

US3032242

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:52:51

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:19:33
Amendment Manager: User entered '16 Feb 2021 23:59'	System	19 Nov 2020 23:19:33

US3032242

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:52:51

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:19:33
Amendment Manager: User entered 'Day 187'	System	19 Nov 2020 23:19:33

US3032242

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:52:51

[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 (6C42AABB-C8BC-44AC-B3C0-D8720CCF0DD6)', Time: '2021-02-19T09:20:47', User OID: 'PatientReportedOutcome (US3032242)', ODM File OID: '5324f05a-9e04-4d99-8d42-2c7b92e15f3e'	System	19 Feb 2021 15:20:59
User entered 'No (N)'	System	19 Feb 2021 15:20:59

US3032242

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:52:51

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 (6C42AABB-C8BC-44AC-B3C0-D8720CCF0DD6)', Time: '2021-02-19T09:20:51', User OID: 'PatientReportedOutcome (US3032242)', ODM File OID: '5324f05a-9e04-4d99-8d42-2c7b92e15f3e'	System	19 Feb 2021 15:20:59
User entered 'No (N)'	System	19 Feb 2021 15:20:59

US3032242

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:52:51

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6C42AABB-C8BC-44AC-B3C0-D8720CCF0DD6)', Time: '2021-02-19T09:20:56', User OID: 'PatientReportedOutcome (US3032242)', ODM File OID: '5324f05a-9e04-4d99-8d42-2c7b92e15f3e' User entered '19 Feb 2021 09:20:56'	System	19 Feb 2021 15:20:59
	System	19 Feb 2021 15:20:59

US3032242

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:52:51

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:19:33
Amendment Manager: User entered '19 Feb 2021 00:01'	System	19 Nov 2020 23:19:33

US3032242

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:52:51

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:19:33
Amendment Manager: User entered '23 Feb 2021 23:59'	System	19 Nov 2020 23:19:33

US3032242

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:52:51

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:19:33
Amendment Manager: User entered 'Day 194'	System	19 Nov 2020 23:19:33

US3032242

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:52:51

[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 (6C42AABB-C8BC-44AC-B3C0-D8720CCF0DD6)', Time: '2021-02-26T02:57:54-06:00', User OID: 'PatientReportedOutcome (US3032242)', ODM File OID: 'c339f30f-6201-487e-a364-215751e172c4'	System	26 Feb 2021 08:58:08
User entered 'No (N)'	System	26 Feb 2021 08:58:08

US3032242

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:52:51

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 (6C42AABB-C8BC-44AC-B3C0-D8720CCF0DD6)', Time: '2021-02-26T02:58:01-06:00', User OID: 'PatientReportedOutcome (US3032242)', ODM File OID: 'c339f30f-6201-487e-a364-215751e172c4'	System	26 Feb 2021 08:58:08
User entered 'No (N)'	System	26 Feb 2021 08:58:08

US3032242

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:52:51

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6C42AABB-C8BC-44AC-B3C0-D8720CCF0DD6)', Time: '2021-02-26T02:58:06-06:00', User OID: 'PatientReportedOutcome (US3032242)', ODM File OID: 'c339f30f-6201-487e-a364-215751e172c4' User entered '26 Feb 2021 08:58:06'	System	26 Feb 2021 08:58:08
	System	26 Feb 2021 08:58:08

US3032242

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:52:51

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:19:33
Amendment Manager: User entered '26 Feb 2021 00:01'	System	19 Nov 2020 23:19:33

US3032242

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:52:51

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:19:33
Amendment Manager: User entered '02 Mar 2021 23:59'	System	19 Nov 2020 23:19:33

US3032242

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:52:51

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:19:33
Amendment Manager: User entered 'Day 201'	System	19 Nov 2020 23:19:33

US3032242

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:52:51

[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 (6C42AABB-C8BC-44AC-B3C0-D8720CCF0DD6)', Time: '2021-03-05T02:49:20-06:00', User OID: 'PatientReportedOutcome (US3032242)', ODM File OID: '46f6950d-daf7-4d35-ab32-07c9569024a5'	System	05 Mar 2021 08:49:33
User entered 'No (N)'	System	05 Mar 2021 08:49:33

US3032242

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:52:51

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 (6C42AABB-C8BC-44AC-B3C0-D8720CCF0DD6)', Time: '2021-03-05T02:49:24-06:00', User OID: 'PatientReportedOutcome (US3032242)', ODM File OID: '46f6950d-daf7-4d35-ab32-07c9569024a5'	System	05 Mar 2021 08:49:33
User entered 'No (N)'	System	05 Mar 2021 08:49:33

US3032242

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:52:51

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6C42AABB-C8BC-44AC-B3C0-D8720CCF0DD6)', Time: '2021-03-05T02:49:28-06:00', User OID: 'PatientReportedOutcome (US3032242)', ODM File OID: '46f6950d-daf7-4d35-ab32-07c9569024a5' User entered '05 Mar 2021 02:49:28'	System	05 Mar 2021 08:49:33
	System	05 Mar 2021 08:49:33

US3032242

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:52:51

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:19:33
Amendment Manager: User entered '05 Mar 2021 00:01'	System	19 Nov 2020 23:19:33

US3032242

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:52:51

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:19:33
Amendment Manager: User entered '09 Mar 2021 23:59'	System	19 Nov 2020 23:19:33

US3032242

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:52:51

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:19:33
Amendment Manager: User entered 'Day 208'	System	19 Nov 2020 23:19:33

US3032242

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:52:51

[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 (6C42AABB-C8BC-44AC-B3C0-D8720CCF0DD6)', Time: '2021-03-12T15:17:08-06:00', User OID: 'PatientReportedOutcome (US3032242)', ODM File OID: 'c2804809-0b0a-46a7-bcc5-cb2704a41a57'	System	12 Mar 2021 21:17:38
User entered 'No (N)'	System	12 Mar 2021 21:17:38

US3032242

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:52:51

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 (6C42AABB-C8BC-44AC-B3C0-D8720CCF0DD6)', Time: '2021-03-12T15:17:14-06:00', User OID: 'PatientReportedOutcome (US3032242)', ODM File OID: 'c2804809-0b0a-46a7-bcc5-cb2704a41a57'	System	12 Mar 2021 21:17:38
User entered 'No (N)'	System	12 Mar 2021 21:17:38

US3032242

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:52:51

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6C42AABB-C8BC-44AC-B3C0-D8720CCF0DD6)', Time: '2021-03-12T15:17:18-06:00', User OID: 'PatientReportedOutcome (US3032242)', ODM File OID: 'c2804809-0b0a-46a7-bcc5-cb2704a41a57'	System	12 Mar 2021 21:17:38
User entered '12 Mar 2021 15:17:18'	System	12 Mar 2021 21:17:38

US3032242

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:52:51

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:19:33
Amendment Manager: User entered '12 Mar 2021 00:01'	System	19 Nov 2020 23:19:33

US3032242

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:52:51

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:19:33
Amendment Manager: User entered '16 Mar 2021 23:59'	System	19 Nov 2020 23:19:33

US3032242

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:52:51

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:19:33
Amendment Manager: User entered 'Day 215'	System	19 Nov 2020 23:19:33

US3032242

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:52:51

[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 (6C42AABB-C8BC-44AC-B3C0-D8720CCF0DD6)', Time: '2021-03-19T02:44:43-05:00', User OID: 'PatientReportedOutcome (US3032242)', ODM File OID: 'a34a990a-cf9c-4f2b-8119-0310cb256c73'	System	19 Mar 2021 07:44:57
User entered 'No (N)'	System	19 Mar 2021 07:44:57

US3032242

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:52:51

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 (6C42AABB-C8BC-44AC-B3C0-D8720CCF0DD6)', Time: '2021-03-19T02:44:50-05:00', User OID: 'PatientReportedOutcome (US3032242)', ODM File OID: 'a34a990a-cf9c-4f2b-8119-0310cb256c73'	System	19 Mar 2021 07:44:57
User entered 'No (N)'	System	19 Mar 2021 07:44:57

US3032242

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:52:51

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6C42AABB-C8BC-44AC-B3C0-D8720CCF0DD6)', Time: '2021-03-19T02:44:54-05:00', User OID: 'PatientReportedOutcome (US3032242)', ODM File OID: 'a34a990a-cf9c-4f2b-8119-0310cb256c73' User entered '19 Mar 2021 02:44:54'	System	19 Mar 2021 07:44:57
	System	19 Mar 2021 07:44:57

US3032242

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:52:51

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:19:33
Amendment Manager: User entered '19 Mar 2021 00:01'	System	19 Nov 2020 23:19:33

US3032242

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:52:51

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:19:33
Amendment Manager: User entered '23 Mar 2021 23:59'	System	19 Nov 2020 23:19:33

US3032242

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:52:51

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:19:33
Amendment Manager: User entered 'Day 222'	System	19 Nov 2020 23:19:33

US3032242

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:52:51

[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 (6C42AABB-C8BC-44AC-B3C0-D8720CCF0DD6)', Time: '2021-03-26T02:35:09-05:00', User OID: 'PatientReportedOutcome (US3032242)', ODM File OID: '7be29c9a-1f13-46c8-b4a3-eda90fd0a4f0'	System	26 Mar 2021 07:35:21
User entered 'No (N)'	System	26 Mar 2021 07:35:21

US3032242

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:52:51

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 (6C42AABB-C8BC-44AC-B3C0-D8720CCF0DD6)', Time: '2021-03-26T02:35:13-05:00', User OID: 'PatientReportedOutcome (US3032242)', ODM File OID: '7be29c9a-1f13-46c8-b4a3-eda90fd0a4f0'	System	26 Mar 2021 07:35:21
User entered 'No (N)'	System	26 Mar 2021 07:35:21

US3032242

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:52:51

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6C42AABB-C8BC-44AC-B3C0-D8720CCF0DD6)', Time: '2021-03-26T02:35:16-05:00', User OID: 'PatientReportedOutcome (US3032242)', ODM File OID: '7be29c9a-1f13-46c8-b4a3-eda90fd0a4f0'	System	26 Mar 2021 07:35:21
User entered '26 Mar 2021 02:35:16'	System	26 Mar 2021 07:35:21

US3032242

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:52:51

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:19:33
Amendment Manager: User entered '26 Mar 2021 00:01'	System	19 Nov 2020 23:19:33

US3032242

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:52:51

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:19:33
Amendment Manager: User entered '30 Mar 2021 23:59'	System	19 Nov 2020 23:19:33

US3032242

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:52:51

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:19:33
Amendment Manager: User entered 'Day 229'	System	19 Nov 2020 23:19:33

US3032242

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:52:51

[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 (6C42AABB-C8BC-44AC-B3C0-D8720CCF0DD6)', Time: '2021-04-02T02:42:48-05:00', User OID: 'PatientReportedOutcome (US3032242)', ODM File OID: 'a4f84aec-89ec-41d3-96e1-0ad45c11abf5'	System	02 Apr 2021 07:43:04
User entered 'No (N)'	System	02 Apr 2021 07:43:04

US3032242

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:52:51

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 (6C42AABB-C8BC-44AC-B3C0-D8720CCF0DD6)', Time: '2021-04-02T02:42:56-05:00', User OID: 'PatientReportedOutcome (US3032242)', ODM File OID: 'a4f84aec-89ec-41d3-96e1-0ad45c11abf5'	System	02 Apr 2021 07:43:04
User entered 'No (N)'	System	02 Apr 2021 07:43:04

US3032242

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:52:51

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6C42AABB-C8BC-44AC-B3C0-D8720CCF0DD6)', Time: '2021-04-02T02:43:00-05:00', User OID: 'PatientReportedOutcome (US3032242)', ODM File OID: 'a4f84aec-89ec-41d3-96e1-0ad45c11abf5'	System	02 Apr 2021 07:43:04
User entered '02 Apr 2021 02:43:00'	System	02 Apr 2021 07:43:04

US3032242

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:52:51

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:19:33
Amendment Manager: User entered '02 Apr 2021 00:01'	System	19 Nov 2020 23:19:33

US3032242

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:52:51

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:19:33
Amendment Manager: User entered '06 Apr 2021 23:59'	System	19 Nov 2020 23:19:33

US3032242

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:52:51

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:19:33
Amendment Manager: User entered 'Day 236'	System	19 Nov 2020 23:19:33

US3032242

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:52:51

[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 (6C42AABB-C8BC-44AC-B3C0-D8720CCF0DD6)', Time: '2021-04-09T02:34:13-05:00', User OID: 'PatientReportedOutcome (US3032242)', ODM File OID: 'd1c14425-e44b-4e27-8147-84b7cdd073a2'	System	09 Apr 2021 07:34:25
User entered 'No (N)'	System	09 Apr 2021 07:34:25

US3032242

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:52:51

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 (6C42AABB-C8BC-44AC-B3C0-D8720CCF0DD6)', Time: '2021-04-09T02:34:19-05:00', User OID: 'PatientReportedOutcome (US3032242)', ODM File OID: 'd1c14425-e44b-4e27-8147-84b7cdd073a2'	System	09 Apr 2021 07:34:25
User entered 'No (N)'	System	09 Apr 2021 07:34:25

US3032242

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:52:51

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6C42AABB-C8BC-44AC-B3C0-D8720CCF0DD6)', Time: '2021-04-09T02:34:22-05:00', User OID: 'PatientReportedOutcome (US3032242)', ODM File OID: 'd1c14425-e44b-4e27-8147-84b7cdd073a2'	System	09 Apr 2021 07:34:25
User entered '09 Apr 2021 02:34:22'	System	09 Apr 2021 07:34:25

US3032242

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:52:51

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:19:33
Amendment Manager: User entered '09 Apr 2021 00:01'	System	19 Nov 2020 23:19:33

US3032242

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:52:51

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:19:33
Amendment Manager: User entered '13 Apr 2021 23:59'	System	19 Nov 2020 23:19:33

US3032242

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:52:51

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:19:33
Amendment Manager: User entered 'Day 243'	System	19 Nov 2020 23:19:33

US3032242

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:52:51

[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 (6C42AABB-C8BC-44AC-B3C0-D8720CCF0DD6)', Time: '2021-04-16T02:40:14-05:00', User OID: 'PatientReportedOutcome (US3032242)', ODM File OID: '3afc3af9-9934-4aae-a9c5-b8046e4c3d36'	System	16 Apr 2021 07:40:28
User entered 'No (N)'	System	16 Apr 2021 07:40:28

US3032242

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:52:51

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 (6C42AABB-C8BC-44AC-B3C0-D8720CCF0DD6)', Time: '2021-04-16T02:40:21-05:00', User OID: 'PatientReportedOutcome (US3032242)', ODM File OID: '3afc3af9-9934-4aae-a9c5-b8046e4c3d36'	System	16 Apr 2021 07:40:28
User entered 'No (N)'	System	16 Apr 2021 07:40:28

US3032242

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:52:51

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6C42AABB-C8BC-44AC-B3C0-D8720CCF0DD6)', Time: '2021-04-16T02:40:25-05:00', User OID: 'PatientReportedOutcome (US3032242)', ODM File OID: '3afc3af9-9934-4aae-a9c5-b8046e4c3d36'	System	16 Apr 2021 07:40:28
User entered '16 Apr 2021 02:40:25'	System	16 Apr 2021 07:40:28

US3032242

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:52:51

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:19:33
Amendment Manager: User entered '16 Apr 2021 00:01'	System	19 Nov 2020 23:19:33

US3032242

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:52:51

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:19:33
Amendment Manager: User entered '20 Apr 2021 23:59'	System	19 Nov 2020 23:19:33

US3032242

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:52:51

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:19:33
Amendment Manager: User entered 'Day 250'	System	19 Nov 2020 23:19:33

US3032242

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:52:51

[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 (6C42AABB-C8BC-44AC-B3C0-D8720CCF0DD6)', Time: '2021-04-23T03:09:30-05:00', User OID: 'PatientReportedOutcome (US3032242)', ODM File OID: 'da1c63d6-8bd4-4ce1-b53c-55ca41dfbbe7'	System	23 Apr 2021 08:09:41
User entered 'No (N)'	System	23 Apr 2021 08:09:41

US3032242

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:52:51

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 (6C42AABB-C8BC-44AC-B3C0-D8720CCF0DD6)', Time: '2021-04-23T03:09:35-05:00', User OID: 'PatientReportedOutcome (US3032242)', ODM File OID: 'da1c63d6-8bd4-4ce1-b53c-55ca41dfbbe7'	System	23 Apr 2021 08:09:41
User entered 'No (N)'	System	23 Apr 2021 08:09:41

US3032242

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:52:51

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6C42AABB-C8BC-44AC-B3C0-D8720CCF0DD6)', Time: '2021-04-23T03:09:38-05:00', User OID: 'PatientReportedOutcome (US3032242)', ODM File OID: 'da1c63d6-8bd4-4ce1-b53c-55ca41dfbbe7'	System	23 Apr 2021 08:09:41
User entered '23 Apr 2021 03:09:38'	System	23 Apr 2021 08:09:41

US3032242

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:52:51

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:19:33
Amendment Manager: User entered '23 Apr 2021 00:01'	System	19 Nov 2020 23:19:33

US3032242

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:52:51

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:19:33
Amendment Manager: User entered '27 Apr 2021 23:59'	System	19 Nov 2020 23:19:33

US3032242

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:52:51

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:19:33
Amendment Manager: User entered 'Day 257'	System	19 Nov 2020 23:19:33

US3032242

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:52:51

[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 (6C42AABB-C8BC-44AC-B3C0-D8720CCF0DD6)', Time: '2021-04-30T02:59:28-05:00', User OID: 'PatientReportedOutcome (US3032242)', ODM File OID: '60ca05db-d659-4f36-815d-44d2ad33df2b'	System	30 Apr 2021 07:59:42
User entered 'No (N)'	System	30 Apr 2021 07:59:42

US3032242

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:52:51

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 (6C42AABB-C8BC-44AC-B3C0-D8720CCF0DD6)', Time: '2021-04-30T02:59:34-05:00', User OID: 'PatientReportedOutcome (US3032242)', ODM File OID: '60ca05db-d659-4f36-815d-44d2ad33df2b'	System	30 Apr 2021 07:59:42
User entered 'No (N)'	System	30 Apr 2021 07:59:42

US3032242

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:52:51

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6C42AABB-C8BC-44AC-B3C0-D8720CCF0DD6)', Time: '2021-04-30T02:59:37-05:00', User OID: 'PatientReportedOutcome (US3032242)', ODM File OID: '60ca05db-d659-4f36-815d-44d2ad33df2b' User entered '30 Apr 2021 02:59:37'	System	30 Apr 2021 07:59:42
	System	30 Apr 2021 07:59:42

US3032242

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:52:51

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:19:33
Amendment Manager: User entered '30 Apr 2021 00:01'	System	19 Nov 2020 23:19:33

US3032242

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:52:51

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:19:33
Amendment Manager: User entered '04 May 2021 23:59'	System	19 Nov 2020 23:19:33

US3032242

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:52:51

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:19:33
Amendment Manager: User entered 'Day 264'	System	19 Nov 2020 23:19:33

US3032242

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:52:51

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:19:33
Amendment Manager: User entered '07 May 2021 00:01'	System	19 Nov 2020 23:19:33

US3032242

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:52:51

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:19:33
Amendment Manager: User entered '11 May 2021 23:59'	System	19 Nov 2020 23:19:33

US3032242

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:52:51

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:19:33
Amendment Manager: User entered 'Day 271'	System	19 Nov 2020 23:19:33

US3032242

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:52:51

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:19:33
Amendment Manager: User entered '14 May 2021 00:01'	System	19 Nov 2020 23:19:33

US3032242

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:52:51

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:19:33
Amendment Manager: User entered '18 May 2021 23:59'	System	19 Nov 2020 23:19:33

US3032242

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:52:51

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:19:33
Amendment Manager: User entered 'Day 278'	System	19 Nov 2020 23:19:33

US3032242

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:52:51

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:19:33
Amendment Manager: User entered '21 May 2021 00:01'	System	19 Nov 2020 23:19:33

US3032242

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:52:51

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:19:33
Amendment Manager: User entered '25 May 2021 23:59'	System	19 Nov 2020 23:19:33

US3032242

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:52:51

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:19:33
Amendment Manager: User entered 'Day 285'	System	19 Nov 2020 23:19:33

US3032242

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:52:51

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:19:33
Amendment Manager: User entered '28 May 2021 00:01'	System	19 Nov 2020 23:19:33

US3032242

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:52:51

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:19:33
Amendment Manager: User entered '01 Jun 2021 23:59'	System	19 Nov 2020 23:19:33

US3032242

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:52:51

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:19:33
Amendment Manager: User entered 'Day 292'	System	19 Nov 2020 23:19:33

US3032242

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:52:51

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:19:33
Amendment Manager: User entered '04 Jun 2021 00:01'	System	19 Nov 2020 23:19:33

US3032242

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:52:51

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:19:33
Amendment Manager: User entered '08 Jun 2021 23:59'	System	19 Nov 2020 23:19:33

US3032242

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:52:51

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:19:33
Amendment Manager: User entered 'Day 299'	System	19 Nov 2020 23:19:33

US3032242

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:52:51

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:19:33
Amendment Manager: User entered '11 Jun 2021 00:01'	System	19 Nov 2020 23:19:33

US3032242

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:52:51

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:19:33
Amendment Manager: User entered '15 Jun 2021 23:59'	System	19 Nov 2020 23:19:33

US3032242

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:52:51

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:19:33
Amendment Manager: User entered 'Day 306'	System	19 Nov 2020 23:19:33

US3032242

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:52:51

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:19:33
Amendment Manager: User entered '18 Jun 2021 00:01'	System	19 Nov 2020 23:19:33

US3032242

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:52:51

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:19:33
Amendment Manager: User entered '22 Jun 2021 23:59'	System	19 Nov 2020 23:19:33

US3032242

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:52:51

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:19:33
Amendment Manager: User entered 'Day 313'	System	19 Nov 2020 23:19:33

US3032242

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:52:51

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:19:33
Amendment Manager: User entered '25 Jun 2021 00:01'	System	19 Nov 2020 23:19:33

US3032242

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:52:51

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:19:33
Amendment Manager: User entered '29 Jun 2021 23:59'	System	19 Nov 2020 23:19:33

US3032242

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:52:51

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:19:33
Amendment Manager: User entered 'Day 320'	System	19 Nov 2020 23:19:33

US3032242

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:52:51

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:19:33
Amendment Manager: User entered '02 Jul 2021 00:01'	System	19 Nov 2020 23:19:33

US3032242

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:52:51

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:19:33
Amendment Manager: User entered '06 Jul 2021 23:59'	System	19 Nov 2020 23:19:33

US3032242

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:52:51

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:19:33
Amendment Manager: User entered 'Day 327'	System	19 Nov 2020 23:19:33

US3032242

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:52:51

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:19:33
Amendment Manager: User entered '09 Jul 2021 00:01'	System	19 Nov 2020 23:19:33

US3032242

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:52:51

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:19:33
Amendment Manager: User entered '13 Jul 2021 23:59'	System	19 Nov 2020 23:19:33

US3032242

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:52:51

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:19:33
Amendment Manager: User entered 'Day 334'	System	19 Nov 2020 23:19:33

US3032242

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:52:51

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:19:33
Amendment Manager: User entered '16 Jul 2021 00:01'	System	19 Nov 2020 23:19:33

US3032242

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:52:51

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:19:33
Amendment Manager: User entered '20 Jul 2021 23:59'	System	19 Nov 2020 23:19:33

US3032242

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:52:51

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:19:33
Amendment Manager: User entered 'Day 341'	System	19 Nov 2020 23:19:33

US3032242

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:52:51

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:19:33
Amendment Manager: User entered '23 Jul 2021 00:01'	System	19 Nov 2020 23:19:33

US3032242

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:52:51

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:19:33
Amendment Manager: User entered '27 Jul 2021 23:59'	System	19 Nov 2020 23:19:33

US3032242

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:52:51

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:19:33
Amendment Manager: User entered 'Day 348'	System	19 Nov 2020 23:19:33

US3032242

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:52:51

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:19:33
Amendment Manager: User entered '30 Jul 2021 00:01'	System	19 Nov 2020 23:19:33

US3032242

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:52:51

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:19:33
Amendment Manager: User entered '03 Aug 2021 23:59'	System	19 Nov 2020 23:19:33

US3032242

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:52:51

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:19:33
Amendment Manager: User entered 'Day 355'	System	19 Nov 2020 23:19:33

US3032242

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:52:51

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:19:33
Amendment Manager: User entered '06 Aug 2021 00:01'	System	19 Nov 2020 23:19:33

US3032242

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:52:51

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:19:33
Amendment Manager: User entered '10 Aug 2021 23:59'	System	19 Nov 2020 23:19:33

US3032242

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:52:51

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:19:33
Amendment Manager: User entered 'Day 362'	System	19 Nov 2020 23:19:33

US3032242

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:52:51

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:19:33
Amendment Manager: User entered '13 Aug 2021 00:01'	System	19 Nov 2020 23:19:33

US3032242

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:52:51

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:19:33
Amendment Manager: User entered '17 Aug 2021 23:59'	System	19 Nov 2020 23:19:33

US3032242

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:52:51

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:19:33
Amendment Manager: User entered 'Day 369'	System	19 Nov 2020 23:19:33

US3032242

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:52:51

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:19:33
Amendment Manager: User entered '20 Aug 2021 00:01'	System	19 Nov 2020 23:19:33

US3032242

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:52:51

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:19:33
Amendment Manager: User entered '24 Aug 2021 23:59'	System	19 Nov 2020 23:19:33

US3032242

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:52:51

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:19:33
Amendment Manager: User entered 'Day 376'	System	19 Nov 2020 23:19:33

US3032242

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:52:51

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:19:33
Amendment Manager: User entered '27 Aug 2021 00:01'	System	19 Nov 2020 23:19:33

US3032242

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:52:51

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:19:33
Amendment Manager: User entered '31 Aug 2021 23:59'	System	19 Nov 2020 23:19:33

US3032242

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:52:51

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:19:33
Amendment Manager: User entered 'Day 383'	System	19 Nov 2020 23:19:33

US3032242

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:52:51

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:19:33
Amendment Manager: User entered '03 Sep 2021 00:01'	System	19 Nov 2020 23:19:33

US3032242

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:52:51

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:19:33
Amendment Manager: User entered '07 Sep 2021 23:59'	System	19 Nov 2020 23:19:33

US3032242

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:52:51

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:19:33
Amendment Manager: User entered 'Day 390'	System	19 Nov 2020 23:19:33

US3032242

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:52:51

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:19:33
Amendment Manager: User entered '10 Sep 2021 00:01'	System	19 Nov 2020 23:19:33

US3032242

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:52:51

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:19:33
Amendment Manager: User entered '14 Sep 2021 23:59'	System	19 Nov 2020 23:19:33

US3032242

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:52:51

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:19:33
Amendment Manager: User entered 'Day 397'	System	19 Nov 2020 23:19:33

US3032242

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:52:51

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:19:33
Amendment Manager: User entered '17 Sep 2021 00:01'	System	19 Nov 2020 23:19:33

US3032242

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:52:51

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:19:33
Amendment Manager: User entered '21 Sep 2021 23:59'	System	19 Nov 2020 23:19:33

US3032242

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:52:51

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:19:33
Amendment Manager: User entered 'Day 404'	System	19 Nov 2020 23:19:33

US3032242

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:52:51

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:19:33
Amendment Manager: User entered '24 Sep 2021 00:01'	System	19 Nov 2020 23:19:33

US3032242

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:52:51

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:19:33
Amendment Manager: User entered '28 Sep 2021 23:59'	System	19 Nov 2020 23:19:33

US3032242

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:52:51

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:19:33
Amendment Manager: User entered 'Day 411'	System	19 Nov 2020 23:19:33

US3032242

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:52:51

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:19:33
Amendment Manager: User entered '01 Oct 2021 00:01'	System	19 Nov 2020 23:19:33

US3032242

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:52:51

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:19:33
Amendment Manager: User entered '05 Oct 2021 23:59'	System	19 Nov 2020 23:19:33

US3032242

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:52:51

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:19:33
Amendment Manager: User entered 'Day 418'	System	19 Nov 2020 23:19:33

US3032242

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:52:51

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:19:33
Amendment Manager: User entered '08 Oct 2021 00:01'	System	19 Nov 2020 23:19:33

US3032242

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:52:51

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:19:33
Amendment Manager: User entered '12 Oct 2021 23:59'	System	19 Nov 2020 23:19:33

US3032242

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:52:51

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:19:33
Amendment Manager: User entered 'Day 425'	System	19 Nov 2020 23:19:33

US3032242

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:52:51

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:19:33
Amendment Manager: User entered '15 Oct 2021 00:01'	System	19 Nov 2020 23:19:33

US3032242

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:52:51

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:19:33
Amendment Manager: User entered '19 Oct 2021 23:59'	System	19 Nov 2020 23:19:33

US3032242

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:52:51

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:19:33
Amendment Manager: User entered 'Day 432'	System	19 Nov 2020 23:19:33

US3032242

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:52:51

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:19:33
Amendment Manager: User entered '22 Oct 2021 00:01'	System	19 Nov 2020 23:19:33

US3032242

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:52:51

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:19:33
Amendment Manager: User entered '26 Oct 2021 23:59'	System	19 Nov 2020 23:19:33

US3032242

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:52:51

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:19:33
Amendment Manager: User entered 'Day 439'	System	19 Nov 2020 23:19:33

US3032242

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:52:51

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:19:33
Amendment Manager: User entered '29 Oct 2021 00:01'	System	19 Nov 2020 23:19:33

US3032242

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:52:51

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:19:33
Amendment Manager: User entered '02 Nov 2021 23:59'	System	19 Nov 2020 23:19:33

US3032242

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:52:51

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:19:33
Amendment Manager: User entered 'Day 446'	System	19 Nov 2020 23:19:33

US3032242

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:52:51

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:19:33
Amendment Manager: User entered '05 Nov 2021 00:01'	System	19 Nov 2020 23:19:33

US3032242

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:52:51

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:19:33
Amendment Manager: User entered '09 Nov 2021 23:59'	System	19 Nov 2020 23:19:33

US3032242

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:52:51

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:19:33
Amendment Manager: User entered 'Day 453'	System	19 Nov 2020 23:19:33

US3032242

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:52:51

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:19:33
Amendment Manager: User entered '12 Nov 2021 00:01'	System	19 Nov 2020 23:19:33

US3032242

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:52:51

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:19:33
Amendment Manager: User entered '16 Nov 2021 23:59'	System	19 Nov 2020 23:19:33

US3032242

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:52:51

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:19:33
Amendment Manager: User entered 'Day 460'	System	19 Nov 2020 23:19:33

US3032242

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:52:51

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:19:33
Amendment Manager: User entered '19 Nov 2021 00:01'	System	19 Nov 2020 23:19:33

US3032242

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:52:51

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:19:33
Amendment Manager: User entered '23 Nov 2021 23:59'	System	19 Nov 2020 23:19:33

US3032242

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:52:51

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:19:33
Amendment Manager: User entered 'Day 467'	System	19 Nov 2020 23:19:33

US3032242

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:52:51

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:19:33
Amendment Manager: User entered '26 Nov 2021 00:01'	System	19 Nov 2020 23:19:33

US3032242

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:52:51

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:19:33
Amendment Manager: User entered '30 Nov 2021 23:59'	System	19 Nov 2020 23:19:33

US3032242

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:52:51

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:19:33
Amendment Manager: User entered 'Day 474'	System	19 Nov 2020 23:19:33

US3032242

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:52:51

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:19:33
Amendment Manager: User entered '03 Dec 2021 00:01'	System	19 Nov 2020 23:19:33

US3032242

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:52:51

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:19:33
Amendment Manager: User entered '07 Dec 2021 23:59'	System	19 Nov 2020 23:19:33

US3032242

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:52:51

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:19:33
Amendment Manager: User entered 'Day 481'	System	19 Nov 2020 23:19:33

US3032242

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:52:51

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:19:33
Amendment Manager: User entered '10 Dec 2021 00:01'	System	19 Nov 2020 23:19:33

US3032242

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:52:51

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:19:33
Amendment Manager: User entered '14 Dec 2021 23:59'	System	19 Nov 2020 23:19:33

US3032242

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:52:51

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:19:33
Amendment Manager: User entered 'Day 488'	System	19 Nov 2020 23:19:33

US3032242

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:52:51

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:19:33
Amendment Manager: User entered '17 Dec 2021 00:01'	System	19 Nov 2020 23:19:33

US3032242

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:52:51

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:19:33
Amendment Manager: User entered '21 Dec 2021 23:59'	System	19 Nov 2020 23:19:33

US3032242

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:52:51

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:19:33
Amendment Manager: User entered 'Day 495'	System	19 Nov 2020 23:19:33

US3032242

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:52:51

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:19:33
Amendment Manager: User entered '24 Dec 2021 00:01'	System	19 Nov 2020 23:19:33

US3032242

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:52:51

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:19:33
Amendment Manager: User entered '28 Dec 2021 23:59'	System	19 Nov 2020 23:19:33

US3032242

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:52:51

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:19:33
Amendment Manager: User entered 'Day 502'	System	19 Nov 2020 23:19:33

US3032242

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:52:51

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:19:33
Amendment Manager: User entered '31 Dec 2021 00:01'	System	19 Nov 2020 23:19:33

US3032242

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:52:51

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:19:33
Amendment Manager: User entered '04 Jan 2022 23:59'	System	19 Nov 2020 23:19:33

US3032242

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:52:51

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:19:33
Amendment Manager: User entered 'Day 509'	System	19 Nov 2020 23:19:33

US3032242

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:52:51

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:19:33
Amendment Manager: User entered '07 Jan 2022 00:01'	System	19 Nov 2020 23:19:33

US3032242

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:52:51

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:19:33
Amendment Manager: User entered '11 Jan 2022 23:59'	System	19 Nov 2020 23:19:33

US3032242

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:52:51

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:19:33
Amendment Manager: User entered 'Day 516'	System	19 Nov 2020 23:19:33

US3032242

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:52:51

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:19:33
Amendment Manager: User entered '14 Jan 2022 00:01'	System	19 Nov 2020 23:19:33

US3032242

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:52:51

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:19:33
Amendment Manager: User entered '18 Jan 2022 23:59'	System	19 Nov 2020 23:19:33

US3032242

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:52:51

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:19:33
Amendment Manager: User entered 'Day 523'	System	19 Nov 2020 23:19:33

US3032242

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:52:51

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:19:33
Amendment Manager: User entered '21 Jan 2022 00:01'	System	19 Nov 2020 23:19:33

US3032242

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:52:51

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:19:33
Amendment Manager: User entered '25 Jan 2022 23:59'	System	19 Nov 2020 23:19:33

US3032242

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:52:51

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:19:33
Amendment Manager: User entered 'Day 530'	System	19 Nov 2020 23:19:33

US3032242

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:52:51

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:19:33
Amendment Manager: User entered '28 Jan 2022 00:01'	System	19 Nov 2020 23:19:33

US3032242

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:52:51

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:19:33
Amendment Manager: User entered '01 Feb 2022 23:59'	System	19 Nov 2020 23:19:33

US3032242

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:52:51

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:19:33
Amendment Manager: User entered 'Day 537'	System	19 Nov 2020 23:19:33

US3032242

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:52:51

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:19:33
Amendment Manager: User entered '04 Feb 2022 00:01'	System	19 Nov 2020 23:19:33

US3032242

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:52:51

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:19:33
Amendment Manager: User entered '08 Feb 2022 23:59'	System	19 Nov 2020 23:19:33

US3032242

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:52:51

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:19:33
Amendment Manager: User entered 'Day 544'	System	19 Nov 2020 23:19:33

US3032242

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:52:51

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:19:33
Amendment Manager: User entered '11 Feb 2022 00:01'	System	19 Nov 2020 23:19:33

US3032242

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:52:51

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:19:33
Amendment Manager: User entered '15 Feb 2022 23:59'	System	19 Nov 2020 23:19:33

US3032242

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:52:51

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:19:33
Amendment Manager: User entered 'Day 551'	System	19 Nov 2020 23:19:33

US3032242

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:52:51

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:19:33
Amendment Manager: User entered '18 Feb 2022 00:01'	System	19 Nov 2020 23:19:33

US3032242

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:52:51

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:19:33
Amendment Manager: User entered '22 Feb 2022 23:59'	System	19 Nov 2020 23:19:33

US3032242

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:52:51

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:19:33
Amendment Manager: User entered 'Day 558'	System	19 Nov 2020 23:19:33

US3032242

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:52:51

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:19:33
Amendment Manager: User entered '25 Feb 2022 00:01'	System	19 Nov 2020 23:19:33

US3032242

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:52:51

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:19:33
Amendment Manager: User entered '01 Mar 2022 23:59'	System	19 Nov 2020 23:19:33

US3032242

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:52:51

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:19:33
Amendment Manager: User entered 'Day 565'	System	19 Nov 2020 23:19:33

US3032242

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:52:51

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:19:33
Amendment Manager: User entered '04 Mar 2022 00:01'	System	19 Nov 2020 23:19:33

US3032242

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:52:51

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:19:33
Amendment Manager: User entered '08 Mar 2022 23:59'	System	19 Nov 2020 23:19:33

US3032242

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:52:51

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:19:33
Amendment Manager: User entered 'Day 572'	System	19 Nov 2020 23:19:33

US3032242

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:52:51

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:19:33
Amendment Manager: User entered '11 Mar 2022 00:01'	System	19 Nov 2020 23:19:33

US3032242

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:52:51

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:19:33
Amendment Manager: User entered '15 Mar 2022 23:59'	System	19 Nov 2020 23:19:33

US3032242

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:52:51

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:19:33
Amendment Manager: User entered 'Day 579'	System	19 Nov 2020 23:19:33

US3032242

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:52:51

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:19:33
Amendment Manager: User entered '18 Mar 2022 00:01'	System	19 Nov 2020 23:19:33

US3032242

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:52:51

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:19:33
Amendment Manager: User entered '22 Mar 2022 23:59'	System	19 Nov 2020 23:19:33

US3032242

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:52:51

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:19:33
Amendment Manager: User entered 'Day 586'	System	19 Nov 2020 23:19:33

US3032242

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:52:51

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:19:33
Amendment Manager: User entered '25 Mar 2022 00:01'	System	19 Nov 2020 23:19:33

US3032242

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:52:51

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:19:33
Amendment Manager: User entered '29 Mar 2022 23:59'	System	19 Nov 2020 23:19:33

US3032242

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:52:51

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:19:33
Amendment Manager: User entered 'Day 593'	System	19 Nov 2020 23:19:33

US3032242

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:52:51

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:19:33
Amendment Manager: User entered '01 Apr 2022 00:01'	System	19 Nov 2020 23:19:33

US3032242

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:52:51

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:19:33
Amendment Manager: User entered '05 Apr 2022 23:59'	System	19 Nov 2020 23:19:33

US3032242

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:52:51

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:19:33
Amendment Manager: User entered 'Day 600'	System	19 Nov 2020 23:19:33

US3032242

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:52:51

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:19:33
Amendment Manager: User entered '08 Apr 2022 00:01'	System	19 Nov 2020 23:19:33

US3032242

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:52:51

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:19:33
Amendment Manager: User entered '12 Apr 2022 23:59'	System	19 Nov 2020 23:19:33

US3032242

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:52:51

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:19:33
Amendment Manager: User entered 'Day 607'	System	19 Nov 2020 23:19:33

US3032242

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:52:51

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:19:33
Amendment Manager: User entered '15 Apr 2022 00:01'	System	19 Nov 2020 23:19:33

US3032242

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:52:51

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:19:33
Amendment Manager: User entered '19 Apr 2022 23:59'	System	19 Nov 2020 23:19:33

US3032242

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:52:51

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:19:33
Amendment Manager: User entered 'Day 614'	System	19 Nov 2020 23:19:33

US3032242

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:52:51

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:19:33
Amendment Manager: User entered '22 Apr 2022 00:01'	System	19 Nov 2020 23:19:33

US3032242

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:52:51

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:19:33
Amendment Manager: User entered '26 Apr 2022 23:59'	System	19 Nov 2020 23:19:33

US3032242

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:52:51

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:19:33
Amendment Manager: User entered 'Day 621'	System	19 Nov 2020 23:19:33

US3032242

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:52:51

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:19:33
Amendment Manager: User entered '29 Apr 2022 00:01'	System	19 Nov 2020 23:19:33

US3032242

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:52:51

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:19:33
Amendment Manager: User entered '03 May 2022 23:59'	System	19 Nov 2020 23:19:33

US3032242

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:52:51

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:19:33
Amendment Manager: User entered 'Day 628'	System	19 Nov 2020 23:19:33

US3032242

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:52:51

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:19:33
Amendment Manager: User entered '06 May 2022 00:01'	System	19 Nov 2020 23:19:33

US3032242

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:52:51

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:19:33
Amendment Manager: User entered '10 May 2022 23:59'	System	19 Nov 2020 23:19:33

US3032242

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:52:51

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:19:33
Amendment Manager: User entered 'Day 635'	System	19 Nov 2020 23:19:33

US3032242

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:52:51

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:19:33
Amendment Manager: User entered '13 May 2022 00:01'	System	19 Nov 2020 23:19:33

US3032242

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:52:51

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:19:33
Amendment Manager: User entered '17 May 2022 23:59'	System	19 Nov 2020 23:19:33

US3032242

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:52:51

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:19:33
Amendment Manager: User entered 'Day 642'	System	19 Nov 2020 23:19:33

US3032242

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:52:51

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:19:33
Amendment Manager: User entered '20 May 2022 00:01'	System	19 Nov 2020 23:19:33

US3032242

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:52:51

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:19:33
Amendment Manager: User entered '24 May 2022 23:59'	System	19 Nov 2020 23:19:33

US3032242

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:52:51

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:19:33
Amendment Manager: User entered 'Day 649'	System	19 Nov 2020 23:19:33

US3032242

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:52:51

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:19:33
Amendment Manager: User entered '27 May 2022 00:01'	System	19 Nov 2020 23:19:33

US3032242

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:52:51

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:19:33
Amendment Manager: User entered '31 May 2022 23:59'	System	19 Nov 2020 23:19:33

US3032242

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:52:51

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:19:33
Amendment Manager: User entered 'Day 656'	System	19 Nov 2020 23:19:33

US3032242

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:52:51

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:19:33
Amendment Manager: User entered '03 Jun 2022 00:01'	System	19 Nov 2020 23:19:33

US3032242

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:52:51

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:19:33
Amendment Manager: User entered '07 Jun 2022 23:59'	System	19 Nov 2020 23:19:33

US3032242

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:52:51

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:19:33
Amendment Manager: User entered 'Day 663'	System	19 Nov 2020 23:19:33

US3032242

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:52:51

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:19:33
Amendment Manager: User entered '10 Jun 2022 00:01'	System	19 Nov 2020 23:19:33

US3032242

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:52:51

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:19:33
Amendment Manager: User entered '14 Jun 2022 23:59'	System	19 Nov 2020 23:19:33

US3032242

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:52:51

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:19:33
Amendment Manager: User entered 'Day 670'	System	19 Nov 2020 23:19:33

US3032242

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:52:51

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:19:33
Amendment Manager: User entered '17 Jun 2022 00:01'	System	19 Nov 2020 23:19:33

US3032242

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:52:51

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:19:33
Amendment Manager: User entered '21 Jun 2022 23:59'	System	19 Nov 2020 23:19:33

US3032242

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:52:51

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:19:33
Amendment Manager: User entered 'Day 677'	System	19 Nov 2020 23:19:33

US3032242

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:52:51

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:19:33
Amendment Manager: User entered '24 Jun 2022 00:01'	System	19 Nov 2020 23:19:33

US3032242

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:52:51

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:19:33
Amendment Manager: User entered '28 Jun 2022 23:59'	System	19 Nov 2020 23:19:33

US3032242

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:52:51

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:19:33
Amendment Manager: User entered 'Day 684'	System	19 Nov 2020 23:19:33

US3032242

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:52:51

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:19:33
Amendment Manager: User entered '01 Jul 2022 00:01'	System	19 Nov 2020 23:19:33

US3032242

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:52:51

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:19:33
Amendment Manager: User entered '05 Jul 2022 23:59'	System	19 Nov 2020 23:19:33

US3032242

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:52:51

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:19:33
Amendment Manager: User entered 'Day 691'	System	19 Nov 2020 23:19:33

US3032242

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:52:51

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:19:33
Amendment Manager: User entered '08 Jul 2022 00:01'	System	19 Nov 2020 23:19:33

US3032242

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:52:51

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:19:33
Amendment Manager: User entered '12 Jul 2022 23:59'	System	19 Nov 2020 23:19:33

US3032242

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:52:51

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:19:33
Amendment Manager: User entered 'Day 698'	System	19 Nov 2020 23:19:33

US3032242

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:52:51

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:19:33
Amendment Manager: User entered '15 Jul 2022 00:01'	System	19 Nov 2020 23:19:33

US3032242

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:52:51

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:19:33
Amendment Manager: User entered '19 Jul 2022 23:59'	System	19 Nov 2020 23:19:33

US3032242

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:52:51

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:19:33
Amendment Manager: User entered 'Day 705'	System	19 Nov 2020 23:19:33

US3032242

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:52:51

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:19:33
Amendment Manager: User entered '22 Jul 2022 00:01'	System	19 Nov 2020 23:19:33

US3032242

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:52:51

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:19:33
Amendment Manager: User entered '26 Jul 2022 23:59'	System	19 Nov 2020 23:19:33

US3032242

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:52:51

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:19:33
Amendment Manager: User entered 'Day 712'	System	19 Nov 2020 23:19:33

US3032242

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:52:51

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:19:33
Amendment Manager: User entered '29 Jul 2022 00:01'	System	19 Nov 2020 23:19:33

US3032242

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:52:51

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:19:33
Amendment Manager: User entered '02 Aug 2022 23:59'	System	19 Nov 2020 23:19:33

US3032242

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:52:51

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:19:33
Amendment Manager: User entered 'Day 719'	System	19 Nov 2020 23:19:33

US3032242

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:52:51

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:19:33
Amendment Manager: User entered '05 Aug 2022 00:01'	System	19 Nov 2020 23:19:33

US3032242

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:52:51

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:19:33
Amendment Manager: User entered '09 Aug 2022 23:59'	System	19 Nov 2020 23:19:33

US3032242

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:52:51

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:19:33
Amendment Manager: User entered 'Day 726'	System	19 Nov 2020 23:19:33

US3032242

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:52:51

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:19:33
Amendment Manager: User entered '12 Aug 2022 00:01'	System	19 Nov 2020 23:19:33

US3032242

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:52:51

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:19:33
Amendment Manager: User entered '16 Aug 2022 23:59'	System	19 Nov 2020 23:19:33

US3032242

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:52:51

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:19:33
Amendment Manager: User entered 'Day 733'	System	19 Nov 2020 23:19:33

US3032242

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:52:51

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:19:33
Amendment Manager: User entered '19 Aug 2022 00:01'	System	19 Nov 2020 23:19:33

US3032242

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:52:51

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:19:33
Amendment Manager: User entered '23 Aug 2022 23:59'	System	19 Nov 2020 23:19:33

US3032242

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:52:51

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:19:33
Amendment Manager: User entered 'Day 740'	System	19 Nov 2020 23:19:33

US3032242

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:52:51

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:19:33
Amendment Manager: User entered '26 Aug 2022 00:01'	System	19 Nov 2020 23:19:33

US3032242

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:52:51

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:19:33
Amendment Manager: User entered '30 Aug 2022 23:59'	System	19 Nov 2020 23:19:33

US3032242

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:52:51

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:19:33
Amendment Manager: User entered 'Day 747'	System	19 Nov 2020 23:19:33

US3032242

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:52:51

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:19:33
Amendment Manager: User entered '02 Sep 2022 00:01'	System	19 Nov 2020 23:19:33

US3032242

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:52:51

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:19:33
Amendment Manager: User entered '06 Sep 2022 23:59'	System	19 Nov 2020 23:19:33

US3032242

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:52:51

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:19:33
Amendment Manager: User entered 'Day 754'	System	19 Nov 2020 23:19:33

US3032242

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:52:51

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:19:33
Amendment Manager: User entered '09 Sep 2022 00:01'	System	19 Nov 2020 23:19:33

US3032242

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:52:51

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:19:33
Amendment Manager: User entered '13 Sep 2022 23:59'	System	19 Nov 2020 23:19:33

US3032242

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:52:51

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:19:33
Amendment Manager: User entered 'Day 761'	System	19 Nov 2020 23:19:33

US3032242

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:52:51

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:19:33
Amendment Manager: User entered '16 Sep 2022 00:01'	System	19 Nov 2020 23:19:33

US3032242

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:52:51

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:19:33
Amendment Manager: User entered '20 Sep 2022 23:59'	System	19 Nov 2020 23:19:33

US3032242

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:52:51

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:19:33
Amendment Manager: User entered 'Day 768'	System	19 Nov 2020 23:19:33

US3032242

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:52:51

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:19:33
Amendment Manager: User entered '23 Sep 2022 00:01'	System	19 Nov 2020 23:19:33

US3032242

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:52:51

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:19:33
Amendment Manager: User entered '27 Sep 2022 23:59'	System	19 Nov 2020 23:19:33

US3032242

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:52:51

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:19:33
Amendment Manager: User entered 'Day 775'	System	19 Nov 2020 23:19:33

US3032242

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:52:51

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:19:33
Amendment Manager: User entered '30 Sep 2022 00:01'	System	19 Nov 2020 23:19:33

US3032242

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:52:51

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:19:33
Amendment Manager: User entered '04 Oct 2022 23:59'	System	19 Nov 2020 23:19:33

US3032242

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:52:51

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:19:33
Amendment Manager: User entered 'Day 782'	System	19 Nov 2020 23:19:33

US3032242

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:52:51

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:19:33
Amendment Manager: User entered '07 Oct 2022 00:01'	System	19 Nov 2020 23:19:33

US3032242

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:52:51

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:19:33
Amendment Manager: User entered '11 Oct 2022 23:59'	System	19 Nov 2020 23:19:33

US3032242

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:52:51

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:19:33
Amendment Manager: User entered 'Day 789'	System	19 Nov 2020 23:19:33

US3032242

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:52:51

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:19:33
Amendment Manager: User entered '14 Oct 2022 00:01'	System	19 Nov 2020 23:19:33

US3032242

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:52:51

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:19:33
Amendment Manager: User entered '18 Oct 2022 23:59'	System	19 Nov 2020 23:19:33

US3032242

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:52:51

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:19:33
Amendment Manager: User entered 'Day 796'	System	19 Nov 2020 23:19:33

US3032242

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:52:51

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:19:33
Amendment Manager: User entered '21 Oct 2022 00:01'	System	19 Nov 2020 23:19:33

US3032242

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:52:51

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:19:33
Amendment Manager: User entered '25 Oct 2022 23:59'	System	19 Nov 2020 23:19:33

US3032242

Folder: Cosmetic Injections and Dermal Fillers

Form: Cosmetic Injection_ Dermal Filler eDiary (1)

Generated On: 09 Jun 2021 14:52:51

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)	24 Apr 2021 12:21:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6C42AABB-C8BC-44AC-B3C0-D8720CCF0DD6)', Time: '2021-03-01T03:25:27-06:00', User OID: 'PatientReportedOutcome (US3032242)', ODM File OID: '329a07ca-765f-4a8b-b841-c5a83fdb356'	System	02 Mar 2021 12:45:23
User entered 'No (N)'	System	02 Mar 2021 12:45:23

US3032242

Folder: Cosmetic Injections and Dermal Fillers

Form: Cosmetic Injection_ Dermal Filler eDiary (1)

Generated On: 09 Jun 2021 14:52:51

[Date & Time of Submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 12:21:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6C42AABB-C8BC-44AC-B3C0-D8720CCF0DD6)', Time: '2021-03-01T03:25:45-06:00', User OID: 'PatientReportedOutcome (US3032242)', ODM File OID: '329a07ca-765f-4a8b-b841-c5a83fdb356'	System	02 Mar 2021 12:45:23
User entered '01 Mar 2021 03:25:45'	System	02 Mar 2021 12:45:23

US3032242

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 09 Jun 2021 14:52:51

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:25:04
DataPoint Verified.		03 Dec 2020 16:47:13
User signature succeeded.	Keith Vrbicky (b) (4)	10 Nov 2020 21:41:06
User entered 'Yes (Y)'	(b) (4) Chelsie Nutsch (b) (4) (b) (4)	10 Nov 2020 15:27:21

US3032242

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 09 Jun 2021 14:52:51

Date of Contact or Contact Attempt (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:25:04
DataPoint Verified.		03 Dec 2020 16:47:13
User signature succeeded.	Keith Vrbicky (b) (4)	10 Nov 2020 21:41:06
User entered '10 Nov 2020'	(b) (4) Chelsie Nutsch (b) (4) (b) (4)	10 Nov 2020 15:27:21

US3032242

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 09 Jun 2021 14:52:51

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:25:04
DataPoint Verified.		03 Dec 2020 16:47:13
User signature succeeded.	Keith Vrbicky (b) (4)	10 Nov 2020 21:41:06
User entered 'Contact Made (CONTACT MADE)'	(b) (4) Chelsie Nutsch (b) (4) (b) (4)	10 Nov 2020 15:27:21

US3032242

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 09 Jun 2021 14:52:51

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:25:04
DataPoint Verified.		03 Dec 2020 16:47:13
User signature succeeded.	Keith Vrbicky (b) (4)	10 Nov 2020 21:41:06
User entered empty.	(b) (4) Chelsie Nutsch (b) (4) (b) (4)	10 Nov 2020 15:27:21

US3032242

Folder: Safety Call Day 85 (1)

Form: Continuing

Generated On: 09 Jun 2021 14:52:51

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:25:04
User signature succeeded.	Keith Vrbicky (b) (4)	10 Nov 2020 21:41:06
User entered 'Yes (Y)'	(b) (4) Chelsie Nutsch (b) (4)	10 Nov 2020 15:27:26

US3032242

Folder: Safety Call Day 85 (1)

Form: Continuing

Generated On: 09 Jun 2021 14:52:51

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:25:04
User entered '1'	System	10 Nov 2020 15:27:26

US3032242

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 09 Jun 2021 14:52:51

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 15:09:58
User signature succeeded.	Keith Vrbicky (b) (4)	05 Feb 2021 19:41:27
User entered 'Yes (Y)'	(b) (4) Chelsie Nutsch (b) (4)	05 Feb 2021 15:12:28

US3032242

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 09 Jun 2021 14:52:51

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 15:09:58
User signature succeeded.	Keith Vrbicky (b) (4)	05 Feb 2021 19:41:27
User entered '14 Dec 2020'	(b) (4) Chelsie Nutsch (b) (4)	05 Feb 2021 15:12:28

US3032242

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 09 Jun 2021 14:52:51

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 15:09:58
User signature succeeded.	Keith Vrbicky (b) (4)	05 Feb 2021 19:41:27
User entered 'Contact Made (CONTACT MADE)'	(b) (4) Chelsie Nutsch (b) (4)	05 Feb 2021 15:12:28

US3032242

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 09 Jun 2021 14:52:51

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 15:09:58
User signature succeeded.	Keith Vrbicky (b) (4)	05 Feb 2021 19:41:27
User entered empty.	(b) (4) Chelsie Nutsch (b) (4)	05 Feb 2021 15:12:28

US3032242

Folder: Safety Call Day 119 (1)

Form: Continuing

Generated On: 09 Jun 2021 14:52:51

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 15:09:58
User signature succeeded.	Keith Vrbicky (b) (4)	05 Feb 2021 19:41:27
User entered 'Yes (Y)' reason for change: Data Entry Error	(b) (4) Chelsie Nutsch (b) (4)	05 Feb 2021 15:12:40
User entered 'No (N)'	(b) (4) Chelsie Nutsch (b) (4)	05 Feb 2021 15:12:32

US3032242

Folder: Safety Call Day 119 (1)

Form: Continuing

Generated On: 09 Jun 2021 14:52:51

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 15:09:58
User entered '1'	System	05 Feb 2021 15:12:40
User entered empty.	System	05 Feb 2021 15:12:32

US3032242

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 09 Jun 2021 14:52:51

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 15:09:58
User signature succeeded.	Keith Vrbicky (b) (4)	05 Feb 2021 19:41:27
User closed query 'Was Contact Attempted? = Yes and 'Date of Contact or Contact Attempt' or ' Please select one status for the follow-up contact' is missing. Please review and reconcile.' (Site from System).	(b) (4)	05 Feb 2021 15:14:02
User opened query 'Was Contact Attempted? = Yes and 'Date of Contact or Contact Attempt' or ' Please select one status for the follow-up contact' is missing. Please review and reconcile.' (Site from System).	System	05 Feb 2021 15:13:04
User entered 'Yes (Y)'	Chelsie Nutsch (b) (4)	05 Feb 2021 15:13:04
	(b) (4)	

US3032242

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 09 Jun 2021 14:52:51

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 15:09:58
User signature succeeded.	Keith Vrbicky (b) (4)	05 Feb 2021 19:41:27
User entered '13 Jan 2021' reason for change: Data Entry Error	(b) (4)	05 Feb 2021 15:14:02
User entered empty.	Chelsie Nutsch (b) (4)	05 Feb 2021 15:13:04
	(b) (4)	

US3032242

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 09 Jun 2021 14:52:51

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 15:09:58
User signature succeeded.	Keith Vrbicky (b) (4)	05 Feb 2021 19:41:27
User entered 'Contact Made (CONTACT MADE)' reason for change: Data Entry Error	(b) (4) Chelsie Nutsch (b) (4)	05 Feb 2021 15:23:18
User entered 'Contact Not Made (CONTACT NOT MADE)'	(b) (4) Chelsie Nutsch (b) (4)	05 Feb 2021 15:13:04

US3032242

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 09 Jun 2021 14:52:51

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 15:09:58
User signature succeeded.	Keith Vrbicky (b) (4)	05 Feb 2021 19:41:27
User entered empty; reason for change Data Entry Error	(b) (4) Chelsie Nutsch (b) (4)	05 Feb 2021 15:23:18
User entered 'Subject did not answer x3. Will continue attempts'	Chelsie Nutsch (b) (4)	05 Feb 2021 15:13:04

US3032242

Folder: Safety Call Day 149 (1)

Form: Continuing

Generated On: 09 Jun 2021 14:52:51

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 15:09:58
User signature succeeded.	Keith Vrbicky (b) (4)	05 Feb 2021 19:41:27
User entered 'Yes (Y)'	(b) (4) Chelsie Nutsch (b) (4)	05 Feb 2021 15:23:25

US3032242

Folder: Safety Call Day 149 (1)

Form: Continuing

Generated On: 09 Jun 2021 14:52:51

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 15:09:58
User entered '1'	System	05 Feb 2021 15:23:25

US3032242

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 09 Jun 2021 14:52:51

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 15:09:58
User signature succeeded.	Keith Vrbicky (b) (4)	18 Mar 2021 21:20:21
User entered 'Yes (Y)'	(b) (4) Linden DeBoer (b) (4)	11 Mar 2021 22:14:58
	(b) (4)	

US3032242

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 09 Jun 2021 14:52:51

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 15:09:58
User signature succeeded.	Keith Vrbicky (b) (4)	18 Mar 2021 21:20:21
User entered '12 Feb 2021'	(b) (4) Linden DeBoer (b) (4)	11 Mar 2021 22:14:58
	(b) (4)	

US3032242

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 09 Jun 2021 14:52:51

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 15:09:58
User signature succeeded.	Keith Vrbicky (b) (4)	18 Mar 2021 21:20:21
User entered 'Contact Made (CONTACT MADE)'	(b) (4) Linden DeBoer (b) (4)	11 Mar 2021 22:14:58

US3032242

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 09 Jun 2021 14:52:51

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 15:09:58
User signature succeeded.	Keith Vrbicky (b) (4)	18 Mar 2021 21:20:21
User entered empty.	Linden DeBoer (b) (4)	11 Mar 2021 22:14:58

US3032242

Folder: Safety Call Day 179 (1)

Form: Continuing

Generated On: 09 Jun 2021 14:52:51

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 15:09:58
User signature succeeded.	Keith Vrbicky (b) (4)	18 Mar 2021 21:20:21
User entered 'Yes (Y)'	(b) (4) Linden DeBoer (b) (4)	11 Mar 2021 22:15:02

US3032242

Folder: Safety Call Day 179 (1)

Form: Continuing

Generated On: 09 Jun 2021 14:52:51

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 15:09:58
User entered 'I'	System	11 Mar 2021 22:15:02

US3032242

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Generated On: 09 Jun 2021 14:52:51

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 15:09:58
User signature succeeded.	Keith Vrbicky (b) (4)	06 Apr 2021 15:40:50
User entered 'Yes (Y)'	(b) (4) Kelsey Kelley (b) (4)	25 Mar 2021 19:55:32

US3032242

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Generated On: 09 Jun 2021 14:52:51

Visit date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 15:09:58
User signature succeeded.	Keith Vrbicky (b) (4)	06 Apr 2021 15:40:50
User entered '25 Mar 2021'	(b) (4) Kelsey Kelley (b) (4)	25 Mar 2021 19:55:32

US3032242

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Generated On: 09 Jun 2021 14:52:51

[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 15:09:58
User signature succeeded.	Keith Vrbicky (b) (4)	06 Apr 2021 15:40:50
User entered 'Clinic (Clinic)'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	25 Mar 2021 19:55:32

US3032242

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Generated On: 09 Jun 2021 14:52:51

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 15:09:58
User entered 'VISIT4'	System	25 Mar 2021 19:55:32

US3032242

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 14:52:51

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 15:09:58
User signature succeeded.	Keith Vrbicky (b) (4) (b) (4)	06 Apr 2021 15:40:50
User entered 'No (N)'	Samantha Wieseler (b) (4) (b) (4)	30 Mar 2021 21:35:48

US3032242

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 14:52:51

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 15:09:58
User signature succeeded.	Keith Vrbicky (b) (4)	06 Apr 2021 15:40:50
User entered empty.	(b) (4) Samantha Wieseler (b) (4)	30 Mar 2021 21:35:48

US3032242

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 14:52:51

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 15:09:58
User signature succeeded.	Keith Vrbicky (b) (4) (b) (4)	06 Apr 2021 15:40:50
User entered empty.	Samantha Wieseler (b) (4) (b) (4)	30 Mar 2021 21:35:48

US3032242

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 14:52:51

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 15:09:58
User entered empty.	System	30 Mar 2021 21:35:48

US3032242

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 14:52:51

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 15:09:58
User signature succeeded.	Keith Vrbicky (b) (4) (b) (4)	06 Apr 2021 15:40:50
User entered empty.	Samantha Wieseler (b) (4) (b) (4)	30 Mar 2021 21:35:48

US3032242

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 14:52:51

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 15:09:58
User signature succeeded.	Keith Vrbicky (b) (4) (b) (4)	06 Apr 2021 15:40:50
User entered empty.	Samantha Wieseler (b) (4) (b) (4)	30 Mar 2021 21:35:48

US3032242

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 14:52:51

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 15:09:58
User signature succeeded.	Keith Vrbicky (b) (4) (b) (4)	06 Apr 2021 15:40:50
User entered empty.	Samantha Wieseler (b) (4) (b) (4)	30 Mar 2021 21:35:48

US3032242

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 14:52:51

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 15:09:58
User signature succeeded.	Keith Vrbicky (b) (4) (b) (4)	06 Apr 2021 15:40:50
User entered empty.	Samantha Wieseler (b) (4) (b) (4)	30 Mar 2021 21:35:48

US3032242

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 14:52:51

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 15:09:58
User entered empty.	System	30 Mar 2021 21:35:48

US3032242

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 14:52:51

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 15:09:58
User signature succeeded.	Keith Vrbicky (b) (4) (b) (4)	06 Apr 2021 15:40:50
User entered empty.	Samantha Wieseler (b) (4) (b) (4)	30 Mar 2021 21:35:48

US3032242

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 14:52:51

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 15:09:58
User entered empty.	System	30 Mar 2021 21:35:48

US3032242

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 14:52:51

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 15:09:58
User signature succeeded.	Keith Vrbicky (b) (4) (b) (4)	06 Apr 2021 15:40:50
User entered empty.	Samantha Wieseler (b) (4) (b) (4)	30 Mar 2021 21:35:48

US3032242

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 14:52:51

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 15:09:58
User entered empty.	System	30 Mar 2021 21:35:48

US3032242

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 14:52:51

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 15:09:58
User signature succeeded.	Keith Vrbicky (b) (4) (b) (4)	06 Apr 2021 15:40:50
User entered empty.	Samantha Wieseler (b) (4) (b) (4)	30 Mar 2021 21:35:48

US3032242

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 14:52:51

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 15:09:58
User entered empty.	System	30 Mar 2021 21:35:48

US3032242

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 14:52:51

[Height \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 15:09:58

US3032242

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 14:52:51

Weight (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 15:09:58

US3032242

Folder: Visit 4 Day 209 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 14:52:51

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 15:09:58
User signature succeeded.	Keith Vrbicky (b) (4)	06 Apr 2021 15:40:50
User entered 'No (N)'	(b) (4) Kelsey Kelley (b) (4)	25 Mar 2021 19:55:51

US3032242

Folder: Visit 4 Day 209 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 14:52:51

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 15:09:58
User signature succeeded.	Keith Vrbicky (b) (4)	06 Apr 2021 15:40:50
User entered empty.	(b) (4) Kelsey Kelley (b) (4)	25 Mar 2021 19:55:51

US3032242

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 14:52:51

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 15:09:58
User signature succeeded.	Keith Vrbicky (b) (4) (b) (4)	06 Apr 2021 15:40:50
User entered 'Yes (Y)'	Kelsey Kelley (b) (4) (b) (4)	25 Mar 2021 19:57:03

US3032242

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 14:52:51

Collection date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 15:09:58
User signature succeeded.	Keith Vrbicky (b) (4)	06 Apr 2021 15:40:50
User entered '25 Mar 2021'	(b) (4) Kelsey Kelley (b) (4)	25 Mar 2021 19:57:03
	(b) (4)	

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Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 14:52:51

Collection time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 15:09:58
User signature succeeded.	Keith Vrbicky (b) (4)	06 Apr 2021 15:40:50
User entered '13:11'	(b) (4) Kelsey Kelley (b) (4)	25 Mar 2021 19:57:03

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Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 14:52:51

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 15:09:58
User entered '25 Mar 2021 13:11'	System	25 Mar 2021 19:57:03

US3032242

Folder: Visit 4 Day 209 (1)

Form: Continuing

Generated On: 09 Jun 2021 14:52:51

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 15:09:58
User signature succeeded.	Keith Vrbicky (b) (4)	06 Apr 2021 15:40:50
User entered 'Yes (Y)'	(b) (4) Kelsey Kelley (b) (4)	25 Mar 2021 19:57:16

US3032242

Folder: Visit 4 Day 209 (1)

Form: Continuing

Generated On: 09 Jun 2021 14:52:51

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 15:09:58
User entered '1'	System	25 Mar 2021 19:57:16

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

Form: Visit Date

Generated On: 09 Jun 2021 14:52:51

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:06:09
User signature succeeded.	Keith Vrbicky (b) (4)	12 Feb 2021 19:56:37
User entered 'Yes (Y)'	(b) (4) Kelsey Kelley (b) (4)	09 Feb 2021 23:14:22

US3032242

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

Form: Visit Date

Generated On: 09 Jun 2021 14:52:51

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:06:09
User signature succeeded.	Keith Vrbicky (b) (4)	12 Feb 2021 19:56:37
User entered '9 Feb 2021'	(b) (4) Kelsey Kelley (b) (4)	09 Feb 2021 23:14:22
	(b) (4)	

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

Form: Visit Date

Generated On: 09 Jun 2021 14:52:51

[Was visit performed at the participant's home or at the clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:06:09
User signature succeeded.	Keith Vrbicky (b) (4)	12 Feb 2021 19:56:37
User entered 'Clinic (Clinic)'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	09 Feb 2021 23:14:22

US3032242

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

Form: Visit Date

Generated On: 09 Jun 2021 14:52:51

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:06:09
User entered 'UNBLND_DECIDE'	System	09 Feb 2021 23:14:22

US3032242

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

Form: Unblinding

Generated On: 09 Jun 2021 14:52:51

Date of updated informed consent (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:06:09
User signature succeeded.	Keith Vrbicky (b) (4)	12 Feb 2021 19:56:37
User entered '9 Feb 2021'	(b) (4) Kelsey Kelley (b) (4)	09 Feb 2021 23:15:18
	(b) (4)	

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

Form: Unblinding

Generated On: 09 Jun 2021 14:52:51

[N/A - Subject Unblinded under Amendment 5 and Discontinued from Study](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:06:09
User signature succeeded.	Keith Vrbicky (b) (4)	18 Mar 2021 21:20:21
User entered '0' WR# 5295537	(b) (4)	10 Mar 2021 16:55:28
Amendment Manager inserted this DataPoint.	System	06 Mar 2021 13:10:20

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

Form: Unblinding

Generated On: 09 Jun 2021 14:52:51

[Was the participant unblinded?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:06:09
User signature succeeded.	Keith Vrbicky (b) (4)	12 Feb 2021 19:56:37
User entered 'Yes (Y)'	(b) (4) Kelsey Kelley (b) (4)	09 Feb 2021 23:15:18

US3032242

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

Form: Unblinding

Generated On: 09 Jun 2021 14:52:51

[Under what version of the Protocol was the Participant unblinded?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:06:09
User signature succeeded.	Keith Vrbicky (b) (4)	18 Mar 2021 21:20:21
User entered 'AMENDMENT 6 OR LATER (AMENDMENT 6 OR LATER)' WR# 5295537	(b) (4)	10 Mar 2021 16:55:28
Amendment Manager inserted this DataPoint.	System	06 Mar 2021 13:10:20

US3032242

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

Form: Unblinding

Generated On: 09 Jun 2021 14:52:51

Date of unblinding (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:06:09
User signature succeeded.	Keith Vrbicky (b) (4)	12 Feb 2021 19:56:37
User entered '9 Feb 2021'	(b) (4) Kelsey Kelley (b) (4)	09 Feb 2021 23:15:18
	(b) (4)	

US3032242

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

Form: Unblinding

Generated On: 09 Jun 2021 14:52:51

[Participant randomization assignment](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:06:09
User signature succeeded.	Keith Vrbicky (b) (4)	12 Feb 2021 19:56:37
User entered 'Placebo (Placebo)'	(b) (4) Kelsey Kelley (b) (4)	09 Feb 2021 23:15:18

US3032242

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

Form: Unblinding

Generated On: 09 Jun 2021 14:52:51

[Actual Dose 1](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:06:09
User signature succeeded.	Keith Vrbicky (b) (4)	12 Feb 2021 19:56:37
User entered 'Placebo (Placebo)'	(b) (4) Kelsey Kelley (b) (4)	09 Feb 2021 23:15:18

US3032242

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

Form: Unblinding

Generated On: 09 Jun 2021 14:52:51

[Actual Dose 2](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:06:09
User signature succeeded.	Keith Vrbicky (b) (4)	12 Feb 2021 19:56:37
User entered 'Placebo (Placebo)'	(b) (4) Kelsey Kelley (b) (4)	09 Feb 2021 23:15:18

US3032242

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

Form: Unblinding

Generated On: 09 Jun 2021 14:52:51

[Will participant receive mRNA-1273?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:06:09
User signature succeeded.	Keith Vrbicky (b) (4)	22 Feb 2021 17:26:08
Signature has been broken.	(b) (4) Kelsey Kelley (b) (4)	19 Feb 2021 21:15:34
User entered 'Yes (Y)' reason for change: New Information	(b) (4) Kelsey Kelley (b) (4)	19 Feb 2021 21:15:34
User signature succeeded.	Keith Vrbicky (b) (4)	12 Feb 2021 19:56:37
User entered 'No (N)'	(b) (4) Kelsey Kelley (b) (4)	09 Feb 2021 23:15:18

US3032242

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

Form: Unblinding

Generated On: 09 Jun 2021 14:52:51

[Placebo Only Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:06:09
User entered '1'	System	09 Feb 2021 23:15:18

US3032242

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

Form: Unblinding

Generated On: 09 Jun 2021 14:52:51

[Continuing with mRNA-1273](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:06:09
User entered '1'	System	19 Feb 2021 21:15:34
User entered empty.	System	09 Feb 2021 23:15:18

US3032242

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

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 14:52:51

[Height](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:06:09
User signature succeeded.	Keith Vrbicky (b) (4) (b) (4)	22 Feb 2021 17:26:08
User entered missing code ND - Not Done.	Kelsey Kelley (b) (4) (b) (4)	19 Feb 2021 21:18:38

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

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 14:52:51

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:06:09
User signature succeeded.	Keith Vrbicky (b) (4)	22 Feb 2021 17:26:08
User entered missing code ND - Not Done.	(b) (4) Kelsey Kelley (b) (4)	19 Feb 2021 21:18:38
	(b) (4)	

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

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 14:52:51

BMI (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:06:09
User entered empty.	System	19 Feb 2021 21:18:38
DataPoint set to visible.	System	19 Feb 2021 21:15:34

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

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 14:52:51

[Height](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:06:09
User signature succeeded.	Keith Vrbicky (b) (4) (b) (4)	22 Feb 2021 17:26:08
User entered missing code ND - Not Done.	Kelsey Kelley (b) (4) (b) (4)	19 Feb 2021 21:18:38

US3032242

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

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 14:52:51

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:06:09
User signature succeeded.	Keith Vrbicky (b) (4)	22 Feb 2021 17:26:08
User entered missing code ND - Not Done.	(b) (4) Kelsey Kelley (b) (4)	19 Feb 2021 21:18:38

US3032242

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

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 14:52:51

BMI (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:06:09
User entered empty.	System	19 Feb 2021 21:18:38
DataPoint set to visible.	System	19 Feb 2021 21:15:34

US3032242

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

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 14:52:51

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:06:09
User accepted default value 'Pre-Dose (PREDOSE)'	Kelsey Kelley (b) (4) (b) (4)	19 Feb 2021 21:18:38

US3032242

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

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 14:52:51

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:06:09
User signature succeeded.	Keith Vrbicky (b) (4)	22 Feb 2021 17:26:08
User entered 'Yes (Y)'	(b) (4) Kelsey Kelley (b) (4)	19 Feb 2021 21:18:38

US3032242

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

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 14:52:51

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:06:09
User signature succeeded.	Keith Vrbicky (b) (4)	22 Feb 2021 17:26:08
User entered '19 Feb 2021'	(b) (4) Kelsey Kelley (b) (4)	19 Feb 2021 21:18:38
	(b) (4)	

US3032242

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

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 14:52:51

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:06:09
User signature succeeded.	Keith Vrbicky (b) (4)	22 Feb 2021 17:26:08
User entered '10:06'	(b) (4) Kelsey Kelley (b) (4)	19 Feb 2021 21:18:38
	(b) (4)	

US3032242

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

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 14:52:51

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:06:09
User entered '19 Feb 2021 10:06'	System	19 Feb 2021 21:18:38

US3032242

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

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 14:52:51

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:06:09
User signature succeeded.	Keith Vrbicky (b) (4)	22 Feb 2021 17:26:08
User entered '36.9' C	(b) (4) Kelsey Kelley (b) (4) (b) (4)	19 Feb 2021 21:18:38

US3032242

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

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 14:52:51

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:06:09
User signature succeeded.	Keith Vrbicky (b) (4)	22 Feb 2021 17:26:08
User entered 'Oral (Oral)'	(b) (4) Kelsey Kelley (b) (4)	19 Feb 2021 21:18:38
	(b) (4)	

US3032242

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

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 14:52:51

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:06:09
User signature succeeded.	Keith Vrbicky (b) (4)	22 Feb 2021 17:26:08
User entered empty.	(b) (4) Kelsey Kelley (b) (4)	19 Feb 2021 21:18:38
	(b) (4)	

US3032242

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

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 14:52:51

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:06:09
User signature succeeded.	Keith Vrbicky (b) (4)	22 Feb 2021 17:26:08
User entered '96'	(b) (4) Kelsey Kelley (b) (4)	19 Feb 2021 21:18:38

US3032242

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

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 14:52:51

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:06:09
User entered 'bpm'	System	19 Feb 2021 21:18:38

US3032242

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

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 14:52:51

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:06:09
User signature succeeded.	Keith Vrbicky (b) (4)	22 Feb 2021 17:26:08
User entered '20'	(b) (4) Kelsey Kelley (b) (4)	19 Feb 2021 21:18:38

US3032242

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

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 14:52:51

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:06:09
User entered 'breaths/min'	System	19 Feb 2021 21:18:38

US3032242

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

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 14:52:51

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:06:09
User signature succeeded.	Keith Vrbicky (b) (4)	22 Feb 2021 17:26:08
User entered '104'	(b) (4) Kelsey Kelley (b) (4)	19 Feb 2021 21:18:38

US3032242

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

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 14:52:51

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:06:09
User entered 'mmHg'	System	19 Feb 2021 21:18:38

US3032242

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

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 14:52:51

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:06:09
User signature succeeded.	Keith Vrbicky (b) (4)	22 Feb 2021 17:26:08
User entered '78'	(b) (4) Kelsey Kelley (b) (4)	19 Feb 2021 21:18:38

US3032242

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

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 14:52:51

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:06:09
User entered 'mmHg'	System	19 Feb 2021 21:18:38

US3032242

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

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 14:52:51

[Height](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:06:09
User signature succeeded.	Keith Vrbicky (b) (4)	22 Feb 2021 17:26:08
User entered missing code ND - Not Done.	(b) (4) Kelsey Kelley (b) (4)	19 Feb 2021 21:18:38

US3032242

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

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 14:52:51

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:06:09
User signature succeeded.	Keith Vrbicky (b) (4) (b) (4)	22 Feb 2021 17:26:08
User entered missing code ND - Not Done.	Kelsey Kelley (b) (4) (b) (4)	19 Feb 2021 21:18:38

US3032242

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

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 14:52:51

BMI (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:06:09
User entered empty.	System	19 Feb 2021 21:18:38
DataPoint set to visible.	System	19 Feb 2021 21:15:34

US3032242

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

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 14:52:51

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:06:09
User accepted default value 'Post-Dose (POSTDOSE)'	Kelsey Kelley (b) (4) (b) (4)	19 Feb 2021 21:19:46

US3032242

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

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 14:52:51

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:06:09
User signature succeeded.	Keith Vrbicky (b) (4)	22 Feb 2021 17:26:08
User entered 'Yes (Y)'	(b) (4) Kelsey Kelley (b) (4)	19 Feb 2021 21:19:46
	(b) (4)	

US3032242

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

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 14:52:51

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:06:09
User signature succeeded.	Keith Vrbicky (b) (4)	22 Feb 2021 17:26:08
User entered '19 Feb 2021'	(b) (4) Kelsey Kelley (b) (4)	19 Feb 2021 21:19:46
	(b) (4)	

US3032242

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

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 14:52:51

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:06:09
User signature succeeded.	Keith Vrbicky (b) (4)	22 Feb 2021 17:26:08
User entered '11:15'	(b) (4) Kelsey Kelley (b) (4)	19 Feb 2021 21:19:46

US3032242

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

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 14:52:51

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:06:09
User entered '19 Feb 2021 11:15'	System	19 Feb 2021 21:19:46

US3032242

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

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 14:52:51

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:06:09
User signature succeeded.	Keith Vrbicky (b) (4)	22 Feb 2021 17:26:08
User entered '36.7' C	(b) (4) Kelsey Kelley (b) (4)	19 Feb 2021 21:19:46
	(b) (4)	

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

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 14:52:51

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:06:09
User signature succeeded.	Keith Vrbicky (b) (4)	22 Feb 2021 17:26:08
User entered 'Oral (Oral)'	(b) (4) Kelsey Kelley (b) (4)	19 Feb 2021 21:19:46
	(b) (4)	

US3032242

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

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 14:52:51

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:06:09
User signature succeeded.	Keith Vrbicky (b) (4)	22 Feb 2021 17:26:08
User entered empty.	(b) (4) Kelsey Kelley (b) (4)	19 Feb 2021 21:19:46
	(b) (4)	

US3032242

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

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 14:52:51

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:06:09
User signature succeeded.	Keith Vrbicky (b) (4)	22 Feb 2021 17:26:08
User entered '84'	Kelsey Kelley (b) (4)	19 Feb 2021 21:19:46

US3032242

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

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 14:52:51

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:06:09
User entered 'bpm'	System	19 Feb 2021 21:19:46

US3032242

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

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 14:52:51

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:06:09
User signature succeeded.	Keith Vrbicky (b) (4)	22 Feb 2021 17:26:08
User entered '15'	(b) (4) Kelsey Kelley (b) (4)	19 Feb 2021 21:19:46

US3032242

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

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 14:52:51

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:06:09
User entered 'breaths/min'	System	19 Feb 2021 21:19:46

US3032242

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

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 14:52:51

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:06:09
User signature succeeded.	Keith Vrbicky (b) (4)	22 Feb 2021 17:26:08
User entered '95'	(b) (4) Kelsey Kelley (b) (4)	19 Feb 2021 21:19:46

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

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 14:52:51

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:06:09
User entered 'mmHg'	System	19 Feb 2021 21:19:46

US3032242

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

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 14:52:51

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:06:09
User signature succeeded.	Keith Vrbicky (b) (4)	22 Feb 2021 17:26:08
User entered '74'	(b) (4) Kelsey Kelley (b) (4)	19 Feb 2021 21:19:46

US3032242

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

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 14:52:51

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:06:09
User entered 'mmHg'	System	19 Feb 2021 21:19:46

US3032242

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

Form: Physical Examination

Generated On: 09 Jun 2021 14:52:51

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:06:09
User signature succeeded.	Keith Vrbicky (b) (4)	22 Feb 2021 17:26:08
User entered 'Yes (Y)'	(b) (4) Kelsey Kelley (b) (4)	19 Feb 2021 21:18:48

US3032242

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

Form: Physical Examination

Generated On: 09 Jun 2021 14:52:51

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:06:09
User signature succeeded.	Keith Vrbicky (b) (4)	22 Feb 2021 17:26:08
User entered '19 Feb 2021'	(b) (4) Kelsey Kelley (b) (4)	19 Feb 2021 21:18:48
	(b) (4)	

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

Form: Exposure

Generated On: 09 Jun 2021 14:52:51

[Was study treatment given?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:06:09
User signature succeeded.	Keith Vrbicky (b) (4)	22 Feb 2021 17:26:08
User entered 'Yes (Y)'	(b) (4) Kelsey Kelley (b) (4)	19 Feb 2021 21:19:11

US3032242

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

Form: Exposure

Generated On: 09 Jun 2021 14:52:51

[If No, reason not given](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:06:09
User signature succeeded.	Keith Vrbicky (b) (4)	22 Feb 2021 17:26:08
User entered empty.	(b) (4) Kelsey Kelley (b) (4)	19 Feb 2021 21:19:11
	(b) (4)	

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

Form: Exposure

Generated On: 09 Jun 2021 14:52:51

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:06:09
User signature succeeded.	Keith Vrbicky (b) (4)	22 Feb 2021 17:26:08
User entered empty.	(b) (4) Kelsey Kelley (b) (4)	19 Feb 2021 21:19:11
	(b) (4)	

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

Form: Exposure

Generated On: 09 Jun 2021 14:52:51

[What was the study treatment? \(Unblinded\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:06:09
User entered 'mRNA-1273'	System	19 Feb 2021 21:19:11
DataPoint set to visible.	System	19 Feb 2021 21:15:34

US3032242

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

Form: Exposure

Generated On: 09 Jun 2021 14:52:51

What was the treatment date? (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:06:09
User signature succeeded.	Keith Vrbicky (b) (4)	22 Feb 2021 17:26:08
User entered '19 Feb 2021'	(b) (4) Kelsey Kelley (b) (4)	19 Feb 2021 21:19:11
	(b) (4)	

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

Form: Exposure

Generated On: 09 Jun 2021 14:52:51

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:06:09
User signature succeeded.	Keith Vrbicky (b) (4)	22 Feb 2021 17:26:08
User entered '10:43'	(b) (4) Kelsey Kelley (b) (4)	19 Feb 2021 21:19:11

US3032242

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

Form: Exposure

Generated On: 09 Jun 2021 14:52:51

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:06:09
User entered '19 Feb 2021 10:43'	System	19 Feb 2021 21:19:11

US3032242

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

Form: Exposure

Generated On: 09 Jun 2021 14:52:51

Which arm was used to give treatment?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:06:09
User signature succeeded.	Keith Vrbicky (b) (4)	22 Feb 2021 17:26:08
User entered 'Left Arm (LEFT ARM)'	(b) (4) Kelsey Kelley (b) (4)	19 Feb 2021 21:19:11
	(b) (4)	

US3032242

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

Form: Exposure

Generated On: 09 Jun 2021 14:52:51

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:06:09
User entered 'ONCE'	System	19 Feb 2021 21:19:11

US3032242

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

Form: Exposure

Generated On: 09 Jun 2021 14:52:51

What was the route of administration for the study treatment?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:06:09
User entered 'INTRAMUSCULAR'	System	19 Feb 2021 21:19:11

US3032242

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

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 14:52:51

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:06:09
User signature succeeded.	Keith Vrbicky (b) (4)	12 Feb 2021 19:56:37
User entered 'Yes (Y)'	(b) (4) Kelsey Kelley (b) (4)	09 Feb 2021 23:16:38

US3032242

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

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 14:52:51

Collection date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:06:09
User signature succeeded.	Keith Vrbicky (b) (4)	12 Feb 2021 19:56:37
User entered '9 Feb 2021'	(b) (4) Kelsey Kelley (b) (4)	09 Feb 2021 23:16:38
	(b) (4)	

US3032242

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

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 14:52:51

Collection time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:06:09
User signature succeeded.	Keith Vrbicky (b) (4)	12 Feb 2021 19:56:37
User entered '12:46'	(b) (4) Kelsey Kelley (b) (4)	09 Feb 2021 23:16:38

US3032242

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

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 14:52:51

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:06:09
User entered '9 Feb 2021 12:46'	System	09 Feb 2021 23:16:38

US3032242

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

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 09 Jun 2021 14:52:51

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:06:09
User signature succeeded.	Keith Vrbicky (b) (4)	12 Feb 2021 19:56:37
User entered 'Yes (Y)'	(b) (4) Kelsey Kelley (b) (4)	09 Feb 2021 23:16:48

US3032242

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

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 09 Jun 2021 14:52:51

Collection date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:06:09
User signature succeeded.	Keith Vrbicky (b) (4)	12 Feb 2021 19:56:37
User entered '9 Feb 2021'	(b) (4) Kelsey Kelley (b) (4)	09 Feb 2021 23:16:48
	(b) (4)	

US3032242

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

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 09 Jun 2021 14:52:51

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:06:09
User signature succeeded.	Keith Vrbicky (b) (4)	12 Feb 2021 19:56:37
User entered '12:43'	(b) (4) Kelsey Kelley (b) (4)	09 Feb 2021 23:16:48

US3032242

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

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 09 Jun 2021 14:52:51

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:06:09
User entered '9 Feb 2021 12:43'	System	09 Feb 2021 23:16:48

US3032242

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

Form: Continuing

Generated On: 09 Jun 2021 14:52:51

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:06:09
User signature succeeded.	Keith Vrbicky (b) (4)	22 Feb 2021 17:26:08
User entered 'Yes (Y)'	(b) (4) Kelsey Kelley (b) (4)	19 Feb 2021 21:15:42

US3032242

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

Form: Continuing

Generated On: 09 Jun 2021 14:52:51

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:06:09
User entered '1'	System	19 Feb 2021 21:15:42

US3032242

Folder: Safety Call OL-D8 (1)

Form: Safety Call

Generated On: 09 Jun 2021 14:52:51

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:06:09
User signature succeeded.	Keith Vrbicky (b) (4)	18 Mar 2021 21:20:21
User entered 'Yes (Y)'	(b) (4) Linden DeBoer (b) (4)	11 Mar 2021 22:15:13

US3032242

Folder: Safety Call OL-D8 (1)

Form: Safety Call

Generated On: 09 Jun 2021 14:52:51

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:06:09
User signature succeeded.	Keith Vrbicky (b) (4)	18 Mar 2021 21:20:21
User entered '1 Mar 2021'	(b) (4) Linden DeBoer (b) (4)	11 Mar 2021 22:15:13
	(b) (4)	

US3032242

Folder: Safety Call OL-D8 (1)

Form: Safety Call

Generated On: 09 Jun 2021 14:52:51

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:06:09
User signature succeeded.	Keith Vrbicky (b) (4)	18 Mar 2021 21:20:21
User entered 'Contact Made (CONTACT MADE)'	(b) (4) Linden DeBoer (b) (4)	11 Mar 2021 22:15:13

US3032242

Folder: Safety Call OL-D8 (1)

Form: Safety Call

Generated On: 09 Jun 2021 14:52:51

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:06:09
User signature succeeded.	Keith Vrbicky (b) (4)	18 Mar 2021 21:20:21
User entered empty.	(b) (4) Linden DeBoer (b) (4)	11 Mar 2021 22:15:13
	(b) (4)	

US3032242

Folder: Safety Call OL-D8 (1)

Form: Continuing

Generated On: 09 Jun 2021 14:52:51

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:06:09
User signature succeeded.	Keith Vrbicky (b) (4)	18 Mar 2021 21:20:21
User entered 'Yes (Y)'	Linden DeBoer (b) (4)	11 Mar 2021 22:15:18

US3032242

Folder: Safety Call OL-D8 (1)

Form: Continuing

Generated On: 09 Jun 2021 14:52:51

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:06:09
User entered '1'	System	11 Mar 2021 22:15:18

US3032242

Folder: Safety Call OL-D8 (1)

Form: Continuing

Generated On: 09 Jun 2021 14:52:51

[OLD29 Placebo Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:06:09
User entered '1'	System	11 Mar 2021 22:15:18
DataPoint set to visible.	System	11 Mar 2021 22:15:18

US3032242

Folder: OL-D29 (1)

Form: Visit Date

Generated On: 09 Jun 2021 14:52:51

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:06:09
User signature succeeded.	Keith Vrbicky (b) (4) (b) (4)	06 Apr 2021 15:40:50
User entered 'Yes (Y)'	Kelsey Kelley (b) (4) (b) (4)	25 Mar 2021 19:57:31

US3032242

Folder: OL-D29 (1)

Form: Visit Date

Generated On: 09 Jun 2021 14:52:51

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:06:09
User signature succeeded.	Keith Vrbicky (b) (4)	06 Apr 2021 15:40:50
User entered '18 Mar 2021'	(b) (4) Kelsey Kelley (b) (4)	25 Mar 2021 19:57:31
	(b) (4)	

US3032242

Folder: OL-D29 (1)

Form: Visit Date

Generated On: 09 Jun 2021 14:52:51

[Was visit performed at the participant's home or at the clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:06:09
User signature succeeded.	Keith Vrbicky (b) (4)	06 Apr 2021 15:40:50
User entered 'Clinic (Clinic)'	(b) (4) Kelsey Kelley (b) (4)	25 Mar 2021 19:57:31

US3032242

Folder: OL-D29 (1)

Form: Visit Date

Generated On: 09 Jun 2021 14:52:51

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:06:09
User entered 'OLD29'	System	25 Mar 2021 19:57:31

US3032242

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 14:52:51

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:06:09
User accepted default value 'Pre-Dose (PREDOSE)'	Kelsey Kelley (b) (4) (b) (4)	25 Mar 2021 19:58:20

US3032242

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 14:52:51

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:06:09
User signature succeeded.	Keith Vrbicky (b) (4)	06 Apr 2021 15:40:50
User entered 'Yes (Y)'	(b) (4) Kelsey Kelley (b) (4)	25 Mar 2021 19:58:20

US3032242

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 14:52:51

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:06:09
User signature succeeded.	Keith Vrbicky (b) (4)	06 Apr 2021 15:40:50
User entered '18 Mar 2021'	(b) (4) Kelsey Kelley (b) (4)	25 Mar 2021 19:58:20

US3032242

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 14:52:51

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:06:09
User signature succeeded.	Keith Vrbicky (b) (4)	06 Apr 2021 15:40:50
User entered '11:05'	(b) (4) Kelsey Kelley (b) (4)	25 Mar 2021 19:58:20

US3032242

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 14:52:51

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:06:09
User entered '18 Mar 2021 11:05'	System	25 Mar 2021 19:58:20

US3032242

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 14:52:51

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:06:09
User signature succeeded.	Keith Vrbicky (b) (4) (b) (4)	06 Apr 2021 15:40:50
User entered '36.8' C	Kelsey Kelley (b) (4) (b) (4)	25 Mar 2021 19:58:20

US3032242

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 14:52:51

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:06:09
User signature succeeded.	Keith Vrbicky (b) (4) (b) (4)	06 Apr 2021 15:40:50
User entered 'Oral (Oral)'	Kelsey Kelley (b) (4) (b) (4)	25 Mar 2021 19:58:20

US3032242

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 14:52:51

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:06:09
User signature succeeded.	Keith Vrbicky (b) (4)	06 Apr 2021 15:40:50
User entered empty.	(b) (4) Kelsey Kelley (b) (4)	25 Mar 2021 19:58:20

US3032242

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 14:52:51

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:06:09
User signature succeeded.	Keith Vrbicky (b) (4) (b) (4)	06 Apr 2021 15:40:50
User entered '79'	Kelsey Kelley (b) (4) (b) (4)	25 Mar 2021 19:58:20

US3032242

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 14:52:51

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:06:09
User entered 'bpm'	System	25 Mar 2021 19:58:20

US3032242

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 14:52:51

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:06:09
User signature succeeded.	Keith Vrbicky (b) (4) (b) (4)	06 Apr 2021 15:40:50
User entered '16'	Kelsey Kelley (b) (4) (b) (4)	25 Mar 2021 19:58:20

US3032242

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 14:52:51

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:06:09
User entered 'breaths/min'	System	25 Mar 2021 19:58:20

US3032242

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 14:52:51

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:06:09
User signature succeeded.	Keith Vrbicky (b) (4) (b) (4)	06 Apr 2021 15:40:50
User entered '108'	Kelsey Kelley (b) (4) (b) (4)	25 Mar 2021 19:58:20

US3032242

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 14:52:51

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:06:09
User entered 'mmHg'	System	25 Mar 2021 19:58:20

US3032242

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 14:52:51

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:06:09
User signature succeeded.	Keith Vrbicky (b) (4) (b) (4)	06 Apr 2021 15:40:50
User entered '77'	Kelsey Kelley (b) (4) (b) (4)	25 Mar 2021 19:58:20

US3032242

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 14:52:51

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:06:09
User entered 'mmHg'	System	25 Mar 2021 19:58:20

US3032242

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 14:52:51

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:06:09
User accepted default value 'Post-Dose (POSTDOSE)'	Kelsey Kelley (b) (4) (b) (4)	25 Mar 2021 19:59:00

US3032242

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 14:52:51

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:06:09
User signature succeeded.	Keith Vrbicky (b) (4) (b) (4)	06 Apr 2021 15:40:50
User entered 'Yes (Y)'	Kelsey Kelley (b) (4) (b) (4)	25 Mar 2021 19:59:00

US3032242

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 14:52:51

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:06:09
User signature succeeded.	Keith Vrbicky (b) (4)	06 Apr 2021 15:40:50
User entered '18 Mar 2021'	(b) (4) Kelsey Kelley (b) (4)	25 Mar 2021 19:59:00
	(b) (4)	

US3032242

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 14:52:51

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:06:09
User signature succeeded.	Keith Vrbicky (b) (4)	06 Apr 2021 15:40:50
User entered '12:29'	(b) (4) Kelsey Kelley (b) (4)	25 Mar 2021 19:59:00

US3032242

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 14:52:51

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:06:09
User entered '18 Mar 2021 12:29'	System	25 Mar 2021 19:59:00

US3032242

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 14:52:51

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:06:09
User signature succeeded.	Keith Vrbicky (b) (4) (b) (4)	06 Apr 2021 15:40:50
User entered '36.7' C	Kelsey Kelley (b) (4) (b) (4)	25 Mar 2021 19:59:00

US3032242

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 14:52:51

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:06:09
User signature succeeded.	Keith Vrbicky (b) (4) (b) (4)	06 Apr 2021 15:40:50
User entered 'Oral (Oral)'	Kelsey Kelley (b) (4) (b) (4)	25 Mar 2021 19:59:00

US3032242

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 14:52:51

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:06:09
User signature succeeded.	Keith Vrbicky (b) (4)	06 Apr 2021 15:40:50
User entered empty.	(b) (4) Kelsey Kelley (b) (4)	25 Mar 2021 19:59:00
	(b) (4)	

US3032242

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 14:52:51

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:06:09
User signature succeeded.	Keith Vrbicky (b) (4) (b) (4)	06 Apr 2021 15:40:50
User entered '75'	Kelsey Kelley (b) (4) (b) (4)	25 Mar 2021 19:59:00

US3032242

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 14:52:51

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:06:09
User entered 'bpm'	System	25 Mar 2021 19:59:00

US3032242

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 14:52:51

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:06:09
User signature succeeded.	Keith Vrbicky (b) (4) (b) (4)	06 Apr 2021 15:40:50
User entered '15'	Kelsey Kelley (b) (4) (b) (4)	25 Mar 2021 19:59:00

US3032242

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 14:52:51

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:06:09
User entered 'breaths/min'	System	25 Mar 2021 19:59:00

US3032242

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 14:52:51

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:06:09
User signature succeeded.	Keith Vrbicky (b) (4) (b) (4)	06 Apr 2021 15:40:50
User entered '118'	Kelsey Kelley (b) (4) (b) (4)	25 Mar 2021 19:59:00

US3032242

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 14:52:51

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:06:09
User entered 'mmHg'	System	25 Mar 2021 19:59:00

US3032242

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 14:52:51

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:06:09
User signature succeeded.	Keith Vrbicky (b) (4) (b) (4)	06 Apr 2021 15:40:50
User entered '76'	Kelsey Kelley (b) (4) (b) (4)	25 Mar 2021 19:59:00

US3032242

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 14:52:51

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:06:09
User entered 'mmHg'	System	25 Mar 2021 19:59:00

US3032242

Folder: OL-D29 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 14:52:51

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:06:09
User signature succeeded.	Keith Vrbicky (b) (4)	06 Apr 2021 15:40:50
User entered 'Yes (Y)'	(b) (4) Kelsey Kelley (b) (4)	25 Mar 2021 19:58:28

US3032242

Folder: OL-D29 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 14:52:51

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:06:09
User signature succeeded.	Keith Vrbicky (b) (4)	06 Apr 2021 15:40:50
User entered '18 Mar 2021'	(b) (4) Kelsey Kelley (b) (4)	25 Mar 2021 19:58:28
	(b) (4)	

US3032242

Folder: OL-D29 (1)

Form: Exposure

Generated On: 09 Jun 2021 14:52:51

[Was study treatment given?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:06:09
User signature succeeded.	Keith Vrbicky (b) (4)	06 Apr 2021 15:40:50
User entered 'Yes (Y)'	(b) (4) Kelsey Kelley (b) (4)	25 Mar 2021 19:58:37

US3032242

Folder: OL-D29 (1)

Form: Exposure

Generated On: 09 Jun 2021 14:52:51

[If No, reason not given](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:06:09
User signature succeeded.	Keith Vrbicky (b) (4)	06 Apr 2021 15:40:50
User entered empty.	(b) (4) Kelsey Kelley (b) (4)	25 Mar 2021 19:58:37

US3032242

Folder: OL-D29 (1)

Form: Exposure

Generated On: 09 Jun 2021 14:52:51

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:06:09
User signature succeeded.	Keith Vrbicky (b) (4)	06 Apr 2021 15:40:50
User entered empty.	(b) (4) Kelsey Kelley (b) (4)	25 Mar 2021 19:58:37
	(b) (4)	

US3032242

Folder: OL-D29 (1)

Form: Exposure

Generated On: 09 Jun 2021 14:52:51

[What was the study treatment? \(Unblinded\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:06:09
User entered 'mRNA-1273'	System	25 Mar 2021 19:58:37
DataPoint set to visible.	System	11 Mar 2021 22:15:18

US3032242

Folder: OL-D29 (1)

Form: Exposure

Generated On: 09 Jun 2021 14:52:51

[What was the treatment date? \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:06:09
User signature succeeded.	Keith Vrbicky (b) (4)	06 Apr 2021 15:40:50
User entered '18 Mar 2021'	(b) (4) Kelsey Kelley (b) (4)	25 Mar 2021 19:58:37

US3032242

Folder: OL-D29 (1)

Form: Exposure

Generated On: 09 Jun 2021 14:52:51

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:06:09
User signature succeeded.	Keith Vrbicky (b) (4)	06 Apr 2021 15:40:50
User entered '11:57'	(b) (4) Kelsey Kelley (b) (4)	25 Mar 2021 19:58:37

US3032242

Folder: OL-D29 (1)

Form: Exposure

Generated On: 09 Jun 2021 14:52:51

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:06:09
User entered '18 Mar 2021 11:57'	System	25 Mar 2021 19:58:37

US3032242

Folder: OL-D29 (1)

Form: Exposure

Generated On: 09 Jun 2021 14:52:51

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:06:09
User signature succeeded.	Keith Vrbicky (b) (4)	06 Apr 2021 15:40:50
User entered 'Left Arm (LEFT ARM)'	Kelsey Kelley (b) (4)	25 Mar 2021 19:58:37

US3032242

Folder: OL-D29 (1)

Form: Exposure

Generated On: 09 Jun 2021 14:52:51

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:06:09
User entered 'ONCE'	System	25 Mar 2021 19:58:37

US3032242

Folder: OL-D29 (1)

Form: Exposure

Generated On: 09 Jun 2021 14:52:51

[What was the route of administration for the study treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:06:09
User entered 'INTRAMUSCULAR'	System	25 Mar 2021 19:58:37

US3032242

Folder: OL-D29 (1)

Form: Continuing

Generated On: 09 Jun 2021 14:52:51

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:06:09
User signature succeeded.	Keith Vrbicky (b) (4)	06 Apr 2021 15:40:50
User entered 'Yes (Y)'	(b) (4) Kelsey Kelley (b) (4)	25 Mar 2021 19:58:39
	(b) (4)	

US3032242

Folder: OL-D29 (1)

Form: Continuing

Generated On: 09 Jun 2021 14:52:51

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:06:09
User entered '1'	System	25 Mar 2021 19:58:39

US3032242

Folder: Safety Call OL-D36 (1)

Form: Safety Call

Generated On: 09 Jun 2021 14:52:51

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:06:09
User signature succeeded.	Keith Vrbicky (b) (4)	06 Apr 2021 15:40:50
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	25 Mar 2021 20:28:26

US3032242

Folder: Safety Call OL-D36 (1)

Form: Safety Call

Generated On: 09 Jun 2021 14:52:51

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:06:09
User signature succeeded.	Keith Vrbicky (b) (4)	06 Apr 2021 15:40:50
User entered '25 Mar 2021'	(b) (4) (b) (4), (b) (6)	25 Mar 2021 20:28:26

US3032242

Folder: Safety Call OL-D36 (1)

Form: Safety Call

Generated On: 09 Jun 2021 14:52:51

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:06:09
User signature succeeded.	Keith Vrbicky (b) (4)	06 Apr 2021 15:40:50
User entered 'Contact Made (CONTACT MADE)'	(b) (4) (b) (4), (b) (6)	25 Mar 2021 20:28:26

US3032242

Folder: Safety Call OL-D36 (1)

Form: Safety Call

Generated On: 09 Jun 2021 14:52:51

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:06:09
User signature succeeded.	Keith Vrbicky (b) (4)	06 Apr 2021 15:40:50
User entered empty.	(b) (4) (b) (4), (b) (6)	25 Mar 2021 20:28:26

US3032242

Folder: Safety Call OL-D36 (1)

Form: Continuing

Generated On: 09 Jun 2021 14:52:51

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:06:09
User signature succeeded.	Keith Vrbicky (b) (4)	06 Apr 2021 15:40:50
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	25 Mar 2021 20:30:02

US3032242

Folder: Safety Call OL-D36 (1)

Form: Continuing

Generated On: 09 Jun 2021 14:52:51

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:06:09
User entered 'I'	System	25 Mar 2021 20:30:02

US3032242

Folder: OL-D57 (1)

Form: Visit Date

Generated On: 09 Jun 2021 14:52:51

[Was this visit performed?](#)

Audit	User	Time (GMT)
User signature succeeded.	Keith Vrbicky (b) (4)	14 Apr 2021 19:22:59
	(b) (4)	
User entered 'Yes (Y)'	Kelsey Kelley (b) (4)	13 Apr 2021 18:43:18
	(b) (4)	

US3032242

Folder: OL-D57 (1)

Form: Visit Date

Generated On: 09 Jun 2021 14:52:51

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

Audit	User	Time (GMT)
User signature succeeded.	Keith Vrbicky (b) (4)	14 Apr 2021 19:22:59
	(b) (4)	
User entered '13 Apr 2021'	Kelsey Kelley (b) (4)	13 Apr 2021 18:43:18
	(b) (4)	

US3032242

Folder: OL-D57 (1)

Form: Visit Date

Generated On: 09 Jun 2021 14:52:51

[Was visit performed at the participant's home or at the clinic?](#)

Audit	User	Time (GMT)
User signature succeeded.	Keith Vrbicky (b) (4)	14 Apr 2021 19:22:59
	(b) (4)	
User entered 'Clinic (Clinic)'	Kelsey Kelley (b) (4)	13 Apr 2021 18:43:18
	(b) (4)	

US3032242

Folder: OL-D57 (1)

Form: Visit Date

Generated On: 09 Jun 2021 14:52:51

[Folder OID](#)

Audit	User	Time (GMT)
User entered 'OLD57'	System	13 Apr 2021 18:43:18

US3032242

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 14:52:51

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
User signature succeeded.	Keith Vrbicky (b) (4)	14 Apr 2021 19:22:59
	(b) (4)	
User entered 'Yes (Y)'	Kelsey Kelley (b) (4)	13 Apr 2021 18:43:37
	(b) (4)	

US3032242

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 14:52:51

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Keith Vrbicky (b) (4)	14 Apr 2021 19:22:59
	(b) (4)	
User entered '13 Apr 2021'	Kelsey Kelley (b) (4)	13 Apr 2021 18:43:37
	(b) (4)	

US3032242

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 14:52:51

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

Audit	User	Time (GMT)
User signature succeeded.	Keith Vrbicky (b) (4)	14 Apr 2021 19:22:59
	(b) (4)	
User entered '12:55'	Kelsey Kelley (b) (4)	13 Apr 2021 18:43:37
	(b) (4)	

US3032242

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 14:52:51

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

Audit	User	Time (GMT)
User entered '13 Apr 2021 12:55'	System	13 Apr 2021 18:43:37

US3032242

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 14:52:51

Temperature (xxx.x)

Audit	User	Time (GMT)
User signature succeeded.	Keith Vrbicky (b) (4)	14 Apr 2021 19:22:59
	(b) (4)	
User entered '36.7' C	Kelsey Kelley (b) (4)	13 Apr 2021 18:43:37
	(b) (4)	

US3032242

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 14:52:51

[Route of measurement](#)

Audit	User	Time (GMT)
User signature succeeded.	Keith Vrbicky (b) (4)	14 Apr 2021 19:22:59
	(b) (4)	
User entered 'Oral (Oral)'	Kelsey Kelley (b) (4)	13 Apr 2021 18:43:37
	(b) (4)	

US3032242

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 14:52:51

[If Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Keith Vrbicky (b) (4)	14 Apr 2021 19:22:59
	(b) (4)	
User entered empty.	Kelsey Kelley (b) (4)	13 Apr 2021 18:43:37
	(b) (4)	

US3032242

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 14:52:51

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Keith Vrbicky (b) (4) (b) (4)	14 Apr 2021 19:22:59
User entered '55'	Kelsey Kelley (b) (4) (b) (4)	13 Apr 2021 18:43:37

US3032242

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 14:52:51

[Pulse units](#)

Audit	User	Time (GMT)
User entered 'bpm'	System	13 Apr 2021 18:43:37

US3032242

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 14:52:51

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

Audit	User	Time (GMT)
User signature succeeded.	Keith Vrbicky (b) (4)	14 Apr 2021 19:22:59
	(b) (4)	
User entered '17'	Kelsey Kelley (b) (4)	13 Apr 2021 18:43:37
	(b) (4)	

US3032242

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 14:52:51

[Respiratory Rate units](#)

Audit	User	Time (GMT)
User entered 'breaths/min'	System	13 Apr 2021 18:43:37

US3032242

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 14:52:51

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

Audit	User	Time (GMT)
User signature succeeded.	Keith Vrbicky (b) (4)	14 Apr 2021 19:22:59
	(b) (4)	
User entered '117'	Kelsey Kelley (b) (4)	13 Apr 2021 18:43:37
	(b) (4)	

US3032242

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 14:52:51

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered 'mmHg'	System	13 Apr 2021 18:43:37

US3032242

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 14:52:51

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

Audit	User	Time (GMT)
User signature succeeded.	Keith Vrbicky (b) (4)	14 Apr 2021 19:22:59
	(b) (4)	
User entered '64'	Kelsey Kelley (b) (4)	13 Apr 2021 18:43:37
	(b) (4)	

US3032242

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 14:52:51

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered 'mmHg'	System	13 Apr 2021 18:43:37

US3032242

Folder: OL-D57 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 14:52:51

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
User signature succeeded.	Keith Vrbicky (b) (4)	14 Apr 2021 19:22:59
	(b) (4)	
User entered 'No (N)'	Kelsey Kelley (b) (4)	13 Apr 2021 18:44:16
	(b) (4)	

US3032242

Folder: OL-D57 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 14:52:51

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Keith Vrbicky (b) (4)	14 Apr 2021 19:22:59
	(b) (4)	
User entered empty.	Kelsey Kelley (b) (4)	13 Apr 2021 18:44:16
	(b) (4)	

US3032242

Folder: OL-D57 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 14:52:51

[Was the sample collected?](#)

Audit	User	Time (GMT)
User signature succeeded.	Keith Vrbicky (b) (4)	14 Apr 2021 19:22:59
	(b) (4)	
User entered 'Yes (Y)'	Kelsey Kelley (b) (4)	13 Apr 2021 18:44:24
	(b) (4)	

US3032242

Folder: OL-D57 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 14:52:51

Collection date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Keith Vrbicky (b) (4)	14 Apr 2021 19:22:59
	(b) (4)	
User entered '13 Apr 2021'	Kelsey Kelley (b) (4)	13 Apr 2021 18:44:24
	(b) (4)	

US3032242

Folder: OL-D57 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 14:52:51

Collection time (00:00-23:59)

Audit	User	Time (GMT)
User signature succeeded.	Keith Vrbicky (b) (4)	14 Apr 2021 19:22:59
	(b) (4)	
User entered '13:04'	Kelsey Kelley (b) (4)	13 Apr 2021 18:44:24
	(b) (4)	

US3032242

Folder: OL-D57 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 14:52:51

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

Audit	User	Time (GMT)
User entered '13 Apr 2021 13:04'	System	13 Apr 2021 18:44:24

US3032242

Folder: Adverse Events

Form: Adverse Events Summary

Generated On: 09 Jun 2021 14:52:51

[Did the participant experience any adverse events?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 06:09:04
DataPoint Verified.	(b) (4)	11 Mar 2021 22:49:12
User signature succeeded.	Keith Vrbicky (b) (4)	05 Feb 2021 19:41:27
User entered 'Yes (Y)'	(b) (4) Linden DeBoer (b) (4)	05 Feb 2021 14:49:37
	(b) (4)	

US3032242

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 14:52:51

[AEID](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Mar 2021 22:54:14
User signature succeeded.	Keith Vrbicky (b) (4)	22 Feb 2021 17:26:08
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	08 Feb 2021 15:49:27
User entered 'USA-US032-2021-mRNA-1273-P301000006'	System	08 Feb 2021 15:49:16
User entered 'New'	(b) (4), (b) (6)	08 Feb 2021 15:49:16

US3032242

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 14:52:51

[Adverse event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Mar 2021 22:54:14
User signature succeeded.	Keith Vrbicky (b) (4)	22 Feb 2021 17:26:08
User coded data point as SOC: Neoplasms benign, malignant and unspecified (incl cysts and polyps), HLT: Reproductive neoplasms female malignant and unspecified, HLT: Endometrial neoplasms malignant, PT: Endometrial cancer, LLT: Endometrial cancer - version MedDRA\23.0.	Coder Import (b) (4)	05 Feb 2021 14:54:42
User coded data point as Term Coded data point by User: Coder System - version MedDRA\23.0.	Coder Import (b) (4)	05 Feb 2021 14:54:42
Data point term sent to Coder	System	05 Feb 2021 14:53:58
User entered 'Endometrial Cancer'	Linden DeBoer (b) (4)	05 Feb 2021 14:53:05

US3032242

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 14:52:51

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Mar 2021 22:54:14
User signature succeeded.	Keith Vrbicky (b) (4)	22 Feb 2021 17:26:08
User entered 'Yes (Y)'	(b) (4) Linden DeBoer (b) (4)	05 Feb 2021 14:53:05
	(b) (4)	

US3032242

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 14:52:51

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Mar 2021 22:54:14
User signature succeeded.	Keith Vrbicky (b) (4)	22 Feb 2021 17:26:08
User entered 'No (N)'	(b) (4) Linden DeBoer (b) (4)	05 Feb 2021 14:53:05
	(b) (4)	

US3032242

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 14:52:51

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Mar 2021 22:54:14
User signature succeeded.	Keith Vrbicky (b) (4)	22 Feb 2021 17:26:08
User entered 'No (N)'	(b) (4) Linden DeBoer (b) (4)	05 Feb 2021 14:53:05
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 14:52:51

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Mar 2021 22:54:14
User signature succeeded.	Keith Vrbicky (b) (4)	22 Feb 2021 17:26:08
User entered '29 Dec 2020'	(b) (4) Linden DeBoer (b) (4)	05 Feb 2021 14:53:05
	(b) (4)	

US3032242

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 14:52:51

Start time (00:00-23:59)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Mar 2021 22:54:14
User signature succeeded.	Keith Vrbicky (b) (4)	22 Feb 2021 17:26:08
User entered empty.	(b) (4) Linden DeBoer (b) (4)	05 Feb 2021 14:53:05
	(b) (4)	

US3032242

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 14:52:51

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	05 Feb 2021 14:53:05

US3032242

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 14:52:51

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Keith Vrbicky (b) (4)	09 Apr 2021 18:08:00
DataPoint Un-verified.	(b) (4)	
	Kelsey Kelley (b) (4)	05 Apr 2021 20:40:32
	(b) (4)	
User entered 'Yes (Y)' reason for change: New Information	Kelsey Kelley (b) (4)	05 Apr 2021 20:40:32
DataPoint Verified.	(b) (4), (b) (6)	11 Mar 2021 22:54:14
Signature has been broken.	Kelsey Kelley (b) (4)	23 Feb 2021 23:40:38
	(b) (4)	
User entered 'No (N)' reason for change: New Information	Kelsey Kelley (b) (4)	23 Feb 2021 23:40:38
	(b) (4)	
User signature succeeded.	Keith Vrbicky (b) (4)	22 Feb 2021 17:26:08
	(b) (4)	
User entered 'Yes (Y)' reason for change: Data Entry Error	Chelsie Nutsch (b) (4)	05 Feb 2021 22:42:40
	(b) (4)	
User entered 'No (N)' reason for change: Data Entry Error	Kelsey Kelley (b) (4)	05 Feb 2021 20:58:11
	(b) (4)	
User entered 'Yes (Y)'	Linden DeBoer (b) (4)	05 Feb 2021 14:53:05
	(b) (4)	

US3032242

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 14:52:51

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
User closed query 'PV Query: Please provide the event end date, when available. If a new baseline has been established (diagnosis of stabilized, chronic or recurrent condition) for the subject, then the SAE is considered resolved with sequelae and an end date should be associated at that time.?Please leave query open until information is available.' (Site from Safety).	(b) (4), (b) (6)	30 Apr 2021 13:37:16
Query 'PV Query: Please provide the event end date, when available. If a new baseline has been established (diagnosis of stabilized, chronic or recurrent condition) for the subject, then the SAE is considered resolved with sequelae and an end date should be associated at that time.?Please leave query open until information is available.' answered with 'no new baseline has been established. Records have been requested for updates, at this time no new updates. ' (Site from Safety).	Samantha Wieseler (b) (4) (b) (4)	29 Apr 2021 15:07:58
User opened query 'PV Query: Please provide the event end date, when available. If a new baseline has been established (diagnosis of stabilized, chronic or recurrent condition) for the subject, then the SAE is considered resolved with sequelae and an end date should be associated at that time.?Please leave query open until information is available.' (Site from Safety).	(b) (4), (b) (6)	29 Apr 2021 14:34:58
Query 'PV Query: Please provide the event end date, when available. If a new baseline has been established (diagnosis of stabilized, chronic or recurrent condition) for the subject, then the SAE is considered resolved with sequelae and an end date should be associated at that ' canceled (Site from Safety).	(b) (4), (b) (6)	15 Apr 2021 16:06:05
User opened query 'PV Query: Please provide the event end date, when available. If a new baseline has been established (diagnosis of stabilized, chronic or recurrent condition) for the subject, then the SAE is considered resolved with sequelae and an end date should be associated at that ' (Site from Safety).	(b) (4), (b) (6)	15 Apr 2021 16:05:07
User signature succeeded.	Keith Vrbicky (b) (4) (b) (4)	09 Apr 2021 18:08:00

US3032242

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 14:52:51

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Un-verified.	Kelsey Kelley (b) (4)	05 Apr 2021 20:40:32
	(b) (4)	
User entered empty; reason for change New Information	Kelsey Kelley (b) (4)	05 Apr 2021 20:40:32
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	11 Mar 2021 22:54:14
Signature has been broken.	Kelsey Kelley (b) (4)	23 Feb 2021 23:40:38
	(b) (4)	
User entered '5 Feb 2021' reason for change: New Information	Kelsey Kelley (b) (4)	23 Feb 2021 23:40:38
User signature succeeded.	(b) (4)	
	Keith Vrbicky (b) (4)	22 Feb 2021 17:26:08
	(b) (4)	
User closed query 'Ongoing is No, but End Date is missing. Please provide.' (Site from System).	System	05 Feb 2021 22:42:40
User closed query 'Outcome is not Recovered/Resolved, Recovered/Resolved with sequelae or Fatal, but End Date is provided. Please correct.' (Site from System).	System	05 Feb 2021 22:42:23
Query 'Outcome is not Recovered/Resolved, Recovered/Resolved with sequelae or Fatal, but End Date is provided. Please correct.' answered by data change (Site from System).	System	05 Feb 2021 22:42:23
User opened query 'Ongoing is No, but End Date is missing. Please provide.' (Site from System).	System	05 Feb 2021 22:42:23
User entered empty; reason for change Data Entry Error	Chelsie Nutsch (b) (4)	05 Feb 2021 22:42:23
	(b) (4)	
User opened query 'Outcome is not Recovered/Resolved, Recovered/Resolved with sequelae or Fatal, but End Date is provided. Please correct.' (Site from System).	System	05 Feb 2021 20:58:11
User entered '1 Feb 2021' reason for change: Data Entry Error	Kelsey Kelley (b) (4)	05 Feb 2021 20:58:11
	(b) (4)	
User entered empty.	Linden DeBoer (b) (4)	05 Feb 2021 14:53:05
	(b) (4)	

US3032242

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 14:52:51

End time (00:00-23:59)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Mar 2021 22:54:14
User signature succeeded.	Keith Vrbicky (b) (4)	22 Feb 2021 17:26:08
User entered empty.	(b) (4) Linden DeBoer (b) (4)	05 Feb 2021 14:53:05

US3032242

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 14:52:51

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Query 'PV Query: Please provide the event end date, when available. If a new baseline has been established (diagnosis of stabilized, chronic or recurrent condition) for the subject, then the SAE is considered resolved with sequelae and an end date should be associated at that time.?Please leave query open until information is available.' canceled (Site from Safety).	(b) (4), (b) (6)	29 Apr 2021 14:35:46
User opened query 'PV Query: Please provide the event end date, when available. If a new baseline has been established (diagnosis of stabilized, chronic or recurrent condition) for the subject, then the SAE is considered resolved with sequelae and an end date should be associated at that time.?Please leave query open until information is available.' (Site from Safety).	(b) (4), (b) (6)	10 Feb 2021 17:20:48
User entered empty.	System	05 Feb 2021 14:53:05

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[Severity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Mar 2021 22:54:14
User signature succeeded.	Keith Vrbicky (b) (4)	22 Feb 2021 17:26:08
User entered 'Grade 3/Severe (Grade 3/Severe)'	(b) (4) Linden DeBoer (b) (4)	05 Feb 2021 14:53:05

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Folder: Adverse Events

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[Is the adverse event serious?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Mar 2021 22:54:14
User signature succeeded.	Keith Vrbicky (b) (4)	22 Feb 2021 17:26:08
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	05 Feb 2021 20:58:11
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	05 Feb 2021 14:53:05
User entered 'Yes (Y)'	Linden DeBoer (b) (4) (b) (4)	05 Feb 2021 14:53:05

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Folder: Adverse Events

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[Death](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Mar 2021 22:54:14
User signature succeeded.	Keith Vrbicky (b) (4)	22 Feb 2021 17:26:08
User entered '0'	(b) (4) Linden DeBoer (b) (4)	05 Feb 2021 14:53:05

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Folder: Adverse Events

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[Life threatening](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Mar 2021 22:54:14
User signature succeeded.	Keith Vrbicky (b) (4)	22 Feb 2021 17:26:08
User entered '0'	(b) (4) Linden DeBoer (b) (4)	05 Feb 2021 14:53:05

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Folder: Adverse Events

Form: Adverse Events (1)

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Requires inpatient or prolongation of existing Hospitalization

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Mar 2021 22:54:14
User signature succeeded.	Keith Vrbicky (b) (4)	22 Feb 2021 17:26:08
User closed query 'PV Query: Please confirm if the subject was hospitalized for hysterectomy and dates of hospitalization. If so, please reassess the reported seriousness criterion and determine if any other seriousness criteria were met (i.e. hospitalization).' (Site from Safety).	(b) (4) (b) (4), (b) (6)	19 Feb 2021 18:42:56
Query 'PV Query: Please confirm if the subject was hospitalized for hysterectomy and dates of hospitalization. If so, please reassess the reported seriousness criterion and determine if any other seriousness criteria were met (i.e. hospitalization).' answered with 'The subject was hospitalized <24 hours. ' (Site from Safety).	Chelsie Nutsch (b) (4) (b) (4)	19 Feb 2021 17:53:31
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), (b) (6)	15 Feb 2021 18:23:13
User opened query 'PV Query: Please confirm if the subject was hospitalized for hysterectomy and dates of hospitalization. If so, please reassess the reported seriousness criterion and determine if any other seriousness criteria were met (i.e. hospitalization).' (Site from Safety).	(b) (4), (b) (6)	10 Feb 2021 17:19:51
Query 'Requires inpatient or prolongation of existing Hospitalization is not checked, but hospitalization data has been provided. Please correct.' answered with 'Cancer diagnosis. awaiting medical records. ' (Site from System).	Linden DeBoer (b) (4) (b) (4)	05 Feb 2021 14:53:41
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	05 Feb 2021 14:53:05
User entered '0'	Linden DeBoer (b) (4) (b) (4)	05 Feb 2021 14:53:05

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Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Mar 2021 22:54:14
User signature succeeded.	Keith Vrbicky (b) (4)	22 Feb 2021 17:26:08
User entered empty.	(b) (4) Linden DeBoer (b) (4)	05 Feb 2021 14:53:05

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Form: Adverse Events (1)

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Hospital Discharge Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Mar 2021 22:54:14
User signature succeeded.	Keith Vrbicky (b) (4)	22 Feb 2021 17:26:08
User entered empty.	(b) (4) Linden DeBoer (b) (4)	05 Feb 2021 14:53:05

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Form: Adverse Events (1)

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[Admitted to ICU?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Mar 2021 22:54:14
User signature succeeded.	Keith Vrbicky (b) (4)	22 Feb 2021 17:26:08
User closed query 'Admitted to ICU? is Unknown. However, this data must be collected. Please leave this query open until the response can be updated to Yes or No.' (Site from System).	(b) (4)	05 Feb 2021 14:53:54
Query 'Admitted to ICU? is Unknown. However, this System data must be collected. Please leave this query open until the response can be updated to Yes or No.' answered by data change (Site from System).	System	05 Feb 2021 14:53:54
User entered 'No (N)' reason for change: Data Entry Error	Linden DeBoer (b) (4)	05 Feb 2021 14:53:54
User opened query 'Admitted to ICU? is Unknown. However, this data must be collected. Please leave this query open until the response can be updated to Yes or No.' (Site from System).	(b) (4)	05 Feb 2021 14:53:05
User entered 'Unknown (UNK)'	System	05 Feb 2021 14:53:05
	Linden DeBoer (b) (4)	05 Feb 2021 14:53:05
	(b) (4)	

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[Number of Days in ICU](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Mar 2021 22:54:14
User signature succeeded.	Keith Vrbicky (b) (4)	22 Feb 2021 17:26:08
User entered empty.	(b) (4) Linden DeBoer (b) (4)	05 Feb 2021 14:53:05
	(b) (4)	

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[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Mar 2021 22:54:14
User signature succeeded.	Keith Vrbicky (b) (4)	22 Feb 2021 17:26:08
User entered '0'	(b) (4) Linden DeBoer (b) (4)	05 Feb 2021 14:53:05
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (1)

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[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Mar 2021 22:54:14
User signature succeeded.	Keith Vrbicky (b) (4)	22 Feb 2021 17:26:08
User entered '0'	(b) (4) Linden DeBoer (b) (4)	05 Feb 2021 14:53:05
	(b) (4)	

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[Other medically important event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Mar 2021 22:54:14
User signature succeeded.	Keith Vrbicky (b) (4)	22 Feb 2021 17:26:08
User entered '1' reason for change: New Information	(b) (4) Kelsey Kelley (b) (4)	05 Feb 2021 20:58:11
User entered '0'	(b) (4) Linden DeBoer (b) (4)	05 Feb 2021 14:53:05

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Form: Adverse Events (1)

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[Relationship to investigational product](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Mar 2021 22:54:14
User signature succeeded.	Keith Vrbicky (b) (4)	22 Feb 2021 17:26:08
User closed query 'PV Query Urgent: Please provide updated causality assessment for the event as soon as possible, as per protocol, related or not related should be used.' (Site from Safety).	(b) (4) (b) (4), (b) (6)	19 Feb 2021 18:43:17
Query 'PV Query Urgent: Please provide updated causality assessment for the event as soon as possible, as per protocol, related or not related should be used.' answered with 'data updated' (Site from Safety).	Chelsie Nutsch (b) (4) (b) (4)	19 Feb 2021 17:57:41
User entered 'Not Related (NOT RELATED)' reason for change: Data Entry Error	Chelsie Nutsch (b) (4) (b) (4)	19 Feb 2021 17:57:15
User opened query 'PV Query Urgent: Please provide updated causality assessment for the event as soon as possible, as per protocol, related or not related should be used.' (Site from Safety).	(b) (4), (b) (6)	10 Feb 2021 17:18:40
User entered 'Not Applicable (NOT APPLICABLE)'	Linden DeBoer (b) (4) (b) (4)	05 Feb 2021 14:53:05

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Form: Adverse Events (1)

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[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
User signature succeeded.	Keith Vrbicky (b) (4)	19 Apr 2021 15:27:13
DataPoint Un-verified.	(b) (4)	
	Samantha Wieseler (b) (4)	16 Apr 2021 21:21:14
	(b) (4)	
Signature has been broken.	Samantha Wieseler (b) (4)	16 Apr 2021 21:21:14
	(b) (4)	
User entered 'Not Related (NOT RELATED)' reason for change: Data Entry Error	Samantha Wieseler (b) (4)	16 Apr 2021 21:21:14
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	11 Mar 2021 22:54:14
	(b) (4)	
User signature succeeded.	Keith Vrbicky (b) (4)	22 Feb 2021 17:26:08
	(b) (4)	
User entered 'Not Applicable (NOT APPLICABLE)'	Linden DeBoer (b) (4)	05 Feb 2021 14:53:05
	(b) (4)	

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Action taken with investigational product

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Mar 2021 22:54:14
User signature succeeded.	Keith Vrbicky (b) (4)	22 Feb 2021 17:26:08
User entered 'Not Applicable (NOT APPLICABLE)'	(b) (4) Linden DeBoer (b) (4)	05 Feb 2021 14:53:05

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Folder: Adverse Events

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None

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Mar 2021 22:54:14
User signature succeeded.	Keith Vrbicky (b) (4)	22 Feb 2021 17:26:08
User entered '0'	(b) (4) Linden DeBoer (b) (4)	05 Feb 2021 14:53:05

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Folder: Adverse Events

Form: Adverse Events (1)

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[Concomitant Medication](#)

Audit	User	Time (GMT)
User closed query 'PV Query: Please provide any other treatment given for the event including medical intervention as only hysterectomy was reported. Please add any treatment medications to the concomitant medication eCRF (including dates of administration, dose, units, frequency, route and indication). If no treatment was provided, please state so.' (Site from Safety).	(b) (4), (b) (6)	26 Apr 2021 20:03:26
Query 'PV Query: Please provide any other treatment given for the event including medical intervention as only hysterectomy was reported. Please add any treatment medications to the concomitant medication eCRF (including dates of administration, dose, units, frequency, route and indication). If no treatment was provided, please state so.' answered with 'updated. Medical records for most recent visits have requested and will update eCRF when available.' (Site from Safety).	Chelsie Nutsch (b) (4) (b) (4)	26 Apr 2021 14:13:47
User opened query 'PV Query: Please provide any other treatment given for the event including medical intervention as only hysterectomy was reported. Please add any treatment medications to the concomitant medication eCRF (including dates of administration, dose, units, frequency, route and indication). If no treatment was provided, please state so.' (Site from Safety). DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 17:45:46
User closed query 'Per DM CLR: Other Action Taken = Concomitant Medication, however there is no Concomitant Medication recorded that matches this AE (verbatim) during this timeframe. Please review and add a Con Medication as appropriate or update action taken. ' (Site from DM).		11 Mar 2021 22:54:14
User signature succeeded.	Keith Vrbicky (b) (4) (b) (4)	26 Feb 2021 13:51:26
		22 Feb 2021 17:26:08

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 14:52:51

[Concomitant Medication](#)

Audit	User	Time (GMT)
User closed query 'PV Query: Please provide any other treatment given for the event including medical intervention as only hysterectomy was reported. Please add any treatment medications to the concomitant medication eCRF (including dates of administration, dose, units, frequency, route and indication). If no treatment was provided, please state so.' (Site from Safety).	(b) (4), (b) (6)	19 Feb 2021 18:43:23
Query 'Per DM CLR: Other Action Taken = Concomitant Medication, however there is no Concomitant Medication recorded that matches this AE (verbatim) during this timeframe. Please review and add a Con Medication as appropriate or update action taken.	Chelsie Nutsch (b) (4)	19 Feb 2021 17:57:57
' answered with 'data updated' (Site from DM).	(b) (4)	
Query 'PV Query: Please provide any other treatment given for the event including medical intervention as only hysterectomy was reported. Please add any treatment medications to the concomitant medication eCRF (including dates of administration, dose, units, frequency, route and indication). If no treatment was provided, please state so.' answered with 'data updated' (Site from Safety).	Chelsie Nutsch (b) (4)	19 Feb 2021 17:57:52
User entered '0' reason for change: Data Entry Error	Chelsie Nutsch (b) (4)	19 Feb 2021 17:57:15
User opened query 'Per DM CLR: Other Action Taken = Concomitant Medication, however there is no Concomitant Medication recorded that matches this AE (verbatim) during this timeframe. Please review and add a Con Medication as appropriate or update action taken.	(b) (4), (b) (6)	15 Feb 2021 00:56:20
' (Site from DM).		
User opened query 'PV Query: Please provide any other treatment given for the event including medical intervention as only hysterectomy was reported. Please add any treatment medications to the concomitant medication eCRF (including dates of administration, dose, units, frequency, route and indication). If no treatment was provided, please state so.' (Site from Safety).		10 Feb 2021 17:24:42
User entered '1' reason for change: Data Entry Error	Chelsie Nutsch (b) (4)	05 Feb 2021 22:42:23
	(b) (4)	

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[Concomitant Medication](#)

Audit	User	Time (GMT)
User entered '0'	Linden DeBoer (b) (4) (b) (4)	05 Feb 2021 14:53:05

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[Concomitant Procedure](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Mar 2021 22:54:14
User signature succeeded.	Keith Vrbicky (b) (4)	22 Feb 2021 17:26:08
User entered '1'	(b) (4) Linden DeBoer (b) (4)	05 Feb 2021 14:53:05

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[Outcome](#)

Audit	User	Time (GMT)
User closed query 'PV Query: Please provide the final event outcome, when available. If the event has reached a new baseline where the subject has stabilized with ongoing symptoms/medications; then outcome would be Recovered/Resolved with sequelae with sequelae being the ongoing conditions.' (Site from Safety).	(b) (4), (b) (6)	26 Apr 2021 20:03:28
Query 'PV Query: Please provide the final event outcome, when available. If the event has reached a new baseline where the subject has stabilized with ongoing symptoms/medications; then outcome would be Recovered/Resolved with sequelae with sequelae being the ongoing conditions.' answered with 'not recovered/resolved. chemotherapy starting 12may2021' (Site from Safety).	Chelsie Nutsch (b) (4) (b) (4)	26 Apr 2021 14:15:44
User opened query 'PV Query: Please provide the final event outcome, when available. If the event has reached a new baseline where the subject has stabilized with ongoing symptoms/medications; then outcome would be Recovered/Resolved with sequelae with sequelae being the ongoing conditions.' (Site from Safety).	(b) (4), (b) (6)	23 Apr 2021 17:45:59
User closed query 'PV Query: Please provide the final event outcome, when available. If the event has reached a new baseline where the subject has stabilized with ongoing symptoms/medications; then outcome would be Recovered/Resolved with sequelae with sequelae being the ongoing conditions' (Site from Safety).	(b) (4), (b) (6)	19 Apr 2021 14:38:58
Query 'PV Query: Please provide the final event outcome, when available. If the event has reached a new baseline where the subject has stabilized with ongoing symptoms/medications; then outcome would be Recovered/Resolved with sequelae with sequelae being the ongoing conditions' answered with 'subject has not hit a new baseline yet. therefore AE is still considered recovering/resolving' (Site from Safety).	Samantha Wieseler (b) (4) (b) (4)	16 Apr 2021 21:19:49

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[Outcome](#)

Audit	User	Time (GMT)
User opened query 'PV Query: Please provide the final event outcome, when available. If the event has reached a new baseline where the subject has stabilized with ongoing symptoms/medications; then outcome would be Recovered/Resolved with sequelae with sequelae being the ongoing conditions' (Site from Safety). User signature succeeded.	(b) (4), (b) (6) [REDACTED]	15 Apr 2021 16:06:28
DataPoint Un-verified.	Keith Vrbicky (b) (4) [REDACTED]	09 Apr 2021 18:08:00
User entered 'Recovering/Resolving (RECOVERING/RESOLVING)' reason for change: New Information DataPoint Verified.	Kelsey Kelley (b) (4) [REDACTED]	05 Apr 2021 20:40:32
Signature has been broken.	Kelsey Kelley (b) (4) [REDACTED]	05 Apr 2021 20:40:32
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)' reason for change: New Information User signature succeeded.	(b) (4), (b) (6) [REDACTED]	11 Mar 2021 22:54:14
User closed query 'PV Query: Please provide the final event outcome, when available. If the event has reached a new baseline where the subject has stabilized with ongoing symptoms/medications; then outcome would be Recovered/Resolved with sequelae with sequelae being the ongoing conditions.' (Site from Safety). Query 'PV Query: Please provide the final event outcome, when available. If the event has reached a new baseline where the subject has stabilized with ongoing symptoms/medications; then outcome would be Recovered/Resolved with sequelae with sequelae being the ongoing conditions.' answered with 'Event is still ongoing.' (Site from Safety).	Kelsey Kelley (b) (4) [REDACTED]	23 Feb 2021 23:40:38
	Keith Vrbicky (b) (4) [REDACTED]	23 Feb 2021 23:40:38
	(b) (4) [REDACTED]	22 Feb 2021 17:26:08
	(b) (4), (b) (6) [REDACTED]	19 Feb 2021 18:43:28
	Chelsie Nutsch (b) (4) [REDACTED]	19 Feb 2021 17:58:18

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[Outcome](#)

Audit	User	Time (GMT)
User opened query 'PV Query: Please provide the final event outcome, when available. If the event has reached a new baseline where the subject has stabilized with ongoing symptoms/medications; then outcome would be Recovered/Resolved with sequelae with sequelae being the ongoing conditions.' (Site from Safety).	(b) (4), (b) (6)	10 Feb 2021 17:22:47
User entered 'Recovering/Resolving (RECOVERING/RESOLVING)' reason for change: Data Entry Error	Kelsey Kelley (b) (4) (b) (4)	05 Feb 2021 20:58:51
User entered 'Unknown (UNKNOWN)'	Linden DeBoer (b) (4) (b) (4)	05 Feb 2021 14:53:05

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If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Mar 2021 22:54:14
User signature succeeded.	Keith Vrbicky (b) (4)	22 Feb 2021 17:26:08
User entered empty.	(b) (4) Linden DeBoer (b) (4)	05 Feb 2021 14:53:05

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[Narrative](#)

Audit	User	Time (GMT)
User signature succeeded.	Keith Vrbicky (b) (4) (b) (4)	03 May 2021 16:17:41

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[Narrative](#)

Audit	User	Time (GMT)
User entered 'SUBJECT ENTERED IN HER EDAIRY 05/FEB/2021 THAT MEDICAL ATTENTION WAS NEEDED. SITE THEN CALLED SUBJECT AND SUBJECT REPORTED THE CANCER AND THAT SHE HAD A HYSTERECTOMY 01FEB2021. MEDICAL RELEASE HAS BEEN SENT TO SUBJECT. FOLLOW UP TREATMENT IS UNKNOWN AT THIS TIME. AWAITING A PATHOLOGY REPORT. UPDATE 17FEB2021: MEDICAL RECORDS RECEIVED AND REVIEWED. THE SUBJECT WAS SEEN 23DEC2020 BY HER OB/GYN FOR EVALUATION OF POST-MENOPAUSAL VAGINAL BLEEDING THAT WORSENEED OVER ONE MONTH. COPOSCOPY WAS PERFORMED WHICH RESULTED IN RESULTS OF ENDOMETRIAL ADENOCARCINOMA GRADE 2/3. THE SUBJECT HAD NOT HAD A PAP SMEAR IN THE LAST 25 YEARS. TREATMENT WILL BE BASED ON RECOMMENDATION MADE BY THE ONCOLOGIST. UPDATE 26APR2021: FINAL DIAGNOSIS FROM SUBJECTS 23DEC2020 ENDOMETRIAL BIOPSY AND COLPOSCOPY: A) ENDOCERVICAL POLYP EXCISION: BENIGN. B) ENDOCERVIX CURRETAGE: SCAN BENIGN ECTOCERVICAL TISSUE, MUCUS, AND INFLAMMATORY DEBRIS. C) ENDOMETRIAL BIOPSY: ADENOCARCINOMA, GRADE 2/3. Update 29Apr2021: gynecologist oncologist performed davinci-assisted total laparoscopic hysterectomy w/ bilateral oophorectomy and right pelvic sentinel lymph node biopsy. pathology revealed endometrial cancer fig0 grade 3 with a 2.7x2.5x1.0 cm mass which extended deep into the myometrium and lymphovascular invasion was present. the right pelvic sentinel lymph node was biopsied and negative for carcinoma. she was treated with radiation (4500 cGy delivered om 25 fractions) final pathology consistent with grade 3 histology, stage 1B with >95%	Kelsey Kelley (b) (4) (b) (4)	30 Apr 2021 16:09:53

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[Narrative](#)

Audit	User	Time (GMT)
myometrial invasion tL VSI negative right pelvic SLN. subject has completed radiation treatments. she will begin chemotherapy (taxol/carboplatin) on 12May2021.' reason for change: Data Entry Error 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)	26 Apr 2021 20:03:30
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 'all current medical records will be redacted and sent to Moderna safety committee. Updated medical records have been requested. ' (Site from Safety).	Chelsie Nutsch (b) (4)	26 Apr 2021 14:31:55
DataPoint Un-verified.	Chelsie Nutsch (b) (4)	26 Apr 2021 14:30:37
Signature has been broken.	Chelsie Nutsch (b) (4)	26 Apr 2021 14:30:37

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[Narrative](#)

Audit	User	Time (GMT)
User entered 'SUBJECT ENTERED IN HER EDAIRY 05/FEB/2021 THAT MEDICAL ATTENTION WAS NEEDED. SITE THEN CALLED SUBJECT AND SUBJECT REPORTED THE CANCER AND THAT SHE HAD A HYSTERECTOMY 01FEB2021. MEDICAL RELEASE HAS BEEN SENT TO SUBJECT. FOLLOW UP TREATMENT IS UNKNOWN AT THIS TIME. AWAITING A PATHOLOGY REPORT. UPDATE 17FEB2021: MEDICAL RECORDS RECEIVED AND REVIEWED. THE SUBJECT WAS SEEN 23DEC2020 BY HER OB/GYN FOR EVALUATION OF POST-MENOPAUSAL VAGINAL BLEEDING THAT WORSENEED OVER ONE MONTH. COPOSCOPY WAS PERFORMED WHICH RESULTED IN RESULTS OF ENDOMETRIAL ADENOCARCINOMA GRADE 2/3. THE SUBJECT HAD NOT HAD A PAP SMEAR IN THE LAST 25 YEARS. TREATMENT WILL BE BASED ON RECOMMENDATION MADE BY THE ONCOLOGIST. Update 26apr2021: Final diagnosis from subjects 23Dec2020 endometrial biopsy and colposcopy: A) endocervical polyp excision: benign. B) endocervix curretage: scan benign ectocervical tissue, mucus, and inflammatory debris. C) Endometrial biopsy: Adenocarcinoma, grade 2/3.' reason for change: Data Entry Error	Chelsie Nutsch (b) (4) (b) (4)	26 Apr 2021 14:30:37
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)	23 Apr 2021 17:45:34

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 14:52:51

[Narrative](#)

Audit	User	Time (GMT)
User closed query 'PV Query: Study procedure refers to the information outlined in the protocol and whether something like the administration technique or some part of the protocol could be causative of this event. Since the subject received the study drug this should be Related or Not Related. Please update accordingly.' (Site from Safety).	(b) (4), (b) (6)	19 Apr 2021 14:39:08
User closed query 'PV Query: Please provide any other treatment given for the event including medical intervention as only hysterectomy was reported. Please add any treatment medications to the concomitant medication eCRF (including dates of administration, dose, units, frequency, route and indication). If no treatment was provided, please state so.' (Site from Safety).	(b) (4), (b) (6)	19 Apr 2021 14:39:06
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)	19 Apr 2021 14:39:03
Query 'PV Query: Study procedure refers to the information outlined in the protocol and whether something like the administration technique or some part of the protocol could be causative of this event. Since the subject received the study drug this should be Related or Not Related. Please update accordingly.' answered with 'updated' (Site from Safety).	Samantha Wieseler (b) (4)	16 Apr 2021 21:21:29
Query 'PV Query: Please provide any other treatment given for the event including medical intervention as only hysterectomy was reported. Please add any treatment medications to the concomitant medication eCRF (including dates of administration, dose, units, frequency, route and indication). If no treatment was provided, please state so.' answered with 'will update when radiation starts. at this time no new information. ' (Site from Safety).	Samantha Wieseler (b) (4)	16 Apr 2021 21:20:50

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Audit	User	Time (GMT)
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 'will update once radiation starts at this moment no new information. ' (Site from Safety).	Samantha Wieseler (b) (4)	16 Apr 2021 21:20:13
User opened query 'PV Query: Study procedure refers to the information outlined in the protocol and whether something like the administration technique or some part of the protocol could be causative of this event. Since the subject received the study drug this should be Related or Not Related. Please update accordingly.' (Site from Safety).	(b) (4), (b) (6)	15 Apr 2021 16:09:25
User opened query 'PV Query: Please provide any other treatment given for the event including medical intervention as only hysterectomy was reported. Please add any treatment medications to the concomitant medication eCRF (including dates of administration, dose, units, frequency, route and indication). If no treatment was provided, please state so.' (Site from Safety).	(b) (4), (b) (6)	15 Apr 2021 16:03:52
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)	15 Apr 2021 16:02:51
User closed query 'Per DM CLR: Narrative = POST-MENOPAUSAL VAGINAL BLEEDING THAT WORSENEED OVER ONE MONTH. However, please review and verify if this should be recorded as a separate AE. If yes, ensure to record this medical condition in the AE eCRF as appropriate.' (Site from DM).	(b) (4), (b) (6)	31 Mar 2021 12:01:54

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[Narrative](#)

Audit	User	Time (GMT)
User closed query 'Per DM CLR: Narrative = COPOSCOPY WAS PERFORMED. However, this is not recorded in the ConProc eCRF. Please review and ensure that this is captured in the appropriate eCRF. ' (Site from DM).	(b) (4), (b) (6)	30 Mar 2021 08:10:29
Query 'Per DM CLR: Narrative = POST-MENOPAUSAL VAGINAL BLEEDING THAT WORSENERD OVER ONE MONTH. However, please review and verify if this should be recorded as a separate AE. If yes, ensure to record this medical condition in the AE eCRF as appropriate.' answered with 'Agreed. Data updated. Thank you. ' (Site from DM).	Chelsie Nutsch (b) (4) (b) (4)	26 Mar 2021 13:52:15
Query 'Per DM CLR: Narrative = COPOSCOPY WAS PERFORMED. However, this is not recorded in the ConProc eCRF. Please review and ensure that this is captured in the appropriate eCRF. ' answered with 'Done. Thank you' (Site from DM). DataPoint Verified.	Chelsie Nutsch (b) (4) (b) (4)	26 Mar 2021 13:52:02
User opened query 'Per DM CLR: Narrative = POST-MENOPAUSAL VAGINAL BLEEDING THAT WORSENERD OVER ONE MONTH. However, please review and verify if this should be recorded as a separate AE. If yes, ensure to record this medical condition in the AE eCRF as appropriate.' (Site from DM).	(b) (4), (b) (6)	11 Mar 2021 22:54:14
User opened query 'Per DM CLR: Narrative = COPOSCOPY WAS PERFORMED. However, this is not recorded in the ConProc eCRF. Please review and ensure that this is captured in the appropriate eCRF. ' (Site from DM).	(b) (4), (b) (6)	10 Mar 2021 11:55:37
User signature succeeded.	(b) (4), (b) (6)	28 Feb 2021 02:05:23
User signature succeeded.	Keith Vrbicky (b) (4) (b) (4)	22 Feb 2021 17:26:08
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)	19 Feb 2021 18:43:32

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[Narrative](#)

Audit	User	Time (GMT)
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 'data updated' (Site from Safety).	Chelsie Nutsch (b) (4) (b) (4)	19 Feb 2021 17:58:29
User entered 'SUBJECT ENTERED IN HER EDAIRY 05/FEB/2021 THAT MEDICAL ATTENTION WAS NEEDED. SITE THEN CALLED SUBJECT AND SUBJECT REPORTED THE CANCER AND THAT SHE HAD A HYSTERECTOMY 01FEB2021. MEDICAL RELEASE HAS BEEN SENT TO SUBJECT. FOLLOW UP TREATMENT IS UNKNOWN AT THIS TIME. AWAITING A PATHOLOGY REPORT. UPDATE 17FEB2021: MEDICAL RECORDS RECEIVED AND REVIEWED. THE SUBJECT WAS SEEN 23DEC2020 BY HER OB/GYN FOR EVALUATION OF POST-MENOPAUSAL VAGINAL BLEEDING THAT WORSENERED OVER ONE MONTH. COPOSCOPY WAS PERFORMED WHICH RESULTED IN RESULTS OF ENDOMETRIAL ADENOCARCINOMA GRADE 2/3. THE SUBJECT HAD NOT HAD A PAP SMEAR IN THE LAST 25 YEARS. TREATMENT WILL BE BASED ON RECOMMENDATION MADE BY THE ONCOLOGIST.' reason for change: Data Entry Error	Chelsie Nutsch (b) (4) (b) (4)	19 Feb 2021 17:57:32

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[Narrative](#)

Audit	User	Time (GMT)
User entered 'SUBJECT ENTERED IN HER EDairy 05/FEB/2021 THAT MEDICAL ATTENTION WAS NEEDED. SITE THEN CALLED SUBJECT AND SUBJECT REPORTED THE CANCER AND THAT SHE HAD A HYSTERECTOMY 01FEB2021. MEDICAL RELEASE HAS BEEN SENT TO SUBJECT. FOLLOW UP TREATMENT IS UNKNOWN AT THIS TIME. AWAITING A PATHOLOGY REPORT. Update 17Feb2021: medical records received and reviewed. The subject was seen 23Dec2020 by her OB/GYN for evaluation of post-menopausal vaginal bleeding that worsened over one month. Coposcopy was performed which resulted in results of endometrial adenocarcinoma grade 2/3. The subject had not had a PAP smear in the last 25 years. Treatment will be based on recommendation made by the oncologist.' reason for change: Data Entry Error	Chelsie Nutsch (b) (4) (b) (4)	19 Feb 2021 17:57:15
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)	10 Feb 2021 17:21:58
User entered 'Subject entered in her edairy 05/Feb/2021 that medical attention was needed. Site then called subject and subject reported the cancer and that she had a hysterectomy 01Feb2021. Medical release has been sent to subject. Follow up treatment is unknown at this time. Awaiting a pathology report.'	Linden DeBoer (b) (4) (b) (4)	05 Feb 2021 14:53:05

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Serious Adverse Event Derived (CSA Programming Field Only)

Audit	User	Time (GMT)
User entered '1'	System	05 Feb 2021 14:53:05

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 14:52:51

Medically Attended AE Derived (CSA Programming Field Only)

Audit	User	Time (GMT)
User entered '1'	System	05 Feb 2021 14:53:05

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 14:52:51

[Admitted to ICU Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '0'	System	05 Feb 2021 14:53:05

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[AEID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:39:17

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[Adverse event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:39:17
User signature succeeded.	Keith Vrbicky (b) (4)	09 Apr 2021 18:08:00
User coded data point as SOC: Reproductive system and breast disorders, HLG: Menopause related conditions, HLT: Menopausal effects on the genitourinary tract, PT: Postmenopausal haemorrhage, LLT: Postmenopausal bleeding - version MedDRA\23.0.	Coder Import (b) (4)	29 Mar 2021 14:17:07
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\23.0.	Coder Import (b) (4)	29 Mar 2021 14:17:07
Data point term sent to Coder	System	26 Mar 2021 13:54:42
User entered 'Postmenopausal vaginal bleeding'	Chelsie Nutsch (b) (4)	26 Mar 2021 13:54:33

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[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:39:17
User signature succeeded.	Keith Vrbicky (b) (4)	09 Apr 2021 18:08:00
User entered 'Yes (Y)'	(b) (4) Chelsie Nutsch (b) (4)	26 Mar 2021 13:54:33

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Folder: Adverse Events

Form: Adverse Events (2)

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[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:39:17
User signature succeeded.	Keith Vrbicky (b) (4)	09 Apr 2021 18:08:00
User entered 'No (N)'	(b) (4) Chelsie Nutsch (b) (4)	26 Mar 2021 13:54:33

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Folder: Adverse Events

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[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:39:17
User signature succeeded.	Keith Vrbicky (b) (4)	09 Apr 2021 18:08:00
User entered 'No (N)'	(b) (4) Chelsie Nutsch (b) (4)	26 Mar 2021 13:54:33

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 14:52:51

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:39:17
User signature succeeded.	Keith Vrbicky (b) (4)	09 Apr 2021 18:08:00
User entered '23 Nov 2020'	(b) (4) Chelsie Nutsch (b) (4)	26 Mar 2021 13:54:33

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 14:52:51

Start time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:39:17
User signature succeeded.	Keith Vrbicky (b) (4)	09 Apr 2021 18:08:00
User entered empty.	(b) (4) Chelsie Nutsch (b) (4)	26 Mar 2021 13:54:33

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[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:39:17
User entered empty.	System	26 Mar 2021 13:54:33

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[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:39:17
User signature succeeded.	Keith Vrbicky (b) (4)	09 Apr 2021 18:08:00
User entered 'No (N)'	(b) (4) Chelsie Nutsch (b) (4)	26 Mar 2021 13:54:33

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Folder: Adverse Events

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If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:39:17
User signature succeeded.	Keith Vrbicky (b) (4)	09 Apr 2021 18:08:00
User entered '1 Feb 2021'	(b) (4) Chelsie Nutsch (b) (4)	26 Mar 2021 13:54:33

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 14:52:51

End time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:39:17
User signature succeeded.	Keith Vrbicky (b) (4)	09 Apr 2021 18:08:00
User entered empty.	(b) (4) Chelsie Nutsch (b) (4)	26 Mar 2021 13:54:33

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Folder: Adverse Events

Form: Adverse Events (2)

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[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:39:17
User entered empty.	System	26 Mar 2021 13:54:33

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Folder: Adverse Events

Form: Adverse Events (2)

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[Severity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:39:17
User signature succeeded.	Keith Vrbicky (b) (4)	09 Apr 2021 18:08:00
User entered 'Grade 2/Moderate (Grade 2/Moderate)'	(b) (4) Chelsie Nutsch (b) (4)	26 Mar 2021 13:54:33

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[Is the adverse event serious?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:39:17
User signature succeeded.	Keith Vrbicky (b) (4)	09 Apr 2021 18:08:00
User entered 'No (N)'	(b) (4) Chelsie Nutsch (b) (4)	26 Mar 2021 13:54:33

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Folder: Adverse Events

Form: Adverse Events (2)

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Death

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:39:17
User signature succeeded.	Keith Vrbicky (b) (4)	09 Apr 2021 18:08:00
User entered '0'	(b) (4) Chelsie Nutsch (b) (4)	26 Mar 2021 13:54:33

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Folder: Adverse Events

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[Life threatening](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:39:17
User signature succeeded.	Keith Vrbicky (b) (4)	09 Apr 2021 18:08:00
User entered '0'	(b) (4) Chelsie Nutsch (b) (4)	26 Mar 2021 13:54:33

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[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:39:17
User signature succeeded.	Keith Vrbicky (b) (4)	09 Apr 2021 18:08:00
User entered '0'	(b) (4) Chelsie Nutsch (b) (4)	26 Mar 2021 13:54:33

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Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:39:17
User signature succeeded.	Keith Vrbicky (b) (4)	09 Apr 2021 18:08:00
User entered empty.	(b) (4) Chelsie Nutsch (b) (4)	26 Mar 2021 13:54:33

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Hospital Discharge Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:39:17
User signature succeeded.	Keith Vrbicky (b) (4)	09 Apr 2021 18:08:00
User entered empty.	(b) (4) Chelsie Nutsch (b) (4)	26 Mar 2021 13:54:33

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[Admitted to ICU?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:39:17
User signature succeeded.	Keith Vrbicky (b) (4)	09 Apr 2021 18:08:00
User entered empty.	(b) (4) Chelsie Nutsch (b) (4)	26 Mar 2021 13:54:33

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[Number of Days in ICU](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:39:17
User signature succeeded.	Keith Vrbicky (b) (4)	09 Apr 2021 18:08:00
User entered empty.	(b) (4) Chelsie Nutsch (b) (4)	26 Mar 2021 13:54:33

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[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:39:17
User signature succeeded.	Keith Vrbicky (b) (4)	09 Apr 2021 18:08:00
User entered '0'	(b) (4) Chelsie Nutsch (b) (4)	26 Mar 2021 13:54:33

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[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:39:17
User signature succeeded.	Keith Vrbicky (b) (4)	09 Apr 2021 18:08:00
User entered '0'	(b) (4) Chelsie Nutsch (b) (4)	26 Mar 2021 13:54:33

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[Other medically important event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:39:17
User signature succeeded.	Keith Vrbicky (b) (4)	09 Apr 2021 18:08:00
User entered '0'	(b) (4) Chelsie Nutsch (b) (4)	26 Mar 2021 13:54:33

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[Relationship to investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:39:17
User signature succeeded.	Keith Vrbicky (b) (4)	09 Apr 2021 18:08:00
User entered 'Not Related (NOT RELATED)'	(b) (4) Chelsie Nutsch (b) (4)	26 Mar 2021 13:54:33

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[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:39:17
User signature succeeded.	Keith Vrbicky (b) (4)	09 Apr 2021 18:08:00
User entered 'Not Related (NOT RELATED)'	(b) (4) Chelsie Nutsch (b) (4)	26 Mar 2021 13:54:33

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Action taken with investigational product

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:39:17
User signature succeeded.	Keith Vrbicky (b) (4)	09 Apr 2021 18:08:00
User closed query 'Per CDM: Per CCGs, if the AE started after the last dose, 'Not applicable' should be selected for Action taken with investigational product. Please review and update this field as appropriate, else clarify. ' (Site from DM).	(b) (4) (b) (4), (b) (6)	07 Apr 2021 11:42:39
Query 'Per CDM: Per CCGs, if the AE started after the last dose, 'Not applicable' should be selected for Action taken with investigational product. Please review and update this field as appropriate, else clarify. ' answered with 'updated' (Site from DM).	Samantha Wieseler (b) (4) (b) (4)	06 Apr 2021 20:42:57
User entered 'Not Applicable (NOT APPLICABLE)' reason for change: Data Entry Error	Samantha Wieseler (b) (4) (b) (4)	06 Apr 2021 20:42:36
User opened query 'Per CDM: Per CCGs, if the AE started after the last dose, 'Not applicable' should be selected for Action taken with investigational product. Please review and update this field as appropriate, else clarify. ' (Site from DM).	(b) (4), (b) (6)	06 Apr 2021 05:46:01
User closed query 'Data is required. Please complete.' (Site from System).	System	26 Mar 2021 13:54:39
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	26 Mar 2021 13:54:39
User entered 'None (NONE)' reason for change: Data Entry Error	Chelsie Nutsch (b) (4) (b) (4)	26 Mar 2021 13:54:39
User opened query 'Data is required. Please complete.' (Site from System).	System	26 Mar 2021 13:54:33
User entered empty.	Chelsie Nutsch (b) (4) (b) (4)	26 Mar 2021 13:54:33

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None

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:39:17
User signature succeeded.	Keith Vrbicky (b) (4)	09 Apr 2021 18:08:00
User entered '0'	(b) (4) Chelsie Nutsch (b) (4)	26 Mar 2021 13:54:33

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[Concomitant Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:39:17
User signature succeeded.	Keith Vrbicky (b) (4)	09 Apr 2021 18:08:00
User entered '0'	(b) (4) Chelsie Nutsch (b) (4)	26 Mar 2021 13:54:33

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[Concomitant Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:39:17
User signature succeeded.	Keith Vrbicky (b) (4)	09 Apr 2021 18:08:00
User entered '1'	(b) (4) Chelsie Nutsch (b) (4)	26 Mar 2021 13:54:33

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[Outcome](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:39:17
User signature succeeded.	Keith Vrbicky (b) (4)	09 Apr 2021 18:08:00
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)'	(b) (4) Chelsie Nutsch (b) (4)	26 Mar 2021 13:54:33

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If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:39:17
User signature succeeded.	Keith Vrbicky (b) (4)	09 Apr 2021 18:08:00
User entered empty.	(b) (4) Chelsie Nutsch (b) (4)	26 Mar 2021 13:54:33

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[Narrative](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:39:17
User signature succeeded.	Keith Vrbicky (b) (4)	09 Apr 2021 18:08:00
User entered empty.	(b) (4) Chelsie Nutsch (b) (4)	26 Mar 2021 13:54:33

US3032242

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 14:52:51

Serious Adverse Event Derived (CSA Programming Field Only)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:39:17
User entered '0'	System	26 Mar 2021 13:54:33

US3032242

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 14:52:51

Medically Attended AE Derived (CSA Programming Field Only)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:39:17
User entered '1'	System	26 Mar 2021 13:54:33

US3032242

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 14:52:51

[Admitted to ICU Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:39:17

US3032242

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 14:52:51

[AEID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:30:26

US3032242

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 14:52:51

[Adverse event](#)

Audit	User	Time (GMT)
User signature succeeded.	Keith Vrbicky (b) (4)	03 May 2021 16:17:41
Data hard locked.	(b) (4) (b) (4), (b) (6)	30 Apr 2021 17:30:26
User coded data point as SOC: Reproductive system and breast disorders, HLG: Cervix disorders (excl infections and inflammations), HLT: Cervix neoplasms, PT: Cervical polyp, LLT: Cervical polyp - version MedDRA\\23.0.	Coder Import (b) (4)	26 Apr 2021 15:14:35
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	26 Apr 2021 15:14:35
Data point term sent to Coder	System	26 Apr 2021 15:13:51
User entered 'cervical polyp'	Kelsey Kelley (b) (4)	26 Apr 2021 15:13:00
	(b) (4)	

US3032242

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 14:52:51

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
User signature succeeded.	Keith Vrbicky (b) (4)	03 May 2021 16:17:41
Data hard locked.	(b) (4) (b) (4), (b) (6)	30 Apr 2021 17:30:26
User entered 'Yes (Y)'	Kelsey Kelley (b) (4) (b) (4)	26 Apr 2021 15:13:00

US3032242

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 14:52:51

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
User signature succeeded.	Keith Vrbicky (b) (4)	03 May 2021 16:17:41
Data hard locked.	(b) (4) (b) (4), (b) (6)	30 Apr 2021 17:30:26
User entered 'No (N)'	Kelsey Kelley (b) (4) (b) (4)	26 Apr 2021 15:13:00

US3032242

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 14:52:51

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
User signature succeeded.	Keith Vrbicky (b) (4)	03 May 2021 16:17:41
Data hard locked.	(b) (4) (b) (4), (b) (6)	30 Apr 2021 17:30:26
User entered 'No (N)'	Kelsey Kelley (b) (4) (b) (4)	26 Apr 2021 15:13:00

US3032242

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 14:52:51

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Keith Vrbicky (b) (4)	03 May 2021 16:17:41
Data hard locked.	(b) (4) (b) (4), (b) (6)	30 Apr 2021 17:30:26
User entered '23 Dec 2020'	Kelsey Kelley (b) (4) (b) (4)	26 Apr 2021 15:13:00

US3032242

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 14:52:51

Start time (00:00-23:59)

Audit	User	Time (GMT)
User signature succeeded.	Keith Vrbicky (b) (4)	03 May 2021 16:17:41
Data hard locked.	(b) (4) (b) (4), (b) (6)	30 Apr 2021 17:30:26
User entered empty.	Kelsey Kelley (b) (4) (b) (4)	26 Apr 2021 15:13:00

US3032242

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 14:52:51

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:30:26
User entered empty.	System	26 Apr 2021 15:13:00

US3032242

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 14:52:51

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Keith Vrbicky (b) (4)	03 May 2021 16:17:41
Data hard locked.	(b) (4) (b) (4), (b) (6)	30 Apr 2021 17:30:26
User entered 'No (N)'	Kelsey Kelley (b) (4) (b) (4)	26 Apr 2021 15:13:00

US3032242

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 14:52:51

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Keith Vrbicky (b) (4)	03 May 2021 16:17:41
Data hard locked.	(b) (4) (b) (4), (b) (6)	30 Apr 2021 17:30:26
User entered '23 Dec 2020'	Kelsey Kelley (b) (4) (b) (4)	26 Apr 2021 15:13:00

US3032242

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 14:52:51

End time (00:00-23:59)

Audit	User	Time (GMT)
User signature succeeded.	Keith Vrbicky (b) (4)	03 May 2021 16:17:41
Data hard locked.	(b) (4) (b) (4), (b) (6)	30 Apr 2021 17:30:26
User entered empty.	Kelsey Kelley (b) (4) (b) (4)	26 Apr 2021 15:13:00

US3032242

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 14:52:51

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	Diana Ceron (1757 - DianaPPD1)	30 Apr 2021 17:30:26
User entered empty.	System	26 Apr 2021 15:13:00

US3032242

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 14:52:51

[Severity](#)

Audit	User	Time (GMT)
User signature succeeded.	Keith Vrbicky (b) (4)	03 May 2021 16:17:41
Data hard locked.	(b) (4) (b) (4), (b) (6)	30 Apr 2021 17:30:26
User entered 'Grade 1/Mild (Grade 1/Mild)'	Kelsey Kelley (b) (4) (b) (4)	26 Apr 2021 15:13:00

US3032242

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 14:52:51

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
User signature succeeded.	Keith Vrbicky (b) (4)	03 May 2021 16:17:41
Data hard locked.	(b) (4) (b) (4), (b) (6)	30 Apr 2021 17:30:26
User entered 'No (N)'	Kelsey Kelley (b) (4) (b) (4)	26 Apr 2021 15:13:00

US3032242

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 14:52:51

Death

Audit	User	Time (GMT)
User signature succeeded.	Keith Vrbicky (b) (4)	03 May 2021 16:17:41
Data hard locked.	(b) (4) (b) (4), (b) (6)	30 Apr 2021 17:30:26
User entered '0'	Kelsey Kelley (b) (4) (b) (4)	26 Apr 2021 15:13:00

US3032242

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 14:52:51

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Keith Vrbicky (b) (4)	03 May 2021 16:17:41
Data hard locked.	(b) (4) (b) (4), (b) (6)	30 Apr 2021 17:30:26
User entered '0'	Kelsey Kelley (b) (4) (b) (4)	26 Apr 2021 15:13:00

US3032242

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 14:52:51

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Keith Vrbicky (b) (4)	03 May 2021 16:17:41
Data hard locked.	(b) (4) (b) (4), (b) (6)	30 Apr 2021 17:30:26
User entered '0'	Kelsey Kelley (b) (4) (b) (4)	26 Apr 2021 15:13:00

US3032242

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 14:52:51

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Keith Vrbicky (b) (4)	03 May 2021 16:17:41
Data hard locked.	(b) (4) (b) (4), (b) (6)	30 Apr 2021 17:30:26
User entered empty.	Kelsey Kelley (b) (4) (b) (4)	26 Apr 2021 15:13:00

US3032242

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 14:52:51

Hospital Discharge Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Keith Vrbicky (b) (4)	03 May 2021 16:17:41
Data hard locked.	(b) (4) (b) (4), (b) (6)	30 Apr 2021 17:30:26
User entered empty.	Kelsey Kelley (b) (4) (b) (4)	26 Apr 2021 15:13:00

US3032242

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 14:52:51

[Admitted to ICU?](#)

Audit	User	Time (GMT)
User signature succeeded.	Keith Vrbicky (b) (4)	03 May 2021 16:17:41
Data hard locked.	(b) (4) (b) (4), (b) (6)	30 Apr 2021 17:30:26
User entered empty.	Kelsey Kelley (b) (4) (b) (4)	26 Apr 2021 15:13:00

US3032242

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 14:52:51

[Number of Days in ICU](#)

Audit	User	Time (GMT)
User signature succeeded.	Keith Vrbicky (b) (4)	03 May 2021 16:17:41
Data hard locked.	(b) (4) (b) (4), (b) (6)	30 Apr 2021 17:30:26
User entered empty.	Kelsey Kelley (b) (4) (b) (4)	26 Apr 2021 15:13:00

US3032242

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 14:52:51

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Keith Vrbicky (b) (4)	03 May 2021 16:17:41
Data hard locked.	(b) (4) (b) (4), (b) (6)	30 Apr 2021 17:30:26
User entered '0'	Kelsey Kelley (b) (4) (b) (4)	26 Apr 2021 15:13:00

US3032242

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 14:52:51

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Keith Vrbicky (b) (4)	03 May 2021 16:17:41
Data hard locked.	(b) (4) (b) (4), (b) (6)	30 Apr 2021 17:30:26
User entered '0'	Kelsey Kelley (b) (4) (b) (4)	26 Apr 2021 15:13:00

US3032242

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 14:52:51

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Keith Vrbicky (b) (4)	03 May 2021 16:17:41
Data hard locked.	(b) (4) (b) (4), (b) (6)	30 Apr 2021 17:30:26
User entered '0'	Kelsey Kelley (b) (4) (b) (4)	26 Apr 2021 15:13:00

US3032242

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 14:52:51

[Relationship to investigational product](#)

Audit	User	Time (GMT)
User signature succeeded.	Keith Vrbicky (b) (4)	03 May 2021 16:17:41
Data hard locked.	(b) (4) (b) (4), (b) (6)	30 Apr 2021 17:30:26
User entered 'Not Related (NOT RELATED)'	Kelsey Kelley (b) (4) (b) (4)	26 Apr 2021 15:13:00

US3032242

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 14:52:51

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
User signature succeeded.	Keith Vrbicky (b) (4)	03 May 2021 16:17:41
Data hard locked.	(b) (4) (b) (4), (b) (6)	30 Apr 2021 17:30:26
User entered 'Not Related (NOT RELATED)'	Kelsey Kelley (b) (4) (b) (4)	26 Apr 2021 15:13:00

US3032242

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 14:52:51

Action taken with investigational product

Audit	User	Time (GMT)
User signature succeeded.	Keith Vrbicky (b) (4)	03 May 2021 16:17:41
Data hard locked.	(b) (4) (b) (4), (b) (6)	30 Apr 2021 17:30:26
User entered 'Not Applicable (NOT APPLICABLE)'	Kelsey Kelley (b) (4) (b) (4)	26 Apr 2021 15:13:00

US3032242

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 14:52:51

[None](#)

Audit	User	Time (GMT)
User signature succeeded.	Keith Vrbicky (b) (4)	03 May 2021 16:17:41
Data hard locked.	(b) (4) (b) (4), (b) (6)	30 Apr 2021 17:30:26
User entered '0'	Kelsey Kelley (b) (4) (b) (4)	26 Apr 2021 15:13:00

US3032242

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 14:52:51

[Concomitant Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Keith Vrbicky (b) (4)	03 May 2021 16:17:41
Data hard locked.	(b) (4) (b) (4), (b) (6)	30 Apr 2021 17:30:26
User entered '0'	Kelsey Kelley (b) (4) (b) (4)	26 Apr 2021 15:13:00

US3032242

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 14:52:51

[Concomitant Procedure](#)

Audit	User	Time (GMT)
User signature succeeded.	Keith Vrbicky (b) (4)	03 May 2021 16:17:41
Data hard locked.	(b) (4) (b) (4), (b) (6)	30 Apr 2021 17:30:26
User entered '1'	Kelsey Kelley (b) (4) (b) (4)	26 Apr 2021 15:13:00

US3032242

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 14:52:51

[Outcome](#)

Audit	User	Time (GMT)
User signature succeeded.	Keith Vrbicky (b) (4)	03 May 2021 16:17:41
Data hard locked.	(b) (4) (b) (4), (b) (6)	30 Apr 2021 17:30:26
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)'	Kelsey Kelley (b) (4) (b) (4)	26 Apr 2021 15:13:00

US3032242

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 14:52:51

If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:

Audit	User	Time (GMT)
User signature succeeded.	Keith Vrbicky (b) (4)	03 May 2021 16:17:41
Data hard locked.	(b) (4) (b) (4), (b) (6)	30 Apr 2021 17:30:26
User entered empty.	Kelsey Kelley (b) (4) (b) (4)	26 Apr 2021 15:13:00

US3032242

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 14:52:51

[Narrative](#)

Audit	User	Time (GMT)
User signature succeeded.	Keith Vrbicky (b) (4)	03 May 2021 16:17:41
Data hard locked.	(b) (4) (b) (4), (b) (6)	30 Apr 2021 17:30:26
User entered empty.	Kelsey Kelley (b) (4) (b) (4)	26 Apr 2021 15:13:00

US3032242

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 14:52:51

Serious Adverse Event Derived (CSA Programming Field Only)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:30:26
User entered '0'	System	26 Apr 2021 15:13:00

US3032242

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 14:52:51

Medically Attended AE Derived (CSA Programming Field Only)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:30:26
User entered '1'	System	26 Apr 2021 15:13:00

US3032242

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 14:52:51

Admitted to ICU Derived (CSA Programming Field Only)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:30:26

US3032242

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination Summary

Generated On: 09 Jun 2021 14:52:51

[Were any prior/concomitant medications and/or vaccinations taken?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 06:09:04
DataPoint Verified.		03 Dec 2020 16:32:59
User signature succeeded.	Keith Vrbicky (b) (4)	01 Oct 2020 22:01:37
User entered 'Yes (Y)'	(b) (4) Samantha Wieseler (b) (4)	30 Sep 2020 21:59:14
	(b) (4)	

US3032242

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 14:52:51

Name of Medication

Audit	User	Time (GMT)
User coded data point as ATC: CARDIOVASCULAR SYSTEM, ATC: AGENTS ACTING ON THE RENIN-ANGIOTENSIN SYSTEM, ATC: ACE INHIBITORS, PLAIN, ATC: ACE INHIBITORS, PLAIN, PRODUCT: LISINOPRIL - version WHODrug-Global-B3\202003.	Coder Import (b) (4) (b) (4)	26 Apr 2021 15:14:35
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\202003.	Coder Import (b) (4) (b) (4)	26 Apr 2021 15:14:35
Data point term sent to Coder Coding entries removed.	System Kelsey Kelley (b) (4) (b) (4)	26 Apr 2021 15:13:51 26 Apr 2021 15:13:40
DataPoint Verified.	(b) (4), (b) (6)	03 Dec 2020 16:32:33
User signature succeeded.	Keith Vrbicky (b) (4) (b) (4)	01 Oct 2020 22:01:37
User coded data point as ATC: CARDIOVASCULAR SYSTEM, ATC: AGENTS ACTING ON THE RENIN-ANGIOTENSIN SYSTEM, ATC: ACE INHIBITORS, PLAIN, ATC: ACE INHIBITORS, PLAIN, PRODUCT: LISINOPRIL - version WHODrug-Global-B3\202003.	Coder Import (b) (4) (b) (4)	01 Oct 2020 06:11:10
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\202003.	Coder Import (b) (4) (b) (4)	01 Oct 2020 06:11:10
Data point term sent to Coder User entered 'lisinopril'	System Samantha Wieseler (b) (4) (b) (4)	30 Sep 2020 22:00:53 30 Sep 2020 22:00:24

US3032242

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 14:52:51

[Prophylaxis](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	03 Dec 2020 16:32:33
User signature succeeded.	Keith Vrbicky (b) (4) (b) (4)	01 Oct 2020 22:01:37
User entered 'No (N)'	Samantha Wieseler (b) (4) (b) (4)	30 Sep 2020 22:00:24

US3032242

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 14:52:51

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Keith Vrbicky (b) (4) (b) (4)	03 May 2021 16:17:41
DataPoint Un-verified.	Kelsey Kelley (b) (4) (b) (4)	26 Apr 2021 15:13:40
Signature has been broken.	Kelsey Kelley (b) (4) (b) (4)	26 Apr 2021 15:13:40
User entered 'HYPERTENSION' reason for change: Data Entry Error	Kelsey Kelley (b) (4) (b) (4)	26 Apr 2021 15:13:40
DataPoint Verified.	(b) (4), (b) (6)	03 Dec 2020 16:32:33
User signature succeeded.	Keith Vrbicky (b) (4) (b) (4)	01 Oct 2020 22:01:37
User entered 'hypertesnsion'	Samantha Wieseler (b) (4) (b) (4)	30 Sep 2020 22:00:24

US3032242

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 14:52:51

[Dose per administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	03 Dec 2020 16:32:33
User signature succeeded.	Keith Vrbicky (b) (4) (b) (4)	01 Oct 2020 22:01:37
User entered '20'	Samantha Wieseler (b) (4) (b) (4)	30 Sep 2020 22:00:24

US3032242

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 14:52:51

[Dose unit](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	03 Dec 2020 16:32:33
User signature succeeded.	Keith Vrbicky (b) (4) (b) (4)	01 Oct 2020 22:01:37
User entered 'mg (mg)'	Samantha Wieseler (b) (4) (b) (4)	30 Sep 2020 22:00:24

US3032242

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 14:52:51

If dose unit is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	03 Dec 2020 16:32:33
User signature succeeded.	Keith Vrbicky (b) (4) (b) (4)	01 Oct 2020 22:01:37
User entered empty.	Samantha Wieseler (b) (4) (b) (4)	30 Sep 2020 22:00:24

US3032242

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 14:52:51

[Frequency](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	03 Dec 2020 16:32:33
User signature succeeded.	Keith Vrbicky (b) (4) (b) (4)	01 Oct 2020 22:01:37
User entered 'once daily (QD)'	Samantha Wieseler (b) (4) (b) (4)	30 Sep 2020 22:00:24

US3032242

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 14:52:51

If frequency is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	03 Dec 2020 16:32:33
User signature succeeded.	Keith Vrbicky (b) (4) (b) (4)	01 Oct 2020 22:01:37
User entered empty.	Samantha Wieseler (b) (4) (b) (4)	30 Sep 2020 22:00:24

US3032242

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 14:52:51

[Route of administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	03 Dec 2020 16:32:33
User signature succeeded.	Keith Vrbicky (b) (4) (b) (4)	01 Oct 2020 22:01:37
User entered 'Oral (ORAL)'	Samantha Wieseler (b) (4) (b) (4)	30 Sep 2020 22:00:24

US3032242

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 14:52:51

If route of administration is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	03 Dec 2020 16:32:33
User signature succeeded.	Keith Vrbicky (b) (4) (b) (4)	01 Oct 2020 22:01:37
User entered empty.	Samantha Wieseler (b) (4) (b) (4)	30 Sep 2020 22:00:24

US3032242

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 14:52:51

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	03 Dec 2020 16:32:33
User signature succeeded.	Keith Vrbicky (b) (4) (b) (4)	01 Oct 2020 22:01:37
User entered 'Un UNK 2010'	Samantha Wieseler (b) (4) (b) (4)	30 Sep 2020 22:00:24

US3032242

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 14:52:51

Start date completely unknown

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	03 Dec 2020 16:32:33
User signature succeeded.	Keith Vrbicky (b) (4)	01 Oct 2020 22:01:37
User entered '0'	(b) (4) Samantha Wieseler (b) (4)	30 Sep 2020 22:00:24
	(b) (4)	

US3032242

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 14:52:51

[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	03 Dec 2020 16:32:33
User signature succeeded.	Keith Vrbicky (b) (4) (b) (4)	01 Oct 2020 22:01:37
User entered 'Yes (Y)'	Samantha Wieseler (b) (4) (b) (4)	30 Sep 2020 22:00:24

US3032242

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 14:52:51

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	03 Dec 2020 16:32:33
User signature succeeded.	Keith Vrbicky (b) (4)	01 Oct 2020 22:01:37
User entered empty.	(b) (4) Samantha Wieseler (b) (4)	30 Sep 2020 22:00:24
	(b) (4)	

US3032242

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 14:52:51

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	03 Dec 2020 16:32:33
User signature succeeded.	Keith Vrbicky (b) (4) (b) (4)	01 Oct 2020 22:01:37
User entered 'No (N)'	Samantha Wieseler (b) (4) (b) (4)	30 Sep 2020 22:00:24

US3032242

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 14:52:51

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	30 Sep 2020 22:00:24

US3032242

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 14:52:51

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	30 Sep 2020 22:00:24

US3032242

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 14:52:51

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	30 Sep 2020 22:00:24

US3032242

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 14:52:51

[Name of Medication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	03 Dec 2020 16:32:33
User signature succeeded.	Keith Vrbicky (b) (4)	01 Oct 2020 22:01:37
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: DRUGS FOR ACID RELATED DISORDERS, ATC: DRUGS FOR PEPTIC ULCER AND GASTRO-OESOPHAGEAL REFLUX DISEASE (GORD), ATC: PROTON PUMP INHIBITORS, PRODUCT: PANTOPRAZOLE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	30 Sep 2020 22:02:45
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	30 Sep 2020 22:02:45
Data point term sent to Coder	System	30 Sep 2020 22:01:55
User entered 'Pantoprazole'	Samantha Wieseler (b) (4)	30 Sep 2020 22:01:13

US3032242

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 14:52:51

[Prophylaxis](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	03 Dec 2020 16:32:33
User signature succeeded.	Keith Vrbicky (b) (4) (b) (4)	01 Oct 2020 22:01:37
User entered 'No (N)'	Samantha Wieseler (b) (4) (b) (4)	30 Sep 2020 22:01:13

US3032242

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 14:52:51

[Indication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	03 Dec 2020 16:32:33
User signature succeeded.	Keith Vrbicky (b) (4) (b) (4)	01 Oct 2020 22:01:37
User entered 'gastroesophageal reflux disease'	Samantha Wieseler (b) (4) (b) (4)	30 Sep 2020 22:01:13

US3032242

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 14:52:51

[Dose per administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	03 Dec 2020 16:32:33
User signature succeeded.	Keith Vrbicky (b) (4)	01 Oct 2020 22:01:37
User entered '40'	(b) (4) Samantha Wieseler (b) (4)	30 Sep 2020 22:01:13
	(b) (4)	

US3032242

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 14:52:51

[Dose unit](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	03 Dec 2020 16:32:33
User signature succeeded.	Keith Vrbicky (b) (4) (b) (4)	01 Oct 2020 22:01:37
User entered 'mg (mg)'	Samantha Wieseler (b) (4) (b) (4)	30 Sep 2020 22:01:13

US3032242

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 14:52:51

If dose unit is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	03 Dec 2020 16:32:33
User signature succeeded.	Keith Vrbicky (b) (4) (b) (4)	01 Oct 2020 22:01:37
User entered empty.	Samantha Wieseler (b) (4) (b) (4)	30 Sep 2020 22:01:13

US3032242

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 14:52:51

[Frequency](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	03 Dec 2020 16:32:33
User signature succeeded.	Keith Vrbicky (b) (4) (b) (4)	01 Oct 2020 22:01:37
User entered 'once daily (QD)'	Samantha Wieseler (b) (4) (b) (4)	30 Sep 2020 22:01:13

US3032242

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 14:52:51

If frequency is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	03 Dec 2020 16:32:33
User signature succeeded.	Keith Vrbicky (b) (4) (b) (4)	01 Oct 2020 22:01:37
User entered empty.	Samantha Wieseler (b) (4) (b) (4)	30 Sep 2020 22:01:13

US3032242

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 14:52:51

[Route of administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	03 Dec 2020 16:32:33
User signature succeeded.	Keith Vrbicky (b) (4) (b) (4)	01 Oct 2020 22:01:37
User entered 'Oral (ORAL)'	Samantha Wieseler (b) (4) (b) (4)	30 Sep 2020 22:01:13

US3032242

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 14:52:51

If route of administration is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	03 Dec 2020 16:32:33
User signature succeeded.	Keith Vrbicky (b) (4) (b) (4)	01 Oct 2020 22:01:37
User entered empty.	Samantha Wieseler (b) (4) (b) (4)	30 Sep 2020 22:01:13

US3032242

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 14:52:51

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	03 Dec 2020 16:32:33
User signature succeeded.	Keith Vrbicky (b) (4) (b) (4)	01 Oct 2020 22:01:37
User entered 'Un UNK 2010'	Samantha Wieseler (b) (4) (b) (4)	30 Sep 2020 22:01:13

US3032242

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 14:52:51

Start date completely unknown

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	03 Dec 2020 16:32:33
User signature succeeded.	Keith Vrbicky (b) (4) (b) (4)	01 Oct 2020 22:01:37
User entered '0'	Samantha Wieseler (b) (4) (b) (4)	30 Sep 2020 22:01:13

US3032242

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 14:52:51

[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	03 Dec 2020 16:32:33
User signature succeeded.	Keith Vrbicky (b) (4) (b) (4)	01 Oct 2020 22:01:37
User entered 'Yes (Y)'	Samantha Wieseler (b) (4) (b) (4)	30 Sep 2020 22:01:13

US3032242

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 14:52:51

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	03 Dec 2020 16:32:33
User signature succeeded.	Keith Vrbicky (b) (4)	01 Oct 2020 22:01:37
User entered empty.	(b) (4) Samantha Wieseler (b) (4)	30 Sep 2020 22:01:13
	(b) (4)	

US3032242

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 14:52:51

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	03 Dec 2020 16:32:33
User signature succeeded.	Keith Vrbicky (b) (4) (b) (4)	01 Oct 2020 22:01:37
User entered 'No (N)'	Samantha Wieseler (b) (4) (b) (4)	30 Sep 2020 22:01:13

US3032242

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 14:52:51

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	30 Sep 2020 22:01:13

US3032242

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 14:52:51

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	30 Sep 2020 22:01:13

US3032242

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 14:52:51

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	30 Sep 2020 22:01:13

US3032242

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 14:52:51

[Name of Medication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	03 Dec 2020 16:32:33
User coded data point as ATC: BLOOD AND BLOOD FORMING ORGANS, ATC: ANTITHROMBOTIC AGENTS, ATC: ANTITHROMBOTIC AGENTS, ATC: PLATELET AGGREGATION INHIBITORS EXCL. HEPARIN, PRODUCT: ACETYLSALICYLIC ACID, PRODUCTSYNONYM: ASPIRIN [ACETYLSALICYLIC ACID] - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	24 Nov 2020 19:14:05
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	24 Nov 2020 19:14:05
Data point term sent to Coder Coding entries removed.	System Linden DeBoer (b) (4)	24 Nov 2020 19:12:39 24 Nov 2020 19:12:23
User coded data point as ATC: BLOOD AND BLOOD FORMING ORGANS, ATC: ANTITHROMBOTIC AGENTS, ATC: ANTITHROMBOTIC AGENTS, ATC: PLATELET AGGREGATION INHIBITORS EXCL. HEPARIN, PRODUCT: ACETYLSALICYLIC ACID, PRODUCTSYNONYM: ASPIRIN [ACETYLSALICYLIC ACID] - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	07 Nov 2020 19:11:34
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	07 Nov 2020 19:11:34
Data point term sent to Coder Coding entries removed.	System Linden DeBoer (b) (4)	07 Nov 2020 19:10:18 07 Nov 2020 19:10:06
User signature succeeded.	(b) (4) Keith Vrbicky (b) (4) (b) (4)	01 Oct 2020 22:01:37

US3032242

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 14:52:51

Name of Medication

Audit	User	Time (GMT)
User coded data point as ATC: BLOOD AND BLOOD FORMING ORGANS, ATC: ANTITHROMBOTIC AGENTS, ATC: ANTITHROMBOTIC AGENTS, ATC: PLATELET AGGREGATION INHIBITORS EXCL. HEPARIN, PRODUCT: ACETYLSALICYLIC ACID, PRODUCTSYNONYM: ASPIRIN [ACETYLSALICYLIC ACID] - version WHODrug-Global-B3\202003.	Coder Import (b) (4)	30 Sep 2020 22:02:45
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\202003.	Coder Import (b) (4)	30 Sep 2020 22:02:45
Data point term sent to Coder	System	30 Sep 2020 22:01:54
User entered 'Aspirin'	Samantha Wieseler (b) (4)	30 Sep 2020 22:01:47

US3032242

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 14:52:51

[Prophylaxis](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	03 Dec 2020 16:32:33
User signature succeeded.	Keith Vrbicky (b) (4) (b) (4)	01 Oct 2020 22:01:37
User entered 'Yes (Y)'	Samantha Wieseler (b) (4) (b) (4)	30 Sep 2020 22:01:47

US3032242

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 14:52:51

[Indication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	03 Dec 2020 16:32:33
User signature succeeded.	Keith Vrbicky (b) (4)	24 Nov 2020 20:29:22
Signature has been broken.	(b) (4)	
	Linden DeBoer (b) (4)	24 Nov 2020 19:12:23
	(b) (4)	
User entered 'CARDIAC Prophylaxis' reason for change: Data Entry Error	Linden DeBoer (b) (4)	24 Nov 2020 19:12:23
	(b) (4)	
User closed query 'Per DM CLR: Please note that this condition is not recorded on the Med History eCRF. Please review Con Med use and add a medical condition and all applicable details to the appropriate Med History eCRF. (Site from DM).	(b) (4), (b) (6)	09 Nov 2020 13:17:51
User signature succeeded.	Keith Vrbicky (b) (4)	08 Nov 2020 23:40:39
	(b) (4)	
Query 'Per DM CLR: Please note that this condition is not recorded on the Med History eCRF. Please review Con Med use and add a medical condition and all applicable details to the appropriate Med History eCRF. answered with 'data updated' (Site from DM).	Linden DeBoer (b) (4)	07 Nov 2020 19:10:16
	(b) (4)	
Signature has been broken.	Linden DeBoer (b) (4)	07 Nov 2020 19:10:06
	(b) (4)	
User entered 'CARDIAC health' reason for change: Data Entry Error	Linden DeBoer (b) (4)	07 Nov 2020 19:10:06
	(b) (4)	
User opened query 'Per DM CLR: Please note that this condition is not recorded on the Med History eCRF. Please review Con Med use and add a medical condition and all applicable details to the appropriate Med History eCRF. (Site from DM).	(b) (4), (b) (6)	04 Nov 2020 00:01:43
User signature succeeded.	Keith Vrbicky (b) (4)	01 Oct 2020 22:01:37
	(b) (4)	
User entered 'Cardiac Disease'	Samantha Wieseler (b) (4)	30 Sep 2020 22:01:47
	(b) (4)	

US3032242

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 14:52:51

[Dose per administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	03 Dec 2020 16:32:33
User signature succeeded.	Keith Vrbicky (b) (4) (b) (4)	01 Oct 2020 22:01:37
User entered '81'	Samantha Wieseler (b) (4) (b) (4)	30 Sep 2020 22:01:47

US3032242

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 14:52:51

[Dose unit](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	03 Dec 2020 16:32:33
User signature succeeded.	Keith Vrbicky (b) (4) (b) (4)	01 Oct 2020 22:01:37
User entered 'mg (mg)'	Samantha Wieseler (b) (4) (b) (4)	30 Sep 2020 22:01:47

US3032242

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 14:52:51

If dose unit is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	03 Dec 2020 16:32:33
User signature succeeded.	Keith Vrbicky (b) (4) (b) (4)	01 Oct 2020 22:01:37
User entered empty.	Samantha Wieseler (b) (4) (b) (4)	30 Sep 2020 22:01:47

US3032242

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 14:52:51

[Frequency](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	03 Dec 2020 16:32:33
User signature succeeded.	Keith Vrbicky (b) (4)	01 Oct 2020 22:01:37
User entered 'once daily (QD)'	(b) (4) Samantha Wieseler (b) (4)	30 Sep 2020 22:01:47
	(b) (4)	

US3032242

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 14:52:51

If frequency is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	03 Dec 2020 16:32:33
User signature succeeded.	Keith Vrbicky (b) (4) (b) (4)	01 Oct 2020 22:01:37
User entered empty.	Samantha Wieseler (b) (4) (b) (4)	30 Sep 2020 22:01:47

US3032242

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 14:52:51

[Route of administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	03 Dec 2020 16:32:33
User signature succeeded.	Keith Vrbicky (b) (4) (b) (4)	01 Oct 2020 22:01:37
User entered 'Oral (ORAL)'	Samantha Wieseler (b) (4) (b) (4)	30 Sep 2020 22:01:47

US3032242

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 14:52:51

If route of administration is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	03 Dec 2020 16:32:33
User signature succeeded.	Keith Vrbicky (b) (4) (b) (4)	01 Oct 2020 22:01:37
User entered empty.	Samantha Wieseler (b) (4) (b) (4)	30 Sep 2020 22:01:47

US3032242

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 14:52:51

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	03 Dec 2020 16:32:33
User signature succeeded.	Keith Vrbicky (b) (4)	01 Oct 2020 22:01:37
User entered 'Un UNK 2010'	(b) (4) Samantha Wieseler (b) (4)	30 Sep 2020 22:01:47
	(b) (4)	

US3032242

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 14:52:51

Start date completely unknown

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	03 Dec 2020 16:32:33
User signature succeeded.	Keith Vrbicky (b) (4) (b) (4)	01 Oct 2020 22:01:37
User entered '0'	Samantha Wieseler (b) (4) (b) (4)	30 Sep 2020 22:01:47

US3032242

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 14:52:51

[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	03 Dec 2020 16:32:33
User signature succeeded.	Keith Vrbicky (b) (4) (b) (4)	01 Oct 2020 22:01:37
User entered 'Yes (Y)'	Samantha Wieseler (b) (4) (b) (4)	30 Sep 2020 22:01:47

US3032242

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 14:52:51

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	03 Dec 2020 16:32:33
User signature succeeded.	Keith Vrbicky (b) (4) (b) (4)	01 Oct 2020 22:01:37
User entered empty.	Samantha Wieseler (b) (4) (b) (4)	30 Sep 2020 22:01:47

US3032242

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 14:52:51

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	03 Dec 2020 16:32:33
User signature succeeded.	Keith Vrbicky (b) (4) (b) (4)	01 Oct 2020 22:01:37
User entered 'No (N)'	Samantha Wieseler (b) (4) (b) (4)	30 Sep 2020 22:01:47

US3032242

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 14:52:51

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	30 Sep 2020 22:01:47

US3032242

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 14:52:51

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	30 Sep 2020 22:01:47

US3032242

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 14:52:51

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	30 Sep 2020 22:01:47

US3032242

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 14:52:51

[Name of Medication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	03 Dec 2020 16:32:33
User signature succeeded.	Keith Vrbicky (b) (4)	01 Oct 2020 22:01:37
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: DRUGS FOR ACID RELATED DISORDERS, ATC: DRUGS FOR PEPTIC ULCER AND GASTRO-OESOPHAGEAL REFLUX DISEASE (GORD), ATC: H2-RECEPTOR ANTAGONISTS, PRODUCT: FAMOTIDINE, PRODUCTSYNONYM: PEPCID [FAMOTIDINE] - version WHODrug-Global-B3\202003.	Coder Import (b) (4)	30 Sep 2020 22:03:46
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\202003.	Coder Import (b) (4)	30 Sep 2020 22:03:46
Data point term sent to Coder User entered 'Pepcid'	System Samantha Wieseler (b) (4)	30 Sep 2020 22:02:57 30 Sep 2020 22:02:52

US3032242

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 14:52:51

[Prophylaxis](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	03 Dec 2020 16:32:33
User signature succeeded.	Keith Vrbicky (b) (4) (b) (4)	01 Oct 2020 22:01:37
User entered 'No (N)'	Samantha Wieseler (b) (4) (b) (4)	30 Sep 2020 22:02:52

US3032242

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 14:52:51

[Indication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	03 Dec 2020 16:32:33
User signature succeeded.	Keith Vrbicky (b) (4) (b) (4)	01 Oct 2020 22:01:37
User entered 'gastroesophageal reflux disease'	Samantha Wieseler (b) (4) (b) (4)	30 Sep 2020 22:02:52

US3032242

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 14:52:51

[Dose per administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	03 Dec 2020 16:32:33
User signature succeeded.	Keith Vrbicky (b) (4) (b) (4)	01 Oct 2020 22:01:37
User entered '40'	Samantha Wieseler (b) (4) (b) (4)	30 Sep 2020 22:02:52

US3032242

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 14:52:51

[Dose unit](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	03 Dec 2020 16:32:33
User signature succeeded.	Keith Vrbicky (b) (4) (b) (4)	01 Oct 2020 22:01:37
User entered 'mg (mg)'	Samantha Wieseler (b) (4) (b) (4)	30 Sep 2020 22:02:52

US3032242

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 14:52:51

If dose unit is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	03 Dec 2020 16:32:33
User signature succeeded.	Keith Vrbicky (b) (4) (b) (4)	01 Oct 2020 22:01:37
User entered empty.	Samantha Wieseler (b) (4) (b) (4)	30 Sep 2020 22:02:52

US3032242

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 14:52:51

[Frequency](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	03 Dec 2020 16:32:33
User signature succeeded.	Keith Vrbicky (b) (4) (b) (4)	01 Oct 2020 22:01:37
User entered 'once daily (QD)'	Samantha Wieseler (b) (4) (b) (4)	30 Sep 2020 22:02:52

US3032242

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 14:52:51

If frequency is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	03 Dec 2020 16:32:33
User signature succeeded.	Keith Vrbicky (b) (4) (b) (4)	01 Oct 2020 22:01:37
User entered empty.	Samantha Wieseler (b) (4) (b) (4)	30 Sep 2020 22:02:52

US3032242

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 14:52:51

[Route of administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	03 Dec 2020 16:32:33
User signature succeeded.	Keith Vrbicky (b) (4) (b) (4)	01 Oct 2020 22:01:37
User entered 'Oral (ORAL)'	Samantha Wieseler (b) (4) (b) (4)	30 Sep 2020 22:02:52

US3032242

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 14:52:51

If route of administration is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	03 Dec 2020 16:32:33
User signature succeeded.	Keith Vrbicky (b) (4) (b) (4)	01 Oct 2020 22:01:37
User entered empty.	Samantha Wieseler (b) (4) (b) (4)	30 Sep 2020 22:02:52

US3032242

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 14:52:51

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	03 Dec 2020 16:32:33
User signature succeeded.	Keith Vrbicky (b) (4) (b) (4)	01 Oct 2020 22:01:37
User entered 'Un UNK 2010'	Samantha Wieseler (b) (4) (b) (4)	30 Sep 2020 22:02:52

US3032242

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 14:52:51

Start date completely unknown

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	03 Dec 2020 16:32:33
User signature succeeded.	Keith Vrbicky (b) (4) (b) (4)	01 Oct 2020 22:01:37
User entered '0'	Samantha Wieseler (b) (4) (b) (4)	30 Sep 2020 22:02:52

US3032242

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 14:52:51

[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	03 Dec 2020 16:32:33
User signature succeeded.	Keith Vrbicky (b) (4) (b) (4)	01 Oct 2020 22:01:37
User entered 'Yes (Y)'	Samantha Wieseler (b) (4) (b) (4)	30 Sep 2020 22:02:52

US3032242

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 14:52:51

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	03 Dec 2020 16:32:33
User signature succeeded.	Keith Vrbicky (b) (4) (b) (4)	01 Oct 2020 22:01:37
User entered empty.	Samantha Wieseler (b) (4) (b) (4)	30 Sep 2020 22:02:52

US3032242

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 14:52:51

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	03 Dec 2020 16:32:33
User signature succeeded.	Keith Vrbicky (b) (4) (b) (4)	01 Oct 2020 22:01:37
User entered 'No (N)'	Samantha Wieseler (b) (4) (b) (4)	30 Sep 2020 22:02:52

US3032242

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 14:52:51

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	30 Sep 2020 22:02:52

US3032242

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 14:52:51

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	30 Sep 2020 22:02:52

US3032242

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 14:52:51

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	30 Sep 2020 22:02:52

US3032242

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 14:52:51

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 05:31:00
DataPoint Verified.		03 Dec 2020 16:32:33
User signature succeeded.	Keith Vrbicky (b) (4)	01 Oct 2020 22:01:37
User coded data point as ATC: MUSCULO-SKELETAL SYSTEM, ATC: ANTIINFLAMMATORY AND ANTIRHEUMATIC PRODUCTS, ATC: ANTIINFLAMMATORY AND ANTIRHEUMATIC PRODUCTS, NON-STEROIDS, ATC: PROPIONIC ACID DERIVATIVES, PRODUCT: IBUPROFEN, PRODUCTSYNONYM: ADVIL [IBUPROFEN] - version WHODrug-Global-B3\202003.	(b) (4) Coder Import (b) (4) (b) (4)	30 Sep 2020 22:05:41
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\202003.	Coder Import (b) (4) (b) (4)	30 Sep 2020 22:05:41
Data point term sent to Coder	System	30 Sep 2020 22:03:57
User entered 'Advil'	Samantha Wieseler (b) (4) (b) (4)	30 Sep 2020 22:03:35

US3032242

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 14:52:51

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 05:31:00
DataPoint Verified.	(b) (4)	03 Dec 2020 16:32:33
User signature succeeded.	(b) (4)	01 Oct 2020 22:01:37
User entered 'No (N)'	(b) (4) Samantha Wieseler (b) (4) (b) (4)	30 Sep 2020 22:03:35

US3032242

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 14:52:51

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 05:31:00
DataPoint Verified.		03 Dec 2020 16:32:33
User signature succeeded.	Keith Vrbicky (b) (4)	01 Oct 2020 22:01:37
User entered 'knee pain'	(b) (4) Samantha Wieseler (b) (4)	30 Sep 2020 22:03:35
	(b) (4)	

US3032242

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 14:52:51

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 05:31:00
DataPoint Verified.		03 Dec 2020 16:32:33
User signature succeeded.	Keith Vrbicky (b) (4)	01 Oct 2020 22:01:37
User entered '400'	(b) (4) Samantha Wieseler (b) (4) (b) (4)	30 Sep 2020 22:03:35

US3032242

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 14:52:51

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 05:31:00
DataPoint Verified.		03 Dec 2020 16:32:33
User signature succeeded.	Keith Vrbicky (b) (4)	01 Oct 2020 22:01:37
User entered 'mg (mg)'	(b) (4) Samantha Wieseler (b) (4) (b) (4)	30 Sep 2020 22:03:35

US3032242

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 14:52:51

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 05:31:00
DataPoint Verified.		03 Dec 2020 16:32:33
User signature succeeded.	Keith Vrbicky (b) (4)	01 Oct 2020 22:01:37
User entered empty.	(b) (4) Samantha Wieseler (b) (4) (b) (4)	30 Sep 2020 22:03:35

US3032242

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 14:52:51

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 05:31:00
DataPoint Verified.		03 Dec 2020 16:32:33
User signature succeeded.	Keith Vrbicky (b) (4)	01 Oct 2020 22:01:37
User entered 'as needed (PRN)'	(b) (4) Samantha Wieseler (b) (4)	30 Sep 2020 22:03:35
	(b) (4)	

US3032242

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 14:52:51

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 05:31:00
DataPoint Verified.		03 Dec 2020 16:32:33
User signature succeeded.	Keith Vrbicky (b) (4)	01 Oct 2020 22:01:37
User entered empty.	(b) (4) Samantha Wieseler (b) (4)	30 Sep 2020 22:03:35
	(b) (4)	

US3032242

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 14:52:51

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 05:31:00
DataPoint Verified.		03 Dec 2020 16:32:33
User signature succeeded.	Keith Vrbicky (b) (4)	01 Oct 2020 22:01:37
User entered 'Oral (ORAL)'	(b) (4) Samantha Wieseler (b) (4)	30 Sep 2020 22:03:35
	(b) (4)	

US3032242

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 14:52:51

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 05:31:00
DataPoint Verified.		03 Dec 2020 16:32:33
User signature succeeded.	Keith Vrbicky (b) (4)	01 Oct 2020 22:01:37
User entered empty.	(b) (4) Samantha Wieseler (b) (4)	30 Sep 2020 22:03:35
	(b) (4)	

US3032242

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 14:52:51

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 05:31:00
DataPoint Verified.		03 Dec 2020 16:32:33
User signature succeeded.	Keith Vrbicky (b) (4)	01 Oct 2020 22:01:37
User entered 'UN UNK 2016'	(b) (4) Samantha Wieseler (b) (4)	30 Sep 2020 22:03:35
	(b) (4)	

US3032242

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 14:52:51

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 05:31:00
DataPoint Verified.		03 Dec 2020 16:32:33
User signature succeeded.	Keith Vrbicky (b) (4)	01 Oct 2020 22:01:37
User entered '0'	(b) (4) Samantha Wieseler (b) (4) (b) (4)	30 Sep 2020 22:03:35

US3032242

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 14:52:51

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 05:31:00
DataPoint Verified.	(b) (4)	11 Mar 2021 22:59:16
User signature succeeded.	Keith Vrbicky (b) (4)	22 Feb 2021 17:26:08
DataPoint Un-verified.	(b) (4) Kelsey Kelley (b) (4)	19 Feb 2021 21:16:28
Signature has been broken.	(b) (4) Kelsey Kelley (b) (4)	19 Feb 2021 21:16:28
User entered 'No (N)' reason for change: Data Entry Error	(b) (4) Kelsey Kelley (b) (4)	19 Feb 2021 21:16:28
DataPoint Verified.	(b) (4), (b) (6)	03 Dec 2020 16:32:33
User signature succeeded.	Keith Vrbicky (b) (4)	01 Oct 2020 22:01:37
User entered 'Yes (Y)'	(b) (4) Samantha Wieseler (b) (4)	30 Sep 2020 22:03:35
	(b) (4)	

US3032242

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 14:52:51

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 05:31:00
DataPoint Verified.	(b) (4)	11 Mar 2021 22:59:16
User signature succeeded.	Keith Vrbicky (b) (4)	22 Feb 2021 17:26:08
DataPoint Un-verified.	(b) (4)	
	Kelsey Kelley (b) (4)	19 Feb 2021 21:16:28
Signature has been broken.	(b) (4)	
	Kelsey Kelley (b) (4)	19 Feb 2021 21:16:28
User entered '25 Jan 2021' reason for change: Data Entry Error	(b) (4)	
	Kelsey Kelley (b) (4)	19 Feb 2021 21:16:28
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	03 Dec 2020 16:32:33
User signature succeeded.	Keith Vrbicky (b) (4)	01 Oct 2020 22:01:37
User entered empty.	(b) (4)	
	Samantha Wieseler (b) (4)	30 Sep 2020 22:03:35
	(b) (4)	

US3032242

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 14:52:51

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 05:31:00
DataPoint Verified.		03 Dec 2020 16:32:33
User signature succeeded.	Keith Vrbicky (b) (4)	01 Oct 2020 22:01:37
User entered 'No (N)'	(b) (4) Samantha Wieseler (b) (4) (b) (4)	30 Sep 2020 22:03:35

US3032242

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 14:52:51

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 05:31:00
User entered empty.	System	30 Sep 2020 22:03:35

US3032242

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 14:52:51

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 05:31:00
User entered empty.	System	30 Sep 2020 22:03:35

US3032242

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 14:52:51

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 05:31:00
User entered empty.	System	30 Sep 2020 22:03:35

US3032242

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 14:52:51

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 07:54:20
DataPoint Verified.	(b) (4)	03 Dec 2020 16:32:33
User signature succeeded.	Keith Vrbicky (b) (4)	08 Nov 2020 23:40:39
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.	(b) (4) Coder Import (b) (4)	07 Nov 2020 19:13:34
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\202003.	Coder Import (b) (4)	07 Nov 2020 19:13:34
Data point term sent to Coder	System	07 Nov 2020 19:12:19
User entered 'Influenza vaccine'	Linden DeBoer (b) (4) (b) (4)	07 Nov 2020 19:11:25

US3032242

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 14:52:51

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 07:54:20
DataPoint Verified.	(b) (4)	11 Mar 2021 22:59:16
User signature succeeded.	Keith Vrbicky (b) (4)	16 Dec 2020 20:10:46
User closed query 'Per DM CLR: Please review response as supplements/vitamins/contraceptives and vaccines are considered as prophylaxis. Update as appropriate. ' (Site from DM).	(b) (4) (b) (4), (b) (6)	15 Dec 2020 16:33:57
Query 'Per DM CLR: Please review response as supplements/vitamins/contraceptives and vaccines are considered as prophylaxis. Update as appropriate. ' answered with 'data is correct as entered' (Site from DM).	Linden DeBoer (b) (4) (b) (4)	11 Dec 2020 15:48:40
DataPoint Un-verified.	Kelsey Kelley (b) (4) (b) (4)	10 Dec 2020 16:21:14
Signature has been broken.	Kelsey Kelley (b) (4) (b) (4)	10 Dec 2020 16:21:14
User entered 'Yes (Y)' reason for change: Data Entry Error	Kelsey Kelley (b) (4) (b) (4)	10 Dec 2020 16:21:14
User opened query 'Per DM CLR: Please review response as supplements/vitamins/contraceptives and vaccines are considered as prophylaxis. Update as appropriate. ' (Site from DM).	(b) (4), (b) (6)	09 Dec 2020 07:56:22
DataPoint Verified.	(b) (4), (b) (6)	03 Dec 2020 16:32:33
User signature succeeded.	Keith Vrbicky (b) (4) (b) (4)	08 Nov 2020 23:40:39
User entered 'No (N)'	Linden DeBoer (b) (4) (b) (4)	07 Nov 2020 19:11:25

US3032242

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 14:52:51

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 07:54:20
DataPoint Verified.		03 Dec 2020 16:32:33
User signature succeeded.	Keith Vrbicky (b) (4)	08 Nov 2020 23:40:39
User entered 'flu vaccine'	(b) (4) Linden DeBoer (b) (4)	07 Nov 2020 19:11:25
	(b) (4)	

US3032242

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 14:52:51

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 07:54:20
DataPoint Verified.		03 Dec 2020 16:32:33
User signature succeeded.	Keith Vrbicky (b) (4)	08 Nov 2020 23:40:39
User entered '.5'	(b) (4) Linden DeBoer (b) (4)	07 Nov 2020 19:11:25
	(b) (4)	

US3032242

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 14:52:51

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 07:54:20
DataPoint Verified.		03 Dec 2020 16:32:33
User signature succeeded.	Keith Vrbicky (b) (4)	08 Nov 2020 23:40:39
User entered 'mL (mL)'	(b) (4) Linden DeBoer (b) (4)	07 Nov 2020 19:11:25
	(b) (4)	

US3032242

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 14:52:51

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 07:54:20
DataPoint Verified.		03 Dec 2020 16:32:33
User signature succeeded.	Keith Vrbicky (b) (4)	08 Nov 2020 23:40:39
User entered empty.	(b) (4) Linden DeBoer (b) (4)	07 Nov 2020 19:11:25
	(b) (4)	

US3032242

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 14:52:51

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 07:54:20
DataPoint Verified.	(b) (4)	11 Mar 2021 22:59:16
User signature succeeded.	Keith Vrbicky (b) (4)	23 Dec 2020 15:54:56
DataPoint Un-verified.	(b) (4)	
	Kelsey Kelley (b) (4)	18 Dec 2020 23:10:36
Signature has been broken.	(b) (4)	
	Kelsey Kelley (b) (4)	18 Dec 2020 23:10:36
User entered 'once (ONCE)' reason for change: Data	(b) (4)	
Entry Error	Kelsey Kelley (b) (4)	18 Dec 2020 23:10:36
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	03 Dec 2020 16:32:33
User signature succeeded.	Keith Vrbicky (b) (4)	08 Nov 2020 23:40:39
	(b) (4)	
User entered 'other (OTHER)'	Linden DeBoer (b) (4)	07 Nov 2020 19:11:25
	(b) (4)	

US3032242

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 14:52:51

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 07:54:20
DataPoint Verified.	(b) (4), (b) (6)	11 Mar 2021 22:59:16
User signature succeeded.	Keith Vrbicky (b) (4)	23 Dec 2020 15:54:56
User closed query 'Per CDM: Kindly Check if the frequency can be selected from one of the above option present frequency and remove it from other. ' (Site from DM).	(b) (4) (b) (4), (b) (6)	21 Dec 2020 06:35:20
Query 'Per CDM: Kindly Check if the frequency can be selected from one of the above option present frequency and remove it from other. ' answered with 'Data updated' (Site from DM).	Kelsey Kelley (b) (4) (b) (4)	18 Dec 2020 23:10:41
DataPoint Un-verified.	Kelsey Kelley (b) (4) (b) (4)	18 Dec 2020 23:10:36
Signature has been broken.	Kelsey Kelley (b) (4) (b) (4)	18 Dec 2020 23:10:36
User entered empty; reason for change Data Entry Error	Kelsey Kelley (b) (4) (b) (4)	18 Dec 2020 23:10:36
User opened query 'Per CDM: Kindly Check if the frequency can be selected from one of the above option present frequency and remove it from other. ' (Site from DM).	(b) (4), (b) (6)	18 Dec 2020 09:38:44
DataPoint Verified.	(b) (4), (b) (6)	03 Dec 2020 16:32:33
User signature succeeded.	Keith Vrbicky (b) (4) (b) (4)	08 Nov 2020 23:40:39
User entered 'once'	Linden DeBoer (b) (4) (b) (4)	07 Nov 2020 19:11:25

US3032242

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 14:52:51

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 07:54:20
DataPoint Verified.		03 Dec 2020 16:32:33
User signature succeeded.	Keith Vrbicky (b) (4)	08 Nov 2020 23:40:39
User entered 'Intramuscular (INTRAMUSCULAR)'	(b) (4) Linden DeBoer (b) (4)	07 Nov 2020 19:11:25
	(b) (4)	

US3032242

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 14:52:51

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 07:54:20
DataPoint Verified.		03 Dec 2020 16:32:33
User signature succeeded.	Keith Vrbicky (b) (4)	08 Nov 2020 23:40:39
User entered empty.	(b) (4) Linden DeBoer (b) (4) (b) (4)	07 Nov 2020 19:11:25

US3032242

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 14:52:51

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 07:54:20
DataPoint Verified.		03 Dec 2020 16:32:33
User signature succeeded.	Keith Vrbicky (b) (4)	08 Nov 2020 23:40:39
User entered '02 Oct 2020'	(b) (4) Linden DeBoer (b) (4)	07 Nov 2020 19:11:25
	(b) (4)	

US3032242

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 14:52:51

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 07:54:20
DataPoint Verified.		03 Dec 2020 16:32:33
User signature succeeded.	Keith Vrbicky (b) (4)	08 Nov 2020 23:40:39
User entered '0'	(b) (4) Linden DeBoer (b) (4)	07 Nov 2020 19:11:25
	(b) (4)	

US3032242

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 14:52:51

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 07:54:20
DataPoint Verified.		03 Dec 2020 16:32:33
User signature succeeded.	Keith Vrbicky (b) (4)	08 Nov 2020 23:40:39
User entered 'No (N)'	(b) (4) Linden DeBoer (b) (4)	07 Nov 2020 19:11:25
	(b) (4)	

US3032242

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 14:52:51

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 07:54:20
DataPoint Verified.		03 Dec 2020 16:32:33
User signature succeeded.	Keith Vrbicky (b) (4)	08 Nov 2020 23:40:39
User entered '02 Oct 2020'	(b) (4) Linden DeBoer (b) (4) (b) (4)	07 Nov 2020 19:11:25

US3032242

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 14:52:51

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 07:54:20
DataPoint Verified.		03 Dec 2020 16:32:33
User signature succeeded.	Keith Vrbicky (b) (4)	08 Nov 2020 23:40:39
User entered 'No (N)'	(b) (4) Linden DeBoer (b) (4)	07 Nov 2020 19:11:25
	(b) (4)	

US3032242

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 14:52:51

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 07:54:20
User entered empty.	System	07 Nov 2020 19:11:25

US3032242

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 14:52:51

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 07:54:20
User entered empty.	System	07 Nov 2020 19:11:25

US3032242

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 14:52:51

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 07:54:20
User entered empty.	System	07 Nov 2020 19:11:25

US3032242

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 14:52:51

[Name of Medication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Mar 2021 22:59:16
User signature succeeded.	Keith Vrbicky (b) (4)	22 Feb 2021 17:26:08
User coded data point as ATC: NERVOUS SYSTEM, ATC: ANALGESICS, ATC: OTHER ANALGESICS AND ANTIPYRETICS, ATC: ANILIDES, PRODUCT: PARACETAMOL, PRODUCTSYNONYM: ACETAMINOPHEN - version WHODrug-Global-B3\202003.	Coder Import (b) (4)	19 Feb 2021 21:19:02
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\202003.	Coder Import (b) (4)	19 Feb 2021 21:19:02
Data point term sent to Coder	System	19 Feb 2021 21:17:36
User entered 'Acetaminophen'	Kelsey Kelley (b) (4)	19 Feb 2021 21:17:28

US3032242

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 14:52:51

[Prophylaxis](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Mar 2021 22:59:16
User signature succeeded.	Keith Vrbicky (b) (4)	22 Feb 2021 17:26:08
User entered 'No (N)'	(b) (4) Kelsey Kelley (b) (4)	19 Feb 2021 21:17:28
	(b) (4)	

US3032242

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 14:52:51

[Indication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Mar 2021 22:59:16
User signature succeeded.	Keith Vrbicky (b) (4)	22 Feb 2021 17:26:08
User entered 'knee pain'	(b) (4) Kelsey Kelley (b) (4)	19 Feb 2021 21:17:28

US3032242

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 14:52:51

[Dose per administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Mar 2021 22:59:16
User signature succeeded.	Keith Vrbicky (b) (4)	22 Feb 2021 17:26:08
User entered '500'	(b) (4) Kelsey Kelley (b) (4)	19 Feb 2021 21:17:28

US3032242

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 14:52:51

[Dose unit](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Mar 2021 22:59:16
User signature succeeded.	Keith Vrbicky (b) (4)	22 Feb 2021 17:26:08
User entered 'mg (mg)'	(b) (4) Kelsey Kelley (b) (4)	19 Feb 2021 21:17:28
	(b) (4)	

US3032242

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 14:52:51

If dose unit is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Mar 2021 22:59:16
User signature succeeded.	Keith Vrbicky (b) (4)	22 Feb 2021 17:26:08
User entered empty.	(b) (4) Kelsey Kelley (b) (4)	19 Feb 2021 21:17:28

US3032242

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 14:52:51

[Frequency](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Mar 2021 22:59:16
User signature succeeded.	Keith Vrbicky (b) (4)	22 Feb 2021 17:26:08
User entered 'four times daily (QID)'	(b) (4) Kelsey Kelley (b) (4)	19 Feb 2021 21:17:28
	(b) (4)	

US3032242

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 14:52:51

If frequency is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Mar 2021 22:59:16
User signature succeeded.	Keith Vrbicky (b) (4)	22 Feb 2021 17:26:08
User entered empty.	(b) (4) Kelsey Kelley (b) (4)	19 Feb 2021 21:17:28
	(b) (4)	

US3032242

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 14:52:51

[Route of administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Mar 2021 22:59:16
User signature succeeded.	Keith Vrbicky (b) (4)	22 Feb 2021 17:26:08
User entered 'Oral (ORAL)'	(b) (4) Kelsey Kelley (b) (4)	19 Feb 2021 21:17:28
	(b) (4)	

US3032242

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 14:52:51

If route of administration is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Mar 2021 22:59:16
User signature succeeded.	Keith Vrbicky (b) (4)	22 Feb 2021 17:26:08
User entered empty.	(b) (4) Kelsey Kelley (b) (4)	19 Feb 2021 21:17:28

US3032242

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 14:52:51

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Mar 2021 22:59:16
User signature succeeded.	Keith Vrbicky (b) (4)	22 Feb 2021 17:26:08
User entered '01 Feb 2021'	(b) (4) Kelsey Kelley (b) (4)	19 Feb 2021 21:17:28
	(b) (4)	

US3032242

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 14:52:51

Start date completely unknown

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Mar 2021 22:59:16
User signature succeeded.	Keith Vrbicky (b) (4)	22 Feb 2021 17:26:08
User entered '0'	(b) (4) Kelsey Kelley (b) (4)	19 Feb 2021 21:17:28
	(b) (4)	

US3032242

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 14:52:51

[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Mar 2021 22:59:16
User signature succeeded.	Keith Vrbicky (b) (4)	22 Feb 2021 17:26:08
User entered 'Yes (Y)'	(b) (4) Kelsey Kelley (b) (4)	19 Feb 2021 21:17:28

US3032242

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 14:52:51

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Mar 2021 22:59:16
User signature succeeded.	Keith Vrbicky (b) (4)	22 Feb 2021 17:26:08
User entered empty.	(b) (4) Kelsey Kelley (b) (4)	19 Feb 2021 21:17:28
	(b) (4)	

US3032242

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 14:52:51

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Mar 2021 22:59:16
User signature succeeded.	Keith Vrbicky (b) (4)	22 Feb 2021 17:26:08
User closed query 'Data is required. Please complete.' (Site from System).	(b) (4)	19 Feb 2021 21:17:33
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	19 Feb 2021 21:17:33
User entered 'No (N)' reason for change: Data Entry Error	Kelsey Kelley (b) (4)	19 Feb 2021 21:17:33
User opened query 'Data is required. Please complete.' (Site from System).	(b) (4)	19 Feb 2021 21:17:28
User entered empty.	System	19 Feb 2021 21:17:28
	Kelsey Kelley (b) (4)	19 Feb 2021 21:17:28
	(b) (4)	

US3032242

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 14:52:51

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '4'	System	19 Feb 2021 21:17:28

US3032242

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 14:52:51

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	19 Feb 2021 21:17:28

US3032242

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 14:52:51

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	19 Feb 2021 21:17:28

US3032242

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 14:52:51

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Keith Vrbicky (b) (4)	03 May 2021 16:17:41
User coded data point as ATC: CARDIOVASCULAR SYSTEM, ATC: DIURETICS, ATC: LOW-CEILING DIURETICS, THIAZIDES, ATC: THIAZIDES, PLAIN, PRODUCT: HYDROCHLOROTHIAZIDE - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4) (b) (4)	26 Apr 2021 15:15:36
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	26 Apr 2021 15:15:36
Data point term sent to Coder	System	26 Apr 2021 15:14:52
User entered 'hydrochlorothiazide'	Kelsey Kelley (b) (4) (b) (4)	26 Apr 2021 15:14:10

US3032242

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 14:52:51

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Keith Vrbicky (b) (4)	03 May 2021 16:17:41
	(b) (4)	
User entered 'No (N)'	Kelsey Kelley (b) (4)	26 Apr 2021 15:14:10
	(b) (4)	

US3032242

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 14:52:51

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Keith Vrbicky (b) (4)	03 May 2021 16:17:41
	(b) (4)	
User entered 'hypertension'	Kelsey Kelley (b) (4)	26 Apr 2021 15:14:10
	(b) (4)	

US3032242

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 14:52:51

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Keith Vrbicky (b) (4)	03 May 2021 16:17:41
	(b) (4)	
User entered '25'	Kelsey Kelley (b) (4)	26 Apr 2021 15:14:10
	(b) (4)	

US3032242

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 14:52:51

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Keith Vrbicky (b) (4)	03 May 2021 16:17:41
	(b) (4)	
User entered 'mg (mg)'	Kelsey Kelley (b) (4)	26 Apr 2021 15:14:10
	(b) (4)	

US3032242

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 14:52:51

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Keith Vrbicky (b) (4)	03 May 2021 16:17:41
	(b) (4)	
User entered empty.	Kelsey Kelley (b) (4)	26 Apr 2021 15:14:10
	(b) (4)	

US3032242

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 14:52:51

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Keith Vrbicky (b) (4)	03 May 2021 16:17:41
User entered 'once daily (QD)'	(b) (4) Kelsey Kelley (b) (4)	26 Apr 2021 15:14:10
	(b) (4)	

US3032242

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 14:52:51

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Keith Vrbicky (b) (4)	03 May 2021 16:17:41
	(b) (4)	
User entered empty.	Kelsey Kelley (b) (4)	26 Apr 2021 15:14:10
	(b) (4)	

US3032242

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 14:52:51

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Keith Vrbicky (b) (4)	03 May 2021 16:17:41
	(b) (4)	
User entered 'Oral (ORAL)'	Kelsey Kelley (b) (4)	26 Apr 2021 15:14:10
	(b) (4)	

US3032242

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 14:52:51

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Keith Vrbicky (b) (4)	03 May 2021 16:17:41
	(b) (4)	
User entered empty.	Kelsey Kelley (b) (4)	26 Apr 2021 15:14:10
	(b) (4)	

US3032242

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 14:52:51

Start date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Keith Vrbicky (b) (4)	03 May 2021 16:17:41
	(b) (4)	
User entered 'un UNK 2010'	Kelsey Kelley (b) (4)	26 Apr 2021 15:14:10
	(b) (4)	

US3032242

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 14:52:51

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Keith Vrbicky (b) (4)	03 May 2021 16:17:41
	(b) (4)	
User entered '0'	Kelsey Kelley (b) (4)	26 Apr 2021 15:14:10
	(b) (4)	

US3032242

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 14:52:51

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Keith Vrbicky (b) (4)	03 May 2021 16:17:41
	(b) (4)	
User entered 'Yes (Y)'	Kelsey Kelley (b) (4)	26 Apr 2021 15:14:10
	(b) (4)	

US3032242

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 14:52:51

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

Audit	User	Time (GMT)
User signature succeeded.	Keith Vrbicky (b) (4)	03 May 2021 16:17:41
	(b) (4)	
User entered empty.	Kelsey Kelley (b) (4)	26 Apr 2021 15:14:10
	(b) (4)	

US3032242

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 14:52:51

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Keith Vrbicky (b) (4)	03 May 2021 16:17:41
	(b) (4)	
User entered 'No (N)'	Kelsey Kelley (b) (4)	26 Apr 2021 15:14:10
	(b) (4)	

US3032242

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 14:52:51

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	26 Apr 2021 15:14:10

US3032242

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 14:52:51

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	26 Apr 2021 15:14:10

US3032242

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 14:52:51

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	26 Apr 2021 15:14:10

US3032242

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 14:52:51

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Keith Vrbicky (b) (4)	03 May 2021 16:17:41
User coded data point as ATC: GENITO URINARY SYSTEM AND SEX HORMONES, ATC: SEX HORMONES AND MODULATORS OF THE GENITAL SYSTEM, ATC: PROGESTOGENS, ATC: PREGNEN (4) DERIVATIVES, PRODUCT: MEDROXYPROGESTERONE - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4)	30 Apr 2021 17:22:06
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	30 Apr 2021 17:22:06
Data point term sent to Coder	System	30 Apr 2021 15:48:35
User entered 'Medroxyprogesterone'	Kelsey Kelley (b) (4) (b) (4)	30 Apr 2021 15:48:01

US3032242

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 14:52:51

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Keith Vrbicky (b) (4)	03 May 2021 16:17:41
User entered 'No (N)'	(b) (4) Kelsey Kelley (b) (4)	30 Apr 2021 15:48:01
	(b) (4)	

US3032242

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 14:52:51

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Keith Vrbicky (b) (4)	03 May 2021 16:17:41
User entered 'postmenopausal vaginal bleeding'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	30 Apr 2021 15:48:01

US3032242

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 14:52:51

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Keith Vrbicky (b) (4)	03 May 2021 16:17:41
	(b) (4)	
User entered '10'	Kelsey Kelley (b) (4)	30 Apr 2021 15:48:01
	(b) (4)	

US3032242

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 14:52:51

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Keith Vrbicky (b) (4)	03 May 2021 16:17:41
	(b) (4)	
User entered 'mg (mg)'	Kelsey Kelley (b) (4)	30 Apr 2021 15:48:01
	(b) (4)	

US3032242

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 14:52:51

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Keith Vrbicky (b) (4) (b) (4)	03 May 2021 16:17:41
User entered empty.	Kelsey Kelley (b) (4) (b) (4)	30 Apr 2021 15:48:01

US3032242

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 14:52:51

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Keith Vrbicky (b) (4)	03 May 2021 16:17:41
User entered 'once daily (QD)'	(b) (4) Kelsey Kelley (b) (4)	30 Apr 2021 15:48:01
	(b) (4)	

US3032242

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 14:52:51

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Keith Vrbicky (b) (4)	03 May 2021 16:17:41
	(b) (4)	
User entered empty.	Kelsey Kelley (b) (4)	30 Apr 2021 15:48:01
	(b) (4)	

US3032242

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 14:52:51

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Keith Vrbicky (b) (4)	03 May 2021 16:17:41
	(b) (4)	
User entered 'Oral (ORAL)'	Kelsey Kelley (b) (4)	30 Apr 2021 15:48:01
	(b) (4)	

US3032242

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 14:52:51

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Keith Vrbicky (b) (4)	03 May 2021 16:17:41
	(b) (4)	
User entered empty.	Kelsey Kelley (b) (4)	30 Apr 2021 15:48:01
	(b) (4)	

US3032242

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 14:52:51

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Keith Vrbicky (b) (4)	03 May 2021 16:17:41
	(b) (4)	
User entered '22 Dec 2020'	Kelsey Kelley (b) (4)	30 Apr 2021 15:48:01
	(b) (4)	

US3032242

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 14:52:51

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Keith Vrbicky (b) (4)	03 May 2021 16:17:41
	(b) (4)	
User entered '0'	Kelsey Kelley (b) (4)	30 Apr 2021 15:48:01
	(b) (4)	

US3032242

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 14:52:51

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Keith Vrbicky (b) (4)	03 May 2021 16:17:41
User entered 'No (N)'	(b) (4) Kelsey Kelley (b) (4)	30 Apr 2021 15:48:01
	(b) (4)	

US3032242

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 14:52:51

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

Audit	User	Time (GMT)
User signature succeeded.	Keith Vrbicky (b) (4)	03 May 2021 16:17:41
	(b) (4)	
User entered '01 Jan 2021'	Kelsey Kelley (b) (4)	30 Apr 2021 15:48:01
	(b) (4)	

US3032242

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 14:52:51

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Keith Vrbicky (b) (4)	03 May 2021 16:17:41
	(b) (4)	
User closed query 'Data is required. Please complete.' (Site from System).	System	30 Apr 2021 15:48:06
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	30 Apr 2021 15:48:06
User entered 'No (N)' reason for change: Data Entry Error	Kelsey Kelley (b) (4)	30 Apr 2021 15:48:06
	(b) (4)	
User opened query 'Data is required. Please complete.' (Site from System).	System	30 Apr 2021 15:48:01
User entered empty.	Kelsey Kelley (b) (4)	30 Apr 2021 15:48:01
	(b) (4)	

US3032242

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 14:52:51

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	30 Apr 2021 15:48:01

US3032242

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 14:52:51

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	30 Apr 2021 15:48:01

US3032242

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 14:52:51

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	30 Apr 2021 15:48:01

US3032242

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 14:52:51

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Keith Vrbicky (b) (4)	03 May 2021 16:17:41
User coded data point as ATC: BLOOD AND BLOOD FORMING ORGANS, ATC: BLOOD SUBSTITUTES AND PERFUSION SOLUTIONS, ATC: I.V. SOLUTIONS, ATC: SOLUTIONS AFFECTING THE ELECTROLYTE BALANCE, PRODUCT: SODIUM CHLORIDE - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4)	30 Apr 2021 17:17:08
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	30 Apr 2021 17:17:08
Data point term sent to Coder	System	30 Apr 2021 15:49:36
User entered 'normal saline'	Kelsey Kelley (b) (4) (b) (4)	30 Apr 2021 15:48:57

US3032242

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 14:52:51

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Keith Vrbicky (b) (4)	03 May 2021 16:17:41
User entered 'No (N)'	(b) (4) Kelsey Kelley (b) (4)	30 Apr 2021 15:48:57
	(b) (4)	

US3032242

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 14:52:51

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Keith Vrbicky (b) (4)	03 May 2021 16:17:41
	(b) (4)	
User entered 'hysterectomy'	Kelsey Kelley (b) (4)	30 Apr 2021 15:48:57
	(b) (4)	

US3032242

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 14:52:51

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Keith Vrbicky (b) (4)	03 May 2021 16:17:41
	(b) (4)	
User entered '750'	Kelsey Kelley (b) (4)	30 Apr 2021 15:48:57
	(b) (4)	

US3032242

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 14:52:51

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Keith Vrbicky (b) (4)	03 May 2021 16:17:41
	(b) (4)	
User entered 'mL (mL)'	Kelsey Kelley (b) (4)	30 Apr 2021 15:48:57
	(b) (4)	

US3032242

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 14:52:51

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Keith Vrbicky (b) (4)	03 May 2021 16:17:41
	(b) (4)	
User entered empty.	Kelsey Kelley (b) (4)	30 Apr 2021 15:48:57
	(b) (4)	

US3032242

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 14:52:51

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Keith Vrbicky (b) (4)	03 May 2021 16:17:41
User entered 'once (ONCE)'	(b) (4) Kelsey Kelley (b) (4)	30 Apr 2021 15:48:57
	(b) (4)	

US3032242

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 14:52:51

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Keith Vrbicky (b) (4)	03 May 2021 16:17:41
	(b) (4)	
User entered empty.	Kelsey Kelley (b) (4)	30 Apr 2021 15:48:57
	(b) (4)	

US3032242

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 14:52:51

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Keith Vrbicky (b) (4)	03 May 2021 16:17:41
User entered 'Intravenous (INTRAVENOUS)'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	30 Apr 2021 15:48:57

US3032242

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 14:52:51

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Keith Vrbicky (b) (4)	03 May 2021 16:17:41
	(b) (4)	
User entered empty.	Kelsey Kelley (b) (4)	30 Apr 2021 15:48:57
	(b) (4)	

US3032242

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 14:52:51

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Keith Vrbicky (b) (4)	03 May 2021 16:17:41
	(b) (4)	
User entered '01 Feb 2021'	Kelsey Kelley (b) (4)	30 Apr 2021 15:48:57
	(b) (4)	

US3032242

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 14:52:51

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Keith Vrbicky (b) (4)	03 May 2021 16:17:41
	(b) (4)	
User entered '0'	Kelsey Kelley (b) (4)	30 Apr 2021 15:48:57
	(b) (4)	

US3032242

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 14:52:51

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Keith Vrbicky (b) (4)	03 May 2021 16:17:41
	(b) (4)	
User entered 'No (N)'	Kelsey Kelley (b) (4)	30 Apr 2021 15:48:57
	(b) (4)	

US3032242

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 14:52:51

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

Audit	User	Time (GMT)
User signature succeeded.	Keith Vrbicky (b) (4)	03 May 2021 16:17:41
	(b) (4)	
User entered '01 Feb 2021'	Kelsey Kelley (b) (4)	30 Apr 2021 15:48:57
	(b) (4)	

US3032242

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 14:52:51

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Keith Vrbicky (b) (4)	03 May 2021 16:17:41
	(b) (4)	
User entered 'No (N)'	Kelsey Kelley (b) (4)	30 Apr 2021 15:48:57
	(b) (4)	

US3032242

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 14:52:51

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	30 Apr 2021 15:48:57

US3032242

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 14:52:51

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	30 Apr 2021 15:48:57

US3032242

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 14:52:51

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	30 Apr 2021 15:48:57

US3032242

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 14:52:51

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Keith Vrbicky (b) (4)	03 May 2021 16:17:41
User coded data point as ATC: NERVOUS SYSTEM, ATC: ANALGESICS, ATC: OPIOIDS, ATC: OTHER OPIOIDS, PRODUCT: TRAMADOL - version WHODrug-Global-B3\202003.	(b) (4) (b) (4) Coder Import (b) (4)	30 Apr 2021 17:13:10
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\202003.	Coder Import (b) (4) (b) (4)	30 Apr 2021 17:13:10
Data point term sent to Coder	System	30 Apr 2021 15:49:37
User entered 'tramadol'	Kelsey Kelley (b) (4) (b) (4)	30 Apr 2021 15:49:29

US3032242

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 14:52:51

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Keith Vrbicky (b) (4)	03 May 2021 16:17:41
User entered 'No (N)'	(b) (4) Kelsey Kelley (b) (4)	30 Apr 2021 15:49:29
	(b) (4)	

US3032242

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 14:52:51

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Keith Vrbicky (b) (4)	03 May 2021 16:17:41
User entered 'hysterectomy'	(b) (4) Kelsey Kelley (b) (4)	30 Apr 2021 15:49:29
	(b) (4)	

US3032242

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 14:52:51

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Keith Vrbicky (b) (4)	03 May 2021 16:17:41
	(b) (4)	
User entered '50'	Kelsey Kelley (b) (4)	30 Apr 2021 15:49:29
	(b) (4)	

US3032242

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 14:52:51

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Keith Vrbicky (b) (4)	03 May 2021 16:17:41
	(b) (4)	
User entered 'mg (mg)'	Kelsey Kelley (b) (4)	30 Apr 2021 15:49:29
	(b) (4)	

US3032242

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 14:52:51

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Keith Vrbicky (b) (4)	03 May 2021 16:17:41
	(b) (4)	
User entered empty.	Kelsey Kelley (b) (4)	30 Apr 2021 15:49:29
	(b) (4)	

US3032242

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 14:52:51

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Keith Vrbicky (b) (4)	03 May 2021 16:17:41
	(b) (4)	
User entered 'as needed (PRN)'	Kelsey Kelley (b) (4)	30 Apr 2021 15:49:29
	(b) (4)	

US3032242

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 14:52:51

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Keith Vrbicky (b) (4)	03 May 2021 16:17:41
	(b) (4)	
User entered empty.	Kelsey Kelley (b) (4)	30 Apr 2021 15:49:29
	(b) (4)	

US3032242

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 14:52:51

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Keith Vrbicky (b) (4)	03 May 2021 16:17:41
	(b) (4)	
User entered 'Oral (ORAL)'	Kelsey Kelley (b) (4)	30 Apr 2021 15:49:29
	(b) (4)	

US3032242

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 14:52:51

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Keith Vrbicky (b) (4)	03 May 2021 16:17:41
	(b) (4)	
User entered empty.	Kelsey Kelley (b) (4)	30 Apr 2021 15:49:29
	(b) (4)	

US3032242

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 14:52:51

Start date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Keith Vrbicky (b) (4)	03 May 2021 16:17:41
	(b) (4)	
User entered '01 Feb 2021'	Kelsey Kelley (b) (4)	30 Apr 2021 15:49:29
	(b) (4)	

US3032242

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 14:52:51

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Keith Vrbicky (b) (4)	03 May 2021 16:17:41
	(b) (4)	
User entered '0'	Kelsey Kelley (b) (4)	30 Apr 2021 15:49:29
	(b) (4)	

US3032242

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 14:52:51

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Keith Vrbicky (b) (4)	03 May 2021 16:17:41
	(b) (4)	
User entered 'No (N)'	Kelsey Kelley (b) (4)	30 Apr 2021 15:49:29
	(b) (4)	

US3032242

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 14:52:51

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

Audit	User	Time (GMT)
User signature succeeded.	Keith Vrbicky (b) (4)	03 May 2021 16:17:41
	(b) (4)	
User entered '15 Feb 2021'	Kelsey Kelley (b) (4)	30 Apr 2021 15:49:29
	(b) (4)	

US3032242

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 14:52:51

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Keith Vrbicky (b) (4)	03 May 2021 16:17:41
	(b) (4)	
User entered 'No (N)'	Kelsey Kelley (b) (4)	30 Apr 2021 15:49:29
	(b) (4)	

US3032242

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 14:52:51

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	30 Apr 2021 15:49:29

US3032242

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 14:52:51

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	30 Apr 2021 15:49:29

US3032242

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 14:52:51

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	30 Apr 2021 15:49:29

US3032242

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 14:52:51

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Keith Vrbicky (b) (4)	03 May 2021 16:17:41
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: VITAMINS, ATC: VITAMIN A AND D, INCL. COMBINATIONS OF THE TWO, ATC: VITAMIN D AND ANALOGUES, PRODUCT: COLECALCIFEROL, PRODUCTSYNONYM: VITAMIN D3 - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	30 Apr 2021 15:52:09
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	30 Apr 2021 15:52:09
Data point term sent to Coder	System	30 Apr 2021 15:51:38
User entered 'vitamin D3'	Kelsey Kelley (b) (4)	30 Apr 2021 15:50:39

US3032242

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 14:52:51

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Keith Vrbicky (b) (4)	03 May 2021 16:17:41
User entered 'No (N)'	(b) (4) Kelsey Kelley (b) (4)	30 Apr 2021 15:50:39
	(b) (4)	

US3032242

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 14:52:51

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Keith Vrbicky (b) (4)	03 May 2021 16:17:41
	(b) (4)	
User entered 'endometrial cancer'	Kelsey Kelley (b) (4)	30 Apr 2021 15:50:39
	(b) (4)	

US3032242

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 14:52:51

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Keith Vrbicky (b) (4)	03 May 2021 16:17:41
	(b) (4)	
User entered '5000'	Kelsey Kelley (b) (4)	30 Apr 2021 15:50:39
	(b) (4)	

US3032242

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 14:52:51

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Keith Vrbicky (b) (4)	03 May 2021 16:17:41
User entered 'Other (OTHER)'	(b) (4) Kelsey Kelley (b) (4)	30 Apr 2021 15:50:39
	(b) (4)	

US3032242

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 14:52:51

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Keith Vrbicky (b) (4)	03 May 2021 16:17:41
	(b) (4)	
User entered 'units'	Kelsey Kelley (b) (4)	30 Apr 2021 15:50:39
	(b) (4)	

US3032242

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 14:52:51

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Keith Vrbicky (b) (4)	03 May 2021 16:17:41
	(b) (4)	
User entered 'once daily (QD)'	Kelsey Kelley (b) (4)	30 Apr 2021 15:50:39
	(b) (4)	

US3032242

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 14:52:51

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Keith Vrbicky (b) (4)	03 May 2021 16:17:41
	(b) (4)	
User entered empty.	Kelsey Kelley (b) (4)	30 Apr 2021 15:50:39
	(b) (4)	

US3032242

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 14:52:51

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Keith Vrbicky (b) (4)	03 May 2021 16:17:41
	(b) (4)	
User entered 'Oral (ORAL)'	Kelsey Kelley (b) (4)	30 Apr 2021 15:50:39
	(b) (4)	

US3032242

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 14:52:51

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Keith Vrbicky (b) (4)	03 May 2021 16:17:41
	(b) (4)	
User entered empty.	Kelsey Kelley (b) (4)	30 Apr 2021 15:50:39
	(b) (4)	

US3032242

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 14:52:51

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Keith Vrbicky (b) (4)	03 May 2021 16:17:41
	(b) (4)	
User entered '01 Feb 2021'	Kelsey Kelley (b) (4)	30 Apr 2021 15:50:39
	(b) (4)	

US3032242

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 14:52:51

Start date completely unknown

Audit	User	Time (GMT)
User signature succeeded.	Keith Vrbicky (b) (4)	03 May 2021 16:17:41
	(b) (4)	
User entered '0'	Kelsey Kelley (b) (4)	30 Apr 2021 15:50:39
	(b) (4)	

US3032242

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 14:52:51

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Keith Vrbicky (b) (4)	03 May 2021 16:17:41
	(b) (4)	
User entered 'Yes (Y)'	Kelsey Kelley (b) (4)	30 Apr 2021 15:50:39
	(b) (4)	

US3032242

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 14:52:51

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

Audit	User	Time (GMT)
User signature succeeded.	Keith Vrbicky (b) (4)	03 May 2021 16:17:41
	(b) (4)	
User entered empty.	Kelsey Kelley (b) (4)	30 Apr 2021 15:50:39
	(b) (4)	

US3032242

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 14:52:51

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Keith Vrbicky (b) (4)	03 May 2021 16:17:41
	(b) (4)	
User entered 'No (N)'	Kelsey Kelley (b) (4)	30 Apr 2021 15:50:39
	(b) (4)	

US3032242

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 14:52:51

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	30 Apr 2021 15:50:39

US3032242

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 14:52:51

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	30 Apr 2021 15:50:39

US3032242

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 14:52:51

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	30 Apr 2021 15:50:39

US3032242

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 14:52:51

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Keith Vrbicky (b) (4)	03 May 2021 16:17:41
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: DRUGS FOR CONSTIPATION, ATC: DRUGS FOR CONSTIPATION, ATC: SOFTENERS, EMOLLIENTS, PRODUCT: DOCUSATE SODIUM - version WHODrug-Global-B3\202003.	(b) (4) Coder Import (b) (4)	30 Apr 2021 17:53:05
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\202003.	Coder Import (b) (4)	30 Apr 2021 17:53:05
Data point term sent to Coder	System	30 Apr 2021 15:53:39
User entered 'Docusate sodium'	Kelsey Kelley (b) (4)	30 Apr 2021 15:53:23

US3032242

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 14:52:51

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Keith Vrbicky (b) (4)	03 May 2021 16:17:41
User entered 'No (N)'	(b) (4) Kelsey Kelley (b) (4)	30 Apr 2021 15:53:23
	(b) (4)	

US3032242

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 14:52:51

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Keith Vrbicky (b) (4)	03 May 2021 16:17:41
User entered 'hysterectomy'	(b) (4) Kelsey Kelley (b) (4)	30 Apr 2021 15:53:23
	(b) (4)	

US3032242

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 14:52:51

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Keith Vrbicky (b) (4)	03 May 2021 16:17:41
	(b) (4)	
User entered '200'	Kelsey Kelley (b) (4)	30 Apr 2021 15:53:23
	(b) (4)	

US3032242

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 14:52:51

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Keith Vrbicky (b) (4)	03 May 2021 16:17:41
	(b) (4)	
User entered 'mg (mg)'	Kelsey Kelley (b) (4)	30 Apr 2021 15:53:23
	(b) (4)	

US3032242

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 14:52:51

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Keith Vrbicky (b) (4) (b) (4)	03 May 2021 16:17:41
User entered empty.	Kelsey Kelley (b) (4) (b) (4)	30 Apr 2021 15:53:23

US3032242

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 14:52:51

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Keith Vrbicky (b) (4)	03 May 2021 16:17:41
User entered 'once daily (QD)'	(b) (4) Kelsey Kelley (b) (4)	30 Apr 2021 15:53:23
	(b) (4)	

US3032242

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 14:52:51

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Keith Vrbicky (b) (4)	03 May 2021 16:17:41
	(b) (4)	
User entered empty.	Kelsey Kelley (b) (4)	30 Apr 2021 15:53:23
	(b) (4)	

US3032242

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 14:52:51

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Keith Vrbicky (b) (4)	03 May 2021 16:17:41
	(b) (4)	
User entered 'Oral (ORAL)'	Kelsey Kelley (b) (4)	30 Apr 2021 15:53:23
	(b) (4)	

US3032242

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 14:52:51

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Keith Vrbicky (b) (4)	03 May 2021 16:17:41
	(b) (4)	
User entered empty.	Kelsey Kelley (b) (4)	30 Apr 2021 15:53:23
	(b) (4)	

US3032242

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 14:52:51

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Keith Vrbicky (b) (4)	03 May 2021 16:17:41
	(b) (4)	
User entered '02 Feb 2021'	Kelsey Kelley (b) (4)	30 Apr 2021 15:53:23
	(b) (4)	

US3032242

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 14:52:51

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Keith Vrbicky (b) (4)	03 May 2021 16:17:41
	(b) (4)	
User entered '0'	Kelsey Kelley (b) (4)	30 Apr 2021 15:53:23
	(b) (4)	

US3032242

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 14:52:51

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Keith Vrbicky (b) (4)	03 May 2021 16:17:41
	(b) (4)	
User entered 'No (N)'	Kelsey Kelley (b) (4)	30 Apr 2021 15:53:23
	(b) (4)	

US3032242

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 14:52:51

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

Audit	User	Time (GMT)
User signature succeeded.	Keith Vrbicky (b) (4)	03 May 2021 16:17:41
	(b) (4)	
User entered '15 Feb 2021'	Kelsey Kelley (b) (4)	30 Apr 2021 15:53:23
	(b) (4)	

US3032242

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 14:52:51

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Keith Vrbicky (b) (4)	03 May 2021 16:17:41
User entered 'No (N)'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	30 Apr 2021 15:53:23

US3032242

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 14:52:51

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	30 Apr 2021 15:53:23

US3032242

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 14:52:51

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	30 Apr 2021 15:53:23

US3032242

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 14:52:51

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	30 Apr 2021 15:53:23

US3032242

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 14:52:51

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Keith Vrbicky (b) (4)	03 May 2021 16:17:41
User coded data point as ATC: NERVOUS SYSTEM, ATC: ANESTHETICS, ATC: ANESTHETICS, LOCAL, ATC: AMIDES, PRODUCT: ROPIVACAINE - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4)	01 May 2021 12:09:38
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	01 May 2021 12:09:38
Data point term sent to Coder	System	30 Apr 2021 15:54:42
User entered '0.5% ropivacaine'	Kelsey Kelley (b) (4)	30 Apr 2021 15:54:28

US3032242

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 14:52:51

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Keith Vrbicky (b) (4)	03 May 2021 16:17:41
	(b) (4)	
User entered 'No (N)'	Kelsey Kelley (b) (4)	30 Apr 2021 15:54:28
	(b) (4)	

US3032242

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 14:52:51

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Keith Vrbicky (b) (4)	03 May 2021 16:17:41
	(b) (4)	
User entered 'hysterectomy'	Kelsey Kelley (b) (4)	30 Apr 2021 15:54:28
	(b) (4)	

US3032242

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 14:52:51

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Keith Vrbicky (b) (4)	03 May 2021 16:17:41
	(b) (4)	
User entered '25'	Kelsey Kelley (b) (4)	30 Apr 2021 15:54:28
	(b) (4)	

US3032242

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 14:52:51

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Keith Vrbicky (b) (4)	03 May 2021 16:17:41
	(b) (4)	
User entered 'mL (mL)'	Kelsey Kelley (b) (4)	30 Apr 2021 15:54:28
	(b) (4)	

US3032242

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 14:52:51

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Keith Vrbicky (b) (4) (b) (4)	03 May 2021 16:17:41
User entered empty.	Kelsey Kelley (b) (4) (b) (4)	30 Apr 2021 15:54:28

US3032242

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 14:52:51

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Keith Vrbicky (b) (4)	03 May 2021 16:17:41
	(b) (4)	
User entered 'once (ONCE)'	Kelsey Kelley (b) (4)	30 Apr 2021 15:54:28
	(b) (4)	

US3032242

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 14:52:51

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Keith Vrbicky (b) (4)	03 May 2021 16:17:41
	(b) (4)	
User entered empty.	Kelsey Kelley (b) (4)	30 Apr 2021 15:54:28
	(b) (4)	

US3032242

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 14:52:51

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Keith Vrbicky (b) (4)	03 May 2021 16:17:41
	(b) (4)	
User entered 'Other (OTHER)'	Kelsey Kelley (b) (4)	30 Apr 2021 15:54:28
	(b) (4)	

US3032242

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 14:52:51

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Keith Vrbicky (b) (4)	03 May 2021 16:17:41
	(b) (4)	
User entered 'Epidural'	Kelsey Kelley (b) (4)	30 Apr 2021 15:54:28
	(b) (4)	

US3032242

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 14:52:51

Start date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Keith Vrbicky (b) (4)	03 May 2021 16:17:41
	(b) (4)	
User entered '01 Feb 2021'	Kelsey Kelley (b) (4)	30 Apr 2021 15:54:28
	(b) (4)	

US3032242

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 14:52:51

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Keith Vrbicky (b) (4)	03 May 2021 16:17:41
	(b) (4)	
User entered '0'	Kelsey Kelley (b) (4)	30 Apr 2021 15:54:28
	(b) (4)	

US3032242

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 14:52:51

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Keith Vrbicky (b) (4)	03 May 2021 16:17:41
	(b) (4)	
User entered 'No (N)'	Kelsey Kelley (b) (4)	30 Apr 2021 15:54:28
	(b) (4)	

US3032242

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 14:52:51

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

Audit	User	Time (GMT)
User signature succeeded.	Keith Vrbicky (b) (4)	03 May 2021 16:17:41
	(b) (4)	
User entered '01 Feb 2021'	Kelsey Kelley (b) (4)	30 Apr 2021 15:54:28
	(b) (4)	

US3032242

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 14:52:51

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Keith Vrbicky (b) (4)	03 May 2021 16:17:41
	(b) (4)	
User entered 'No (N)'	Kelsey Kelley (b) (4)	30 Apr 2021 15:54:28
	(b) (4)	

US3032242

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 14:52:51

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	30 Apr 2021 15:54:28

US3032242

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 14:52:51

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	30 Apr 2021 15:54:28

US3032242

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 14:52:51

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	30 Apr 2021 15:54:28

US3032242

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures Summary

Generated On: 09 Jun 2021 14:52:51

[Were any concomitant procedures performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 06:09:04
DataPoint Verified.	(b) (4)	11 Mar 2021 22:57:50
User signature succeeded.	Keith Vrbicky (b) (4)	05 Feb 2021 19:41:27
DataPoint Un-verified.	(b) (4)	
	Linden DeBoer (b) (4)	05 Feb 2021 14:54:11
Signature has been broken.	(b) (4)	
	Linden DeBoer (b) (4)	05 Feb 2021 14:54:11
User entered 'Yes (Y)' reason for change: Data Entry Error	(b) (4)	
	Linden DeBoer (b) (4)	05 Feb 2021 14:54:11
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	03 Dec 2020 16:32:54
User signature succeeded.	Keith Vrbicky (b) (4)	08 Nov 2020 23:40:39
	(b) (4)	
User entered 'No (N)'	Linden DeBoer (b) (4)	07 Nov 2020 19:09:48
	(b) (4)	

US3032242

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (1)

Generated On: 09 Jun 2021 14:52:51

Procedure/Surgery date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Mar 2021 22:57:54
User signature succeeded.	Keith Vrbicky (b) (4)	05 Feb 2021 19:41:27
User entered '01 Feb 2021'	(b) (4) Linden DeBoer (b) (4)	05 Feb 2021 14:54:32
	(b) (4)	

US3032242

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (1)

Generated On: 09 Jun 2021 14:52:51

[Procedure/Surgery](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Mar 2021 22:57:54
User signature succeeded.	Keith Vrbicky (b) (4)	05 Feb 2021 19:41:27
User entered 'hysterectomy'	(b) (4) Linden DeBoer (b) (4)	05 Feb 2021 14:54:32

US3032242

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (1)

Generated On: 09 Jun 2021 14:52:51

[Indication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Mar 2021 22:57:54
User signature succeeded.	Keith Vrbicky (b) (4)	05 Feb 2021 19:41:27
User entered 'Adverse Event (AE)'	(b) (4) Linden DeBoer (b) (4)	05 Feb 2021 14:54:32

US3032242

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (1)

Generated On: 09 Jun 2021 14:52:51

If indication is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Mar 2021 22:57:54
User signature succeeded.	Keith Vrbicky (b) (4)	05 Feb 2021 19:41:27
User entered empty.	(b) (4) Linden DeBoer (b) (4)	05 Feb 2021 14:54:32
	(b) (4)	

US3032242

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (2)

Generated On: 09 Jun 2021 14:52:51

Procedure/Surgery date (dd MMM yyyy)

Audit	User	Time (GMT)
User closed query 'Per DM CLR: Please review the Date of this procedure/Surgery, as it is out of the expected timeframe with AE# 1 (ENDOMETRIAL CANCER, 29 DEC 2020 - 5 FEB 2021). Please review and reconcile date of procedure or clarify as necessary. ' (Site from DM).	(b) (4), (b) (6)	09 Apr 2021 11:47:09
User signature succeeded.	Keith Vrbicky (b) (4)	06 Apr 2021 15:40:50
Query 'Per DM CLR: Please review the Date of this procedure/Surgery, as it is out of the expected timeframe with AE# 1 (ENDOMETRIAL CANCER, 29 DEC 2020 - 5 FEB 2021). Please review and reconcile date of procedure or clarify as necessary. ' answered with 'AE is still ongoing. Updated eCRF' (Site from DM).	(b) (4) Kelsey Kelley (b) (4)	05 Apr 2021 20:41:03
User opened query 'Per DM CLR: Please review the Date of this procedure/Surgery, as it is out of the expected timeframe with AE# 1 (ENDOMETRIAL CANCER, 29 DEC 2020 - 5 FEB 2021). Please review and reconcile date of procedure or clarify as necessary. ' (Site from DM).	(b) (4), (b) (6)	04 Apr 2021 09:09:18
Query 'Per DM CLR: Please review the Date of this procedure/Surgery, as it is out of the expected timeframe with AE# 1 (ENDOMETRIAL CANCER, start date 29 DEC 2020 - 5 FEB 2021). Please review and reconcile date of procedure or clarify as necessary. ' canceled (Site from DM).	(b) (4), (b) (6)	04 Apr 2021 09:09:03
User opened query 'Per DM CLR: Please review the Date of this procedure/Surgery, as it is out of the expected timeframe with AE# 1 (ENDOMETRIAL CANCER, start date 29 DEC 2020 - 5 FEB 2021). Please review and reconcile date of procedure or clarify as necessary. ' (Site from DM).	(b) (4), (b) (6)	04 Apr 2021 09:08:54
User entered '22 Mar 2021'	Kelsey Kelley (b) (4)	25 Mar 2021 20:02:27

US3032242

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (2)

Generated On: 09 Jun 2021 14:52:51

[Procedure/Surgery](#)

Audit	User	Time (GMT)
User signature succeeded.	Keith Vrbicky (b) (4)	06 Apr 2021 15:40:50
	(b) (4)	
User entered 'radiation to pelvic region'	Kelsey Kelley (b) (4)	25 Mar 2021 20:02:27
	(b) (4)	

US3032242

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (2)

Generated On: 09 Jun 2021 14:52:51

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Keith Vrbicky (b) (4)	06 Apr 2021 15:40:50
User entered 'Adverse Event (AE)'	(b) (4) Kelsey Kelley (b) (4)	25 Mar 2021 20:02:27
	(b) (4)	

US3032242

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (2)

Generated On: 09 Jun 2021 14:52:51

If indication is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Keith Vrbicky (b) (4)	06 Apr 2021 15:40:50
	(b) (4)	
User entered empty.	Kelsey Kelley (b) (4)	25 Mar 2021 20:02:27
	(b) (4)	

US3032242

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (3)

Generated On: 09 Jun 2021 14:52:51

Procedure/Surgery date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Keith Vrbicky (b) (4)	06 Apr 2021 15:40:50
	(b) (4)	
User entered '23 Dec 2020'	Chelsie Nutsch (b) (4)	26 Mar 2021 13:55:23
	(b) (4)	

US3032242

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (3)

Generated On: 09 Jun 2021 14:52:51

[Procedure/Surgery](#)

Audit	User	Time (GMT)
User signature succeeded.	Keith Vrbicky (b) (4)	06 Apr 2021 15:40:50
	(b) (4)	
User entered 'Colposcopy'	Chelsie Nutsch (b) (4)	26 Mar 2021 13:55:23
	(b) (4)	

US3032242

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (3)

Generated On: 09 Jun 2021 14:52:51

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Keith Vrbicky (b) (4)	06 Apr 2021 15:40:50
	(b) (4)	
User entered 'Adverse Event (AE)'	Chelsie Nutsch (b) (4)	26 Mar 2021 13:55:23
	(b) (4)	

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Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (3)

Generated On: 09 Jun 2021 14:52:51

If indication is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Keith Vrbicky (b) (4)	06 Apr 2021 15:40:50
	(b) (4)	
User entered empty.	Chelsie Nutsch (b) (4)	26 Mar 2021 13:55:23
	(b) (4)	

US3032242

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (4)

Generated On: 09 Jun 2021 14:52:51

Procedure/Surgery date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Keith Vrbicky (b) (4)	03 May 2021 16:17:41
	(b) (4)	
User entered '23 Sep 2020'	Kelsey Kelley (b) (4)	26 Apr 2021 15:15:24
	(b) (4)	

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Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (4)

Generated On: 09 Jun 2021 14:52:51

[Procedure/Surgery](#)

Audit	User	Time (GMT)
User signature succeeded.	Keith Vrbicky (b) (4) (b) (4)	03 May 2021 16:17:41
User entered 'endometrial biopsy'	Kelsey Kelley (b) (4) (b) (4)	26 Apr 2021 15:15:24

US3032242

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (4)

Generated On: 09 Jun 2021 14:52:51

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Keith Vrbicky (b) (4)	03 May 2021 16:17:41
User entered 'Adverse Event (AE)'	(b) (4) Kelsey Kelley (b) (4)	26 Apr 2021 15:15:24
	(b) (4)	

US3032242

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (4)

Generated On: 09 Jun 2021 14:52:51

If indication is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Keith Vrbicky (b) (4) (b) (4)	03 May 2021 16:17:41
User entered empty.	Kelsey Kelley (b) (4) (b) (4)	26 Apr 2021 15:15:24

US3032242

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (5)

Generated On: 09 Jun 2021 14:52:51

Procedure/Surgery date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Keith Vrbicky (b) (4)	03 May 2021 16:17:41
	(b) (4)	
User entered '23 Dec 2020'	Kelsey Kelley (b) (4)	26 Apr 2021 15:15:50
	(b) (4)	

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Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (5)

Generated On: 09 Jun 2021 14:52:51

[Procedure/Surgery](#)

Audit	User	Time (GMT)
User signature succeeded.	Keith Vrbicky (b) (4)	03 May 2021 16:17:41
User entered 'local excision of cervical polyp'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	26 Apr 2021 15:15:50

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Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (5)

Generated On: 09 Jun 2021 14:52:51

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Keith Vrbicky (b) (4)	03 May 2021 16:17:41
User entered 'Adverse Event (AE)'	(b) (4) Kelsey Kelley (b) (4)	26 Apr 2021 15:15:50
	(b) (4)	

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Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (5)

Generated On: 09 Jun 2021 14:52:51

If indication is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Keith Vrbicky (b) (4) (b) (4)	03 May 2021 16:17:41
User entered empty.	Kelsey Kelley (b) (4) (b) (4)	26 Apr 2021 15:15:50

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Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (6)

Generated On: 09 Jun 2021 14:52:51

Procedure/Surgery date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Keith Vrbicky (b) (4)	03 May 2021 16:17:41
	(b) (4)	
User entered '22 Dec 2020'	Kelsey Kelley (b) (4)	30 Apr 2021 15:41:12
	(b) (4)	

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Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (6)

Generated On: 09 Jun 2021 14:52:51

[Procedure/Surgery](#)

Audit	User	Time (GMT)
User signature succeeded.	Keith Vrbicky (b) (4)	03 May 2021 16:17:41
User entered 'pelvic ultrasound'	(b) (4) Kelsey Kelley (b) (4)	30 Apr 2021 15:41:12
	(b) (4)	

US3032242

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (6)

Generated On: 09 Jun 2021 14:52:51

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Keith Vrbicky (b) (4)	03 May 2021 16:17:41
User entered 'Adverse Event (AE)'	(b) (4) Kelsey Kelley (b) (4)	30 Apr 2021 15:41:12
	(b) (4)	

US3032242

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (6)

Generated On: 09 Jun 2021 14:52:51

If indication is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Keith Vrbicky (b) (4) (b) (4)	03 May 2021 16:17:41
User entered empty.	Kelsey Kelley (b) (4) (b) (4)	30 Apr 2021 15:41:12

US3032242

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (7)

Generated On: 09 Jun 2021 14:52:51

Procedure/Surgery date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Keith Vrbicky (b) (4)	03 May 2021 16:17:41
	(b) (4)	
User entered '22 Dec 2020'	Kelsey Kelley (b) (4)	30 Apr 2021 15:41:28
	(b) (4)	

US3032242

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (7)

Generated On: 09 Jun 2021 14:52:51

[Procedure/Surgery](#)

Audit	User	Time (GMT)
User signature succeeded.	Keith Vrbicky (b) (4)	03 May 2021 16:17:41
	(b) (4)	
User entered 'complete blood count'	Kelsey Kelley (b) (4)	30 Apr 2021 15:41:28
	(b) (4)	

US3032242

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (7)

Generated On: 09 Jun 2021 14:52:51

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Keith Vrbicky (b) (4)	03 May 2021 16:17:41
User entered 'Adverse Event (AE)'	(b) (4) Kelsey Kelley (b) (4)	30 Apr 2021 15:41:28
	(b) (4)	

US3032242

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (7)

Generated On: 09 Jun 2021 14:52:51

If indication is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Keith Vrbicky (b) (4)	03 May 2021 16:17:41
	(b) (4)	
User entered empty.	Kelsey Kelley (b) (4)	30 Apr 2021 15:41:28
	(b) (4)	

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Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (8)

Generated On: 09 Jun 2021 14:52:51

Procedure/Surgery date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Keith Vrbicky (b) (4)	03 May 2021 16:17:41
	(b) (4)	
User entered '01 Feb 2021'	Kelsey Kelley (b) (4)	30 Apr 2021 15:41:53
	(b) (4)	

US3032242

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (8)

Generated On: 09 Jun 2021 14:52:51

[Procedure/Surgery](#)

Audit	User	Time (GMT)
User signature succeeded.	Keith Vrbicky (b) (4)	03 May 2021 16:17:41
	(b) (4)	
User entered 'BILATERAL SALPINGO-oophorectomy' reason for change: Data Entry Error	Kelsey Kelley (b) (4)	30 Apr 2021 15:42:06
	(b) (4)	
User entered 'Bilateral salpingo-ectomy'	Kelsey Kelley (b) (4)	30 Apr 2021 15:41:53
	(b) (4)	

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Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (8)

Generated On: 09 Jun 2021 14:52:51

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Keith Vrbicky (b) (4)	03 May 2021 16:17:41
User entered 'Adverse Event (AE)'	(b) (4) Kelsey Kelley (b) (4)	30 Apr 2021 15:41:53
	(b) (4)	

US3032242

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (8)

Generated On: 09 Jun 2021 14:52:51

If indication is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Keith Vrbicky (b) (4)	03 May 2021 16:17:41
	(b) (4)	
User entered empty.	Kelsey Kelley (b) (4)	30 Apr 2021 15:41:53
	(b) (4)	

US3032242

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (9)

Generated On: 09 Jun 2021 14:52:51

Procedure/Surgery date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Keith Vrbicky (b) (4)	03 May 2021 16:17:41
	(b) (4)	
User entered '01 Feb 2021'	Kelsey Kelley (b) (4)	30 Apr 2021 15:42:37
	(b) (4)	

US3032242

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (9)

Generated On: 09 Jun 2021 14:52:51

[Procedure/Surgery](#)

Audit	User	Time (GMT)
User signature succeeded.	Keith Vrbicky (b) (4)	03 May 2021 16:17:41
User entered 'right pelvic sentinel lymph node biopsy'	(b) (4) Kelsey Kelley (b) (4)	30 Apr 2021 15:42:37
	(b) (4)	

US3032242

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (9)

Generated On: 09 Jun 2021 14:52:51

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Keith Vrbicky (b) (4)	03 May 2021 16:17:41
User entered 'Adverse Event (AE)'	(b) (4) Kelsey Kelley (b) (4)	30 Apr 2021 15:42:37
	(b) (4)	

US3032242

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (9)

Generated On: 09 Jun 2021 14:52:51

If indication is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Keith Vrbicky (b) (4)	03 May 2021 16:17:41
	(b) (4)	
User entered empty.	Kelsey Kelley (b) (4)	30 Apr 2021 15:42:37
	(b) (4)	

US3032242

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (10)

Generated On: 09 Jun 2021 14:52:51

Procedure/Surgery date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Keith Vrbicky (b) (4)	03 May 2021 16:17:41
	(b) (4)	
User entered '01 Feb 2021'	Kelsey Kelley (b) (4)	30 Apr 2021 15:43:08
	(b) (4)	

US3032242

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (10)

Generated On: 09 Jun 2021 14:52:51

[Procedure/Surgery](#)

Audit	User	Time (GMT)
User signature succeeded.	Keith Vrbicky (b) (4)	03 May 2021 16:17:41
User entered 'excision of a left vulvar intradermal melanocytic nevus'	(b) (4) Kelsey Kelley (b) (4)	30 Apr 2021 15:43:08

US3032242

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (10)

Generated On: 09 Jun 2021 14:52:51

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Keith Vrbicky (b) (4)	03 May 2021 16:17:41
User entered 'Adverse Event (AE)'	(b) (4) Kelsey Kelley (b) (4)	30 Apr 2021 15:43:08
	(b) (4)	

US3032242

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (10)

Generated On: 09 Jun 2021 14:52:51

If indication is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Keith Vrbicky (b) (4)	03 May 2021 16:17:41
	(b) (4)	
User entered empty.	Kelsey Kelley (b) (4)	30 Apr 2021 15:43:08
	(b) (4)	

US3032242

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (11)

Generated On: 09 Jun 2021 14:52:51

Procedure/Surgery date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Keith Vrbicky (b) (4)	03 May 2021 16:17:41
	(b) (4)	
User entered '14 Jan 2021'	Kelsey Kelley (b) (4)	30 Apr 2021 15:43:30
	(b) (4)	

US3032242

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (11)

Generated On: 09 Jun 2021 14:52:51

[Procedure/Surgery](#)

Audit	User	Time (GMT)
User signature succeeded.	Keith Vrbicky (b) (4)	03 May 2021 16:17:41
	(b) (4)	
User entered 'CT of abdomen'	Kelsey Kelley (b) (4)	30 Apr 2021 15:43:30
	(b) (4)	

US3032242

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (11)

Generated On: 09 Jun 2021 14:52:51

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Keith Vrbicky (b) (4)	03 May 2021 16:17:41
User entered 'Adverse Event (AE)'	(b) (4) Kelsey Kelley (b) (4)	30 Apr 2021 15:43:30
	(b) (4)	

US3032242

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (11)

Generated On: 09 Jun 2021 14:52:51

If indication is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Keith Vrbicky (b) (4) (b) (4)	03 May 2021 16:17:41
User entered empty.	Kelsey Kelley (b) (4) (b) (4)	30 Apr 2021 15:43:30

US3032242

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (12)

Generated On: 09 Jun 2021 14:52:51

Procedure/Surgery date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Keith Vrbicky (b) (4)	03 May 2021 16:17:41
	(b) (4)	
User entered '01 Feb 2021'	Kelsey Kelley (b) (4)	30 Apr 2021 15:43:52
	(b) (4)	

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Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (12)

Generated On: 09 Jun 2021 14:52:51

[Procedure/Surgery](#)

Audit	User	Time (GMT)
User signature succeeded.	Keith Vrbicky (b) (4)	03 May 2021 16:17:41
	(b) (4)	
User entered 'foley catheter'	Kelsey Kelley (b) (4)	30 Apr 2021 15:43:52
	(b) (4)	

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Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (12)

Generated On: 09 Jun 2021 14:52:51

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Keith Vrbicky (b) (4)	03 May 2021 16:17:41
User entered 'Adverse Event (AE)'	(b) (4) Kelsey Kelley (b) (4)	30 Apr 2021 15:43:52
	(b) (4)	

US3032242

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (12)

Generated On: 09 Jun 2021 14:52:51

If indication is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Keith Vrbicky (b) (4) (b) (4)	03 May 2021 16:17:41
User entered empty.	Kelsey Kelley (b) (4) (b) (4)	30 Apr 2021 15:43:52

US3032242

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (13)

Generated On: 09 Jun 2021 14:52:51

Procedure/Surgery date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Keith Vrbicky (b) (4)	03 May 2021 16:17:41
	(b) (4)	
User entered '15 Feb 2021'	Kelsey Kelley (b) (4)	30 Apr 2021 15:44:21
	(b) (4)	

US3032242

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (13)

Generated On: 09 Jun 2021 14:52:51

[Procedure/Surgery](#)

Audit	User	Time (GMT)
User signature succeeded.	Keith Vrbicky (b) (4)	03 May 2021 16:17:41
	(b) (4)	
User entered 'Ct of chest' reason for change: Data Entry Error	Kelsey Kelley (b) (4)	30 Apr 2021 15:44:34
	(b) (4)	
User entered 'endometrial cancer'	Kelsey Kelley (b) (4)	30 Apr 2021 15:44:21
	(b) (4)	

US3032242

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (13)

Generated On: 09 Jun 2021 14:52:51

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Keith Vrbicky (b) (4)	03 May 2021 16:17:41
User entered 'Adverse Event (AE)'	(b) (4) Kelsey Kelley (b) (4)	30 Apr 2021 15:44:21
	(b) (4)	

US3032242

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (13)

Generated On: 09 Jun 2021 14:52:51

If indication is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Keith Vrbicky (b) (4)	03 May 2021 16:17:41
	(b) (4)	
User entered empty.	Kelsey Kelley (b) (4)	30 Apr 2021 15:44:21
	(b) (4)	

US3032242

Folder: SAE USA-US032-2021-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 09 Jun 2021 14:52:51

[SAEID](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Mar 2021 22:49:05
User signature succeeded.	Keith Vrbicky (b) (4)	12 Feb 2021 19:56:37
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	08 Feb 2021 15:49:49
User entered 'USA-US032-2021-MRNA-1273-P301000006'	System	08 Feb 2021 15:49:16

US3032242

Folder: SAE USA-US032-2021-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 09 Jun 2021 14:52:51

Serious

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Mar 2021 22:49:05
User signature succeeded.	Keith Vrbicky (b) (4)	12 Feb 2021 19:56:37
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	08 Feb 2021 15:49:49
User entered 'Yes (Y)'	System	08 Feb 2021 15:49:16

US3032242

Folder: SAE USA-US032-2021-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 09 Jun 2021 14:52:51

[Death](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Mar 2021 22:49:05
User signature succeeded.	Keith Vrbicky (b) (4)	12 Feb 2021 19:56:37
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	08 Feb 2021 15:49:49
User entered 'No (N)'	System	08 Feb 2021 15:49:16

US3032242

Folder: SAE USA-US032-2021-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 09 Jun 2021 14:52:51

[Life threatening](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Mar 2021 22:49:05
User signature succeeded.	Keith Vrbicky (b) (4)	12 Feb 2021 19:56:37
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	08 Feb 2021 15:49:49
User entered 'No (N)'	System	08 Feb 2021 15:49:16

US3032242

Folder: SAE USA-US032-2021-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 09 Jun 2021 14:52:51

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Mar 2021 22:49:05
User signature succeeded.	Keith Vrbicky (b) (4)	12 Feb 2021 19:56:37
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	08 Feb 2021 15:49:49
User entered 'No (N)'	System	08 Feb 2021 15:49:16

US3032242

Folder: SAE USA-US032-2021-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 09 Jun 2021 14:52:51

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Mar 2021 22:49:05
User signature succeeded.	Keith Vrbicky (b) (4)	12 Feb 2021 19:56:37
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	08 Feb 2021 15:49:49
User entered 'No (N)'	System	08 Feb 2021 15:49:16

US3032242

Folder: SAE USA-US032-2021-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 09 Jun 2021 14:52:51

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Mar 2021 22:49:05
User signature succeeded.	Keith Vrbicky (b) (4)	12 Feb 2021 19:56:37
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	08 Feb 2021 15:49:49
User entered 'No (N)'	System	08 Feb 2021 15:49:16

US3032242

Folder: SAE USA-US032-2021-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 09 Jun 2021 14:52:51

[Other medically important event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Mar 2021 22:49:05
User signature succeeded.	Keith Vrbicky (b) (4)	12 Feb 2021 19:56:37
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	08 Feb 2021 15:49:49
User entered 'Yes (Y)'	System	08 Feb 2021 15:49:16

US3032242

Folder: SAE USA-US032-2021-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 09 Jun 2021 14:52:51

[Investigator's First Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Mar 2021 22:49:05
User signature succeeded.	Keith Vrbicky (b) (4)	12 Feb 2021 19:56:37
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	08 Feb 2021 15:49:49
User entered 'Keith'	System	08 Feb 2021 15:49:16

US3032242

Folder: SAE USA-US032-2021-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 09 Jun 2021 14:52:51

[Investigator's Last Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Mar 2021 22:49:05
User signature succeeded.	Keith Vrbicky (b) (4)	12 Feb 2021 19:56:37
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	08 Feb 2021 15:49:49
User entered 'Vrbicky'	System	08 Feb 2021 15:49:16

US3032242

Folder: SAE USA-US032-2021-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 09 Jun 2021 14:52:51

[Investigator Country](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Mar 2021 22:49:05
Reviewed for Safety.		19 Feb 2021 18:43:48
User signature succeeded.	Keith Vrbicky (b) (4)	12 Feb 2021 19:56:37
User entered 'US'	(b) (4) System	08 Feb 2021 15:50:02

US3032242

Folder: SAE USA-US032-2021-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 09 Jun 2021 14:52:51

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '7'	System	30 Apr 2021 17:33:41
User entered '6'	System	26 Apr 2021 20:03:51
User entered '5'	System	19 Apr 2021 14:39:28
User entered '4'	System	06 Apr 2021 19:03:28
Signature has been broken.	System	24 Feb 2021 13:45:27
User entered '3'	System	24 Feb 2021 13:45:27
User signature succeeded.	Keith Vrbicky (b) (4)	22 Feb 2021 17:26:08
	(b) (4)	
Signature has been broken.	System	19 Feb 2021 18:44:06
User entered '2'	System	19 Feb 2021 18:44:06
User signature succeeded.	Keith Vrbicky (b) (4)	12 Feb 2021 19:56:37
	(b) (4)	
User entered '1'	System	08 Feb 2021 15:50:02

US3032242

Folder: SAE USA-US032-2021-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 09 Jun 2021 14:52:51

[SAEID](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Mar 2021 22:49:05
User signature succeeded.	Keith Vrbicky (b) (4)	12 Feb 2021 19:56:37
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	08 Feb 2021 15:49:49
User entered 'USA-US032-2021-MRNA-1273-P301000006'	System	08 Feb 2021 15:49:16

US3032242

Folder: SAE USA-US032-2021-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 09 Jun 2021 14:52:51

Serious

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Mar 2021 22:49:05
User signature succeeded.	Keith Vrbicky (b) (4)	12 Feb 2021 19:56:37
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	08 Feb 2021 15:49:49
User entered 'Yes (Y)'	System	08 Feb 2021 15:49:16

US3032242

Folder: SAE USA-US032-2021-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 09 Jun 2021 14:52:51

Death

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Mar 2021 22:49:05
User signature succeeded.	Keith Vrbicky (b) (4)	12 Feb 2021 19:56:37
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	08 Feb 2021 15:49:49
User entered 'No (N)'	System	08 Feb 2021 15:49:16

US3032242

Folder: SAE USA-US032-2021-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 09 Jun 2021 14:52:51

[Life threatening](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Mar 2021 22:49:05
User signature succeeded.	Keith Vrbicky (b) (4)	12 Feb 2021 19:56:37
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	08 Feb 2021 15:49:49
User entered 'No (N)'	System	08 Feb 2021 15:49:16

US3032242

Folder: SAE USA-US032-2021-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 09 Jun 2021 14:52:51

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Mar 2021 22:49:05
User signature succeeded.	Keith Vrbicky (b) (4)	12 Feb 2021 19:56:37
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	08 Feb 2021 15:49:49
User entered 'No (N)'	System	08 Feb 2021 15:49:16

US3032242

Folder: SAE USA-US032-2021-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 09 Jun 2021 14:52:51

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Mar 2021 22:49:05
User signature succeeded.	Keith Vrbicky (b) (4)	12 Feb 2021 19:56:37
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	08 Feb 2021 15:49:49
User entered 'No (N)'	System	08 Feb 2021 15:49:16

US3032242

Folder: SAE USA-US032-2021-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 09 Jun 2021 14:52:51

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Mar 2021 22:49:05
User signature succeeded.	Keith Vrbicky (b) (4)	12 Feb 2021 19:56:37
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	08 Feb 2021 15:49:49
User entered 'No (N)'	System	08 Feb 2021 15:49:16

US3032242

Folder: SAE USA-US032-2021-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 09 Jun 2021 14:52:51

[Other medically important event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Mar 2021 22:49:05
User signature succeeded.	Keith Vrbicky (b) (4)	12 Feb 2021 19:56:37
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	08 Feb 2021 15:49:49
User entered 'Yes (Y)'	System	08 Feb 2021 15:49:16

US3032242

Folder: SAE USA-US032-2021-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 09 Jun 2021 14:52:51

[Investigator's First Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Mar 2021 22:49:05
User signature succeeded.	Keith Vrbicky (b) (4)	12 Feb 2021 19:56:37
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	08 Feb 2021 15:49:49
User entered 'Keith'	System	08 Feb 2021 15:49:16

US3032242

Folder: SAE USA-US032-2021-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 09 Jun 2021 14:52:51

[Investigator's Last Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Mar 2021 22:49:05
User signature succeeded.	Keith Vrbicky (b) (4)	12 Feb 2021 19:56:37
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	08 Feb 2021 15:49:49
User entered 'Vrbicky'	System	08 Feb 2021 15:49:16

US3032242

Folder: SAE USA-US032-2021-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 09 Jun 2021 14:52:51

[Investigator Country](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Mar 2021 22:49:05
Reviewed for Safety.		19 Feb 2021 18:43:48
User signature succeeded.	Keith Vrbicky (b) (4)	12 Feb 2021 19:56:37
User entered 'US'	(b) (4) System	08 Feb 2021 15:50:02

US3032242

Folder: SAE USA-US032-2021-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 09 Jun 2021 14:52:51

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '7'	System	30 Apr 2021 17:33:41
User entered '6'	System	26 Apr 2021 20:03:51
User entered '5'	System	19 Apr 2021 14:39:28
User entered '4'	System	06 Apr 2021 19:03:28
Signature has been broken.	System	24 Feb 2021 13:45:27
User entered '3'	System	24 Feb 2021 13:45:27
User signature succeeded.	Keith Vrbicky (b) (4)	22 Feb 2021 17:26:08
	(b) (4)	
Signature has been broken.	System	19 Feb 2021 18:44:06
User entered '2'	System	19 Feb 2021 18:44:06
User signature succeeded.	Keith Vrbicky (b) (4)	12 Feb 2021 19:56:37
	(b) (4)	
User entered '1'	System	08 Feb 2021 15:50:02

US3032242

Folder: SAE USA-US032-2021-MRNA-1273-P301000006

Form: Safety Report Form (1)

Generated On: 09 Jun 2021 14:52:51

Date of submission (Pre-filled from custom function)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Mar 2021 22:49:05
User signature succeeded.	Keith Vrbicky (b) (4)	12 Feb 2021 19:56:37
User entered '08/Feb/2021 15:49'	(b) (4) System	08 Feb 2021 15:50:02

US3032242

Folder: SAE USA-US032-2021-MRNA-1273-P301000006

Form: Safety Report Form (1)

Generated On: 09 Jun 2021 14:52:51

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)
DataPoint Verified.	(b) (4), (b) (6)	11 Mar 2021 22:49:05
Reviewed for Safety.	(b) (4), (b) (6)	19 Feb 2021 18:43:48
User signature succeeded.	Keith Vrbicky (b) (4)	12 Feb 2021 19:56:37
User entered '1'	(b) (4) (b) (4), (b) (6)	08 Feb 2021 15:50:02

US3032242

Folder: SAE USA-US032-2021-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 09 Jun 2021 14:52:51

[SAEID](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Mar 2021 22:49:05
User signature succeeded.	Keith Vrbicky (b) (4)	12 Feb 2021 19:56:37
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	08 Feb 2021 15:49:49
User entered 'USA-US032-2021-MRNA-1273-P301000006'	System	08 Feb 2021 15:49:16

US3032242

Folder: SAE USA-US032-2021-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 09 Jun 2021 14:52:51

Serious

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Mar 2021 22:49:05
User signature succeeded.	Keith Vrbicky (b) (4)	12 Feb 2021 19:56:37
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	08 Feb 2021 15:49:49
User entered 'Yes (Y)'	System	08 Feb 2021 15:49:16

US3032242

Folder: SAE USA-US032-2021-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 09 Jun 2021 14:52:51

Death

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Mar 2021 22:49:05
User signature succeeded.	Keith Vrbicky (b) (4)	12 Feb 2021 19:56:37
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	08 Feb 2021 15:49:49
User entered 'No (N)'	System	08 Feb 2021 15:49:16

US3032242

Folder: SAE USA-US032-2021-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 09 Jun 2021 14:52:51

[Life threatening](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Mar 2021 22:49:05
User signature succeeded.	Keith Vrbicky (b) (4)	12 Feb 2021 19:56:37
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	08 Feb 2021 15:49:49
User entered 'No (N)'	System	08 Feb 2021 15:49:16

US3032242

Folder: SAE USA-US032-2021-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 09 Jun 2021 14:52:51

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Mar 2021 22:49:05
User signature succeeded.	Keith Vrbicky (b) (4)	12 Feb 2021 19:56:37
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	08 Feb 2021 15:49:49
User entered 'No (N)'	System	08 Feb 2021 15:49:16

US3032242

Folder: SAE USA-US032-2021-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 09 Jun 2021 14:52:51

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Mar 2021 22:49:05
User signature succeeded.	Keith Vrbicky (b) (4)	12 Feb 2021 19:56:37
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	08 Feb 2021 15:49:49
User entered 'No (N)'	System	08 Feb 2021 15:49:16

US3032242

Folder: SAE USA-US032-2021-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 09 Jun 2021 14:52:51

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Mar 2021 22:49:05
User signature succeeded.	Keith Vrbicky (b) (4)	12 Feb 2021 19:56:37
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	08 Feb 2021 15:49:49
User entered 'No (N)'	System	08 Feb 2021 15:49:16

US3032242

Folder: SAE USA-US032-2021-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 09 Jun 2021 14:52:51

[Other medically important event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Mar 2021 22:49:05
User signature succeeded.	Keith Vrbicky (b) (4)	12 Feb 2021 19:56:37
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	08 Feb 2021 15:49:49
User entered 'Yes (Y)'	System	08 Feb 2021 15:49:16

US3032242

Folder: SAE USA-US032-2021-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 09 Jun 2021 14:52:51

[Investigator's First Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Mar 2021 22:49:05
User signature succeeded.	Keith Vrbicky (b) (4)	12 Feb 2021 19:56:37
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	08 Feb 2021 15:49:49
User entered 'Keith'	System	08 Feb 2021 15:49:16

US3032242

Folder: SAE USA-US032-2021-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 09 Jun 2021 14:52:51

[Investigator's Last Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Mar 2021 22:49:05
User signature succeeded.	Keith Vrbicky (b) (4)	12 Feb 2021 19:56:37
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	08 Feb 2021 15:49:49
User entered 'Vrbicky'	System	08 Feb 2021 15:49:16

US3032242

Folder: SAE USA-US032-2021-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 09 Jun 2021 14:52:51

[Investigator Country](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Mar 2021 22:49:05
Reviewed for Safety.		19 Feb 2021 18:43:48
User signature succeeded.	Keith Vrbicky (b) (4)	12 Feb 2021 19:56:37
User entered 'US'	(b) (4) System	08 Feb 2021 15:50:02

US3032242

Folder: SAE USA-US032-2021-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 09 Jun 2021 14:52:51

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '7'	System	30 Apr 2021 17:33:41
User entered '6'	System	26 Apr 2021 20:03:51
User entered '5'	System	19 Apr 2021 14:39:28
User entered '4'	System	06 Apr 2021 19:03:28
Signature has been broken.	System	24 Feb 2021 13:45:27
User entered '3'	System	24 Feb 2021 13:45:27
User signature succeeded.	Keith Vrbicky (b) (4)	22 Feb 2021 17:26:08
	(b) (4)	
Signature has been broken.	System	19 Feb 2021 18:44:06
User entered '2'	System	19 Feb 2021 18:44:06
User signature succeeded.	Keith Vrbicky (b) (4)	12 Feb 2021 19:56:37
	(b) (4)	
User entered '1'	System	08 Feb 2021 15:50:02

US3032242

Folder: SAE USA-US032-2021-MRNA-1273-P301000006

Form: Safety Report Form (2)

Generated On: 09 Jun 2021 14:52:51

Date of submission (Pre-filled from custom function)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Mar 2021 22:49:05
User signature succeeded.	Keith Vrbicky (b) (4)	22 Feb 2021 17:26:08
User entered '19/Feb/2021 12:44'	(b) (4) System	19 Feb 2021 18:44:06

US3032242

Folder: SAE USA-US032-2021-MRNA-1273-P301000006

Form: Safety Report Form (2)

Generated On: 09 Jun 2021 14:52:51

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)
DataPoint Verified.	(b) (4), (b) (6)	11 Mar 2021 22:49:05
Reviewed for Safety.		24 Feb 2021 13:45:13
User signature succeeded.	Keith Vrbicky (b) (4)	22 Feb 2021 17:26:08
User entered '1'	(b) (4) (b) (4), (b) (6)	19 Feb 2021 18:44:06

US3032242

Folder: SAE USA-US032-2021-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 09 Jun 2021 14:52:51

[SAEID](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Mar 2021 22:49:05
User signature succeeded.	Keith Vrbicky (b) (4)	12 Feb 2021 19:56:37
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	08 Feb 2021 15:49:49
User entered 'USA-US032-2021-MRNA-1273-P301000006'	System	08 Feb 2021 15:49:16

US3032242

Folder: SAE USA-US032-2021-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 09 Jun 2021 14:52:51

Serious

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Mar 2021 22:49:05
User signature succeeded.	Keith Vrbicky (b) (4)	12 Feb 2021 19:56:37
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	08 Feb 2021 15:49:49
User entered 'Yes (Y)'	System	08 Feb 2021 15:49:16

US3032242

Folder: SAE USA-US032-2021-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 09 Jun 2021 14:52:51

Death

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Mar 2021 22:49:05
User signature succeeded.	Keith Vrbicky (b) (4)	12 Feb 2021 19:56:37
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	08 Feb 2021 15:49:49
User entered 'No (N)'	System	08 Feb 2021 15:49:16

US3032242

Folder: SAE USA-US032-2021-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 09 Jun 2021 14:52:51

[Life threatening](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Mar 2021 22:49:05
User signature succeeded.	Keith Vrbicky (b) (4)	12 Feb 2021 19:56:37
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	08 Feb 2021 15:49:49
User entered 'No (N)'	System	08 Feb 2021 15:49:16

US3032242

Folder: SAE USA-US032-2021-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 09 Jun 2021 14:52:51

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Mar 2021 22:49:05
User signature succeeded.	Keith Vrbicky (b) (4)	12 Feb 2021 19:56:37
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	08 Feb 2021 15:49:49
User entered 'No (N)'	System	08 Feb 2021 15:49:16

US3032242

Folder: SAE USA-US032-2021-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 09 Jun 2021 14:52:51

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Mar 2021 22:49:05
User signature succeeded.	Keith Vrbicky (b) (4)	12 Feb 2021 19:56:37
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	08 Feb 2021 15:49:49
User entered 'No (N)'	System	08 Feb 2021 15:49:16

US3032242

Folder: SAE USA-US032-2021-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 09 Jun 2021 14:52:51

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Mar 2021 22:49:05
User signature succeeded.	Keith Vrbicky (b) (4)	12 Feb 2021 19:56:37
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	08 Feb 2021 15:49:49
User entered 'No (N)'	System	08 Feb 2021 15:49:16

US3032242

Folder: SAE USA-US032-2021-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 09 Jun 2021 14:52:51

[Other medically important event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Mar 2021 22:49:05
User signature succeeded.	Keith Vrbicky (b) (4)	12 Feb 2021 19:56:37
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	08 Feb 2021 15:49:49
User entered 'Yes (Y)'	System	08 Feb 2021 15:49:16

US3032242

Folder: SAE USA-US032-2021-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 09 Jun 2021 14:52:51

[Investigator's First Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Mar 2021 22:49:05
User signature succeeded.	Keith Vrbicky (b) (4)	12 Feb 2021 19:56:37
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	08 Feb 2021 15:49:49
User entered 'Keith'	System	08 Feb 2021 15:49:16

US3032242

Folder: SAE USA-US032-2021-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 09 Jun 2021 14:52:51

[Investigator's Last Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Mar 2021 22:49:05
User signature succeeded.	Keith Vrbicky (b) (4)	12 Feb 2021 19:56:37
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	08 Feb 2021 15:49:49
User entered 'Vrbicky'	System	08 Feb 2021 15:49:16

US3032242

Folder: SAE USA-US032-2021-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 09 Jun 2021 14:52:51

[Investigator Country](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Mar 2021 22:49:05
Reviewed for Safety.	(b) (4)	19 Feb 2021 18:43:48
User signature succeeded.	Keith Vrbicky (b) (4)	12 Feb 2021 19:56:37
User entered 'US'	(b) (4) System	08 Feb 2021 15:50:02

US3032242

Folder: SAE USA-US032-2021-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 09 Jun 2021 14:52:51

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '7'	System	30 Apr 2021 17:33:41
User entered '6'	System	26 Apr 2021 20:03:51
User entered '5'	System	19 Apr 2021 14:39:28
User entered '4'	System	06 Apr 2021 19:03:28
Signature has been broken.	System	24 Feb 2021 13:45:27
User entered '3'	System	24 Feb 2021 13:45:27
User signature succeeded.	Keith Vrbicky (b) (4)	22 Feb 2021 17:26:08
	(b) (4)	
Signature has been broken.	System	19 Feb 2021 18:44:06
User entered '2'	System	19 Feb 2021 18:44:06
User signature succeeded.	Keith Vrbicky (b) (4)	12 Feb 2021 19:56:37
	(b) (4)	
User entered '1'	System	08 Feb 2021 15:50:02

US3032242

Folder: SAE USA-US032-2021-MRNA-1273-P301000006

Form: Safety Report Form (3)

Generated On: 09 Jun 2021 14:52:51

Date of submission (Pre-filled from custom function)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Mar 2021 22:49:05
User signature succeeded.	Keith Vrbicky (b) (4)	04 Mar 2021 16:04:16
User entered '24/Feb/2021 07:45'	(b) (4) System	24 Feb 2021 13:45:27

US3032242

Folder: SAE USA-US032-2021-MRNA-1273-P301000006

Form: Safety Report Form (3)

Generated On: 09 Jun 2021 14:52:51

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)	06 Apr 2021 19:03:39
DataPoint Verified.		11 Mar 2021 22:49:05
User signature succeeded.	Keith Vrbicky (b) (4)	04 Mar 2021 16:04:16
User entered '1'	(b) (4) (b) (4), (b) (6)	24 Feb 2021 13:45:27

US3032242

Folder: SAE USA-US032-2021-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 09 Jun 2021 14:52:51

[SAEID](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Mar 2021 22:49:05
User signature succeeded.	Keith Vrbicky (b) (4)	12 Feb 2021 19:56:37
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	08 Feb 2021 15:49:49
User entered 'USA-US032-2021-MRNA-1273-P301000006'	System	08 Feb 2021 15:49:16

US3032242

Folder: SAE USA-US032-2021-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 09 Jun 2021 14:52:51

Serious

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Mar 2021 22:49:05
User signature succeeded.	Keith Vrbicky (b) (4)	12 Feb 2021 19:56:37
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	08 Feb 2021 15:49:49
User entered 'Yes (Y)'	System	08 Feb 2021 15:49:16

US3032242

Folder: SAE USA-US032-2021-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 09 Jun 2021 14:52:51

Death

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Mar 2021 22:49:05
User signature succeeded.	Keith Vrbicky (b) (4)	12 Feb 2021 19:56:37
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	08 Feb 2021 15:49:49
User entered 'No (N)'	System	08 Feb 2021 15:49:16

US3032242

Folder: SAE USA-US032-2021-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 09 Jun 2021 14:52:51

[Life threatening](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Mar 2021 22:49:05
User signature succeeded.	Keith Vrbicky (b) (4)	12 Feb 2021 19:56:37
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	08 Feb 2021 15:49:49
User entered 'No (N)'	System	08 Feb 2021 15:49:16

US3032242

Folder: SAE USA-US032-2021-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 09 Jun 2021 14:52:51

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Mar 2021 22:49:05
User signature succeeded.	Keith Vrbicky (b) (4)	12 Feb 2021 19:56:37
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	08 Feb 2021 15:49:49
User entered 'No (N)'	System	08 Feb 2021 15:49:16

US3032242

Folder: SAE USA-US032-2021-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 09 Jun 2021 14:52:51

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Mar 2021 22:49:05
User signature succeeded.	Keith Vrbicky (b) (4)	12 Feb 2021 19:56:37
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	08 Feb 2021 15:49:49
User entered 'No (N)'	System	08 Feb 2021 15:49:16

US3032242

Folder: SAE USA-US032-2021-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 09 Jun 2021 14:52:51

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Mar 2021 22:49:05
User signature succeeded.	Keith Vrbicky (b) (4)	12 Feb 2021 19:56:37
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	08 Feb 2021 15:49:49
User entered 'No (N)'	System	08 Feb 2021 15:49:16

US3032242

Folder: SAE USA-US032-2021-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 09 Jun 2021 14:52:51

[Other medically important event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Mar 2021 22:49:05
User signature succeeded.	Keith Vrbicky (b) (4)	12 Feb 2021 19:56:37
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	08 Feb 2021 15:49:49
User entered 'Yes (Y)'	System	08 Feb 2021 15:49:16

US3032242

Folder: SAE USA-US032-2021-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 09 Jun 2021 14:52:51

[Investigator's First Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Mar 2021 22:49:05
User signature succeeded.	Keith Vrbicky (b) (4)	12 Feb 2021 19:56:37
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	08 Feb 2021 15:49:49
User entered 'Keith'	System	08 Feb 2021 15:49:16

US3032242

Folder: SAE USA-US032-2021-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 09 Jun 2021 14:52:51

[Investigator's Last Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Mar 2021 22:49:05
User signature succeeded.	Keith Vrbicky (b) (4)	12 Feb 2021 19:56:37
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	08 Feb 2021 15:49:49
User entered 'Vrbicky'	System	08 Feb 2021 15:49:16

US3032242

Folder: SAE USA-US032-2021-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 09 Jun 2021 14:52:51

[Investigator Country](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Mar 2021 22:49:05
Reviewed for Safety.		19 Feb 2021 18:43:48
User signature succeeded.	Keith Vrbicky (b) (4)	12 Feb 2021 19:56:37
User entered 'US'	(b) (4) System	08 Feb 2021 15:50:02

US3032242

Folder: SAE USA-US032-2021-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 09 Jun 2021 14:52:51

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '7'	System	30 Apr 2021 17:33:41
User entered '6'	System	26 Apr 2021 20:03:51
User entered '5'	System	19 Apr 2021 14:39:28
User entered '4'	System	06 Apr 2021 19:03:28
Signature has been broken.	System	24 Feb 2021 13:45:27
User entered '3'	System	24 Feb 2021 13:45:27
User signature succeeded.	Keith Vrbrick (b) (4)	22 Feb 2021 17:26:08
	(b) (4)	
Signature has been broken.	System	19 Feb 2021 18:44:06
User entered '2'	System	19 Feb 2021 18:44:06
User signature succeeded.	Keith Vrbrick (b) (4)	12 Feb 2021 19:56:37
	(b) (4)	
User entered '1'	System	08 Feb 2021 15:50:02

US3032242

Folder: SAE USA-US032-2021-MRNA-1273-P301000006

Form: Safety Report Form (4)

Generated On: 09 Jun 2021 14:52:51

Date of submission (Pre-filled from custom function)

Audit	User	Time (GMT)
User signature succeeded.	Keith Vrbicky (b) (4)	09 Apr 2021 18:08:00
User entered '06/Apr/2021 15:03'	(b) (4) System	06 Apr 2021 19:03:28

US3032242

Folder: SAE USA-US032-2021-MRNA-1273-P301000006

Form: Safety Report Form (4)

Generated On: 09 Jun 2021 14:52:51

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.	Keith Vrbicky (b) (4)	09 Apr 2021 18:08:00
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	06 Apr 2021 19:03:39
User entered 'I'		06 Apr 2021 19:03:28

US3032242

Folder: SAE USA-US032-2021-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 09 Jun 2021 14:52:51

[SAEID](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Mar 2021 22:49:05
User signature succeeded.	Keith Vrbicky (b) (4)	12 Feb 2021 19:56:37
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	08 Feb 2021 15:49:49
User entered 'USA-US032-2021-MRNA-1273-P301000006'	System	08 Feb 2021 15:49:16

US3032242

Folder: SAE USA-US032-2021-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 09 Jun 2021 14:52:51

Serious

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Mar 2021 22:49:05
User signature succeeded.	Keith Vrbicky (b) (4)	12 Feb 2021 19:56:37
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	08 Feb 2021 15:49:49
User entered 'Yes (Y)'	System	08 Feb 2021 15:49:16

US3032242

Folder: SAE USA-US032-2021-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 09 Jun 2021 14:52:51

Death

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Mar 2021 22:49:05
User signature succeeded.	Keith Vrbicky (b) (4)	12 Feb 2021 19:56:37
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	08 Feb 2021 15:49:49
User entered 'No (N)'	System	08 Feb 2021 15:49:16

US3032242

Folder: SAE USA-US032-2021-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 09 Jun 2021 14:52:51

[Life threatening](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Mar 2021 22:49:05
User signature succeeded.	Keith Vrbicky (b) (4)	12 Feb 2021 19:56:37
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	08 Feb 2021 15:49:49
User entered 'No (N)'	System	08 Feb 2021 15:49:16

US3032242

Folder: SAE USA-US032-2021-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 09 Jun 2021 14:52:51

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Mar 2021 22:49:05
User signature succeeded.	Keith Vrbicky (b) (4)	12 Feb 2021 19:56:37
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	08 Feb 2021 15:49:49
User entered 'No (N)'	System	08 Feb 2021 15:49:16

US3032242

Folder: SAE USA-US032-2021-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 09 Jun 2021 14:52:51

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Mar 2021 22:49:05
User signature succeeded.	Keith Vrbicky (b) (4)	12 Feb 2021 19:56:37
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	08 Feb 2021 15:49:49
User entered 'No (N)'	System	08 Feb 2021 15:49:16

US3032242

Folder: SAE USA-US032-2021-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 09 Jun 2021 14:52:51

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Mar 2021 22:49:05
User signature succeeded.	Keith Vrbicky (b) (4)	12 Feb 2021 19:56:37
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	08 Feb 2021 15:49:49
User entered 'No (N)'	System	08 Feb 2021 15:49:16

US3032242

Folder: SAE USA-US032-2021-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 09 Jun 2021 14:52:51

[Other medically important event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Mar 2021 22:49:05
User signature succeeded.	Keith Vrbicky (b) (4)	12 Feb 2021 19:56:37
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	08 Feb 2021 15:49:49
User entered 'Yes (Y)'	System	08 Feb 2021 15:49:16

US3032242

Folder: SAE USA-US032-2021-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 09 Jun 2021 14:52:51

[Investigator's First Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Mar 2021 22:49:05
User signature succeeded.	Keith Vrbicky (b) (4)	12 Feb 2021 19:56:37
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	08 Feb 2021 15:49:49
User entered 'Keith'	System	08 Feb 2021 15:49:16

US3032242

Folder: SAE USA-US032-2021-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 09 Jun 2021 14:52:51

[Investigator's Last Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Mar 2021 22:49:05
User signature succeeded.	Keith Vrbicky (b) (4)	12 Feb 2021 19:56:37
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	08 Feb 2021 15:49:49
User entered 'Vrbicky'	System	08 Feb 2021 15:49:16

US3032242

Folder: SAE USA-US032-2021-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 09 Jun 2021 14:52:51

[Investigator Country](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Mar 2021 22:49:05
Reviewed for Safety.		19 Feb 2021 18:43:48
User signature succeeded.	Keith Vrbicky (b) (4)	12 Feb 2021 19:56:37
User entered 'US'	(b) (4) System	08 Feb 2021 15:50:02

US3032242

Folder: SAE USA-US032-2021-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 09 Jun 2021 14:52:51

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '7'	System	30 Apr 2021 17:33:41
User entered '6'	System	26 Apr 2021 20:03:51
User entered '5'	System	19 Apr 2021 14:39:28
User entered '4'	System	06 Apr 2021 19:03:28
Signature has been broken.	System	24 Feb 2021 13:45:27
User entered '3'	System	24 Feb 2021 13:45:27
User signature succeeded.	Keith Vrbicky (b) (4)	22 Feb 2021 17:26:08
	(b) (4)	
Signature has been broken.	System	19 Feb 2021 18:44:06
User entered '2'	System	19 Feb 2021 18:44:06
User signature succeeded.	Keith Vrbicky (b) (4)	12 Feb 2021 19:56:37
	(b) (4)	
User entered '1'	System	08 Feb 2021 15:50:02

US3032242

Folder: SAE USA-US032-2021-MRNA-1273-P301000006

Form: Safety Report Form (5)

Generated On: 09 Jun 2021 14:52:51

Date of submission (Pre-filled from custom function)

Audit	User	Time (GMT)
User signature succeeded.	Keith Vrbicky (b) (4)	19 Apr 2021 15:27:13
User entered '19/Apr/2021 10:39'	(b) (4) System	19 Apr 2021 14:39:28

US3032242

Folder: SAE USA-US032-2021-MRNA-1273-P301000006

Form: Safety Report Form (5)

Generated On: 09 Jun 2021 14:52:51

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)	26 Apr 2021 20:03:40
User signature succeeded.	Keith Vrbicky (b) (4)	19 Apr 2021 15:27:13
User entered 'I'	(b) (4) (b) (4), (b) (6)	19 Apr 2021 14:39:28

US3032242

Folder: SAE USA-US032-2021-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 09 Jun 2021 14:52:51

[SAEID](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Mar 2021 22:49:05
User signature succeeded.	Keith Vrbicky (b) (4)	12 Feb 2021 19:56:37
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	08 Feb 2021 15:49:49
User entered 'USA-US032-2021-MRNA-1273-P301000006'	System	08 Feb 2021 15:49:16

US3032242

Folder: SAE USA-US032-2021-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 09 Jun 2021 14:52:51

Serious

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Mar 2021 22:49:05
User signature succeeded.	Keith Vrbicky (b) (4)	12 Feb 2021 19:56:37
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	08 Feb 2021 15:49:49
User entered 'Yes (Y)'	System	08 Feb 2021 15:49:16

US3032242

Folder: SAE USA-US032-2021-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 09 Jun 2021 14:52:51

[Death](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Mar 2021 22:49:05
User signature succeeded.	Keith Vrbicky (b) (4)	12 Feb 2021 19:56:37
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	08 Feb 2021 15:49:49
User entered 'No (N)'	System	08 Feb 2021 15:49:16

US3032242

Folder: SAE USA-US032-2021-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 09 Jun 2021 14:52:51

[Life threatening](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Mar 2021 22:49:05
User signature succeeded.	Keith Vrbicky (b) (4)	12 Feb 2021 19:56:37
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	08 Feb 2021 15:49:49
User entered 'No (N)'	System	08 Feb 2021 15:49:16

US3032242

Folder: SAE USA-US032-2021-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 09 Jun 2021 14:52:51

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Mar 2021 22:49:05
User signature succeeded.	Keith Vrbicky (b) (4)	12 Feb 2021 19:56:37
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	08 Feb 2021 15:49:49
User entered 'No (N)'	System	08 Feb 2021 15:49:16

US3032242

Folder: SAE USA-US032-2021-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 09 Jun 2021 14:52:51

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Mar 2021 22:49:05
User signature succeeded.	Keith Vrbicky (b) (4)	12 Feb 2021 19:56:37
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	08 Feb 2021 15:49:49
User entered 'No (N)'	System	08 Feb 2021 15:49:16

US3032242

Folder: SAE USA-US032-2021-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 09 Jun 2021 14:52:51

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Mar 2021 22:49:05
User signature succeeded.	Keith Vrbicky (b) (4)	12 Feb 2021 19:56:37
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	08 Feb 2021 15:49:49
User entered 'No (N)'	System	08 Feb 2021 15:49:16

US3032242

Folder: SAE USA-US032-2021-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 09 Jun 2021 14:52:51

[Other medically important event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Mar 2021 22:49:05
User signature succeeded.	Keith Vrbicky (b) (4)	12 Feb 2021 19:56:37
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	08 Feb 2021 15:49:49
User entered 'Yes (Y)'	System	08 Feb 2021 15:49:16

US3032242

Folder: SAE USA-US032-2021-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 09 Jun 2021 14:52:51

[Investigator's First Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Mar 2021 22:49:05
User signature succeeded.	Keith Vrbicky (b) (4)	12 Feb 2021 19:56:37
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	08 Feb 2021 15:49:49
User entered 'Keith'	System	08 Feb 2021 15:49:16

US3032242

Folder: SAE USA-US032-2021-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 09 Jun 2021 14:52:51

[Investigator's Last Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Mar 2021 22:49:05
User signature succeeded.	Keith Vrbicky (b) (4)	12 Feb 2021 19:56:37
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	08 Feb 2021 15:49:49
User entered 'Vrbicky'	System	08 Feb 2021 15:49:16

US3032242

Folder: SAE USA-US032-2021-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 09 Jun 2021 14:52:51

[Investigator Country](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Mar 2021 22:49:05
Reviewed for Safety.		19 Feb 2021 18:43:48
User signature succeeded.	Keith Vrbicky (b) (4)	12 Feb 2021 19:56:37
User entered 'US'	(b) (4) System	08 Feb 2021 15:50:02

US3032242

Folder: SAE USA-US032-2021-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 09 Jun 2021 14:52:51

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '7'	System	30 Apr 2021 17:33:41
User entered '6'	System	26 Apr 2021 20:03:51
User entered '5'	System	19 Apr 2021 14:39:28
User entered '4'	System	06 Apr 2021 19:03:28
Signature has been broken.	System	24 Feb 2021 13:45:27
User entered '3'	System	24 Feb 2021 13:45:27
User signature succeeded.	Keith Vrbecky (b) (4)	22 Feb 2021 17:26:08
	(b) (4)	
Signature has been broken.	System	19 Feb 2021 18:44:06
User entered '2'	System	19 Feb 2021 18:44:06
User signature succeeded.	Keith Vrbecky (b) (4)	12 Feb 2021 19:56:37
	(b) (4)	
User entered '1'	System	08 Feb 2021 15:50:02

US3032242

Folder: SAE USA-US032-2021-MRNA-1273-P301000006

Form: Safety Report Form (6)

Generated On: 09 Jun 2021 14:52:51

Date of submission (Pre-filled from custom function)

Audit	User	Time (GMT)
User signature succeeded.	Keith Vrbicky (b) (4)	03 May 2021 16:17:41
User entered '26/Apr/2021 16:03'	(b) (4) System	26 Apr 2021 20:03:51

US3032242

Folder: SAE USA-US032-2021-MRNA-1273-P301000006

Form: Safety Report Form (6)

Generated On: 09 Jun 2021 14:52:51

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.	Keith Vrbicky (b) (4)	03 May 2021 16:17:41
Reviewed for Safety.	(b) (4) (d) (4), (b) (6)	30 Apr 2021 17:31:49
User entered 'I'		26 Apr 2021 20:03:51

US3032242

Folder: SAE USA-US032-2021-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 09 Jun 2021 14:52:51

[SAEID](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Mar 2021 22:49:05
User signature succeeded.	Keith Vrbicky (b) (4)	12 Feb 2021 19:56:37
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	08 Feb 2021 15:49:49
User entered 'USA-US032-2021-MRNA-1273-P301000006'	System	08 Feb 2021 15:49:16

US3032242

Folder: SAE USA-US032-2021-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 09 Jun 2021 14:52:51

Serious

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Mar 2021 22:49:05
User signature succeeded.	Keith Vrbicky (b) (4)	12 Feb 2021 19:56:37
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	08 Feb 2021 15:49:49
User entered 'Yes (Y)'	System	08 Feb 2021 15:49:16

US3032242

Folder: SAE USA-US032-2021-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 09 Jun 2021 14:52:51

Death

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Mar 2021 22:49:05
User signature succeeded.	Keith Vrbicky (b) (4)	12 Feb 2021 19:56:37
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	08 Feb 2021 15:49:49
User entered 'No (N)'	System	08 Feb 2021 15:49:16

US3032242

Folder: SAE USA-US032-2021-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 09 Jun 2021 14:52:51

[Life threatening](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Mar 2021 22:49:05
User signature succeeded.	Keith Vrbicky (b) (4)	12 Feb 2021 19:56:37
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	08 Feb 2021 15:49:49
User entered 'No (N)'	System	08 Feb 2021 15:49:16

US3032242

Folder: SAE USA-US032-2021-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 09 Jun 2021 14:52:51

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Mar 2021 22:49:05
User signature succeeded.	Keith Vrbicky (b) (4)	12 Feb 2021 19:56:37
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	08 Feb 2021 15:49:49
User entered 'No (N)'	System	08 Feb 2021 15:49:16

US3032242

Folder: SAE USA-US032-2021-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 09 Jun 2021 14:52:51

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Mar 2021 22:49:05
User signature succeeded.	Keith Vrbicky (b) (4)	12 Feb 2021 19:56:37
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	08 Feb 2021 15:49:49
User entered 'No (N)'	System	08 Feb 2021 15:49:16

US3032242

Folder: SAE USA-US032-2021-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 09 Jun 2021 14:52:51

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Mar 2021 22:49:05
User signature succeeded.	Keith Vrbicky (b) (4)	12 Feb 2021 19:56:37
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	08 Feb 2021 15:49:49
User entered 'No (N)'	System	08 Feb 2021 15:49:16

US3032242

Folder: SAE USA-US032-2021-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 09 Jun 2021 14:52:51

[Other medically important event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Mar 2021 22:49:05
User signature succeeded.	Keith Vrbicky (b) (4)	12 Feb 2021 19:56:37
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	08 Feb 2021 15:49:49
User entered 'Yes (Y)'	System	08 Feb 2021 15:49:16

US3032242

Folder: SAE USA-US032-2021-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 09 Jun 2021 14:52:51

[Investigator's First Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Mar 2021 22:49:05
User signature succeeded.	Keith Vrbicky (b) (4)	12 Feb 2021 19:56:37
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	08 Feb 2021 15:49:49
User entered 'Keith'	System	08 Feb 2021 15:49:16

US3032242

Folder: SAE USA-US032-2021-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 09 Jun 2021 14:52:51

[Investigator's Last Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Mar 2021 22:49:05
User signature succeeded.	Keith Vrbicky (b) (4)	12 Feb 2021 19:56:37
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	08 Feb 2021 15:49:49
User entered 'Vrbicky'	System	08 Feb 2021 15:49:16

US3032242

Folder: SAE USA-US032-2021-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 09 Jun 2021 14:52:51

[Investigator Country](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Mar 2021 22:49:05
Reviewed for Safety.	(b) (4), (b) (6)	19 Feb 2021 18:43:48
User signature succeeded.	Keith Vrbicky (b) (4)	12 Feb 2021 19:56:37
User entered 'US'	(b) (4) System	08 Feb 2021 15:50:02

US3032242

Folder: SAE USA-US032-2021-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 09 Jun 2021 14:52:51

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '7'	System	30 Apr 2021 17:33:41
User entered '6'	System	26 Apr 2021 20:03:51
User entered '5'	System	19 Apr 2021 14:39:28
User entered '4'	System	06 Apr 2021 19:03:28
Signature has been broken.	System	24 Feb 2021 13:45:27
User entered '3'	System	24 Feb 2021 13:45:27
User signature succeeded.	Keith Vrbicky (b) (4)	22 Feb 2021 17:26:08
	(b) (4)	
Signature has been broken.	System	19 Feb 2021 18:44:06
User entered '2'	System	19 Feb 2021 18:44:06
User signature succeeded.	Keith Vrbicky (b) (4)	12 Feb 2021 19:56:37
	(b) (4)	
User entered '1'	System	08 Feb 2021 15:50:02

US3032242

Folder: SAE USA-US032-2021-MRNA-1273-P301000006

Form: Safety Report Form (7)

Generated On: 09 Jun 2021 14:52:51

Date of submission (Pre-filled from custom function)

Audit	User	Time (GMT)
User signature succeeded.	Keith Vrbicky (b) (4)	03 May 2021 16:17:41
User entered '30/Apr/2021 10:33'	(b) (4) System	30 Apr 2021 17:33:41

US3032242

Folder: SAE USA-US032-2021-MRNA-1273-P301000006

Form: Safety Report Form (7)

Generated On: 09 Jun 2021 14:52:51

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.	Keith Vrbicky (b) (4)	03 May 2021 16:17:41
User entered 'I'	(b) (4) (b) (4), (b) (6)	30 Apr 2021 17:33:41