

US3342200 (Prod: Tekton Research- Austin)

Generated By: KC Joubran

Generated On: 09 Jun 2021 17:05:26

All time stamps listed in this document are displayed in GMT

US3342200

Form: Participant Creation

Data signed: (b) (4) 13 Mar 2021 15:24:14

Generated On: 09 Jun 2021 17:05:26

Participant ID

US3342200

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

US3342200

Folder: Screening

Form: Visit Date

Data signed: (b) (4) 13 Mar 2021 16:12:03

Generated On: 09 Jun 2021 17:05:26

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	04 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	SCRN

US3342200

Folder: Screening

Form: Demographics

Data signed: (b) (4) 13 Mar 2021 16:12:03

Generated On: 09 Jun 2021 17:05:26

Date of Birth (MMM yyyy)	(b) (6) 1975
Age	44
Age Units	YEARS
Age (Derived)	44
Sex	Female <input checked="" type="radio"/> Male <input type="radio"/>
Ethnicity	Hispanic or Latino <input checked="" type="radio"/> Not Hispanic or Latino <input 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

US3342200

Folder: Screening

Form: Enrollment

Data signed: (b) (4) 13 Mar 2021 16:12:03

Generated On: 09 Jun 2021 17:05:26

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

US3342200

Folder: Screening

Form: Inclusion/Exclusion Criteria Summary

Data signed: (b) (4) 13 Mar 2021 16:12:03

Generated On: 09 Jun 2021 17:05:26

Did the participant meet all eligibility criteria?

Yes ☒

No ☐

US3342200

Folder: Screening

Form: Medical History Summary

Data signed: (b) (4) 13 Mar 2021 16:12:03

Generated On: 09 Jun 2021 17:05:26

Were any significant conditions reported?

Yes ☒

No ☐

US3342200

Folder: Screening

Form: Medical History (1)

Data signed: (b) (4) 29 Mar 2021 15:07:51

Generated On: 09 Jun 2021 17:05:26

Condition	HYSTERECTOMY
Start date (dd MMM yyyy)	12 NOV 2018
Start date completely unknown	False
Condition ongoing at study entry	Yes <input type="radio"/> No <input checked="" type="radio"/>
If No, please specify the stop date (dd MMM yyyy)	12 NOV 2018
Stop date completely unknown	False
Start Month and Year (derived)	NOV 2018
Start Year (derived)	2018
Stop Month and Year (derived)	NOV 2018
Stop Year (derived)	2018

US3342200

Folder: Screening

Form: Medical History (2)

Data signed: (b) (4) 29 Mar 2021 15:07:51

Generated On: 09 Jun 2021 17:05:26

Condition	PRECANCEROUS CERVICAL CELLS
Start date (dd MMM yyyy)	UN UNK 2018
Start date completely unknown	False
Condition ongoing at study entry	Yes <input type="radio"/> No <input checked="" type="radio"/>
If No, please specify the stop date (dd MMM yyyy)	12 NOV 2018
Stop date completely unknown	False
Start Month and Year (derived)	JAN 2018
Start Year (derived)	2018
Stop Month and Year (derived)	NOV 2018
Stop Year (derived)	2018

US3342200

Folder: Screening

Form: Medical History (3)

Data signed: (b) (4) 29 Mar 2021 15:07:51

Generated On: 09 Jun 2021 17:05:26

Condition	KIDNEY STONES
Start date (dd MMM yyyy)	UN UNK 2019
Start date completely unknown	False
Condition ongoing at study entry	Yes <input type="radio"/> No <input checked="" type="radio"/>
If No, please specify the stop date (dd MMM yyyy)	UN UNK 2019
Stop date completely unknown	False
Start Month and Year (derived)	JAN 2019
Start Year (derived)	2019
Stop Month and Year (derived)	JAN 2019
Stop Year (derived)	2019

US3342200

Folder: Screening

Form: Medical History (4)

Data signed: (b) (4) 29 Mar 2021 15:07:51

Generated On: 09 Jun 2021 17:05:26

Condition	SEASONAL ALLERGIES
Start date (dd MMM yyyy)	UN UNK 1993
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 1993
Start Year (derived)	1993
Stop Month and Year (derived)	
Stop Year (derived)	

US3342200

Folder: Screening

Form: Medical History (5)

Data signed: (b) (4) 29 Mar 2021 15:07:51

Generated On: 09 Jun 2021 17:05:26

Condition	ATOPIC DERMATITIS
Start date (dd MMM yyyy)	UN UNK 1990
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 1990
Start Year (derived)	1990
Stop Month and Year (derived)	
Stop Year (derived)	

US3342200

Folder: Screening

Form: Medical History (6)

Data signed: (b) (4) 29 Mar 2021 15:07:51

Generated On: 09 Jun 2021 17:05:26

Condition	LATEX ALLERGY - HIVES
Start date (dd MMM yyyy)	UN UNK 1993
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 1993
Start Year (derived)	1993
Stop Month and Year (derived)	_____
Stop Year (derived)	_____

US3342200

Folder: Screening

Form: Medical History (7)

Data signed: (b) (4) 29 Mar 2021 15:07:51

Generated On: 09 Jun 2021 17:05:26

Condition	VITAMIN D DEFICIENCY
Start date (dd MMM yyyy)	UN UNK 2015
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 2015
Start Year (derived)	2015
Stop Month and Year (derived)	_____
Stop Year (derived)	_____

US3342200

Folder: Screening

Form: Medical History (8)

Data signed: (b) (4) 29 Mar 2021 15:07:51

Generated On: 09 Jun 2021 17:05:26

Condition	JOINT PAIN BILATERAL SHOULDERS
Start date (dd MMM yyyy)	UN MAY 2020
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)	MAY 2020
Start Year (derived)	2020
Stop Month and Year (derived)	_____
Stop Year (derived)	_____

US3342200

Folder: Screening

Form: Medical History (9)

Data signed: (b) (4) 29 Mar 2021 15:07:51

Generated On: 09 Jun 2021 17:05:26

Condition	JOINT PAIN BILATERAL LOWER EXTREMITIES
Start date (dd MMM yyyy)	UN MAY 2020
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)	MAY 2020
Start Year (derived)	2020
Stop Month and Year (derived)	
Stop Year (derived)	

US3342200

Folder: Screening

Form: Medical History (10)

Data signed: (b) (4) 29 Mar 2021 15:07:51

Generated On: 09 Jun 2021 17:05:26

Condition	RIGHT BREAST LUMP BENIGN
Start date (dd MMM yyyy)	UN AUG 2020
Start date completely unknown	False
Condition ongoing at study entry	Yes <input type="radio"/> No <input checked="" type="radio"/>
If No, please specify the stop date (dd MMM yyyy)	UN AUG 2020
Stop date completely unknown	False
Start Month and Year (derived)	AUG 2020
Start Year (derived)	2020
Stop Month and Year (derived)	AUG 2020
Stop Year (derived)	2020

US3342200

Folder: Screening

Form: Medical History (11)

Data signed: (b) (4) 29 Mar 2021 15:07:51

Generated On: 09 Jun 2021 17:05:26

Condition	RIGHT BREAST LUMP BIOPSY
Start date (dd MMM yyyy)	UN AUG 2020
Start date completely unknown	False
Condition ongoing at study entry	Yes <input type="radio"/> No <input checked="" type="radio"/>
If No, please specify the stop date (dd MMM yyyy)	UN AUG 2020
Stop date completely unknown	False
Start Month and Year (derived)	AUG 2020
Start Year (derived)	2020
Stop Month and Year (derived)	AUG 2020
Stop Year (derived)	2020

US3342200

Folder: Screening

Form: Medical History (12)

Data signed: (b) (4) 29 Mar 2021 15:07:51

Generated On: 09 Jun 2021 17:05:26

Condition	MAMMOGRAM
Start date (dd MMM yyyy)	UN JUL 2020
Start date completely unknown	False
Condition ongoing at study entry	Yes <input type="radio"/> No <input checked="" type="radio"/>
If No, please specify the stop date (dd MMM yyyy)	UN JUL 2020
Stop date completely unknown	False
Start Month and Year (derived)	JUL 2020
Start Year (derived)	2020
Stop Month and Year (derived)	JUL 2020
Stop Year (derived)	2020

US3342200

Folder: Screening

Form: Vital Signs

Data signed: (b) (4) 13 Mar 2021 16:12:03

Generated On: 09 Jun 2021 17:05:26

Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (<i>dd MMM yyyy</i>)	4 SEP 2020
Time of assessment (<i>00:00-23:59</i>)	15:59 (24 HR)
Vital Signs Date and Time (derived)	4 SEP 2020 15:59
Height (<i>xxx.x</i>)	163.5 cm
Weight (<i>xxx.x</i>)	065.4 kg
BMI (<i>xxx.x</i>)	24.46483 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)	

US3342200

Folder: Screening

Form: Physical Examination

Data signed: (b) (4) 13 Mar 2021 16:12:03

Generated On: 09 Jun 2021 17:05:26

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

4 SEP 2020

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

US3342200

Folder: Screening

Form: Childbearing Potential

Data signed: (b) (4) 13 Mar 2021 16:12:03

Generated On: 09 Jun 2021 17:05:26

Date of assessment (dd MMM yyyy) 4 SEP 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) 12 NOV 2018

Date of surgery unknown False

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

Date of last menstruation unknown False

US3342200

Folder: Screening

Form: Risk of Exposure

Data signed: (b) (4) 13 Mar 2021 16:12:03

Generated On: 09 Jun 2021 17:05:26

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

US3342200

Folder: Screening

Form: Risk of Exposure

Data signed: (b) (4) 13 Mar 2021 16:12:03

Generated On: 09 Jun 2021 17:05:26

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	

US3342200

Folder: Visit 1 Day 1

Form: Visit Date

Data signed: (b) (4) 12 Feb 2021 23:50:35

Generated On: 09 Jun 2021 17:05:26

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	4 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	VISIT1

US3342200

Folder: Visit 1 Day 1

Form: Randomization

Data signed: (b) (4) 12 Feb 2021 23:50:35

Generated On: 09 Jun 2021 17:05:26

What was the date of randomization? (dd MMM yyyy) 04 SEP 2020

What was the participant's randomization number? 111836

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 ☒

US3342200

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Data signed: (b) (4) 12 Feb 2021 23:50:35

Generated On: 09 Jun 2021 17:05:26

Height	ND - Not Done
Weight	ND - Not Done

US3342200

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Data signed: (b) (4) 12 Feb 2021 23:50:35

Generated On: 09 Jun 2021 17:05:26

Height	ND - Not Done
Weight	ND - Not Done
Timepoint	Pre-Dose <input checked="" type="radio"/> Post-Dose <input type="radio"/>
Were vital signs assessed?	Yes <input checked="" type="radio"/> No <input type="radio"/>
Date of assessment (dd MMM yyyy)	4 SEP 2020
Time of assessment (00:00-23:59)	15:59 (24 HR)
Vital Signs Date and Time (derived)	4 SEP 2020 15:59
Temperature (xxx.x)	98.4 F
Route of measurement	Oral <input checked="" type="radio"/> Axillary <input type="radio"/> Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	73 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	12 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	115 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	79 mmHg
Diastolic Blood Pressure units	MMHG

US3342200

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Data signed: (b) (4) 12 Feb 2021 23:50:35

Generated On: 09 Jun 2021 17:05:26

Height	ND - Not Done
Weight	ND - Not Done
Timepoint	Pre-Dose <input type="radio"/> Post-Dose <input checked="" type="radio"/>
Were vital signs assessed?	Yes <input checked="" type="radio"/> No <input type="radio"/>
Date of assessment (dd MMM yyyy)	4 SEP 2020
Time of assessment (00:00-23:59)	17:21 (24 HR)
Vital Signs Date and Time (derived)	4 SEP 2020 17:21
Temperature (xxx.x)	98.7 F
Route of measurement	Oral <input checked="" type="radio"/> Axillary <input type="radio"/> Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	81 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	12 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	109 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	80 mmHg
Diastolic Blood Pressure units	MMHG

US3342200

Folder: Visit 1 Day 1

Form: Physical Examination

Data signed: (b) (4) 12 Feb 2021 23:50:35

Generated On: 09 Jun 2021 17:05:26

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.

US3342200

Folder: Visit 1 Day 1

Form: Exposure

Data signed: (b) (4) 12 Feb 2021 23:50:35

Generated On: 09 Jun 2021 17:05:26

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) 4 SEP 2020

What was the treatment time? (00:00-23:59) 16:51 (24 HR)

Treatment Date and Time (derived) 4 SEP 2020 16:51

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

What was the frequency of the study treatment dosing? ONCE

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

US3342200

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Data signed: (b) (4) 12 Feb 2021 23:50:35

Generated On: 09 Jun 2021 17:05:26

Was the sample collected?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Collection date (dd MMM yyyy)	4 SEP 2020
Collection time (00:00-23:59)	16:24 (24 HR)
Collection date and time (derived)	4 SEP 2020 16:24

US3342200

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab

Data signed: (b) (4) 12 Feb 2021 23:50:35

Generated On: 09 Jun 2021 17:05:26

Collection date (dd MMM yyyy)			4 SEP 2020
Lab Test	Was the sample collected?	Collection time (00:00 - 23:59)	Collection date and time (derived)
Nasopharyngeal Swab 1	Yes	16:25	4 SEP 2020 16:25
Nasopharyngeal Swab 2	No		

US3342200

Folder: Visit 1 Day 1

Form: Continuing

Data signed: (b) (4) 12 Feb 2021 23:50:35

Generated On: 09 Jun 2021 17:05:26

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3342200

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 17:05:26

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

98.7 °F

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

Yes ☐

No ☒

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

PC Time Stamp

04 SEP 2020 17:22

PC Open Date & Time

04 SEP 2020 17:11

PC Close Date & Time

04 SEP 2020 19:41

US3342200

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 17:05:26

TIMEPOINT

DAY 1, AFTER VACCINATION
(AT HOME)

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

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

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

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

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

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

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

Was **TEMPERATURE** taken? Yes ☒ No ☐

Please record your **TEMPERATURE** in °F 98.4 °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	04 SEP 2020 20:40
PC Open Date & Time	04 SEP 2020 20:36
PC Close Date & Time	05 SEP 2020 11:59

US3342200

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 17:05:26

TIMEPOINT

DAY 2

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.8 °F

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

Yes ☐

No ☒

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

PC Time Stamp

05 SEP 2020 12:02

PC Open Date & Time

05 SEP 2020 12:00

PC Close Date & Time

06 SEP 2020 11:59

US3342200

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 17:05:26

TIMEPOINT

DAY 3

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.6 °F

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

Yes ☐

No ☒

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

PC Time Stamp

06 SEP 2020 18:35

PC Open Date & Time

06 SEP 2020 12:00

PC Close Date & Time

07 SEP 2020 11:59

US3342200

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 17:05:26

TIMEPOINT

DAY 4

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

98.7 °F

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

Yes ☐

No ☒

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

PC Time Stamp

07 SEP 2020 18:23

PC Open Date & Time

07 SEP 2020 12:00

PC Close Date & Time

08 SEP 2020 11:59

US3342200

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 17:05:26

TIMEPOINT

DAY 5

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

98.7 °F

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

Yes ☐

No ☒

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

PC Time Stamp

09 SEP 2020 03:17

PC Open Date & Time

08 SEP 2020 12:00

PC Close Date & Time

09 SEP 2020 11:59

US3342200

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 17:05:26

TIMEPOINT

DAY 6

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

98.3 °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

09 SEP 2020 14:29

PC Open Date & Time

09 SEP 2020 12:00

PC Close Date & Time

10 SEP 2020 11:59

US3342200

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 17:05:26

TIMEPOINT

DAY 7

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.6 °F

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

Yes ☐

No ☒

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

PC Time Stamp

10 SEP 2020 12:20

PC Open Date & Time

10 SEP 2020 12:00

PC Close Date & Time

11 SEP 2020 11:59

US3342200

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 17:05:26

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

04 SEP 2020 17:23

PC Open Date & Time

04 SEP 2020 17:11

PC Close Date & Time

04 SEP 2020 19:41

US3342200

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 17:05:26

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

04 SEP 2020 20:40

PC Open Date & Time

04 SEP 2020 20:36

PC Close Date & Time

05 SEP 2020 11:59

US3342200

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 17:05:26

TIMEPOINT

DAY 2

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

05 SEP 2020 12:02

PC Open Date & Time

05 SEP 2020 12:00

PC Close Date & Time

06 SEP 2020 11:59

US3342200

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 17:05:26

TIMEPOINT

DAY 3

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

06 SEP 2020 18:36

PC Open Date & Time

06 SEP 2020 12:00

PC Close Date & Time

07 SEP 2020 11:59

US3342200

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 17:05:26

TIMEPOINT

DAY 4

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

07 SEP 2020 18:23

PC Open Date & Time

07 SEP 2020 12:00

PC Close Date & Time

08 SEP 2020 11:59

US3342200

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 17:05:26

TIMEPOINT

DAY 5

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

09 SEP 2020 03:17

PC Open Date & Time

08 SEP 2020 12:00

PC Close Date & Time

09 SEP 2020 11:59

US3342200

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 17:05:26

TIMEPOINT

DAY 6

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

09 SEP 2020 14:29

PC Open Date & Time

09 SEP 2020 12:00

PC Close Date & Time

10 SEP 2020 11:59

US3342200

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 17:05:26

TIMEPOINT

DAY 7

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

10 SEP 2020 12:20

PC Open Date & Time

10 SEP 2020 12:00

PC Close Date & Time

11 SEP 2020 11:59

US3342200

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:05:26

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 ☐

US3342200

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:05:26

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

No ☒

Yes ☐

PC Time stamp	04 SEP 2020 17:24
---------------	-------------------

PC Open Date & Time	04 SEP 2020 17:11
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PC Close Date & Time	04 SEP 2020 19:41
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US3342200

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:05:26

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 ☐

US3342200

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:05:26

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

No ☒

Yes ☐

PC Time stamp	04 SEP 2020 20:41
PC Open Date & Time	04 SEP 2020 20:36
PC Close Date & Time	05 SEP 2020 11:59

US3342200

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:05:26

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 ☒

US3342200

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:05:26

Yes <input type="checkbox"/>	
PC Time stamp	05 SEP 2020 12:03
PC Open Date & Time	05 SEP 2020 12:00
PC Close Date & Time	06 SEP 2020 11:59

US3342200

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:05:26

TIMEPOINT

DAY 3

HEADACHE

None ☒

No interference with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

FATIGUE

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

NAUSEA/VOMITING

None ☒

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

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

Prevents daily activity, requires
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity
not requiring medical attention ☐

Prevents daily activity and
requires medical attention ☐

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

No ☒

PRODUCTION RELEASE (v12.003
EAB) (1725)

56 of 4196

US3342200

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:05:26

Yes <input type="checkbox"/>	
PC Time stamp	06 SEP 2020 18:37
PC Open Date & Time	06 SEP 2020 12:00
PC Close Date & Time	07 SEP 2020 11:59

US3342200

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:05:26

TIMEPOINT

DAY 4

HEADACHE

None ☒

No interference with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

FATIGUE

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

NAUSEA/VOMITING

None ☒

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

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

Prevents daily activity, requires
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity
not requiring medical attention ☐

Prevents daily activity and
requires medical attention ☐

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

No ☒

PRODUCTION RELEASE (v12.003
EAB) (1725)

58 of 4196

US3342200

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:05:26

Yes <input type="checkbox"/>	
PC Time stamp	07 SEP 2020 18:24
PC Open Date & Time	07 SEP 2020 12:00
PC Close Date & Time	08 SEP 2020 11:59

US3342200

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:05:26

TIMEPOINT

DAY 5

HEADACHE

None ☒

No interference with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

FATIGUE

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

NAUSEA/VOMITING

None ☒

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

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

Prevents daily activity, requires
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity
not requiring medical attention ☐

Prevents daily activity and
requires medical attention ☐

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

No ☒

PRODUCTION RELEASE (v12.003

60 of 4196

EAB) (1725)

US3342200

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:05:26

Yes <input type="checkbox"/>	
PC Time stamp	09 SEP 2020 03:18
PC Open Date & Time	08 SEP 2020 12:00
PC Close Date & Time	09 SEP 2020 11:59

US3342200

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:05:26

TIMEPOINT

DAY 6

HEADACHE

None ☒

No interference with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

FATIGUE

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

NAUSEA/VOMITING

None ☒

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

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

Prevents daily activity, requires
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity
not requiring medical attention ☐

Prevents daily activity and
requires medical attention ☐

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

No ☒

PRODUCTION RELEASE (v12.003
EAB) (1725)

62 of 4196

US3342200

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:05:26

Yes <input type="checkbox"/>	
PC Time stamp	09 SEP 2020 14:30
PC Open Date & Time	09 SEP 2020 12:00
PC Close Date & Time	10 SEP 2020 11:59

US3342200

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:05:26

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 ☒

US3342200

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:05:26

Yes <input type="checkbox"/>	
PC Time stamp	10 SEP 2020 12:21
PC Open Date & Time	10 SEP 2020 12:00
PC Close Date & Time	11 SEP 2020 11:59

US3342200

Folder: Safety Call Day 8 (1)

Form: Safety Call

Data signed: (b) (4) 12 Feb 2021 23:50:35

Generated On: 09 Jun 2021 17:05:26

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

14 SEP 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3342200

Folder: Safety Call Day 8 (1)

Form: Continuing

Data signed: (b) (4) 12 Feb 2021 23:50:35

Generated On: 09 Jun 2021 17:05:26

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3342200

Folder: Safety Call Day 15 (1)

Form: Safety Call

Data signed: (b) (4) 12 Feb 2021 23:50:35

Generated On: 09 Jun 2021 17:05:26

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

21 SEP 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3342200

Folder: Safety Call Day 15 (1)

Form: Continuing

Data signed: (b) (4) 12 Feb 2021 23:50:35

Generated On: 09 Jun 2021 17:05:26

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3342200

Folder: Safety Call Day 22 (1)

Form: Safety Call

Data signed: (b) (4) 12 Feb 2021 23:50:35

Generated On: 09 Jun 2021 17:05:26

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

28 SEP 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3342200

Folder: Safety Call Day 22 (1)

Form: Continuing

Data signed: (b) (4) 12 Feb 2021 23:50:35

Generated On: 09 Jun 2021 17:05:26

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3342200

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Data signed: (b) (4) 12 Feb 2021 23:50:36

Generated On: 09 Jun 2021 17:05:26

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	30 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

US3342200

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Data signed: (b) (4) 12 Feb 2021 23:50:36

Generated On: 09 Jun 2021 17:05:26

Timepoint	Pre-Dose <input checked="" type="radio"/>
	Post-Dose <input type="radio"/>
Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (dd MMM yyyy)	30 SEP 2020
Time of assessment (00:00-23:59)	10:20 (24 HR)
Vital Signs Date and Time (derived)	30 SEP 2020 10:20
Temperature (xxx.x)	98.7 F
Route of measurement	Oral <input checked="" type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	77 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	14 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	116 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	79 mmHg
Diastolic Blood Pressure units	MMHG

US3342200

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Data signed: (b) (4) 12 Feb 2021 23:50:36

Generated On: 09 Jun 2021 17:05:26

Timepoint	Pre-Dose <input type="radio"/>
	Post-Dose <input checked="" type="radio"/>
Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (dd MMM yyyy)	30 SEP 2020
Time of assessment (00:00-23:59)	11:32 (24 HR)
Vital Signs Date and Time (derived)	30 SEP 2020 11:32
Temperature (xxx.x)	99.1 F
Route of measurement	Oral <input checked="" type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	71 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	12 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	107 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	68 mmHg
Diastolic Blood Pressure units	MMHG

US3342200

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Data signed: (b) (4) 12 Feb 2021 23:50:36

Generated On: 09 Jun 2021 17:05:26

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

30 SEP 2020

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

US3342200

Folder: Visit 2 Day 29 (1)

Form: Exposure

Data signed: (b) (4) 12 Feb 2021 23:50:36

Generated On: 09 Jun 2021 17:05:26

Was study treatment given? Yes ☒ No ☐

If No, reason not given

Participant declined due to Adverse Event ☐

Physician withheld dose due to Adverse Event ☐

Death ☐

Lost To Follow-Up ☐

Physician Decision ☐

Pregnancy ☐

Protocol Deviation ☐

Study Terminated by Sponsor ☐

Withdrawal of Consent by Participant ☐

Confirmed COVID-19 ☐

Other ☐

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

What was the study treatment? MRNA-1273 OR PLACEBO

What was the treatment date? (dd MMM yyyy) 30 SEP 2020

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

Treatment Date and Time (derived) 30 SEP 2020 10:59

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

US3342200

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 12 Feb 2021 23:50:36

Generated On: 09 Jun 2021 17:05:26

Was the sample collected?

Yes ☒

No ☐

Collection date (dd MMM yyyy)

30 SEP 2020

Collection time (00:00-23:59)

10:48 (24 HR)

Collection date and time (derived)

30 SEP 2020 10:48

US3342200

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab

Data signed: (b) (4) 12 Feb 2021 23:50:36

Generated On: 09 Jun 2021 17:05:26

Collection date (dd MMM yyyy)			30 SEP 2020
Lab Test	Was the sample collected?	Collection time (00:00 - 23:59)	Collection date and time (derived)
Nasopharyngeal Swab 1	Yes	10:50	30 SEP 2020 10:50
Nasopharyngeal Swab 2	No		

US3342200

Folder: Visit 2 Day 29 (1)

Form: Continuing

Data signed: (b) (4) 12 Feb 2021 23:50:36

Generated On: 09 Jun 2021 17:05:26

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3342200

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 17:05:26

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

99.1 °F

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

Yes ☐
No ☒

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

PC Time Stamp 30 SEP 2020 11:37

PC Open Date & Time 30 SEP 2020 11:19

PC Close Date & Time 30 SEP 2020 13:49

US3342200

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 17:05:26

TIMEPOINT

DAY 1, AFTER VACCINATION
(AT HOME)

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

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

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

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

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

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

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

Was **TEMPERATURE** taken? Yes ☒ No ☐

Please record your **TEMPERATURE** in °F 98.6 °F

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

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

PC Time Stamp	01 OCT 2020 06:41
PC Open Date & Time	30 SEP 2020 14:44
PC Close Date & Time	01 OCT 2020 11:59

US3342200

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 17:05:26

TIMEPOINT

DAY 2

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

98.7 °F

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

Yes ☐

No ☒

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

PC Time Stamp 01 OCT 2020 12:00

PC Open Date & Time 01 OCT 2020 12:00

PC Close Date & Time 02 OCT 2020 11:59

US3342200

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 17:05:26

TIMEPOINT

DAY 3

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

98.0 °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

02 OCT 2020 12:03

PC Open Date & Time

02 OCT 2020 12:00

PC Close Date & Time

03 OCT 2020 11:59

US3342200

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 17:05:26

TIMEPOINT

DAY 4

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

98.7 °F

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

Yes ☒

No ☐

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

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

True

To **PREVENT** pain or fever from occurring

False

PC Time Stamp

04 OCT 2020 07:02

PC Open Date & Time

03 OCT 2020 12:00

PC Close Date & Time

04 OCT 2020 11:59

US3342200

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 17:05:26

TIMEPOINT

DAY 5

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

98.1 °F

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

Yes ☐

No ☒

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

PC Time Stamp

04 OCT 2020 12:34

PC Open Date & Time

04 OCT 2020 12:00

PC Close Date & Time

05 OCT 2020 11:59

US3342200

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 17:05:26

TIMEPOINT

DAY 6

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.6 °F

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

Yes ☐

No ☒

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

PC Time Stamp

06 OCT 2020 02:34

PC Open Date & Time

05 OCT 2020 12:00

PC Close Date & Time

06 OCT 2020 11:59

US3342200

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 17:05:26

TIMEPOINT

DAY 7

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

98.4 °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

07 OCT 2020 04:29

PC Open Date & Time

06 OCT 2020 12:00

PC Close Date & Time

07 OCT 2020 11:59

US3342200

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 17:05:26

TIMEPOINT

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

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

Please select one response below

None ☒

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

Please select one response below

None ☒

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

30 SEP 2020 11:38

PC Open Date & Time

30 SEP 2020 11:19

PC Close Date & Time

30 SEP 2020 13:49

US3342200

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 17:05:26

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

01 OCT 2020 06:41

PC Open Date & Time

30 SEP 2020 14:44

PC Close Date & Time

01 OCT 2020 11:59

US3342200

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 17:05:26

TIMEPOINT

DAY 2

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

01 OCT 2020 12:01

PC Open Date & Time

01 OCT 2020 12:00

PC Close Date & Time

02 OCT 2020 11:59

US3342200

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 17:05:26

TIMEPOINT

DAY 3

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

02 OCT 2020 12:03

PC Open Date & Time

02 OCT 2020 12:00

PC Close Date & Time

03 OCT 2020 11:59

US3342200

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 17:05:26

TIMEPOINT

DAY 4

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

04 OCT 2020 07:03

PC Open Date & Time

03 OCT 2020 12:00

PC Close Date & Time

04 OCT 2020 11:59

US3342200

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 17:05:26

TIMEPOINT

DAY 5

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

04 OCT 2020 12:34

PC Open Date & Time

04 OCT 2020 12:00

PC Close Date & Time

05 OCT 2020 11:59

US3342200

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 17:05:26

TIMEPOINT

DAY 6

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

06 OCT 2020 02:36

PC Open Date & Time

05 OCT 2020 12:00

PC Close Date & Time

06 OCT 2020 11:59

US3342200

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 17:05:26

TIMEPOINT

DAY 7

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

07 OCT 2020 04:29

PC Open Date & Time

06 OCT 2020 12:00

PC Close Date & Time

07 OCT 2020 11:59

US3342200

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:05:26

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 ☐

US3342200

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:05:26

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

No ☒

Yes ☐

PC Time stamp	30 SEP 2020 11:43
PC Open Date & Time	30 SEP 2020 11:19
PC Close Date & Time	30 SEP 2020 13:49

US3342200

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:05:26

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 ☐

US3342200

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:05:26

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

No ☒

Yes ☐

PC Time stamp	01 OCT 2020 06:42
PC Open Date & Time	30 SEP 2020 14:44
PC Close Date & Time	01 OCT 2020 11:59

US3342200

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:05:26

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 ☒

PRODUCTION RELEASE (v12.003

100 of 4196

EAB) (1725)

US3342200

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:05:26

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

US3342200

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:05:26

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 ☒

US3342200

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:05:26

Yes <input type="checkbox"/>	
PC Time stamp	02 OCT 2020 12:04
PC Open Date & Time	02 OCT 2020 12:00
PC Close Date & Time	03 OCT 2020 11:59

US3342200

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:05:26

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 ☒

US3342200

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:05:26

Yes <input type="checkbox"/>	
PC Time stamp	04 OCT 2020 07:04
PC Open Date & Time	03 OCT 2020 12:00
PC Close Date & Time	04 OCT 2020 11:59

US3342200

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:05:26

TIMEPOINT

DAY 5

HEADACHE

None ☒

No interference with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

FATIGUE

None ☐

No interference with activity ☒

Some interference with activity ☐

Significant; prevents daily
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☐

No interference with activity ☐

Some interference with activity ☒

Significant; prevents daily
activity ☐

NAUSEA/VOMITING

None ☒

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

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

Prevents daily activity, requires
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity
not requiring medical attention ☐

Prevents daily activity and
requires medical attention ☐

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

No ☒

PRODUCTION RELEASE (v12.003

106 of 4196

EAB) (1725)

US3342200

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:05:26

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

US3342200

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:05:26

TIMEPOINT

DAY 6

HEADACHE

None ☒

No interference with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

FATIGUE

None ☐

No interference with activity ☐

Some interference with activity ☒

Significant; prevents daily
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☐

No interference with activity ☐

Some interference with activity ☒

Significant; prevents daily
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☐

No interference with activity ☐

Some interference with activity ☒

Significant; prevents daily
activity ☐

NAUSEA/VOMITING

None ☒

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

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

Prevents daily activity, requires
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity
not requiring medical attention ☐

Prevents daily activity and
requires medical attention ☐

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

No ☒

PRODUCTION RELEASE (v12.003

108 of 4196

EAB) (1725)

US3342200

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:05:26

Yes <input type="checkbox"/>	
PC Time stamp	06 OCT 2020 02:37
PC Open Date & Time	05 OCT 2020 12:00
PC Close Date & Time	06 OCT 2020 11:59

US3342200

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:05:26

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 ☒

US3342200

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:05:26

Yes <input type="checkbox"/>	
PC Time stamp	07 OCT 2020 04:30
PC Open Date & Time	06 OCT 2020 12:00
PC Close Date & Time	07 OCT 2020 11:59

US3342200

Folder: Diary Dose 2 (1)

Form: Fatigue_Day(8)

Generated On: 09 Jun 2021 17:05:26

TIMEPOINT

DAY 8

Select one response below to indicate the intensity of your

None ☐

FATIGUE

No interference with activity ☒

Some interference with activity ☐

Significant; prevents daily activity ☐

PC Time Stamp 07 OCT 2020 16:48

PC Open Date & Time 07 OCT 2020 12:00

PC Close Date & Time 08 OCT 2020 11:59

US3342200

Folder: Diary Dose 2 (1)

Form: Fatigue_Day(9)

Generated On: 09 Jun 2021 17:05:26

TIMEPOINT

DAY 9

Select one response below to indicate the intensity of your

None ☐

FATIGUE

No interference with activity ☐

Some interference with activity ☒

Significant; prevents daily activity ☐

PC Time Stamp

08 OCT 2020 12:00

PC Open Date & Time

08 OCT 2020 12:00

PC Close Date & Time

09 OCT 2020 11:59

US3342200

Folder: Diary Dose 2 (1)

Form: Fatigue_Day(10)

Generated On: 09 Jun 2021 17:05:26

TIMEPOINT

DAY 10

Select one response below to indicate the intensity of your

None ☐

FATIGUE

No interference with activity ☒

Some interference with activity ☐

Significant; prevents daily activity ☐

PC Time Stamp

09 OCT 2020 12:14

PC Open Date & Time

09 OCT 2020 12:00

PC Close Date & Time

10 OCT 2020 11:59

US3342200

Folder: Diary Dose 2 (1)

Form: Fatigue_Day(11)

Generated On: 09 Jun 2021 17:05:26

TIMEPOINT

DAY 11

Select one response below to indicate the intensity of your

None ☐

FATIGUE

No interference with activity ☐

Some interference with activity ☒

Significant; prevents daily activity ☐

PC Time Stamp 10 OCT 2020 12:04

PC Open Date & Time 10 OCT 2020 12:00

PC Close Date & Time 11 OCT 2020 11:59

US3342200

Folder: Diary Dose 2 (1)

Form: Fatigue_Day(12)

Generated On: 09 Jun 2021 17:05:26

TIMEPOINT

DAY 12

Select one response below to indicate the intensity of your

None ☐

FATIGUE

No interference with activity ☒

Some interference with activity ☐

Significant; prevents daily activity ☐

PC Time Stamp

11 OCT 2020 17:26

PC Open Date & Time

11 OCT 2020 12:00

PC Close Date & Time

12 OCT 2020 11:59

US3342200

Folder: Diary Dose 2 (1)

Form: Fatigue_Day(13)

Generated On: 09 Jun 2021 17:05:26

TIMEPOINT

DAY 13

Select one response below to indicate the intensity of your

None ☐

FATIGUE

No interference with activity ☐

Some interference with activity ☒

Significant; prevents daily activity ☐

PC Time Stamp

12 OCT 2020 16:02

PC Open Date & Time

12 OCT 2020 12:00

PC Close Date & Time

13 OCT 2020 11:59

US3342200

Folder: Diary Dose 2 (1)

Form: Fatigue_Day(14)

Generated On: 09 Jun 2021 17:05:26

TIMEPOINT

DAY 14

Select one response below to indicate the intensity of your

None ☐

FATIGUE

No interference with activity ☐

Some interference with activity ☒

Significant; prevents daily activity ☐

PC Time Stamp

14 OCT 2020 06:26

PC Open Date & Time

13 OCT 2020 12:00

PC Close Date & Time

14 OCT 2020 11:59

US3342200

Folder: Diary Dose 2 (1)

Form: Fatigue_Day(15)

Generated On: 09 Jun 2021 17:05:26

TIMEPOINT

DAY 15

Select one response below to indicate the intensity of your

None ☐

FATIGUE

No interference with activity ☒

Some interference with activity ☐

Significant; prevents daily activity ☐

PC Time Stamp

14 OCT 2020 13:40

PC Open Date & Time

14 OCT 2020 12:00

PC Close Date & Time

15 OCT 2020 11:59

US3342200

Folder: Diary Dose 2 (1)

Form: Fatigue_Day(16)

Generated On: 09 Jun 2021 17:05:26

TIMEPOINT

DAY 16

Select one response below to indicate the intensity of your

None ☐

FATIGUE

No interference with activity ☒

Some interference with activity ☐

Significant; prevents daily activity ☐

PC Time Stamp

16 OCT 2020 02:16

PC Open Date & Time

15 OCT 2020 12:00

PC Close Date & Time

16 OCT 2020 11:59

US3342200

Folder: Diary Dose 2 (1)

Form: Fatigue_Day(17)

Generated On: 09 Jun 2021 17:05:26

TIMEPOINT

DAY 17

Select one response below to indicate the intensity of your

None ☒

FATIGUE

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily activity ☐

PC Time Stamp

16 OCT 2020 12:08

PC Open Date & Time

16 OCT 2020 12:00

PC Close Date & Time

17 OCT 2020 11:59

US3342200

Folder: Diary Dose 2 (1)

Form: MuscleAche_Day(8)

Generated On: 09 Jun 2021 17:05:26

TIMEPOINT

DAY 8

Select one response below to indicate the intensity of your **MUSCLE**

ACHES ALL OVER BODY

None ☐

No interference with activity ☒

Some interference with activity ☐

Significant; prevents daily activity ☐

PC Time stamp 07 OCT 2020 16:48

PC Open Date & Time 07 OCT 2020 12:00

PC Close Date & Time 08 OCT 2020 11:59

US3342200

Folder: Diary Dose 2 (1)

Form: MuscleAche_Day(9)

Generated On: 09 Jun 2021 17:05:26

TIMEPOINT

DAY 9

Select one response below to indicate the intensity of your **MUSCLE**

ACHES ALL OVER BODY

None ☐

No interference with activity ☒

Some interference with activity ☐

Significant; prevents daily activity ☐

PC Time stamp	08 OCT 2020 12:00
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PC Open Date & Time	08 OCT 2020 12:00
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PC Close Date & Time	09 OCT 2020 11:59
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US3342200

Folder: Diary Dose 2 (1)

Form: MuscleAche_Day(10)

Generated On: 09 Jun 2021 17:05:26

TIMEPOINT

DAY 10

Select one response below to indicate the intensity of your **MUSCLE**

None ☐

ACHES ALL OVER BODY

No interference with activity ☒

Some interference with activity ☐

Significant; prevents daily activity ☐

PC Time stamp

09 OCT 2020 12:15

PC Open Date & Time

09 OCT 2020 12:00

PC Close Date & Time

10 OCT 2020 11:59

US3342200

Folder: Diary Dose 2 (1)

Form: MuscleAche_Day(11)

Generated On: 09 Jun 2021 17:05:26

TIMEPOINT

DAY 11

Select one response below to indicate the intensity of your **MUSCLE**

ACHES ALL OVER BODY

None ☐

No interference with activity ☐

Some interference with activity ☒

Significant; prevents daily activity ☐

PC Time stamp 10 OCT 2020 12:04

PC Open Date & Time 10 OCT 2020 12:00

PC Close Date & Time 11 OCT 2020 11:59

US3342200

Folder: Diary Dose 2 (1)

Form: MuscleAche_Day(12)

Generated On: 09 Jun 2021 17:05:26

TIMEPOINT

DAY 12

Select one response below to indicate the intensity of your **MUSCLE**

ACHES ALL OVER BODY

None ☐

No interference with activity ☒

Some interference with activity ☐

Significant; prevents daily activity ☐

PC Time stamp 11 OCT 2020 17:26

PC Open Date & Time 11 OCT 2020 12:00

PC Close Date & Time 12 OCT 2020 11:59

US3342200

Folder: Diary Dose 2 (1)

Form: MuscleAche_Day(13)

Generated On: 09 Jun 2021 17:05:26

TIMEPOINT

DAY 13

Select one response below to indicate the intensity of your **MUSCLE**

ACHES ALL OVER BODY

None ☐

No interference with activity ☒

Some interference with activity ☐

Significant; prevents daily activity ☐

PC Time stamp 12 OCT 2020 16:02

PC Open Date & Time 12 OCT 2020 12:00

PC Close Date & Time 13 OCT 2020 11:59

US3342200

Folder: Diary Dose 2 (1)

Form: MuscleAche_Day(14)

Generated On: 09 Jun 2021 17:05:26

TIMEPOINT

DAY 14

Select one response below to indicate the intensity of your **MUSCLE**

ACHES ALL OVER BODY

None ☐

No interference with activity ☒

Some interference with activity ☐

Significant; prevents daily activity ☐

PC Time stamp

14 OCT 2020 06:26

PC Open Date & Time

13 OCT 2020 12:00

PC Close Date & Time

14 OCT 2020 11:59

US3342200

Folder: Diary Dose 2 (1)

Form: MuscleAche_Day(15)

Generated On: 09 Jun 2021 17:05:26

TIMEPOINT

DAY 15

Select one response below to indicate the intensity of your **MUSCLE**

ACHES ALL OVER BODY

None ☐

No interference with activity ☒

Some interference with activity ☐

Significant; prevents daily activity ☐

PC Time stamp 14 OCT 2020 13:40

PC Open Date & Time 14 OCT 2020 12:00

PC Close Date & Time 15 OCT 2020 11:59

US3342200

Folder: Diary Dose 2 (1)

Form: MuscleAche_Day(16)

Generated On: 09 Jun 2021 17:05:26

TIMEPOINT

DAY 16

Select one response below to indicate the intensity of your **MUSCLE**

ACHES ALL OVER BODY

None ☐

No interference with activity ☒

Some interference with activity ☐

Significant; prevents daily activity ☐

PC Time stamp 16 OCT 2020 02:16

PC Open Date & Time 15 OCT 2020 12:00

PC Close Date & Time 16 OCT 2020 11:59

US3342200

Folder: Diary Dose 2 (1)

Form: MuscleAche_Day(17)

Generated On: 09 Jun 2021 17:05:26

TIMEPOINT

DAY 17

Select one response below to indicate the intensity of your **MUSCLE**

None ☒

ACHES ALL OVER BODY

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily activity ☐

PC Time stamp 16 OCT 2020 12:08

PC Open Date & Time 16 OCT 2020 12:00

PC Close Date & Time 17 OCT 2020 11:59

US3342200

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(8)

Generated On: 09 Jun 2021 17:05:26

TIMEPOINT

DAY 8

Select one response below to indicate the intensity of your **JOINT**
ACHES IN SEVERAL JOINTS

None ☐

No interference with activity ☐

Some interference with activity ☒

Significant; prevents daily
activity ☐

PC Time stamp 07 OCT 2020 16:48

PC Open Date & Time 07 OCT 2020 12:00

PC Close Date & Time 08 OCT 2020 11:59

US3342200

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(9)

Generated On: 09 Jun 2021 17:05:26

TIMEPOINT

DAY 9

Select one response below to indicate the intensity of your **JOINT**
ACHES IN SEVERAL JOINTS

None ☐

No interference with activity ☐

Some interference with activity ☒

Significant; prevents daily
activity ☐

PC Time stamp 08 OCT 2020 12:00

PC Open Date & Time 08 OCT 2020 12:00

PC Close Date & Time 09 OCT 2020 11:59

US3342200

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(10)

Generated On: 09 Jun 2021 17:05:26

TIMEPOINT

DAY 10

Select one response below to indicate the intensity of your **JOINT**
ACHES IN SEVERAL JOINTS

None ☐

No interference with activity ☐

Some interference with activity ☒

Significant; prevents daily activity ☐

PC Time stamp 09 OCT 2020 12:15

PC Open Date & Time 09 OCT 2020 12:00

PC Close Date & Time 10 OCT 2020 11:59

US3342200

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(11)

Generated On: 09 Jun 2021 17:05:26

TIMEPOINT

DAY 11

Select one response below to indicate the intensity of your **JOINT**
ACHES IN SEVERAL JOINTS

None ☐

No interference with activity ☐

Some interference with activity ☒

Significant; prevents daily
activity ☐

PC Time stamp 10 OCT 2020 12:04

PC Open Date & Time 10 OCT 2020 12:00

PC Close Date & Time 11 OCT 2020 11:59

US3342200

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(12)

Generated On: 09 Jun 2021 17:05:26

TIMEPOINT

DAY 12

Select one response below to indicate the intensity of your **JOINT**
ACHES IN SEVERAL JOINTS

None ☐

No interference with activity ☐

Some interference with activity ☒

Significant; prevents daily
activity ☐

PC Time stamp 11 OCT 2020 17:26

PC Open Date & Time 11 OCT 2020 12:00

PC Close Date & Time 12 OCT 2020 11:59

US3342200

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(13)

Generated On: 09 Jun 2021 17:05:26

TIMEPOINT

DAY 13

Select one response below to indicate the intensity of your **JOINT**
ACHES IN SEVERAL JOINTS

None ☐

No interference with activity ☐

Some interference with activity ☒

Significant; prevents daily
activity ☐

PC Time stamp 12 OCT 2020 16:02

PC Open Date & Time 12 OCT 2020 12:00

PC Close Date & Time 13 OCT 2020 11:59

US3342200

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(14)

Generated On: 09 Jun 2021 17:05:26

TIMEPOINT

DAY 14

Select one response below to indicate the intensity of your **JOINT**
ACHES IN SEVERAL JOINTS

None ☐

No interference with activity ☐

Some interference with activity ☒

Significant; prevents daily
activity ☐

PC Time stamp 14 OCT 2020 06:26

PC Open Date & Time 13 OCT 2020 12:00

PC Close Date & Time 14 OCT 2020 11:59

US3342200

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(15)

Generated On: 09 Jun 2021 17:05:26

TIMEPOINT

DAY 15

Select one response below to indicate the intensity of your **JOINT**
ACHES IN SEVERAL JOINTS

None ☐

No interference with activity ☒

Some interference with activity ☐

Significant; prevents daily
activity ☐

PC Time stamp 14 OCT 2020 13:41

PC Open Date & Time 14 OCT 2020 12:00

PC Close Date & Time 15 OCT 2020 11:59

US3342200

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(16)

Generated On: 09 Jun 2021 17:05:26

TIMEPOINT

DAY 16

Select one response below to indicate the intensity of your **JOINT**
ACHES IN SEVERAL JOINTS

None ☐

No interference with activity ☐

Some interference with activity ☒

Significant; prevents daily
activity ☐

PC Time stamp 16 OCT 2020 02:17

PC Open Date & Time 15 OCT 2020 12:00

PC Close Date & Time 16 OCT 2020 11:59

US3342200

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(17)

Generated On: 09 Jun 2021 17:05:26

TIMEPOINT

DAY 17

Select one response below to indicate the intensity of your **JOINT**
ACHES IN SEVERAL JOINTS

None ☐

No interference with activity ☒

Some interference with activity ☐

Significant; prevents daily
activity ☐

PC Time stamp 16 OCT 2020 12:08

PC Open Date & Time 16 OCT 2020 12:00

PC Close Date & Time 17 OCT 2020 11:59

US3342200

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(18)

Generated On: 09 Jun 2021 17:05:26

TIMEPOINT

DAY 18

Select one response below to indicate the intensity of your **JOINT**
ACHES IN SEVERAL JOINTS

None ☐

No interference with activity ☐

Some interference with activity ☒

Significant; prevents daily
activity ☐

PC Time stamp 17 OCT 2020 15:00

PC Open Date & Time 17 OCT 2020 12:00

PC Close Date & Time 18 OCT 2020 11:59

US3342200

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(19)

Generated On: 09 Jun 2021 17:05:26

TIMEPOINT

DAY 19

Select one response below to indicate the intensity of your **JOINT**
ACHES IN SEVERAL JOINTS

None ☐

No interference with activity ☒

Some interference with activity ☐

Significant; prevents daily
activity ☐

PC Time stamp 18 OCT 2020 12:10

PC Open Date & Time 18 OCT 2020 12:00

PC Close Date & Time 19 OCT 2020 11:59

US3342200

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(20)

Generated On: 09 Jun 2021 17:05:26

TIMEPOINT

DAY 20

Select one response below to indicate the intensity of your **JOINT**
ACHES IN SEVERAL JOINTS

None ☐

No interference with activity ☐

Some interference with activity ☒

Significant; prevents daily activity ☐

PC Time stamp 19 OCT 2020 16:38

PC Open Date & Time 19 OCT 2020 12:00

PC Close Date & Time 20 OCT 2020 11:59

US3342200

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(21)

Generated On: 09 Jun 2021 17:05:26

TIMEPOINT

DAY 21

Select one response below to indicate the intensity of your **JOINT**
ACHES IN SEVERAL JOINTS

None ☐

No interference with activity ☐

Some interference with activity ☒

Significant; prevents daily
activity ☐

PC Time stamp 20 OCT 2020 12:39

PC Open Date & Time 20 OCT 2020 12:00

PC Close Date & Time 21 OCT 2020 11:59

US3342200

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(22)

Generated On: 09 Jun 2021 17:05:26

TIMEPOINT

DAY 22

Select one response below to indicate the intensity of your **JOINT**
ACHES IN SEVERAL JOINTS

None ☐

No interference with activity ☐

Some interference with activity ☒

Significant; prevents daily
activity ☐

PC Time stamp 21 OCT 2020 12:04

PC Open Date & Time 21 OCT 2020 12:00

PC Close Date & Time 22 OCT 2020 11:59

US3342200

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(23)

Generated On: 09 Jun 2021 17:05:26

TIMEPOINT

DAY 23

Select one response below to indicate the intensity of your **JOINT**
ACHES IN SEVERAL JOINTS

None ☐

No interference with activity ☐

Some interference with activity ☒

Significant; prevents daily
activity ☐

PC Time stamp 22 OCT 2020 12:08

PC Open Date & Time 22 OCT 2020 12:00

PC Close Date & Time 23 OCT 2020 11:59

US3342200

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(24)

Generated On: 09 Jun 2021 17:05:26

TIMEPOINT

DAY 24

Select one response below to indicate the intensity of your **JOINT**
ACHES IN SEVERAL JOINTS

None ☐

No interference with activity ☐

Some interference with activity ☒

Significant; prevents daily
activity ☐

PC Time stamp 23 OCT 2020 12:00

PC Open Date & Time 23 OCT 2020 12:00

PC Close Date & Time 24 OCT 2020 11:59

US3342200

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(25)

Generated On: 09 Jun 2021 17:05:26

TIMEPOINT

DAY 25

Select one response below to indicate the intensity of your **JOINT**
ACHES IN SEVERAL JOINTS

None ☐

No interference with activity ☒

Some interference with activity ☐

Significant; prevents daily
activity ☐

PC Time stamp 24 OCT 2020 17:55

PC Open Date & Time 24 OCT 2020 12:00

PC Close Date & Time 25 OCT 2020 11:59

US3342200

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(26)

Generated On: 09 Jun 2021 17:05:26

TIMEPOINT

DAY 26

Select one response below to indicate the intensity of your **JOINT**
ACHES IN SEVERAL JOINTS

None ☐

No interference with activity ☐

Some interference with activity ☒

Significant; prevents daily
activity ☐

PC Time stamp 25 OCT 2020 13:14

PC Open Date & Time 25 OCT 2020 12:00

PC Close Date & Time 26 OCT 2020 11:59

US3342200

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(27)

Generated On: 09 Jun 2021 17:05:26

TIMEPOINT

DAY 27

Select one response below to indicate the intensity of your **JOINT**
ACHES IN SEVERAL JOINTS

None ☐

No interference with activity ☒

Some interference with activity ☐

Significant; prevents daily
activity ☐

PC Time stamp 26 OCT 2020 12:00

PC Open Date & Time 26 OCT 2020 12:00

PC Close Date & Time 27 OCT 2020 11:59

US3342200

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(28)

Generated On: 09 Jun 2021 17:05:26

TIMEPOINT

DAY 28

Select one response below to indicate the intensity of your **JOINT**
ACHES IN SEVERAL JOINTS

None ☐

No interference with activity ☐

Some interference with activity ☒

Significant; prevents daily
activity ☐

PC Time stamp 27 OCT 2020 12:15

PC Open Date & Time 27 OCT 2020 12:00

PC Close Date & Time 28 OCT 2020 11:59

US3342200

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(29)

Generated On: 09 Jun 2021 17:05:26

TIMEPOINT

DAY 29

Select one response below to indicate the intensity of your **JOINT**
ACHES IN SEVERAL JOINTS

None ☐

No interference with activity ☐

Some interference with activity ☒

Significant; prevents daily activity ☐

PC Time stamp 28 OCT 2020 13:15

PC Open Date & Time 28 OCT 2020 12:00

PC Close Date & Time 29 OCT 2020 11:59

US3342200

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(30)

Generated On: 09 Jun 2021 17:05:26

TIMEPOINT

DAY 30

Select one response below to indicate the intensity of your **JOINT**
ACHES IN SEVERAL JOINTS

None ☐

No interference with activity ☐

Some interference with activity ☒

Significant; prevents daily activity ☐

PC Time stamp 29 OCT 2020 13:11

PC Open Date & Time 29 OCT 2020 12:00

PC Close Date & Time 30 OCT 2020 11:59

US3342200

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(31)

Generated On: 09 Jun 2021 17:05:26

TIMEPOINT

DAY 31

Select one response below to indicate the intensity of your **JOINT**
ACHES IN SEVERAL JOINTS

None ☐

No interference with activity ☐

Some interference with activity ☒

Significant; prevents daily activity ☐

PC Time stamp 30 OCT 2020 12:00

PC Open Date & Time 30 OCT 2020 12:00

PC Close Date & Time 31 OCT 2020 11:59

US3342200

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(32)

Generated On: 09 Jun 2021 17:05:26

TIMEPOINT

DAY 32

Select one response below to indicate the intensity of your **JOINT**
ACHES IN SEVERAL JOINTS

None ☐

No interference with activity ☐

Some interference with activity ☒

Significant; prevents daily
activity ☐

PC Time stamp

31 OCT 2020 16:56

PC Open Date & Time

31 OCT 2020 12:00

PC Close Date & Time

01 NOV 2020 11:59

US3342200

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(33)

Generated On: 09 Jun 2021 17:05:26

TIMEPOINT

DAY 33

Select one response below to indicate the intensity of your **JOINT**
ACHES IN SEVERAL JOINTS

None ☐

No interference with activity ☐

Some interference with activity ☒

Significant; prevents daily activity ☐

PC Time stamp

01 NOV 2020 14:03

PC Open Date & Time

01 NOV 2020 12:00

PC Close Date & Time

02 NOV 2020 11:59

US3342200

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(34)

Generated On: 09 Jun 2021 17:05:26

TIMEPOINT

DAY 34

Select one response below to indicate the intensity of your **JOINT**
ACHES IN SEVERAL JOINTS

None ☐

No interference with activity ☐

Some interference with activity ☒

Significant; prevents daily
activity ☐

PC Time stamp 02 NOV 2020 17:31

PC Open Date & Time 02 NOV 2020 12:00

PC Close Date & Time 03 NOV 2020 11:59

US3342200

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(35)

Generated On: 09 Jun 2021 17:05:26

TIMEPOINT

DAY 35

Select one response below to indicate the intensity of your **JOINT**
ACHES IN SEVERAL JOINTS

None ☐

No interference with activity ☐

Some interference with activity ☒

Significant; prevents daily
activity ☐

PC Time stamp 03 NOV 2020 18:01

PC Open Date & Time 03 NOV 2020 12:00

PC Close Date & Time 04 NOV 2020 11:59

US3342200

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(36)

Generated On: 09 Jun 2021 17:05:26

TIMEPOINT

DAY 36

Select one response below to indicate the intensity of your **JOINT**
ACHES IN SEVERAL JOINTS

None ☐

No interference with activity ☐

Some interference with activity ☒

Significant; prevents daily activity ☐

PC Time stamp 05 NOV 2020 06:41

PC Open Date & Time 04 NOV 2020 12:00

PC Close Date & Time 05 NOV 2020 11:59

US3342200

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(37)

Generated On: 09 Jun 2021 17:05:26

TIMEPOINT

DAY 37

Select one response below to indicate the intensity of your **JOINT**
ACHES IN SEVERAL JOINTS

None ☐

No interference with activity ☒

Some interference with activity ☐

Significant; prevents daily
activity ☐

PC Time stamp 05 NOV 2020 12:13

PC Open Date & Time 05 NOV 2020 12:00

PC Close Date & Time 06 NOV 2020 11:59

US3342200

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(38)

Generated On: 09 Jun 2021 17:05:26

TIMEPOINT

DAY 38

Select one response below to indicate the intensity of your **JOINT**
ACHES IN SEVERAL JOINTS

None ☐

No interference with activity ☐

Some interference with activity ☒

Significant; prevents daily
activity ☐

PC Time stamp 07 NOV 2020 04:41

PC Open Date & Time 06 NOV 2020 12:00

PC Close Date & Time 07 NOV 2020 11:59

US3342200

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(39)

Generated On: 09 Jun 2021 17:05:26

TIMEPOINT

DAY 39

Select one response below to indicate the intensity of your **JOINT**
ACHES IN SEVERAL JOINTS

None ☐

No interference with activity ☐

Some interference with activity ☒

Significant; prevents daily activity ☐

PC Time stamp 07 NOV 2020 12:30

PC Open Date & Time 07 NOV 2020 12:00

PC Close Date & Time 08 NOV 2020 11:59

US3342200

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(40)

Generated On: 09 Jun 2021 17:05:26

TIMEPOINT

DAY 40

Select one response below to indicate the intensity of your **JOINT**
ACHES IN SEVERAL JOINTS

None ☐

No interference with activity ☐

Some interference with activity ☒

Significant; prevents daily
activity ☐

PC Time stamp

08 NOV 2020 12:00

PC Open Date & Time

08 NOV 2020 12:00

PC Close Date & Time

09 NOV 2020 11:59

US3342200

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(41)

Generated On: 09 Jun 2021 17:05:26

TIMEPOINT

DAY 41

Select one response below to indicate the intensity of your **JOINT**
ACHES IN SEVERAL JOINTS

None ☐

No interference with activity ☐

Some interference with activity ☒

Significant; prevents daily
activity ☐

PC Time stamp

09 NOV 2020 21:21

PC Open Date & Time

09 NOV 2020 12:00

PC Close Date & Time

10 NOV 2020 11:59

US3342200

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(42)

Generated On: 09 Jun 2021 17:05:26

TIMEPOINT

DAY 42

Select one response below to indicate the intensity of your **JOINT**
ACHES IN SEVERAL JOINTS

None ☐

No interference with activity ☐

Some interference with activity ☒

Significant; prevents daily
activity ☐

PC Time stamp 11 NOV 2020 04:15

PC Open Date & Time 10 NOV 2020 12:00

PC Close Date & Time 11 NOV 2020 11:59

US3342200

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(43)

Generated On: 09 Jun 2021 17:05:26

TIMEPOINT

DAY 43

Select one response below to indicate the intensity of your **JOINT**
ACHES IN SEVERAL JOINTS

None ☐

No interference with activity ☐

Some interference with activity ☒

Significant; prevents daily
activity ☐

PC Time stamp 11 NOV 2020 17:04

PC Open Date & Time 11 NOV 2020 12:00

PC Close Date & Time 12 NOV 2020 11:59

US3342200

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(44)

Generated On: 09 Jun 2021 17:05:26

TIMEPOINT

DAY 44

Select one response below to indicate the intensity of your **JOINT**
ACHES IN SEVERAL JOINTS

None ☐

No interference with activity ☐

Some interference with activity ☒

Significant; prevents daily
activity ☐

PC Time stamp 12 NOV 2020 14:39

PC Open Date & Time 12 NOV 2020 12:00

PC Close Date & Time 13 NOV 2020 11:59

US3342200

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(45)

Generated On: 09 Jun 2021 17:05:26

TIMEPOINT

DAY 45

Select one response below to indicate the intensity of your **JOINT**
ACHES IN SEVERAL JOINTS

None ☐

No interference with activity ☐

Some interference with activity ☒

Significant; prevents daily
activity ☐

PC Time stamp 13 NOV 2020 18:17

PC Open Date & Time 13 NOV 2020 12:00

PC Close Date & Time 14 NOV 2020 11:59

US3342200

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(46)

Generated On: 09 Jun 2021 17:05:26

TIMEPOINT

DAY 46

Select one response below to indicate the intensity of your **JOINT**
ACHES IN SEVERAL JOINTS

None ☐

No interference with activity ☒

Some interference with activity ☐

Significant; prevents daily
activity ☐

PC Time stamp 15 NOV 2020 04:11

PC Open Date & Time 14 NOV 2020 12:00

PC Close Date & Time 15 NOV 2020 11:59

US3342200

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(47)

Generated On: 09 Jun 2021 17:05:26

TIMEPOINT

DAY 47

Select one response below to indicate the intensity of your **JOINT**
ACHES IN SEVERAL JOINTS

None ☐

No interference with activity ☐

Some interference with activity ☒

Significant; prevents daily
activity ☐

PC Time stamp 15 NOV 2020 15:24

PC Open Date & Time 15 NOV 2020 12:00

PC Close Date & Time 16 NOV 2020 11:59

US3342200

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(48)

Generated On: 09 Jun 2021 17:05:26

TIMEPOINT

DAY 48

Select one response below to indicate the intensity of your **JOINT**
ACHES IN SEVERAL JOINTS

None ☐

No interference with activity ☐

Some interference with activity ☒

Significant; prevents daily
activity ☐

PC Time stamp 16 NOV 2020 13:51

PC Open Date & Time 16 NOV 2020 12:00

PC Close Date & Time 17 NOV 2020 11:59

US3342200

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(49)

Generated On: 09 Jun 2021 17:05:26

TIMEPOINT

DAY 49

Select one response below to indicate the intensity of your **JOINT**

None ☐

ACHES IN SEVERAL JOINTS

No interference with activity ☐

Some interference with activity ☒

Significant; prevents daily activity ☐

PC Time stamp

18 NOV 2020 00:03

PC Open Date & Time

17 NOV 2020 12:00

PC Close Date & Time

18 NOV 2020 11:59

US3342200

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(50)

Generated On: 09 Jun 2021 17:05:26

TIMEPOINT

DAY 50

Select one response below to indicate the intensity of your **JOINT**
ACHES IN SEVERAL JOINTS

None ☐

No interference with activity ☐

Some interference with activity ☒

Significant; prevents daily
activity ☐

PC Time stamp 18 NOV 2020 12:33

PC Open Date & Time 18 NOV 2020 12:00

PC Close Date & Time 19 NOV 2020 11:59

US3342200

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(51)

Generated On: 09 Jun 2021 17:05:26

TIMEPOINT

DAY 51

Select one response below to indicate the intensity of your **JOINT**
ACHES IN SEVERAL JOINTS

None ☐

No interference with activity ☐

Some interference with activity ☒

Significant; prevents daily
activity ☐

PC Time stamp 20 NOV 2020 05:59

PC Open Date & Time 19 NOV 2020 12:00

PC Close Date & Time 20 NOV 2020 11:59

US3342200

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(52)

Generated On: 09 Jun 2021 17:05:26

TIMEPOINT

DAY 52

Select one response below to indicate the intensity of your **JOINT**
ACHES IN SEVERAL JOINTS

None ☐

No interference with activity ☐

Some interference with activity ☒

Significant; prevents daily
activity ☐

PC Time stamp 21 NOV 2020 04:06

PC Open Date & Time 20 NOV 2020 12:00

PC Close Date & Time 21 NOV 2020 11:59

US3342200

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(53)

Generated On: 09 Jun 2021 17:05:26

TIMEPOINT

DAY 53

Select one response below to indicate the intensity of your **JOINT**
ACHES IN SEVERAL JOINTS

None ☐

No interference with activity ☒

Some interference with activity ☐

Significant; prevents daily
activity ☐

PC Time stamp 22 NOV 2020 00:46

PC Open Date & Time 21 NOV 2020 12:00

PC Close Date & Time 22 NOV 2020 11:59

US3342200

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(54)

Generated On: 09 Jun 2021 17:05:26

TIMEPOINT

DAY 54

Select one response below to indicate the intensity of your **JOINT**
ACHES IN SEVERAL JOINTS

None ☐

No interference with activity ☐

Some interference with activity ☒

Significant; prevents daily
activity ☐

PC Time stamp 22 NOV 2020 17:30

PC Open Date & Time 22 NOV 2020 12:00

PC Close Date & Time 23 NOV 2020 11:59

US3342200

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(55)

Generated On: 09 Jun 2021 17:05:26

TIMEPOINT

DAY 55

Select one response below to indicate the intensity of your **JOINT**
ACHES IN SEVERAL JOINTS

None ☐

No interference with activity ☐

Some interference with activity ☒

Significant; prevents daily
activity ☐

PC Time stamp 23 NOV 2020 12:02

PC Open Date & Time 23 NOV 2020 12:00

PC Close Date & Time 24 NOV 2020 11:59

US3342200

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(56)

Generated On: 09 Jun 2021 17:05:26

TIMEPOINT

DAY 56

Select one response below to indicate the intensity of your **JOINT**
ACHES IN SEVERAL JOINTS

None ☐

No interference with activity ☐

Some interference with activity ☒

Significant; prevents daily
activity ☐

PC Time stamp 24 NOV 2020 13:09

PC Open Date & Time 24 NOV 2020 12:00

PC Close Date & Time 25 NOV 2020 11:59

US3342200

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(57)

Generated On: 09 Jun 2021 17:05:26

TIMEPOINT

DAY 57

Select one response below to indicate the intensity of your **JOINT**
ACHES IN SEVERAL JOINTS

None ☐

No interference with activity ☐

Some interference with activity ☒

Significant; prevents daily
activity ☐

PC Time stamp 25 NOV 2020 16:13

PC Open Date & Time 25 NOV 2020 12:00

PC Close Date & Time 26 NOV 2020 11:59

US3342200

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(58)

Generated On: 09 Jun 2021 17:05:26

TIMEPOINT

DAY 58

Select one response below to indicate the intensity of your **JOINT**
ACHES IN SEVERAL JOINTS

None ☐

No interference with activity ☐

Some interference with activity ☒

Significant; prevents daily activity ☐

PC Time stamp 26 NOV 2020 12:17

PC Open Date & Time 26 NOV 2020 12:00

PC Close Date & Time 27 NOV 2020 11:59

US3342200

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(59)

Generated On: 09 Jun 2021 17:05:26

TIMEPOINT

DAY 59

Select one response below to indicate the intensity of your **JOINT**
ACHES IN SEVERAL JOINTS

None ☐

No interference with activity ☐

Some interference with activity ☒

Significant; prevents daily activity ☐

PC Time stamp 27 NOV 2020 12:04

PC Open Date & Time 27 NOV 2020 12:00

PC Close Date & Time 28 NOV 2020 11:59

US3342200

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(60)

Generated On: 09 Jun 2021 17:05:26

TIMEPOINT

DAY 60

Select one response below to indicate the intensity of your **JOINT**
ACHES IN SEVERAL JOINTS

None ☐

No interference with activity ☐

Some interference with activity ☒

Significant; prevents daily
activity ☐

PC Time stamp 28 NOV 2020 13:17

PC Open Date & Time 28 NOV 2020 12:00

PC Close Date & Time 29 NOV 2020 11:59

US3342200

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(61)

Generated On: 09 Jun 2021 17:05:26

TIMEPOINT

DAY 61

Select one response below to indicate the intensity of your **JOINT**
ACHES IN SEVERAL JOINTS

None ☐

No interference with activity ☐

Some interference with activity ☒

Significant; prevents daily
activity ☐

PC Time stamp 29 NOV 2020 12:13

PC Open Date & Time 29 NOV 2020 12:00

PC Close Date & Time 30 NOV 2020 11:59

US3342200

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(62)

Generated On: 09 Jun 2021 17:05:26

TIMEPOINT

DAY 62

Select one response below to indicate the intensity of your **JOINT**
ACHES IN SEVERAL JOINTS

None ☐

No interference with activity ☐

Some interference with activity ☒

Significant; prevents daily
activity ☐

PC Time stamp 30 NOV 2020 13:17

PC Open Date & Time 30 NOV 2020 12:00

PC Close Date & Time 01 DEC 2020 11:59

US3342200

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(63)

Generated On: 09 Jun 2021 17:05:26

TIMEPOINT

DAY 63

Select one response below to indicate the intensity of your **JOINT**
ACHES IN SEVERAL JOINTS

None ☐

No interference with activity ☐

Some interference with activity ☒

Significant; prevents daily
activity ☐

PC Time stamp 02 DEC 2020 04:51

PC Open Date & Time 01 DEC 2020 12:00

PC Close Date & Time 02 DEC 2020 11:59

US3342200

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(64)

Generated On: 09 Jun 2021 17:05:26

TIMEPOINT

DAY 64

Select one response below to indicate the intensity of your **JOINT**
ACHES IN SEVERAL JOINTS

None ☐

No interference with activity ☐

Some interference with activity ☒

Significant; prevents daily
activity ☐

PC Time stamp 02 DEC 2020 12:00

PC Open Date & Time 02 DEC 2020 12:00

PC Close Date & Time 03 DEC 2020 11:59

US3342200

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(65)

Generated On: 09 Jun 2021 17:05:26

TIMEPOINT

DAY 65

Select one response below to indicate the intensity of your **JOINT**

None ☐

ACHES IN SEVERAL JOINTS

No interference with activity ☐

Some interference with activity ☒

Significant; prevents daily activity ☐

PC Time stamp

03 DEC 2020 13:03

PC Open Date & Time

03 DEC 2020 12:00

PC Close Date & Time

04 DEC 2020 11:59

US3342200

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(66)

Generated On: 09 Jun 2021 17:05:26

TIMEPOINT

DAY 66

Select one response below to indicate the intensity of your **JOINT**
ACHES IN SEVERAL JOINTS

None ☐

No interference with activity ☐

Some interference with activity ☒

Significant; prevents daily
activity ☐

PC Time stamp 04 DEC 2020 12:00

PC Open Date & Time 04 DEC 2020 12:00

PC Close Date & Time 05 DEC 2020 11:59

US3342200

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(67)

Generated On: 09 Jun 2021 17:05:26

TIMEPOINT

DAY 67

Select one response below to indicate the intensity of your **JOINT**
ACHES IN SEVERAL JOINTS

None ☐

No interference with activity ☐

Some interference with activity ☒

Significant; prevents daily
activity ☐

PC Time stamp 05 DEC 2020 19:56

PC Open Date & Time 05 DEC 2020 12:00

PC Close Date & Time 06 DEC 2020 11:59

US3342200

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(68)

Generated On: 09 Jun 2021 17:05:26

TIMEPOINT

DAY 68

Select one response below to indicate the intensity of your **JOINT**
ACHES IN SEVERAL JOINTS

None ☐

No interference with activity ☐

Some interference with activity ☒

Significant; prevents daily
activity ☐

PC Time stamp 06 DEC 2020 12:50

PC Open Date & Time 06 DEC 2020 12:00

PC Close Date & Time 07 DEC 2020 11:59

US3342200

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(69)

Generated On: 09 Jun 2021 17:05:26

TIMEPOINT

DAY 69

Select one response below to indicate the intensity of your **JOINT**
ACHES IN SEVERAL JOINTS

None ☐

No interference with activity ☐

Some interference with activity ☒

Significant; prevents daily
activity ☐

PC Time stamp 07 DEC 2020 12:07

PC Open Date & Time 07 DEC 2020 12:00

PC Close Date & Time 08 DEC 2020 11:59

US3342200

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(70)

Generated On: 09 Jun 2021 17:05:26

TIMEPOINT

DAY 70

Select one response below to indicate the intensity of your **JOINT**
ACHES IN SEVERAL JOINTS

None ☐

No interference with activity ☐

Some interference with activity ☒

Significant; prevents daily
activity ☐

PC Time stamp 08 DEC 2020 13:05

PC Open Date & Time 08 DEC 2020 12:00

PC Close Date & Time 09 DEC 2020 11:59

US3342200

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(71)

Generated On: 09 Jun 2021 17:05:26

TIMEPOINT

DAY 71

Select one response below to indicate the intensity of your **JOINT**
ACHES IN SEVERAL JOINTS

None ☐

No interference with activity ☒

Some interference with activity ☐

Significant; prevents daily
activity ☐

PC Time stamp 09 DEC 2020 13:54

PC Open Date & Time 09 DEC 2020 12:00

PC Close Date & Time 10 DEC 2020 11:59

US3342200

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(72)

Generated On: 09 Jun 2021 17:05:26

TIMEPOINT

DAY 72

Select one response below to indicate the intensity of your **JOINT**
ACHES IN SEVERAL JOINTS

None ☐

No interference with activity ☐

Some interference with activity ☒

Significant; prevents daily
activity ☐

PC Time stamp 10 DEC 2020 12:39

PC Open Date & Time 10 DEC 2020 12:00

PC Close Date & Time 11 DEC 2020 11:59

US3342200

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(73)

Generated On: 09 Jun 2021 17:05:26

TIMEPOINT

DAY 73

Select one response below to indicate the intensity of your **JOINT**
ACHES IN SEVERAL JOINTS

None ☐

No interference with activity ☐

Some interference with activity ☒

Significant; prevents daily
activity ☐

PC Time stamp 11 DEC 2020 12:19

PC Open Date & Time 11 DEC 2020 12:00

PC Close Date & Time 12 DEC 2020 11:59

US3342200

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(74)

Generated On: 09 Jun 2021 17:05:26

TIMEPOINT

DAY 74

Select one response below to indicate the intensity of your **JOINT**

ACHES IN SEVERAL JOINTS

None ☐

No interference with activity ☐

Some interference with activity ☒

Significant; prevents daily activity ☐

PC Time stamp 13 DEC 2020 00:06

PC Open Date & Time 12 DEC 2020 12:00

PC Close Date & Time 13 DEC 2020 11:59

US3342200

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(75)

Generated On: 09 Jun 2021 17:05:26

TIMEPOINT

DAY 75

Select one response below to indicate the intensity of your **JOINT**
ACHES IN SEVERAL JOINTS

None ☐

No interference with activity ☐

Some interference with activity ☒

Significant; prevents daily
activity ☐

PC Time stamp 14 DEC 2020 03:28

PC Open Date & Time 13 DEC 2020 12:00

PC Close Date & Time 14 DEC 2020 11:59

US3342200

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(76)

Generated On: 09 Jun 2021 17:05:26

TIMEPOINT

DAY 76

Select one response below to indicate the intensity of your **JOINT**
ACHES IN SEVERAL JOINTS

None ☐

No interference with activity ☐

Some interference with activity ☒

Significant; prevents daily
activity ☐

PC Time stamp 14 DEC 2020 13:29

PC Open Date & Time 14 DEC 2020 12:00

PC Close Date & Time 15 DEC 2020 11:59

US3342200

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(77)

Generated On: 09 Jun 2021 17:05:26

TIMEPOINT

DAY 77

Select one response below to indicate the intensity of your **JOINT**
ACHES IN SEVERAL JOINTS

None ☐

No interference with activity ☐

Some interference with activity ☒

Significant; prevents daily
activity ☐

PC Time stamp 15 DEC 2020 15:07

PC Open Date & Time 15 DEC 2020 12:00

PC Close Date & Time 16 DEC 2020 11:59

US3342200

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(78)

Generated On: 09 Jun 2021 17:05:26

TIMEPOINT

DAY 78

Select one response below to indicate the intensity of your **JOINT**
ACHES IN SEVERAL JOINTS

None ☐

No interference with activity ☐

Some interference with activity ☒

Significant; prevents daily
activity ☐

PC Time stamp 16 DEC 2020 15:44

PC Open Date & Time 16 DEC 2020 12:00

PC Close Date & Time 17 DEC 2020 11:59

US3342200

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(79)

Generated On: 09 Jun 2021 17:05:26

TIMEPOINT

DAY 79

Select one response below to indicate the intensity of your **JOINT**
ACHES IN SEVERAL JOINTS

None ☐

No interference with activity ☐

Some interference with activity ☒

Significant; prevents daily
activity ☐

PC Time stamp 17 DEC 2020 12:39

PC Open Date & Time 17 DEC 2020 12:00

PC Close Date & Time 18 DEC 2020 11:59

US3342200

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(80)

Generated On: 09 Jun 2021 17:05:26

TIMEPOINT

DAY 80

Select one response below to indicate the intensity of your **JOINT**
ACHES IN SEVERAL JOINTS

None ☐

No interference with activity ☐

Some interference with activity ☒

Significant; prevents daily
activity ☐

PC Time stamp 18 DEC 2020 12:21

PC Open Date & Time 18 DEC 2020 12:00

PC Close Date & Time 19 DEC 2020 11:59

US3342200

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(81)

Generated On: 09 Jun 2021 17:05:26

TIMEPOINT

DAY 81

Select one response below to indicate the intensity of your **JOINT**
ACHES IN SEVERAL JOINTS

None ☐

No interference with activity ☐

Some interference with activity ☒

Significant; prevents daily
activity ☐

PC Time stamp 19 DEC 2020 15:04

PC Open Date & Time 19 DEC 2020 12:00

PC Close Date & Time 20 DEC 2020 11:59

US3342200

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(82)

Generated On: 09 Jun 2021 17:05:26

TIMEPOINT

DAY 82

Select one response below to indicate the intensity of your **JOINT**
ACHES IN SEVERAL JOINTS

None ☐

No interference with activity ☐

Some interference with activity ☒

Significant; prevents daily
activity ☐

PC Time stamp 20 DEC 2020 12:00

PC Open Date & Time 20 DEC 2020 12:00

PC Close Date & Time 21 DEC 2020 11:59

US3342200

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(83)

Generated On: 09 Jun 2021 17:05:26

TIMEPOINT

DAY 83

Select one response below to indicate the intensity of your **JOINT**
ACHES IN SEVERAL JOINTS

None ☐

No interference with activity ☐

Some interference with activity ☒

Significant; prevents daily
activity ☐

PC Time stamp 21 DEC 2020 17:43

PC Open Date & Time 21 DEC 2020 12:00

PC Close Date & Time 22 DEC 2020 11:59

US3342200

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(84)

Generated On: 09 Jun 2021 17:05:26

TIMEPOINT

DAY 84

Select one response below to indicate the intensity of your **JOINT**
ACHES IN SEVERAL JOINTS

None ☐

No interference with activity ☐

Some interference with activity ☒

Significant; prevents daily activity ☐

PC Time stamp 22 DEC 2020 13:31

PC Open Date & Time 22 DEC 2020 12:00

PC Close Date & Time 23 DEC 2020 11:59

US3342200

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(85)

Generated On: 09 Jun 2021 17:05:26

TIMEPOINT

DAY 85

Select one response below to indicate the intensity of your **JOINT**
ACHES IN SEVERAL JOINTS

None ☐

No interference with activity ☐

Some interference with activity ☒

Significant; prevents daily
activity ☐

PC Time stamp 23 DEC 2020 19:04

PC Open Date & Time 23 DEC 2020 12:00

PC Close Date & Time 24 DEC 2020 11:59

US3342200

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(86)

Generated On: 09 Jun 2021 17:05:26

TIMEPOINT

DAY 86

Select one response below to indicate the intensity of your **JOINT**
ACHES IN SEVERAL JOINTS

None ☐

No interference with activity ☐

Some interference with activity ☒

Significant; prevents daily
activity ☐

PC Time stamp

24 DEC 2020 19:14

PC Open Date & Time

24 DEC 2020 12:00

PC Close Date & Time

25 DEC 2020 11:59

US3342200

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(87)

Generated On: 09 Jun 2021 17:05:26

TIMEPOINT

DAY 87

Select one response below to indicate the intensity of your **JOINT**
ACHES IN SEVERAL JOINTS

None ☐

No interference with activity ☐

Some interference with activity ☒

Significant; prevents daily
activity ☐

PC Time stamp 25 DEC 2020 12:18

PC Open Date & Time 25 DEC 2020 12:00

PC Close Date & Time 26 DEC 2020 11:59

US3342200

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(88)

Generated On: 09 Jun 2021 17:05:26

TIMEPOINT

DAY 88

Select one response below to indicate the intensity of your **JOINT**
ACHES IN SEVERAL JOINTS

None ☐

No interference with activity ☐

Some interference with activity ☒

Significant; prevents daily
activity ☐

PC Time stamp 26 DEC 2020 12:45

PC Open Date & Time 26 DEC 2020 12:00

PC Close Date & Time 27 DEC 2020 11:59

US3342200

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(89)

Generated On: 09 Jun 2021 17:05:26

TIMEPOINT

DAY 89

Select one response below to indicate the intensity of your **JOINT**
ACHES IN SEVERAL JOINTS

None ☐

No interference with activity ☐

Some interference with activity ☒

Significant; prevents daily
activity ☐

PC Time stamp 27 DEC 2020 12:00

PC Open Date & Time 27 DEC 2020 12:00

PC Close Date & Time 28 DEC 2020 11:59

US3342200

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(90)

Generated On: 09 Jun 2021 17:05:26

TIMEPOINT

DAY 90

Select one response below to indicate the intensity of your **JOINT**

None ☐

ACHES IN SEVERAL JOINTS

No interference with activity ☐

Some interference with activity ☒

Significant; prevents daily activity ☐

PC Time stamp

29 DEC 2020 03:15

PC Open Date & Time

28 DEC 2020 12:00

PC Close Date & Time

29 DEC 2020 11:59

US3342200

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(91)

Generated On: 09 Jun 2021 17:05:26

TIMEPOINT

DAY 91

Select one response below to indicate the intensity of your **JOINT**
ACHES IN SEVERAL JOINTS

None ☐

No interference with activity ☐

Some interference with activity ☒

Significant; prevents daily activity ☐

PC Time stamp 29 DEC 2020 16:08

PC Open Date & Time 29 DEC 2020 12:00

PC Close Date & Time 30 DEC 2020 11:59

US3342200

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(92)

Generated On: 09 Jun 2021 17:05:26

TIMEPOINT

DAY 92

Select one response below to indicate the intensity of your **JOINT**
ACHES IN SEVERAL JOINTS

None ☐

No interference with activity ☐

Some interference with activity ☒

Significant; prevents daily
activity ☐

PC Time stamp 30 DEC 2020 12:34

PC Open Date & Time 30 DEC 2020 12:00

PC Close Date & Time 31 DEC 2020 11:59

US3342200

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(93)

Generated On: 09 Jun 2021 17:05:26

TIMEPOINT

DAY 93

Select one response below to indicate the intensity of your **JOINT**
ACHES IN SEVERAL JOINTS

None ☐

No interference with activity ☐

Some interference with activity ☒

Significant; prevents daily
activity ☐

PC Time stamp 31 DEC 2020 19:26

PC Open Date & Time 31 DEC 2020 12:00

PC Close Date & Time 01 JAN 2021 11:59

US3342200

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(94)

Generated On: 09 Jun 2021 17:05:26

TIMEPOINT

DAY 94

Select one response below to indicate the intensity of your **JOINT**
ACHES IN SEVERAL JOINTS

None ☐

No interference with activity ☐

Some interference with activity ☒

Significant; prevents daily
activity ☐

PC Time stamp

01 JAN 2021 21:03

PC Open Date & Time

01 JAN 2021 12:00

PC Close Date & Time

02 JAN 2021 11:59

US3342200

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(95)

Generated On: 09 Jun 2021 17:05:26

TIMEPOINT

DAY 95

Select one response below to indicate the intensity of your **JOINT**
ACHES IN SEVERAL JOINTS

None ☐

No interference with activity ☐

Some interference with activity ☒

Significant; prevents daily
activity ☐

PC Time stamp 02 JAN 2021 15:51

PC Open Date & Time 02 JAN 2021 12:00

PC Close Date & Time 03 JAN 2021 11:59

US3342200

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(96)

Generated On: 09 Jun 2021 17:05:26

TIMEPOINT

DAY 96

Select one response below to indicate the intensity of your **JOINT**
ACHES IN SEVERAL JOINTS

None ☐

No interference with activity ☐

Some interference with activity ☒

Significant; prevents daily
activity ☐

PC Time stamp 03 JAN 2021 20:32

PC Open Date & Time 03 JAN 2021 12:00

PC Close Date & Time 04 JAN 2021 11:59

US3342200

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(97)

Generated On: 09 Jun 2021 17:05:26

TIMEPOINT

DAY 97

Select one response below to indicate the intensity of your **JOINT**
ACHES IN SEVERAL JOINTS

None ☐

No interference with activity ☐

Some interference with activity ☒

Significant; prevents daily
activity ☐

PC Time stamp

04 JAN 2021 14:45

PC Open Date & Time

04 JAN 2021 12:00

PC Close Date & Time

05 JAN 2021 11:59

US3342200

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(98)

Generated On: 09 Jun 2021 17:05:26

TIMEPOINT

DAY 98

Select one response below to indicate the intensity of your **JOINT**
ACHES IN SEVERAL JOINTS

None ☐

No interference with activity ☐

Some interference with activity ☒

Significant; prevents daily
activity ☐

PC Time stamp 05 JAN 2021 12:09

PC Open Date & Time 05 JAN 2021 12:00

PC Close Date & Time 06 JAN 2021 11:59

US3342200

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(99)

Generated On: 09 Jun 2021 17:05:26

TIMEPOINT

DAY 99

Select one response below to indicate the intensity of your **JOINT**
ACHES IN SEVERAL JOINTS

None ☐

No interference with activity ☐

Some interference with activity ☒

Significant; prevents daily
activity ☐

PC Time stamp 06 JAN 2021 13:05

PC Open Date & Time 06 JAN 2021 12:00

PC Close Date & Time 07 JAN 2021 11:59

US3342200

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(100)

Generated On: 09 Jun 2021 17:05:26

TIMEPOINT

DAY 100

Select one response below to indicate the intensity of your **JOINT**
ACHES IN SEVERAL JOINTS

None ☐

No interference with activity ☐

Some interference with activity ☒

Significant; prevents daily
activity ☐

PC Time stamp

07 JAN 2021 12:00

PC Open Date & Time

07 JAN 2021 12:00

PC Close Date & Time

08 JAN 2021 11:59

US3342200

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(101)

Generated On: 09 Jun 2021 17:05:26

TIMEPOINT

DAY 101

Select one response below to indicate the intensity of your **JOINT**
ACHES IN SEVERAL JOINTS

None ☐

No interference with activity ☐

Some interference with activity ☒

Significant; prevents daily
activity ☐

PC Time stamp

08 JAN 2021 23:59

PC Open Date & Time

08 JAN 2021 12:00

PC Close Date & Time

09 JAN 2021 11:59

US3342200

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(102)

Generated On: 09 Jun 2021 17:05:26

TIMEPOINT

DAY 102

Select one response below to indicate the intensity of your **JOINT**
ACHES IN SEVERAL JOINTS

None ☐

No interference with activity ☐

Some interference with activity ☒

Significant; prevents daily
activity ☐

PC Time stamp

09 JAN 2021 12:05

PC Open Date & Time

09 JAN 2021 12:00

PC Close Date & Time

10 JAN 2021 11:59

US3342200

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(103)

Generated On: 09 Jun 2021 17:05:26

TIMEPOINT

DAY 103

Select one response below to indicate the intensity of your **JOINT**
ACHES IN SEVERAL JOINTS

None ☐

No interference with activity ☐

Some interference with activity ☒

Significant; prevents daily
activity ☐

PC Time stamp

10 JAN 2021 16:49

PC Open Date & Time

10 JAN 2021 12:00

PC Close Date & Time

11 JAN 2021 11:59

US3342200

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(104)

Generated On: 09 Jun 2021 17:05:26

TIMEPOINT

DAY 104

Select one response below to indicate the intensity of your **JOINT**
ACHES IN SEVERAL JOINTS

None ☐

No interference with activity ☐

Some interference with activity ☒

Significant; prevents daily
activity ☐

PC Time stamp

11 JAN 2021 12:01

PC Open Date & Time

11 JAN 2021 12:00

PC Close Date & Time

12 JAN 2021 11:59

US3342200

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(105)

Generated On: 09 Jun 2021 17:05:26

TIMEPOINT

DAY 105

Select one response below to indicate the intensity of your **JOINT**
ACHES IN SEVERAL JOINTS

None ☐

No interference with activity ☐

Some interference with activity ☒

Significant; prevents daily
activity ☐

PC Time stamp

12 JAN 2021 13:03

PC Open Date & Time

12 JAN 2021 12:00

PC Close Date & Time

13 JAN 2021 11:59

US3342200

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(106)

Generated On: 09 Jun 2021 17:05:26

TIMEPOINT

DAY 106

Select one response below to indicate the intensity of your **JOINT**
ACHES IN SEVERAL JOINTS

None ☐

No interference with activity ☐

Some interference with activity ☒

Significant; prevents daily
activity ☐

PC Time stamp

14 JAN 2021 03:41

PC Open Date & Time

13 JAN 2021 12:00

PC Close Date & Time

14 JAN 2021 11:59

US3342200

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(107)

Generated On: 09 Jun 2021 17:05:26

TIMEPOINT

DAY 107

Select one response below to indicate the intensity of your **JOINT**
ACHES IN SEVERAL JOINTS

None ☐

No interference with activity ☐

Some interference with activity ☒

Significant; prevents daily
activity ☐

PC Time stamp

14 JAN 2021 16:03

PC Open Date & Time

14 JAN 2021 12:00

PC Close Date & Time

15 JAN 2021 11:59

US3342200

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(108)

Generated On: 09 Jun 2021 17:05:26

TIMEPOINT

DAY 108

Select one response below to indicate the intensity of your **JOINT**
ACHES IN SEVERAL JOINTS

None ☐

No interference with activity ☐

Some interference with activity ☒

Significant; prevents daily
activity ☐

PC Time stamp

16 JAN 2021 03:13

PC Open Date & Time

15 JAN 2021 12:00

PC Close Date & Time

16 JAN 2021 11:59

US3342200

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(109)

Generated On: 09 Jun 2021 17:05:26

TIMEPOINT

DAY 109

Select one response below to indicate the intensity of your **JOINT**
ACHES IN SEVERAL JOINTS

None ☐

No interference with activity ☐

Some interference with activity ☒

Significant; prevents daily
activity ☐

PC Time stamp

16 JAN 2021 12:37

PC Open Date & Time

16 JAN 2021 12:00

PC Close Date & Time

17 JAN 2021 11:59

US3342200

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(110)

Generated On: 09 Jun 2021 17:05:26

TIMEPOINT

DAY 110

Select one response below to indicate the intensity of your **JOINT**
ACHES IN SEVERAL JOINTS

None ☐

No interference with activity ☐

Some interference with activity ☒

Significant; prevents daily
activity ☐

PC Time stamp

18 JAN 2021 00:19

PC Open Date & Time

17 JAN 2021 12:00

PC Close Date & Time

18 JAN 2021 11:59

US3342200

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(111)

Generated On: 09 Jun 2021 17:05:26

TIMEPOINT

DAY 111

Select one response below to indicate the intensity of your **JOINT**
ACHES IN SEVERAL JOINTS

None ☐

No interference with activity ☐

Some interference with activity ☒

Significant; prevents daily
activity ☐

PC Time stamp

19 JAN 2021 03:08

PC Open Date & Time

18 JAN 2021 12:00

PC Close Date & Time

19 JAN 2021 11:59

US3342200

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(112)

Generated On: 09 Jun 2021 17:05:26

TIMEPOINT

DAY 112

Select one response below to indicate the intensity of your **JOINT**
ACHES IN SEVERAL JOINTS

None ☐

No interference with activity ☐

Some interference with activity ☒

Significant; prevents daily
activity ☐

PC Time stamp

19 JAN 2021 12:01

PC Open Date & Time

19 JAN 2021 12:00

PC Close Date & Time

20 JAN 2021 11:59

US3342200

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(113)

Generated On: 09 Jun 2021 17:05:26

TIMEPOINT

DAY 113

Select one response below to indicate the intensity of your **JOINT**
ACHES IN SEVERAL JOINTS

None ☐

No interference with activity ☐

Some interference with activity ☒

Significant; prevents daily
activity ☐

PC Time stamp

20 JAN 2021 15:17

PC Open Date & Time

20 JAN 2021 12:00

PC Close Date & Time

21 JAN 2021 11:59

US3342200

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(114)

Generated On: 09 Jun 2021 17:05:26

TIMEPOINT

DAY 114

Select one response below to indicate the intensity of your **JOINT**
ACHES IN SEVERAL JOINTS

None ☐

No interference with activity ☐

Some interference with activity ☒

Significant; prevents daily
activity ☐

PC Time stamp

21 JAN 2021 12:00

PC Open Date & Time

21 JAN 2021 12:00

PC Close Date & Time

22 JAN 2021 11:59

US3342200

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(115)

Generated On: 09 Jun 2021 17:05:26

TIMEPOINT

DAY 115

Select one response below to indicate the intensity of your **JOINT**
ACHES IN SEVERAL JOINTS

None ☐

No interference with activity ☐

Some interference with activity ☒

Significant; prevents daily
activity ☐

PC Time stamp

22 JAN 2021 12:55

PC Open Date & Time

22 JAN 2021 12:00

PC Close Date & Time

23 JAN 2021 11:59

US3342200

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(116)

Generated On: 09 Jun 2021 17:05:26

TIMEPOINT

DAY 116

Select one response below to indicate the intensity of your **JOINT**
ACHES IN SEVERAL JOINTS

None ☐

No interference with activity ☐

Some interference with activity ☒

Significant; prevents daily
activity ☐

PC Time stamp

23 JAN 2021 12:37

PC Open Date & Time

23 JAN 2021 12:00

PC Close Date & Time

24 JAN 2021 11:59

US3342200

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(117)

Generated On: 09 Jun 2021 17:05:26

TIMEPOINT

DAY 117

Select one response below to indicate the intensity of your **JOINT**
ACHES IN SEVERAL JOINTS

None ☐

No interference with activity ☐

Some interference with activity ☒

Significant; prevents daily
activity ☐

PC Time stamp

24 JAN 2021 21:42

PC Open Date & Time

24 JAN 2021 12:00

PC Close Date & Time

25 JAN 2021 11:59

US3342200

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(118)

Generated On: 09 Jun 2021 17:05:26

TIMEPOINT

DAY 118

Select one response below to indicate the intensity of your **JOINT**
ACHES IN SEVERAL JOINTS

None ☐

No interference with activity ☐

Some interference with activity ☒

Significant; prevents daily
activity ☐

PC Time stamp

25 JAN 2021 17:48

PC Open Date & Time

25 JAN 2021 12:00

PC Close Date & Time

26 JAN 2021 11:59

US3342200

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(119)

Generated On: 09 Jun 2021 17:05:26

TIMEPOINT

DAY 119

Select one response below to indicate the intensity of your **JOINT**
ACHES IN SEVERAL JOINTS

None ☐

No interference with activity ☐

Some interference with activity ☒

Significant; prevents daily
activity ☐

PC Time stamp

26 JAN 2021 19:10

PC Open Date & Time

26 JAN 2021 12:00

PC Close Date & Time

27 JAN 2021 11:59

US3342200

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(120)

Generated On: 09 Jun 2021 17:05:26

TIMEPOINT

DAY 120

Select one response below to indicate the intensity of your **JOINT**
ACHES IN SEVERAL JOINTS

None ☐

No interference with activity ☐

Some interference with activity ☒

Significant; prevents daily
activity ☐

PC Time stamp

27 JAN 2021 19:46

PC Open Date & Time

27 JAN 2021 12:00

PC Close Date & Time

28 JAN 2021 11:59

US3342200

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(121)

Generated On: 09 Jun 2021 17:05:26

TIMEPOINT

DAY 121

Select one response below to indicate the intensity of your **JOINT**
ACHES IN SEVERAL JOINTS

None ☐

No interference with activity ☐

Some interference with activity ☒

Significant; prevents daily
activity ☐

PC Time stamp

28 JAN 2021 12:00

PC Open Date & Time

28 JAN 2021 12:00

PC Close Date & Time

29 JAN 2021 11:59

US3342200

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(122)

Generated On: 09 Jun 2021 17:05:26

TIMEPOINT

DAY 122

Select one response below to indicate the intensity of your **JOINT**
ACHES IN SEVERAL JOINTS

None ☐

No interference with activity ☐

Some interference with activity ☒

Significant; prevents daily
activity ☐

PC Time stamp

30 JAN 2021 05:35

PC Open Date & Time

29 JAN 2021 12:00

PC Close Date & Time

30 JAN 2021 11:59

US3342200

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(123)

Generated On: 09 Jun 2021 17:05:26

TIMEPOINT

DAY 123

Select one response below to indicate the intensity of your **JOINT**
ACHES IN SEVERAL JOINTS

None ☐

No interference with activity ☐

Some interference with activity ☒

Significant; prevents daily
activity ☐

PC Time stamp

31 JAN 2021 09:35

PC Open Date & Time

30 JAN 2021 12:00

PC Close Date & Time

31 JAN 2021 11:59

US3342200

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(124)

Generated On: 09 Jun 2021 17:05:26

TIMEPOINT

DAY 124

Select one response below to indicate the intensity of your **JOINT**
ACHES IN SEVERAL JOINTS

None ☐

No interference with activity ☐

Some interference with activity ☒

Significant; prevents daily
activity ☐

PC Time stamp

31 JAN 2021 14:18

PC Open Date & Time

31 JAN 2021 12:00

PC Close Date & Time

01 FEB 2021 11:59

US3342200

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(125)

Generated On: 09 Jun 2021 17:05:26

TIMEPOINT

DAY 125

Select one response below to indicate the intensity of your **JOINT**
ACHES IN SEVERAL JOINTS

None ☐

No interference with activity ☐

Some interference with activity ☒

Significant; prevents daily
activity ☐

PC Time stamp

01 FEB 2021 13:44

PC Open Date & Time

01 FEB 2021 12:00

PC Close Date & Time

02 FEB 2021 11:59

US3342200

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(126)

Generated On: 09 Jun 2021 17:05:26

TIMEPOINT

DAY 126

Select one response below to indicate the intensity of your **JOINT**
ACHES IN SEVERAL JOINTS

None ☐

No interference with activity ☐

Some interference with activity ☒

Significant; prevents daily
activity ☐

PC Time stamp

02 FEB 2021 12:01

PC Open Date & Time

02 FEB 2021 12:00

PC Close Date & Time

03 FEB 2021 11:59

US3342200

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(127)

Generated On: 09 Jun 2021 17:05:26

TIMEPOINT

DAY 127

Select one response below to indicate the intensity of your **JOINT**
ACHES IN SEVERAL JOINTS

None ☐

No interference with activity ☐

Some interference with activity ☒

Significant; prevents daily
activity ☐

PC Time stamp

03 FEB 2021 18:10

PC Open Date & Time

03 FEB 2021 12:00

PC Close Date & Time

04 FEB 2021 11:59

US3342200

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(128)

Generated On: 09 Jun 2021 17:05:26

TIMEPOINT

DAY 128

Select one response below to indicate the intensity of your **JOINT**
ACHES IN SEVERAL JOINTS

None ☐

No interference with activity ☐

Some interference with activity ☒

Significant; prevents daily
activity ☐

PC Time stamp

04 FEB 2021 12:02

PC Open Date & Time

04 FEB 2021 12:00

PC Close Date & Time

05 FEB 2021 11:59

US3342200

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(129)

Generated On: 09 Jun 2021 17:05:26

TIMEPOINT

DAY 129

Select one response below to indicate the intensity of your **JOINT**
ACHES IN SEVERAL JOINTS

None ☐

No interference with activity ☐

Some interference with activity ☒

Significant; prevents daily
activity ☐

PC Time stamp

05 FEB 2021 13:10

PC Open Date & Time

05 FEB 2021 12:00

PC Close Date & Time

06 FEB 2021 11:59

US3342200

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(130)

Generated On: 09 Jun 2021 17:05:26

TIMEPOINT

DAY 130

Select one response below to indicate the intensity of your **JOINT**
ACHES IN SEVERAL JOINTS

None ☐

No interference with activity ☐

Some interference with activity ☒

Significant; prevents daily
activity ☐

PC Time stamp

06 FEB 2021 21:15

PC Open Date & Time

06 FEB 2021 12:00

PC Close Date & Time

07 FEB 2021 11:59

US3342200

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(131)

Generated On: 09 Jun 2021 17:05:26

TIMEPOINT

DAY 131

Select one response below to indicate the intensity of your **JOINT**
ACHES IN SEVERAL JOINTS

None ☐

No interference with activity ☐

Some interference with activity ☒

Significant; prevents daily
activity ☐

PC Time stamp

08 FEB 2021 06:00

PC Open Date & Time

07 FEB 2021 12:00

PC Close Date & Time

08 FEB 2021 11:59

US3342200

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(132)

Generated On: 09 Jun 2021 17:05:26

TIMEPOINT

DAY 132

Select one response below to indicate the intensity of your **JOINT**
ACHES IN SEVERAL JOINTS

None ☐

No interference with activity ☒

Some interference with activity ☐

Significant; prevents daily
activity ☐

PC Time stamp

08 FEB 2021 13:09

PC Open Date & Time

08 FEB 2021 12:00

PC Close Date & Time

09 FEB 2021 11:59

US3342200

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(133)

Generated On: 09 Jun 2021 17:05:26

TIMEPOINT

DAY 133

Select one response below to indicate the intensity of your **JOINT**
ACHES IN SEVERAL JOINTS

None ☐

No interference with activity ☐

Some interference with activity ☒

Significant; prevents daily
activity ☐

PC Time stamp

09 FEB 2021 16:43

PC Open Date & Time

09 FEB 2021 12:00

PC Close Date & Time

10 FEB 2021 11:59

US3342200

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(134)

Generated On: 09 Jun 2021 17:05:26

TIMEPOINT

DAY 134

Select one response below to indicate the intensity of your **JOINT**
ACHES IN SEVERAL JOINTS

None ☐

No interference with activity ☐

Some interference with activity ☒

Significant; prevents daily
activity ☐

PC Time stamp

11 FEB 2021 03:47

PC Open Date & Time

10 FEB 2021 12:00

PC Close Date & Time

11 FEB 2021 11:59

US3342200

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(135)

Generated On: 09 Jun 2021 17:05:26

TIMEPOINT

DAY 135

Select one response below to indicate the intensity of your **JOINT**
ACHES IN SEVERAL JOINTS

None ☐

No interference with activity ☐

Some interference with activity ☒

Significant; prevents daily
activity ☐

PC Time stamp

11 FEB 2021 12:37

PC Open Date & Time

11 FEB 2021 12:00

PC Close Date & Time

12 FEB 2021 11:59

US3342200

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(136)

Generated On: 09 Jun 2021 17:05:26

TIMEPOINT

DAY 136

Select one response below to indicate the intensity of your **JOINT**
ACHES IN SEVERAL JOINTS

None ☐

No interference with activity ☐

Some interference with activity ☒

Significant; prevents daily
activity ☐

PC Time stamp

12 FEB 2021 12:56

PC Open Date & Time

12 FEB 2021 12:00

PC Close Date & Time

13 FEB 2021 11:59

US3342200

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(137)

Generated On: 09 Jun 2021 17:05:26

TIMEPOINT

DAY 137

Select one response below to indicate the intensity of your **JOINT**
ACHES IN SEVERAL JOINTS

None ☐

No interference with activity ☐

Some interference with activity ☒

Significant; prevents daily
activity ☐

PC Time stamp

13 FEB 2021 12:28

PC Open Date & Time

13 FEB 2021 12:00

PC Close Date & Time

14 FEB 2021 11:59

US3342200

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(138)

Generated On: 09 Jun 2021 17:05:26

TIMEPOINT

DAY 138

Select one response below to indicate the intensity of your **JOINT**
ACHES IN SEVERAL JOINTS

None ☐

No interference with activity ☐

Some interference with activity ☒

Significant; prevents daily
activity ☐

PC Time stamp

14 FEB 2021 13:08

PC Open Date & Time

14 FEB 2021 12:00

PC Close Date & Time

15 FEB 2021 11:59

US3342200

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(139)

Generated On: 09 Jun 2021 17:05:26

TIMEPOINT

DAY 139

Select one response below to indicate the intensity of your **JOINT**
ACHES IN SEVERAL JOINTS

None ☐

No interference with activity ☐

Some interference with activity ☒

Significant; prevents daily
activity ☐

PC Time stamp

15 FEB 2021 12:00

PC Open Date & Time

15 FEB 2021 12:00

PC Close Date & Time

16 FEB 2021 11:59

US3342200

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(140)

Generated On: 09 Jun 2021 17:05:26

TIMEPOINT

DAY 140

Select one response below to indicate the intensity of your **JOINT**
ACHES IN SEVERAL JOINTS

None ☐

No interference with activity ☐

Some interference with activity ☒

Significant; prevents daily
activity ☐

PC Time stamp

16 FEB 2021 18:19

PC Open Date & Time

16 FEB 2021 12:00

PC Close Date & Time

17 FEB 2021 11:59

US3342200

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(141)

Generated On: 09 Jun 2021 17:05:26

TIMEPOINT

DAY 141

Select one response below to indicate the intensity of your **JOINT**
ACHES IN SEVERAL JOINTS

None ☐

No interference with activity ☐

Some interference with activity ☒

Significant; prevents daily
activity ☐

PC Time stamp

17 FEB 2021 12:34

PC Open Date & Time

17 FEB 2021 12:00

PC Close Date & Time

18 FEB 2021 11:59

US3342200

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(142)

Generated On: 09 Jun 2021 17:05:26

TIMEPOINT

DAY 142

Select one response below to indicate the intensity of your **JOINT**
ACHES IN SEVERAL JOINTS

None ☐

No interference with activity ☐

Some interference with activity ☒

Significant; prevents daily
activity ☐

PC Time stamp

18 FEB 2021 12:43

PC Open Date & Time

18 FEB 2021 12:00

PC Close Date & Time

19 FEB 2021 11:59

US3342200

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(143)

Generated On: 09 Jun 2021 17:05:26

TIMEPOINT

DAY 143

Select one response below to indicate the intensity of your **JOINT**
ACHES IN SEVERAL JOINTS

None ☐

No interference with activity ☐

Some interference with activity ☒

Significant; prevents daily
activity ☐

PC Time stamp

19 FEB 2021 16:11

PC Open Date & Time

19 FEB 2021 12:00

PC Close Date & Time

20 FEB 2021 11:59

US3342200

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(144)

Generated On: 09 Jun 2021 17:05:26

TIMEPOINT

DAY 144

Select one response below to indicate the intensity of your **JOINT**
ACHES IN SEVERAL JOINTS

None ☐

No interference with activity ☐

Some interference with activity ☒

Significant; prevents daily
activity ☐

PC Time stamp

20 FEB 2021 18:18

PC Open Date & Time

20 FEB 2021 12:00

PC Close Date & Time

21 FEB 2021 11:59

US3342200

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(145)

Generated On: 09 Jun 2021 17:05:26

TIMEPOINT

DAY 145

Select one response below to indicate the intensity of your **JOINT**
ACHES IN SEVERAL JOINTS

None ☐

No interference with activity ☐

Some interference with activity ☒

Significant; prevents daily
activity ☐

PC Time stamp

21 FEB 2021 12:00

PC Open Date & Time

21 FEB 2021 12:00

PC Close Date & Time

22 FEB 2021 11:59

US3342200

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(146)

Generated On: 09 Jun 2021 17:05:26

TIMEPOINT

DAY 146

Select one response below to indicate the intensity of your **JOINT**
ACHES IN SEVERAL JOINTS

None ☐

No interference with activity ☐

Some interference with activity ☒

Significant; prevents daily
activity ☐

PC Time stamp

22 FEB 2021 12:02

PC Open Date & Time

22 FEB 2021 12:00

PC Close Date & Time

23 FEB 2021 11:59

US3342200

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(147)

Generated On: 09 Jun 2021 17:05:26

TIMEPOINT

DAY 147

Select one response below to indicate the intensity of your **JOINT**
ACHES IN SEVERAL JOINTS

None ☐

No interference with activity ☐

Some interference with activity ☒

Significant; prevents daily
activity ☐

PC Time stamp

23 FEB 2021 18:58

PC Open Date & Time

23 FEB 2021 12:00

PC Close Date & Time

24 FEB 2021 11:59

US3342200

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(148)

Generated On: 09 Jun 2021 17:05:26

TIMEPOINT

DAY 148

Select one response below to indicate the intensity of your **JOINT**
ACHES IN SEVERAL JOINTS

None ☐

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☒

PC Time stamp

24 FEB 2021 18:01

PC Open Date & Time

24 FEB 2021 12:00

PC Close Date & Time

25 FEB 2021 11:59

US3342200

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(149)

Generated On: 09 Jun 2021 17:05:26

TIMEPOINT

DAY 149

Select one response below to indicate the intensity of your **JOINT**
ACHES IN SEVERAL JOINTS

None ☐

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

PC Time stamp

PC Open Date & Time

25 FEB 2021 12:00

PC Close Date & Time

26 FEB 2021 11:59

US3342200

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(150)

Generated On: 09 Jun 2021 17:05:26

TIMEPOINT

DAY 150

Select one response below to indicate the intensity of your **JOINT**
ACHES IN SEVERAL JOINTS

None ☐

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

PC Time stamp

PC Open Date & Time

26 FEB 2021 12:00

PC Close Date & Time

27 FEB 2021 11:59

US3342200

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(8)

Generated On: 09 Jun 2021 17:05:26

TIMEPOINT	DAY 8
Did you receive any MEDICAL ATTENTION (doctor visit, other) for any illness or symptoms?	No <input checked="" type="radio"/> Yes <input type="radio"/>
PC Time stamp	07 OCT 2020 16:49
PC Open Date & Time	07 OCT 2020 12:00
PC Close Date & Time	08 OCT 2020 11:59

US3342200

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(9)

Generated On: 09 Jun 2021 17:05:26

TIMEPOINT	DAY 9
Did you receive any MEDICAL ATTENTION (doctor visit, other) for any illness or symptoms?	No <input checked="" type="radio"/> Yes <input type="radio"/>
PC Time stamp	08 OCT 2020 12:00
PC Open Date & Time	08 OCT 2020 12:00
PC Close Date & Time	09 OCT 2020 11:59

US3342200

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(10)

Generated On: 09 Jun 2021 17:05:26

TIMEPOINT	DAY 10
Did you receive any MEDICAL ATTENTION (doctor visit, other) for any illness or symptoms?	No <input checked="" type="radio"/> Yes <input type="radio"/>
PC Time stamp	09 OCT 2020 12:15
PC Open Date & Time	09 OCT 2020 12:00
PC Close Date & Time	10 OCT 2020 11:59

US3342200

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(11)

Generated On: 09 Jun 2021 17:05:26

TIMEPOINT	DAY 11
Did you receive any MEDICAL ATTENTION (doctor visit, other) for any illness or symptoms?	No <input checked="" type="radio"/> Yes <input type="radio"/>
PC Time stamp	10 OCT 2020 12:04
PC Open Date & Time	10 OCT 2020 12:00
PC Close Date & Time	11 OCT 2020 11:59

US3342200

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(12)

Generated On: 09 Jun 2021 17:05:26

TIMEPOINT	DAY 12
Did you receive any MEDICAL ATTENTION (doctor visit, other) for any illness or symptoms?	No <input checked="" type="radio"/> Yes <input type="radio"/>
PC Time stamp	11 OCT 2020 17:27
PC Open Date & Time	11 OCT 2020 12:00
PC Close Date & Time	12 OCT 2020 11:59

US3342200

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(13)

Generated On: 09 Jun 2021 17:05:26

TIMEPOINT	DAY 13
Did you receive any MEDICAL ATTENTION (doctor visit, other) for any illness or symptoms?	No <input type="checkbox"/> Yes <input checked="" type="checkbox"/>
PC Time stamp	12 OCT 2020 16:02
PC Open Date & Time	12 OCT 2020 12:00
PC Close Date & Time	13 OCT 2020 11:59

US3342200

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(14)

Generated On: 09 Jun 2021 17:05:26

TIMEPOINT	DAY 14
Did you receive any MEDICAL ATTENTION (doctor visit, other) for any illness or symptoms?	No <input checked="" type="radio"/> Yes <input type="radio"/>
PC Time stamp	14 OCT 2020 06:26
PC Open Date & Time	13 OCT 2020 12:00
PC Close Date & Time	14 OCT 2020 11:59

US3342200

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(15)

Generated On: 09 Jun 2021 17:05:26

TIMEPOINT	DAY 15
Did you receive any MEDICAL ATTENTION (doctor visit, other) for any illness or symptoms?	No <input checked="" type="radio"/> Yes <input type="radio"/>
PC Time stamp	14 OCT 2020 13:41
PC Open Date & Time	14 OCT 2020 12:00
PC Close Date & Time	15 OCT 2020 11:59

US3342200

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(16)

Generated On: 09 Jun 2021 17:05:26

TIMEPOINT	DAY 16
Did you receive any MEDICAL ATTENTION (doctor visit, other) for any illness or symptoms?	No <input checked="" type="radio"/> Yes <input type="radio"/>
PC Time stamp	16 OCT 2020 02:17
PC Open Date & Time	15 OCT 2020 12:00
PC Close Date & Time	16 OCT 2020 11:59

US3342200

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(17)

Generated On: 09 Jun 2021 17:05:26

TIMEPOINT	DAY 17
Did you receive any MEDICAL ATTENTION (doctor visit, other) for any illness or symptoms?	No <input checked="" type="radio"/> Yes <input type="radio"/>
PC Time stamp	16 OCT 2020 12:08
PC Open Date & Time	16 OCT 2020 12:00
PC Close Date & Time	17 OCT 2020 11:59

US3342200

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(18)

Generated On: 09 Jun 2021 17:05:26

TIMEPOINT	DAY 18
Did you receive any MEDICAL ATTENTION (doctor visit, other) for any illness or symptoms?	No <input checked="" type="radio"/> Yes <input type="radio"/>
PC Time stamp	17 OCT 2020 15:00
PC Open Date & Time	17 OCT 2020 12:00
PC Close Date & Time	18 OCT 2020 11:59

US3342200

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(19)

Generated On: 09 Jun 2021 17:05:26

TIMEPOINT	DAY 19
Did you receive any MEDICAL ATTENTION (doctor visit, other) for any illness or symptoms?	No <input checked="" type="radio"/> Yes <input type="radio"/>
PC Time stamp	18 OCT 2020 12:10
PC Open Date & Time	18 OCT 2020 12:00
PC Close Date & Time	19 OCT 2020 11:59

US3342200

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(20)

Generated On: 09 Jun 2021 17:05:26

TIMEPOINT	DAY 20
Did you receive any MEDICAL ATTENTION (doctor visit, other) for any illness or symptoms?	No <input checked="" type="radio"/> Yes <input type="radio"/>
PC Time stamp	19 OCT 2020 16:38
PC Open Date & Time	19 OCT 2020 12:00
PC Close Date & Time	20 OCT 2020 11:59

US3342200

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(21)

Generated On: 09 Jun 2021 17:05:26

TIMEPOINT	DAY 21
Did you receive any MEDICAL ATTENTION (doctor visit, other) for any illness or symptoms?	No <input checked="" type="radio"/> Yes <input type="radio"/>
PC Time stamp	20 OCT 2020 12:39
PC Open Date & Time	20 OCT 2020 12:00
PC Close Date & Time	21 OCT 2020 11:59

US3342200

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(22)

Generated On: 09 Jun 2021 17:05:26

TIMEPOINT	DAY 22
Did you receive any MEDICAL ATTENTION (doctor visit, other) for any illness or symptoms?	No <input checked="" type="radio"/> Yes <input type="radio"/>
PC Time stamp	21 OCT 2020 12:04
PC Open Date & Time	21 OCT 2020 12:00
PC Close Date & Time	22 OCT 2020 11:59

US3342200

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(23)

Generated On: 09 Jun 2021 17:05:26

TIMEPOINT	DAY 23
Did you receive any MEDICAL ATTENTION (doctor visit, other) for any illness or symptoms?	No <input checked="" type="radio"/> Yes <input type="radio"/>
PC Time stamp	22 OCT 2020 12:08
PC Open Date & Time	22 OCT 2020 12:00
PC Close Date & Time	23 OCT 2020 11:59

US3342200

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(24)

Generated On: 09 Jun 2021 17:05:26

TIMEPOINT	DAY 24
Did you receive any MEDICAL ATTENTION (doctor visit, other) for any illness or symptoms?	No <input checked="" type="radio"/> Yes <input type="radio"/>
PC Time stamp	23 OCT 2020 12:00
PC Open Date & Time	23 OCT 2020 12:00
PC Close Date & Time	24 OCT 2020 11:59

US3342200

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(25)

Generated On: 09 Jun 2021 17:05:26

TIMEPOINT	DAY 25
Did you receive any MEDICAL ATTENTION (doctor visit, other) for any illness or symptoms?	No <input checked="" type="radio"/> Yes <input type="radio"/>
PC Time stamp	24 OCT 2020 18:10
PC Open Date & Time	24 OCT 2020 12:00
PC Close Date & Time	25 OCT 2020 11:59

US3342200

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(26)

Generated On: 09 Jun 2021 17:05:26

TIMEPOINT	DAY 26
Did you receive any MEDICAL ATTENTION (doctor visit, other) for any illness or symptoms?	No <input checked="" type="radio"/> Yes <input type="radio"/>
PC Time stamp	25 OCT 2020 13:15
PC Open Date & Time	25 OCT 2020 12:00
PC Close Date & Time	26 OCT 2020 11:59

US3342200

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(27)

Generated On: 09 Jun 2021 17:05:26

TIMEPOINT	DAY 27
Did you receive any MEDICAL ATTENTION (doctor visit, other) for any illness or symptoms?	No <input checked="" type="radio"/> Yes <input type="radio"/>
PC Time stamp	26 OCT 2020 12:00
PC Open Date & Time	26 OCT 2020 12:00
PC Close Date & Time	27 OCT 2020 11:59

US3342200

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(28)

Generated On: 09 Jun 2021 17:05:26

TIMEPOINT	DAY 28
Did you receive any MEDICAL ATTENTION (doctor visit, other) for any illness or symptoms?	No <input checked="" type="radio"/> Yes <input type="radio"/>
PC Time stamp	27 OCT 2020 12:15
PC Open Date & Time	27 OCT 2020 12:00
PC Close Date & Time	28 OCT 2020 11:59

US3342200

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(29)

Generated On: 09 Jun 2021 17:05:26

TIMEPOINT	DAY 29
Did you receive any MEDICAL ATTENTION (doctor visit, other) for any illness or symptoms?	No <input checked="" type="radio"/> Yes <input type="radio"/>
PC Time stamp	28 OCT 2020 13:15
PC Open Date & Time	28 OCT 2020 12:00
PC Close Date & Time	29 OCT 2020 11:59

US3342200

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(30)

Generated On: 09 Jun 2021 17:05:26

TIMEPOINT	DAY 30
Did you receive any MEDICAL ATTENTION (doctor visit, other) for any illness or symptoms?	No <input checked="" type="radio"/> Yes <input type="radio"/>
PC Time stamp	29 OCT 2020 13:11
PC Open Date & Time	29 OCT 2020 12:00
PC Close Date & Time	30 OCT 2020 11:59

US3342200

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(31)

Generated On: 09 Jun 2021 17:05:26

TIMEPOINT	DAY 31
Did you receive any MEDICAL ATTENTION (doctor visit, other) for any illness or symptoms?	No <input checked="" type="radio"/> Yes <input type="radio"/>
PC Time stamp	30 OCT 2020 12:00
PC Open Date & Time	30 OCT 2020 12:00
PC Close Date & Time	31 OCT 2020 11:59

US3342200

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(32)

Generated On: 09 Jun 2021 17:05:26

TIMEPOINT	DAY 32
Did you receive any MEDICAL ATTENTION (doctor visit, other) for any illness or symptoms?	No <input checked="" type="radio"/> Yes <input type="radio"/>
PC Time stamp	31 OCT 2020 16:57
PC Open Date & Time	31 OCT 2020 12:00
PC Close Date & Time	01 NOV 2020 11:59

US3342200

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(33)

Generated On: 09 Jun 2021 17:05:26

TIMEPOINT	DAY 33
Did you receive any MEDICAL ATTENTION (doctor visit, other) for any illness or symptoms?	No <input checked="" type="radio"/> Yes <input type="radio"/>
PC Time stamp	01 NOV 2020 14:20
PC Open Date & Time	01 NOV 2020 12:00
PC Close Date & Time	02 NOV 2020 11:59

US3342200

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(34)

Generated On: 09 Jun 2021 17:05:26

TIMEPOINT	DAY 34
Did you receive any MEDICAL ATTENTION (doctor visit, other) for any illness or symptoms?	No <input checked="" type="radio"/> Yes <input type="radio"/>
PC Time stamp	02 NOV 2020 17:32
PC Open Date & Time	02 NOV 2020 12:00
PC Close Date & Time	03 NOV 2020 11:59

US3342200

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(35)

Generated On: 09 Jun 2021 17:05:26

TIMEPOINT

DAY 35

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

No ☐

Yes ☒

PC Time stamp

03 NOV 2020 18:02

PC Open Date & Time

03 NOV 2020 12:00

PC Close Date & Time

04 NOV 2020 11:59

US3342200

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(36)

Generated On: 09 Jun 2021 17:05:26

TIMEPOINT	DAY 36
Did you receive any MEDICAL ATTENTION (doctor visit, other) for any illness or symptoms?	No <input type="radio"/> Yes <input checked="" type="radio"/>
PC Time stamp	05 NOV 2020 06:41
PC Open Date & Time	04 NOV 2020 12:00
PC Close Date & Time	05 NOV 2020 11:59

US3342200

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(37)

Generated On: 09 Jun 2021 17:05:26

TIMEPOINT	DAY 37
Did you receive any MEDICAL ATTENTION (doctor visit, other) for any illness or symptoms?	No <input checked="" type="radio"/> Yes <input type="radio"/>
PC Time stamp	05 NOV 2020 12:13
PC Open Date & Time	05 NOV 2020 12:00
PC Close Date & Time	06 NOV 2020 11:59

US3342200

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(38)

Generated On: 09 Jun 2021 17:05:26

TIMEPOINT

DAY 38

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

No ☐

Yes ☒

PC Time stamp

07 NOV 2020 04:42

PC Open Date & Time

06 NOV 2020 12:00

PC Close Date & Time

07 NOV 2020 11:59

US3342200

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(39)

Generated On: 09 Jun 2021 17:05:26

TIMEPOINT	DAY 39
Did you receive any MEDICAL ATTENTION (doctor visit, other) for any illness or symptoms?	No <input checked="" type="radio"/> Yes <input type="radio"/>
PC Time stamp	07 NOV 2020 12:30
PC Open Date & Time	07 NOV 2020 12:00
PC Close Date & Time	08 NOV 2020 11:59

US3342200

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(40)

Generated On: 09 Jun 2021 17:05:26

TIMEPOINT	DAY 40
Did you receive any MEDICAL ATTENTION (doctor visit, other) for any illness or symptoms?	No <input checked="" type="radio"/> Yes <input type="radio"/>
PC Time stamp	08 NOV 2020 12:01
PC Open Date & Time	08 NOV 2020 12:00
PC Close Date & Time	09 NOV 2020 11:59

US3342200

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(41)

Generated On: 09 Jun 2021 17:05:26

TIMEPOINT	DAY 41
Did you receive any MEDICAL ATTENTION (doctor visit, other) for any illness or symptoms?	No <input type="checkbox"/> Yes <input checked="" type="checkbox"/>
PC Time stamp	09 NOV 2020 21:21
PC Open Date & Time	09 NOV 2020 12:00
PC Close Date & Time	10 NOV 2020 11:59

US3342200

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(42)

Generated On: 09 Jun 2021 17:05:26

TIMEPOINT	DAY 42
Did you receive any MEDICAL ATTENTION (doctor visit, other) for any illness or symptoms?	No <input checked="" type="radio"/> Yes <input type="radio"/>
PC Time stamp	11 NOV 2020 04:16
PC Open Date & Time	10 NOV 2020 12:00
PC Close Date & Time	11 NOV 2020 11:59

US3342200

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(43)

Generated On: 09 Jun 2021 17:05:26

TIMEPOINT	DAY 43
Did you receive any MEDICAL ATTENTION (doctor visit, other) for any illness or symptoms?	No <input checked="" type="radio"/> Yes <input type="radio"/>
PC Time stamp	11 NOV 2020 17:05
PC Open Date & Time	11 NOV 2020 12:00
PC Close Date & Time	12 NOV 2020 11:59

US3342200

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(44)

Generated On: 09 Jun 2021 17:05:26

TIMEPOINT	DAY 44
Did you receive any MEDICAL ATTENTION (doctor visit, other) for any illness or symptoms?	No <input checked="" type="radio"/> Yes <input type="radio"/>
PC Time stamp	12 NOV 2020 14:39
PC Open Date & Time	12 NOV 2020 12:00
PC Close Date & Time	13 NOV 2020 11:59

US3342200

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(45)

Generated On: 09 Jun 2021 17:05:26

TIMEPOINT	DAY 45
Did you receive any MEDICAL ATTENTION (doctor visit, other) for any illness or symptoms?	No <input checked="" type="radio"/> Yes <input type="radio"/>
PC Time stamp	13 NOV 2020 18:17
PC Open Date & Time	13 NOV 2020 12:00
PC Close Date & Time	14 NOV 2020 11:59

US3342200

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(46)

Generated On: 09 Jun 2021 17:05:26

TIMEPOINT	DAY 46
Did you receive any MEDICAL ATTENTION (doctor visit, other) for any illness or symptoms?	No <input checked="" type="radio"/> Yes <input type="radio"/>
PC Time stamp	15 NOV 2020 04:11
PC Open Date & Time	14 NOV 2020 12:00
PC Close Date & Time	15 NOV 2020 11:59

US3342200

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(47)

Generated On: 09 Jun 2021 17:05:26

TIMEPOINT	DAY 47
Did you receive any MEDICAL ATTENTION (doctor visit, other) for any illness or symptoms?	No <input checked="" type="radio"/> Yes <input type="radio"/>
PC Time stamp	15 NOV 2020 15:24
PC Open Date & Time	15 NOV 2020 12:00
PC Close Date & Time	16 NOV 2020 11:59

US3342200

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(48)

Generated On: 09 Jun 2021 17:05:26

TIMEPOINT	DAY 48
Did you receive any MEDICAL ATTENTION (doctor visit, other) for any illness or symptoms?	No <input checked="" type="radio"/> Yes <input type="radio"/>
PC Time stamp	16 NOV 2020 13:51
PC Open Date & Time	16 NOV 2020 12:00
PC Close Date & Time	17 NOV 2020 11:59

US3342200

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(49)

Generated On: 09 Jun 2021 17:05:26

TIMEPOINT	DAY 49
Did you receive any MEDICAL ATTENTION (doctor visit, other) for any illness or symptoms?	No <input checked="" type="radio"/> Yes <input type="radio"/>
PC Time stamp	18 NOV 2020 00:04
PC Open Date & Time	17 NOV 2020 12:00
PC Close Date & Time	18 NOV 2020 11:59

US3342200

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(50)

Generated On: 09 Jun 2021 17:05:26

TIMEPOINT	DAY 50
Did you receive any MEDICAL ATTENTION (doctor visit, other) for any illness or symptoms?	No <input type="checkbox"/> Yes <input checked="" type="checkbox"/>
PC Time stamp	18 NOV 2020 12:33
PC Open Date & Time	18 NOV 2020 12:00
PC Close Date & Time	19 NOV 2020 11:59

US3342200

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(51)

Generated On: 09 Jun 2021 17:05:26

TIMEPOINT	DAY 51
Did you receive any MEDICAL ATTENTION (doctor visit, other) for any illness or symptoms?	No <input checked="" type="radio"/> Yes <input type="radio"/>
PC Time stamp	20 NOV 2020 05:59
PC Open Date & Time	19 NOV 2020 12:00
PC Close Date & Time	20 NOV 2020 11:59

US3342200

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(52)

Generated On: 09 Jun 2021 17:05:26

TIMEPOINT	DAY 52
Did you receive any MEDICAL ATTENTION (doctor visit, other) for any illness or symptoms?	No <input checked="" type="radio"/> Yes <input type="radio"/>
PC Time stamp	21 NOV 2020 04:06
PC Open Date & Time	20 NOV 2020 12:00
PC Close Date & Time	21 NOV 2020 11:59

US3342200

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(53)

Generated On: 09 Jun 2021 17:05:26

TIMEPOINT	DAY 53
Did you receive any MEDICAL ATTENTION (doctor visit, other) for any illness or symptoms?	No <input checked="" type="radio"/> Yes <input type="radio"/>
PC Time stamp	22 NOV 2020 00:46
PC Open Date & Time	21 NOV 2020 12:00
PC Close Date & Time	22 NOV 2020 11:59

US3342200

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(54)

Generated On: 09 Jun 2021 17:05:26

TIMEPOINT	DAY 54
Did you receive any MEDICAL ATTENTION (doctor visit, other) for any illness or symptoms?	No <input checked="" type="radio"/> Yes <input type="radio"/>
PC Time stamp	22 NOV 2020 17:30
PC Open Date & Time	22 NOV 2020 12:00
PC Close Date & Time	23 NOV 2020 11:59

US3342200

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(55)

Generated On: 09 Jun 2021 17:05:26

TIMEPOINT	DAY 55
Did you receive any MEDICAL ATTENTION (doctor visit, other) for any illness or symptoms?	No <input type="checkbox"/> Yes <input checked="" type="checkbox"/>
PC Time stamp	23 NOV 2020 12:02
PC Open Date & Time	23 NOV 2020 12:00
PC Close Date & Time	24 NOV 2020 11:59

US3342200

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(56)

Generated On: 09 Jun 2021 17:05:26

TIMEPOINT	DAY 56
Did you receive any MEDICAL ATTENTION (doctor visit, other) for any illness or symptoms?	No <input checked="" type="radio"/> Yes <input type="radio"/>
PC Time stamp	24 NOV 2020 13:10
PC Open Date & Time	24 NOV 2020 12:00
PC Close Date & Time	25 NOV 2020 11:59

US3342200

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(57)

Generated On: 09 Jun 2021 17:05:26

TIMEPOINT	DAY 57
Did you receive any MEDICAL ATTENTION (doctor visit, other) for any illness or symptoms?	No <input type="radio"/> Yes <input checked="" type="radio"/>
PC Time stamp	25 NOV 2020 16:13
PC Open Date & Time	25 NOV 2020 12:00
PC Close Date & Time	26 NOV 2020 11:59

US3342200

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(58)

Generated On: 09 Jun 2021 17:05:26

TIMEPOINT	DAY 58
Did you receive any MEDICAL ATTENTION (doctor visit, other) for any illness or symptoms?	No <input checked="" type="radio"/> Yes <input type="radio"/>
PC Time stamp	26 NOV 2020 12:17
PC Open Date & Time	26 NOV 2020 12:00
PC Close Date & Time	27 NOV 2020 11:59

US3342200

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(59)

Generated On: 09 Jun 2021 17:05:26

TIMEPOINT	DAY 59
Did you receive any MEDICAL ATTENTION (doctor visit, other) for any illness or symptoms?	No <input checked="" type="radio"/> Yes <input type="radio"/>
PC Time stamp	27 NOV 2020 12:04
PC Open Date & Time	27 NOV 2020 12:00
PC Close Date & Time	28 NOV 2020 11:59

US3342200

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(60)

Generated On: 09 Jun 2021 17:05:26

TIMEPOINT	DAY 60
Did you receive any MEDICAL ATTENTION (doctor visit, other) for any illness or symptoms?	No <input checked="" type="radio"/> Yes <input type="radio"/>
PC Time stamp	28 NOV 2020 13:17
PC Open Date & Time	28 NOV 2020 12:00
PC Close Date & Time	29 NOV 2020 11:59

US3342200

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(61)

Generated On: 09 Jun 2021 17:05:26

TIMEPOINT	DAY 61
Did you receive any MEDICAL ATTENTION (doctor visit, other) for any illness or symptoms?	No <input checked="" type="radio"/> Yes <input type="radio"/>
PC Time stamp	29 NOV 2020 12:13
PC Open Date & Time	29 NOV 2020 12:00
PC Close Date & Time	30 NOV 2020 11:59

US3342200

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(62)

Generated On: 09 Jun 2021 17:05:26

TIMEPOINT	DAY 62
Did you receive any MEDICAL ATTENTION (doctor visit, other) for any illness or symptoms?	No <input type="checkbox"/> Yes <input checked="" type="checkbox"/>
PC Time stamp	30 NOV 2020 13:17
PC Open Date & Time	30 NOV 2020 12:00
PC Close Date & Time	01 DEC 2020 11:59

US3342200

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(63)

Generated On: 09 Jun 2021 17:05:26

TIMEPOINT	DAY 63
Did you receive any MEDICAL ATTENTION (doctor visit, other) for any illness or symptoms?	No <input checked="" type="radio"/> Yes <input type="radio"/>
PC Time stamp	02 DEC 2020 04:51
PC Open Date & Time	01 DEC 2020 12:00
PC Close Date & Time	02 DEC 2020 11:59

US3342200

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(64)

Generated On: 09 Jun 2021 17:05:26

TIMEPOINT	DAY 64
Did you receive any MEDICAL ATTENTION (doctor visit, other) for any illness or symptoms?	No <input type="radio"/> Yes <input checked="" type="radio"/>
PC Time stamp	02 DEC 2020 12:01
PC Open Date & Time	02 DEC 2020 12:00
PC Close Date & Time	03 DEC 2020 11:59

US3342200

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(65)

Generated On: 09 Jun 2021 17:05:26

TIMEPOINT	DAY 65
Did you receive any MEDICAL ATTENTION (doctor visit, other) for any illness or symptoms?	No <input type="checkbox"/> Yes <input checked="" type="checkbox"/>
PC Time stamp	03 DEC 2020 13:03
PC Open Date & Time	03 DEC 2020 12:00
PC Close Date & Time	04 DEC 2020 11:59

US3342200

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(66)

Generated On: 09 Jun 2021 17:05:26

TIMEPOINT	DAY 66
Did you receive any MEDICAL ATTENTION (doctor visit, other) for any illness or symptoms?	No <input checked="" type="radio"/> Yes <input type="radio"/>
PC Time stamp	04 DEC 2020 12:00
PC Open Date & Time	04 DEC 2020 12:00
PC Close Date & Time	05 DEC 2020 11:59

US3342200

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(67)

Generated On: 09 Jun 2021 17:05:26

TIMEPOINT	DAY 67
Did you receive any MEDICAL ATTENTION (doctor visit, other) for any illness or symptoms?	No <input checked="" type="radio"/> Yes <input type="radio"/>
PC Time stamp	05 DEC 2020 19:56
PC Open Date & Time	05 DEC 2020 12:00
PC Close Date & Time	06 DEC 2020 11:59

US3342200

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(68)

Generated On: 09 Jun 2021 17:05:26

TIMEPOINT	DAY 68
Did you receive any MEDICAL ATTENTION (doctor visit, other) for any illness or symptoms?	No <input checked="" type="radio"/> Yes <input type="radio"/>
PC Time stamp	06 DEC 2020 12:50
PC Open Date & Time	06 DEC 2020 12:00
PC Close Date & Time	07 DEC 2020 11:59

US3342200

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(69)

Generated On: 09 Jun 2021 17:05:26

TIMEPOINT	DAY 69
Did you receive any MEDICAL ATTENTION (doctor visit, other) for any illness or symptoms?	No <input type="checkbox"/> Yes <input checked="" type="checkbox"/>
PC Time stamp	07 DEC 2020 12:07
PC Open Date & Time	07 DEC 2020 12:00
PC Close Date & Time	08 DEC 2020 11:59

US3342200

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(70)

Generated On: 09 Jun 2021 17:05:26

TIMEPOINT	DAY 70
Did you receive any MEDICAL ATTENTION (doctor visit, other) for any illness or symptoms?	No <input checked="" type="radio"/> Yes <input type="radio"/>
PC Time stamp	08 DEC 2020 13:05
PC Open Date & Time	08 DEC 2020 12:00
PC Close Date & Time	09 DEC 2020 11:59

US3342200

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(71)

Generated On: 09 Jun 2021 17:05:26

TIMEPOINT	DAY 71
Did you receive any MEDICAL ATTENTION (doctor visit, other) for any illness or symptoms?	No <input checked="" type="radio"/> Yes <input type="radio"/>
PC Time stamp	09 DEC 2020 13:54
PC Open Date & Time	09 DEC 2020 12:00
PC Close Date & Time	10 DEC 2020 11:59

US3342200

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(72)

Generated On: 09 Jun 2021 17:05:26

TIMEPOINT	DAY 72
Did you receive any MEDICAL ATTENTION (doctor visit, other) for any illness or symptoms?	No <input checked="" type="radio"/> Yes <input type="radio"/>
PC Time stamp	10 DEC 2020 12:39
PC Open Date & Time	10 DEC 2020 12:00
PC Close Date & Time	11 DEC 2020 11:59

US3342200

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(73)

Generated On: 09 Jun 2021 17:05:26

TIMEPOINT	DAY 73
Did you receive any MEDICAL ATTENTION (doctor visit, other) for any illness or symptoms?	No <input checked="" type="radio"/> Yes <input type="radio"/>
PC Time stamp	11 DEC 2020 12:19
PC Open Date & Time	11 DEC 2020 12:00
PC Close Date & Time	12 DEC 2020 11:59

US3342200

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(74)

Generated On: 09 Jun 2021 17:05:26

TIMEPOINT	DAY 74
Did you receive any MEDICAL ATTENTION (doctor visit, other) for any illness or symptoms?	No <input checked="" type="radio"/> Yes <input type="radio"/>
PC Time stamp	13 DEC 2020 00:06
PC Open Date & Time	12 DEC 2020 12:00
PC Close Date & Time	13 DEC 2020 11:59

US3342200

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(75)

Generated On: 09 Jun 2021 17:05:26

TIMEPOINT	DAY 75
Did you receive any MEDICAL ATTENTION (doctor visit, other) for any illness or symptoms?	No <input checked="" type="radio"/> Yes <input type="radio"/>
PC Time stamp	14 DEC 2020 03:28
PC Open Date & Time	13 DEC 2020 12:00
PC Close Date & Time	14 DEC 2020 11:59

US3342200

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(76)

Generated On: 09 Jun 2021 17:05:26

TIMEPOINT	DAY 76
Did you receive any MEDICAL ATTENTION (doctor visit, other) for any illness or symptoms?	No <input checked="" type="radio"/> Yes <input type="radio"/>
PC Time stamp	14 DEC 2020 13:30
PC Open Date & Time	14 DEC 2020 12:00
PC Close Date & Time	15 DEC 2020 11:59

US3342200

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(77)

Generated On: 09 Jun 2021 17:05:26

TIMEPOINT	DAY 77
Did you receive any MEDICAL ATTENTION (doctor visit, other) for any illness or symptoms?	No <input checked="" type="radio"/> Yes <input type="radio"/>
PC Time stamp	15 DEC 2020 15:07
PC Open Date & Time	15 DEC 2020 12:00
PC Close Date & Time	16 DEC 2020 11:59

US3342200

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(78)

Generated On: 09 Jun 2021 17:05:26

TIMEPOINT	DAY 78
Did you receive any MEDICAL ATTENTION (doctor visit, other) for any illness or symptoms?	No <input checked="" type="radio"/> Yes <input type="radio"/>
PC Time stamp	16 DEC 2020 16:05
PC Open Date & Time	16 DEC 2020 12:00
PC Close Date & Time	17 DEC 2020 11:59

US3342200

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(79)

Generated On: 09 Jun 2021 17:05:26

TIMEPOINT	DAY 79
Did you receive any MEDICAL ATTENTION (doctor visit, other) for any illness or symptoms?	No <input checked="" type="radio"/> Yes <input type="radio"/>
PC Time stamp	17 DEC 2020 12:39
PC Open Date & Time	17 DEC 2020 12:00
PC Close Date & Time	18 DEC 2020 11:59

US3342200

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(80)

Generated On: 09 Jun 2021 17:05:26

TIMEPOINT	DAY 80
Did you receive any MEDICAL ATTENTION (doctor visit, other) for any illness or symptoms?	No <input checked="" type="radio"/> Yes <input type="radio"/>
PC Time stamp	18 DEC 2020 12:21
PC Open Date & Time	18 DEC 2020 12:00
PC Close Date & Time	19 DEC 2020 11:59

US3342200

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(81)

Generated On: 09 Jun 2021 17:05:26

TIMEPOINT

DAY 81

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

No ☒

Yes ☐

PC Time stamp

19 DEC 2020 15:04

PC Open Date & Time

19 DEC 2020 12:00

PC Close Date & Time

20 DEC 2020 11:59

US3342200

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(82)

Generated On: 09 Jun 2021 17:05:26

TIMEPOINT	DAY 82
Did you receive any MEDICAL ATTENTION (doctor visit, other) for any illness or symptoms?	No <input checked="" type="radio"/> Yes <input type="radio"/>
PC Time stamp	20 DEC 2020 12:00
PC Open Date & Time	20 DEC 2020 12:00
PC Close Date & Time	21 DEC 2020 11:59

US3342200

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(83)

Generated On: 09 Jun 2021 17:05:26

TIMEPOINT	DAY 83
Did you receive any MEDICAL ATTENTION (doctor visit, other) for any illness or symptoms?	No <input checked="" type="radio"/> Yes <input type="radio"/>
PC Time stamp	21 DEC 2020 17:44
PC Open Date & Time	21 DEC 2020 12:00
PC Close Date & Time	22 DEC 2020 11:59

US3342200

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(84)

Generated On: 09 Jun 2021 17:05:26

TIMEPOINT	DAY 84
Did you receive any MEDICAL ATTENTION (doctor visit, other) for any illness or symptoms?	No <input checked="" type="radio"/> Yes <input type="radio"/>
PC Time stamp	22 DEC 2020 13:32
PC Open Date & Time	22 DEC 2020 12:00
PC Close Date & Time	23 DEC 2020 11:59

US3342200

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(85)

Generated On: 09 Jun 2021 17:05:26

TIMEPOINT	DAY 85
Did you receive any MEDICAL ATTENTION (doctor visit, other) for any illness or symptoms?	No <input checked="" type="radio"/> Yes <input type="radio"/>
PC Time stamp	23 DEC 2020 19:04
PC Open Date & Time	23 DEC 2020 12:00
PC Close Date & Time	24 DEC 2020 11:59

US3342200

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(86)

Generated On: 09 Jun 2021 17:05:26

TIMEPOINT	DAY 86
Did you receive any MEDICAL ATTENTION (doctor visit, other) for any illness or symptoms?	No <input checked="" type="radio"/> Yes <input type="radio"/>
PC Time stamp	24 DEC 2020 19:14
PC Open Date & Time	24 DEC 2020 12:00
PC Close Date & Time	25 DEC 2020 11:59

US3342200

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(87)

Generated On: 09 Jun 2021 17:05:26

TIMEPOINT	DAY 87
Did you receive any MEDICAL ATTENTION (doctor visit, other) for any illness or symptoms?	No <input checked="" type="radio"/> Yes <input type="radio"/>
PC Time stamp	25 DEC 2020 12:18
PC Open Date & Time	25 DEC 2020 12:00
PC Close Date & Time	26 DEC 2020 11:59

US3342200

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(88)

Generated On: 09 Jun 2021 17:05:26

TIMEPOINT	DAY 88
Did you receive any MEDICAL ATTENTION (doctor visit, other) for any illness or symptoms?	No <input checked="" type="radio"/> Yes <input type="radio"/>
PC Time stamp	26 DEC 2020 12:46
PC Open Date & Time	26 DEC 2020 12:00
PC Close Date & Time	27 DEC 2020 11:59

US3342200

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(89)

Generated On: 09 Jun 2021 17:05:26

TIMEPOINT	DAY 89
Did you receive any MEDICAL ATTENTION (doctor visit, other) for any illness or symptoms?	No <input checked="" type="radio"/> Yes <input type="radio"/>
PC Time stamp	27 DEC 2020 12:00
PC Open Date & Time	27 DEC 2020 12:00
PC Close Date & Time	28 DEC 2020 11:59

US3342200

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(90)

Generated On: 09 Jun 2021 17:05:26

TIMEPOINT	DAY 90
Did you receive any MEDICAL ATTENTION (doctor visit, other) for any illness or symptoms?	No <input checked="" type="radio"/> Yes <input type="radio"/>
PC Time stamp	29 DEC 2020 03:15
PC Open Date & Time	28 DEC 2020 12:00
PC Close Date & Time	29 DEC 2020 11:59

US3342200

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(91)

Generated On: 09 Jun 2021 17:05:26

TIMEPOINT	DAY 91
Did you receive any MEDICAL ATTENTION (doctor visit, other) for any illness or symptoms?	No <input checked="" type="radio"/> Yes <input type="radio"/>
PC Time stamp	29 DEC 2020 16:08
PC Open Date & Time	29 DEC 2020 12:00
PC Close Date & Time	30 DEC 2020 11:59

US3342200

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(92)

Generated On: 09 Jun 2021 17:05:26

TIMEPOINT	DAY 92
Did you receive any MEDICAL ATTENTION (doctor visit, other) for any illness or symptoms?	No <input checked="" type="radio"/> Yes <input type="radio"/>
PC Time stamp	30 DEC 2020 12:34
PC Open Date & Time	30 DEC 2020 12:00
PC Close Date & Time	31 DEC 2020 11:59

US3342200

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(93)

Generated On: 09 Jun 2021 17:05:26

TIMEPOINT	DAY 93
Did you receive any MEDICAL ATTENTION (doctor visit, other) for any illness or symptoms?	No <input checked="" type="radio"/> Yes <input type="radio"/>
PC Time stamp	31 DEC 2020 19:26
PC Open Date & Time	31 DEC 2020 12:00
PC Close Date & Time	01 JAN 2021 11:59

US3342200

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(94)

Generated On: 09 Jun 2021 17:05:26

TIMEPOINT	DAY 94
Did you receive any MEDICAL ATTENTION (doctor visit, other) for any illness or symptoms?	No <input checked="" type="radio"/> Yes <input type="radio"/>
PC Time stamp	01 JAN 2021 21:03
PC Open Date & Time	01 JAN 2021 12:00
PC Close Date & Time	02 JAN 2021 11:59

US3342200

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(95)

Generated On: 09 Jun 2021 17:05:26

TIMEPOINT	DAY 95
Did you receive any MEDICAL ATTENTION (doctor visit, other) for any illness or symptoms?	No <input checked="" type="radio"/> Yes <input type="radio"/>
PC Time stamp	02 JAN 2021 15:52
PC Open Date & Time	02 JAN 2021 12:00
PC Close Date & Time	03 JAN 2021 11:59

US3342200

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(96)

Generated On: 09 Jun 2021 17:05:26

TIMEPOINT	DAY 96
Did you receive any MEDICAL ATTENTION (doctor visit, other) for any illness or symptoms?	No <input checked="" type="radio"/> Yes <input type="radio"/>
PC Time stamp	03 JAN 2021 20:33
PC Open Date & Time	03 JAN 2021 12:00
PC Close Date & Time	04 JAN 2021 11:59

US3342200

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(97)

Generated On: 09 Jun 2021 17:05:26

TIMEPOINT	DAY 97
Did you receive any MEDICAL ATTENTION (doctor visit, other) for any illness or symptoms?	No <input checked="" type="radio"/> Yes <input type="radio"/>
PC Time stamp	04 JAN 2021 14:57
PC Open Date & Time	04 JAN 2021 12:00
PC Close Date & Time	05 JAN 2021 11:59

US3342200

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(98)

Generated On: 09 Jun 2021 17:05:26

TIMEPOINT	DAY 98
Did you receive any MEDICAL ATTENTION (doctor visit, other) for any illness or symptoms?	No <input checked="" type="radio"/> Yes <input type="radio"/>
PC Time stamp	05 JAN 2021 12:09
PC Open Date & Time	05 JAN 2021 12:00
PC Close Date & Time	06 JAN 2021 11:59

US3342200

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(99)

Generated On: 09 Jun 2021 17:05:26

TIMEPOINT	DAY 99
Did you receive any MEDICAL ATTENTION (doctor visit, other) for any illness or symptoms?	No <input checked="" type="radio"/> Yes <input type="radio"/>
PC Time stamp	06 JAN 2021 13:05
PC Open Date & Time	06 JAN 2021 12:00
PC Close Date & Time	07 JAN 2021 11:59

US3342200

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(100)

Generated On: 09 Jun 2021 17:05:26

TIMEPOINT	DAY 100
Did you receive any MEDICAL ATTENTION (doctor visit, other) for any illness or symptoms?	No <input checked="" type="radio"/> Yes <input type="radio"/>
PC Time stamp	07 JAN 2021 12:00
PC Open Date & Time	07 JAN 2021 12:00
PC Close Date & Time	08 JAN 2021 11:59

US3342200

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(101)

Generated On: 09 Jun 2021 17:05:26

TIMEPOINT	DAY 101
Did you receive any MEDICAL ATTENTION (doctor visit, other) for any illness or symptoms?	No <input checked="" type="radio"/> Yes <input type="radio"/>
PC Time stamp	08 JAN 2021 23:59
PC Open Date & Time	08 JAN 2021 12:00
PC Close Date & Time	09 JAN 2021 11:59

US3342200

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(102)

Generated On: 09 Jun 2021 17:05:26

TIMEPOINT	DAY 102
Did you receive any MEDICAL ATTENTION (doctor visit, other) for any illness or symptoms?	No <input checked="" type="radio"/> Yes <input type="radio"/>
PC Time stamp	09 JAN 2021 12:05
PC Open Date & Time	09 JAN 2021 12:00
PC Close Date & Time	10 JAN 2021 11:59

US3342200

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(103)

Generated On: 09 Jun 2021 17:05:26

TIMEPOINT	DAY 103
Did you receive any MEDICAL ATTENTION (doctor visit, other) for any illness or symptoms?	No <input checked="" type="radio"/> Yes <input type="radio"/>
PC Time stamp	10 JAN 2021 16:56
PC Open Date & Time	10 JAN 2021 12:00
PC Close Date & Time	11 JAN 2021 11:59

US3342200

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(104)

Generated On: 09 Jun 2021 17:05:26

TIMEPOINT	DAY 104
Did you receive any MEDICAL ATTENTION (doctor visit, other) for any illness or symptoms?	No <input checked="" type="radio"/> Yes <input type="radio"/>
PC Time stamp	11 JAN 2021 12:02
PC Open Date & Time	11 JAN 2021 12:00
PC Close Date & Time	12 JAN 2021 11:59

US3342200

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(105)

Generated On: 09 Jun 2021 17:05:26

TIMEPOINT	DAY 105
Did you receive any MEDICAL ATTENTION (doctor visit, other) for any illness or symptoms?	No <input checked="" type="radio"/> Yes <input type="radio"/>
PC Time stamp	12 JAN 2021 13:03
PC Open Date & Time	12 JAN 2021 12:00
PC Close Date & Time	13 JAN 2021 11:59

US3342200

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(106)

Generated On: 09 Jun 2021 17:05:26

TIMEPOINT	DAY 106
Did you receive any MEDICAL ATTENTION (doctor visit, other) for any illness or symptoms?	No <input checked="" type="radio"/> Yes <input type="radio"/>
PC Time stamp	14 JAN 2021 03:41
PC Open Date & Time	13 JAN 2021 12:00
PC Close Date & Time	14 JAN 2021 11:59

US3342200

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(107)

Generated On: 09 Jun 2021 17:05:26

TIMEPOINT	DAY 107
Did you receive any MEDICAL ATTENTION (doctor visit, other) for any illness or symptoms?	No <input checked="" type="radio"/> Yes <input type="radio"/>
PC Time stamp	14 JAN 2021 16:03
PC Open Date & Time	14 JAN 2021 12:00
PC Close Date & Time	15 JAN 2021 11:59

US3342200

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(108)

Generated On: 09 Jun 2021 17:05:26

TIMEPOINT	DAY 108
Did you receive any MEDICAL ATTENTION (doctor visit, other) for any illness or symptoms?	No <input checked="" type="radio"/> Yes <input type="radio"/>
PC Time stamp	16 JAN 2021 03:14
PC Open Date & Time	15 JAN 2021 12:00
PC Close Date & Time	16 JAN 2021 11:59

US3342200

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(109)

Generated On: 09 Jun 2021 17:05:26

TIMEPOINT	DAY 109
Did you receive any MEDICAL ATTENTION (doctor visit, other) for any illness or symptoms?	No <input checked="" type="radio"/> Yes <input type="radio"/>
PC Time stamp	16 JAN 2021 12:37
PC Open Date & Time	16 JAN 2021 12:00
PC Close Date & Time	17 JAN 2021 11:59

US3342200

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(110)

Generated On: 09 Jun 2021 17:05:26

TIMEPOINT	DAY 110
Did you receive any MEDICAL ATTENTION (doctor visit, other) for any illness or symptoms?	No <input checked="" type="radio"/> Yes <input type="radio"/>
PC Time stamp	18 JAN 2021 00:19
PC Open Date & Time	17 JAN 2021 12:00
PC Close Date & Time	18 JAN 2021 11:59

US3342200

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(111)

Generated On: 09 Jun 2021 17:05:26

TIMEPOINT	DAY 111
Did you receive any MEDICAL ATTENTION (doctor visit, other) for any illness or symptoms?	No <input checked="" type="radio"/> Yes <input type="radio"/>
PC Time stamp	19 JAN 2021 03:08
PC Open Date & Time	18 JAN 2021 12:00
PC Close Date & Time	19 JAN 2021 11:59

US3342200

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(112)

Generated On: 09 Jun 2021 17:05:26

TIMEPOINT	DAY 112
Did you receive any MEDICAL ATTENTION (doctor visit, other) for any illness or symptoms?	No <input checked="" type="radio"/> Yes <input type="radio"/>
PC Time stamp	19 JAN 2021 12:01
PC Open Date & Time	19 JAN 2021 12:00
PC Close Date & Time	20 JAN 2021 11:59

US3342200

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(113)

Generated On: 09 Jun 2021 17:05:26

TIMEPOINT	DAY 113
Did you receive any MEDICAL ATTENTION (doctor visit, other) for any illness or symptoms?	No <input checked="" type="radio"/> Yes <input type="radio"/>
PC Time stamp	20 JAN 2021 15:17
PC Open Date & Time	20 JAN 2021 12:00
PC Close Date & Time	21 JAN 2021 11:59

US3342200

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(114)

Generated On: 09 Jun 2021 17:05:26

TIMEPOINT	DAY 114
Did you receive any MEDICAL ATTENTION (doctor visit, other) for any illness or symptoms?	No <input checked="" type="radio"/> Yes <input type="radio"/>
PC Time stamp	21 JAN 2021 12:00
PC Open Date & Time	21 JAN 2021 12:00
PC Close Date & Time	22 JAN 2021 11:59

US3342200

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(115)

Generated On: 09 Jun 2021 17:05:26

TIMEPOINT	DAY 115
Did you receive any MEDICAL ATTENTION (doctor visit, other) for any illness or symptoms?	No <input checked="" type="radio"/> Yes <input type="radio"/>
PC Time stamp	22 JAN 2021 12:55
PC Open Date & Time	22 JAN 2021 12:00
PC Close Date & Time	23 JAN 2021 11:59

US3342200

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(116)

Generated On: 09 Jun 2021 17:05:26

TIMEPOINT	DAY 116
Did you receive any MEDICAL ATTENTION (doctor visit, other) for any illness or symptoms?	No <input checked="" type="radio"/> Yes <input type="radio"/>
PC Time stamp	23 JAN 2021 12:37
PC Open Date & Time	23 JAN 2021 12:00
PC Close Date & Time	24 JAN 2021 11:59

US3342200

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(117)

Generated On: 09 Jun 2021 17:05:26

TIMEPOINT	DAY 117
Did you receive any MEDICAL ATTENTION (doctor visit, other) for any illness or symptoms?	No <input checked="" type="radio"/> Yes <input type="radio"/>
PC Time stamp	24 JAN 2021 21:42
PC Open Date & Time	24 JAN 2021 12:00
PC Close Date & Time	25 JAN 2021 11:59

US3342200

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(118)

Generated On: 09 Jun 2021 17:05:26

TIMEPOINT	DAY 118
Did you receive any MEDICAL ATTENTION (doctor visit, other) for any illness or symptoms?	No <input checked="" type="radio"/> Yes <input type="radio"/>
PC Time stamp	25 JAN 2021 17:48
PC Open Date & Time	25 JAN 2021 12:00
PC Close Date & Time	26 JAN 2021 11:59

US3342200

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(119)

Generated On: 09 Jun 2021 17:05:26

TIMEPOINT	DAY 119
Did you receive any MEDICAL ATTENTION (doctor visit, other) for any illness or symptoms?	No <input checked="" type="radio"/> Yes <input type="radio"/>
PC Time stamp	26 JAN 2021 19:10
PC Open Date & Time	26 JAN 2021 12:00
PC Close Date & Time	27 JAN 2021 11:59

US3342200

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(120)

Generated On: 09 Jun 2021 17:05:26

TIMEPOINT	DAY 120
Did you receive any MEDICAL ATTENTION (doctor visit, other) for any illness or symptoms?	No <input checked="" type="radio"/> Yes <input type="radio"/>
PC Time stamp	27 JAN 2021 19:46
PC Open Date & Time	27 JAN 2021 12:00
PC Close Date & Time	28 JAN 2021 11:59

US3342200

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(121)

Generated On: 09 Jun 2021 17:05:26

TIMEPOINT	DAY 121
Did you receive any MEDICAL ATTENTION (doctor visit, other) for any illness or symptoms?	No <input checked="" type="radio"/> Yes <input type="radio"/>
PC Time stamp	28 JAN 2021 12:00
PC Open Date & Time	28 JAN 2021 12:00
PC Close Date & Time	29 JAN 2021 11:59

US3342200

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(122)

Generated On: 09 Jun 2021 17:05:26

TIMEPOINT	DAY 122
Did you receive any MEDICAL ATTENTION (doctor visit, other) for any illness or symptoms?	No <input checked="" type="radio"/> Yes <input type="radio"/>
PC Time stamp	30 JAN 2021 05:35
PC Open Date & Time	29 JAN 2021 12:00
PC Close Date & Time	30 JAN 2021 11:59

US3342200

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(123)

Generated On: 09 Jun 2021 17:05:26

TIMEPOINT

DAY 123

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

No ☒

Yes ☐

PC Time stamp

31 JAN 2021 09:35

PC Open Date & Time

30 JAN 2021 12:00

PC Close Date & Time

31 JAN 2021 11:59

US3342200

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(124)

Generated On: 09 Jun 2021 17:05:26

TIMEPOINT	DAY 124
Did you receive any MEDICAL ATTENTION (doctor visit, other) for any illness or symptoms?	No <input checked="" type="radio"/> Yes <input type="radio"/>
PC Time stamp	31 JAN 2021 14:18
PC Open Date & Time	31 JAN 2021 12:00
PC Close Date & Time	01 FEB 2021 11:59

US3342200

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(125)

Generated On: 09 Jun 2021 17:05:26

TIMEPOINT	DAY 125
Did you receive any MEDICAL ATTENTION (doctor visit, other) for any illness or symptoms?	No <input checked="" type="radio"/> Yes <input type="radio"/>
PC Time stamp	01 FEB 2021 13:44
PC Open Date & Time	01 FEB 2021 12:00
PC Close Date & Time	02 FEB 2021 11:59

US3342200

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(126)

Generated On: 09 Jun 2021 17:05:26

TIMEPOINT	DAY 126
Did you receive any MEDICAL ATTENTION (doctor visit, other) for any illness or symptoms?	No <input checked="" type="radio"/> Yes <input type="radio"/>
PC Time stamp	02 FEB 2021 12:01
PC Open Date & Time	02 FEB 2021 12:00
PC Close Date & Time	03 FEB 2021 11:59

US3342200

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(127)

Generated On: 09 Jun 2021 17:05:26

TIMEPOINT	DAY 127
Did you receive any MEDICAL ATTENTION (doctor visit, other) for any illness or symptoms?	No <input checked="" type="radio"/> Yes <input type="radio"/>
PC Time stamp	03 FEB 2021 18:10
PC Open Date & Time	03 FEB 2021 12:00
PC Close Date & Time	04 FEB 2021 11:59

US3342200

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(128)

Generated On: 09 Jun 2021 17:05:26

TIMEPOINT	DAY 128
Did you receive any MEDICAL ATTENTION (doctor visit, other) for any illness or symptoms?	No <input checked="" type="radio"/> Yes <input type="radio"/>
PC Time stamp	04 FEB 2021 12:02
PC Open Date & Time	04 FEB 2021 12:00
PC Close Date & Time	05 FEB 2021 11:59

US3342200

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(129)

Generated On: 09 Jun 2021 17:05:26

TIMEPOINT	DAY 129
Did you receive any MEDICAL ATTENTION (doctor visit, other) for any illness or symptoms?	No <input checked="" type="radio"/> Yes <input type="radio"/>
PC Time stamp	05 FEB 2021 13:11
PC Open Date & Time	05 FEB 2021 12:00
PC Close Date & Time	06 FEB 2021 11:59

US3342200

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(130)

Generated On: 09 Jun 2021 17:05:26

TIMEPOINT	DAY 130
Did you receive any MEDICAL ATTENTION (doctor visit, other) for any illness or symptoms?	No <input checked="" type="radio"/> Yes <input type="radio"/>
PC Time stamp	06 FEB 2021 21:16
PC Open Date & Time	06 FEB 2021 12:00
PC Close Date & Time	07 FEB 2021 11:59

US3342200

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(131)

Generated On: 09 Jun 2021 17:05:26

TIMEPOINT	DAY 131
Did you receive any MEDICAL ATTENTION (doctor visit, other) for any illness or symptoms?	No <input checked="" type="radio"/> Yes <input type="radio"/>
PC Time stamp	08 FEB 2021 06:00
PC Open Date & Time	07 FEB 2021 12:00
PC Close Date & Time	08 FEB 2021 11:59

US3342200

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(132)

Generated On: 09 Jun 2021 17:05:26

TIMEPOINT	DAY 132
Did you receive any MEDICAL ATTENTION (doctor visit, other) for any illness or symptoms?	No <input checked="" type="radio"/> Yes <input type="radio"/>
PC Time stamp	08 FEB 2021 13:09
PC Open Date & Time	08 FEB 2021 12:00
PC Close Date & Time	09 FEB 2021 11:59

US3342200

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(133)

Generated On: 09 Jun 2021 17:05:26

TIMEPOINT	DAY 133
Did you receive any MEDICAL ATTENTION (doctor visit, other) for any illness or symptoms?	No <input checked="" type="radio"/> Yes <input type="radio"/>
PC Time stamp	09 FEB 2021 16:43
PC Open Date & Time	09 FEB 2021 12:00
PC Close Date & Time	10 FEB 2021 11:59

US3342200

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(134)

Generated On: 09 Jun 2021 17:05:26

TIMEPOINT	DAY 134
Did you receive any MEDICAL ATTENTION (doctor visit, other) for any illness or symptoms?	No <input checked="" type="radio"/> Yes <input type="radio"/>
PC Time stamp	11 FEB 2021 03:47
PC Open Date & Time	10 FEB 2021 12:00
PC Close Date & Time	11 FEB 2021 11:59

US3342200

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(135)

Generated On: 09 Jun 2021 17:05:26

TIMEPOINT	DAY 135
Did you receive any MEDICAL ATTENTION (doctor visit, other) for any illness or symptoms?	No <input checked="" type="radio"/> Yes <input type="radio"/>
PC Time stamp	11 FEB 2021 12:37
PC Open Date & Time	11 FEB 2021 12:00
PC Close Date & Time	12 FEB 2021 11:59

US3342200

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(136)

Generated On: 09 Jun 2021 17:05:26

TIMEPOINT	DAY 136
Did you receive any MEDICAL ATTENTION (doctor visit, other) for any illness or symptoms?	No <input checked="" type="radio"/> Yes <input type="radio"/>
PC Time stamp	12 FEB 2021 12:57
PC Open Date & Time	12 FEB 2021 12:00
PC Close Date & Time	13 FEB 2021 11:59

US3342200

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(137)

Generated On: 09 Jun 2021 17:05:26

TIMEPOINT

DAY 137

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

No ☒

Yes ☐

PC Time stamp

13 FEB 2021 12:28

PC Open Date & Time

13 FEB 2021 12:00

PC Close Date & Time

14 FEB 2021 11:59

US3342200

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(138)

Generated On: 09 Jun 2021 17:05:26

TIMEPOINT	DAY 138
Did you receive any MEDICAL ATTENTION (doctor visit, other) for any illness or symptoms?	No <input checked="" type="radio"/> Yes <input type="radio"/>
PC Time stamp	14 FEB 2021 13:08
PC Open Date & Time	14 FEB 2021 12:00
PC Close Date & Time	15 FEB 2021 11:59

US3342200

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(139)

Generated On: 09 Jun 2021 17:05:26

TIMEPOINT	DAY 139
Did you receive any MEDICAL ATTENTION (doctor visit, other) for any illness or symptoms?	No <input checked="" type="radio"/> Yes <input type="radio"/>
PC Time stamp	15 FEB 2021 12:00
PC Open Date & Time	15 FEB 2021 12:00
PC Close Date & Time	16 FEB 2021 11:59

US3342200

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(140)

Generated On: 09 Jun 2021 17:05:26

TIMEPOINT	DAY 140
Did you receive any MEDICAL ATTENTION (doctor visit, other) for any illness or symptoms?	No <input checked="" type="radio"/> Yes <input type="radio"/>
PC Time stamp	16 FEB 2021 18:19
PC Open Date & Time	16 FEB 2021 12:00
PC Close Date & Time	17 FEB 2021 11:59

US3342200

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(141)

Generated On: 09 Jun 2021 17:05:26

TIMEPOINT	DAY 141
Did you receive any MEDICAL ATTENTION (doctor visit, other) for any illness or symptoms?	No <input checked="" type="radio"/> Yes <input type="radio"/>
PC Time stamp	17 FEB 2021 12:34
PC Open Date & Time	17 FEB 2021 12:00
PC Close Date & Time	18 FEB 2021 11:59

US3342200

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(142)

Generated On: 09 Jun 2021 17:05:26

TIMEPOINT	DAY 142
Did you receive any MEDICAL ATTENTION (doctor visit, other) for any illness or symptoms?	No <input checked="" type="radio"/> Yes <input type="radio"/>
PC Time stamp	18 FEB 2021 12:43
PC Open Date & Time	18 FEB 2021 12:00
PC Close Date & Time	19 FEB 2021 11:59

US3342200

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(143)

Generated On: 09 Jun 2021 17:05:26

TIMEPOINT	DAY 143
Did you receive any MEDICAL ATTENTION (doctor visit, other) for any illness or symptoms?	No <input checked="" type="radio"/> Yes <input type="radio"/>
PC Time stamp	19 FEB 2021 16:12
PC Open Date & Time	19 FEB 2021 12:00
PC Close Date & Time	20 FEB 2021 11:59

US3342200

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(144)

Generated On: 09 Jun 2021 17:05:26

TIMEPOINT	DAY 144
Did you receive any MEDICAL ATTENTION (doctor visit, other) for any illness or symptoms?	No <input checked="" type="radio"/> Yes <input type="radio"/>
PC Time stamp	20 FEB 2021 18:19
PC Open Date & Time	20 FEB 2021 12:00
PC Close Date & Time	21 FEB 2021 11:59

US3342200

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(145)

Generated On: 09 Jun 2021 17:05:26

TIMEPOINT

DAY 145

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

No ☒

Yes ☐

PC Time stamp

21 FEB 2021 12:00

PC Open Date & Time

21 FEB 2021 12:00

PC Close Date & Time

22 FEB 2021 11:59

US3342200

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(146)

Generated On: 09 Jun 2021 17:05:26

TIMEPOINT	DAY 146
Did you receive any MEDICAL ATTENTION (doctor visit, other) for any illness or symptoms?	No <input checked="" type="radio"/> Yes <input type="radio"/>
PC Time stamp	22 FEB 2021 12:02
PC Open Date & Time	22 FEB 2021 12:00
PC Close Date & Time	23 FEB 2021 11:59

US3342200

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(147)

Generated On: 09 Jun 2021 17:05:26

TIMEPOINT	DAY 147
Did you receive any MEDICAL ATTENTION (doctor visit, other) for any illness or symptoms?	No <input checked="" type="radio"/> Yes <input type="radio"/>
PC Time stamp	23 FEB 2021 18:58
PC Open Date & Time	23 FEB 2021 12:00
PC Close Date & Time	24 FEB 2021 11:59

US3342200

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(148)

Generated On: 09 Jun 2021 17:05:26

TIMEPOINT	DAY 148
Did you receive any MEDICAL ATTENTION (doctor visit, other) for any illness or symptoms?	No <input checked="" type="radio"/> Yes <input type="radio"/>
PC Time stamp	24 FEB 2021 18:01
PC Open Date & Time	24 FEB 2021 12:00
PC Close Date & Time	25 FEB 2021 11:59

US3342200

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(149)

Generated On: 09 Jun 2021 17:05:26

TIMEPOINT	DAY 149
Did you receive any MEDICAL ATTENTION (doctor visit, other) for any illness or symptoms?	No <input type="checkbox"/>
	Yes <input type="checkbox"/>
PC Time stamp	
PC Open Date & Time	25 FEB 2021 12:00
PC Close Date & Time	26 FEB 2021 11:59

US3342200

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(150)

Generated On: 09 Jun 2021 17:05:26

TIMEPOINT	DAY 150
Did you receive any MEDICAL ATTENTION (doctor visit, other) for any illness or symptoms?	No <input type="radio"/>
	Yes <input type="radio"/>
PC Time stamp	
PC Open Date & Time	26 FEB 2021 12:00
PC Close Date & Time	27 FEB 2021 11:59

US3342200

Folder: Safety Call Day 36 (1)

Form: Safety Call

Data signed: (b) (4) 12 Feb 2021 23:50:35

Generated On: 09 Jun 2021 17:05:26

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

7 OCT 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3342200

Folder: Safety Call Day 36 (1)

Form: Continuing

Data signed: (b) (4) 12 Feb 2021 23:50:35

Generated On: 09 Jun 2021 17:05:26

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3342200

Folder: Safety Call Day 43 (1)

Form: Safety Call

Data signed: (b) (4) 12 Feb 2021 23:50:35

Generated On: 09 Jun 2021 17:05:26

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

14 OCT 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3342200

Folder: Safety Call Day 43 (1)

Form: Continuing

Data signed: (b) (4) 12 Feb 2021 23:50:35

Generated On: 09 Jun 2021 17:05:26

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3342200

Folder: Safety Call Day 50 (1)

Form: Safety Call

Data signed: (b) (4) 12 Feb 2021 23:50:35

Generated On: 09 Jun 2021 17:05:26

Was Contact Attempted? Yes ☒
No ☐

Date of Contact or Contact Attempt (dd MMM yyyy) 21 OCT 2020

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

Comments

If Contact Not Made, please provide Comments

US3342200

Folder: Safety Call Day 50 (1)

Form: Continuing

Data signed: (b) (4) 12 Feb 2021 23:50:35

Generated On: 09 Jun 2021 17:05:26

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3342200

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Data signed: (b) (4) 12 Feb 2021 23:50:36

Generated On: 09 Jun 2021 17:05:26

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	26 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

US3342200

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Data signed: (b) (4) 12 Feb 2021 23:50:36

Generated On: 09 Jun 2021 17:05:26

Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (dd MMM yyyy)	26 OCT 2020
Time of assessment (00:00-23:59)	15:30 (24 HR)
Vital Signs Date and Time (derived)	26 OCT 2020 15:30
Temperature (xxx.x)	98.8 F
Route of measurement	Oral <input checked="" type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	71 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	14 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	117 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	77 mmHg
Diastolic Blood Pressure units	MMHG
Height (derived)	
Weight (derived)	

US3342200

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Data signed: (b) (4) 12 Feb 2021 23:50:36

Generated On: 09 Jun 2021 17:05:26

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

26 OCT 2020

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

US3342200

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 12 Feb 2021 23:50:36

Generated On: 09 Jun 2021 17:05:26

Was the sample collected?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Collection date (dd MMM yyyy)	26 OCT 2020
Collection time (00:00-23:59)	17:06 (24 HR)
Collection date and time (derived)	26 OCT 2020 17:06

US3342200

Folder: Visit 3 Day 57 (1)

Form: Continuing

Data signed: (b) (4) 12 Feb 2021 23:50:36

Generated On: 09 Jun 2021 17:05:26

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3342200

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:05:26

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

04 NOV 2020 09:43:22

Patient Cloud Open Date & Time

04 NOV 2020 00:01

Patient Cloud Close Date & Time

08 NOV 2020 23:59

US3342200

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:05:26

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

11 NOV 2020 04:16:48

Patient Cloud Open Date & Time

11 NOV 2020 00:01

Patient Cloud Close Date & Time

15 NOV 2020 23:59

US3342200

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:05:26

TIMEPOINT

DAY 78

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

18 NOV 2020 00:04:41

Patient Cloud Open Date & Time

18 NOV 2020 00:01

Patient Cloud Close Date & Time

22 NOV 2020 23:59

US3342200

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:05:26

TIMEPOINT	DAY 82
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 checked="" type="radio"/> Yes <input type="radio"/>
Date and time of submission	22 NOV 2020 00:48:10
Patient Cloud Open Date & Time	22 NOV 2020 00:01
Patient Cloud Close Date & Time	26 NOV 2020 23:59

US3342200

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:05:26

TIMEPOINT	DAY 89
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	29 NOV 2020 00:36:27
Patient Cloud Open Date & Time	29 NOV 2020 00:01
Patient Cloud Close Date & Time	03 DEC 2020 23:59

US3342200

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:05:26

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	06 DEC 2020 10:45:02
Patient Cloud Open Date & Time	06 DEC 2020 00:01
Patient Cloud Close Date & Time	10 DEC 2020 23:59

US3342200

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:05:26

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 <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 checked="" type="radio"/> Yes <input type="radio"/>
Date and time of submission	13 DEC 2020 00:07:01
Patient Cloud Open Date & Time	13 DEC 2020 00:01
Patient Cloud Close Date & Time	17 DEC 2020 23:59

US3342200

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:05:26

TIMEPOINT

DAY 110

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

20 DEC 2020 12:00:28

Patient Cloud Open Date & Time

20 DEC 2020 00:01

Patient Cloud Close Date & Time

24 DEC 2020 23:59

US3342200

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:05:26

TIMEPOINT

DAY 117

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

27 DEC 2020 02:51:03

Patient Cloud Open Date & Time

27 DEC 2020 00:01

Patient Cloud Close Date & Time

31 DEC 2020 23:59

US3342200

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:05:26

TIMEPOINT

DAY 124

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

03 JAN 2021 04:01:54

Patient Cloud Open Date & Time

03 JAN 2021 00:01

Patient Cloud Close Date & Time

07 JAN 2021 23:59

US3342200

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:05:26

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	10 JAN 2021 05:03:27
Patient Cloud Open Date & Time	10 JAN 2021 00:01
Patient Cloud Close Date & Time	14 JAN 2021 23:59

US3342200

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:05:26

TIMEPOINT

DAY 138

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

17 JAN 2021 00:04:13

Patient Cloud Open Date & Time

17 JAN 2021 00:01

Patient Cloud Close Date & Time

21 JAN 2021 23:59

US3342200

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:05:26

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

24 JAN 2021 00:01:39

Patient Cloud Open Date & Time

24 JAN 2021 00:01

Patient Cloud Close Date & Time

28 JAN 2021 23:59

US3342200

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:05:26

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

31 JAN 2021 09:35:54

Patient Cloud Open Date & Time

31 JAN 2021 00:01

Patient Cloud Close Date & Time

04 FEB 2021 23:59

US3342200

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:05:26

TIMEPOINT

DAY 159

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

07 FEB 2021 04:32:51

Patient Cloud Open Date & Time

07 FEB 2021 00:01

Patient Cloud Close Date & Time

11 FEB 2021 23:59

US3342200

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:05:26

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	14 FEB 2021 04:43:10
Patient Cloud Open Date & Time	14 FEB 2021 00:01
Patient Cloud Close Date & Time	18 FEB 2021 23:59

US3342200

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:05:26

TIMEPOINT

DAY 173

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

21 FEB 2021 09:38:17

Patient Cloud Open Date & Time

21 FEB 2021 00:01

Patient Cloud Close Date & Time

25 FEB 2021 23:59

US3342200

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:05:26

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	28 FEB 2021 06:32:13
Patient Cloud Open Date & Time	28 FEB 2021 00:01
Patient Cloud Close Date & Time	04 MAR 2021 23:59

US3342200

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:05:26

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 ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

07 MAR 2021 02:55:07

Patient Cloud Open Date & Time

07 MAR 2021 00:01

Patient Cloud Close Date & Time

11 MAR 2021 23:59

US3342200

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:05:26

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	14 MAR 2021 05:56:17
Patient Cloud Open Date & Time	14 MAR 2021 00:01
Patient Cloud Close Date & Time	18 MAR 2021 23:59

US3342200

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:05:26

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

21 MAR 2021 12:30:58

Patient Cloud Open Date & Time

21 MAR 2021 00:01

Patient Cloud Close Date & Time

25 MAR 2021 23:59

US3342200

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:05:26

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

28 MAR 2021 05:11:47

Patient Cloud Open Date & Time

28 MAR 2021 00:01

Patient Cloud Close Date & Time

01 APR 2021 23:59

US3342200

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:05:26

TIMEPOINT

DAY 215

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

04 APR 2021 03:46:44

Patient Cloud Open Date & Time

04 APR 2021 00:01

Patient Cloud Close Date & Time

08 APR 2021 23:59

US3342200

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:05:26

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 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 checked="" type="radio"/> Yes <input type="radio"/>
Date and time of submission	11 APR 2021 02:29:48
Patient Cloud Open Date & Time	11 APR 2021 00:01
Patient Cloud Close Date & Time	15 APR 2021 23:59

US3342200

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:05:26

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 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 checked="" type="radio"/> Yes <input type="radio"/>
Date and time of submission	18 APR 2021 06:57:36
Patient Cloud Open Date & Time	18 APR 2021 00:01
Patient Cloud Close Date & Time	22 APR 2021 23:59

US3342200

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:05:26

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 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 checked="" type="radio"/> Yes <input type="radio"/>
Date and time of submission	25 APR 2021 07:36:33
Patient Cloud Open Date & Time	25 APR 2021 00:01
Patient Cloud Close Date & Time	29 APR 2021 23:59

US3342200

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:05:26

TIMEPOINT

DAY 243

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

02 MAY 2021 06:48:36

Patient Cloud Open Date & Time

02 MAY 2021 00:01

Patient Cloud Close Date & Time

06 MAY 2021 23:59

US3342200

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:05:26

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

US3342200

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:05:26

Please contact your study clinic immediately. Click below to confirm that you have read this 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 MAY 2021 00:01

[Patient Cloud Close Date & Time](#)

13 MAY 2021 23:59

US3342200

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:05:26

TIMEPOINT

DAY 257

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

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

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

US3342200

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:05:26

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

[Patient Cloud Open Date & Time](#)

16 MAY 2021 00:01

[Patient Cloud Close Date & Time](#)

20 MAY 2021 23:59

US3342200

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:05:26

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

US3342200

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:05:26

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

[Patient Cloud Open Date & Time](#)

23 MAY 2021 00:01

[Patient Cloud Close Date & Time](#)

27 MAY 2021 23:59

US3342200

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:05:26

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

US3342200

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:05:26

Please contact your study clinic immediately. Click below to confirm that you have read this 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 MAY 2021 00:01

[Patient Cloud Close Date & Time](#)

03 JUN 2021 23:59

US3342200

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:05:26

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

US3342200

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:05:26

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

[Patient Cloud Open Date & Time](#)

06 JUN 2021 00:01

[Patient Cloud Close Date & Time](#)

10 JUN 2021 23:59

US3342200

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:05:26

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

US3342200

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:05:26

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

[Patient Cloud Open Date & Time](#)

13 JUN 2021 00:01

[Patient Cloud Close Date & Time](#)

17 JUN 2021 23:59

US3342200

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:05:26

TIMEPOINT

DAY 292

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

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

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

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

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

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

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

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

US3342200

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:05:26

Please contact your study clinic immediately. Click below to confirm that you have read this 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 JUN 2021 00:01

[Patient Cloud Close Date & Time](#)

24 JUN 2021 23:59

US3342200

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:05:26

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

US3342200

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:05:26

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

[Patient Cloud Open Date & Time](#)

27 JUN 2021 00:01

[Patient Cloud Close Date & Time](#)

01 JUL 2021 23:59

US3342200

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:05:26

TIMEPOINT

DAY 306

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3342200

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:05:26

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

[Patient Cloud Open Date & Time](#)

04 JUL 2021 00:01

[Patient Cloud Close Date & Time](#)

08 JUL 2021 23:59

US3342200

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:05:26

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 ☐

US3342200

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:05:26

Please contact your study clinic immediately. Click below to confirm that you have read this 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 JUL 2021 00:01

[Patient Cloud Close Date & Time](#)

15 JUL 2021 23:59

US3342200

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:05:26

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

US3342200

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:05:26

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
Patient Cloud Open Date & Time	18 JUL 2021 00:01
Patient Cloud Close Date & Time	22 JUL 2021 23:59

US3342200

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:05:26

TIMEPOINT

DAY 327

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

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

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

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

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

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

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

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

US3342200

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:05:26

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

US3342200

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:05:26

TIMEPOINT

DAY 334

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

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

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

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

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

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

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

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

US3342200

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:05:26

Please contact your study clinic immediately. Click below to confirm that you have read this 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 AUG 2021 00:01

[Patient Cloud Close Date & Time](#)

05 AUG 2021 23:59

US3342200

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:05:26

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

US3342200

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:05:26

Please contact your study clinic immediately. Click below to confirm that you have read this 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 AUG 2021 00:01

[Patient Cloud Close Date & Time](#)

12 AUG 2021 23:59

US3342200

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:05:26

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

US3342200

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:05:26

Please contact your study clinic immediately. Click below to confirm that you have read this 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 AUG 2021 00:01

[Patient Cloud Close Date & Time](#)

19 AUG 2021 23:59

US3342200

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:05:26

TIMEPOINT

DAY 355

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

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

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

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

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

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

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

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

US3342200

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:05:26

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
Patient Cloud Open Date & Time	22 AUG 2021 00:01
Patient Cloud Close Date & Time	26 AUG 2021 23:59

US3342200

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:05:26

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

US3342200

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:05:26

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

[Patient Cloud Open Date & Time](#)

29 AUG 2021 00:01

[Patient Cloud Close Date & Time](#)

02 SEP 2021 23:59

US3342200

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:05:26

TIMEPOINT

DAY 369

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

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

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

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

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

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

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

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

US3342200

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:05:26

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

[Patient Cloud Open Date & Time](#)

05 SEP 2021 00:01

[Patient Cloud Close Date & Time](#)

09 SEP 2021 23:59

US3342200

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:05:26

TIMEPOINT

DAY 376

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3342200

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:05:26

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

[Patient Cloud Open Date & Time](#)

12 SEP 2021 00:01

[Patient Cloud Close Date & Time](#)

16 SEP 2021 23:59

US3342200

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:05:26

TIMEPOINT

DAY 383

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

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

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

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

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

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

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

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

US3342200

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:05:26

Please contact your study clinic immediately. Click below to confirm that you have read this 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 SEP 2021 00:01

[Patient Cloud Close Date & Time](#)

23 SEP 2021 23:59

US3342200

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:05:26

TIMEPOINT

DAY 390

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

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

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

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

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

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

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

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

US3342200

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:05:26

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

[Patient Cloud Open Date & Time](#)

26 SEP 2021 00:01

[Patient Cloud Close Date & Time](#)

30 SEP 2021 23:59

US3342200

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:05:26

TIMEPOINT

DAY 397

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3342200

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:05:26

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

Patient Cloud Open Date & Time	03 OCT 2021 00:01
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Patient Cloud Close Date & Time	07 OCT 2021 23:59
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US3342200

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:05:26

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

US3342200

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:05:26

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

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

US3342200

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:05:26

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

US3342200

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:05:26

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

US3342200

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:05:26

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 ☐

US3342200

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:05:26

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

24 OCT 2021 00:01

[Patient Cloud Close Date & Time](#)

28 OCT 2021 23:59

US3342200

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:05:26

TIMEPOINT

DAY 425

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

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

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

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

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

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

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

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

US3342200

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:05:26

Please contact your study clinic immediately. Click below to confirm that you have read this 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 OCT 2021 00:01

[Patient Cloud Close Date & Time](#)

04 NOV 2021 23:59

US3342200

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:05:26

TIMEPOINT

DAY 432

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

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

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

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

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

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

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

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

US3342200

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:05:26

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

07 NOV 2021 00:01

[Patient Cloud Close Date & Time](#)

11 NOV 2021 23:59

US3342200

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:05:26

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 ☐

US3342200

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:05:26

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

[Patient Cloud Open Date & Time](#)

14 NOV 2021 00:01

[Patient Cloud Close Date & Time](#)

18 NOV 2021 23:59

US3342200

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:05:26

TIMEPOINT

DAY 446

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

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

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

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

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

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

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

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

US3342200

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:05:26

Please contact your study clinic immediately. Click below to confirm that you have read this 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 NOV 2021 00:01

[Patient Cloud Close Date & Time](#)

25 NOV 2021 23:59

US3342200

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:05:26

TIMEPOINT

DAY 453

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

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

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

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

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

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

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

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

US3342200

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:05:26

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

[Patient Cloud Open Date & Time](#)

28 NOV 2021 00:01

[Patient Cloud Close Date & Time](#)

02 DEC 2021 23:59

US3342200

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:05:26

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

US3342200

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:05:26

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

Patient Cloud Open Date & Time	05 DEC 2021 00:01
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Patient Cloud Close Date & Time	09 DEC 2021 23:59
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US3342200

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:05:26

TIMEPOINT

DAY 467

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

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

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

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

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

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

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

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

US3342200

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:05:26

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
Patient Cloud Open Date & Time	12 DEC 2021 00:01
Patient Cloud Close Date & Time	16 DEC 2021 23:59

US3342200

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:05:26

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 ☐

US3342200

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:05:26

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

[Patient Cloud Open Date & Time](#)

19 DEC 2021 00:01

[Patient Cloud Close Date & Time](#)

23 DEC 2021 23:59

US3342200

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:05:26

TIMEPOINT

DAY 481

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3342200

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:05:26

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

US3342200

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:05:26

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

US3342200

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:05:26

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

[Patient Cloud Open Date & Time](#)

02 JAN 2022 00:01

[Patient Cloud Close Date & Time](#)

06 JAN 2022 23:59

US3342200

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:05:26

TIMEPOINT

DAY 495

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

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

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

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

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

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

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

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

US3342200

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:05:26

Please contact your study clinic immediately. Click below to confirm that you have read this 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 JAN 2022 00:01

[Patient Cloud Close Date & Time](#)

13 JAN 2022 23:59

US3342200

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:05:26

TIMEPOINT

DAY 502

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

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

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

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

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

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

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

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

US3342200

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:05:26

Please contact your study clinic immediately. Click below to confirm that you have read this 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 JAN 2022 00:01

[Patient Cloud Close Date & Time](#)

20 JAN 2022 23:59

US3342200

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:05:26

TIMEPOINT

DAY 509

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3342200

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:05:26

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

[Patient Cloud Open Date & Time](#)

23 JAN 2022 00:01

[Patient Cloud Close Date & Time](#)

27 JAN 2022 23:59

US3342200

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:05:26

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 ☐

US3342200

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:05:26

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

[Patient Cloud Open Date & Time](#)

30 JAN 2022 00:01

[Patient Cloud Close Date & Time](#)

03 FEB 2022 23:59

US3342200

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:05:26

TIMEPOINT

DAY 523

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

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

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

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

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

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

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

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

US3342200

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:05:26

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

06 FEB 2022 00:01

[Patient Cloud Close Date & Time](#)

10 FEB 2022 23:59

US3342200

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:05:26

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

US3342200

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:05:26

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

[Patient Cloud Open Date & Time](#)

13 FEB 2022 00:01

[Patient Cloud Close Date & Time](#)

17 FEB 2022 23:59

US3342200

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:05:26

TIMEPOINT

DAY 537

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

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

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

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

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

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

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

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

US3342200

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:05:26

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

[Patient Cloud Open Date & Time](#)

20 FEB 2022 00:01

[Patient Cloud Close Date & Time](#)

24 FEB 2022 23:59

US3342200

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:05:26

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

US3342200

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:05:26

Please contact your study clinic immediately. Click below to confirm that you have read this 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 FEB 2022 00:01

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03 MAR 2022 23:59

US3342200

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:05:26

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 ☐

US3342200

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:05:26

Please contact your study clinic immediately. Click below to confirm that you have read this 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 MAR 2022 00:01

[Patient Cloud Close Date & Time](#)

10 MAR 2022 23:59

US3342200

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:05:26

TIMEPOINT

DAY 558

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

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

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

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

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

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

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

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

US3342200

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:05:26

Please contact your study clinic immediately. Click below to confirm that you have read this 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 MAR 2022 00:01

[Patient Cloud Close Date & Time](#)

17 MAR 2022 23:59

US3342200

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:05:26

TIMEPOINT

DAY 565

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

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

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

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

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

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

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

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

US3342200

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:05:26

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

[Patient Cloud Open Date & Time](#)

20 MAR 2022 00:01

[Patient Cloud Close Date & Time](#)

24 MAR 2022 23:59

US3342200

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:05:26

TIMEPOINT

DAY 572

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

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

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

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

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

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

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

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

US3342200

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:05:26

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

[Patient Cloud Open Date & Time](#)

27 MAR 2022 00:01

[Patient Cloud Close Date & Time](#)

31 MAR 2022 23:59

US3342200

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:05:26

TIMEPOINT

DAY 579

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

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

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

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

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

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

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

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

US3342200

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:05:26

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

[Patient Cloud Open Date & Time](#)

03 APR 2022 00:01

[Patient Cloud Close Date & Time](#)

07 APR 2022 23:59

US3342200

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:05:26

TIMEPOINT

DAY 586

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3342200

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:05:26

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

[Patient Cloud Open Date & Time](#)

10 APR 2022 00:01

[Patient Cloud Close Date & Time](#)

14 APR 2022 23:59

US3342200

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:05:26

TIMEPOINT

DAY 593

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

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

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

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

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

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

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

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

US3342200

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:05:26

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

[Patient Cloud Open Date & Time](#)

17 APR 2022 00:01

[Patient Cloud Close Date & Time](#)

21 APR 2022 23:59

US3342200

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:05:26

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

US3342200

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:05:26

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

[Patient Cloud Open Date & Time](#)

24 APR 2022 00:01

[Patient Cloud Close Date & Time](#)

28 APR 2022 23:59

US3342200

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:05:26

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

US3342200

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:05:26

Please contact your study clinic immediately. Click below to confirm that you have read this 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 MAY 2022 00:01

[Patient Cloud Close Date & Time](#)

05 MAY 2022 23:59

US3342200

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:05:26

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

US3342200

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:05:26

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

[Patient Cloud Open Date & Time](#)

08 MAY 2022 00:01

[Patient Cloud Close Date & Time](#)

12 MAY 2022 23:59

US3342200

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:05:26

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

US3342200

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:05:26

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

[Patient Cloud Open Date & Time](#)

15 MAY 2022 00:01

[Patient Cloud Close Date & Time](#)

19 MAY 2022 23:59

US3342200

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:05:26

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 ☐

US3342200

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:05:26

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

[Patient Cloud Open Date & Time](#)

22 MAY 2022 00:01

[Patient Cloud Close Date & Time](#)

26 MAY 2022 23:59

US3342200

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:05:26

TIMEPOINT

DAY 635

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

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

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

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

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

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

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

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

US3342200

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:05:26

Please contact your study clinic immediately. Click below to confirm that you have read this 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 MAY 2022 00:01

[Patient Cloud Close Date & Time](#)

02 JUN 2022 23:59

US3342200

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:05:26

TIMEPOINT

DAY 642

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

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

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

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

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

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

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

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

US3342200

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:05:26

Please contact your study clinic immediately. Click below to confirm that you have read this 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 JUN 2022 00:01

[Patient Cloud Close Date & Time](#)

09 JUN 2022 23:59

US3342200

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:05:26

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

US3342200

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:05:26

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

[Patient Cloud Open Date & Time](#)

12 JUN 2022 00:01

[Patient Cloud Close Date & Time](#)

16 JUN 2022 23:59

US3342200

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:05:26

TIMEPOINT

DAY 656

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

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

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

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

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

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

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

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

US3342200

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:05:26

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

[Patient Cloud Open Date & Time](#)

19 JUN 2022 00:01

[Patient Cloud Close Date & Time](#)

23 JUN 2022 23:59

US3342200

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:05:26

TIMEPOINT

DAY 663

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

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

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

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

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

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

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

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

US3342200

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:05:26

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

[Patient Cloud Open Date & Time](#)

26 JUN 2022 00:01

[Patient Cloud Close Date & Time](#)

30 JUN 2022 23:59

US3342200

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:05:26

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

US3342200

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:05:26

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

[Patient Cloud Open Date & Time](#)

03 JUL 2022 00:01

[Patient Cloud Close Date & Time](#)

07 JUL 2022 23:59

US3342200

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:05:26

TIMEPOINT

DAY 677

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

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

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

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

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

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

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

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

US3342200

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:05:26

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

[Patient Cloud Open Date & Time](#)

10 JUL 2022 00:01

[Patient Cloud Close Date & Time](#)

14 JUL 2022 23:59

US3342200

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:05:26

TIMEPOINT

DAY 684

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3342200

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:05:26

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

[Patient Cloud Open Date & Time](#)

17 JUL 2022 00:01

[Patient Cloud Close Date & Time](#)

21 JUL 2022 23:59

US3342200

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:05:26

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

US3342200

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:05:26

Please contact your study clinic immediately. Click below to confirm that you have read this 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 JUL 2022 00:01

[Patient Cloud Close Date & Time](#)

28 JUL 2022 23:59

US3342200

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:05:26

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 ☐

US3342200

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:05:26

Please contact your study clinic immediately. Click below to confirm that you have read this 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 JUL 2022 00:01

[Patient Cloud Close Date & Time](#)

04 AUG 2022 23:59

US3342200

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:05:26

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 ☐

US3342200

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:05:26

Please contact your study clinic immediately. Click below to confirm that you have read this 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 AUG 2022 00:01

[Patient Cloud Close Date & Time](#)

11 AUG 2022 23:59

US3342200

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:05:26

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

US3342200

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:05:26

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

[Patient Cloud Open Date & Time](#)

14 AUG 2022 00:01

[Patient Cloud Close Date & Time](#)

18 AUG 2022 23:59

US3342200

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:05:26

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

US3342200

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:05:26

Please contact your study clinic immediately. Click below to confirm that you have read this 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 AUG 2022 00:01

[Patient Cloud Close Date & Time](#)

25 AUG 2022 23:59

US3342200

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:05:26

TIMEPOINT

DAY 726

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

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

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

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

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

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

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

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

US3342200

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:05:26

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

[Patient Cloud Open Date & Time](#)

28 AUG 2022 00:01

[Patient Cloud Close Date & Time](#)

01 SEP 2022 23:59

US3342200

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:05:26

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

US3342200

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:05:26

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

[Patient Cloud Open Date & Time](#)

04 SEP 2022 00:01

[Patient Cloud Close Date & Time](#)

08 SEP 2022 23:59

US3342200

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:05:26

TIMEPOINT	DAY 740
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

US3342200

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:05:26

Please contact your study clinic immediately. Click below to confirm that you have read this 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 SEP 2022 00:01

[Patient Cloud Close Date & Time](#)

15 SEP 2022 23:59

US3342200

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:05:26

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

US3342200

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:05:26

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

[Patient Cloud Open Date & Time](#)

18 SEP 2022 00:01

[Patient Cloud Close Date & Time](#)

22 SEP 2022 23:59

US3342200

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:05:26

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

US3342200

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:05:26

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

[Patient Cloud Open Date & Time](#)

25 SEP 2022 00:01

[Patient Cloud Close Date & Time](#)

29 SEP 2022 23:59

US3342200

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:05:26

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 ☐

US3342200

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:05:26

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

Patient Cloud Open Date & Time	02 OCT 2022 00:01
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Patient Cloud Close Date & Time	06 OCT 2022 23:59
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US3342200

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:05:26

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

US3342200

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:05:26

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

[Patient Cloud Open Date & Time](#)

09 OCT 2022 00:01

[Patient Cloud Close Date & Time](#)

13 OCT 2022 23:59

US3342200

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:05:26

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 ☐

US3342200

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:05:26

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
Patient Cloud Open Date & Time	16 OCT 2022 00:01
Patient Cloud Close Date & Time	20 OCT 2022 23:59

US3342200

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:05:26

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 ☐

US3342200

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:05:26

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
Patient Cloud Open Date & Time	23 OCT 2022 00:01
Patient Cloud Close Date & Time	27 OCT 2022 23:59

US3342200

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:05:26

TIMEPOINT

DAY 789

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3342200

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:05:26

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

[Patient Cloud Open Date & Time](#)

30 OCT 2022 00:01

[Patient Cloud Close Date & Time](#)

03 NOV 2022 23:59

US3342200

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:05:26

TIMEPOINT	DAY 796
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>

US3342200

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:05:26

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

[Patient Cloud Open Date & Time](#)

06 NOV 2022 00:01

[Patient Cloud Close Date & Time](#)

10 NOV 2022 23:59

US3342200

Folder: Cosmetic Injections and Dermal Fillers

Form: Cosmetic Injection_ Dermal Filler eDiary

Generated On: 09 Jun 2021 17:05:26

Have you ever received facial cosmetic injections, such as Juvederm, Voluma, Radiesse, Restylane, Botox or other?	Have you ever received a dermal filler, such as Juvederm, Voluma, Radiesse, Restylane, or Botox or other for a medical indication such as a migraine headache?	Date & Time of Submission
No		28 FEB 2021 06:32:26

US3342200

Folder: Safety Call Day 85 (1)

Form: Safety Call

Data signed: (b) (4) 13 Mar 2021 16:12:03

Generated On: 09 Jun 2021 17:05:26

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

23 NOV 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3342200

Folder: Safety Call Day 85 (1)

Form: Continuing

Data signed: (b) (4) 13 Mar 2021 15:24:15

Generated On: 09 Jun 2021 17:05:26

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3342200

Folder: Safety Call Day 119 (1)

Form: Safety Call

Data signed: (b) (4) 13 Mar 2021 15:24:15

Generated On: 09 Jun 2021 17:05:26

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

30 DEC 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3342200

Folder: Safety Call Day 119 (1)

Form: Continuing

Data signed: (b) (4) 13 Mar 2021 15:24:15

Generated On: 09 Jun 2021 17:05:26

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3342200

Folder: Safety Call Day 149 (1)

Form: Safety Call

Data signed: (b) (4) 29 Mar 2021 15:07:51

Generated On: 09 Jun 2021 17:05:26

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

25 JAN 2021

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3342200

Folder: Safety Call Day 149 (1)

Form: Continuing

Data signed: (b) (4) 29 Mar 2021 15:07:51

Generated On: 09 Jun 2021 17:05:26

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3342200

Folder: Safety Call Day 179 (1)

Form: Safety Call

Data signed: (b) (4) 29 Mar 2021 15:07:51

Generated On: 09 Jun 2021 17:05:26

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

VISIT WAS CANCELLED DUE TO
SITE CLOSURE (WINTER STORM
URI). PD NOTED.

If Contact Not Made, please provide Comments

US3342200

Folder: Safety Call Day 179 (1)

Form: Continuing

Data signed: (b) (4) 29 Mar 2021 15:07:51

Generated On: 09 Jun 2021 17:05:26

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3342200

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Data signed: (b) (4) 29 Mar 2021 15:07:51

Generated On: 09 Jun 2021 17:05:26

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

Visit date (dd MMM yyyy)	26 MAR 2021
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Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>

Folder OID	VISIT4
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US3342200

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Data signed: (b) (4) 12 Apr 2021 15:51:33

Generated On: 09 Jun 2021 17:05:26

Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (dd MMM yyyy)	26 MAR 2021
Time of assessment (00:00-23:59)	15:50 (24 HR)
Vital Signs Date and Time (derived)	26 MAR 2021 15:50
Temperature (xxx.x)	98.2 F
Route of measurement	Oral <input checked="" type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	76 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	12 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	112 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	75 mmHg
Diastolic Blood Pressure units	MMHG
Height (derived)	
Weight (derived)	

US3342200

Folder: Visit 4 Day 209 (1)

Form: Physical Examination

Data signed: (b) (4) 29 Mar 2021 15:07:51

Generated On: 09 Jun 2021 17:05:26

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

26 MAR 2021

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

US3342200

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 12 Apr 2021 15:51:33

Generated On: 09 Jun 2021 17:05:26

Was the sample collected?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Collection date (dd MMM yyyy)	26 MAR 2021
Collection time (00:00-23:59)	16:33 (24 HR)
Collection date and time (derived)	26 MAR 2021 16:33

US3342200

Folder: Visit 4 Day 209 (1)

Form: Continuing

Data signed: (b) (4) 29 Mar 2021 15:07:51

Generated On: 09 Jun 2021 17:05:26

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3342200

Folder: Safety Call Day 239 (1)

Form: Safety Call

Data signed: (b) (4) 28 Apr 2021 22:33:29

Generated On: 09 Jun 2021 17:05:26

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

28 APR 2021

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3342200

Folder: Safety Call Day 239 (1)

Form: Continuing

Data signed: (b) (4) 28 Apr 2021 22:33:29

Generated On: 09 Jun 2021 17:05:26

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3342200

Folder: Safety Call Day 269 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:05:26

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

US3342200

Folder: Safety Call Day 269 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:05:26

Is the participant continuing to the next visit?

Yes ☐

No ☐

Continuing Flag

US3342200

Folder: Covid-19 Assessment (1)

Form: COVID-19 Contact

Generated On: 09 Jun 2021 17:05:26

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"/>

US3342200

Folder: Covid-19 Assessment (1)

Form: Generate Next COVID-19 Assessment

Generated On: 09 Jun 2021 17:05:26

Generate Next COVID-19 Assessment

Yes ☐

No ☐

US3342200

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

Form: Visit Date

Data signed: (b) (4) 13 Mar 2021 15:24:15

Generated On: 09 Jun 2021 17:05:26

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

Visit date (dd MMM yyyy)	15 JAN 2021
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Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>

Folder OID	UNBLND_DECIDE
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US3342200

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

Form: Unblinding

Data signed: (b) (4) 13 Mar 2021 15:24:15

Generated On: 09 Jun 2021 17:05:26

Date of updated informed consent (<i>dd MMM yyyy</i>)	15 JAN 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>)	15 JAN 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

US3342200

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

Form: Vital Signs - Dosing

Data signed: (b) (4) 13 Mar 2021 15:24:15

Generated On: 09 Jun 2021 17:05:26

Height	163.5 cm
Weight	65.4 kg
BMI (xxx.x)	24.46483

US3342200

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

Form: Vital Signs - Dosing (1)

Data signed: (b) (4) 13 Mar 2021 15:24:15

Generated On: 09 Jun 2021 17:05:26

Height	163.5 cm
Weight	65.4 kg
BMI (xxx.x)	24.46483
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)	15 JAN 2021
Time of assessment (00:00-23:59)	13:52 (24 HR)
Vital Signs Date and Time (derived)	15 JAN 2021 13:52
Temperature (xxx.x)	97.9 F
Route of measurement	Oral <input checked="" type="radio"/> Axillary <input type="radio"/> Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	79 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	14 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	127 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	85 mmHg
Diastolic Blood Pressure units	MMHG

US3342200

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

Form: Vital Signs - Dosing (2)

Data signed: (b) (4) 13 Mar 2021 15:24:15

Generated On: 09 Jun 2021 17:05:26

Height	163.5 cm
Weight	65.4 kg
BMI (xxx.x)	24.46483
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)	15 JAN 2021
Time of assessment (00:00-23:59)	15:33 (24 HR)
Vital Signs Date and Time (derived)	15 JAN 2021 15:33
Temperature (xxx.x)	97.0 F
Route of measurement	Oral <input checked="" type="radio"/> Axillary <input type="radio"/> Other <input type="radio"/>
If Other, specify _____	
Pulse (xxx)	74 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	123 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	83 mmHg
Diastolic Blood Pressure units	MMHG

US3342200

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

Form: Physical Examination

Data signed: (b) (4) 13 Mar 2021 15:24:15

Generated On: 09 Jun 2021 17:05:26

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

15 JAN 2021

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

US3342200

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

Form: Exposure

Data signed: (b) (4) 13 Mar 2021 15:24:15

Generated On: 09 Jun 2021 17:05:26

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) 15 JAN 2021

What was the treatment time? (00:00-23:59) 15:03 (24 HR)

Treatment Date and Time (derived) 15 JAN 2021 15:03

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

US3342200

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

Form: Immunogenicity Assessment

Data signed: (b) (4) 13 Mar 2021 15:24:15

Generated On: 09 Jun 2021 17:05:26

Was the sample collected?

Yes ☒

No ☐

Collection date (dd MMM yyyy)

15 JAN 2021

Collection time (00:00-23:59)

14:30 (24 HR)

Collection date and time (derived)

15 JAN 2021 14:30

US3342200

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

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Data signed: (b) (4) 13 Mar 2021 15:24:15

Generated On: 09 Jun 2021 17:05:26

Was the sample collected?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>

Collection date (dd MMM yyyy)	15 JAN 2021
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Collection time (00:00 - 23:59)	14:31
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Collection Date and Time (derived)	15 JAN 2021 14:31
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US3342200

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

Form: Continuing

Data signed: (b) (4) 13 Mar 2021 15:24:15

Generated On: 09 Jun 2021 17:05:26

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3342200

Folder: Safety Call OL-D8 (1)

Form: Safety Call

Data signed: (b) (4) 13 Mar 2021 16:12:03

Generated On: 09 Jun 2021 17:05:26

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

22 JAN 2021

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3342200

Folder: Safety Call OL-D8 (1)

Form: Continuing

Data signed: (b) (4) 13 Mar 2021 16:12:03

Generated On: 09 Jun 2021 17:05:26

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

US3342200

Folder: OL-D29 (1)

Form: Visit Date

Data signed: (b) (4) 29 Mar 2021 15:07:51

Generated On: 09 Jun 2021 17:05:26

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	23 FEB 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

US3342200

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Data signed: (b) (4) 13 Mar 2021 15:24:15

Generated On: 09 Jun 2021 17:05:26

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)	23 FEB 2021
Time of assessment (00:00-23:59)	08:46 (24 HR)
Vital Signs Date and Time (derived)	23 FEB 2021 08:46
Temperature (xxx.x)	98.3 F
Route of measurement	Oral <input checked="" type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	81 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	121 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	79 mmHg
Diastolic Blood Pressure units	MMHG

US3342200

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Data signed: (b) (4) 13 Mar 2021 15:24:15

Generated On: 09 Jun 2021 17:05:26

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)	23 FEB 2021
Time of assessment (00:00-23:59)	10:12 (24 HR)
Vital Signs Date and Time (derived)	23 FEB 2021 10:12
Temperature (xxx.x)	98.4 F
Route of measurement	Oral <input checked="" type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	76 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	14 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	128 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	84 mmHg
Diastolic Blood Pressure units	MMHG

US3342200

Folder: OL-D29 (1)

Form: Physical Examination

Data signed: (b) (4) 13 Mar 2021 15:24:15

Generated On: 09 Jun 2021 17:05:26

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.

US3342200

Folder: OL-D29 (1)

Form: Exposure

Data signed: (b) (4) 13 Mar 2021 15:24:15

Generated On: 09 Jun 2021 17:05:26

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) 23 FEB 2021

What was the treatment time? (00:00-23:59) 09:42 (24 HR)

Treatment Date and Time (derived) 23 FEB 2021 09:42

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

US3342200

Folder: OL-D29 (1)

Form: Continuing

Data signed: (b) (4) 13 Mar 2021 15:24:15

Generated On: 09 Jun 2021 17:05:26

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3342200

Folder: Safety Call OL-D36 (1)

Form: Safety Call

Data signed: (b) (4) 13 Mar 2021 16:12:03

Generated On: 09 Jun 2021 17:05:26

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

02 MAR 2021

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3342200

Folder: Safety Call OL-D36 (1)

Form: Continuing

Data signed: (b) (4) 13 Mar 2021 16:12:03

Generated On: 09 Jun 2021 17:05:26

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3342200

Folder: OL-D57 (1)

Form: Visit Date

Data signed: (b) (4) 29 Mar 2021 15:07:51

Generated On: 09 Jun 2021 17:05:26

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	26 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	OLD57

US3342200

Folder: OL-D57 (1)

Form: Vital Signs

Data signed: (b) (4) 29 Mar 2021 15:07:51

Generated On: 09 Jun 2021 17:05:26

Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (<i>dd MMM yyyy</i>)	26 MAR 2021
Time of assessment (<i>00:00-23:59</i>)	15:50 (24 HR)
Vital Signs Date and Time (derived)	26 MAR 2021 15:50
Temperature (<i>xxx.x</i>)	98.2 F
Route of measurement	Oral <input checked="" type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	
Pulse (<i>xxx</i>)	76 beats/min
Pulse units	BPM
Respiratory Rate (<i>xxx</i>)	12 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (<i>xxx</i>)	112 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (<i>xxx</i>)	75 mmHg
Diastolic Blood Pressure units	MMHG
Height (derived)	
Weight (derived)	

US3342200

Folder: OL-D57 (1)

Form: Physical Examination

Data signed: (b) (4) 29 Mar 2021 15:07:51

Generated On: 09 Jun 2021 17:05:26

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

26 MAR 2021

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

US3342200

Folder: OL-D57 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 12 Apr 2021 15:51:33

Generated On: 09 Jun 2021 17:05:26

Was the sample collected?

Yes ☒

No ☐

Collection date (dd MMM yyyy)

26 MAR 2021

Collection time (00:00-23:59)

16:33 (24 HR)

Collection date and time (derived)

26 MAR 2021 16:33

US3342200

Folder: Unscheduled 23 Feb 2021

Form: Unscheduled Visit Assessment

Data signed: (b) (4) 13 Mar 2021 16:12:03

Generated On: 09 Jun 2021 17:05:26

Visit Date	23 FEB 2021
Please check all assessments that apply for this visit	
Physical Exam	False
Vital Signs	False
Immunogenicity Assessment	True
Pregnancy Test	False

US3342200

Folder: **Unscheduled 23 Feb 2021**

Form: **Immunogenicity Assessment**

Data signed: (b) (4) 13 Mar 2021 16:12:03

Generated On: 09 Jun 2021 17:05:26

Was the sample collected?

Yes ☒

No ☐

Collection date (*dd MMM yyyy*)

23 FEB 2021

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

09:03 (24 HR)

Collection date and time (derived)

23 FEB 2021 09:03

US3342200

Folder: Adverse Events

Form: Adverse Events Summary

Data signed: (b) (4) 22 Mar 2021 13:29:43

Generated On: 09 Jun 2021 17:05:26

Did the participant experience any adverse events?

Yes ☒

No ☐

If Yes, enter details on the Adverse Events form.

US3342200

Folder: Adverse Events

Form: Adverse Events (1)

Data signed: (b) (4) 28 Apr 2021 22:33:29

Generated On: 09 Jun 2021 17:05:26

AEID

Adverse event

ATOPIC DERMATITIS
EXACERBATION

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)

04 SEP 2020

Start time (00:00-23:59)

22:00 (24 HR)

AE start date and time (derived)

04 SEP 2020 22:00

Ongoing?

Yes ☐

No ☒

If not Ongoing, end date (dd MMM yyyy)

16 OCT 2020

End time (00:00-23:59)

09:00 (24 HR)

AE End Date and Time (derived)

16 OCT 2020 09:00

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 ☐

PRODUCTION RELEASE (v12.003

661 of 4196

EAB) (1725)

US3342200

Folder: Adverse Events

Form: Adverse Events (1)

Data signed: (b) (4) 28 Apr 2021 22:33:29

Generated On: 09 Jun 2021 17:05:26

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 checked="" type="radio"/> Dose Delayed <input type="radio"/> Investigational Product Withdrawn <input type="radio"/> Not Applicable <input type="radio"/>
Other action taken (check all that apply)	
None	False
Concomitant Medication	True
Concomitant Procedure	False
Outcome	Fatal <input type="radio"/> Not Recovered/Not Resolved <input type="radio"/> Recovered/Resolved <input checked="" type="radio"/> Recovered/Resolved with Sequelae <input type="radio"/> Recovering/Resolving <input type="radio"/> Unknown <input type="radio"/>
If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:	
Narrative	
Serious Adverse Event Derived (CSA Programming Field Only)	0
Medically Attended AE Derived (CSA Programming Field Only)	0
Admitted to ICU Derived (CSA Programming Field Only)	

US3342200

Folder: Adverse Events

Form: Adverse Events (2)

Data signed: (b) (4) 28 Apr 2021 22:33:29

Generated On: 09 Jun 2021 17:05:26

AEID

Adverse event

MYALGIA BILATERAL UPPER
ARMS AND HIPS

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)

5 OCT 2020

Start time (00:00-23:59)

AE start date and time (derived)

Ongoing?

Yes ☐

No ☒

If not Ongoing, end date (dd MMM yyyy)

16 OCT 2020

End time (00:00-23:59)

AE End Date and Time (derived)

Severity

Grade 1/Mild ☒

Grade 2/Moderate ☐

Grade 3/Severe ☐

Grade 4 ☐

Is the adverse event serious?

Yes ☐

No ☒

AE is serious due To (check all that apply)

Death

False

Life threatening

False

Requires inpatient or prolongation of existing Hospitalization

False

Hospital Admission Date (dd MMM yyyy)

Hospital Discharge Date (dd MMM yyyy)

Admitted to ICU?

Yes ☐

No ☐

Unknown ☐

PRODUCTION RELEASE (v12.003

EAB) (1725)

663 of 4196

US3342200

Folder: Adverse Events

Form: Adverse Events (2)

Data signed: (b) (4) 28 Apr 2021 22:33:29

Generated On: 09 Jun 2021 17:05:26

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 type="radio"/> Related <input checked="" 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	True
Concomitant Medication	False
Concomitant Procedure	False
Outcome	Fatal <input type="radio"/> Not Recovered/Not Resolved <input type="radio"/> Recovered/Resolved <input checked="" type="radio"/> Recovered/Resolved with Sequelae <input type="radio"/> Recovering/Resolving <input type="radio"/> Unknown <input type="radio"/>
If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:	
Narrative	
Serious Adverse Event Derived (CSA Programming Field Only)	0
Medically Attended AE Derived (CSA Programming Field Only)	0
Admitted to ICU Derived (CSA Programming Field Only)	

US3342200

Folder: Adverse Events

Form: Adverse Events (3)

Data signed: (b) (4) 28 Apr 2021 22:33:29

Generated On: 09 Jun 2021 17:05:26

AEID

Adverse event

FATIGUE

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)

4 OCT 2020

Start time (00:00-23:59)

AE start date and time (derived)

Ongoing?

Yes ☐

No ☒

If not Ongoing, end date (dd MMM yyyy)

16 OCT 2020

End time (00:00-23:59)

AE End Date and Time (derived)

Severity

Grade 1/Mild ☒

Grade 2/Moderate ☐

Grade 3/Severe ☐

Grade 4 ☐

Is the adverse event serious?

Yes ☐

No ☒

AE is serious due To (check all that apply)

Death

False

Life threatening

False

Requires inpatient or prolongation of existing Hospitalization

False

Hospital Admission Date (dd MMM yyyy)

Hospital Discharge Date (dd MMM yyyy)

Admitted to ICU?

Yes ☐

No ☐

Unknown ☐

Number of Days in ICU

PRODUCTION RELEASE (v12.003

665 of 4196

EAB) (1725)

US3342200

Folder: Adverse Events

Form: Adverse Events (3)

Data signed: (b) (4) 28 Apr 2021 22:33:29

Generated On: 09 Jun 2021 17:05:26

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 type="radio"/> Related <input checked="" 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 checked="" type="radio"/> Dose Delayed <input type="radio"/> Investigational Product <input type="radio"/> Withdrawn <input type="radio"/> Not Applicable <input type="radio"/>
Other action taken (check all that apply)	
None	True
Concomitant Medication	False
Concomitant Procedure	False
Outcome	Fatal <input type="radio"/> Not Recovered/Not Resolved <input type="radio"/> Recovered/Resolved <input checked="" type="radio"/> Recovered/Resolved with Sequelae <input type="radio"/> Recovering/Resolving <input type="radio"/> Unknown <input type="radio"/>
If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:	
<hr/>	
Narrative	
<hr/>	
Serious Adverse Event Derived (CSA Programming Field Only)	0
Medically Attended AE Derived (CSA Programming Field Only)	0
Admitted to ICU Derived (CSA Programming Field Only)	

US3342200

Folder: Adverse Events

Form: Adverse Events (4)

Data signed: (b) (4) 28 Apr 2021 22:33:29

Generated On: 09 Jun 2021 17:05:26

AEID	USA-US203-2020-MRNA-1273-P30 1000006
Adverse event	DUCTAL CARCINOMA IN SITU RIGHT BREAST
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)	20 NOV 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)	13 JAN 2021
End time (00:00-23:59)	
AE End Date and Time (derived)	
Severity	Grade 1/Mild <input type="radio"/> Grade 2/Moderate <input type="radio"/> Grade 3/Severe <input checked="" type="radio"/> Grade 4 <input type="radio"/>
Is the adverse event serious?	Yes <input checked="" type="radio"/> No <input type="radio"/>
AE is serious due To (check all that apply)	
Death	False
Life threatening	False
Requires inpatient or prolongation of existing Hospitalization	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"/>
PRODUCTION RELEASE (v12.003 EAB) (1725)	667 of 4196

US3342200

Folder: Adverse Events

Form: Adverse Events (4)

Data signed: (b) (4) 28 Apr 2021 22:33:29

Generated On: 09 Jun 2021 17:05:26

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 <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 type="radio"/> Recovered/Resolved with Sequelae <input checked="" type="radio"/> Recovering/Resolving <input type="radio"/> Unknown <input type="radio"/>
If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:	PATIENT REPORTS SHE WILL BE STARTING HORMONE BLOCKER MEDICATION THIS THURSDAY (04MAR2021) AS RECOMMENDED BY ONCOLOGIST FOR PREVENTION OF DUCTAL CARCINOMA RECURRENCE.

Narrative

PRODUCTION RELEASE (v12.003
EAB) (1725)

668 of 4196

US3342200

Folder: Adverse Events

Form: Adverse Events (4)

Data signed: (b) (4) 28 Apr 2021 22:33:29

Generated On: 09 Jun 2021 17:05:26

PATIENT HAD AN ABNORMAL MAMMOGRAM JUL2020 RIGHT BREAST AND HAD A RIGHT BREAST BIOSPY. RESULTS FROM ULTRASOUND AND MAMMOGRAM SHOWED CATEGORY 3 LESION AT SITE OF MASS. RESULTS FROM AUG2020 BIOPSY WERE BENIGN WITH FIBROCYSTIC CHANGES AND CALCIFICATIONS. PATIENT HAD U/S NOV2020 AND THEN HAD A LUMPECTOMY OF RIGHT BREAST 18NOV2020. PATIENT WAS DIAGNOSED WITH DUCTAL CARCINOMA IN SITU OF THE RIGHT BREAST FOLLOWING BIOPSY ON 20NOV2020. PATHOLOGY REPORT SHOWED CATEGORY 3 LESION AT SITE OF MASS. PATHOLOGY REPORT IDENTIFIED DUCTAL CARCINOMA IN SITU GRADE 2-3 MEASURING YP YO 9 MM IN DIMESNION. PATIENT WILL BE SEEING BREAST CANCER SPECIALIST AND HAS NOT STARTED MEDICATION OR RADIATION AT THIS TIME. PATIENT SAW ONCOLOGIST 13JAN2021. TOLD HER LESION WAS "PRE-CANCER" AND THAT SHE WOULD NOT NEED ANY FURTHER RADIATION OR MEDICATION AT THIS TIME.

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)	

US3342200

Folder: Adverse Events

Form: Adverse Events (5)

Data signed: (b) (4) 28 Apr 2021 22:33:29

Generated On: 09 Jun 2021 17:05:26

AEID

Adverse event

RADIATION DERMATITIS

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)

21 JAN 2021

Start time (00:00-23:59)

AE start date and time (derived)

Ongoing?

Yes ☐

No ☒

If not Ongoing, end date (dd MMM yyyy)

11 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 ☐

Number of Days in ICU

PRODUCTION RELEASE (v12.003

670 of 4196

EAB) (1725)

US3342200

Folder: Adverse Events

Form: Adverse Events (5)

Data signed: (b) (4) 28 Apr 2021 22:33:29

Generated On: 09 Jun 2021 17:05:26

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	True
Concomitant Procedure	False
Outcome	Fatal <input type="radio"/> Not Recovered/Not Resolved <input type="radio"/> Recovered/Resolved <input checked="" type="radio"/> Recovered/Resolved with Sequelae <input type="radio"/> Recovering/Resolving <input type="radio"/> Unknown <input type="radio"/>
If outcome is Recovered/Resolved with Sequelae, please specify the sequelae: _____	
Narrative _____	
Serious Adverse Event Derived (CSA Programming Field Only)	0
Medically Attended AE Derived (CSA Programming Field Only)	1
Admitted to ICU Derived (CSA Programming Field Only)	_____

US3342200

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination Summary

Data signed: (b) (4) 13 Mar 2021 15:24:14

Generated On: 09 Jun 2021 17:05:26

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

Yes ☒

No ☐

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

US3342200

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Data signed: (b) (4) 30 Apr 2021 22:17:54

Generated On: 09 Jun 2021 17:05:26

Name of Medication VITAMIN D

Prophylaxis Yes ☐
No ☒

Indication VITAMIN D DEFICIENCY

Dose per administration 5000

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

PRODUCTION RELEASE (v12.003

673 of 4196

EAB) (1725)

US3342200

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Data signed: (b) (4) 30 Apr 2021 22:17:54

Generated On: 09 Jun 2021 17:05:26

	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 2015	
Start date completely unknown	False	
Ongoing?	Yes	<input checked="" type="radio"/>
	No	<input type="radio"/>
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived)	1	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input checked="" type="radio"/>
	804	<input type="radio"/>

US3342200

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Data signed: (b) (4) 30 Apr 2021 22:17:54

Generated On: 09 Jun 2021 17:05:26

Name of Medication SINGULAIR

Prophylaxis Yes ☐
No ☒

Indication SEASONAL ALLERGIES

Dose per administration 10

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

PRODUCTION RELEASE (v12.003

EAB) (1725)

675 of 4196

US3342200

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Data signed: (b) (4) 30 Apr 2021 22:17:54

Generated On: 09 Jun 2021 17:05:26

	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) _____		
Interval Dosage Unit Number (derived) _____		
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input type="radio"/>

US3342200

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Data signed: (b) (4) 30 Apr 2021 22:17:54

Generated On: 09 Jun 2021 17:05:26

Name of Medication FLU VACCINE

Prophylaxis Yes ☒
No ☐

Indication INFLUENZA PREVENTION

Dose per administration 1

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

If dose unit is Other, specify INJECTION

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

If frequency is Other, specify

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

PRODUCTION RELEASE (v12.003

EAB) (1725)

677 of 4196

US3342200

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Data signed: (b) (4) 30 Apr 2021 22:17:54

Generated On: 09 Jun 2021 17:05:26

	Intramuscular	<input checked="" type="radio"/>
	Respiratory (Inhalation)	<input type="radio"/>
	Intralesional	<input type="radio"/>
	Intraperitoneal	<input type="radio"/>
	Nasal	<input type="radio"/>
	Vaginal	<input type="radio"/>
	Rectal	<input type="radio"/>
	Intravenous	<input type="radio"/>
	Intravenous Bolus	<input type="radio"/>
	Intravenous Drip	<input type="radio"/>
	Other	<input type="radio"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)		05 AUG 2020
Start date completely unknown		False
Ongoing?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
If not Ongoing, End date (dd MMM yyyy)		05 AUG 2020
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived) _____		
Interval Dosage Unit Number (derived) _____		
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input type="radio"/>

US3342200

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Data signed: (b) (4) 30 Apr 2021 22:17:54

Generated On: 09 Jun 2021 17:05:26

Name of Medication TRIAMCINOLONE 1%

Prophylaxis Yes ☐
No ☒

Indication ATOPIC DERMATITIS

Dose per administration 1

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

If dose unit is Other, specify APPLICATION

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

679 of 4196

EAB) (1725)

US3342200

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Data signed: (b) (4) 30 Apr 2021 22:17:54

Generated On: 09 Jun 2021 17:05:26

	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 2000	
Start date completely unknown	False	
Ongoing?	Yes	<input checked="" type="radio"/>
	No	<input type="radio"/>
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived) _____		
Interval Dosage Unit Number (derived) _____		
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input type="radio"/>

US3342200

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Data signed: (b) (4) 30 Apr 2021 22:17:54

Generated On: 09 Jun 2021 17:05:26

Name of Medication ACETAMINOPHEN EXTRA
STRENGTH

Prophylaxis Yes ☐
No ☒

Indication HEADACHE (SOLICITED
REACTION - VACCINE #2)

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 ☐

PRODUCTION RELEASE (v12.003
EAB) (1725)

681 of 4196

US3342200

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Data signed: (b) (4) 30 Apr 2021 22:17:54

Generated On: 09 Jun 2021 17:05:26

	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)		03 OCT 2020
Start date completely unknown		False
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)		03 OCT 2020
Was this medication taken for solicited event?	Yes	<input checked="" type="checkbox"/>
	No	<input type="checkbox"/>
Separate Dosage Number (derived) _____		
Interval Dosage Unit Number (derived) _____		
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input type="checkbox"/>

US3342200

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Data signed: (b) (4) 30 Apr 2021 22:17:54

Generated On: 09 Jun 2021 17:05:26

Name of Medication SILVER SULFADIAZINE

Prophylaxis Yes ☐
No ☒

Indication RADIATION DERMATITIS

Dose per administration 1

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

If dose unit is Other, specify APPLICATION

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)

683 of 4196

US3342200

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Data signed: (b) (4) 30 Apr 2021 22:17:54

Generated On: 09 Jun 2021 17:05:26

	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)	21 JAN 2021	
Start date completely unknown	False	
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)	11 FEB 2021	
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived)	2	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input checked="" type="checkbox"/>

US3342200

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Data signed: (b) (4) 30 Apr 2021 22:17:54

Generated On: 09 Jun 2021 17:05:26

Name of Medication TAMOXIFEN

Prophylaxis Yes ☐
No ☒

Indication DUCTAL CARCINOMA IN SITU
RIGHT BREAST

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 ☐

PRODUCTION RELEASE (v12.003
EAB) (1725)

685 of 4196

US3342200

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Data signed: (b) (4) 30 Apr 2021 22:17:54

Generated On: 09 Jun 2021 17:05:26

	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)		10 APR 2021
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"/>

US3342200

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures Summary

Data signed: (b) (4) 13 Mar 2021 15:24:15

Generated On: 09 Jun 2021 17:05:26

Were any concomitant procedures performed?

Yes ☒

No ☐

If yes, please complete Concomitant Procedures form.

US3342200

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures

Data signed: (b) (4) 22 Mar 2021 13:32:48

Generated On: 09 Jun 2021 17:05:26

Procedure/Surgery date (dd MMM yyyy)	Procedure/Surgery	Indication	If indication is Other, specify
18 NOV 2020	RIGHT BREAST LUMPECTOMY	Adverse Event	
06 NOV 2020	RIGHT BREAST ULTRASOUND	Diagnostic	
22 DEC 2020	RADIATION THERAPY	Adverse Event	

US3342200

Folder: End of Study (1)

Form: Dosing Discontinuation

Generated On: 09 Jun 2021 17:05:26

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

US3342200

Folder: End of Study (1)

Form: End of Study / Study Discontinuation

Generated On: 09 Jun 2021 17:05:26

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 ☐

US3342200

Folder: SAE USA-US203-2020-MRNA-1273-P301000006

Form: Safety Report Form

Data signed: (b) (4) 30 Apr 2021 22:17:54

Generated On: 09 Jun 2021 17:05:26

SAEID	USA-US203-2020-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	PAUL
Investigator's Last Name	PICKRELL
Site Address: Street	
Site Address: City	
Site Address: State	
Site Address: Postal Code	
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	10

US3342200

Folder: SAE USA-US203-2020-MRNA-1273-P301000006

Form: Safety Report Form (1)

Data signed: (b) (4) 30 Apr 2021 22:17:54

Generated On: 09 Jun 2021 17:05:26

SAEID	USA-US203-2020-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	PAUL
Investigator's Last Name	PICKRELL
Site Address: Street	
Site Address: City	
Site Address: State	
Site Address: Postal Code	
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	10
Date of submission (Pre-filled from custom function)	24/NOV/2020 20:40
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

US3342200

Folder: SAE USA-US203-2020-MRNA-1273-P301000006

Form: Safety Report Form (2)

Data signed: (b) (4) 30 Apr 2021 22:17:54

Generated On: 09 Jun 2021 17:05:26

SAEID	USA-US203-2020-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	PAUL
Investigator's Last Name	PICKRELL
Site Address: Street	
Site Address: City	
Site Address: State	
Site Address: Postal Code	
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	10
Date of submission (Pre-filled from custom function)	04/DEC/2020 09:37
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

US3342200

Folder: SAE USA-US203-2020-MRNA-1273-P301000006

Form: Safety Report Form (3)

Data signed: (b) (4) 30 Apr 2021 22:17:54

Generated On: 09 Jun 2021 17:05:26

SAEID	USA-US203-2020-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	PAUL
Investigator's Last Name	PICKRELL
Site Address: Street	
Site Address: City	
Site Address: State	
Site Address: Postal Code	
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	10
Date of submission (Pre-filled from custom function)	10/DEC/2020 13:48
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

US3342200

Folder: SAE USA-US203-2020-MRNA-1273-P301000006

Form: Safety Report Form (4)

Data signed: (b) (4) 30 Apr 2021 22:17:54

Generated On: 09 Jun 2021 17:05:26

SAEID	USA-US203-2020-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	PAUL
Investigator's Last Name	PICKRELL
Site Address: Street	
Site Address: City	
Site Address: State	
Site Address: Postal Code	
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	10
Date of submission (Pre-filled from custom function)	19/JAN/2021 11:03
Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.	True

US3342200

Folder: SAE USA-US203-2020-MRNA-1273-P301000006

Form: Safety Report Form (5)

Data signed: (b) (4) 30 Apr 2021 22:17:54

Generated On: 09 Jun 2021 17:05:26

SAEID	USA-US203-2020-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	PAUL
Investigator's Last Name	PICKRELL
Site Address: Street	
Site Address: City	
Site Address: State	
Site Address: Postal Code	
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	10
Date of submission (Pre-filled from custom function)	08/FEB/2021 12:17
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

US3342200

Folder: SAE USA-US203-2020-MRNA-1273-P301000006

Form: Safety Report Form (6)

Data signed: (b) (4) 30 Apr 2021 22:17:54

Generated On: 09 Jun 2021 17:05:26

SAEID	USA-US203-2020-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	PAUL
Investigator's Last Name	PICKRELL
Site Address: Street	
Site Address: City	
Site Address: State	
Site Address: Postal Code	
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	10
Date of submission (Pre-filled from custom function)	03/MAR/2021 11:21
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

US3342200

Folder: SAE USA-US203-2020-MRNA-1273-P301000006

Form: Safety Report Form (7)

Data signed: (b) (4) 30 Apr 2021 22:17:54

Generated On: 09 Jun 2021 17:05:26

SAEID	USA-US203-2020-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	PAUL
Investigator's Last Name	PICKRELL
Site Address: Street	
Site Address: City	
Site Address: State	
Site Address: Postal Code	
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	10
Date of submission (Pre-filled from custom function)	12/MAR/2021 12:18
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

US3342200

Folder: SAE USA-US203-2020-MRNA-1273-P301000006

Form: Safety Report Form (8)

Data signed: (b) (4) 30 Apr 2021 22:17:54

Generated On: 09 Jun 2021 17:05:26

SAEID	USA-US203-2020-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	PAUL
Investigator's Last Name	PICKRELL
Site Address: Street	
Site Address: City	
Site Address: State	
Site Address: Postal Code	
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	10
Date of submission (Pre-filled from custom function)	15/MAR/2021 13:27
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

US3342200

Folder: SAE USA-US203-2020-MRNA-1273-P301000006

Form: Safety Report Form (9)

Data signed: (b) (4) 30 Apr 2021 22:17:54

Generated On: 09 Jun 2021 17:05:26

SAEID	USA-US203-2020-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	PAUL
Investigator's Last Name	PICKRELL
Site Address: Street	
Site Address: City	
Site Address: State	
Site Address: Postal Code	
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	10
Date of submission (Pre-filled from custom function)	30/MAR/2021 11:11
Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.	True

US3342200

Folder: SAE USA-US203-2020-MRNA-1273-P301000006

Form: Safety Report Form (10)

Data signed: (b) (4) 30 Apr 2021 22:17:54

Generated On: 09 Jun 2021 17:05:26

SAEID	USA-US203-2020-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	PAUL
Investigator's Last Name	PICKRELL
Site Address: Street	
Site Address: City	
Site Address: State	
Site Address: Postal Code	
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	10
Date of submission (Pre-filled from custom function)	29/APR/2021 10:00
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

US3342200 (Prod: Tekton Research- Austin)

US3342200

Form: Participant Creation

Generated On: 09 Jun 2021 17:05:26

[Participant ID](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 17:10:36
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:24:15
User entered 'US3342200'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	04 Sep 2020 21:19:32

US3342200

Folder: Screening

Form: Visit Date

Generated On: 09 Jun 2021 17:05:26

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:18:40
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 16:12:04
User entered 'Yes (Y)'	(b) (4) Stefanie Mott (b) (4)	04 Sep 2020 21:45:17

US3342200

Folder: Screening

Form: Visit Date

Generated On: 09 Jun 2021 17:05:26

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:18:40
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 16:12:04
User entered '04 SEP 2020'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	04 Sep 2020 21:19:33

US3342200

Folder: Screening

Form: Visit Date

Generated On: 09 Jun 2021 17:05:26

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:18:40
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 16:12:04
User entered 'Clinic (Clinic)'	(b) (4) Stefanie Mott (b) (4)	04 Sep 2020 21:45:17

US3342200

Folder: Screening

Form: Visit Date

Generated On: 09 Jun 2021 17:05:26

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:18:40
User entered 'SCRN'	System	04 Sep 2020 21:45:17

US3342200

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 17:05:26

Date of Birth (MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:18:40
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 16:12:04
User entered (b) (6) 1975'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	04 Sep 2020 21:19:34

US3342200

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 17:05:26

[Age](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:18:40
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 16:12:04
User entered '44'	(b) (4) Stefanie Mott (b) (4)	04 Sep 2020 21:45:43

US3342200

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 17:05:26

[Age Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:18:40
User entered 'YEARS'	System	04 Sep 2020 21:45:43

US3342200

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 17:05:26

[Age \(Derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:18:40
User entered '44'	System	04 Sep 2020 21:46:03

US3342200

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 17:05:26

[Sex](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:18:40
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 16:12:04
User entered 'Female (F)'	(b) (4) Stefanie Mott (b) (4)	04 Sep 2020 21:45:43

US3342200

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 17:05:26

[Ethnicity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:18:40
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 16:12:04
User entered 'Hispanic or Latino (HISPANIC OR LATINO)'	(b) (4) Stefanie Mott (b) (4)	04 Sep 2020 21:45:43

US3342200

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 17:05:26

White

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:18:40
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 16:12:04
User entered 'I'	(b) (4) Stefanie Mott (b) (4)	04 Sep 2020 21:45:43

US3342200

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 17:05:26

[Black](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:18:40
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 16:12:04
User entered '0'	(b) (4) Stefanie Mott (b) (4)	04 Sep 2020 21:45:43

US3342200

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 17:05:26

[Asian](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:18:40
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 16:12:04
User entered '0'	(b) (4) Stefanie Mott (b) (4)	04 Sep 2020 21:45:43

US3342200

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 17:05:26

[American Indian or Alaska Native](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:18:40
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 16:12:04
User entered '0'	(b) (4) Stefanie Mott (b) (4)	04 Sep 2020 21:45:43

US3342200

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 17:05:26

[Native Hawaiian or other Pacific Islander](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:18:40
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 16:12:04
User entered '0'	(b) (4) Stefanie Mott (b) (4)	04 Sep 2020 21:45:43

US3342200

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 17:05:26

[Other](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:18:40
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 16:12:04
User entered '0'	(b) (4) Stefanie Mott (b) (4)	04 Sep 2020 21:45:43

US3342200

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 17:05:26

If race is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:18:40
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 16:12:04
User entered empty.	(b) (4) Stefanie Mott (b) (4)	04 Sep 2020 21:45:43

US3342200

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 17:05:26

[Unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:18:40
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 16:12:04
User entered '0'	(b) (4) Stefanie Mott (b) (4)	04 Sep 2020 21:45:43

US3342200

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 17:05:26

[Not reported](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:18:40
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 16:12:04
User entered '0'	(b) (4) Stefanie Mott (b) (4)	04 Sep 2020 21:45:43

US3342200

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 17:05:26

Date of Informed Consent (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:18:40
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 16:12:04
User entered '4 Sep 2020'	(b) (4) Stefanie Mott (b) (4)	04 Sep 2020 21:46:03

US3342200

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 17:05:26

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:18:40
User entered 'Sep 2020'	System	04 Sep 2020 21:46:03

US3342200

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 17:05:26

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:18:40
User entered '2020'	System	04 Sep 2020 21:46:03

US3342200

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 17:05:26

[Protocol Version](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:18:40
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 16:12:04
User entered 'Amendment 3 (3)'	(b) (4) Stefanie Mott (b) (4)	04 Sep 2020 21:46:03

US3342200

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 17:05:26

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:18:40
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 16:12:04
User entered 'Yes (Y)'	(b) (4) Stefanie Mott (b) (4)	04 Sep 2020 21:46:03

US3342200

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 17:05:26

If No, indicate reason for screen fail

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:18:40
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 16:12:04
User entered empty.	(b) (4) Stefanie Mott (b) (4)	04 Sep 2020 21:46:03

US3342200

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 17:05:26

If reason for screen fail is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:18:40
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 16:12:04
User entered empty.	(b) (4) Stefanie Mott (b) (4)	04 Sep 2020 21:46:03

US3342200

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 17:05:26

[Was this participant screened previously?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:18:40
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 16:12:04
User entered 'No (N)'	(b) (4) Stefanie Mott (b) (4)	04 Sep 2020 21:46:03

US3342200

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 17:05:26

[If Yes, previous participant number](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:18:40
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 16:12:04
User entered empty.	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	04 Sep 2020 21:19:33

US3342200

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 17:05:26

[Enrollment Trigger](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:18:40
User entered 'I'	System	04 Sep 2020 21:46:11

US3342200

Folder: Screening

Form: Inclusion/Exclusion Criteria Summary

Generated On: 09 Jun 2021 17:05:26

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:18:40
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 16:12:04
User entered 'Yes (Y)'	(b) (4) Stefanie Mott (b) (4)	04 Sep 2020 21:46:11

US3342200

Folder: Screening

Form: Medical History Summary

Generated On: 09 Jun 2021 17:05:26

[Were any significant conditions reported?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:18:40
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 16:12:04
User entered 'Yes (Y)'	(b) (4) Stefanie Mott (b) (4)	04 Sep 2020 21:46:17

US3342200

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 17:05:26

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:18:40
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 16:12:04
User coded data point as SOC: Surgical and medical procedures, HLGT: Obstetric and gynaecological therapeutic procedures, HLT: Uterine therapeutic procedures, PT: Hysterectomy, LLT: Hysterectomy - version MedDRA\\23.0.	Coder Import (b) (4)	04 Sep 2020 21:58:40
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	04 Sep 2020 21:58:40
Data point term sent to Coder	System	04 Sep 2020 21:57:41
User entered 'HYSTERECTOMY'	Stefanie Mott (b) (4)	04 Sep 2020 21:57:17

US3342200

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 17:05:26

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:18:40
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 16:12:04
User entered '12 Nov 2018'	(b) (4) Stefanie Mott (b) (4)	04 Sep 2020 21:57:17

US3342200

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 17:05:26

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:18:40
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 16:12:04
User entered '0'	(b) (4) Stefanie Mott (b) (4)	04 Sep 2020 21:57:17

US3342200

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 17:05:26

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:18:40
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 16:12:04
User closed query 'Data is required. Please complete.' (Site from System).	(b) (4)	04 Sep 2020 21:58:13
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	04 Sep 2020 21:58:13
User entered 'No (N)' reason for change: Data Entry Error	Stefanie Mott (b) (4)	04 Sep 2020 21:58:13
User opened query 'Data is required. Please complete.' (Site from System).	System	04 Sep 2020 21:57:17
User entered empty.	Stefanie Mott (b) (4)	04 Sep 2020 21:57:17

US3342200

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 17:05:26

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:18:40
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 16:12:04
User entered '12 Nov 2018' reason for change: Data Entry Error	(b) (4)	04 Sep 2020 21:58:13
User entered empty.	Stefanie Mott (b) (4)	04 Sep 2020 21:57:17

US3342200

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 17:05:26

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:18:40
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 16:12:04
User entered '0'	(b) (4) Stefanie Mott (b) (4)	04 Sep 2020 21:57:17

US3342200

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 17:05:26

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:18:40
User entered 'Nov 2018'	System	04 Sep 2020 21:57:17

US3342200

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 17:05:26

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:18:40
User entered '2018'	System	04 Sep 2020 21:57:17

US3342200

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 17:05:26

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:18:40
User entered 'Nov 2018'	System	04 Sep 2020 21:58:13
User entered empty.	System	04 Sep 2020 21:57:17

US3342200

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 17:05:26

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:18:40
User entered '2018'	System	04 Sep 2020 21:58:13
User entered empty.	System	04 Sep 2020 21:57:17

US3342200

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 17:05:26

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:18:40
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 16:12:04
User coded data point as SOC: Investigations, HLG: Investigations, imaging and histopathology procedures NEC, HLT: Investigations NEC, PT: Precancerous cells present, LLT: Precancerous cells present - version MedDRA\\23.0.	Coder Import (b) (4)	05 Sep 2020 07:10:57
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4)	05 Sep 2020 07:10:57
Data point term sent to Coder	System	04 Sep 2020 21:59:43
User entered 'Precancerous cervical cells'	Stefanie Mott (b) (4)	04 Sep 2020 21:59:06

US3342200

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 17:05:26

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:18:40
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 16:12:04
User entered 'UN UNK 2018'	(b) (4) Stefanie Mott (b) (4)	04 Sep 2020 21:59:06

US3342200

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 17:05:26

Start date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:18:40
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 16:12:04
User entered '0'	(b) (4) Stefanie Mott (b) (4)	04 Sep 2020 21:59:06

US3342200

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 17:05:26

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:18:40
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 16:12:04
User entered 'No (N)'	(b) (4) Stefanie Mott (b) (4)	04 Sep 2020 21:59:06

US3342200

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 17:05:26

[If No, please specify the stop date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:18:40
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 16:12:04
User entered '12 Nov 2018'	(b) (4) Stefanie Mott (b) (4)	04 Sep 2020 21:59:06

US3342200

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 17:05:26

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:18:40
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 16:12:04
User entered '0'	(b) (4) Stefanie Mott (b) (4)	04 Sep 2020 21:59:06

US3342200

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 17:05:26

Start Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:18:40
User entered 'Jan 2018'	System	04 Sep 2020 21:59:06

US3342200

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 17:05:26

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:18:40
User entered '2018'	System	04 Sep 2020 21:59:06

US3342200

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 17:05:26

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:18:40
User entered 'Nov 2018'	System	04 Sep 2020 21:59:06

US3342200

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 17:05:26

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:18:40
User entered '2018'	System	04 Sep 2020 21:59:06

US3342200

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 17:05:26

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:18:40
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 16:12:04
User coded data point as SOC: Renal and urinary disorders, HLGT: Urolithiasis, HLT: Renal lithiasis, PT: Nephrolithiasis, LLT: Kidney stones - version MedDRA\\23.0.	Coder Import (b) (4)	04 Sep 2020 22:00:42
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	04 Sep 2020 22:00:42
Data point term sent to Coder	System	04 Sep 2020 21:59:43
User entered 'Kidney stones'	Stefanie Mott (b) (4)	04 Sep 2020 21:59:37

US3342200

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 17:05:26

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:18:40
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 16:12:04
User entered 'UN UNK 2019'	(b) (4) Stefanie Mott (b) (4)	04 Sep 2020 21:59:37

US3342200

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 17:05:26

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:18:40
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 16:12:04
User entered '0'	(b) (4) Stefanie Mott (b) (4)	04 Sep 2020 21:59:37

US3342200

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 17:05:26

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:18:40
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 16:12:04
User entered 'No (N)'	(b) (4) Stefanie Mott (b) (4)	04 Sep 2020 21:59:37

US3342200

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 17:05:26

[If No, please specify the stop date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:18:40
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 16:12:04
User entered 'UN UNK 2019'	(b) (4) Stefanie Mott (b) (4)	04 Sep 2020 21:59:37

US3342200

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 17:05:26

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:18:40
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 16:12:04
User entered '0'	(b) (4) Stefanie Mott (b) (4)	04 Sep 2020 21:59:37

US3342200

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 17:05:26

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:18:40
User entered 'Jan 2019'	System	04 Sep 2020 21:59:37

US3342200

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 17:05:26

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:18:40
User entered '2019'	System	04 Sep 2020 21:59:37

US3342200

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 17:05:26

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:18:40
User entered 'Jan 2019'	System	04 Sep 2020 21:59:37

US3342200

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 17:05:26

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:18:40
User entered '2019'	System	04 Sep 2020 21:59:37

US3342200

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 17:05:26

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:18:40
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 16:12:04
User coded data point as SOC: Immune system disorders, HLGT: Allergic conditions, HLT: Atopic disorders, PT: Seasonal allergy, LLT: Seasonal allergy - version MedDRA\\23.0.	Coder Import (b) (4)	04 Sep 2020 22:01:43
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	04 Sep 2020 22:01:43
Data point term sent to Coder	System	04 Sep 2020 22:00:44
User entered 'Seasonal allergies'	Stefanie Mott (b) (4)	04 Sep 2020 21:59:57

US3342200

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 17:05:26

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:18:40
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 16:12:04
User entered 'UN UNK 1993'	(b) (4) Stefanie Mott (b) (4)	04 Sep 2020 21:59:57

US3342200

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 17:05:26

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:18:40
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 16:12:04
User entered '0'	(b) (4) Stefanie Mott (b) (4)	04 Sep 2020 21:59:57

US3342200

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 17:05:26

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:18:40
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 16:12:04
User entered 'Yes (Y)'	(b) (4) Stefanie Mott (b) (4)	04 Sep 2020 21:59:57

US3342200

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 17:05:26

[If No, please specify the stop date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:18:40
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 16:12:04
User entered empty.	(b) (4) Stefanie Mott (b) (4)	04 Sep 2020 21:59:57

US3342200

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 17:05:26

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:18:40
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 16:12:04
User entered '0'	(b) (4) Stefanie Mott (b) (4)	04 Sep 2020 21:59:57

US3342200

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 17:05:26

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:18:40
User entered 'Jan 1993'	System	04 Sep 2020 21:59:57

US3342200

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 17:05:26

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:18:40
User entered '1993'	System	04 Sep 2020 21:59:57

US3342200

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 17:05:26

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:18:40
User entered empty.	System	04 Sep 2020 21:59:57

US3342200

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 17:05:26

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:18:40
User entered empty.	System	04 Sep 2020 21:59:57

US3342200

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 17:05:26

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:18:40
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 16:12:04
User coded data point as SOC: Skin and subcutaneous tissue disorders, HLGT: Epidermal and dermal conditions, HLT: Dermatitis and eczema, PT: Dermatitis atopic, LLT: Atopic dermatitis - version MedDRA\\23.0.	Coder Import (b) (4)	04 Sep 2020 22:01:42
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	04 Sep 2020 22:01:42
Data point term sent to Coder	System	04 Sep 2020 22:00:46
User entered 'Atopic dermatitis'	Stefanie Mott (b) (4)	04 Sep 2020 22:00:23

US3342200

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 17:05:26

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:18:40
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 16:12:04
User entered 'UN UNK 1990'	(b) (4) Stefanie Mott (b) (4)	04 Sep 2020 22:00:23

US3342200

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 17:05:26

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:18:40
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 16:12:04
User entered '0'	(b) (4) Stefanie Mott (b) (4)	04 Sep 2020 22:00:23

US3342200

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 17:05:26

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:18:40
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 16:12:04
User entered 'Yes (Y)'	(b) (4) Stefanie Mott (b) (4)	04 Sep 2020 22:00:23

US3342200

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 17:05:26

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:18:40
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 16:12:04
User entered empty.	(b) (4) Stefanie Mott (b) (4)	04 Sep 2020 22:00:23

US3342200

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 17:05:26

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:18:40
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 16:12:04
User entered '0'	(b) (4) Stefanie Mott (b) (4)	04 Sep 2020 22:00:23

US3342200

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 17:05:26

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:18:40
User entered 'Jan 1990'	System	04 Sep 2020 22:00:23

US3342200

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 17:05:26

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:18:40
User entered '1990'	System	04 Sep 2020 22:00:23

US3342200

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 17:05:26

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:18:40
User entered empty.	System	04 Sep 2020 22:00:23

US3342200

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 17:05:26

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:18:40
User entered empty.	System	04 Sep 2020 22:00:23

US3342200

Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 17:05:26

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:18:40
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 16:12:04
User coded data point as SOC: Immune system disorders, HLGT: Allergic conditions, HLT: Allergies to foods, food additives, drugs and other chemicals, PT: Rubber sensitivity, LLT: Latex allergy - version MedDRA\\23.0.	Coder Import (b) (4)	04 Sep 2020 23:20:45
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4)	04 Sep 2020 23:20:45
Data point term sent to Coder	System	04 Sep 2020 22:10:02
Coding entries removed.	Stefanie Mott (b) (4)	04 Sep 2020 22:09:48
User entered 'LATEX ALLERGY - hives' reason for change: Data Entry Error	Stefanie Mott (b) (4)	04 Sep 2020 22:09:48
User coded data point as SOC: Immune system disorders, HLGT: Allergic conditions, HLT: Allergies to foods, food additives, drugs and other chemicals, PT: Rubber sensitivity, LLT: Latex allergy - version MedDRA\\23.0.	Coder Import (b) (4)	04 Sep 2020 22:01:43
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	04 Sep 2020 22:01:43
Data point term sent to Coder	System	04 Sep 2020 22:00:46
User entered 'Latex allergy'	Stefanie Mott (b) (4)	04 Sep 2020 22:00:44

US3342200

Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 17:05:26

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:18:40
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 16:12:04
User entered 'UN UNK 1993'	(b) (4) Stefanie Mott (b) (4)	04 Sep 2020 22:00:44

US3342200

Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 17:05:26

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:18:40
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 16:12:04
User entered '0'	(b) (4) Stefanie Mott (b) (4)	04 Sep 2020 22:00:44

US3342200

Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 17:05:26

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:18:40
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 16:12:04
User entered 'Yes (Y)'	(b) (4) Stefanie Mott (b) (4)	04 Sep 2020 22:00:44

US3342200

Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 17:05:26

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:18:40
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 16:12:04
User entered empty.	(b) (4) Stefanie Mott (b) (4)	04 Sep 2020 22:00:44

US3342200

Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 17:05:26

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:18:40
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 16:12:04
User entered '0'	(b) (4) Stefanie Mott (b) (4)	04 Sep 2020 22:00:44

US3342200

Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 17:05:26

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:18:40
User entered 'Jan 1993'	System	04 Sep 2020 22:00:44

US3342200

Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 17:05:26

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:18:40
User entered '1993'	System	04 Sep 2020 22:00:44

US3342200

Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 17:05:26

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:18:40
User entered empty.	System	04 Sep 2020 22:00:44

US3342200

Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 17:05:26

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:18:40
User entered empty.	System	04 Sep 2020 22:00:44

US3342200

Folder: Screening

Form: Medical History (7)

Generated On: 09 Jun 2021 17:05:26

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:18:40
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 16:12:04
User coded data point as SOC: Metabolism and nutrition disorders, HLGT: Vitamin related disorders, HLT: Fat soluble vitamin deficiencies and disorders, PT: Vitamin D deficiency, LLT: Vitamin D deficiency - version MedDRA\\23.0.	Coder Import (b) (4)	04 Sep 2020 22:02:44
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	04 Sep 2020 22:02:44
Data point term sent to Coder	System	04 Sep 2020 22:01:48
User entered 'Vitamin D deficiency'	Stefanie Mott (b) (4)	04 Sep 2020 22:01:13

US3342200

Folder: Screening

Form: Medical History (7)

Generated On: 09 Jun 2021 17:05:26

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:18:40
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 16:12:04
User entered 'UN UNK 2015'	(b) (4) Stefanie Mott (b) (4)	04 Sep 2020 22:01:13

US3342200

Folder: Screening

Form: Medical History (7)

Generated On: 09 Jun 2021 17:05:26

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:18:40
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 16:12:04
User entered '0'	(b) (4) Stefanie Mott (b) (4)	04 Sep 2020 22:01:13

US3342200

Folder: Screening

Form: Medical History (7)

Generated On: 09 Jun 2021 17:05:26

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:18:40
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 16:12:04
User entered 'Yes (Y)'	(b) (4) Stefanie Mott (b) (4)	04 Sep 2020 22:01:13

US3342200

Folder: Screening

Form: Medical History (7)

Generated On: 09 Jun 2021 17:05:26

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:18:40
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 16:12:04
User entered empty.	(b) (4) Stefanie Mott (b) (4)	04 Sep 2020 22:01:13

US3342200

Folder: Screening

Form: Medical History (7)

Generated On: 09 Jun 2021 17:05:26

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:18:40
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 16:12:04
User entered '0'	(b) (4) Stefanie Mott (b) (4)	04 Sep 2020 22:01:13

US3342200

Folder: Screening

Form: Medical History (7)

Generated On: 09 Jun 2021 17:05:26

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:18:40
User entered 'Jan 2015'	System	04 Sep 2020 22:01:13

US3342200

Folder: Screening

Form: Medical History (7)

Generated On: 09 Jun 2021 17:05:26

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:18:40
User entered '2015'	System	04 Sep 2020 22:01:13

US3342200

Folder: Screening

Form: Medical History (7)

Generated On: 09 Jun 2021 17:05:26

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:18:40
User entered empty.	System	04 Sep 2020 22:01:13

US3342200

Folder: Screening

Form: Medical History (7)

Generated On: 09 Jun 2021 17:05:26

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:18:40
User entered empty.	System	04 Sep 2020 22:01:13

US3342200

Folder: Screening

Form: Medical History (8)

Generated On: 09 Jun 2021 17:05:26

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:18:40
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 16:12:04
User coded data point as SOC: Musculoskeletal and connective tissue disorders, HLGT: Joint disorders, HLT: Joint related signs and symptoms, PT: Arthralgia, LLT: Pain in joint involving shoulder region - version MedDRA\\23.0.	Coder Import (b) (4)	08 Oct 2020 17:29:44
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4)	08 Oct 2020 17:29:44
Data point term sent to Coder	System	30 Sep 2020 17:18:46
User entered 'Joint Pain Bilateral Shoulders '	(b) (4), (b) (6)	30 Sep 2020 17:17:58

US3342200

Folder: Screening

Form: Medical History (8)

Generated On: 09 Jun 2021 17:05:26

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:18:40
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 16:12:04
User entered 'UN May 2020'	(b) (4) (b) (4), (b) (6)	30 Sep 2020 17:17:58

US3342200

Folder: Screening

Form: Medical History (8)

Generated On: 09 Jun 2021 17:05:26

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:18:40
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 16:12:04
User entered '0'	(b) (4) (b) (4), (b) (6)	30 Sep 2020 17:17:58

US3342200

Folder: Screening

Form: Medical History (8)

Generated On: 09 Jun 2021 17:05:26

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:18:40
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 16:12:04
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	30 Sep 2020 17:17:58

US3342200

Folder: Screening

Form: Medical History (8)

Generated On: 09 Jun 2021 17:05:26

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:18:40
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 16:12:04
User entered empty.	(b) (4) (b) (4), (b) (6)	30 Sep 2020 17:17:58

US3342200

Folder: Screening

Form: Medical History (8)

Generated On: 09 Jun 2021 17:05:26

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:18:40
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 16:12:04
User entered '0'	(b) (4) (b) (4), (b) (6)	30 Sep 2020 17:17:58

US3342200

Folder: Screening

Form: Medical History (8)

Generated On: 09 Jun 2021 17:05:26

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:18:40
User entered 'May 2020'	System	30 Sep 2020 17:17:58

US3342200

Folder: Screening

Form: Medical History (8)

Generated On: 09 Jun 2021 17:05:26

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:18:40
User entered '2020'	System	30 Sep 2020 17:17:58

US3342200

Folder: Screening

Form: Medical History (8)

Generated On: 09 Jun 2021 17:05:26

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:18:40
User entered empty.	System	30 Sep 2020 17:17:58

US3342200

Folder: Screening

Form: Medical History (8)

Generated On: 09 Jun 2021 17:05:26

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:18:40
User entered empty.	System	30 Sep 2020 17:17:58

US3342200

Folder: Screening

Form: Medical History (9)

Generated On: 09 Jun 2021 17:05:26

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:18:40
User signature succeeded.	Paul Pickrell (b) (4)	29 Mar 2021 15:07:52
User coded data point as SOC: Musculoskeletal and connective tissue disorders, HLGT: Joint disorders, HLT: Joint related signs and symptoms, PT: Arthralgia, LLT: Joint pain - version MedDRA\23.0.	Coder Import (b) (4)	29 Mar 2021 14:45:05
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\23.0.	Coder Import (b) (4)	29 Mar 2021 14:45:05
Data point term sent to Coder	System	15 Mar 2021 14:18:17
Coding entries removed.	Olivia Hapanowicz (b) (4)	15 Mar 2021 14:18:11
Signature has been broken.	(b) (4)	
	Olivia Hapanowicz (b) (4)	15 Mar 2021 14:18:11
User entered 'Joint PAIN BILATERAL LOWER EXTREMITIES' reason for change: Data Entry Error	(b) (4)	
User signature succeeded.	Olivia Hapanowicz (b) (4)	15 Mar 2021 14:18:11
	(b) (4)	
User coded data point as SOC: Musculoskeletal and connective tissue disorders, HLGT: Musculoskeletal and connective tissue disorders NEC, HLT: Musculoskeletal and connective tissue pain and discomfort, PT: Pain in extremity, LLT: Pain of lower extremities - version MedDRA\23.0.	Paul Pickrell (b) (4)	13 Mar 2021 16:12:04
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\23.0.	(b) (4)	
Data point term sent to Coder	Coder Import (b) (4)	30 Sep 2020 17:55:54
User entered 'Bilateral Pain Bilateral lower Extremities'	(b) (4)	
	Coder Import (b) (4)	30 Sep 2020 17:55:54
	(b) (4)	
	System	30 Sep 2020 17:18:47
	(b) (4), (b) (6)	30 Sep 2020 17:18:43

US3342200

Folder: Screening

Form: Medical History (9)

Generated On: 09 Jun 2021 17:05:26

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:18:40
User signature succeeded.	Paul Pickrell (b) (4)	29 Mar 2021 15:07:52
Signature has been broken.	(b) (4)	
	Olivia Hapanowicz (b) (4)	15 Mar 2021 14:18:11
	(b) (4)	
User entered 'UN May 2020' reason for change:	Olivia Hapanowicz (b) (4)	15 Mar 2021 14:18:11
Data Entry Error	(b) (4)	
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 16:12:04
	(b) (4)	
User entered 'UN UNK 2020'	(b) (4), (b) (6)	30 Sep 2020 17:18:43

US3342200

Folder: Screening

Form: Medical History (9)

Generated On: 09 Jun 2021 17:05:26

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:18:40
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 16:12:04
User entered '0'	(b) (4) (b) (4), (b) (6)	30 Sep 2020 17:18:43

US3342200

Folder: Screening

Form: Medical History (9)

Generated On: 09 Jun 2021 17:05:26

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:18:40
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 16:12:04
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	30 Sep 2020 17:18:43

US3342200

Folder: Screening

Form: Medical History (9)

Generated On: 09 Jun 2021 17:05:26

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:18:40
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 16:12:04
User entered empty.	(b) (4) (b) (4), (b) (6)	30 Sep 2020 17:18:43

US3342200

Folder: Screening

Form: Medical History (9)

Generated On: 09 Jun 2021 17:05:26

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:18:40
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 16:12:04
User entered '0'	(b) (4) (b) (4), (b) (6)	30 Sep 2020 17:18:43

US3342200

Folder: Screening

Form: Medical History (9)

Generated On: 09 Jun 2021 17:05:26

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:18:40
User entered 'May 2020'	System	15 Mar 2021 14:18:11
User entered 'Jan 2020'	System	30 Sep 2020 17:18:43

US3342200

Folder: Screening

Form: Medical History (9)

Generated On: 09 Jun 2021 17:05:26

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:18:40
User entered '2020'	System	30 Sep 2020 17:18:43

US3342200

Folder: Screening

Form: Medical History (9)

Generated On: 09 Jun 2021 17:05:26

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:18:40
User entered empty.	System	30 Sep 2020 17:18:43

US3342200

Folder: Screening

Form: Medical History (9)

Generated On: 09 Jun 2021 17:05:26

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:18:40
User entered empty.	System	30 Sep 2020 17:18:43

US3342200

Folder: Screening

Form: Medical History (10)

Generated On: 09 Jun 2021 17:05:26

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:18:40
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 16:12:04
User coded data point as SOC: Neoplasms benign, malignant and unspecified (incl cysts and polyps), HLGT: Breast neoplasms benign (incl nipple), HLT: Breast and nipple neoplasms benign, PT: Benign breast neoplasm, LLT: Breast lump (benign) - version MedDRA\\23.0.	Coder Import (b) (4)	23 Nov 2020 23:05:04
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	23 Nov 2020 23:05:04
Data point term sent to Coder	System	23 Nov 2020 23:03:38
User entered 'right breast lump benign'	Stefanie Mott (b) (4)	23 Nov 2020 23:03:22

US3342200

Folder: Screening

Form: Medical History (10)

Generated On: 09 Jun 2021 17:05:26

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:18:40
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 16:12:04
User entered 'un Aug 2020'	(b) (4) Stefanie Mott (b) (4)	23 Nov 2020 23:03:22

US3342200

Folder: Screening

Form: Medical History (10)

Generated On: 09 Jun 2021 17:05:26

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:18:40
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 16:12:04
User entered '0'	(b) (4) Stefanie Mott (b) (4)	23 Nov 2020 23:03:22

US3342200

Folder: Screening

Form: Medical History (10)

Generated On: 09 Jun 2021 17:05:26

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:18:40
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 16:12:04
User entered 'No (N)'	(b) (4) Stefanie Mott (b) (4)	23 Nov 2020 23:03:22

US3342200

Folder: Screening

Form: Medical History (10)

Generated On: 09 Jun 2021 17:05:26

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:18:40
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 16:12:04
User entered 'un Aug 2020'	(b) (4) Stefanie Mott (b) (4)	23 Nov 2020 23:03:22

US3342200

Folder: Screening

Form: Medical History (10)

Generated On: 09 Jun 2021 17:05:26

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:18:40
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 16:12:04
User entered '0'	(b) (4) Stefanie Mott (b) (4)	23 Nov 2020 23:03:22

US3342200

Folder: Screening

Form: Medical History (10)

Generated On: 09 Jun 2021 17:05:26

Start Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:18:40
User entered 'Aug 2020'	System	23 Nov 2020 23:03:22

US3342200

Folder: Screening

Form: Medical History (10)

Generated On: 09 Jun 2021 17:05:26

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:18:40
User entered '2020'	System	23 Nov 2020 23:03:22

US3342200

Folder: Screening

Form: Medical History (10)

Generated On: 09 Jun 2021 17:05:26

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:18:40
User entered 'Aug 2020'	System	23 Nov 2020 23:03:22

US3342200

Folder: Screening

Form: Medical History (10)

Generated On: 09 Jun 2021 17:05:26

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:18:40
User entered '2020'	System	23 Nov 2020 23:03:22

US3342200

Folder: Screening

Form: Medical History (11)

Generated On: 09 Jun 2021 17:05:26

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:18:40
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 16:12:04
User coded data point as SOC: Investigations, HLG: Reproductive organ and breast investigations (excl hormone analyses), HLT: Reproductive organ and breast histopathology procedures, PT: Biopsy breast, LLT: Breast lump biopsy - version MedDRA\\23.0.	Coder Import (b) (4)	24 Nov 2020 08:10:16
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4)	24 Nov 2020 08:10:16
Data point term sent to Coder	System	23 Nov 2020 23:04:39
User entered 'right breast lump biopsy'	Stefanie Mott (b) (4)	23 Nov 2020 23:03:48

US3342200

Folder: Screening

Form: Medical History (11)

Generated On: 09 Jun 2021 17:05:26

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:18:40
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 16:12:04
User entered 'un Aug 2020'	(b) (4) Stefanie Mott (b) (4)	23 Nov 2020 23:03:48

US3342200

Folder: Screening

Form: Medical History (11)

Generated On: 09 Jun 2021 17:05:26

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:18:40
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 16:12:04
User entered '0'	(b) (4) Stefanie Mott (b) (4)	23 Nov 2020 23:03:48

US3342200

Folder: Screening

Form: Medical History (11)

Generated On: 09 Jun 2021 17:05:26

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:18:40
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 16:12:04
User entered 'No (N)'	(b) (4) Stefanie Mott (b) (4)	23 Nov 2020 23:03:48

US3342200

Folder: Screening

Form: Medical History (11)

Generated On: 09 Jun 2021 17:05:26

[If No, please specify the stop date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:18:40
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 16:12:04
User entered 'un Aug 2020'	(b) (4) Stefanie Mott (b) (4)	23 Nov 2020 23:03:48

US3342200

Folder: Screening

Form: Medical History (11)

Generated On: 09 Jun 2021 17:05:26

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:18:40
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 16:12:04
User entered '0'	(b) (4) Stefanie Mott (b) (4)	23 Nov 2020 23:03:48

US3342200

Folder: Screening

Form: Medical History (11)

Generated On: 09 Jun 2021 17:05:26

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:18:40
User entered 'Aug 2020'	System	23 Nov 2020 23:03:48

US3342200

Folder: Screening

Form: Medical History (11)

Generated On: 09 Jun 2021 17:05:26

Start Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:18:40
User entered '2020'	System	23 Nov 2020 23:03:48

US3342200

Folder: Screening

Form: Medical History (11)

Generated On: 09 Jun 2021 17:05:26

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:18:40
User entered 'Aug 2020'	System	23 Nov 2020 23:03:48

US3342200

Folder: Screening

Form: Medical History (11)

Generated On: 09 Jun 2021 17:05:26

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:18:40
User entered '2020'	System	23 Nov 2020 23:03:48

US3342200

Folder: Screening

Form: Medical History (12)

Generated On: 09 Jun 2021 17:05:26

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:18:40
User signature succeeded.	Paul Pickrell (b) (4)	29 Mar 2021 15:07:52
User coded data point as SOC: Investigations, HLT: Reproductive organ and breast investigations (excl hormone analyses), HLT: Reproductive organ and breast imaging procedures, PT: Mammogram, LLT: Mammogram - version MedDRA\23.0.	Coder Import (b) (4)	15 Mar 2021 14:01:56
User coded data point as Term Coded data point by User: Coder System - version MedDRA\23.0.	Coder Import (b) (4)	15 Mar 2021 14:01:56
Data point term sent to Coder	System	15 Mar 2021 14:00:46
User entered 'mammogram'	Eileen Euperio (b) (4)	15 Mar 2021 13:59:48

US3342200

Folder: Screening

Form: Medical History (12)

Generated On: 09 Jun 2021 17:05:26

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:18:40
User signature succeeded.	Paul Pickrell (b) (4)	29 Mar 2021 15:07:52
User entered 'un Jul 2020'	Eileen Euperio (b) (4)	15 Mar 2021 13:59:48

US3342200

Folder: Screening

Form: Medical History (12)

Generated On: 09 Jun 2021 17:05:26

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:18:40
User signature succeeded.	Paul Pickrell (b) (4)	29 Mar 2021 15:07:52
User entered '0'	Eileen Euperio (b) (4)	15 Mar 2021 13:59:48

US3342200

Folder: Screening

Form: Medical History (12)

Generated On: 09 Jun 2021 17:05:26

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:18:40
User signature succeeded.	Paul Pickrell (b) (4)	29 Mar 2021 15:07:52
User entered 'No (N)'	Eileen Euperio (b) (4)	15 Mar 2021 13:59:48

US3342200

Folder: Screening

Form: Medical History (12)

Generated On: 09 Jun 2021 17:05:26

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:18:40
User signature succeeded.	Paul Pickrell (b) (4)	29 Mar 2021 15:07:52
User entered 'un Jul 2020'	Eileen Euperio (b) (4)	15 Mar 2021 13:59:48

US3342200

Folder: Screening

Form: Medical History (12)

Generated On: 09 Jun 2021 17:05:26

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:18:40
User signature succeeded.	Paul Pickrell (b) (4)	29 Mar 2021 15:07:52
User entered '0'	Eileen Euperio (b) (4)	15 Mar 2021 13:59:48

US3342200

Folder: Screening

Form: Medical History (12)

Generated On: 09 Jun 2021 17:05:26

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:18:40
User entered 'Jul 2020'	System	15 Mar 2021 13:59:48

US3342200

Folder: Screening

Form: Medical History (12)

Generated On: 09 Jun 2021 17:05:26

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:18:40
User entered '2020'	System	15 Mar 2021 13:59:48

US3342200

Folder: Screening

Form: Medical History (12)

Generated On: 09 Jun 2021 17:05:26

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:18:40
User entered 'Jul 2020'	System	15 Mar 2021 13:59:48

US3342200

Folder: Screening

Form: Medical History (12)

Generated On: 09 Jun 2021 17:05:26

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:18:40
User entered '2020'	System	15 Mar 2021 13:59:48

US3342200

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:05:26

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:18:40
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 16:12:04
User entered 'Yes (Y)'	(b) (4) Stefanie Mott (b) (4)	04 Sep 2020 21:47:54

US3342200

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:05:26

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:18:40
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 16:12:04
User entered '4 Sep 2020'	(b) (4) Stefanie Mott (b) (4)	04 Sep 2020 21:47:54

US3342200

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:05:26

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:18:40
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 16:12:04
User entered '15:59'	(b) (4) Stefanie Mott (b) (4)	04 Sep 2020 21:47:54

US3342200

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:05:26

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:18:40
User entered '4 Sep 2020 15:59'	System	04 Sep 2020 21:47:54

US3342200

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:05:26

Height (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:18:40
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 16:12:04
User entered '163.5' cm	(b) (4) Stefanie Mott (b) (4)	04 Sep 2020 21:47:54
DataPoint set to visible.	System	04 Sep 2020 21:46:11

US3342200

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:05:26

Weight (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:18:40
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 16:12:04
User entered '065.4' kg	(b) (4) Stefanie Mott (b) (4)	04 Sep 2020 21:47:54
DataPoint set to visible.	System	04 Sep 2020 21:46:11

US3342200

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:05:26

BMI (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:18:40
User entered '24.46483'	System	04 Sep 2020 21:47:54
DataPoint set to visible.	System	04 Sep 2020 21:46:11

US3342200

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:05:26

[BMI units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:18:40
User entered 'kg/m2'	System	04 Sep 2020 21:47:54
DataPoint set to visible.	System	04 Sep 2020 21:46:11

US3342200

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:05:26

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:18:40
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 16:12:04
User entered missing code ND - Not Done.	(b) (4) Stefanie Mott (b) (4)	04 Sep 2020 21:47:54

US3342200

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:05:26

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:18:40
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 16:12:04
User entered empty.	(b) (4) Stefanie Mott (b) (4)	04 Sep 2020 21:47:54

US3342200

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:05:26

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:18:40
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 16:12:04
User entered empty.	(b) (4) Stefanie Mott (b) (4)	04 Sep 2020 21:47:54

US3342200

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:05:26

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:18:40
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 16:12:04
User entered missing code ND - Not Done.	(b) (4) Stefanie Mott (b) (4)	04 Sep 2020 21:47:54

US3342200

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:05:26

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:18:40
User entered 'bpm'	System	04 Sep 2020 21:47:54

US3342200

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:05:26

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:18:40
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 16:12:04
User entered missing code ND - Not Done.	(b) (4) Stefanie Mott (b) (4)	04 Sep 2020 21:47:54

US3342200

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:05:26

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:18:40
User entered 'breaths/min'	System	04 Sep 2020 21:47:54

US3342200

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:05:26

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:18:40
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 16:12:04
User entered missing code ND - Not Done.	(b) (4) Stefanie Mott (b) (4)	04 Sep 2020 21:47:54

US3342200

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:05:26

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:18:40
User entered 'mmHg'	System	04 Sep 2020 21:47:54

US3342200

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:05:26

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:18:40
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 16:12:04
User entered missing code ND - Not Done.	(b) (4) Stefanie Mott (b) (4)	04 Sep 2020 21:47:54

US3342200

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:05:26

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:18:40
User entered 'mmHg'	System	04 Sep 2020 21:47:54

US3342200

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:05:26

[Height \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:18:40

US3342200

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:05:26

Weight (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:18:40

US3342200

Folder: Screening

Form: Physical Examination

Generated On: 09 Jun 2021 17:05:26

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:18:40
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 16:12:04
User entered 'Yes (Y)'	(b) (4) Stefanie Mott (b) (4)	04 Sep 2020 21:48:07

US3342200

Folder: Screening

Form: Physical Examination

Generated On: 09 Jun 2021 17:05:26

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:18:40
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 16:12:04
User entered '4 Sep 2020'	(b) (4) Stefanie Mott (b) (4)	04 Sep 2020 21:48:07

US3342200

Folder: Screening

Form: Childbearing Potential

Generated On: 09 Jun 2021 17:05:26

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:18:40
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 16:12:04
User entered '4 Sep 2020'	(b) (4) Stefanie Mott (b) (4)	04 Sep 2020 21:50:18

US3342200

Folder: Screening

Form: Childbearing Potential

Generated On: 09 Jun 2021 17:05:26

[Is the participant of childbearing potential?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:18:40
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 16:12:04
User entered 'No (N)'	(b) (4) Stefanie Mott (b) (4)	04 Sep 2020 21:50:18

US3342200

Folder: Screening

Form: Childbearing Potential

Generated On: 09 Jun 2021 17:05:26

[If No, what is the reason?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:18:40
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 16:12:04
User entered 'Surgically sterile (SURGICALLY STERILE)'	(b) (4) Stefanie Mott (b) (4)	04 Sep 2020 21:50:18

US3342200

Folder: Screening

Form: Childbearing Potential

Generated On: 09 Jun 2021 17:05:26

If Partner medically sterile or Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:18:40
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 16:12:04
User entered empty.	(b) (4) Stefanie Mott (b) (4)	04 Sep 2020 21:50:18

US3342200

Folder: Screening

Form: Childbearing Potential

Generated On: 09 Jun 2021 17:05:26

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:18:40
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 16:12:04
User closed query 'Surgically sterile been entered, however date of surgery is missing. Please provide.' (Site from System).	(b) (4)	04 Sep 2020 22:02:01
User entered '12 Nov 2018' reason for change: Data Entry Error	System	04 Sep 2020 22:02:01
User opened query 'Surgically sterile been entered, however date of surgery is missing. Please provide.' (Site from System).	Stefanie Mott (b) (4)	04 Sep 2020 21:50:18
User entered empty.	System	04 Sep 2020 21:50:18

US3342200

Folder: Screening

Form: Childbearing Potential

Generated On: 09 Jun 2021 17:05:26

Date of surgery unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:18:40
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 16:12:04
User entered '0'	(b) (4) Stefanie Mott (b) (4)	04 Sep 2020 21:50:18

US3342200

Folder: Screening

Form: Childbearing Potential

Generated On: 09 Jun 2021 17:05:26

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:18:40
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 16:12:04
User entered empty.	(b) (4) Stefanie Mott (b) (4)	04 Sep 2020 21:50:18

US3342200

Folder: Screening

Form: Childbearing Potential

Generated On: 09 Jun 2021 17:05:26

[Date of last menstruation unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:18:40
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 16:12:04
User entered '0'	(b) (4) Stefanie Mott (b) (4)	04 Sep 2020 21:50:18

US3342200

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:05:26

[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 08:18:40
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 16:12:04
User entered 'No (N)'	(b) (4) Stefanie Mott (b) (4)	04 Sep 2020 21:51:01

US3342200

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:05:26

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 08:18:40
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 16:12:04
User entered 'No (N)'	(b) (4) Stefanie Mott (b) (4)	04 Sep 2020 21:51:01

US3342200

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:05:26

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 08:18:40
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 16:12:04
User entered 'No (N)'	(b) (4) Stefanie Mott (b) (4)	04 Sep 2020 21:51:01

US3342200

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:05:26

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 08:18:40
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 16:12:04
User entered 'No (N)'	(b) (4) Stefanie Mott (b) (4)	04 Sep 2020 21:51:01

US3342200

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:05:26

[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 08:18:40
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 16:12:04
User entered 'No (N)'	(b) (4) Stefanie Mott (b) (4)	04 Sep 2020 21:51:01

US3342200

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:05:26

[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 08:18:40
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 16:12:04
User entered 'No (N)'	(b) (4) Stefanie Mott (b) (4)	04 Sep 2020 21:51:01

US3342200

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:05:26

Border Protection and Military Personnel (e.g., TSA, custom and border protection agents, military personnel not social distancing)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:18:40
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 16:12:04
User entered 'No (N)'	(b) (4) Stefanie Mott (b) (4)	04 Sep 2020 21:51:01

US3342200

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:05:26

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 08:18:40
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 16:12:04
User entered 'No (N)'	(b) (4) Stefanie Mott (b) (4)	04 Sep 2020 21:51:01

US3342200

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:05:26

[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 08:18:40
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 16:12:04
User entered 'No (N)'	(b) (4) Stefanie Mott (b) (4)	04 Sep 2020 21:51:01

US3342200

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:05:26

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 08:18:40
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 16:12:04
User entered 'No (N)'	(b) (4) Stefanie Mott (b) (4)	04 Sep 2020 21:51:01

US3342200

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:05:26

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 08:18:40
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 16:12:04
User entered 'Yes (Y)'	(b) (4) Stefanie Mott (b) (4)	04 Sep 2020 21:51:01

US3342200

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:05:26

[Other](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:18:40
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 16:12:04
User entered 'No (N)'	(b) (4) Stefanie Mott (b) (4)	04 Sep 2020 21:51:01

US3342200

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:05:26

[Specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:18:40
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 16:12:04
User entered empty.	(b) (4) Stefanie Mott (b) (4)	04 Sep 2020 21:51:01

US3342200

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:05:26

No Risk Identified

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:18:40
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 16:12:04
User entered '0'	(b) (4) Stefanie Mott (b) (4)	04 Sep 2020 21:51:01

US3342200

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:05:26

[Resides in Nursing Home or Assisted Living Facility](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:18:40
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 16:12:04
User entered '0'	(b) (4) Stefanie Mott (b) (4)	04 Sep 2020 21:51:01

US3342200

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:05:26

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 08:18:40
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 16:12:04
User entered '0'	(b) (4) Stefanie Mott (b) (4)	04 Sep 2020 21:51:01

US3342200

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:05:26

[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 08:18:40
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 16:12:04
User entered '0'	(b) (4) Stefanie Mott (b) (4)	04 Sep 2020 21:51:01

US3342200

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:05:26

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 08:18:40
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 16:12:04
User entered '0'	(b) (4) Stefanie Mott (b) (4)	04 Sep 2020 21:51:01

US3342200

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:05:26

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:18:40
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 16:12:04
User entered 'I'	(b) (4) Stefanie Mott (b) (4)	04 Sep 2020 21:51:01

US3342200

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:05:26

[Other](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:18:40
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 16:12:04
User entered '0'	(b) (4) Stefanie Mott (b) (4)	04 Sep 2020 21:51:01

US3342200

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:05:26

[Specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:18:40
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 16:12:04
User entered empty.	(b) (4) Stefanie Mott (b) (4)	04 Sep 2020 21:51:01

US3342200

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 09 Jun 2021 17:05:26

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 09:47:07
User signature succeeded.	Paul Pickrell (b) (4)	12 Feb 2021 23:50:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Dec 2020 18:47:36
User entered 'Yes (Y)'	Stefanie Mott (b) (4)	04 Sep 2020 21:51:17

US3342200

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 09 Jun 2021 17:05:26

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 09:47:07
User signature succeeded.	Paul Pickrell (b) (4)	12 Feb 2021 23:50:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Dec 2020 18:47:36
User entered '4 Sep 2020'	Stefanie Mott (b) (4)	04 Sep 2020 21:51:17

US3342200

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 09 Jun 2021 17:05:26

[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 09:47:07
User signature succeeded.	Paul Pickrell (b) (4)	12 Feb 2021 23:50:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Dec 2020 18:47:36
User entered 'Clinic (Clinic)'	Stefanie Mott (b) (4)	04 Sep 2020 21:51:17

US3342200

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 09 Jun 2021 17:05:26

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 09:47:07
User entered 'VISIT1'	System	04 Sep 2020 21:51:17

US3342200

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 17:05:26

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 09:47:07
User signature succeeded.	Paul Pickrell (b) (4)	12 Feb 2021 23:50:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Dec 2020 18:47:42
User entered '04 SEP 2020'	RWS_ENDPOINT ENDPOINT (b) (4)	04 Sep 2020 21:24:20

US3342200

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 17:05:26

[What was the participant's randomization number?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 09:47:07
User signature succeeded.	Paul Pickrell (b) (4)	12 Feb 2021 23:50:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Dec 2020 18:47:42
User entered '111836'	RWS_ENDPOINT ENDPOINT (b) (4)	04 Sep 2020 21:24:20

US3342200

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 17:05:26

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 09:47:07
User signature succeeded.	Paul Pickrell (b) (4)	12 Feb 2021 23:50:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Dec 2020 18:47:42
User entered '>=18 and <65 years and not at risk (1)'	RWS_ENDPOINT ENDPOINT (b) (4)	04 Sep 2020 21:24:20

US3342200

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 17:05:26

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)	14 Apr 2021 09:47:07
User signature succeeded.	Paul Pickrell (b) (4)	12 Feb 2021 23:50:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Dec 2020 18:47:42
User entered 'No (N)'	Stefanie Mott (b) (4)	04 Sep 2020 22:10:53

US3342200

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 17:05:26

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)	14 Apr 2021 09:47:07
User signature succeeded.	Paul Pickrell (b) (4)	12 Feb 2021 23:50:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Dec 2020 18:47:42
User entered 'No (N)'	Stefanie Mott (b) (4)	04 Sep 2020 22:10:53

US3342200

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 17:05:26

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 09:47:07
User signature succeeded.	Paul Pickrell (b) (4)	12 Feb 2021 23:50:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Dec 2020 18:47:42
User entered 'No (N)'	Stefanie Mott (b) (4)	04 Sep 2020 22:10:53

US3342200

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 17:05:26

Diabetes (Type I, Type 2, or gestational)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 09:47:07
User signature succeeded.	Paul Pickrell (b) (4)	12 Feb 2021 23:50:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Dec 2020 18:47:42
User entered 'No (N)'	Stefanie Mott (b) (4)	04 Sep 2020 22:10:53

US3342200

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 17:05:26

[Liver Disease](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 09:47:07
User signature succeeded.	Paul Pickrell (b) (4)	12 Feb 2021 23:50:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Dec 2020 18:47:42
User entered 'No (N)'	Stefanie Mott (b) (4)	04 Sep 2020 22:10:53

US3342200

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 17:05:26

Human Immunodeficiency Virus (HIV) infection

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 09:47:07
User signature succeeded.	Paul Pickrell (b) (4)	12 Feb 2021 23:50:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Dec 2020 18:47:42
User closed query 'Per CDM: This field requires a Yes or No response. Please complete.' (Site from DM).	(b) (4), (b) (6)	03 Dec 2020 19:21:57
Query 'Per CDM: This field requires a Yes or No response. Please complete.' answered with 'updated' (Site from DM).	Eileen Euperio (b) (4) (b) (4)	03 Dec 2020 18:16:09
User entered 'No (N)'	Eileen Euperio (b) (4) (b) (4)	03 Dec 2020 18:16:03
User opened query 'Per CDM: This field requires a Yes or No response. Please complete.' (Site from DM).	(b) (4), (b) (6)	02 Dec 2020 21:56:58
Amendment Manager: DataPoint set to visible.	System	19 Sep 2020 05:30:57
Amendment Manager inserted this DataPoint.	System	19 Sep 2020 05:30:56

US3342200

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 17:05:26

[Height](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 09:47:07
User signature succeeded.	Paul Pickrell (b) (4)	12 Feb 2021 23:50:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Dec 2020 18:47:46
User entered missing code ND - Not Done.	Stefanie Mott (b) (4)	04 Sep 2020 21:54:19

US3342200

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 17:05:26

Weight

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 09:47:07
User signature succeeded.	Paul Pickrell (b) (4)	12 Feb 2021 23:50:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Dec 2020 18:47:46
User entered missing code ND - Not Done.	Stefanie Mott (b) (4)	04 Sep 2020 21:54:19

US3342200

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 17:05:26

[Height](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 09:47:07
User signature succeeded.	Paul Pickrell (b) (4)	12 Feb 2021 23:50:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Dec 2020 18:47:46
User entered missing code ND - Not Done.	Stefanie Mott (b) (4)	04 Sep 2020 21:54:19

US3342200

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 17:05:26

Weight

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 09:47:07
User signature succeeded.	Paul Pickrell (b) (4)	12 Feb 2021 23:50:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Dec 2020 18:47:46
User entered missing code ND - Not Done.	Stefanie Mott (b) (4)	04 Sep 2020 21:54:19

US3342200

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:05:26

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 09:47:07
User accepted default value 'Pre-Dose (PREDOSE)'	Stefanie Mott (b) (4)	04 Sep 2020 21:54:19

US3342200

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:05:26

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 09:47:07
User signature succeeded.	Paul Pickrell (b) (4)	12 Feb 2021 23:50:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Dec 2020 18:47:46
User entered 'Yes (Y)'	Stefanie Mott (b) (4)	04 Sep 2020 21:54:19

US3342200

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:05:26

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 09:47:07
User signature succeeded.	Paul Pickrell (b) (4)	12 Feb 2021 23:50:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Dec 2020 18:47:46
User entered '4 Sep 2020'	Stefanie Mott (b) (4)	04 Sep 2020 21:54:19

US3342200

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:05:26

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 09:47:07
User signature succeeded.	Paul Pickrell (b) (4)	12 Feb 2021 23:50:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Dec 2020 18:47:46
User entered '15:59'	Stefanie Mott (b) (4)	04 Sep 2020 21:54:19

US3342200

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:05:26

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 09:47:07
User entered '4 Sep 2020 15:59'	System	04 Sep 2020 21:54:19

US3342200

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:05:26

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 09:47:07
User signature succeeded.	Paul Pickrell (b) (4)	12 Feb 2021 23:50:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Dec 2020 18:47:46
User entered '98.4' F	Stefanie Mott (b) (4)	04 Sep 2020 21:54:19

US3342200

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:05:26

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 09:47:07
User signature succeeded.	Paul Pickrell (b) (4)	12 Feb 2021 23:50:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Dec 2020 18:47:46
User entered 'Oral (Oral)'	Stefanie Mott (b) (4)	04 Sep 2020 21:54:19

US3342200

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:05:26

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 09:47:07
User signature succeeded.	Paul Pickrell (b) (4)	12 Feb 2021 23:50:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Dec 2020 18:47:46
User entered empty.	Stefanie Mott (b) (4)	04 Sep 2020 21:54:19

US3342200

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:05:26

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 09:47:07
User signature succeeded.	Paul Pickrell (b) (4)	12 Feb 2021 23:50:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Dec 2020 18:47:46
User entered '73'	Stefanie Mott (b) (4)	04 Sep 2020 21:54:19

US3342200

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:05:26

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 09:47:07
User entered 'bpm'	System	04 Sep 2020 21:54:19

US3342200

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:05:26

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 09:47:07
User signature succeeded.	Paul Pickrell (b) (4)	12 Feb 2021 23:50:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Dec 2020 18:47:46
User entered '12'	Stefanie Mott (b) (4)	04 Sep 2020 21:54:19

US3342200

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:05:26

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 09:47:07
User entered 'breaths/min'	System	04 Sep 2020 21:54:19

US3342200

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:05:26

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 09:47:07
User signature succeeded.	Paul Pickrell (b) (4)	12 Feb 2021 23:50:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Dec 2020 18:47:46
User entered '115'	Stefanie Mott (b) (4)	04 Sep 2020 21:54:19

US3342200

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:05:26

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 09:47:07
User entered 'mmHg'	System	04 Sep 2020 21:54:19

US3342200

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:05:26

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 09:47:07
User signature succeeded.	Paul Pickrell (b) (4)	12 Feb 2021 23:50:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Dec 2020 18:47:46
User entered '79'	Stefanie Mott (b) (4)	04 Sep 2020 21:54:19

US3342200

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:05:26

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 09:47:07
User entered 'mmHg'	System	04 Sep 2020 21:54:19

US3342200

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 17:05:26

[Height](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 09:47:07
User signature succeeded.	Paul Pickrell (b) (4)	12 Feb 2021 23:50:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Dec 2020 18:47:46
User entered missing code ND - Not Done.	Stefanie Mott (b) (4)	04 Sep 2020 21:54:19

US3342200

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 17:05:26

Weight

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 09:47:07
User signature succeeded.	Paul Pickrell (b) (4)	12 Feb 2021 23:50:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Dec 2020 18:47:46
User entered missing code ND - Not Done.	Stefanie Mott (b) (4)	04 Sep 2020 21:54:19

US3342200

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:05:26

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 09:47:07
User accepted default value 'Post-Dose (POSTDOSE)'	Stefanie Mott (b) (4)	04 Sep 2020 21:54:19

US3342200

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:05:26

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 09:47:07
User signature succeeded.	Paul Pickrell (b) (4)	12 Feb 2021 23:50:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Dec 2020 18:47:46
User closed query 'Data is required. Please complete.' (Site from System).	System	04 Sep 2020 22:29:21
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	04 Sep 2020 22:29:21
User entered 'Yes (Y)' reason for change: Data Entry Error	Stefanie Mott (b) (4)	04 Sep 2020 22:29:21
User opened query 'Data is required. Please complete.' (Site from System).	System	04 Sep 2020 21:54:19
User entered empty.	Stefanie Mott (b) (4)	04 Sep 2020 21:54:19

US3342200

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:05:26

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 09:47:07
User signature succeeded.	Paul Pickrell (b) (4)	12 Feb 2021 23:50:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Dec 2020 18:47:46
User entered '4 Sep 2020' reason for change: Data Entry Error	Stefanie Mott (b) (4)	04 Sep 2020 22:29:21
User entered empty.	Stefanie Mott (b) (4)	04 Sep 2020 21:54:19

US3342200

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:05:26

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 09:47:07
User signature succeeded.	Paul Pickrell (b) (4)	12 Feb 2021 23:50:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Dec 2020 18:47:46
User entered '17:21' reason for change: Data Entry Error	Stefanie Mott (b) (4)	04 Sep 2020 22:29:21
User entered empty.	Stefanie Mott (b) (4)	04 Sep 2020 21:54:19

US3342200

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:05:26

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 09:47:07
User entered '4 Sep 2020 17:21'	System	04 Sep 2020 22:29:21
User entered empty.	System	04 Sep 2020 21:54:19

US3342200

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:05:26

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 09:47:07
User signature succeeded.	Paul Pickrell (b) (4)	12 Feb 2021 23:50:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Dec 2020 18:47:46
User entered '98.7' F reason for change: Data Entry Error	Stefanie Mott (b) (4)	04 Sep 2020 22:29:21
User entered empty.	Stefanie Mott (b) (4)	04 Sep 2020 21:54:19

US3342200

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:05:26

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 09:47:07
User signature succeeded.	Paul Pickrell (b) (4)	12 Feb 2021 23:50:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Dec 2020 18:47:46
User entered 'Oral (Oral)' reason for change: Data Entry Error	Stefanie Mott (b) (4)	04 Sep 2020 22:29:21
User entered empty.	Stefanie Mott (b) (4)	04 Sep 2020 21:54:19

US3342200

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:05:26

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 09:47:07
User signature succeeded.	Paul Pickrell (b) (4)	12 Feb 2021 23:50:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Dec 2020 18:47:46
User entered empty.	Stefanie Mott (b) (4)	04 Sep 2020 21:54:19

US3342200

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:05:26

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 09:47:07
User signature succeeded.	Paul Pickrell (b) (4)	12 Feb 2021 23:50:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Dec 2020 18:47:46
User entered '81' reason for change: Data Entry Error	Stefanie Mott (b) (4)	04 Sep 2020 22:29:21
User entered empty.	Stefanie Mott (b) (4)	04 Sep 2020 21:54:19

US3342200

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:05:26

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 09:47:07
User entered 'bpm'	System	04 Sep 2020 22:29:21
User entered empty.	System	04 Sep 2020 21:54:19

US3342200

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:05:26

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 09:47:07
User signature succeeded.	Paul Pickrell (b) (4)	12 Feb 2021 23:50:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Dec 2020 18:47:46
User entered '12' reason for change: Data Entry Error	Stefanie Mott (b) (4)	04 Sep 2020 22:29:21
User entered empty.	Stefanie Mott (b) (4)	04 Sep 2020 21:54:19

US3342200

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:05:26

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 09:47:07
User entered 'breaths/min'	System	04 Sep 2020 22:29:21
User entered empty.	System	04 Sep 2020 21:54:19

US3342200

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:05:26

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 09:47:07
User signature succeeded.	Paul Pickrell (b) (4)	12 Feb 2021 23:50:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Dec 2020 18:47:46
User entered '109' reason for change: Data Entry Error	Stefanie Mott (b) (4)	04 Sep 2020 22:29:21
User entered empty.	Stefanie Mott (b) (4)	04 Sep 2020 21:54:19

US3342200

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:05:26

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 09:47:07
User entered 'mmHg'	System	04 Sep 2020 22:29:21
User entered empty.	System	04 Sep 2020 21:54:19

US3342200

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:05:26

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 09:47:07
User signature succeeded.	Paul Pickrell (b) (4)	12 Feb 2021 23:50:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Dec 2020 18:47:46
User entered '80' reason for change: Data Entry Error	Stefanie Mott (b) (4)	04 Sep 2020 22:29:21
User entered empty.	Stefanie Mott (b) (4)	04 Sep 2020 21:54:19

US3342200

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:05:26

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 09:47:07
User entered 'mmHg'	System	04 Sep 2020 22:29:21
User entered empty.	System	04 Sep 2020 21:54:19

US3342200

Folder: Visit 1 Day 1

Form: Physical Examination

Generated On: 09 Jun 2021 17:05:26

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 09:47:07
User signature succeeded.	Paul Pickrell (b) (4)	12 Feb 2021 23:50:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Dec 2020 18:47:51
User entered 'No (N)'	Stefanie Mott (b) (4)	04 Sep 2020 21:54:25

US3342200

Folder: Visit 1 Day 1

Form: Physical Examination

Generated On: 09 Jun 2021 17:05:26

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 09:47:07
User signature succeeded.	Paul Pickrell (b) (4)	12 Feb 2021 23:50:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Dec 2020 18:47:51
User entered empty.	Stefanie Mott (b) (4)	04 Sep 2020 21:54:25

US3342200

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 17:05:26

[Was study treatment given?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 09:47:07
User signature succeeded.	Paul Pickrell (b) (4)	12 Feb 2021 23:50:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Dec 2020 18:47:57
User entered 'Yes (Y)'	Stefanie Mott (b) (4)	04 Sep 2020 21:55:03

US3342200

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 17:05:26

If No, reason not given

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 09:47:07
User signature succeeded.	Paul Pickrell (b) (4)	12 Feb 2021 23:50:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Dec 2020 18:47:57
User entered empty.	Stefanie Mott (b) (4)	04 Sep 2020 21:55:03

US3342200

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 17:05:26

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)	14 Apr 2021 09:47:07
User signature succeeded.	Paul Pickrell (b) (4)	12 Feb 2021 23:50:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Dec 2020 18:47:57
User entered empty.	Stefanie Mott (b) (4)	04 Sep 2020 21:55:03

US3342200

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 17:05:26

[What was the study treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 09:47:07
User entered 'MRNA-1273 OR PLACEBO'	System	04 Sep 2020 21:55:03

US3342200

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 17:05:26

What was the treatment date? (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 09:47:07
User signature succeeded.	Paul Pickrell (b) (4)	12 Feb 2021 23:50:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Dec 2020 18:47:57
User entered '4 Sep 2020'	Stefanie Mott (b) (4)	04 Sep 2020 21:55:03

US3342200

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 17:05:26

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 09:47:07
User signature succeeded.	Paul Pickrell (b) (4)	12 Feb 2021 23:50:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Dec 2020 18:47:57
User entered '16:51'	Stefanie Mott (b) (4)	04 Sep 2020 21:55:03

US3342200

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 17:05:26

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 09:47:07
User entered '4 Sep 2020 16:51'	System	04 Sep 2020 21:55:03

US3342200

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 17:05:26

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 09:47:07
User signature succeeded.	Paul Pickrell (b) (4)	12 Feb 2021 23:50:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Dec 2020 18:47:57
User entered 'Left Arm (LEFT ARM)'	Stefanie Mott (b) (4)	04 Sep 2020 21:55:03

US3342200

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 17:05:26

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 09:47:07
DataPoint Verified.	(b) (4), (b) (6)	09 Dec 2020 18:47:57
User entered 'ONCE'	System	04 Sep 2020 21:55:03

US3342200

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 17:05:26

What was the route of administration for the study treatment?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 09:47:07
User entered 'INTRAMUSCULAR'	System	04 Sep 2020 21:55:03

US3342200

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:05:26

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 09:47:07
User signature succeeded.	Paul Pickrell (b) (4)	12 Feb 2021 23:50:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Dec 2020 18:48:04
User entered 'Yes (Y)'	Stefanie Mott (b) (4)	04 Sep 2020 22:14:21

US3342200

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:05:26

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 09:47:07
User signature succeeded.	Paul Pickrell (b) (4)	12 Feb 2021 23:50:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Dec 2020 18:48:04
User entered '4 Sep 2020'	Stefanie Mott (b) (4)	04 Sep 2020 22:14:21

US3342200

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:05:26

Collection time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 09:47:07
User signature succeeded.	Paul Pickrell (b) (4)	12 Feb 2021 23:50:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Dec 2020 18:48:04
User closed query 'Data is required. Please provide.' (Site from System).	System	08 Sep 2020 20:57:41
User entered '16:24' reason for change: Data Entry Error	Darrell O'Brien (b) (4) (b) (4)	08 Sep 2020 20:57:41
User opened query 'Data is required. Please provide.' (Site from System).	System	04 Sep 2020 22:14:21
User entered empty.	Stefanie Mott (b) (4)	04 Sep 2020 22:14:21

US3342200

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:05:26

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 09:47:07
User entered '4 Sep 2020 16:24'	System	08 Sep 2020 20:57:41
User entered empty.	System	04 Sep 2020 22:14:21

US3342200

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab

Generated On: 09 Jun 2021 17:05:26

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 09:47:07
User signature succeeded.	Paul Pickrell (b) (4)	12 Feb 2021 23:50:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Dec 2020 18:48:10
User entered '4 Sep 2020'	Stefanie Mott (b) (4)	04 Sep 2020 22:14:34

US3342200

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 17:05:26

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 09:47:07
User accepted default value 'Nasopharyngeal Swab 1 (NASAL1)'	Stefanie Mott (b) (4)	04 Sep 2020 22:14:34

US3342200

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 17:05:26

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 09:47:07
User signature succeeded.	Paul Pickrell (b) (4)	12 Feb 2021 23:50:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Dec 2020 18:48:10
User entered 'Yes (Y)'	Stefanie Mott (b) (4)	04 Sep 2020 22:14:34

US3342200

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 17:05:26

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 09:47:07
User signature succeeded.	Paul Pickrell (b) (4)	12 Feb 2021 23:50:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Dec 2020 18:48:10
User closed query "Was the sample collected?" is Yes, however, Collection Time is missing. Please review and reconcile.' (Site from System).	System	08 Sep 2020 20:57:54
Query "Was the sample collected?" is Yes, however, Collection Time is missing. Please review and reconcile.' answered by data change (Site from System).	System	08 Sep 2020 20:57:54
User entered '16:25' reason for change: Data Entry Error	Darrell O'Brien (b) (4) (b) (4)	08 Sep 2020 20:57:54
User opened query "Was the sample collected?" is Yes, however, Collection Time is missing. Please review and reconcile.' (Site from System).	System	04 Sep 2020 22:14:34
User entered empty.	Stefanie Mott (b) (4)	04 Sep 2020 22:14:34

US3342200

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 17:05:26

Collection date and time (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 09:47:07
User entered '4 Sep 2020 16:25'	System	08 Sep 2020 20:57:54
User entered empty.	System	04 Sep 2020 22:14:34

US3342200

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 17:05:26

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 09:47:07
User accepted default value 'Nasopharyngeal Swab 2 (NASAL2)'	Stefanie Mott (b) (4)	04 Sep 2020 22:14:34

US3342200

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 17:05:26

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 09:47:07
User signature succeeded.	Paul Pickrell (b) (4)	12 Feb 2021 23:50:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Dec 2020 18:48:10
User entered 'No (N)'	Stefanie Mott (b) (4)	04 Sep 2020 22:14:34

US3342200

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 17:05:26

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 09:47:07
User signature succeeded.	Paul Pickrell (b) (4)	12 Feb 2021 23:50:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Dec 2020 18:48:10
User entered empty.	Stefanie Mott (b) (4)	04 Sep 2020 22:14:34

US3342200

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 17:05:26

Collection date and time (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 09:47:07
User entered empty.	System	04 Sep 2020 22:14:34

US3342200

Folder: Visit 1 Day 1

Form: Continuing

Generated On: 09 Jun 2021 17:05:26

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 09:47:07
User signature succeeded.	Paul Pickrell (b) (4)	12 Feb 2021 23:50:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Dec 2020 18:48:14
User entered 'Yes (Y)'	Stefanie Mott (b) (4)	04 Sep 2020 22:14:41

US3342200

Folder: Visit 1 Day 1

Form: Continuing

Generated On: 09 Jun 2021 17:05:26

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 09:47:07
User entered '1'	System	04 Sep 2020 22:14:41

US3342200

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 17:05:26

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:04:20
Data entry locked.	System	04 Sep 2020 21:55:03
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	04 Sep 2020 21:55:03

US3342200

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 17:05:26

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:04:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2D2D1647-7C35-4DCA-ADA3-8E1DAA921DDC)', Time: '2020-09-04T17:21:59', User OID: 'PatientReportedOutcome (US3342200)', ODM File OID: '80fdabaf-6790-46cf-89a0-ce5f5f5ae3c4' User entered 'Yes (Y)'	System	04 Sep 2020 22:22:44
	System	04 Sep 2020 22:22:44

US3342200

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 17:05:26

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:04:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2D2D1647-7C35-4DCA-ADA3-8E1DAA921DDC)', Time: '2020-09-04T17:22:30', User OID: 'PatientReportedOutcome (US3342200)', ODM File OID: '80fdabaf-6790-46cf-89a0-ce5f5f5ae3c4' User entered '98.7'	System	04 Sep 2020 22:22:44
	System	04 Sep 2020 22:22:44

US3342200

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 17:05:26

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:04:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2D2D1647-7C35-4DCA-ADA3-8E1DAA921DDC)', Time: '2020-09-04T17:22:35', User OID: 'PatientReportedOutcome (US3342200)', ODM File OID: '80fdabaf-6790-46cf-89a0-ce5f5f5ae3c4'	System	04 Sep 2020 22:22:44
User entered 'No (N)'	System	04 Sep 2020 22:22:44

US3342200

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 17:05:26

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:04:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2D2D1647-7C35-4DCA-ADA3-8E1DAA921DDC)', Time: '2020-09-04T17:22:41', User OID: 'PatientReportedOutcome (US3342200)', ODM File OID: '80fdabaf-6790-46cf-89a0-ce5f5f5ae3c4'	System	04 Sep 2020 22:22:44
User entered '04 Sep 2020 17:22'	System	04 Sep 2020 22:22:44

US3342200

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 17:05:26

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:04:20
User entered '04 Sep 2020 17:11'	System	04 Sep 2020 21:55:03

US3342200

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 17:05:26

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:04:20
User entered '04 Sep 2020 19:41'	System	04 Sep 2020 21:55:03

US3342200

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 17:05:26

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:04:20
Data entry locked.	System	04 Sep 2020 21:55:03
User entered 'Day 1, after vaccination (at home)'	System	04 Sep 2020 21:55:03

US3342200

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 17:05:26

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:04:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2D2D1647-7C35-4DCA-ADA3-8E1DAA921DDC)', Time: '2020-09-04T20:39:50', User OID: 'PatientReportedOutcome (US3342200)', ODM File OID: '21ca14df-9f6b-41d2-a1da-2de5ed8e92bd' User entered 'Yes (Y)'	System	05 Sep 2020 01:40:13
	System	05 Sep 2020 01:40:13

US3342200

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 17:05:26

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:04:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2D2D1647-7C35-4DCA-ADA3-8E1DAA921DDC)', Time: '2020-09-04T20:40:02', User OID: 'PatientReportedOutcome (US3342200)', ODM File OID: '21ca14df-9f6b-41d2-a1da-2de5ed8e92bd' User entered '98.4'	System	05 Sep 2020 01:40:13
	System	05 Sep 2020 01:40:13

US3342200

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 17:05:26

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:04:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2D2D1647-7C35-4DCA-ADA3-8E1DAA921DDC)', Time: '2020-09-04T20:40:06', User OID: 'PatientReportedOutcome (US3342200)', ODM File OID: '21ca14df-9f6b-41d2-a1da-2de5ed8e92bd' User entered 'No (N)'	System	05 Sep 2020 01:40:13
	System	05 Sep 2020 01:40:13

US3342200

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 17:05:26

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:04:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2D2D1647-7C35-4DCA-ADA3-8E1DAA921DDC)', Time: '2020-09-04T20:40:12', User OID: 'PatientReportedOutcome (US3342200)', ODM File OID: '21ca14df-9f6b-41d2-a1da-2de5ed8e92bd' User entered '04 Sep 2020 20:40'	System	05 Sep 2020 01:40:13
	System	05 Sep 2020 01:40:13

US3342200

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 17:05:26

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:04:20
User entered '04 Sep 2020 20:36'	System	04 Sep 2020 21:55:03

US3342200

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 17:05:26

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:04:20
User entered '05 Sep 2020 11:59'	System	04 Sep 2020 21:55:03

US3342200

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 17:05:26

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:04:20
Data entry locked.	System	04 Sep 2020 21:55:03
User entered 'Day 2'	System	04 Sep 2020 21:55:03

US3342200

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 17:05:26

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:04:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2D2D1647-7C35-4DCA-ADA3-8E1DAA921DDC)', Time: '2020-09-05T12:01:11', User OID: 'PatientReportedOutcome (US3342200)', ODM File OID: '57f59e96-b785-4c4a-9907-7e77368c2822'	System	05 Sep 2020 17:02:18
User entered 'Yes (Y)'	System	05 Sep 2020 17:02:18

US3342200

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 17:05:26

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:04:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2D2D1647-7C35-4DCA-ADA3-8E1DAA921DDC)', Time: '2020-09-05T12:02:02', User OID: 'PatientReportedOutcome (US3342200)', ODM File OID: '57f59e96-b785-4c4a-9907-7e77368c2822' User entered '97.8'	System	05 Sep 2020 17:02:18
	System	05 Sep 2020 17:02:18

US3342200

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 17:05:26

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:04:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2D2D1647-7C35-4DCA-ADA3-8E1DAA921DDC)', Time: '2020-09-05T12:02:06', User OID: 'PatientReportedOutcome (US3342200)', ODM File OID: '57f59e96-b785-4c4a-9907-7e77368c2822'	System	05 Sep 2020 17:02:18
User entered 'No (N)'	System	05 Sep 2020 17:02:18

US3342200

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 17:05:26

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:04:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2D2D1647-7C35-4DCA-ADA3-8E1DAA921DDC)', Time: '2020-09-05T12:02:09', User OID: 'PatientReportedOutcome (US3342200)', ODM File OID: '57f59e96-b785-4c4a-9907-7e77368c2822' User entered '05 Sep 2020 12:02'	System	05 Sep 2020 17:02:18
	System	05 Sep 2020 17:02:18

US3342200

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 17:05:26

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:04:20
User entered '05 Sep 2020 12:00'	System	04 Sep 2020 21:55:03

US3342200

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 17:05:26

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:04:20
User entered '06 Sep 2020 11:59'	System	04 Sep 2020 21:55:03

US3342200

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 17:05:26

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:04:20
Data entry locked.	System	04 Sep 2020 21:55:03
User entered 'Day 3'	System	04 Sep 2020 21:55:03

US3342200

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 17:05:26

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:04:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2D2D1647-7C35-4DCA-ADA3-8E1DAA921DDC)', Time: '2020-09-06T18:34:46', User OID: 'PatientReportedOutcome (US3342200)', ODM File OID: 'd7cfad2a-24c5-4217-943c-deaa6e2ea7d6' User entered 'Yes (Y)'	System	06 Sep 2020 23:35:32
	System	06 Sep 2020 23:35:32

US3342200

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 17:05:26

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:04:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2D2D1647-7C35-4DCA-ADA3-8E1DAA921DDC)', Time: '2020-09-06T18:35:11', User OID: 'PatientReportedOutcome (US3342200)', ODM File OID: 'd7cfad2a-24c5-4217-943c-deaa6e2ea7d6' User entered '97.6'	System	06 Sep 2020 23:35:32
	System	06 Sep 2020 23:35:32

US3342200

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 17:05:26

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:04:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2D2D1647-7C35-4DCA-ADA3-8E1DAA921DDC)', Time: '2020-09-06T18:35:16', User OID: 'PatientReportedOutcome (US3342200)', ODM File OID: 'd7cfad2a-24c5-4217-943c-deaa6e2ea7d6'	System	06 Sep 2020 23:35:32
User entered 'No (N)'	System	06 Sep 2020 23:35:32

US3342200

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 17:05:26

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:04:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2D2D1647-7C35-4DCA-ADA3-8E1DAA921DDC)', Time: '2020-09-06T18:35:27', User OID: 'PatientReportedOutcome (US3342200)', ODM File OID: 'd7cfad2a-24c5-4217-943c-deaa6e2ea7d6' User entered '06 Sep 2020 18:35'	System	06 Sep 2020 23:35:32
	System	06 Sep 2020 23:35:32

US3342200

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 17:05:26

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:04:20
User entered '06 Sep 2020 12:00'	System	04 Sep 2020 21:55:03

US3342200

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 17:05:26

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:04:20
User entered '07 Sep 2020 11:59'	System	04 Sep 2020 21:55:03

US3342200

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 17:05:26

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:04:20
Data entry locked.	System	04 Sep 2020 21:55:03
User entered 'Day 4'	System	04 Sep 2020 21:55:03

US3342200

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 17:05:26

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:04:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2D2D1647-7C35-4DCA-ADA3-8E1DAA921DDC)', Time: '2020-09-07T18:21:19', User OID: 'PatientReportedOutcome (US3342200)', ODM File OID: '8471c8a3-726e-4842-a1ba-2d75431376c1' User entered 'Yes (Y)'	System	07 Sep 2020 23:23:11
	System	07 Sep 2020 23:23:11

US3342200

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 17:05:26

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:04:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2D2D1647-7C35-4DCA-ADA3-8E1DAA921DDC)', Time: '2020-09-07T18:22:58', User OID: 'PatientReportedOutcome (US3342200)', ODM File OID: '8471c8a3-726e-4842-a1ba-2d75431376c1' User entered '98.7'	System	07 Sep 2020 23:23:11
	System	07 Sep 2020 23:23:11

US3342200

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 17:05:26

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:04:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2D2D1647-7C35-4DCA-ADA3-8E1DAA921DDC)', Time: '2020-09-07T18:23:02', User OID: 'PatientReportedOutcome (US3342200)', ODM File OID: '8471c8a3-726e-4842-a1ba-2d75431376c1' User entered 'No (N)'	System	07 Sep 2020 23:23:11
	System	07 Sep 2020 23:23:11

US3342200

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 17:05:26

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:04:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2D2D1647-7C35-4DCA-ADA3-8E1DAA921DDC)', Time: '2020-09-07T18:23:09', User OID: 'PatientReportedOutcome (US3342200)', ODM File OID: '8471c8a3-726e-4842-a1ba-2d75431376c1' User entered '07 Sep 2020 18:23'	System	07 Sep 2020 23:23:11
	System	07 Sep 2020 23:23:11

US3342200

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 17:05:26

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:04:20
User entered '07 Sep 2020 12:00'	System	04 Sep 2020 21:55:03

US3342200

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 17:05:26

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:04:20
User entered '08 Sep 2020 11:59'	System	04 Sep 2020 21:55:03

US3342200

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 17:05:26

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:04:20
Data entry locked.	System	04 Sep 2020 21:55:03
User entered 'Day 5'	System	04 Sep 2020 21:55:03

US3342200

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 17:05:26

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:04:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2D2D1647-7C35-4DCA-ADA3-8E1DAA921DDC)', Time: '2020-09-09T03:17:17', User OID: 'PatientReportedOutcome (US3342200)', ODM File OID: 'da4a020d-55ef-489f-a8f2-79d25022e900'	System	09 Sep 2020 08:17:42
User entered 'Yes (Y)'	System	09 Sep 2020 08:17:42

US3342200

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 17:05:26

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:04:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2D2D1647-7C35-4DCA-ADA3-8E1DAA921DDC)', Time: '2020-09-09T03:17:31', User OID: 'PatientReportedOutcome (US3342200)', ODM File OID: 'da4a020d-55ef-489f-a8f2-79d25022e900' User entered '98.7'	System	09 Sep 2020 08:17:42
	System	09 Sep 2020 08:17:42

US3342200

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 17:05:26

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:04:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2D2D1647-7C35-4DCA-ADA3-8E1DAA921DDC)', Time: '2020-09-09T03:17:37', User OID: 'PatientReportedOutcome (US3342200)', ODM File OID: 'da4a020d-55ef-489f-a8f2-79d25022e900'	System	09 Sep 2020 08:17:42
User entered 'No (N)'	System	09 Sep 2020 08:17:42

US3342200

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 17:05:26

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:04:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2D2D1647-7C35-4DCA-ADA3-8E1DAA921DDC)', Time: '2020-09-09T03:17:41', User OID: 'PatientReportedOutcome (US3342200)', ODM File OID: 'da4a020d-55ef-489f-a8f2-79d25022e900' User entered '09 Sep 2020 03:17'	System	09 Sep 2020 08:17:42
	System	09 Sep 2020 08:17:42

US3342200

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 17:05:26

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:04:20
User entered '08 Sep 2020 12:00'	System	04 Sep 2020 21:55:03

US3342200

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 17:05:26

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:04:20
User entered '09 Sep 2020 11:59'	System	04 Sep 2020 21:55:03

US3342200

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 17:05:26

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:04:20
Data entry locked.	System	04 Sep 2020 21:55:03
User entered 'Day 6'	System	04 Sep 2020 21:55:03

US3342200

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 17:05:26

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:04:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2D2D1647-7C35-4DCA-ADA3-8E1DAA921DDC)', Time: '2020-09-09T14:29:14', User OID: 'PatientReportedOutcome (US3342200)', ODM File OID: '78130293-1561-4205-8668-4e676ea32c56'	System	09 Sep 2020 19:29:30
User entered 'Yes (Y)'	System	09 Sep 2020 19:29:30

US3342200

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 17:05:26

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:04:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2D2D1647-7C35-4DCA-ADA3-8E1DAA921DDC)', Time: '2020-09-09T14:29:19', User OID: 'PatientReportedOutcome (US3342200)', ODM File OID: '78130293-1561-4205-8668-4e676ea32c56' User entered '98.3'	System	09 Sep 2020 19:29:30
	System	09 Sep 2020 19:29:30

US3342200

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 17:05:26

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:04:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2D2D1647-7C35-4DCA-ADA3-8E1DAA921DDC)', Time: '2020-09-09T14:29:22', User OID: 'PatientReportedOutcome (US3342200)', ODM File OID: '78130293-1561-4205-8668-4e676ea32c56'	System	09 Sep 2020 19:29:30
User entered 'No (N)'	System	09 Sep 2020 19:29:30

US3342200

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 17:05:26

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:04:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2D2D1647-7C35-4DCA-ADA3-8E1DAA921DDC)', Time: '2020-09-09T14:29:27', User OID: 'PatientReportedOutcome (US3342200)', ODM File OID: '78130293-1561-4205-8668-4e676ea32c56' User entered '09 Sep 2020 14:29'	System	09 Sep 2020 19:29:30
	System	09 Sep 2020 19:29:30

US3342200

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 17:05:26

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:04:20
User entered '09 Sep 2020 12:00'	System	04 Sep 2020 21:55:03

US3342200

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 17:05:26

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:04:20
User entered '10 Sep 2020 11:59'	System	04 Sep 2020 21:55:03

US3342200

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 17:05:26

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:04:20
Data entry locked.	System	04 Sep 2020 21:55:03
User entered 'Day 7'	System	04 Sep 2020 21:55:03

US3342200

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 17:05:26

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:04:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2D2D1647-7C35-4DCA-ADA3-8E1DAA921DDC)', Time: '2020-09-10T12:02:48', User OID: 'PatientReportedOutcome (US3342200)', ODM File OID: 'fb93657f-e5ab-48d6-9917-41847a303122' User entered 'Yes (Y)'	System	10 Sep 2020 17:20:34
	System	10 Sep 2020 17:20:34

US3342200

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 17:05:26

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:04:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2D2D1647-7C35-4DCA-ADA3-8E1DAA921DDC)', Time: '2020-09-10T12:20:16', User OID: 'PatientReportedOutcome (US3342200)', ODM File OID: 'fb93657f-e5ab-48d6-9917-41847a303122' User entered '97.6'	System	10 Sep 2020 17:20:34
	System	10 Sep 2020 17:20:34

US3342200

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 17:05:26

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:04:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2D2D1647-7C35-4DCA-ADA3-8E1DAA921DDC)', Time: '2020-09-10T12:20:22', User OID: 'PatientReportedOutcome (US3342200)', ODM File OID: 'fb93657f-e5ab-48d6-9917-41847a303122' User entered 'No (N)'	System	10 Sep 2020 17:20:34
	System	10 Sep 2020 17:20:34

US3342200

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 17:05:26

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:04:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2D2D1647-7C35-4DCA-ADA3-8E1DAA921DDC)', Time: '2020-09-10T12:20:26', User OID: 'PatientReportedOutcome (US3342200)', ODM File OID: 'fb93657f-e5ab-48d6-9917-41847a303122' User entered '10 Sep 2020 12:20'	System	10 Sep 2020 17:20:34
	System	10 Sep 2020 17:20:34

US3342200

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 17:05:26

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:04:20
User entered '10 Sep 2020 12:00'	System	04 Sep 2020 21:55:03

US3342200

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 17:05:26

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:04:20
User entered '11 Sep 2020 11:59'	System	04 Sep 2020 21:55:03

US3342200

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 17:05:26

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:04:20
Data entry locked.	System	04 Sep 2020 21:55:03
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	04 Sep 2020 21:55:03

US3342200

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 17:05:26

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:04:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2D2D1647-7C35-4DCA-ADA3-8E1DAA921DDC)', Time: '2020-09-04T17:23:04', User OID: 'PatientReportedOutcome (US3342200)', ODM File OID: '844cef55-7307-4b34-ab47-6113932c85e3'	System	04 Sep 2020 22:24:03
User entered 'Does not interfere with activity (2)'	System	04 Sep 2020 22:24:03

US3342200

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 17:05:26

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:04:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2D2D1647-7C35-4DCA-ADA3-8E1DAA921DDC)', Time: '2020-09-04T17:23:08', User OID: 'PatientReportedOutcome (US3342200)', ODM File OID: '844cef55-7307-4b34-ab47-6113932c85e3' User entered 'No (N)'	System	04 Sep 2020 22:24:03
	System	04 Sep 2020 22:24:03

US3342200

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 17:05:26

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:04:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2D2D1647-7C35-4DCA-ADA3-8E1DAA921DDC)', Time: '2020-09-04T17:23:12', User OID: 'PatientReportedOutcome (US3342200)', ODM File OID: '844cef55-7307-4b34-ab47-6113932c85e3' User entered 'No (N)'	System	04 Sep 2020 22:24:03
	System	04 Sep 2020 22:24:03

US3342200

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 17:05:26

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:04:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2D2D1647-7C35-4DCA-ADA3-8E1DAA921DDC)', Time: '2020-09-04T17:23:49', User OID: 'PatientReportedOutcome (US3342200)', ODM File OID: '844cef55-7307-4b34-ab47-6113932c85e3'	System	04 Sep 2020 22:24:03
User entered 'None (1)'	System	04 Sep 2020 22:24:03

US3342200

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 17:05:26

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:04:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2D2D1647-7C35-4DCA-ADA3-8E1DAA921DDC)', Time: '2020-09-04T17:23:59', User OID: 'PatientReportedOutcome (US3342200)', ODM File OID: '844cef55-7307-4b34-ab47-6113932c85e3' User entered '04 Sep 2020 17:23'	System	04 Sep 2020 22:24:03
	System	04 Sep 2020 22:24:03

US3342200

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 17:05:26

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:04:20
User entered '04 Sep 2020 17:11'	System	04 Sep 2020 21:55:03

US3342200

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 17:05:26

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:04:20
User entered '04 Sep 2020 19:41'	System	04 Sep 2020 21:55:03

US3342200

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 17:05:26

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:04:20
Data entry locked.	System	04 Sep 2020 21:55:03
User entered 'Day 1, after vaccination (at home)'	System	04 Sep 2020 21:55:03

US3342200

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 17:05:26

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:04:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2D2D1647-7C35-4DCA-ADA3-8E1DAA921DDC)', Time: '2020-09-04T20:40:26', User OID: 'PatientReportedOutcome (US3342200)', ODM File OID: 'e57835c9-83d0-47a5-9486-50860c25bbcd' User entered 'None (1)'	System	05 Sep 2020 01:40:48
	System	05 Sep 2020 01:40:48

US3342200

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 17:05:26

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:04:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2D2D1647-7C35-4DCA-ADA3-8E1DAA921DDC)', Time: '2020-09-04T20:40:29', User OID: 'PatientReportedOutcome (US3342200)', ODM File OID: 'e57835c9-83d0-47a5-9486-50860c25bbcd' User entered 'No (N)'	System	05 Sep 2020 01:40:48
	System	05 Sep 2020 01:40:48

US3342200

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 17:05:26

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:04:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2D2D1647-7C35-4DCA-ADA3-8E1DAA921DDC)', Time: '2020-09-04T20:40:34', User OID: 'PatientReportedOutcome (US3342200)', ODM File OID: 'e57835c9-83d0-47a5-9486-50860c25bbcd' User entered 'No (N)'	System	05 Sep 2020 01:40:48
	System	05 Sep 2020 01:40:48

US3342200

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 17:05:26

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:04:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2D2D1647-7C35-4DCA-ADA3-8E1DAA921DDC)', Time: '2020-09-04T20:40:43', User OID: 'PatientReportedOutcome (US3342200)', ODM File OID: 'e57835c9-83d0-47a5-9486-50860c25bbcd' User entered 'None (1)'	System	05 Sep 2020 01:40:48
	System	05 Sep 2020 01:40:48

US3342200

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 17:05:26

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:04:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2D2D1647-7C35-4DCA-ADA3-8E1DAA921DDC)', Time: '2020-09-04T20:40:46', User OID: 'PatientReportedOutcome (US3342200)', ODM File OID: 'e57835c9-83d0-47a5-9486-50860c25bbcd' User entered '04 Sep 2020 20:40'	System	05 Sep 2020 01:40:48
	System	05 Sep 2020 01:40:48

US3342200

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 17:05:26

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:04:20
User entered '04 Sep 2020 20:36'	System	04 Sep 2020 21:55:03

US3342200

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 17:05:26

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:04:20
User entered '05 Sep 2020 11:59'	System	04 Sep 2020 21:55:03

US3342200

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 17:05:26

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:04:20
Data entry locked.	System	04 Sep 2020 21:55:03
User entered 'Day 2'	System	04 Sep 2020 21:55:03

US3342200

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 17:05:26

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:04:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2D2D1647-7C35-4DCA-ADA3-8E1DAA921DDC)', Time: '2020-09-05T12:02:16', User OID: 'PatientReportedOutcome (US3342200)', ODM File OID: 'edd2a3b3-6a13-4d41-bd85-5c0b2052eb23'	System	05 Sep 2020 17:03:01
User entered 'None (1)'	System	05 Sep 2020 17:03:01

US3342200

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 17:05:26

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:04:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2D2D1647-7C35-4DCA-ADA3-8E1DAA921DDC)', Time: '2020-09-05T12:02:46', User OID: 'PatientReportedOutcome (US3342200)', ODM File OID: 'edd2a3b3-6a13-4d41-bd85-5c0b2052eb23' User entered 'No (N)'	System	05 Sep 2020 17:03:01
	System	05 Sep 2020 17:03:01

US3342200

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 17:05:26

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:04:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2D2D1647-7C35-4DCA-ADA3-8E1DAA921DDC)', Time: '2020-09-05T12:02:49', User OID: 'PatientReportedOutcome (US3342200)', ODM File OID: 'edd2a3b3-6a13-4d41-bd85-5c0b2052eb23' User entered 'No (N)'	System	05 Sep 2020 17:03:01
	System	05 Sep 2020 17:03:01

US3342200

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 17:05:26

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:04:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2D2D1647-7C35-4DCA-ADA3-8E1DAA921DDC)', Time: '2020-09-05T12:02:54', User OID: 'PatientReportedOutcome (US3342200)', ODM File OID: 'edd2a3b3-6a13-4d41-bd85-5c0b2052eb23' User entered 'None (1)'	System	05 Sep 2020 17:03:01
	System	05 Sep 2020 17:03:01

US3342200

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 17:05:26

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:04:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2D2D1647-7C35-4DCA-ADA3-8E1DAA921DDC)', Time: '2020-09-05T12:02:59', User OID: 'PatientReportedOutcome (US3342200)', ODM File OID: 'edd2a3b3-6a13-4d41-bd85-5c0b2052eb23' User entered '05 Sep 2020 12:02'	System	05 Sep 2020 17:03:01
	System	05 Sep 2020 17:03:01

US3342200

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 17:05:26

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:04:20
User entered '05 Sep 2020 12:00'	System	04 Sep 2020 21:55:03

US3342200

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 17:05:26

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:04:20
User entered '06 Sep 2020 11:59'	System	04 Sep 2020 21:55:03

US3342200

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 17:05:26

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:04:20
Data entry locked.	System	04 Sep 2020 21:55:03
User entered 'Day 3'	System	04 Sep 2020 21:55:03

US3342200

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 17:05:26

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:04:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2D2D1647-7C35-4DCA-ADA3-8E1DAA921DDC)', Time: '2020-09-06T18:35:36', User OID: 'PatientReportedOutcome (US3342200)', ODM File OID: '34ac097e-052c-4f3a-afad-6bed5229d2c6' User entered 'None (1)'	System	06 Sep 2020 23:36:26
	System	06 Sep 2020 23:36:26

US3342200

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 17:05:26

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:04:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2D2D1647-7C35-4DCA-ADA3-8E1DAA921DDC)', Time: '2020-09-06T18:35:42', User OID: 'PatientReportedOutcome (US3342200)', ODM File OID: '34ac097e-052c-4f3a-afad-6bed5229d2c6' User entered 'No (N)'	System	06 Sep 2020 23:36:26
	System	06 Sep 2020 23:36:26

US3342200

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 17:05:26

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:04:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2D2D1647-7C35-4DCA-ADA3-8E1DAA921DDC)', Time: '2020-09-06T18:35:57', User OID: 'PatientReportedOutcome (US3342200)', ODM File OID: '34ac097e-052c-4f3a-afad-6bed5229d2c6' User entered 'No (N)'	System	06 Sep 2020 23:36:26
	System	06 Sep 2020 23:36:26

US3342200

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 17:05:26

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:04:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2D2D1647-7C35-4DCA-ADA3-8E1DAA921DDC)', Time: '2020-09-06T18:36:21', User OID: 'PatientReportedOutcome (US3342200)', ODM File OID: '34ac097e-052c-4f3a-afad-6bed5229d2c6' User entered 'None (1)'	System	06 Sep 2020 23:36:26
	System	06 Sep 2020 23:36:26

US3342200

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 17:05:26

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:04:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2D2D1647-7C35-4DCA-ADA3-8E1DAA921DDC)', Time: '2020-09-06T18:36:24', User OID: 'PatientReportedOutcome (US3342200)', ODM File OID: '34ac097e-052c-4f3a-afad-6bed5229d2c6' User entered '06 Sep 2020 18:36'	System	06 Sep 2020 23:36:26
	System	06 Sep 2020 23:36:26

US3342200

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 17:05:26

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:04:20
User entered '06 Sep 2020 12:00'	System	04 Sep 2020 21:55:03

US3342200

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 17:05:26

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:04:20
User entered '07 Sep 2020 11:59'	System	04 Sep 2020 21:55:03

US3342200

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 17:05:26

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:04:20
Data entry locked.	System	04 Sep 2020 21:55:03
User entered 'Day 4'	System	04 Sep 2020 21:55:03

US3342200

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 17:05:26

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:04:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2D2D1647-7C35-4DCA-ADA3-8E1DAA921DDC)', Time: '2020-09-07T18:23:26', User OID: 'PatientReportedOutcome (US3342200)', ODM File OID: '0f169d51-4674-4faa-92d1-a58b38b47e30'	System	07 Sep 2020 23:23:47
User entered 'None (1)'	System	07 Sep 2020 23:23:47

US3342200

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 17:05:26

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:04:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2D2D1647-7C35-4DCA-ADA3-8E1DAA921DDC)', Time: '2020-09-07T18:23:31', User OID: 'PatientReportedOutcome (US3342200)', ODM File OID: '0f169d51-4674-4faa-92d1-a58b38b47e30' User entered 'No (N)'	System	07 Sep 2020 23:23:47
	System	07 Sep 2020 23:23:47

US3342200

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 17:05:26

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:04:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2D2D1647-7C35-4DCA-ADA3-8E1DAA921DDC)', Time: '2020-09-07T18:23:37', User OID: 'PatientReportedOutcome (US3342200)', ODM File OID: '0f169d51-4674-4faa-92d1-a58b38b47e30' User entered 'No (N)'	System	07 Sep 2020 23:23:47
	System	07 Sep 2020 23:23:47

US3342200

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 17:05:26

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:04:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2D2D1647-7C35-4DCA-ADA3-8E1DAA921DDC)', Time: '2020-09-07T18:23:43', User OID: 'PatientReportedOutcome (US3342200)', ODM File OID: '0f169d51-4674-4faa-92d1-a58b38b47e30' User entered 'None (1)'	System	07 Sep 2020 23:23:47
	System	07 Sep 2020 23:23:47

US3342200

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 17:05:26

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:04:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2D2D1647-7C35-4DCA-ADA3-8E1DAA921DDC)', Time: '2020-09-07T18:23:46', User OID: 'PatientReportedOutcome (US3342200)', ODM File OID: '0f169d51-4674-4faa-92d1-a58b38b47e30' User entered '07 Sep 2020 18:23'	System	07 Sep 2020 23:23:47
	System	07 Sep 2020 23:23:47

US3342200

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 17:05:26

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:04:20
User entered '07 Sep 2020 12:00'	System	04 Sep 2020 21:55:03

US3342200

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 17:05:26

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:04:20
User entered '08 Sep 2020 11:59'	System	04 Sep 2020 21:55:03

US3342200

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 17:05:26

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:04:20
Data entry locked.	System	04 Sep 2020 21:55:03
User entered 'Day 5'	System	04 Sep 2020 21:55:03

US3342200

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 17:05:26

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:04:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2D2D1647-7C35-4DCA-ADA3-8E1DAA921DDC)', Time: '2020-09-09T03:17:45', User OID: 'PatientReportedOutcome (US3342200)', ODM File OID: '71b5e4ba-8749-4b68-b2df-2609433d1a61'	System	09 Sep 2020 08:18:00
User entered 'None (1)'	System	09 Sep 2020 08:18:00

US3342200

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 17:05:26

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:04:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2D2D1647-7C35-4DCA-ADA3-8E1DAA921DDC)', Time: '2020-09-09T03:17:48', User OID: 'PatientReportedOutcome (US3342200)', ODM File OID: '71b5e4ba-8749-4b68-b2df-2609433d1a61' User entered 'No (N)'	System	09 Sep 2020 08:18:00
	System	09 Sep 2020 08:18:00

US3342200

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 17:05:26

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:04:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2D2D1647-7C35-4DCA-ADA3-8E1DAA921DDC)', Time: '2020-09-09T03:17:51', User OID: 'PatientReportedOutcome (US3342200)', ODM File OID: '71b5e4ba-8749-4b68-b2df-2609433d1a61' User entered 'No (N)'	System	09 Sep 2020 08:18:00
	System	09 Sep 2020 08:18:00

US3342200

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 17:05:26

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:04:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2D2D1647-7C35-4DCA-ADA3-8E1DAA921DDC)', Time: '2020-09-09T03:17:54', User OID: 'PatientReportedOutcome (US3342200)', ODM File OID: '71b5e4ba-8749-4b68-b2df-2609433d1a61'	System	09 Sep 2020 08:18:00
User entered 'None (1)'	System	09 Sep 2020 08:18:00

US3342200

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 17:05:26

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:04:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2D2D1647-7C35-4DCA-ADA3-8E1DAA921DDC)', Time: '2020-09-09T03:17:58', User OID: 'PatientReportedOutcome (US3342200)', ODM File OID: '71b5e4ba-8749-4b68-b2df-2609433d1a61' User entered '09 Sep 2020 03:17'	System	09 Sep 2020 08:18:00
	System	09 Sep 2020 08:18:00

US3342200

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 17:05:26

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:04:20
User entered '08 Sep 2020 12:00'	System	04 Sep 2020 21:55:03

US3342200

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 17:05:26

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:04:20
User entered '09 Sep 2020 11:59'	System	04 Sep 2020 21:55:03

US3342200

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 17:05:26

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:04:20
Data entry locked.	System	04 Sep 2020 21:55:03
User entered 'Day 6'	System	04 Sep 2020 21:55:03

US3342200

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 17:05:26

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:04:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2D2D1647-7C35-4DCA-ADA3-8E1DAA921DDC)', Time: '2020-09-09T14:29:32', User OID: 'PatientReportedOutcome (US3342200)', ODM File OID: 'a24a57ad-dcb2-4bb0-a3a8-db7c2946dcd5' User entered 'None (1)'	System	09 Sep 2020 19:29:47
	System	09 Sep 2020 19:29:47

US3342200

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 17:05:26

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:04:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2D2D1647-7C35-4DCA-ADA3-8E1DAA921DDC)', Time: '2020-09-09T14:29:35', User OID: 'PatientReportedOutcome (US3342200)', ODM File OID: 'a24a57ad-dcb2-4bb0-a3a8-db7c2946dcd5' User entered 'No (N)'	System	09 Sep 2020 19:29:47
	System	09 Sep 2020 19:29:47

US3342200

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 17:05:26

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:04:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2D2D1647-7C35-4DCA-ADA3-8E1DAA921DDC)', Time: '2020-09-09T14:29:38', User OID: 'PatientReportedOutcome (US3342200)', ODM File OID: 'a24a57ad-dcb2-4bb0-a3a8-db7c2946dcd5' User entered 'No (N)'	System	09 Sep 2020 19:29:47
	System	09 Sep 2020 19:29:47

US3342200

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 17:05:26

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:04:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2D2D1647-7C35-4DCA-ADA3-8E1DAA921DDC)', Time: '2020-09-09T14:29:42', User OID: 'PatientReportedOutcome (US3342200)', ODM File OID: 'a24a57ad-dcb2-4bb0-a3a8-db7c2946dcd5' User entered 'None (1)'	System	09 Sep 2020 19:29:47
	System	09 Sep 2020 19:29:47

US3342200

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 17:05:26

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:04:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2D2D1647-7C35-4DCA-ADA3-8E1DAA921DDC)', Time: '2020-09-09T14:29:44', User OID: 'PatientReportedOutcome (US3342200)', ODM File OID: 'a24a57ad-dcb2-4bb0-a3a8-db7c2946dcd5' User entered '09 Sep 2020 14:29'	System	09 Sep 2020 19:29:47
	System	09 Sep 2020 19:29:47

US3342200

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 17:05:26

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:04:20
User entered '09 Sep 2020 12:00'	System	04 Sep 2020 21:55:03

US3342200

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 17:05:26

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:04:20
User entered '10 Sep 2020 11:59'	System	04 Sep 2020 21:55:03

US3342200

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 17:05:26

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:04:20
Data entry locked.	System	04 Sep 2020 21:55:03
User entered 'Day 7'	System	04 Sep 2020 21:55:03

US3342200

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 17:05:26

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:04:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2D2D1647-7C35-4DCA-ADA3-8E1DAA921DDC)', Time: '2020-09-10T12:20:32', User OID: 'PatientReportedOutcome (US3342200)', ODM File OID: '96c4b03c-2b80-4dad-8231-74e19634a9ef'	System	10 Sep 2020 17:20:48
User entered 'None (1)'	System	10 Sep 2020 17:20:48

US3342200

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 17:05:26

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:04:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2D2D1647-7C35-4DCA-ADA3-8E1DAA921DDC)', Time: '2020-09-10T12:20:36', User OID: 'PatientReportedOutcome (US3342200)', ODM File OID: '96c4b03c-2b80-4dad-8231-74e19634a9ef' User entered 'No (N)'	System	10 Sep 2020 17:20:48
	System	10 Sep 2020 17:20:48

US3342200

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 17:05:26

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:04:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2D2D1647-7C35-4DCA-ADA3-8E1DAA921DDC)', Time: '2020-09-10T12:20:39', User OID: 'PatientReportedOutcome (US3342200)', ODM File OID: '96c4b03c-2b80-4dad-8231-74e19634a9ef' User entered 'No (N)'	System	10 Sep 2020 17:20:48
	System	10 Sep 2020 17:20:48

US3342200

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 17:05:26

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:04:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2D2D1647-7C35-4DCA-ADA3-8E1DAA921DDC)', Time: '2020-09-10T12:20:42', User OID: 'PatientReportedOutcome (US3342200)', ODM File OID: '96c4b03c-2b80-4dad-8231-74e19634a9ef' User entered 'None (1)'	System	10 Sep 2020 17:20:48
	System	10 Sep 2020 17:20:48

US3342200

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 17:05:26

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:04:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2D2D1647-7C35-4DCA-ADA3-8E1DAA921DDC)', Time: '2020-09-10T12:20:44', User OID: 'PatientReportedOutcome (US3342200)', ODM File OID: '96c4b03c-2b80-4dad-8231-74e19634a9ef' User entered '10 Sep 2020 12:20'	System	10 Sep 2020 17:20:48
	System	10 Sep 2020 17:20:48

US3342200

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 17:05:26

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:04:20
User entered '10 Sep 2020 12:00'	System	04 Sep 2020 21:55:03

US3342200

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 17:05:26

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:04:20
User entered '11 Sep 2020 11:59'	System	04 Sep 2020 21:55:03

US3342200

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:05:26

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:04:20
Data entry locked.	System	04 Sep 2020 21:55:03
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	04 Sep 2020 21:55:03

US3342200

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:05:26

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:04:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2D2D1647-7C35-4DCA-ADA3-8E1DAA921DDC)', Time: '2020-09-04T17:24:09', User OID: 'PatientReportedOutcome (US3342200)', ODM File OID: '95b07862-cd3e-4682-aaec-8b707ab91e54' User entered 'None (0)'	System	04 Sep 2020 22:24:44
	System	04 Sep 2020 22:24:44

US3342200

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:05:26

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:04:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2D2D1647-7C35-4DCA-ADA3-8E1DAA921DDC)', Time: '2020-09-04T17:24:12', User OID: 'PatientReportedOutcome (US3342200)', ODM File OID: '95b07862-cd3e-4682-aaec-8b707ab91e54' User entered 'None (0)'	System	04 Sep 2020 22:24:44
	System	04 Sep 2020 22:24:44

US3342200

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:05:26

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:04:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2D2D1647-7C35-4DCA-ADA3-8E1DAA921DDC)', Time: '2020-09-04T17:24:18', User OID: 'PatientReportedOutcome (US3342200)', ODM File OID: '95b07862-cd3e-4682-aaec-8b707ab91e54' User entered 'None (0)'	System	04 Sep 2020 22:24:44
	System	04 Sep 2020 22:24:44

US3342200

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:05:26

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:04:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2D2D1647-7C35-4DCA-ADA3-8E1DAA921DDC)', Time: '2020-09-04T17:24:23', User OID: 'PatientReportedOutcome (US3342200)', ODM File OID: '95b07862-cd3e-4682-aaec-8b707ab91e54' User entered 'None (0)'	System	04 Sep 2020 22:24:44
	System	04 Sep 2020 22:24:44

US3342200

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:05:26

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:04:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2D2D1647-7C35-4DCA-ADA3-8E1DAA921DDC)', Time: '2020-09-04T17:24:26', User OID: 'PatientReportedOutcome (US3342200)', ODM File OID: '95b07862-cd3e-4682-aaec-8b707ab91e54' User entered 'None (0)'	System	04 Sep 2020 22:24:44
	System	04 Sep 2020 22:24:44

US3342200

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:05:26

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:04:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2D2D1647-7C35-4DCA-ADA3-8E1DAA921DDC)', Time: '2020-09-04T17:24:30', User OID: 'PatientReportedOutcome (US3342200)', ODM File OID: '95b07862-cd3e-4682-aaec-8b707ab91e54' User entered 'None (0)'	System	04 Sep 2020 22:24:44
	System	04 Sep 2020 22:24:44

US3342200

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:05:26

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:04:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2D2D1647-7C35-4DCA-ADA3-8E1DAA921DDC)', Time: '2020-09-04T17:24:37', User OID: 'PatientReportedOutcome (US3342200)', ODM File OID: '95b07862-cd3e-4682-aaec-8b707ab91e54' User entered 'No (N)'	System	04 Sep 2020 22:24:44
	System	04 Sep 2020 22:24:44

US3342200

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:05:26

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:04:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2D2D1647-7C35-4DCA-ADA3-8E1DAA921DDC)', Time: '2020-09-04T17:24:41', User OID: 'PatientReportedOutcome (US3342200)', ODM File OID: '95b07862-cd3e-4682-aaec-8b707ab91e54' User entered '04 Sep 2020 17:24'	System	04 Sep 2020 22:24:44
	System	04 Sep 2020 22:24:44

US3342200

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:05:26

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:04:20
User entered '04 Sep 2020 17:11'	System	04 Sep 2020 21:55:03

US3342200

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:05:26

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:04:20
User entered '04 Sep 2020 19:41'	System	04 Sep 2020 21:55:03

US3342200

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:05:26

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:04:20
Data entry locked.	System	04 Sep 2020 21:55:03
User entered 'Day 1, after vaccination (at home)'	System	04 Sep 2020 21:55:03

US3342200

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:05:26

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:04:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2D2D1647-7C35-4DCA-ADA3-8E1DAA921DDC)', Time: '2020-09-04T20:40:59', User OID: 'PatientReportedOutcome (US3342200)', ODM File OID: '7a915e8c-5ffe-45f7-b01a-ab9dcbbd6e85' User entered 'None (0)'	System	05 Sep 2020 01:41:27
	System	05 Sep 2020 01:41:27

US3342200

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:05:26

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:04:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2D2D1647-7C35-4DCA-ADA3-8E1DAA921DDC)', Time: '2020-09-04T20:41:02', User OID: 'PatientReportedOutcome (US3342200)', ODM File OID: '7a915e8c-5ffe-45f7-b01a-ab9dcbbd6e85' User entered 'None (0)'	System	05 Sep 2020 01:41:27
	System	05 Sep 2020 01:41:27

US3342200

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:05:26

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:04:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2D2D1647-7C35-4DCA-ADA3-8E1DAA921DDC)', Time: '2020-09-04T20:41:05', User OID: 'PatientReportedOutcome (US3342200)', ODM File OID: '7a915e8c-5ffe-45f7-b01a-ab9dcbbd6e85' User entered 'None (0)'	System	05 Sep 2020 01:41:27
	System	05 Sep 2020 01:41:27

US3342200

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:05:26

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:04:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2D2D1647-7C35-4DCA-ADA3-8E1DAA921DDC)', Time: '2020-09-04T20:41:09', User OID: 'PatientReportedOutcome (US3342200)', ODM File OID: '7a915e8c-5ffe-45f7-b01a-ab9dcbbd6e85' User entered 'None (0)'	System	05 Sep 2020 01:41:27
	System	05 Sep 2020 01:41:27

US3342200

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:05:26

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:04:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2D2D1647-7C35-4DCA-ADA3-8E1DAA921DDC)', Time: '2020-09-04T20:41:11', User OID: 'PatientReportedOutcome (US3342200)', ODM File OID: '7a915e8c-5ffe-45f7-b01a-ab9dcbbd6e85' User entered 'None (0)'	System	05 Sep 2020 01:41:27
	System	05 Sep 2020 01:41:27

US3342200

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:05:26

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:04:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2D2D1647-7C35-4DCA-ADA3-8E1DAA921DDC)', Time: '2020-09-04T20:41:14', User OID: 'PatientReportedOutcome (US3342200)', ODM File OID: '7a915e8c-5ffe-45f7-b01a-ab9dcbbd6e85' User entered 'None (0)'	System	05 Sep 2020 01:41:27
	System	05 Sep 2020 01:41:27

US3342200

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:05:26

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:04:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2D2D1647-7C35-4DCA-ADA3-8E1DAA921DDC)', Time: '2020-09-04T20:41:22', User OID: 'PatientReportedOutcome (US3342200)', ODM File OID: '7a915e8c-5ffe-45f7-b01a-ab9dcbbd6e85' User entered 'No (N)'	System	05 Sep 2020 01:41:27
	System	05 Sep 2020 01:41:27

US3342200

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:05:26

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:04:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2D2D1647-7C35-4DCA-ADA3-8E1DAA921DDC)', Time: '2020-09-04T20:41:25', User OID: 'PatientReportedOutcome (US3342200)', ODM File OID: '7a915e8c-5ffe-45f7-b01a-ab9dcbbd6e85' User entered '04 Sep 2020 20:41'	System	05 Sep 2020 01:41:27
	System	05 Sep 2020 01:41:27

US3342200

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:05:26

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:04:20
User entered '04 Sep 2020 20:36'	System	04 Sep 2020 21:55:03

US3342200

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:05:26

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:04:20
User entered '05 Sep 2020 11:59'	System	04 Sep 2020 21:55:03

US3342200

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:05:26

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:04:20
Data entry locked.	System	04 Sep 2020 21:55:03
User entered 'Day 2'	System	04 Sep 2020 21:55:03

US3342200

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:05:26

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:04:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2D2D1647-7C35-4DCA-ADA3-8E1DAA921DDC)', Time: '2020-09-05T12:03:03', User OID: 'PatientReportedOutcome (US3342200)', ODM File OID: 'd3fff3df-a0e5-4844-96ec-98147dc31128' User entered 'None (0)'	System	05 Sep 2020 17:03:36
	System	05 Sep 2020 17:03:36

US3342200

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:05:26

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:04:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2D2D1647-7C35-4DCA-ADA3-8E1DAA921DDC)', Time: '2020-09-05T12:03:06', User OID: 'PatientReportedOutcome (US3342200)', ODM File OID: 'd3fff3df-a0e5-4844-96ec-98147dc31128' User entered 'None (0)'	System	05 Sep 2020 17:03:36
	System	05 Sep 2020 17:03:36

US3342200

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:05:26

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:04:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2D2D1647-7C35-4DCA-ADA3-8E1DAA921DDC)', Time: '2020-09-05T12:03:09', User OID: 'PatientReportedOutcome (US3342200)', ODM File OID: 'd3fff3df-a0e5-4844-96ec-98147dc31128' User entered 'None (0)'	System	05 Sep 2020 17:03:36
	System	05 Sep 2020 17:03:36

US3342200

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:05:26

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:04:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2D2D1647-7C35-4DCA-ADA3-8E1DAA921DDC)', Time: '2020-09-05T12:03:14', User OID: 'PatientReportedOutcome (US3342200)', ODM File OID: 'd3fff3df-a0e5-4844-96ec-98147dc31128' User entered 'None (0)'	System	05 Sep 2020 17:03:36
	System	05 Sep 2020 17:03:36

US3342200

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:05:26

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:04:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2D2D1647-7C35-4DCA-ADA3-8E1DAA921DDC)', Time: '2020-09-05T12:03:16', User OID: 'PatientReportedOutcome (US3342200)', ODM File OID: 'd3fff3df-a0e5-4844-96ec-98147dc31128' User entered 'None (0)'	System	05 Sep 2020 17:03:36
	System	05 Sep 2020 17:03:36

US3342200

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:05:26

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:04:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2D2D1647-7C35-4DCA-ADA3-8E1DAA921DDC)', Time: '2020-09-05T12:03:19', User OID: 'PatientReportedOutcome (US3342200)', ODM File OID: 'd3fff3df-a0e5-4844-96ec-98147dc31128' User entered 'None (0)'	System	05 Sep 2020 17:03:36
	System	05 Sep 2020 17:03:36

US3342200

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:05:26

Did you receive any **MEDICAL ATTENTION** (doctor visit, other) for any illness or symptoms?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:04:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2D2D1647-7C35-4DCA-ADA3-8E1DAA921DDC)', Time: '2020-09-05T12:03:23', User OID: 'PatientReportedOutcome (US3342200)', ODM File OID: 'd3fff3df-a0e5-4844-96ec-98147dc31128' User entered 'No (N)'	System	05 Sep 2020 17:03:36
	System	05 Sep 2020 17:03:36

US3342200

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:05:26

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:04:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2D2D1647-7C35-4DCA-ADA3-8E1DAA921DDC)', Time: '2020-09-05T12:03:33', User OID: 'PatientReportedOutcome (US3342200)', ODM File OID: 'd3fff3df-a0e5-4844-96ec-98147dc31128' User entered '05 Sep 2020 12:03'	System	05 Sep 2020 17:03:36
	System	05 Sep 2020 17:03:36

US3342200

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:05:26

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:04:20
User entered '05 Sep 2020 12:00'	System	04 Sep 2020 21:55:03

US3342200

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:05:26

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:04:20
User entered '06 Sep 2020 11:59'	System	04 Sep 2020 21:55:03

US3342200

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:05:26

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:04:20
Data entry locked.	System	04 Sep 2020 21:55:03
User entered 'Day 3'	System	04 Sep 2020 21:55:03

US3342200

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:05:26

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:04:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2D2D1647-7C35-4DCA-ADA3-8E1DAA921DDC)', Time: '2020-09-06T18:36:32', User OID: 'PatientReportedOutcome (US3342200)', ODM File OID: '1b78fdd8-a347-42b4-946d-5862f33981ed' User entered 'None (0)'	System	06 Sep 2020 23:37:11
	System	06 Sep 2020 23:37:11

US3342200

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:05:26

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:04:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2D2D1647-7C35-4DCA-ADA3-8E1DAA921DDC)', Time: '2020-09-06T18:36:36', User OID: 'PatientReportedOutcome (US3342200)', ODM File OID: '1b78fdd8-a347-42b4-946d-5862f33981ed' User entered 'None (0)'	System	06 Sep 2020 23:37:11
	System	06 Sep 2020 23:37:11

US3342200

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:05:26

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:04:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2D2D1647-7C35-4DCA-ADA3-8E1DAA921DDC)', Time: '2020-09-06T18:36:44', User OID: 'PatientReportedOutcome (US3342200)', ODM File OID: '1b78fdd8-a347-42b4-946d-5862f33981ed' User entered 'None (0)'	System	06 Sep 2020 23:37:11
	System	06 Sep 2020 23:37:11

US3342200

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:05:26

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:04:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2D2D1647-7C35-4DCA-ADA3-8E1DAA921DDC)', Time: '2020-09-06T18:36:51', User OID: 'PatientReportedOutcome (US3342200)', ODM File OID: '1b78fdd8-a347-42b4-946d-5862f33981ed' User entered 'None (0)'	System	06 Sep 2020 23:37:11
	System	06 Sep 2020 23:37:11

US3342200

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:05:26

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:04:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2D2D1647-7C35-4DCA-ADA3-8E1DAA921DDC)', Time: '2020-09-06T18:36:56', User OID: 'PatientReportedOutcome (US3342200)', ODM File OID: '1b78fdd8-a347-42b4-946d-5862f33981ed' User entered 'None (0)'	System	06 Sep 2020 23:37:11
	System	06 Sep 2020 23:37:11

US3342200

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:05:26

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:04:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2D2D1647-7C35-4DCA-ADA3-8E1DAA921DDC)', Time: '2020-09-06T18:36:59', User OID: 'PatientReportedOutcome (US3342200)', ODM File OID: '1b78fdd8-a347-42b4-946d-5862f33981ed' User entered 'None (0)'	System	06 Sep 2020 23:37:11
	System	06 Sep 2020 23:37:11

US3342200

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:05:26

Did you receive any **MEDICAL ATTENTION** (doctor visit, other) for any illness or symptoms?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:04:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2D2D1647-7C35-4DCA-ADA3-8E1DAA921DDC)', Time: '2020-09-06T18:37:04', User OID: 'PatientReportedOutcome (US3342200)', ODM File OID: '1b78fdd8-a347-42b4-946d-5862f33981ed' User entered 'No (N)'	System	06 Sep 2020 23:37:11
	System	06 Sep 2020 23:37:11

US3342200

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:05:26

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:04:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2D2D1647-7C35-4DCA-ADA3-8E1DAA921DDC)', Time: '2020-09-06T18:37:09', User OID: 'PatientReportedOutcome (US3342200)', ODM File OID: '1b78fdd8-a347-42b4-946d-5862f33981ed' User entered '06 Sep 2020 18:37'	System	06 Sep 2020 23:37:11
	System	06 Sep 2020 23:37:11

US3342200

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:05:26

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:04:20
User entered '06 Sep 2020 12:00'	System	04 Sep 2020 21:55:03

US3342200

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:05:26

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:04:20
User entered '07 Sep 2020 11:59'	System	04 Sep 2020 21:55:03

US3342200

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:05:26

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:04:20
Data entry locked.	System	04 Sep 2020 21:55:03
User entered 'Day 4'	System	04 Sep 2020 21:55:03

US3342200

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:05:26

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:04:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2D2D1647-7C35-4DCA-ADA3-8E1DAA921DDC)', Time: '2020-09-07T18:23:53', User OID: 'PatientReportedOutcome (US3342200)', ODM File OID: '9ba9383a-0590-4b1c-86cb-7e82d29d5666' User entered 'None (0)'	System	07 Sep 2020 23:24:32
	System	07 Sep 2020 23:24:32

US3342200

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:05:26

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:04:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2D2D1647-7C35-4DCA-ADA3-8E1DAA921DDC)', Time: '2020-09-07T18:23:58', User OID: 'PatientReportedOutcome (US3342200)', ODM File OID: '9ba9383a-0590-4b1c-86cb-7e82d29d5666' User entered 'None (0)'	System	07 Sep 2020 23:24:32
	System	07 Sep 2020 23:24:32

US3342200

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:05:26

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:04:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2D2D1647-7C35-4DCA-ADA3-8E1DAA921DDC)', Time: '2020-09-07T18:24:03', User OID: 'PatientReportedOutcome (US3342200)', ODM File OID: '9ba9383a-0590-4b1c-86cb-7e82d29d5666' User entered 'None (0)'	System	07 Sep 2020 23:24:32
	System	07 Sep 2020 23:24:32

US3342200

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:05:26

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:04:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2D2D1647-7C35-4DCA-ADA3-8E1DAA921DDC)', Time: '2020-09-07T18:24:10', User OID: 'PatientReportedOutcome (US3342200)', ODM File OID: '9ba9383a-0590-4b1c-86cb-7e82d29d5666' User entered 'None (0)'	System	07 Sep 2020 23:24:32
	System	07 Sep 2020 23:24:32

US3342200

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:05:26

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:04:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2D2D1647-7C35-4DCA-ADA3-8E1DAA921DDC)', Time: '2020-09-07T18:24:13', User OID: 'PatientReportedOutcome (US3342200)', ODM File OID: '9ba9383a-0590-4b1c-86cb-7e82d29d5666' User entered 'None (0)'	System	07 Sep 2020 23:24:32
	System	07 Sep 2020 23:24:32

US3342200

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:05:26

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:04:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2D2D1647-7C35-4DCA-ADA3-8E1DAA921DDC)', Time: '2020-09-07T18:24:17', User OID: 'PatientReportedOutcome (US3342200)', ODM File OID: '9ba9383a-0590-4b1c-86cb-7e82d29d5666' User entered 'None (0)'	System	07 Sep 2020 23:24:32
	System	07 Sep 2020 23:24:32

US3342200

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:05:26

Did you receive any **MEDICAL ATTENTION** (doctor visit, other) for any illness or symptoms?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:04:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2D2D1647-7C35-4DCA-ADA3-8E1DAA921DDC)', Time: '2020-09-07T18:24:24', User OID: 'PatientReportedOutcome (US3342200)', ODM File OID: '9ba9383a-0590-4b1c-86cb-7e82d29d5666' User entered 'No (N)'	System	07 Sep 2020 23:24:32
	System	07 Sep 2020 23:24:32

US3342200

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:05:26

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:04:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2D2D1647-7C35-4DCA-ADA3-8E1DAA921DDC)', Time: '2020-09-07T18:24:27', User OID: 'PatientReportedOutcome (US3342200)', ODM File OID: '9ba9383a-0590-4b1c-86cb-7e82d29d5666' User entered '07 Sep 2020 18:24'	System	07 Sep 2020 23:24:32
	System	07 Sep 2020 23:24:32

US3342200

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:05:26

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:04:20
User entered '07 Sep 2020 12:00'	System	04 Sep 2020 21:55:03

US3342200

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:05:26

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:04:20
User entered '08 Sep 2020 11:59'	System	04 Sep 2020 21:55:03

US3342200

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:05:26

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:04:20
Data entry locked.	System	04 Sep 2020 21:55:03
User entered 'Day 5'	System	04 Sep 2020 21:55:03

US3342200

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:05:26

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:04:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2D2D1647-7C35-4DCA-ADA3-8E1DAA921DDC)', Time: '2020-09-09T03:18:04', User OID: 'PatientReportedOutcome (US3342200)', ODM File OID: '90155f4b-9974-40b4-abef-3dc586523a30' User entered 'None (0)'	System	09 Sep 2020 08:18:28
	System	09 Sep 2020 08:18:28

US3342200

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:05:26

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:04:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2D2D1647-7C35-4DCA-ADA3-8E1DAA921DDC)', Time: '2020-09-09T03:18:05', User OID: 'PatientReportedOutcome (US3342200)', ODM File OID: '90155f4b-9974-40b4-abef-3dc586523a30' User entered 'None (0)'	System	09 Sep 2020 08:18:28
	System	09 Sep 2020 08:18:28

US3342200

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:05:26

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:04:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2D2D1647-7C35-4DCA-ADA3-8E1DAA921DDC)', Time: '2020-09-09T03:18:08', User OID: 'PatientReportedOutcome (US3342200)', ODM File OID: '90155f4b-9974-40b4-abef-3dc586523a30' User entered 'None (0)'	System	09 Sep 2020 08:18:28
	System	09 Sep 2020 08:18:28

US3342200

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:05:26

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:04:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2D2D1647-7C35-4DCA-ADA3-8E1DAA921DDC)', Time: '2020-09-09T03:18:12', User OID: 'PatientReportedOutcome (US3342200)', ODM File OID: '90155f4b-9974-40b4-abef-3dc586523a30' User entered 'None (0)'	System	09 Sep 2020 08:18:28
	System	09 Sep 2020 08:18:28

US3342200

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:05:26

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:04:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2D2D1647-7C35-4DCA-ADA3-8E1DAA921DDC)', Time: '2020-09-09T03:18:14', User OID: 'PatientReportedOutcome (US3342200)', ODM File OID: '90155f4b-9974-40b4-abef-3dc586523a30' User entered 'None (0)'	System	09 Sep 2020 08:18:28
	System	09 Sep 2020 08:18:28

US3342200

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:05:26

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:04:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2D2D1647-7C35-4DCA-ADA3-8E1DAA921DDC)', Time: '2020-09-09T03:18:16', User OID: 'PatientReportedOutcome (US3342200)', ODM File OID: '90155f4b-9974-40b4-abef-3dc586523a30' User entered 'None (0)'	System	09 Sep 2020 08:18:28
	System	09 Sep 2020 08:18:28

US3342200

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:05:26

Did you receive any **MEDICAL ATTENTION** (doctor visit, other) for any illness or symptoms?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:04:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2D2D1647-7C35-4DCA-ADA3-8E1DAA921DDC)', Time: '2020-09-09T03:18:21', User OID: 'PatientReportedOutcome (US3342200)', ODM File OID: '90155f4b-9974-40b4-abef-3dc586523a30' User entered 'No (N)'	System	09 Sep 2020 08:18:28
	System	09 Sep 2020 08:18:28

US3342200

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:05:26

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:04:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2D2D1647-7C35-4DCA-ADA3-8E1DAA921DDC)', Time: '2020-09-09T03:18:26', User OID: 'PatientReportedOutcome (US3342200)', ODM File OID: '90155f4b-9974-40b4-abef-3dc586523a30' User entered '09 Sep 2020 03:18'	System	09 Sep 2020 08:18:28
	System	09 Sep 2020 08:18:28

US3342200

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:05:26

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:04:20
User entered '08 Sep 2020 12:00'	System	04 Sep 2020 21:55:03

US3342200

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:05:26

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:04:20
User entered '09 Sep 2020 11:59'	System	04 Sep 2020 21:55:03

US3342200

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:05:26

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:04:20
Data entry locked.	System	04 Sep 2020 21:55:03
User entered 'Day 6'	System	04 Sep 2020 21:55:03

US3342200

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:05:26

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:04:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2D2D1647-7C35-4DCA-ADA3-8E1DAA921DDC)', Time: '2020-09-09T14:29:50', User OID: 'PatientReportedOutcome (US3342200)', ODM File OID: '39a54276-2e6b-465d-aabd-8810be393315' User entered 'None (0)'	System	09 Sep 2020 19:30:20
	System	09 Sep 2020 19:30:20

US3342200

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:05:26

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:04:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2D2D1647-7C35-4DCA-ADA3-8E1DAA921DDC)', Time: '2020-09-09T14:29:53', User OID: 'PatientReportedOutcome (US3342200)', ODM File OID: '39a54276-2e6b-465d-aabd-8810be393315' User entered 'None (0)'	System	09 Sep 2020 19:30:20
	System	09 Sep 2020 19:30:20

US3342200

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:05:26

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:04:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2D2D1647-7C35-4DCA-ADA3-8E1DAA921DDC)', Time: '2020-09-09T14:29:55', User OID: 'PatientReportedOutcome (US3342200)', ODM File OID: '39a54276-2e6b-465d-aabd-8810be393315' User entered 'None (0)'	System	09 Sep 2020 19:30:20
	System	09 Sep 2020 19:30:20

US3342200

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:05:26

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:04:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2D2D1647-7C35-4DCA-ADA3-8E1DAA921DDC)', Time: '2020-09-09T14:29:58', User OID: 'PatientReportedOutcome (US3342200)', ODM File OID: '39a54276-2e6b-465d-aabd-8810be393315' User entered 'None (0)'	System	09 Sep 2020 19:30:20
	System	09 Sep 2020 19:30:20

US3342200

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:05:26

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:04:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2D2D1647-7C35-4DCA-ADA3-8E1DAA921DDC)', Time: '2020-09-09T14:30:00', User OID: 'PatientReportedOutcome (US3342200)', ODM File OID: '39a54276-2e6b-465d-aabd-8810be393315' User entered 'None (0)'	System	09 Sep 2020 19:30:20
	System	09 Sep 2020 19:30:20

US3342200

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:05:26

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:04:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2D2D1647-7C35-4DCA-ADA3-8E1DAA921DDC)', Time: '2020-09-09T14:30:03', User OID: 'PatientReportedOutcome (US3342200)', ODM File OID: '39a54276-2e6b-465d-aabd-8810be393315' User entered 'None (0)'	System	09 Sep 2020 19:30:20
	System	09 Sep 2020 19:30:20

US3342200

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:05:26

Did you receive any **MEDICAL ATTENTION** (doctor visit, other) for any illness or symptoms?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:04:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2D2D1647-7C35-4DCA-ADA3-8E1DAA921DDC)', Time: '2020-09-09T14:30:07', User OID: 'PatientReportedOutcome (US3342200)', ODM File OID: '39a54276-2e6b-465d-aabd-8810be393315' User entered 'No (N)'	System	09 Sep 2020 19:30:20
	System	09 Sep 2020 19:30:20

US3342200

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:05:26

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:04:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2D2D1647-7C35-4DCA-ADA3-8E1DAA921DDC)', Time: '2020-09-09T14:30:18', User OID: 'PatientReportedOutcome (US3342200)', ODM File OID: '39a54276-2e6b-465d-aabd-8810be393315' User entered '09 Sep 2020 14:30'	System	09 Sep 2020 19:30:20
	System	09 Sep 2020 19:30:20

US3342200

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:05:26

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:04:20
User entered '09 Sep 2020 12:00'	System	04 Sep 2020 21:55:03

US3342200

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:05:26

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:04:20
User entered '10 Sep 2020 11:59'	System	04 Sep 2020 21:55:03

US3342200

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:05:26

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:04:20
Data entry locked.	System	04 Sep 2020 21:55:03
User entered 'Day 7'	System	04 Sep 2020 21:55:03

US3342200

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:05:26

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:04:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2D2D1647-7C35-4DCA-ADA3-8E1DAA921DDC)', Time: '2020-09-10T12:20:49', User OID: 'PatientReportedOutcome (US3342200)', ODM File OID: 'ce9444c4-67c9-4b96-93be-eba69a4eb82f' User entered 'None (0)'	System	10 Sep 2020 17:21:11
	System	10 Sep 2020 17:21:11

US3342200

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:05:26

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:04:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2D2D1647-7C35-4DCA-ADA3-8E1DAA921DDC)', Time: '2020-09-10T12:20:51', User OID: 'PatientReportedOutcome (US3342200)', ODM File OID: 'ce9444c4-67c9-4b96-93be-eba69a4eb82f' User entered 'None (0)'	System	10 Sep 2020 17:21:11
	System	10 Sep 2020 17:21:11

US3342200

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:05:26

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:04:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2D2D1647-7C35-4DCA-ADA3-8E1DAA921DDC)', Time: '2020-09-10T12:20:53', User OID: 'PatientReportedOutcome (US3342200)', ODM File OID: 'ce9444c4-67c9-4b96-93be-eba69a4eb82f' User entered 'None (0)'	System	10 Sep 2020 17:21:11
	System	10 Sep 2020 17:21:11

US3342200

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:05:26

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:04:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2D2D1647-7C35-4DCA-ADA3-8E1DAA921DDC)', Time: '2020-09-10T12:20:56', User OID: 'PatientReportedOutcome (US3342200)', ODM File OID: 'ce9444c4-67c9-4b96-93be-eba69a4eb82f' User entered 'None (0)'	System	10 Sep 2020 17:21:11
	System	10 Sep 2020 17:21:11

US3342200

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:05:26

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:04:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2D2D1647-7C35-4DCA-ADA3-8E1DAA921DDC)', Time: '2020-09-10T12:20:58', User OID: 'PatientReportedOutcome (US3342200)', ODM File OID: 'ce9444c4-67c9-4b96-93be-eba69a4eb82f' User entered 'None (0)'	System	10 Sep 2020 17:21:11
	System	10 Sep 2020 17:21:11

US3342200

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:05:26

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:04:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2D2D1647-7C35-4DCA-ADA3-8E1DAA921DDC)', Time: '2020-09-10T12:21:03', User OID: 'PatientReportedOutcome (US3342200)', ODM File OID: 'ce9444c4-67c9-4b96-93be-eba69a4eb82f' User entered 'None (0)'	System	10 Sep 2020 17:21:11
	System	10 Sep 2020 17:21:11

US3342200

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:05:26

Did you receive any **MEDICAL ATTENTION** (doctor visit, other) for any illness or symptoms?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:04:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2D2D1647-7C35-4DCA-ADA3-8E1DAA921DDC)', Time: '2020-09-10T12:21:05', User OID: 'PatientReportedOutcome (US3342200)', ODM File OID: 'ce9444c4-67c9-4b96-93be-eba69a4eb82f' User entered 'No (N)'	System	10 Sep 2020 17:21:11
	System	10 Sep 2020 17:21:11

US3342200

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:05:26

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:04:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2D2D1647-7C35-4DCA-ADA3-8E1DAA921DDC)', Time: '2020-09-10T12:21:09', User OID: 'PatientReportedOutcome (US3342200)', ODM File OID: 'ce9444c4-67c9-4b96-93be-eba69a4eb82f' User entered '10 Sep 2020 12:21'	System	10 Sep 2020 17:21:11
	System	10 Sep 2020 17:21:11

US3342200

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:05:26

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:04:20
User entered '10 Sep 2020 12:00'	System	04 Sep 2020 21:55:03

US3342200

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:05:26

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:04:20
User entered '11 Sep 2020 11:59'	System	04 Sep 2020 21:55:03

US3342200

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:05:26

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 09:47:07
User signature succeeded.	Paul Pickrell (b) (4)	12 Feb 2021 23:50:36
User entered 'Yes (Y)'	Ethan Shotton (b) (4)	14 Sep 2020 19:49:49

US3342200

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:05:26

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 09:47:07
User signature succeeded.	Paul Pickrell (b) (4)	12 Feb 2021 23:50:36
User entered '14 Sep 2020'	Ethan Shotton (b) (4)	14 Sep 2020 19:49:49

US3342200

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:05:26

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 09:47:07
User signature succeeded.	Paul Pickrell (b) (4)	12 Feb 2021 23:50:36
User entered 'Contact Made (CONTACT MADE)'	Ethan Shotton (b) (4)	14 Sep 2020 19:49:49

US3342200

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:05:26

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 09:47:07
User signature succeeded.	Paul Pickrell (b) (4)	12 Feb 2021 23:50:36
User entered empty.	Ethan Shotton (b) (4)	14 Sep 2020 19:49:49

US3342200

Folder: Safety Call Day 8 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:05:26

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 09:47:07
User signature succeeded.	Paul Pickrell (b) (4)	12 Feb 2021 23:50:36
User entered 'Yes (Y)'	Ethan Shotton (b) (4)	14 Sep 2020 19:49:55

US3342200

Folder: Safety Call Day 8 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:05:26

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 09:47:07
User entered '1'	System	14 Sep 2020 19:49:55

US3342200

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:05:26

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 09:47:07
User signature succeeded.	Paul Pickrell (b) (4)	12 Feb 2021 23:50:36
User entered 'Yes (Y)'	Ethan Shotton (b) (4)	21 Sep 2020 19:27:42

US3342200

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:05:26

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 09:47:07
User signature succeeded.	Paul Pickrell (b) (4)	12 Feb 2021 23:50:36
User entered '21 Sep 2020'	Ethan Shotton (b) (4)	21 Sep 2020 19:27:42

US3342200

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:05:26

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 09:47:07
User signature succeeded.	Paul Pickrell (b) (4)	12 Feb 2021 23:50:36
User entered 'Contact Made (CONTACT MADE)'	Ethan Shotton (b) (4)	21 Sep 2020 19:27:42

US3342200

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:05:26

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 09:47:07
User signature succeeded.	Paul Pickrell (b) (4)	12 Feb 2021 23:50:36
User entered empty.	Ethan Shotton (b) (4)	21 Sep 2020 19:27:42

US3342200

Folder: Safety Call Day 15 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:05:26

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 09:47:07
User signature succeeded.	Paul Pickrell (b) (4)	12 Feb 2021 23:50:36
User entered 'Yes (Y)'	Ethan Shotton (b) (4)	21 Sep 2020 19:27:47

US3342200

Folder: Safety Call Day 15 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:05:26

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 09:47:07
User entered 'I'	System	21 Sep 2020 19:27:47

US3342200

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:05:26

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 09:47:07
User signature succeeded.	Paul Pickrell (b) (4)	12 Feb 2021 23:50:36
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	28 Sep 2020 21:51:48

US3342200

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:05:26

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 09:47:07
User signature succeeded.	Paul Pickrell (b) (4)	12 Feb 2021 23:50:36
User entered '28 Sep 2020'	(b) (4) (b) (4), (b) (6)	28 Sep 2020 21:51:48

US3342200

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:05:26

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 09:47:07
User signature succeeded.	Paul Pickrell (b) (4)	12 Feb 2021 23:50:36
User entered 'Contact Made (CONTACT MADE)'	(b) (4) (b) (4), (b) (6)	28 Sep 2020 21:51:48

US3342200

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:05:26

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 09:47:07
User signature succeeded.	Paul Pickrell (b) (4)	12 Feb 2021 23:50:36
User entered empty.	(b) (4) (b) (4), (b) (6)	28 Sep 2020 21:51:48

US3342200

Folder: Safety Call Day 22 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:05:26

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 09:47:07
User signature succeeded.	Paul Pickrell (b) (4)	12 Feb 2021 23:50:36
User entered 'Yes (Y)' reason for change: Data Entry Error	(b) (4)	
	Morgan Schulle (b) (4)	30 Sep 2020 16:21:02
User entered 'No (N)'	(b) (4)	
	(b) (4), (b) (6)	28 Sep 2020 21:51:51

US3342200

Folder: Safety Call Day 22 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:05:26

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 09:47:07
User entered '1'	System	30 Sep 2020 16:21:02
User entered empty.	System	28 Sep 2020 21:51:51

US3342200

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 09 Jun 2021 17:05:26

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 09:47:07
User signature succeeded.	Paul Pickrell (b) (4)	12 Feb 2021 23:50:36
User entered 'Yes (Y)'	(b) (4) Morgan Schulle (b) (4)	30 Sep 2020 16:21:23

US3342200

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 09 Jun 2021 17:05:26

[Visit date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 09:47:07
User signature succeeded.	Paul Pickrell (b) (4)	12 Feb 2021 23:50:36
User entered '30 Sep 2020'	(b) (4) Morgan Schulle (b) (4)	30 Sep 2020 16:21:23

US3342200

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 09 Jun 2021 17:05:26

[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 09:47:07
User signature succeeded.	Paul Pickrell (b) (4)	12 Feb 2021 23:50:36
User entered 'Clinic (Clinic)'	Morgan Schulle (b) (4)	30 Sep 2020 16:21:23

US3342200

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 09 Jun 2021 17:05:26

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 09:47:07
User entered 'VISIT2'	System	30 Sep 2020 16:21:23

US3342200

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:05:26

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 09:47:07
User accepted default value 'Pre-Dose (PREDOSE)'	(b) (4), (b) (6)	30 Sep 2020 16:30:46

US3342200

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:05:26

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 09:47:07
User signature succeeded.	Paul Pickrell (b) (4)	12 Feb 2021 23:50:36
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	30 Sep 2020 16:30:46

US3342200

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:05:26

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 09:47:07
User signature succeeded.	Paul Pickrell (b) (4)	12 Feb 2021 23:50:36
User entered '30 Sep 2020'	(b) (4) (b) (4), (b) (6)	30 Sep 2020 16:30:46

US3342200

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:05:26

Time of assessment (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 09:47:07
User signature succeeded.	Paul Pickrell (b) (4)	12 Feb 2021 23:50:36
User entered '10:20'	(b) (4) (b) (4), (b) (6)	30 Sep 2020 16:30:46

US3342200

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:05:26

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 09:47:07
User entered '30 Sep 2020 10:20'	System	30 Sep 2020 16:30:46

US3342200

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:05:26

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 09:47:07
User signature succeeded.	Paul Pickrell (b) (4)	12 Feb 2021 23:50:36
User entered '98.7' F	(b) (4) (b) (4), (b) (6)	30 Sep 2020 16:30:46

US3342200

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:05:26

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 09:47:07
User signature succeeded.	Paul Pickrell (b) (4)	12 Feb 2021 23:50:36
User entered 'Oral (Oral)'	(b) (4) (b) (4), (b) (6)	30 Sep 2020 16:30:46

US3342200

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:05:26

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 09:47:07
User signature succeeded.	Paul Pickrell (b) (4)	12 Feb 2021 23:50:36
User entered empty.	(b) (4) (b) (4), (b) (6)	30 Sep 2020 16:30:46

US3342200

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:05:26

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 09:47:07
User signature succeeded.	Paul Pickrell (b) (4)	12 Feb 2021 23:50:36
User entered '77'	(b) (4) (b) (4), (b) (6)	30 Sep 2020 16:30:46

US3342200

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:05:26

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 09:47:07
User entered 'bpm'	System	30 Sep 2020 16:30:46

US3342200

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:05:26

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 09:47:07
User signature succeeded.	Paul Pickrell (b) (4)	12 Feb 2021 23:50:36
User entered '14'	(b) (4) (b) (4), (b) (6)	30 Sep 2020 16:30:46

US3342200

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:05:26

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 09:47:07
User entered 'breaths/min'	System	30 Sep 2020 16:30:46

US3342200

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:05:26

[Systolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 09:47:07
User signature succeeded.	Paul Pickrell (b) (4)	12 Feb 2021 23:50:36
User entered '116'	(b) (4) (b) (4), (b) (6)	30 Sep 2020 16:30:46

US3342200

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:05:26

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 09:47:07
User entered 'mmHg'	System	30 Sep 2020 16:30:46

US3342200

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:05:26

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 09:47:07
User signature succeeded.	Paul Pickrell (b) (4)	12 Feb 2021 23:50:36
User entered '79'	(b) (4) (b) (4), (b) (6)	30 Sep 2020 16:30:46

US3342200

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:05:26

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 09:47:07
User entered 'mmHg'	System	30 Sep 2020 16:30:46

US3342200

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:05:26

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 09:47:07
User accepted default value 'Post-Dose (POSTDOSE)'	(b) (4), (b) (6)	30 Sep 2020 16:30:46

US3342200

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:05:26

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 09:47:07
User signature succeeded.	Paul Pickrell (b) (4)	12 Feb 2021 23:50:36
User closed query 'Data is required. Please complete.' (Site from System).	(b) (4)	30 Sep 2020 16:36:46
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	30 Sep 2020 16:36:46
User entered 'Yes (Y)' reason for change: Data Entry Error	(b) (4), (b) (6)	30 Sep 2020 16:36:46
User opened query 'Data is required. Please complete.' (Site from System).	System	30 Sep 2020 16:30:46
User entered empty.	(b) (4), (b) (6)	30 Sep 2020 16:30:46

US3342200

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:05:26

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 09:47:07
User signature succeeded.	Paul Pickrell (b) (4)	12 Feb 2021 23:50:36
User entered '30 Sep 2020' reason for change: Data Entry Error	(b) (4) (b) (4), (b) (6)	30 Sep 2020 16:36:46
User entered empty.	(b) (4), (b) (6)	30 Sep 2020 16:30:46

US3342200

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:05:26

Time of assessment (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 09:47:07
User signature succeeded.	Paul Pickrell (b) (4)	12 Feb 2021 23:50:36
User entered '11:32' reason for change: Data Entry Error	(b) (4) (b) (4), (b) (6)	30 Sep 2020 16:36:46
User entered empty.	(b) (4), (b) (6)	30 Sep 2020 16:30:46

US3342200

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:05:26

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 09:47:07
User entered '30 Sep 2020 11:32'	System	30 Sep 2020 16:36:46
User entered empty.	System	30 Sep 2020 16:30:46

US3342200

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:05:26

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 09:47:07
User signature succeeded.	Paul Pickrell (b) (4)	12 Feb 2021 23:50:36
User entered '99.1' F reason for change: Data Entry Error	(b) (4) (b) (4), (b) (6)	30 Sep 2020 16:36:46
User entered empty.	(b) (4), (b) (6)	30 Sep 2020 16:30:46

US3342200

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:05:26

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 09:47:07
User signature succeeded.	Paul Pickrell (b) (4)	12 Feb 2021 23:50:36
User entered 'Oral (Oral)' reason for change: Data Entry Error	(b) (4) (b) (4), (b) (6)	30 Sep 2020 16:36:46
User entered empty.	(b) (4), (b) (6)	30 Sep 2020 16:30:46

US3342200

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:05:26

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 09:47:07
User signature succeeded.	Paul Pickrell (b) (4)	12 Feb 2021 23:50:36
User entered empty.	(b) (4) (b) (4), (b) (6)	30 Sep 2020 16:30:46

US3342200

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:05:26

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 09:47:07
User signature succeeded.	Paul Pickrell (b) (4)	12 Feb 2021 23:50:36
User entered '71' reason for change: Data Entry Error	(b) (4) (b) (4), (b) (6)	30 Sep 2020 16:36:46
User entered empty.	(b) (4), (b) (6)	30 Sep 2020 16:30:46

US3342200

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:05:26

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 09:47:07
User entered 'bpm'	System	30 Sep 2020 16:36:46
User entered empty.	System	30 Sep 2020 16:30:46

US3342200

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:05:26

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 09:47:07
User signature succeeded.	Paul Pickrell (b) (4)	12 Feb 2021 23:50:36
User entered '12' reason for change: Data Entry Error	(b) (4) (b) (4), (b) (6)	30 Sep 2020 16:36:46
User entered empty.	(b) (4), (b) (6)	30 Sep 2020 16:30:46

US3342200

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:05:26

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 09:47:07
User entered 'breaths/min'	System	30 Sep 2020 16:36:46
User entered empty.	System	30 Sep 2020 16:30:46

US3342200

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:05:26

[Systolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 09:47:07
User signature succeeded.	Paul Pickrell (b) (4)	12 Feb 2021 23:50:36
User entered '107' reason for change: Data Entry Error	(b) (4) (b) (4), (b) (6)	30 Sep 2020 16:36:46
User entered empty.	(b) (4), (b) (6)	30 Sep 2020 16:30:46

US3342200

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:05:26

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 09:47:07
User entered 'mmHg'	System	30 Sep 2020 16:36:46
User entered empty.	System	30 Sep 2020 16:30:46

US3342200

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:05:26

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 09:47:07
User signature succeeded.	Paul Pickrell (b) (4)	12 Feb 2021 23:50:36
User entered '68' reason for change: Data Entry Error	(b) (4) (b) (4), (b) (6)	30 Sep 2020 16:36:46
User entered empty.	(b) (4), (b) (6)	30 Sep 2020 16:30:46

US3342200

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:05:26

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 09:47:07
User entered 'mmHg'	System	30 Sep 2020 16:36:46
User entered empty.	System	30 Sep 2020 16:30:46

US3342200

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 17:05:26

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 09:47:07
User signature succeeded.	Paul Pickrell (b) (4)	12 Feb 2021 23:50:36
User entered 'Yes (Y)'	(b) (4) Morgan Schulle (b) (4)	30 Sep 2020 16:22:02

US3342200

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 17:05:26

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 09:47:07
User signature succeeded.	Paul Pickrell (b) (4)	12 Feb 2021 23:50:36
User entered '30 Sep 2020'	(b) (4) Morgan Schulle (b) (4)	30 Sep 2020 16:22:02

US3342200

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 17:05:26

[Was study treatment given?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 09:47:07
User signature succeeded.	Paul Pickrell (b) (4)	12 Feb 2021 23:50:36
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	30 Sep 2020 16:25:19

US3342200

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 17:05:26

If No, reason not given

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 09:47:07
User signature succeeded.	Paul Pickrell (b) (4)	12 Feb 2021 23:50:36
User entered empty.	(b) (4) (b) (4), (b) (6)	30 Sep 2020 16:25:19

US3342200

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 17:05:26

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)	14 Apr 2021 09:47:07
User signature succeeded.	Paul Pickrell (b) (4)	12 Feb 2021 23:50:36
User entered empty.	(b) (4) (b) (4), (b) (6)	30 Sep 2020 16:25:19

US3342200

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 17:05:26

[What was the study treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 09:47:07
User entered 'MRNA-1273 OR PLACEBO'	System	30 Sep 2020 16:25:19

US3342200

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 17:05:26

What was the treatment date? (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 09:47:07
User signature succeeded.	Paul Pickrell (b) (4)	12 Feb 2021 23:50:36
User entered '30 Sep 2020'	(b) (4) (b) (4), (b) (6)	30 Sep 2020 16:25:19

US3342200

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 17:05:26

[What was the treatment time? \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 09:47:07
User signature succeeded.	Paul Pickrell (b) (4)	12 Feb 2021 23:50:36
User entered '10:59'	(b) (4) (b) (4), (b) (6)	30 Sep 2020 16:25:19

US3342200

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 17:05:26

[Treatment Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 09:47:07
User entered '30 Sep 2020 10:59'	System	30 Sep 2020 16:25:19

US3342200

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 17:05:26

[Which arm was used to give treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 09:47:07
User signature succeeded.	Paul Pickrell (b) (4)	12 Feb 2021 23:50:36
User entered 'Left Arm (LEFT ARM)'	(b) (4) (b) (4), (b) (6)	30 Sep 2020 16:25:19

US3342200

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 17:05:26

[What was the frequency of the study treatment dosing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 09:47:07
User entered 'ONCE'	System	30 Sep 2020 16:25:19

US3342200

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 17:05:26

What was the route of administration for the study treatment?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 09:47:07
User entered 'INTRAMUSCULAR'	System	30 Sep 2020 16:25:19

US3342200

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:05:26

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 09:47:07
User signature succeeded.	Paul Pickrell (b) (4)	12 Feb 2021 23:50:36
User entered 'Yes (Y)'	(b) (4) Morgan Schulle (b) (4)	06 Oct 2020 13:26:23

US3342200

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:05:26

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 09:47:07
User signature succeeded.	Paul Pickrell (b) (4)	12 Feb 2021 23:50:36
User entered '30 Sep 2020'	(b) (4) Morgan Schulle (b) (4)	06 Oct 2020 13:26:23

US3342200

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:05:26

Collection time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 09:47:07
User signature succeeded.	Paul Pickrell (b) (4)	12 Feb 2021 23:50:36
User entered '10:48'	(b) (4) Morgan Schulle (b) (4)	06 Oct 2020 13:26:23

US3342200

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:05:26

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 09:47:07
User entered '30 Sep 2020 10:48'	System	06 Oct 2020 13:26:23

US3342200

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab

Generated On: 09 Jun 2021 17:05:26

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 09:47:07
User signature succeeded.	Paul Pickrell (b) (4)	12 Feb 2021 23:50:36
User entered '30 Sep 2020'	(b) (4) Morgan Schulle (b) (4)	06 Oct 2020 13:26:39

US3342200

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 17:05:26

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 09:47:07
User accepted default value 'Nasopharyngeal Swab 1 (NASAL1)'	Morgan Schulle (b) (4) (b) (4)	06 Oct 2020 13:26:39

US3342200

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 17:05:26

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 09:47:07
User signature succeeded.	Paul Pickrell (b) (4)	12 Feb 2021 23:50:36
User entered 'Yes (Y)'	(b) (4) Morgan Schulle (b) (4)	06 Oct 2020 13:26:39

US3342200

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 17:05:26

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 09:47:07
User signature succeeded.	Paul Pickrell (b) (4)	12 Feb 2021 23:50:36
User entered '10:50'	(b) (4) Morgan Schulle (b) (4)	06 Oct 2020 13:26:39

US3342200

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 17:05:26

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 09:47:07
User entered '30 Sep 2020 10:50'	System	06 Oct 2020 13:26:39

US3342200

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 17:05:26

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 09:47:07
User accepted default value 'Nasopharyngeal Swab 2 (NASAL2)'	Morgan Schulle (b) (4) (b) (4)	06 Oct 2020 13:26:39

US3342200

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 17:05:26

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 09:47:07
User signature succeeded.	Paul Pickrell (b) (4)	12 Feb 2021 23:50:36
User entered 'No (N)'	(b) (4) Morgan Schulle (b) (4)	06 Oct 2020 13:26:39

US3342200

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 17:05:26

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 09:47:07
User signature succeeded.	Paul Pickrell (b) (4)	12 Feb 2021 23:50:36
User entered empty.	Morgan Schulle (b) (4)	06 Oct 2020 13:26:39

US3342200

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 17:05:26

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 09:47:07
User entered empty.	System	06 Oct 2020 13:26:39

US3342200

Folder: Visit 2 Day 29 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:05:26

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 09:47:07
User signature succeeded.	Paul Pickrell (b) (4)	12 Feb 2021 23:50:36
User entered 'Yes (Y)'	(b) (4) Morgan Schulle (b) (4)	30 Sep 2020 16:22:35

US3342200

Folder: Visit 2 Day 29 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:05:26

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 09:47:07
User entered '1'	System	30 Sep 2020 16:22:35

US3342200

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 17:05:26

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:04:20
Data entry locked.	System	30 Sep 2020 16:25:19
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	30 Sep 2020 16:25:19

US3342200

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 17:05:26

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:04:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2D2D1647-7C35-4DCA-ADA3-8E1DAA921DDC)', Time: '2020-09-30T11:37:10', User OID: 'PatientReportedOutcome (US3342200)', ODM File OID: '69b20c6c-7e46-4b4f-82e4-e0c556c34484' User entered 'Yes (Y)'	System	30 Sep 2020 16:37:36
	System	30 Sep 2020 16:37:36

US3342200

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 17:05:26

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:04:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2D2D1647-7C35-4DCA-ADA3-8E1DAA921DDC)', Time: '2020-09-30T11:37:17', User OID: 'PatientReportedOutcome (US3342200)', ODM File OID: '69b20c6c-7e46-4b4f-82e4-e0c556c34484' User entered '99.1'	System	30 Sep 2020 16:37:36
	System	30 Sep 2020 16:37:36

US3342200

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 17:05:26

Was any **MEDICATION TAKEN** today for pain or fever?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:04:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2D2D1647-7C35-4DCA-ADA3-8E1DAA921DDC)', Time: '2020-09-30T11:37:24', User OID: 'PatientReportedOutcome (US3342200)', ODM File OID: '69b20c6c-7e46-4b4f-82e4-e0c556c34484' User entered 'No (N)'	System	30 Sep 2020 16:37:36
	System	30 Sep 2020 16:37:36

US3342200

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 17:05:26

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:04:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2D2D1647-7C35-4DCA-ADA3-8E1DAA921DDC)', Time: '2020-09-30T11:37:33', User OID: 'PatientReportedOutcome (US3342200)', ODM File OID: '69b20c6c-7e46-4b4f-82e4-e0c556c34484' User entered '30 Sep 2020 11:37'	System	30 Sep 2020 16:37:36
	System	30 Sep 2020 16:37:36

US3342200

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 17:05:26

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:04:20
User entered '30 Sep 2020 11:19'	System	30 Sep 2020 16:25:19

US3342200

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 17:05:26

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:04:20
User entered '30 Sep 2020 13:49'	System	30 Sep 2020 16:25:19

US3342200

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 17:05:26

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:04:20
Data entry locked.	System	30 Sep 2020 16:25:19
User entered 'Day 1, after vaccination (at home)'	System	30 Sep 2020 16:25:19

US3342200

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 17:05:26

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:04:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2D2D1647-7C35-4DCA-ADA3-8E1DAA921DDC)', Time: '2020-10-01T06:41:11', User OID: 'PatientReportedOutcome (US3342200)', ODM File OID: '75eb22fd-cb96-43ec-8c5e-a65bc7db10b5' User entered 'Yes (Y)'	System	01 Oct 2020 11:41:33
	System	01 Oct 2020 11:41:33

US3342200

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 17:05:26

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:04:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2D2D1647-7C35-4DCA-ADA3-8E1DAA921DDC)', Time: '2020-10-01T06:41:19', User OID: 'PatientReportedOutcome (US3342200)', ODM File OID: '75eb22fd-cb96-43ec-8c5e-a65bc7db10b5' User entered '98.6'	System	01 Oct 2020 11:41:33
	System	01 Oct 2020 11:41:33

US3342200

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 17:05:26

Was any **MEDICATION TAKEN** today for pain or fever?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:04:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2D2D1647-7C35-4DCA-ADA3-8E1DAA921DDC)', Time: '2020-10-01T06:41:23', User OID: 'PatientReportedOutcome (US3342200)', ODM File OID: '75eb22fd-cb96-43ec-8c5e-a65bc7db10b5' User entered 'No (N)'	System	01 Oct 2020 11:41:33
	System	01 Oct 2020 11:41:33

US3342200

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 17:05:26

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:04:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2D2D1647-7C35-4DCA-ADA3-8E1DAA921DDC)', Time: '2020-10-01T06:41:28', User OID: 'PatientReportedOutcome (US3342200)', ODM File OID: '75eb22fd-cb96-43ec-8c5e-a65bc7db10b5' User entered '01 Oct 2020 06:41'	System	01 Oct 2020 11:41:33
	System	01 Oct 2020 11:41:33

US3342200

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 17:05:26

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:04:20
User entered '30 Sep 2020 14:44'	System	30 Sep 2020 16:25:19

US3342200

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 17:05:26

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:04:20
User entered '01 Oct 2020 11:59'	System	30 Sep 2020 16:25:19

US3342200

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 17:05:26

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:04:20
Data entry locked.	System	30 Sep 2020 16:25:19
User entered 'Day 2'	System	30 Sep 2020 16:25:19

US3342200

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 17:05:26

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:04:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2D2D1647-7C35-4DCA-ADA3-8E1DAA921DDC)', Time: '2020-10-01T12:00:24', User OID: 'PatientReportedOutcome (US3342200)', ODM File OID: '47b29698-b5fc-4dea-b609-547b865c0914' User entered 'Yes (Y)'	System	01 Oct 2020 17:01:01
	System	01 Oct 2020 17:01:01

US3342200

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 17:05:26

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:04:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2D2D1647-7C35-4DCA-ADA3-8E1DAA921DDC)', Time: '2020-10-01T12:00:41', User OID: 'PatientReportedOutcome (US3342200)', ODM File OID: '47b29698-b5fc-4dea-b609-547b865c0914' User entered '98.7'	System	01 Oct 2020 17:01:01
	System	01 Oct 2020 17:01:01

US3342200

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 17:05:26

Was any **MEDICATION TAKEN** today for pain or fever?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:04:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2D2D1647-7C35-4DCA-ADA3-8E1DAA921DDC)', Time: '2020-10-01T12:00:45', User OID: 'PatientReportedOutcome (US3342200)', ODM File OID: '47b29698-b5fc-4dea-b609-547b865c0914' User entered 'No (N)'	System	01 Oct 2020 17:01:01
	System	01 Oct 2020 17:01:01

US3342200

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 17:05:26

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:04:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2D2D1647-7C35-4DCA-ADA3-8E1DAA921DDC)', Time: '2020-10-01T12:00:49', User OID: 'PatientReportedOutcome (US3342200)', ODM File OID: '47b29698-b5fc-4dea-b609-547b865c0914' User entered '01 Oct 2020 12:00'	System	01 Oct 2020 17:01:01
	System	01 Oct 2020 17:01:01

US3342200

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 17:05:26

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:04:20
User entered '01 Oct 2020 12:00'	System	30 Sep 2020 16:25:19

US3342200

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 17:05:26

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:04:20
User entered '02 Oct 2020 11:59'	System	30 Sep 2020 16:25:19

US3342200

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 17:05:26

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:04:20
Data entry locked.	System	30 Sep 2020 16:25:19
User entered 'Day 3'	System	30 Sep 2020 16:25:19

US3342200

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 17:05:26

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:04:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2D2D1647-7C35-4DCA-ADA3-8E1DAA921DDC)', Time: '2020-10-02T12:00:57', User OID: 'PatientReportedOutcome (US3342200)', ODM File OID: 'dfefe34b-2e99-47a8-953a-a47392d9c6cc' User entered 'Yes (Y)'	System	02 Oct 2020 17:03:22
	System	02 Oct 2020 17:03:22

US3342200

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 17:05:26

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:04:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2D2D1647-7C35-4DCA-ADA3-8E1DAA921DDC)', Time: '2020-10-02T12:03:08', User OID: 'PatientReportedOutcome (US3342200)', ODM File OID: 'dfefe34b-2e99-47a8-953a-a47392d9c6cc' User entered '98.0'	System	02 Oct 2020 17:03:22
	System	02 Oct 2020 17:03:22

US3342200

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 17:05:26

Was any **MEDICATION TAKEN** today for pain or fever?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:04:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2D2D1647-7C35-4DCA-ADA3-8E1DAA921DDC)', Time: '2020-10-02T12:03:12', User OID: 'PatientReportedOutcome (US3342200)', ODM File OID: 'dfefe34b-2e99-47a8-953a-a47392d9c6cc'	System	02 Oct 2020 17:03:22
User entered 'No (N)'	System	02 Oct 2020 17:03:22

US3342200

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 17:05:26

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:04:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2D2D1647-7C35-4DCA-ADA3-8E1DAA921DDC)', Time: '2020-10-02T12:03:18', User OID: 'PatientReportedOutcome (US3342200)', ODM File OID: 'dfefe34b-2e99-47a8-953a-a47392d9c6cc' User entered '02 Oct 2020 12:03'	System	02 Oct 2020 17:03:22
	System	02 Oct 2020 17:03:22

US3342200

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 17:05:26

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:04:20
User entered '02 Oct 2020 12:00'	System	30 Sep 2020 16:25:19

US3342200

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 17:05:26

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:04:20
User entered '03 Oct 2020 11:59'	System	30 Sep 2020 16:25:19

US3342200

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 17:05:26

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:04:20
Data entry locked.	System	30 Sep 2020 16:25:19
User entered 'Day 4'	System	30 Sep 2020 16:25:19

US3342200

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 17:05:26

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:04:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2D2D1647-7C35-4DCA-ADA3-8E1DAA921DDC)', Time: '2020-10-04T06:58:46', User OID: 'PatientReportedOutcome (US3342200)', ODM File OID: 'a0c3f0fa-befc-46ac-863c-aabd3c7caa32' User entered 'Yes (Y)'	System	04 Oct 2020 12:02:50
	System	04 Oct 2020 12:02:50

US3342200

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 17:05:26

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:04:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2D2D1647-7C35-4DCA-ADA3-8E1DAA921DDC)', Time: '2020-10-04T07:01:37', User OID: 'PatientReportedOutcome (US3342200)', ODM File OID: 'a0c3f0fa-befc-46ac-863c-aabd3c7caa32' User entered '98.7'	System	04 Oct 2020 12:02:50
	System	04 Oct 2020 12:02:50

US3342200

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 17:05:26

Was any **MEDICATION TAKEN** today for pain or fever?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:04:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2D2D1647-7C35-4DCA-ADA3-8E1DAA921DDC)', Time: '2020-10-04T07:02:08', User OID: 'PatientReportedOutcome (US3342200)', ODM File OID: 'a0c3f0fa-befc-46ac-863c-aabd3c7caa32'	System	04 Oct 2020 12:02:50
User entered 'Yes (Y)'	System	04 Oct 2020 12:02:50

US3342200

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 17:05:26

To **TREAT** pain or fever that has already occurred

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:04:20
User closed query 'Per the participant response, medication was taken to treat pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' (Site from System). Query 'Per the participant response, medication was taken to treat pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' answered with 'Medication taken has been recorded and EDC updated.' (Site from System).	(b) (4), (b) (6)	09 Nov 2020 16:46:12
Query 'Per the participant response, medication was taken to treat pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' answered with 'Medication taken has been recorded and EDC updated.' (Site from System).	Olivia Hapanowicz (b) (4)	05 Nov 2020 22:58:01
User opened query 'Per the participant response, medication was taken to treat pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' (Site from System).	System	04 Oct 2020 12:02:50
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2D2D1647-7C35-4DCA-ADA3-8E1DAA921DDC)', Time: '2020-10-04T07:02:36', User OID: 'PatientReportedOutcome (US3342200)', ODM File OID: 'a0c3f0fa-befc-46ac-863c-aabd3c7caa32'	System	04 Oct 2020 12:02:50
User entered '1'	System	04 Oct 2020 12:02:50

US3342200

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 17:05:26

To **PREVENT** pain or fever from occurring

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:04:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2D2D1647-7C35-4DCA-ADA3-8E1DAA921DDC)', Time: '2020-10-04T07:02:36', User OID: 'PatientReportedOutcome (US3342200)', ODM File OID: 'a0c3f0fa-befc-46ac-863c-aabd3c7caa32' User entered '0'	System	04 Oct 2020 12:02:50
	System	04 Oct 2020 12:02:50

US3342200

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 17:05:26

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:04:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2D2D1647-7C35-4DCA-ADA3-8E1DAA921DDC)', Time: '2020-10-04T07:02:48', User OID: 'PatientReportedOutcome (US3342200)', ODM File OID: 'a0c3f0fa-befc-46ac-863c-aabd3c7caa32' User entered '04 Oct 2020 07:02'	System	04 Oct 2020 12:02:50
	System	04 Oct 2020 12:02:50

US3342200

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 17:05:26

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:04:20
User entered '03 Oct 2020 12:00'	System	30 Sep 2020 16:25:19

US3342200

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 17:05:26

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:04:20
User entered '04 Oct 2020 11:59'	System	30 Sep 2020 16:25:19

US3342200

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 17:05:26

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:04:20
Data entry locked.	System	30 Sep 2020 16:25:19
User entered 'Day 5'	System	30 Sep 2020 16:25:19

US3342200

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 17:05:26

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:04:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2D2D1647-7C35-4DCA-ADA3-8E1DAA921DDC)', Time: '2020-10-04T12:33:54', User OID: 'PatientReportedOutcome (US3342200)', ODM File OID: 'fd3eb3d4-b289-473a-a3f3-cb2fd5779705' User entered 'Yes (Y)'	System	04 Oct 2020 17:34:18
	System	04 Oct 2020 17:34:18

US3342200

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 17:05:26

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:04:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2D2D1647-7C35-4DCA-ADA3-8E1DAA921DDC)', Time: '2020-10-04T12:34:03', User OID: 'PatientReportedOutcome (US3342200)', ODM File OID: 'fd3eb3d4-b289-473a-a3f3-cb2fd5779705' User entered '98.1'	System	04 Oct 2020 17:34:18
	System	04 Oct 2020 17:34:18

US3342200

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 17:05:26

Was any **MEDICATION TAKEN** today for pain or fever?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:04:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2D2D1647-7C35-4DCA-ADA3-8E1DAA921DDC)', Time: '2020-10-04T12:34:06', User OID: 'PatientReportedOutcome (US3342200)', ODM File OID: 'fd3eb3d4-b289-473a-a3f3-cb2fd5779705'	System	04 Oct 2020 17:34:18
User entered 'No (N)'	System	04 Oct 2020 17:34:18

US3342200

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 17:05:26

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:04:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2D2D1647-7C35-4DCA-ADA3-8E1DAA921DDC)', Time: '2020-10-04T12:34:15', User OID: 'PatientReportedOutcome (US3342200)', ODM File OID: 'fd3eb3d4-b289-473a-a3f3-cb2fd5779705' User entered '04 Oct 2020 12:34'	System	04 Oct 2020 17:34:18
	System	04 Oct 2020 17:34:18

US3342200

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 17:05:26

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:04:20
User entered '04 Oct 2020 12:00'	System	30 Sep 2020 16:25:19

US3342200

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 17:05:26

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:04:20
User entered '05 Oct 2020 11:59'	System	30 Sep 2020 16:25:19

US3342200

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 17:05:26

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:04:20
Data entry locked.	System	30 Sep 2020 16:25:19
User entered 'Day 6'	System	30 Sep 2020 16:25:19

US3342200

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 17:05:26

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:04:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2D2D1647-7C35-4DCA-ADA3-8E1DAA921DDC)', Time: '2020-10-06T02:34:17', User OID: 'PatientReportedOutcome (US3342200)', ODM File OID: '45924544-388c-46be-b865-5ab22528e85f' User entered 'Yes (Y)'	System	06 Oct 2020 07:34:53
	System	06 Oct 2020 07:34:53

US3342200

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 17:05:26

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:04:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2D2D1647-7C35-4DCA-ADA3-8E1DAA921DDC)', Time: '2020-10-06T02:34:31', User OID: 'PatientReportedOutcome (US3342200)', ODM File OID: '45924544-388c-46be-b865-5ab22528e85f' User entered '97.6'	System	06 Oct 2020 07:34:53
	System	06 Oct 2020 07:34:53

US3342200

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 17:05:26

Was any **MEDICATION TAKEN** today for pain or fever?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:04:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2D2D1647-7C35-4DCA-ADA3-8E1DAA921DDC)', Time: '2020-10-06T02:34:39', User OID: 'PatientReportedOutcome (US3342200)', ODM File OID: '45924544-388c-46be-b865-5ab22528e85f' User entered 'No (N)'	System	06 Oct 2020 07:34:53
	System	06 Oct 2020 07:34:53

US3342200

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 17:05:26

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:04:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2D2D1647-7C35-4DCA-ADA3-8E1DAA921DDC)', Time: '2020-10-06T02:34:48', User OID: 'PatientReportedOutcome (US3342200)', ODM File OID: '45924544-388c-46be-b865-5ab22528e85f' User entered '06 Oct 2020 02:34'	System	06 Oct 2020 07:34:53
	System	06 Oct 2020 07:34:53

US3342200

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 17:05:26

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:04:20
User entered '05 Oct 2020 12:00'	System	30 Sep 2020 16:25:19

US3342200

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 17:05:26

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:04:20
User entered '06 Oct 2020 11:59'	System	30 Sep 2020 16:25:19

US3342200

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 17:05:26

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:04:20
Data entry locked.	System	30 Sep 2020 16:25:19
User entered 'Day 7'	System	30 Sep 2020 16:25:19

US3342200

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 17:05:26

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:04:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2D2D1647-7C35-4DCA-ADA3-8E1DAA921DDC)', Time: '2020-10-07T04:15:58', User OID: 'PatientReportedOutcome (US3342200)', ODM File OID: 'd3c3a384-d8f8-4078-b06b-72927dff565f' User entered 'Yes (Y)'	System	07 Oct 2020 09:29:12
	System	07 Oct 2020 09:29:12

US3342200

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 17:05:26

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:04:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2D2D1647-7C35-4DCA-ADA3-8E1DAA921DDC)', Time: '2020-10-07T04:28:53', User OID: 'PatientReportedOutcome (US3342200)', ODM File OID: 'd3c3a384-d8f8-4078-b06b-72927dff565f' User entered '98.4'	System	07 Oct 2020 09:29:12
	System	07 Oct 2020 09:29:12

US3342200

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 17:05:26

Was any **MEDICATION TAKEN** today for pain or fever?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:04:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2D2D1647-7C35-4DCA-ADA3-8E1DAA921DDC)', Time: '2020-10-07T04:28:58', User OID: 'PatientReportedOutcome (US3342200)', ODM File OID: 'd3c3a384-d8f8-4078-b06b-72927dff565f' User entered 'No (N)'	System	07 Oct 2020 09:29:12
	System	07 Oct 2020 09:29:12

US3342200

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 17:05:26

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:04:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2D2D1647-7C35-4DCA-ADA3-8E1DAA921DDC)', Time: '2020-10-07T04:29:10', User OID: 'PatientReportedOutcome (US3342200)', ODM File OID: 'd3c3a384-d8f8-4078-b06b-72927dff565f' User entered '07 Oct 2020 04:29'	System	07 Oct 2020 09:29:12
	System	07 Oct 2020 09:29:12

US3342200

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 17:05:26

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:04:20
User entered '06 Oct 2020 12:00'	System	30 Sep 2020 16:25:19

US3342200

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 17:05:26

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:04:20
User entered '07 Oct 2020 11:59'	System	30 Sep 2020 16:25:19

US3342200

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 17:05:26

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:04:20
Data entry locked.	System	30 Sep 2020 16:25:19
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	30 Sep 2020 16:25:19

US3342200

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 17:05:26

Please record - **PAIN AT INJECTION SITE.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:04:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2D2D1647-7C35-4DCA-ADA3-8E1DAA921DDC)', Time: '2020-09-30T11:38:38', User OID: 'PatientReportedOutcome (US3342200)', ODM File OID: '9d3b31a0-ca9b-4286-88ef-07f6b1c5a2c6'	System	30 Sep 2020 16:38:57
User entered 'None (1)'	System	30 Sep 2020 16:38:57

US3342200

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 17:05:26

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:04:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2D2D1647-7C35-4DCA-ADA3-8E1DAA921DDC)', Time: '2020-09-30T11:38:41', User OID: 'PatientReportedOutcome (US3342200)', ODM File OID: '9d3b31a0-ca9b-4286-88ef-07f6b1c5a2c6' User entered 'No (N)'	System	30 Sep 2020 16:38:57
	System	30 Sep 2020 16:38:57

US3342200

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 17:05:26

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:04:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2D2D1647-7C35-4DCA-ADA3-8E1DAA921DDC)', Time: '2020-09-30T11:38:45', User OID: 'PatientReportedOutcome (US3342200)', ODM File OID: '9d3b31a0-ca9b-4286-88ef-07f6b1c5a2c6' User entered 'No (N)'	System	30 Sep 2020 16:38:57
	System	30 Sep 2020 16:38:57

US3342200

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 17:05:26

Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:04:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2D2D1647-7C35-4DCA-ADA3-8E1DAA921DDC)', Time: '2020-09-30T11:38:50', User OID: 'PatientReportedOutcome (US3342200)', ODM File OID: '9d3b31a0-ca9b-4286-88ef-07f6b1c5a2c6'	System	30 Sep 2020 16:38:57
User entered 'None (1)'	System	30 Sep 2020 16:38:57

US3342200

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 17:05:26

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:04:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2D2D1647-7C35-4DCA-ADA3-8E1DAA921DDC)', Time: '2020-09-30T11:38:54', User OID: 'PatientReportedOutcome (US3342200)', ODM File OID: '9d3b31a0-ca9b-4286-88ef-07f6b1c5a2c6' User entered '30 Sep 2020 11:38'	System	30 Sep 2020 16:38:57
	System	30 Sep 2020 16:38:57

US3342200

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 17:05:26

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:04:20
User entered '30 Sep 2020 11:19'	System	30 Sep 2020 16:25:19

US3342200

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 17:05:26

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:04:20
User entered '30 Sep 2020 13:49'	System	30 Sep 2020 16:25:19

US3342200

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 17:05:26

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:04:20
Data entry locked.	System	30 Sep 2020 16:25:19
User entered 'Day 1, after vaccination (at home)'	System	30 Sep 2020 16:25:19

US3342200

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 17:05:26

Please record - **PAIN AT INJECTION SITE.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:04:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2D2D1647-7C35-4DCA-ADA3-8E1DAA921DDC)', Time: '2020-10-01T06:41:34', User OID: 'PatientReportedOutcome (US3342200)', ODM File OID: '3e132107-0b91-41c8-8c29-ca920531bd22'	System	01 Oct 2020 11:41:51
User entered 'None (1)'	System	01 Oct 2020 11:41:51

US3342200

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 17:05:26

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:04:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2D2D1647-7C35-4DCA-ADA3-8E1DAA921DDC)', Time: '2020-10-01T06:41:38', User OID: 'PatientReportedOutcome (US3342200)', ODM File OID: '3e132107-0b91-41c8-8c29-ca920531bd22' User entered 'No (N)'	System	01 Oct 2020 11:41:51
	System	01 Oct 2020 11:41:51

US3342200

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 17:05:26

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:04:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2D2D1647-7C35-4DCA-ADA3-8E1DAA921DDC)', Time: '2020-10-01T06:41:40', User OID: 'PatientReportedOutcome (US3342200)', ODM File OID: '3e132107-0b91-41c8-8c29-ca920531bd22' User entered 'No (N)'	System	01 Oct 2020 11:41:51
	System	01 Oct 2020 11:41:51

US3342200

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 17:05:26

Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:04:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2D2D1647-7C35-4DCA-ADA3-8E1DAA921DDC)', Time: '2020-10-01T06:41:46', User OID: 'PatientReportedOutcome (US3342200)', ODM File OID: '3e132107-0b91-41c8-8c29-ca920531bd22'	System	01 Oct 2020 11:41:51
User entered 'None (1)'	System	01 Oct 2020 11:41:51

US3342200

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 17:05:26

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:04:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2D2D1647-7C35-4DCA-ADA3-8E1DAA921DDC)', Time: '2020-10-01T06:41:49', User OID: 'PatientReportedOutcome (US3342200)', ODM File OID: '3e132107-0b91-41c8-8c29-ca920531bd22' User entered '01 Oct 2020 06:41'	System	01 Oct 2020 11:41:51
	System	01 Oct 2020 11:41:51

US3342200

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 17:05:26

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:04:20
User entered '30 Sep 2020 14:44'	System	30 Sep 2020 16:25:19

US3342200

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 17:05:26

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:04:20
User entered '01 Oct 2020 11:59'	System	30 Sep 2020 16:25:19

US3342200

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 17:05:26

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:04:20
Data entry locked.	System	30 Sep 2020 16:25:19
User entered 'Day 2'	System	30 Sep 2020 16:25:19

US3342200

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 17:05:26

Please record - **PAIN AT INJECTION SITE.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:04:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2D2D1647-7C35-4DCA-ADA3-8E1DAA921DDC)', Time: '2020-10-01T12:01:00', User OID: 'PatientReportedOutcome (US3342200)', ODM File OID: '30f1bc9b-967b-49f3-96fa-451ab6622ce7' User entered 'None (1)'	System	01 Oct 2020 17:01:49
	System	01 Oct 2020 17:01:49

US3342200

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 17:05:26

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:04:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2D2D1647-7C35-4DCA-ADA3-8E1DAA921DDC)', Time: '2020-10-01T12:00:57', User OID: 'PatientReportedOutcome (US3342200)', ODM File OID: '30f1bc9b-967b-49f3-96fa-451ab6622ce7' User entered 'No (N)'	System	01 Oct 2020 17:01:49
	System	01 Oct 2020 17:01:49

US3342200

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 17:05:26

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:04:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2D2D1647-7C35-4DCA-ADA3-8E1DAA921DDC)', Time: '2020-10-01T12:01:04', User OID: 'PatientReportedOutcome (US3342200)', ODM File OID: '30f1bc9b-967b-49f3-96fa-451ab6622ce7' User entered 'No (N)'	System	01 Oct 2020 17:01:49
	System	01 Oct 2020 17:01:49

US3342200

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 17:05:26

Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:04:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2D2D1647-7C35-4DCA-ADA3-8E1DAA921DDC)', Time: '2020-10-01T12:01:07', User OID: 'PatientReportedOutcome (US3342200)', ODM File OID: '30f1bc9b-967b-49f3-96fa-451ab6622ce7' User entered 'None (1)'	System	01 Oct 2020 17:01:49
	System	01 Oct 2020 17:01:49

US3342200

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 17:05:26

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:04:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2D2D1647-7C35-4DCA-ADA3-8E1DAA921DDC)', Time: '2020-10-01T12:01:11', User OID: 'PatientReportedOutcome (US3342200)', ODM File OID: '30f1bc9b-967b-49f3-96fa-451ab6622ce7' User entered '01 Oct 2020 12:01'	System	01 Oct 2020 17:01:49
	System	01 Oct 2020 17:01:49

US3342200

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 17:05:26

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:04:20
User entered '01 Oct 2020 12:00'	System	30 Sep 2020 16:25:19

US3342200

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 17:05:26

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:04:20
User entered '02 Oct 2020 11:59'	System	30 Sep 2020 16:25:19

US3342200

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 17:05:26

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:04:20
Data entry locked.	System	30 Sep 2020 16:25:19
User entered 'Day 3'	System	30 Sep 2020 16:25:19

US3342200

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 17:05:26

Please record - **PAIN AT INJECTION SITE.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:04:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2D2D1647-7C35-4DCA-ADA3-8E1DAA921DDC)', Time: '2020-10-02T12:03:22', User OID: 'PatientReportedOutcome (US3342200)', ODM File OID: '0181fe75-51ad-4bad-8b89-1a7ae2f4eb5d' User entered 'None (1)'	System	02 Oct 2020 17:03:39
	System	02 Oct 2020 17:03:39

US3342200

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 17:05:26

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:04:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2D2D1647-7C35-4DCA-ADA3-8E1DAA921DDC)', Time: '2020-10-02T12:03:25', User OID: 'PatientReportedOutcome (US3342200)', ODM File OID: '0181fe75-51ad-4bad-8b89-1a7ae2f4eb5d' User entered 'No (N)'	System	02 Oct 2020 17:03:39
	System	02 Oct 2020 17:03:39

US3342200

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 17:05:26

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:04:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2D2D1647-7C35-4DCA-ADA3-8E1DAA921DDC)', Time: '2020-10-02T12:03:28', User OID: 'PatientReportedOutcome (US3342200)', ODM File OID: '0181fe75-51ad-4bad-8b89-1a7ae2f4eb5d' User entered 'No (N)'	System	02 Oct 2020 17:03:39
	System	02 Oct 2020 17:03:39

US3342200

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 17:05:26

Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:04:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2D2D1647-7C35-4DCA-ADA3-8E1DAA921DDC)', Time: '2020-10-02T12:03:31', User OID: 'PatientReportedOutcome (US3342200)', ODM File OID: '0181fe75-51ad-4bad-8b89-1a7ae2f4eb5d' User entered 'None (1)'	System	02 Oct 2020 17:03:39
	System	02 Oct 2020 17:03:39

US3342200

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 17:05:26

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:04:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2D2D1647-7C35-4DCA-ADA3-8E1DAA921DDC)', Time: '2020-10-02T12:03:34', User OID: 'PatientReportedOutcome (US3342200)', ODM File OID: '0181fe75-51ad-4bad-8b89-1a7ae2f4eb5d' User entered '02 Oct 2020 12:03'	System	02 Oct 2020 17:03:39
	System	02 Oct 2020 17:03:39

US3342200

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 17:05:26

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:04:20
User entered '02 Oct 2020 12:00'	System	30 Sep 2020 16:25:19

US3342200

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 17:05:26

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:04:20
User entered '03 Oct 2020 11:59'	System	30 Sep 2020 16:25:19

US3342200

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 17:05:26

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:04:20
Data entry locked.	System	30 Sep 2020 16:25:19
User entered 'Day 4'	System	30 Sep 2020 16:25:19

US3342200

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 17:05:26

Please record - **PAIN AT INJECTION SITE.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:04:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2D2D1647-7C35-4DCA-ADA3-8E1DAA921DDC)', Time: '2020-10-04T07:02:54', User OID: 'PatientReportedOutcome (US3342200)', ODM File OID: '2937f7fc-cfa1-4f0f-a595-f72c1fd99368' User entered 'None (1)'	System	04 Oct 2020 12:03:21
	System	04 Oct 2020 12:03:21

US3342200

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 17:05:26

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:04:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2D2D1647-7C35-4DCA-ADA3-8E1DAA921DDC)', Time: '2020-10-04T07:02:57', User OID: 'PatientReportedOutcome (US3342200)', ODM File OID: '2937f7fc-cfa1-4f0f-a595-f72c1fd99368' User entered 'No (N)'	System	04 Oct 2020 12:03:21
	System	04 Oct 2020 12:03:21

US3342200

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 17:05:26

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:04:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2D2D1647-7C35-4DCA-ADA3-8E1DAA921DDC)', Time: '2020-10-04T07:03:08', User OID: 'PatientReportedOutcome (US3342200)', ODM File OID: '2937f7fc-cfa1-4f0f-a595-f72c1fd99368' User entered 'No (N)'	System	04 Oct 2020 12:03:21
	System	04 Oct 2020 12:03:21

US3342200

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 17:05:26

Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:04:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2D2D1647-7C35-4DCA-ADA3-8E1DAA921DDC)', Time: '2020-10-04T07:03:13', User OID: 'PatientReportedOutcome (US3342200)', ODM File OID: '2937f7fc-cfa1-4f0f-a595-f72c1fd99368' User entered 'None (1)'	System	04 Oct 2020 12:03:21
	System	04 Oct 2020 12:03:21

US3342200

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 17:05:26

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:04:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2D2D1647-7C35-4DCA-ADA3-8E1DAA921DDC)', Time: '2020-10-04T07:03:16', User OID: 'PatientReportedOutcome (US3342200)', ODM File OID: '2937f7fc-cfa1-4f0f-a595-f72c1fd99368' User entered '04 Oct 2020 07:03'	System	04 Oct 2020 12:03:21
	System	04 Oct 2020 12:03:21

US3342200

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 17:05:26

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:04:20
User entered '03 Oct 2020 12:00'	System	30 Sep 2020 16:25:19

US3342200

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 17:05:26

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:04:20
User entered '04 Oct 2020 11:59'	System	30 Sep 2020 16:25:19

US3342200

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 17:05:26

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:04:20
Data entry locked.	System	30 Sep 2020 16:25:19
User entered 'Day 5'	System	30 Sep 2020 16:25:19

US3342200

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 17:05:26

Please record - **PAIN AT INJECTION SITE.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:04:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2D2D1647-7C35-4DCA-ADA3-8E1DAA921DDC)', Time: '2020-10-04T12:34:22', User OID: 'PatientReportedOutcome (US3342200)', ODM File OID: 'd5d1c7de-524c-4c8c-9691-8ee069b3d406' User entered 'None (1)'	System	04 Oct 2020 17:34:35
	System	04 Oct 2020 17:34:35

US3342200

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 17:05:26

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:04:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2D2D1647-7C35-4DCA-ADA3-8E1DAA921DDC)', Time: '2020-10-04T12:34:24', User OID: 'PatientReportedOutcome (US3342200)', ODM File OID: 'd5d1c7de-524c-4c8c-9691-8ee069b3d406' User entered 'No (N)'	System	04 Oct 2020 17:34:35
	System	04 Oct 2020 17:34:35

US3342200

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 17:05:26

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:04:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2D2D1647-7C35-4DCA-ADA3-8E1DAA921DDC)', Time: '2020-10-04T12:34:27', User OID: 'PatientReportedOutcome (US3342200)', ODM File OID: 'd5d1c7de-524c-4c8c-9691-8ee069b3d406' User entered 'No (N)'	System	04 Oct 2020 17:34:35
	System	04 Oct 2020 17:34:35

US3342200

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 17:05:26

Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:04:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2D2D1647-7C35-4DCA-ADA3-8E1DAA921DDC)', Time: '2020-10-04T12:34:31', User OID: 'PatientReportedOutcome (US3342200)', ODM File OID: 'd5d1c7de-524c-4c8c-9691-8ee069b3d406' User entered 'None (1)'	System	04 Oct 2020 17:34:35
	System	04 Oct 2020 17:34:35

US3342200

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 17:05:26

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:04:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2D2D1647-7C35-4DCA-ADA3-8E1DAA921DDC)', Time: '2020-10-04T12:34:33', User OID: 'PatientReportedOutcome (US3342200)', ODM File OID: 'd5d1c7de-524c-4c8c-9691-8ee069b3d406' User entered '04 Oct 2020 12:34'	System	04 Oct 2020 17:34:35
	System	04 Oct 2020 17:34:35

US3342200

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 17:05:26

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:04:20
User entered '04 Oct 2020 12:00'	System	30 Sep 2020 16:25:19

US3342200

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 17:05:26

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:04:20
User entered '05 Oct 2020 11:59'	System	30 Sep 2020 16:25:19

US3342200

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 17:05:26

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:04:20
Data entry locked.	System	30 Sep 2020 16:25:19
User entered 'Day 6'	System	30 Sep 2020 16:25:19

US3342200

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 17:05:26

Please record - **PAIN AT INJECTION SITE.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:04:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2D2D1647-7C35-4DCA-ADA3-8E1DAA921DDC)', Time: '2020-10-06T02:35:31', User OID: 'PatientReportedOutcome (US3342200)', ODM File OID: 'c96a5b0d-b5f9-44a0-abb6-2d4cee58267b' User entered 'None (1)'	System	06 Oct 2020 07:36:19
	System	06 Oct 2020 07:36:19

US3342200

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 17:05:26

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:04:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2D2D1647-7C35-4DCA-ADA3-8E1DAA921DDC)', Time: '2020-10-06T02:35:59', User OID: 'PatientReportedOutcome (US3342200)', ODM File OID: 'c96a5b0d-b5f9-44a0-abb6-2d4cee58267b' User entered 'No (N)'	System	06 Oct 2020 07:36:19
	System	06 Oct 2020 07:36:19

US3342200

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 17:05:26

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:04:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2D2D1647-7C35-4DCA-ADA3-8E1DAA921DDC)', Time: '2020-10-06T02:36:04', User OID: 'PatientReportedOutcome (US3342200)', ODM File OID: 'c96a5b0d-b5f9-44a0-abb6-2d4cee58267b' User entered 'No (N)'	System	06 Oct 2020 07:36:19
	System	06 Oct 2020 07:36:19

US3342200

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 17:05:26

Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:04:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2D2D1647-7C35-4DCA-ADA3-8E1DAA921DDC)', Time: '2020-10-06T02:36:13', User OID: 'PatientReportedOutcome (US3342200)', ODM File OID: 'c96a5b0d-b5f9-44a0-abb6-2d4cee58267b' User entered 'None (1)'	System	06 Oct 2020 07:36:19
	System	06 Oct 2020 07:36:19

US3342200

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 17:05:26

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:04:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2D2D1647-7C35-4DCA-ADA3-8E1DAA921DDC)', Time: '2020-10-06T02:36:16', User OID: 'PatientReportedOutcome (US3342200)', ODM File OID: 'c96a5b0d-b5f9-44a0-abb6-2d4cee58267b' User entered '06 Oct 2020 02:36'	System	06 Oct 2020 07:36:19
	System	06 Oct 2020 07:36:19

US3342200

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 17:05:26

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:04:20
User entered '05 Oct 2020 12:00'	System	30 Sep 2020 16:25:19

US3342200

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 17:05:26

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:04:20
User entered '06 Oct 2020 11:59'	System	30 Sep 2020 16:25:19

US3342200

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 17:05:26

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:04:20
Data entry locked.	System	30 Sep 2020 16:25:19
User entered 'Day 7'	System	30 Sep 2020 16:25:19

US3342200

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 17:05:26

Please record - **PAIN AT INJECTION SITE.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:04:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2D2D1647-7C35-4DCA-ADA3-8E1DAA921DDC)', Time: '2020-10-07T04:29:15', User OID: 'PatientReportedOutcome (US3342200)', ODM File OID: 'f1894783-933b-42bb-8bc1-399cf094aed8'	System	07 Oct 2020 09:29:39
User entered 'None (1)'	System	07 Oct 2020 09:29:39

US3342200

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 17:05:26

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:04:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2D2D1647-7C35-4DCA-ADA3-8E1DAA921DDC)', Time: '2020-10-07T04:29:18', User OID: 'PatientReportedOutcome (US3342200)', ODM File OID: 'f1894783-933b-42bb-8bc1-399cf094aed8' User entered 'No (N)'	System	07 Oct 2020 09:29:39
	System	07 Oct 2020 09:29:39

US3342200

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 17:05:26

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:04:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2D2D1647-7C35-4DCA-ADA3-8E1DAA921DDC)', Time: '2020-10-07T04:29:20', User OID: 'PatientReportedOutcome (US3342200)', ODM File OID: 'f1894783-933b-42bb-8bc1-399cf094aed8' User entered 'No (N)'	System	07 Oct 2020 09:29:39
	System	07 Oct 2020 09:29:39

US3342200

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 17:05:26

Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:04:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2D2D1647-7C35-4DCA-ADA3-8E1DAA921DDC)', Time: '2020-10-07T04:29:27', User OID: 'PatientReportedOutcome (US3342200)', ODM File OID: 'f1894783-933b-42bb-8bc1-399cf094aed8'	System	07 Oct 2020 09:29:39
User entered 'None (1)'	System	07 Oct 2020 09:29:39

US3342200

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 17:05:26

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:04:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2D2D1647-7C35-4DCA-ADA3-8E1DAA921DDC)', Time: '2020-10-07T04:29:32', User OID: 'PatientReportedOutcome (US3342200)', ODM File OID: 'f1894783-933b-42bb-8bc1-399cf094aed8' User entered '07 Oct 2020 04:29'	System	07 Oct 2020 09:29:39
	System	07 Oct 2020 09:29:39

US3342200

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 17:05:26

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:04:20
User entered '06 Oct 2020 12:00'	System	30 Sep 2020 16:25:19

US3342200

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 17:05:26

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:04:20
User entered '07 Oct 2020 11:59'	System	30 Sep 2020 16:25:19

US3342200

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:05:26

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:04:20
Data entry locked.	System	30 Sep 2020 16:25:19
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	30 Sep 2020 16:25:19

US3342200

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:05:26

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:04:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2D2D1647-7C35-4DCA-ADA3-8E1DAA921DDC)', Time: '2020-09-30T11:39:04', User OID: 'PatientReportedOutcome (US3342200)', ODM File OID: 'fc29d477-7150-478f-8b70-5dbfb835a9ba' User entered 'None (0)'	System	30 Sep 2020 16:43:48
	System	30 Sep 2020 16:43:48

US3342200

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:05:26

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:04:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2D2D1647-7C35-4DCA-ADA3-8E1DAA921DDC)', Time: '2020-09-30T11:39:07', User OID: 'PatientReportedOutcome (US3342200)', ODM File OID: 'fc29d477-7150-478f-8b70-5dbfb835a9ba' User entered 'None (0)'	System	30 Sep 2020 16:43:48
	System	30 Sep 2020 16:43:48

US3342200

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:05:26

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:04:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2D2D1647-7C35-4DCA-ADA3-8E1DAA921DDC)', Time: '2020-09-30T11:39:09', User OID: 'PatientReportedOutcome (US3342200)', ODM File OID: 'fc29d477-7150-478f-8b70-5dbfb835a9ba' User entered 'None (0)'	System	30 Sep 2020 16:43:48
	System	30 Sep 2020 16:43:48

US3342200

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:05:26

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:04:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2D2D1647-7C35-4DCA-ADA3-8E1DAA921DDC)', Time: '2020-09-30T11:39:27', User OID: 'PatientReportedOutcome (US3342200)', ODM File OID: 'fc29d477-7150-478f-8b70-5dbfb835a9ba' User entered 'None (0)'	System	30 Sep 2020 16:43:48
	System	30 Sep 2020 16:43:48

US3342200

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:05:26

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:04:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2D2D1647-7C35-4DCA-ADA3-8E1DAA921DDC)', Time: '2020-09-30T11:43:06', User OID: 'PatientReportedOutcome (US3342200)', ODM File OID: 'fc29d477-7150-478f-8b70-5dbfb835a9ba' User entered 'None (0)'	System	30 Sep 2020 16:43:48
	System	30 Sep 2020 16:43:48

US3342200

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:05:26

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:04:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2D2D1647-7C35-4DCA-ADA3-8E1DAA921DDC)', Time: '2020-09-30T11:43:09', User OID: 'PatientReportedOutcome (US3342200)', ODM File OID: 'fc29d477-7150-478f-8b70-5dbfb835a9ba' User entered 'None (0)'	System	30 Sep 2020 16:43:48
	System	30 Sep 2020 16:43:48

US3342200

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:05:26

Did you receive any **MEDICAL ATTENTION** (doctor visit, other) for any illness or symptoms?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:04:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2D2D1647-7C35-4DCA-ADA3-8E1DAA921DDC)', Time: '2020-09-30T11:43:41', User OID: 'PatientReportedOutcome (US3342200)', ODM File OID: 'fc29d477-7150-478f-8b70-5dbfb835a9ba' User entered 'No (N)'	System	30 Sep 2020 16:43:48
	System	30 Sep 2020 16:43:48

US3342200

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:05:26

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:04:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2D2D1647-7C35-4DCA-ADA3-8E1DAA921DDC)', Time: '2020-09-30T11:43:46', User OID: 'PatientReportedOutcome (US3342200)', ODM File OID: 'fc29d477-7150-478f-8b70-5dbfb835a9ba' User entered '30 Sep 2020 11:43'	System	30 Sep 2020 16:43:48
	System	30 Sep 2020 16:43:48

US3342200

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:05:26

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:04:20
User entered '30 Sep 2020 11:19'	System	30 Sep 2020 16:25:19

US3342200

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:05:26

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:04:20
User entered '30 Sep 2020 13:49'	System	30 Sep 2020 16:25:19

US3342200

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:05:26

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:04:20
Data entry locked.	System	30 Sep 2020 16:25:19
User entered 'Day 1, after vaccination (at home)'	System	30 Sep 2020 16:25:19

US3342200

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:05:26

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:04:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2D2D1647-7C35-4DCA-ADA3-8E1DAA921DDC)', Time: '2020-10-01T06:41:55', User OID: 'PatientReportedOutcome (US3342200)', ODM File OID: '7f872140-2480-4ed0-a506-059986fb98c4' User entered 'None (0)'	System	01 Oct 2020 11:43:00
	System	01 Oct 2020 11:43:00

US3342200

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:05:26

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:04:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2D2D1647-7C35-4DCA-ADA3-8E1DAA921DDC)', Time: '2020-10-01T06:42:05', User OID: 'PatientReportedOutcome (US3342200)', ODM File OID: '7f872140-2480-4ed0-a506-059986fb98c4'	System	01 Oct 2020 11:43:00
User entered 'No interference with activity (1)'	System	01 Oct 2020 11:43:00

US3342200

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:05:26

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:04:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2D2D1647-7C35-4DCA-ADA3-8E1DAA921DDC)', Time: '2020-10-01T06:42:17', User OID: 'PatientReportedOutcome (US3342200)', ODM File OID: '7f872140-2480-4ed0-a506-059986fb98c4'	System	01 Oct 2020 11:43:00
User entered 'No interference with activity (1)'	System	01 Oct 2020 11:43:00

US3342200

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:05:26

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:04:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2D2D1647-7C35-4DCA-ADA3-8E1DAA921DDC)', Time: '2020-10-01T06:42:43', User OID: 'PatientReportedOutcome (US3342200)', ODM File OID: '7f872140-2480-4ed0-a506-059986fb98c4'	System	01 Oct 2020 11:43:00
User entered 'No interference with activity (1)'	System	01 Oct 2020 11:43:00

US3342200

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:05:26

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:04:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2D2D1647-7C35-4DCA-ADA3-8E1DAA921DDC)', Time: '2020-10-01T06:42:45', User OID: 'PatientReportedOutcome (US3342200)', ODM File OID: '7f872140-2480-4ed0-a506-059986fb98c4' User entered 'None (0)'	System	01 Oct 2020 11:43:00
	System	01 Oct 2020 11:43:00

US3342200

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:05:26

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:04:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2D2D1647-7C35-4DCA-ADA3-8E1DAA921DDC)', Time: '2020-10-01T06:42:51', User OID: 'PatientReportedOutcome (US3342200)', ODM File OID: '7f872140-2480-4ed0-a506-059986fb98c4' User entered 'None (0)'	System	01 Oct 2020 11:43:00
	System	01 Oct 2020 11:43:00

US3342200

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:05:26

Did you receive any **MEDICAL ATTENTION** (doctor visit, other) for any illness or symptoms?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:04:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2D2D1647-7C35-4DCA-ADA3-8E1DAA921DDC)', Time: '2020-10-01T06:42:54', User OID: 'PatientReportedOutcome (US3342200)', ODM File OID: '7f872140-2480-4ed0-a506-059986fb98c4' User entered 'No (N)'	System	01 Oct 2020 11:43:00
	System	01 Oct 2020 11:43:00

US3342200

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:05:26

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:04:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2D2D1647-7C35-4DCA-ADA3-8E1DAA921DDC)', Time: '2020-10-01T06:42:57', User OID: 'PatientReportedOutcome (US3342200)', ODM File OID: '7f872140-2480-4ed0-a506-059986fb98c4' User entered '01 Oct 2020 06:42'	System	01 Oct 2020 11:43:00
	System	01 Oct 2020 11:43:00

US3342200

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:05:26

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:04:20
User entered '30 Sep 2020 14:44'	System	30 Sep 2020 16:25:19

US3342200

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:05:26

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:04:20
User entered '01 Oct 2020 11:59'	System	30 Sep 2020 16:25:19

US3342200

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:05:26

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:04:20
Data entry locked.	System	30 Sep 2020 16:25:19
User entered 'Day 2'	System	30 Sep 2020 16:25:19

US3342200

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:05:26

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:04:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2D2D1647-7C35-4DCA-ADA3-8E1DAA921DDC)', Time: '2020-10-01T12:01:19', User OID: 'PatientReportedOutcome (US3342200)', ODM File OID: '61b3a620-7b69-4a68-920a-5138e751d577' User entered 'None (0)'	System	01 Oct 2020 17:03:13
	System	01 Oct 2020 17:03:13

US3342200

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:05:26

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:04:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2D2D1647-7C35-4DCA-ADA3-8E1DAA921DDC)', Time: '2020-10-01T12:01:29', User OID: 'PatientReportedOutcome (US3342200)', ODM File OID: '61b3a620-7b69-4a68-920a-5138e751d577'	System	01 Oct 2020 17:03:13
User entered 'Some interference with activity (2)'	System	01 Oct 2020 17:03:13

US3342200

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:05:26

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:04:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2D2D1647-7C35-4DCA-ADA3-8E1DAA921DDC)', Time: '2020-10-01T12:01:34', User OID: 'PatientReportedOutcome (US3342200)', ODM File OID: '61b3a620-7b69-4a68-920a-5138e751d577' User entered 'None (0)'	System	01 Oct 2020 17:03:13
	System	01 Oct 2020 17:03:13

US3342200

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:05:26

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:04:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2D2D1647-7C35-4DCA-ADA3-8E1DAA921DDC)', Time: '2020-10-01T12:01:39', User OID: 'PatientReportedOutcome (US3342200)', ODM File OID: '61b3a620-7b69-4a68-920a-5138e751d577'	System	01 Oct 2020 17:03:13
User entered 'No interference with activity (1)'	System	01 Oct 2020 17:03:13

US3342200

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:05:26

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:04:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2D2D1647-7C35-4DCA-ADA3-8E1DAA921DDC)', Time: '2020-10-01T12:01:44', User OID: 'PatientReportedOutcome (US3342200)', ODM File OID: '61b3a620-7b69-4a68-920a-5138e751d577' User entered 'None (0)'	System	01 Oct 2020 17:03:13
	System	01 Oct 2020 17:03:13

US3342200

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:05:26

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:04:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2D2D1647-7C35-4DCA-ADA3-8E1DAA921DDC)', Time: '2020-10-01T12:01:49', User OID: 'PatientReportedOutcome (US3342200)', ODM File OID: '61b3a620-7b69-4a68-920a-5138e751d577' User entered 'None (0)'	System	01 Oct 2020 17:03:13
	System	01 Oct 2020 17:03:13

US3342200

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:05:26

Did you receive any **MEDICAL ATTENTION** (doctor visit, other) for any illness or symptoms?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:04:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2D2D1647-7C35-4DCA-ADA3-8E1DAA921DDC)', Time: '2020-10-01T12:02:03', User OID: 'PatientReportedOutcome (US3342200)', ODM File OID: '61b3a620-7b69-4a68-920a-5138e751d577'	System	01 Oct 2020 17:03:13
User entered 'No (N)'	System	01 Oct 2020 17:03:13

US3342200

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:05:26

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:04:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2D2D1647-7C35-4DCA-ADA3-8E1DAA921DDC)', Time: '2020-10-01T12:02:06', User OID: 'PatientReportedOutcome (US3342200)', ODM File OID: '61b3a620-7b69-4a68-920a-5138e751d577' User entered '01 Oct 2020 12:02'	System	01 Oct 2020 17:03:13
	System	01 Oct 2020 17:03:13

US3342200

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:05:26

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:04:20
User entered '01 Oct 2020 12:00'	System	30 Sep 2020 16:25:19

US3342200

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:05:26

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:04:20
User entered '02 Oct 2020 11:59'	System	30 Sep 2020 16:25:19

US3342200

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:05:26

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:04:20
Data entry locked.	System	30 Sep 2020 16:25:19
User entered 'Day 3'	System	30 Sep 2020 16:25:19

US3342200

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:05:26

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:04:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2D2D1647-7C35-4DCA-ADA3-8E1DAA921DDC)', Time: '2020-10-02T12:03:53', User OID: 'PatientReportedOutcome (US3342200)', ODM File OID: '0dc3eb28-e0e0-45ea-b3cb-85d7a7367b00' User entered 'None (0)'	System	02 Oct 2020 17:05:53
	System	02 Oct 2020 17:05:53

US3342200

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:05:26

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:04:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2D2D1647-7C35-4DCA-ADA3-8E1DAA921DDC)', Time: '2020-10-02T12:03:59', User OID: 'PatientReportedOutcome (US3342200)', ODM File OID: '0dc3eb28-e0e0-45ea-b3cb-85d7a7367b00' User entered 'None (0)'	System	02 Oct 2020 17:05:53
	System	02 Oct 2020 17:05:53

US3342200

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:05:26

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:04:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2D2D1647-7C35-4DCA-ADA3-8E1DAA921DDC)', Time: '2020-10-02T12:04:26', User OID: 'PatientReportedOutcome (US3342200)', ODM File OID: '0dc3eb28-e0e0-45ea-b3cb-85d7a7367b00' User entered 'None (0)'	System	02 Oct 2020 17:05:53
	System	02 Oct 2020 17:05:53

US3342200

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:05:26

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:04:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2D2D1647-7C35-4DCA-ADA3-8E1DAA921DDC)', Time: '2020-10-02T12:04:33', User OID: 'PatientReportedOutcome (US3342200)', ODM File OID: '0dc3eb28-e0e0-45ea-b3cb-85d7a7367b00'	System	02 Oct 2020 17:05:53
User entered 'Some interference with activity (2)'	System	02 Oct 2020 17:05:53

US3342200

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:05:26

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:04:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2D2D1647-7C35-4DCA-ADA3-8E1DAA921DDC)', Time: '2020-10-02T12:04:41', User OID: 'PatientReportedOutcome (US3342200)', ODM File OID: '0dc3eb28-e0e0-45ea-b3cb-85d7a7367b00' User entered 'None (0)'	System	02 Oct 2020 17:05:53
	System	02 Oct 2020 17:05:53

US3342200

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:05:26

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:04:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2D2D1647-7C35-4DCA-ADA3-8E1DAA921DDC)', Time: '2020-10-02T12:04:44', User OID: 'PatientReportedOutcome (US3342200)', ODM File OID: '0dc3eb28-e0e0-45ea-b3cb-85d7a7367b00' User entered 'None (0)'	System	02 Oct 2020 17:05:53
	System	02 Oct 2020 17:05:53

US3342200

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:05:26

Did you receive any **MEDICAL ATTENTION** (doctor visit, other) for any illness or symptoms?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:04:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2D2D1647-7C35-4DCA-ADA3-8E1DAA921DDC)', Time: '2020-10-02T12:04:49', User OID: 'PatientReportedOutcome (US3342200)', ODM File OID: '0dc3eb28-e0e0-45ea-b3cb-85d7a7367b00' User entered 'No (N)'	System	02 Oct 2020 17:05:53
	System	02 Oct 2020 17:05:53

US3342200

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:05:26

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:04:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2D2D1647-7C35-4DCA-ADA3-8E1DAA921DDC)', Time: '2020-10-02T12:04:52', User OID: 'PatientReportedOutcome (US3342200)', ODM File OID: '0dc3eb28-e0e0-45ea-b3cb-85d7a7367b00' User entered '02 Oct 2020 12:04'	System	02 Oct 2020 17:05:53
	System	02 Oct 2020 17:05:53

US3342200

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:05:26

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:04:20
User entered '02 Oct 2020 12:00'	System	30 Sep 2020 16:25:19

US3342200

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:05:26

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:04:20
User entered '03 Oct 2020 11:59'	System	30 Sep 2020 16:25:19

US3342200

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:05:26

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:04:20
Data entry locked.	System	30 Sep 2020 16:25:19
User entered 'Day 4'	System	30 Sep 2020 16:25:19

US3342200

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:05:26

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:04:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2D2D1647-7C35-4DCA-ADA3-8E1DAA921DDC)', Time: '2020-10-04T07:03:23', User OID: 'PatientReportedOutcome (US3342200)', ODM File OID: 'a872d402-7e83-4975-b197-c55c377a2489' User entered 'None (0)'	System	04 Oct 2020 12:04:45
	System	04 Oct 2020 12:04:45

US3342200

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:05:26

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:04:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2D2D1647-7C35-4DCA-ADA3-8E1DAA921DDC)', Time: '2020-10-04T07:03:26', User OID: 'PatientReportedOutcome (US3342200)', ODM File OID: 'a872d402-7e83-4975-b197-c55c377a2489' User entered 'None (0)'	System	04 Oct 2020 12:04:45
	System	04 Oct 2020 12:04:45

US3342200

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:05:26

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:04:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2D2D1647-7C35-4DCA-ADA3-8E1DAA921DDC)', Time: '2020-10-04T07:03:36', User OID: 'PatientReportedOutcome (US3342200)', ODM File OID: 'a872d402-7e83-4975-b197-c55c377a2489'	System	04 Oct 2020 12:04:45
User entered 'No interference with activity (1)'	System	04 Oct 2020 12:04:45

US3342200

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:05:26

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:04:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2D2D1647-7C35-4DCA-ADA3-8E1DAA921DDC)', Time: '2020-10-04T07:03:43', User OID: 'PatientReportedOutcome (US3342200)', ODM File OID: 'a872d402-7e83-4975-b197-c55c377a2489'	System	04 Oct 2020 12:04:45
User entered 'Some interference with activity (2)'	System	04 Oct 2020 12:04:45

US3342200

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:05:26

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:04:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2D2D1647-7C35-4DCA-ADA3-8E1DAA921DDC)', Time: '2020-10-04T07:03:49', User OID: 'PatientReportedOutcome (US3342200)', ODM File OID: 'a872d402-7e83-4975-b197-c55c377a2489' User entered 'None (0)'	System	04 Oct 2020 12:04:45
	System	04 Oct 2020 12:04:45

US3342200

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:05:26

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:04:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2D2D1647-7C35-4DCA-ADA3-8E1DAA921DDC)', Time: '2020-10-04T07:04:29', User OID: 'PatientReportedOutcome (US3342200)', ODM File OID: 'a872d402-7e83-4975-b197-c55c377a2489' User entered 'None (0)'	System	04 Oct 2020 12:04:45
	System	04 Oct 2020 12:04:45

US3342200

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:05:26

Did you receive any **MEDICAL ATTENTION** (doctor visit, other) for any illness or symptoms?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:04:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2D2D1647-7C35-4DCA-ADA3-8E1DAA921DDC)', Time: '2020-10-04T07:04:36', User OID: 'PatientReportedOutcome (US3342200)', ODM File OID: 'a872d402-7e83-4975-b197-c55c377a2489' User entered 'No (N)'	System	04 Oct 2020 12:04:45
	System	04 Oct 2020 12:04:45

US3342200

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:05:26

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:04:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2D2D1647-7C35-4DCA-ADA3-8E1DAA921DDC)', Time: '2020-10-04T07:04:43', User OID: 'PatientReportedOutcome (US3342200)', ODM File OID: 'a872d402-7e83-4975-b197-c55c377a2489' User entered '04 Oct 2020 07:04'	System	04 Oct 2020 12:04:45
	System	04 Oct 2020 12:04:45

US3342200

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:05:26

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:04:20
User entered '03 Oct 2020 12:00'	System	30 Sep 2020 16:25:19

US3342200

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:05:26

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:04:20
User entered '04 Oct 2020 11:59'	System	30 Sep 2020 16:25:19

US3342200

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:05:26

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:04:20
Data entry locked.	System	30 Sep 2020 16:25:19
User entered 'Day 5'	System	30 Sep 2020 16:25:19

US3342200

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:05:26

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:04:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2D2D1647-7C35-4DCA-ADA3-8E1DAA921DDC)', Time: '2020-10-04T12:34:38', User OID: 'PatientReportedOutcome (US3342200)', ODM File OID: 'fe8fd985-d60d-4bf6-8466-785c6a31d0ae' User entered 'None (0)'	System	04 Oct 2020 17:35:14
	System	04 Oct 2020 17:35:14

US3342200

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:05:26

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:04:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2D2D1647-7C35-4DCA-ADA3-8E1DAA921DDC)', Time: '2020-10-04T12:34:44', User OID: 'PatientReportedOutcome (US3342200)', ODM File OID: 'fe8fd985-d60d-4bf6-8466-785c6a31d0ae'	System	04 Oct 2020 17:35:14
User entered 'No interference with activity (1)'	System	04 Oct 2020 17:35:14

US3342200

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:05:26

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:04:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2D2D1647-7C35-4DCA-ADA3-8E1DAA921DDC)', Time: '2020-10-04T12:34:52', User OID: 'PatientReportedOutcome (US3342200)', ODM File OID: 'fe8fd985-d60d-4bf6-8466-785c6a31d0ae' User entered 'None (0)'	System	04 Oct 2020 17:35:14
	System	04 Oct 2020 17:35:14

US3342200

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:05:26

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:04:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2D2D1647-7C35-4DCA-ADA3-8E1DAA921DDC)', Time: '2020-10-04T12:34:58', User OID: 'PatientReportedOutcome (US3342200)', ODM File OID: 'fe8fd985-d60d-4bf6-8466-785c6a31d0ae' User entered 'Some interference with activity (2)'	System	04 Oct 2020 17:35:14
	System	04 Oct 2020 17:35:14

US3342200

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:05:26

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:04:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2D2D1647-7C35-4DCA-ADA3-8E1DAA921DDC)', Time: '2020-10-04T12:35:01', User OID: 'PatientReportedOutcome (US3342200)', ODM File OID: 'fe8fd985-d60d-4bf6-8466-785c6a31d0ae' User entered 'None (0)'	System	04 Oct 2020 17:35:14
	System	04 Oct 2020 17:35:14

US3342200

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:05:26

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:04:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2D2D1647-7C35-4DCA-ADA3-8E1DAA921DDC)', Time: '2020-10-04T12:35:03', User OID: 'PatientReportedOutcome (US3342200)', ODM File OID: 'fe8fd985-d60d-4bf6-8466-785c6a31d0ae' User entered 'None (0)'	System	04 Oct 2020 17:35:14
	System	04 Oct 2020 17:35:14

US3342200

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:05:26

Did you receive any **MEDICAL ATTENTION** (doctor visit, other) for any illness or symptoms?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:04:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2D2D1647-7C35-4DCA-ADA3-8E1DAA921DDC)', Time: '2020-10-04T12:35:05', User OID: 'PatientReportedOutcome (US3342200)', ODM File OID: 'fe8fd985-d60d-4bf6-8466-785c6a31d0ae' User entered 'No (N)'	System	04 Oct 2020 17:35:14
	System	04 Oct 2020 17:35:14

US3342200

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:05:26

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:04:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2D2D1647-7C35-4DCA-ADA3-8E1DAA921DDC)', Time: '2020-10-04T12:35:08', User OID: 'PatientReportedOutcome (US3342200)', ODM File OID: 'fe8fd985-d60d-4bf6-8466-785c6a31d0ae' User entered '04 Oct 2020 12:35'	System	04 Oct 2020 17:35:14
	System	04 Oct 2020 17:35:14

US3342200

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:05:26

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:04:20
User entered '04 Oct 2020 12:00'	System	30 Sep 2020 16:25:19

US3342200

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:05:26

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:04:20
User entered '05 Oct 2020 11:59'	System	30 Sep 2020 16:25:19

US3342200

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:05:26

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:04:20
Data entry locked.	System	30 Sep 2020 16:25:19
User entered 'Day 6'	System	30 Sep 2020 16:25:19

US3342200

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:05:26

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:04:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2D2D1647-7C35-4DCA-ADA3-8E1DAA921DDC)', Time: '2020-10-06T02:36:27', User OID: 'PatientReportedOutcome (US3342200)', ODM File OID: '3d250f40-9ada-4174-ad1d-0ff2e26c79ca' User entered 'None (0)'	System	06 Oct 2020 07:37:46
	System	06 Oct 2020 07:37:46

US3342200

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:05:26

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:04:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2D2D1647-7C35-4DCA-ADA3-8E1DAA921DDC)', Time: '2020-10-06T02:36:41', User OID: 'PatientReportedOutcome (US3342200)', ODM File OID: '3d250f40-9ada-4174-ad1d-0ff2e26c79ca' User entered 'Some interference with activity (2)'	System	06 Oct 2020 07:37:46
	System	06 Oct 2020 07:37:46

US3342200

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:05:26

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:04:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2D2D1647-7C35-4DCA-ADA3-8E1DAA921DDC)', Time: '2020-10-06T02:36:59', User OID: 'PatientReportedOutcome (US3342200)', ODM File OID: '3d250f40-9ada-4174-ad1d-0ff2e26c79ca' User entered 'Some interference with activity (2)'	System	06 Oct 2020 07:37:46
	System	06 Oct 2020 07:37:46

US3342200

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:05:26

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:04:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2D2D1647-7C35-4DCA-ADA3-8E1DAA921DDC)', Time: '2020-10-06T02:37:10', User OID: 'PatientReportedOutcome (US3342200)', ODM File OID: '3d250f40-9ada-4174-ad1d-0ff2e26c79ca' User entered 'Some interference with activity (2)'	System	06 Oct 2020 07:37:46
	System	06 Oct 2020 07:37:46

US3342200

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:05:26

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:04:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2D2D1647-7C35-4DCA-ADA3-8E1DAA921DDC)', Time: '2020-10-06T02:37:18', User OID: 'PatientReportedOutcome (US3342200)', ODM File OID: '3d250f40-9ada-4174-ad1d-0ff2e26c79ca' User entered 'None (0)'	System	06 Oct 2020 07:37:46
	System	06 Oct 2020 07:37:46

US3342200

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:05:26

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:04:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2D2D1647-7C35-4DCA-ADA3-8E1DAA921DDC)', Time: '2020-10-06T02:37:26', User OID: 'PatientReportedOutcome (US3342200)', ODM File OID: '3d250f40-9ada-4174-ad1d-0ff2e26c79ca' User entered 'None (0)'	System	06 Oct 2020 07:37:46
	System	06 Oct 2020 07:37:46

US3342200

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:05:26

Did you receive any **MEDICAL ATTENTION** (doctor visit, other) for any illness or symptoms?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:04:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2D2D1647-7C35-4DCA-ADA3-8E1DAA921DDC)', Time: '2020-10-06T02:37:36', User OID: 'PatientReportedOutcome (US3342200)', ODM File OID: '3d250f40-9ada-4174-ad1d-0ff2e26c79ca' User entered 'No (N)'	System	06 Oct 2020 07:37:46
	System	06 Oct 2020 07:37:46

US3342200

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:05:26

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:04:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2D2D1647-7C35-4DCA-ADA3-8E1DAA921DDC)', Time: '2020-10-06T02:37:40', User OID: 'PatientReportedOutcome (US3342200)', ODM File OID: '3d250f40-9ada-4174-ad1d-0ff2e26c79ca' User entered '06 Oct 2020 02:37'	System	06 Oct 2020 07:37:46
	System	06 Oct 2020 07:37:46

US3342200

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:05:26

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:04:20
User entered '05 Oct 2020 12:00'	System	30 Sep 2020 16:25:19

US3342200

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:05:26

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:04:20
User entered '06 Oct 2020 11:59'	System	30 Sep 2020 16:25:19

US3342200

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:05:26

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:04:20
Data entry locked.	System	30 Sep 2020 16:25:19
User entered 'Day 7'	System	30 Sep 2020 16:25:19

US3342200

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:05:26

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:04:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2D2D1647-7C35-4DCA-ADA3-8E1DAA921DDC)', Time: '2020-10-07T04:29:40', User OID: 'PatientReportedOutcome (US3342200)', ODM File OID: '11a79136-6434-4090-8b97-3f3306618f76' User entered 'None (0)'	System	07 Oct 2020 09:30:27
	System	07 Oct 2020 09:30:27

US3342200

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:05:26

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:04:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2D2D1647-7C35-4DCA-ADA3-8E1DAA921DDC)', Time: '2020-10-07T04:29:47', User OID: 'PatientReportedOutcome (US3342200)', ODM File OID: '11a79136-6434-4090-8b97-3f3306618f76'	System	07 Oct 2020 09:30:27
User entered 'Some interference with activity (2)'	System	07 Oct 2020 09:30:27

US3342200

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:05:26

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:04:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2D2D1647-7C35-4DCA-ADA3-8E1DAA921DDC)', Time: '2020-10-07T04:29:52', User OID: 'PatientReportedOutcome (US3342200)', ODM File OID: '11a79136-6434-4090-8b97-3f3306618f76'	System	07 Oct 2020 09:30:27
User entered 'Some interference with activity (2)'	System	07 Oct 2020 09:30:27

US3342200

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:05:26

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:04:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2D2D1647-7C35-4DCA-ADA3-8E1DAA921DDC)', Time: '2020-10-07T04:29:58', User OID: 'PatientReportedOutcome (US3342200)', ODM File OID: '11a79136-6434-4090-8b97-3f3306618f76'	System	07 Oct 2020 09:30:27
User entered 'Some interference with activity (2)'	System	07 Oct 2020 09:30:27

US3342200

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:05:26

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:04:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2D2D1647-7C35-4DCA-ADA3-8E1DAA921DDC)', Time: '2020-10-07T04:30:04', User OID: 'PatientReportedOutcome (US3342200)', ODM File OID: '11a79136-6434-4090-8b97-3f3306618f76' User entered 'None (0)'	System	07 Oct 2020 09:30:27
	System	07 Oct 2020 09:30:27

US3342200

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:05:26

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:04:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2D2D1647-7C35-4DCA-ADA3-8E1DAA921DDC)', Time: '2020-10-07T04:30:07', User OID: 'PatientReportedOutcome (US3342200)', ODM File OID: '11a79136-6434-4090-8b97-3f3306618f76' User entered 'None (0)'	System	07 Oct 2020 09:30:27
	System	07 Oct 2020 09:30:27

US3342200

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:05:26

Did you receive any **MEDICAL ATTENTION** (doctor visit, other) for any illness or symptoms?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:04:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2D2D1647-7C35-4DCA-ADA3-8E1DAA921DDC)', Time: '2020-10-07T04:30:15', User OID: 'PatientReportedOutcome (US3342200)', ODM File OID: '11a79136-6434-4090-8b97-3f3306618f76' User entered 'No (N)'	System	07 Oct 2020 09:30:27
	System	07 Oct 2020 09:30:27

US3342200

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:05:26

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:04:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2D2D1647-7C35-4DCA-ADA3-8E1DAA921DDC)', Time: '2020-10-07T04:30:22', User OID: 'PatientReportedOutcome (US3342200)', ODM File OID: '11a79136-6434-4090-8b97-3f3306618f76' User entered '07 Oct 2020 04:30'	System	07 Oct 2020 09:30:27
	System	07 Oct 2020 09:30:27

US3342200

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:05:26

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:04:20
User entered '06 Oct 2020 12:00'	System	30 Sep 2020 16:25:19

US3342200

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:05:26

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:04:20
User entered '07 Oct 2020 11:59'	System	30 Sep 2020 16:25:19

US3342200

Folder: Diary Dose 2 (1)

Form: Fatigue_Day(8)

Generated On: 09 Jun 2021 17:05:26

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:04:20
Data entry locked.	System	06 Oct 2020 07:37:46
User entered 'Day 8'	System	06 Oct 2020 07:37:46

US3342200

Folder: Diary Dose 2 (1)

Form: Fatigue_Day(8)

Generated On: 09 Jun 2021 17:05:26

Select one response below to indicate the intensity of your **FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:04:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2D2D1647-7C35-4DCA-ADA3-8E1DAA921DDC)', Time: '2020-10-07T16:48:16', User OID: 'PatientReportedOutcome (US3342200)', ODM File OID: 'fe01478b-ecfe-49b4-a874-b565657a0dbb'	System	07 Oct 2020 21:48:31
User entered 'No interference with activity (1)'	System	07 Oct 2020 21:48:31

US3342200

Folder: Diary Dose 2 (1)

Form: Fatigue_Day(8)

Generated On: 09 Jun 2021 17:05:26

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:04:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2D2D1647-7C35-4DCA-ADA3-8E1DAA921DDC)', Time: '2020-10-07T16:48:27', User OID: 'PatientReportedOutcome (US3342200)', ODM File OID: 'fe01478b-ecfe-49b4-a874-b565657a0dbb' User entered '07 Oct 2020 16:48'	System	07 Oct 2020 21:48:31
	System	07 Oct 2020 21:48:31

US3342200

Folder: Diary Dose 2 (1)

Form: Fatigue_Day(8)

Generated On: 09 Jun 2021 17:05:26

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:04:20
User entered '07 Oct 2020 12:00'	System	06 Oct 2020 07:37:46

US3342200

Folder: Diary Dose 2 (1)

Form: Fatigue_Day(8)

Generated On: 09 Jun 2021 17:05:26

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:04:20
User entered '08 Oct 2020 11:59'	System	06 Oct 2020 07:37:46

US3342200

Folder: Diary Dose 2 (1)

Form: Fatigue_Day(9)

Generated On: 09 Jun 2021 17:05:26

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:04:20
Data entry locked.	System	07 Oct 2020 09:30:27
User entered 'Day 9'	System	07 Oct 2020 09:30:27

US3342200

Folder: Diary Dose 2 (1)

Form: Fatigue_Day(9)

Generated On: 09 Jun 2021 17:05:26

Select one response below to indicate the intensity of your **FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:04:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2D2D1647-7C35-4DCA-ADA3-8E1DAA921DDC)', Time: '2020-10-08T12:00:16', User OID: 'PatientReportedOutcome (US3342200)', ODM File OID: '50ad4aff-05da-472b-b4d3-c4de1d88957b'	System	08 Oct 2020 17:00:27
User entered 'Some interference with activity (2)'	System	08 Oct 2020 17:00:27

US3342200

Folder: Diary Dose 2 (1)

Form: Fatigue_Day(9)

Generated On: 09 Jun 2021 17:05:26

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:04:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2D2D1647-7C35-4DCA-ADA3-8E1DAA921DDC)', Time: '2020-10-08T12:00:20', User OID: 'PatientReportedOutcome (US3342200)', ODM File OID: '50ad4aff-05da-472b-b4d3-c4de1d88957b' User entered '08 Oct 2020 12:00'	System	08 Oct 2020 17:00:27
	System	08 Oct 2020 17:00:27

US3342200

Folder: Diary Dose 2 (1)

Form: Fatigue_Day(9)

Generated On: 09 Jun 2021 17:05:26

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:04:20
User entered '08 Oct 2020 12:00'	System	07 Oct 2020 09:30:27

US3342200

Folder: Diary Dose 2 (1)

Form: Fatigue_Day(9)

Generated On: 09 Jun 2021 17:05:26

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:04:20
User entered '09 Oct 2020 11:59'	System	07 Oct 2020 09:30:27

US3342200

Folder: Diary Dose 2 (1)

Form: Fatigue_Day(10)

Generated On: 09 Jun 2021 17:05:26

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:04:20
Data entry locked.	System	07 Oct 2020 21:48:31
User entered 'Day 10'	System	07 Oct 2020 21:48:31

US3342200

Folder: Diary Dose 2 (1)

Form: Fatigue_Day(10)

Generated On: 09 Jun 2021 17:05:26

Select one response below to indicate the intensity of your **FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:04:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2D2D1647-7C35-4DCA-ADA3-8E1DAA921DDC)', Time: '2020-10-09T12:14:37', User OID: 'PatientReportedOutcome (US3342200)', ODM File OID: '34596b5e-bb9e-48fe-9901-df55c0ec635c'	System	09 Oct 2020 17:14:47
User entered 'No interference with activity (1)'	System	09 Oct 2020 17:14:47

US3342200

Folder: Diary Dose 2 (1)

Form: Fatigue_Day(10)

Generated On: 09 Jun 2021 17:05:26

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:04:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2D2D1647-7C35-4DCA-ADA3-8E1DAA921DDC)', Time: '2020-10-09T12:14:43', User OID: 'PatientReportedOutcome (US3342200)', ODM File OID: '34596b5e-bb9e-48fe-9901-df55c0ec635c' User entered '09 Oct 2020 12:14'	System	09 Oct 2020 17:14:47
	System	09 Oct 2020 17:14:47

US3342200

Folder: Diary Dose 2 (1)

Form: Fatigue_Day(10)

Generated On: 09 Jun 2021 17:05:26

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:04:20
User entered '09 Oct 2020 12:00'	System	07 Oct 2020 21:48:31

US3342200

Folder: Diary Dose 2 (1)

Form: Fatigue_Day(10)

Generated On: 09 Jun 2021 17:05:26

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:04:20
User entered '10 Oct 2020 11:59'	System	07 Oct 2020 21:48:31

US3342200

Folder: Diary Dose 2 (1)

Form: Fatigue_Day(11)

Generated On: 09 Jun 2021 17:05:26

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:04:20
Data entry locked.	System	08 Oct 2020 17:00:27
User entered 'Day 11'	System	08 Oct 2020 17:00:27

US3342200

Folder: Diary Dose 2 (1)

Form: Fatigue_Day(11)

Generated On: 09 Jun 2021 17:05:26

Select one response below to indicate the intensity of your **FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:04:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2D2D1647-7C35-4DCA-ADA3-8E1DAA921DDC)', Time: '2020-10-10T12:04:02', User OID: 'PatientReportedOutcome (US3342200)', ODM File OID: '9c72b484-b9ee-4f5f-9014-1838b55c550a' User entered 'Some interference with activity (2)'	System	10 Oct 2020 17:04:11
	System	10 Oct 2020 17:04:11

US3342200

Folder: Diary Dose 2 (1)

Form: Fatigue_Day(11)

Generated On: 09 Jun 2021 17:05:26

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:04:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2D2D1647-7C35-4DCA-ADA3-8E1DAA921DDC)', Time: '2020-10-10T12:04:07', User OID: 'PatientReportedOutcome (US3342200)', ODM File OID: '9c72b484-b9ee-4f5f-9014-1838b55c550a' User entered '10 Oct 2020 12:04'	System	10 Oct 2020 17:04:11
	System	10 Oct 2020 17:04:11

US3342200

Folder: Diary Dose 2 (1)

Form: Fatigue_Day(11)

Generated On: 09 Jun 2021 17:05:26

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:04:20
User entered '10 Oct 2020 12:00'	System	08 Oct 2020 17:00:27

US3342200

Folder: Diary Dose 2 (1)

Form: Fatigue_Day(11)

Generated On: 09 Jun 2021 17:05:26

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:04:20
User entered '11 Oct 2020 11:59'	System	08 Oct 2020 17:00:27

US3342200

Folder: Diary Dose 2 (1)

Form: Fatigue_Day(12)

Generated On: 09 Jun 2021 17:05:26

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:04:20
Data entry locked.	System	09 Oct 2020 17:14:47
User entered 'Day 12'	System	09 Oct 2020 17:14:47

US3342200

Folder: Diary Dose 2 (1)

Form: Fatigue_Day(12)

Generated On: 09 Jun 2021 17:05:26

Select one response below to indicate the intensity of your **FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:04:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2D2D1647-7C35-4DCA-ADA3-8E1DAA921DDC)', Time: '2020-10-11T17:26:39', User OID: 'PatientReportedOutcome (US3342200)', ODM File OID: '0fe06727-7158-4a7a-8dd6-55fcfeae94df' User entered 'No interference with activity (1)'	System	11 Oct 2020 22:26:46
	System	11 Oct 2020 22:26:46

US3342200

Folder: Diary Dose 2 (1)

Form: Fatigue_Day(12)

Generated On: 09 Jun 2021 17:05:26

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:04:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2D2D1647-7C35-4DCA-ADA3-8E1DAA921DDC)', Time: '2020-10-11T17:26:42', User OID: 'PatientReportedOutcome (US3342200)', ODM File OID: '0fe06727-7158-4a7a-8dd6-55fcfeae94df' User entered '11 Oct 2020 17:26'	System	11 Oct 2020 22:26:46
	System	11 Oct 2020 22:26:46

US3342200

Folder: Diary Dose 2 (1)

Form: Fatigue_Day(12)

Generated On: 09 Jun 2021 17:05:26

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:04:20
User entered '11 Oct 2020 12:00'	System	09 Oct 2020 17:14:47

US3342200

Folder: Diary Dose 2 (1)

Form: Fatigue_Day(12)

Generated On: 09 Jun 2021 17:05:26

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:04:20
User entered '12 Oct 2020 11:59'	System	09 Oct 2020 17:14:47

US3342200

Folder: Diary Dose 2 (1)

Form: Fatigue_Day(13)

Generated On: 09 Jun 2021 17:05:26

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:04:20
Data entry locked.	System	10 Oct 2020 17:04:11
User entered 'Day 13'	System	10 Oct 2020 17:04:11

US3342200

Folder: Diary Dose 2 (1)

Form: Fatigue_Day(13)

Generated On: 09 Jun 2021 17:05:26

Select one response below to indicate the intensity of your **FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:04:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2D2D1647-7C35-4DCA-ADA3-8E1DAA921DDC)', Time: '2020-10-12T16:02:11', User OID: 'PatientReportedOutcome (US3342200)', ODM File OID: 'dee9ec37-361a-4c46-867d-ccdc9ceccc58'	System	12 Oct 2020 21:02:18
User entered 'Some interference with activity (2)'	System	12 Oct 2020 21:02:18

US3342200

Folder: Diary Dose 2 (1)

Form: Fatigue_Day(13)

Generated On: 09 Jun 2021 17:05:26

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:04:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2D2D1647-7C35-4DCA-ADA3-8E1DAA921DDC)', Time: '2020-10-12T16:02:16', User OID: 'PatientReportedOutcome (US3342200)', ODM File OID: 'dee9ec37-361a-4c46-867d-ccdc9ceccc58' User entered '12 Oct 2020 16:02'	System	12 Oct 2020 21:02:18
	System	12 Oct 2020 21:02:18

US3342200

Folder: Diary Dose 2 (1)

Form: Fatigue_Day(13)

Generated On: 09 Jun 2021 17:05:26

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:04:20
User entered '12 Oct 2020 12:00'	System	10 Oct 2020 17:04:11

US3342200

Folder: Diary Dose 2 (1)

Form: Fatigue_Day(13)

Generated On: 09 Jun 2021 17:05:26

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:04:20
User entered '13 Oct 2020 11:59'	System	10 Oct 2020 17:04:11

US3342200

Folder: Diary Dose 2 (1)

Form: Fatigue_Day(14)

Generated On: 09 Jun 2021 17:05:26

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:04:20
Data entry locked.	System	11 Oct 2020 22:26:46
User entered 'Day 14'	System	11 Oct 2020 22:26:46

US3342200

Folder: Diary Dose 2 (1)

Form: Fatigue_Day(14)

Generated On: 09 Jun 2021 17:05:26

Select one response below to indicate the intensity of your **FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:04:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2D2D1647-7C35-4DCA-ADA3-8E1DAA921DDC)', Time: '2020-10-14T06:26:19', User OID: 'PatientReportedOutcome (US3342200)', ODM File OID: '569524e1-d30e-43cd-a0e3-a2e83b872f31'	System	14 Oct 2020 11:26:26
User entered 'Some interference with activity (2)'	System	14 Oct 2020 11:26:26

US3342200

Folder: Diary Dose 2 (1)

Form: Fatigue_Day(14)

Generated On: 09 Jun 2021 17:05:26

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:04:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2D2D1647-7C35-4DCA-ADA3-8E1DAA921DDC)', Time: '2020-10-14T06:26:23', User OID: 'PatientReportedOutcome (US3342200)', ODM File OID: '569524e1-d30e-43cd-a0e3-a2e83b872f31' User entered '14 Oct 2020 06:26'	System	14 Oct 2020 11:26:26
	System	14 Oct 2020 11:26:26

US3342200

Folder: Diary Dose 2 (1)

Form: Fatigue_Day(14)

Generated On: 09 Jun 2021 17:05:26

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:04:20
User entered '13 Oct 2020 12:00'	System	11 Oct 2020 22:26:46

US3342200

Folder: Diary Dose 2 (1)

Form: Fatigue_Day(14)

Generated On: 09 Jun 2021 17:05:26

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:04:20
User entered '14 Oct 2020 11:59'	System	11 Oct 2020 22:26:46

US3342200

Folder: Diary Dose 2 (1)

Form: Fatigue_Day(15)

Generated On: 09 Jun 2021 17:05:26

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:04:20
Data entry locked.	System	12 Oct 2020 21:02:18
User entered 'Day 15'	System	12 Oct 2020 21:02:18

US3342200

Folder: Diary Dose 2 (1)

Form: Fatigue_Day(15)

Generated On: 09 Jun 2021 17:05:26

Select one response below to indicate the intensity of your **FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:04:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2D2D1647-7C35-4DCA-ADA3-8E1DAA921DDC)', Time: '2020-10-14T13:40:45', User OID: 'PatientReportedOutcome (US3342200)', ODM File OID: '986e6935-bd0c-4f50-9ffc-f066ccc917e5' User entered 'No interference with activity (1)'	System	14 Oct 2020 18:40:52
	System	14 Oct 2020 18:40:52

US3342200

Folder: Diary Dose 2 (1)

Form: Fatigue_Day(15)

Generated On: 09 Jun 2021 17:05:26

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:04:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2D2D1647-7C35-4DCA-ADA3-8E1DAA921DDC)', Time: '2020-10-14T13:40:49', User OID: 'PatientReportedOutcome (US3342200)', ODM File OID: '986e6935-bd0c-4f50-9ffc-f066ccc917e5' User entered '14 Oct 2020 13:40'	System	14 Oct 2020 18:40:52
	System	14 Oct 2020 18:40:52

US3342200

Folder: Diary Dose 2 (1)

Form: Fatigue_Day(15)

Generated On: 09 Jun 2021 17:05:26

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:04:20
User entered '14 Oct 2020 12:00'	System	12 Oct 2020 21:02:18

US3342200

Folder: Diary Dose 2 (1)

Form: Fatigue_Day(15)

Generated On: 09 Jun 2021 17:05:26

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:04:20
User entered '15 Oct 2020 11:59'	System	12 Oct 2020 21:02:18

US3342200

Folder: Diary Dose 2 (1)

Form: Fatigue_Day(16)

Generated On: 09 Jun 2021 17:05:26

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:04:20
Data entry locked.	System	14 Oct 2020 11:26:26
User entered 'Day 16'	System	14 Oct 2020 11:26:26

US3342200

Folder: Diary Dose 2 (1)

Form: Fatigue_Day(16)

Generated On: 09 Jun 2021 17:05:26

Select one response below to indicate the intensity of your **FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:04:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2D2D1647-7C35-4DCA-ADA3-8E1DAA921DDC)', Time: '2020-10-16T02:16:44', User OID: 'PatientReportedOutcome (US3342200)', ODM File OID: 'a16f757d-45d6-43ba-9c4a-ae400b681616' User entered 'No interference with activity (1)'	System	16 Oct 2020 07:16:52
	System	16 Oct 2020 07:16:52

US3342200

Folder: Diary Dose 2 (1)

Form: Fatigue_Day(16)

Generated On: 09 Jun 2021 17:05:26

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:04:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2D2D1647-7C35-4DCA-ADA3-8E1DAA921DDC)', Time: '2020-10-16T02:16:49', User OID: 'PatientReportedOutcome (US3342200)', ODM File OID: 'a16f757d-45d6-43ba-9c4a-ae400b681616' User entered '16 Oct 2020 02:16'	System	16 Oct 2020 07:16:52
	System	16 Oct 2020 07:16:52

US3342200

Folder: Diary Dose 2 (1)

Form: Fatigue_Day(16)

Generated On: 09 Jun 2021 17:05:26

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:04:20
User entered '15 Oct 2020 12:00'	System	14 Oct 2020 11:26:26

US3342200

Folder: Diary Dose 2 (1)

Form: Fatigue_Day(16)

Generated On: 09 Jun 2021 17:05:26

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:04:20
User entered '16 Oct 2020 11:59'	System	14 Oct 2020 11:26:26

US3342200

Folder: Diary Dose 2 (1)

Form: Fatigue_Day(17)

Generated On: 09 Jun 2021 17:05:26

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:04:20
Data entry locked.	System	14 Oct 2020 18:40:52
User entered 'Day 17'	System	14 Oct 2020 18:40:52

US3342200

Folder: Diary Dose 2 (1)

Form: Fatigue_Day(17)

Generated On: 09 Jun 2021 17:05:26

Select one response below to indicate the intensity of your **FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:04:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2D2D1647-7C35-4DCA-ADA3-8E1DAA921DDC)', Time: '2020-10-16T12:08:26', User OID: 'PatientReportedOutcome (US3342200)', ODM File OID: '3cdecbl1a-7eea-405a-8d7d-6906958efe1f' User entered 'None (0)'	System	16 Oct 2020 17:08:35
	System	16 Oct 2020 17:08:35

US3342200

Folder: Diary Dose 2 (1)

Form: Fatigue_Day(17)

Generated On: 09 Jun 2021 17:05:26

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:04:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2D2D1647-7C35-4DCA-ADA3-8E1DAA921DDC)', Time: '2020-10-16T12:08:31', User OID: 'PatientReportedOutcome (US3342200)', ODM File OID: '3cdecbl1a-7eea-405a-8d7d-6906958efe1f' User entered '16 Oct 2020 12:08'	System	16 Oct 2020 17:08:35
	System	16 Oct 2020 17:08:35

US3342200

Folder: Diary Dose 2 (1)

Form: Fatigue_Day(17)

Generated On: 09 Jun 2021 17:05:26

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:04:20
User entered '16 Oct 2020 12:00'	System	14 Oct 2020 18:40:52

US3342200

Folder: Diary Dose 2 (1)

Form: Fatigue_Day(17)

Generated On: 09 Jun 2021 17:05:26

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:04:20
User entered '17 Oct 2020 11:59'	System	14 Oct 2020 18:40:52

US3342200

Folder: Diary Dose 2 (1)

Form: MuscleAche_Day(8)

Generated On: 09 Jun 2021 17:05:26

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:04:20
Data entry locked.	System	06 Oct 2020 07:37:46
User entered 'Day 8'	System	06 Oct 2020 07:37:46

US3342200

Folder: Diary Dose 2 (1)

Form: MuscleAche_Day(8)

Generated On: 09 Jun 2021 17:05:26

Select one response below to indicate the intensity of your **MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:04:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2D2D1647-7C35-4DCA-ADA3-8E1DAA921DDC)', Time: '2020-10-07T16:48:43', User OID: 'PatientReportedOutcome (US3342200)', ODM File OID: '15723c3d-fb3b-4cdb-83ba-a997cdd2e3df' User entered 'No interference with activity (1)'	System	07 Oct 2020 21:48:50
	System	07 Oct 2020 21:48:50

US3342200

Folder: Diary Dose 2 (1)

Form: MuscleAche_Day(8)

Generated On: 09 Jun 2021 17:05:26

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:04:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2D2D1647-7C35-4DCA-ADA3-8E1DAA921DDC)', Time: '2020-10-07T16:48:47', User OID: 'PatientReportedOutcome (US3342200)', ODM File OID: '15723c3d-fb3b-4cdb-83ba-a997cdd2e3df' User entered '07 Oct 2020 16:48'	System	07 Oct 2020 21:48:50
	System	07 Oct 2020 21:48:50

US3342200

Folder: Diary Dose 2 (1)

Form: MuscleAche_Day(8)

Generated On: 09 Jun 2021 17:05:26

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:04:20
User entered '07 Oct 2020 12:00'	System	06 Oct 2020 07:37:46

US3342200

Folder: Diary Dose 2 (1)

Form: MuscleAche_Day(8)

Generated On: 09 Jun 2021 17:05:26

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:04:20
User entered '08 Oct 2020 11:59'	System	06 Oct 2020 07:37:46

US3342200

Folder: Diary Dose 2 (1)

Form: MuscleAche_Day(9)

Generated On: 09 Jun 2021 17:05:26

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:04:20
Data entry locked.	System	07 Oct 2020 09:30:27
User entered 'Day 9'	System	07 Oct 2020 09:30:27

US3342200

Folder: Diary Dose 2 (1)

Form: MuscleAche_Day(9)

Generated On: 09 Jun 2021 17:05:26

Select one response below to indicate the intensity of your **MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:04:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2D2D1647-7C35-4DCA-ADA3-8E1DAA921DDC)', Time: '2020-10-08T12:00:25', User OID: 'PatientReportedOutcome (US3342200)', ODM File OID: 'f7ef84c6-6222-42b0-86aa-4639b335601b' User entered 'No interference with activity (1)'	System	08 Oct 2020 17:00:47
	System	08 Oct 2020 17:00:47

US3342200

Folder: Diary Dose 2 (1)

Form: MuscleAche_Day(9)

Generated On: 09 Jun 2021 17:05:26

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:04:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2D2D1647-7C35-4DCA-ADA3-8E1DAA921DDC)', Time: '2020-10-08T12:00:28', User OID: 'PatientReportedOutcome (US3342200)', ODM File OID: 'f7ef84c6-6222-42b0-86aa-4639b335601b' User entered '08 Oct 2020 12:00'	System	08 Oct 2020 17:00:47
	System	08 Oct 2020 17:00:47

US3342200

Folder: Diary Dose 2 (1)

Form: MuscleAche_Day(9)

Generated On: 09 Jun 2021 17:05:26

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:04:20
User entered '08 Oct 2020 12:00'	System	07 Oct 2020 09:30:27

US3342200

Folder: Diary Dose 2 (1)

Form: MuscleAche_Day(9)

Generated On: 09 Jun 2021 17:05:26

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:04:20
User entered '09 Oct 2020 11:59'	System	07 Oct 2020 09:30:27

US3342200

Folder: Diary Dose 2 (1)

Form: MuscleAche_Day(10)

Generated On: 09 Jun 2021 17:05:26

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:04:20
Data entry locked.	System	07 Oct 2020 21:48:50
User entered 'Day 10'	System	07 Oct 2020 21:48:50

US3342200

Folder: Diary Dose 2 (1)

Form: MuscleAche_Day(10)

Generated On: 09 Jun 2021 17:05:26

Select one response below to indicate the intensity of your **MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:04:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2D2D1647-7C35-4DCA-ADA3-8E1DAA921DDC)', Time: '2020-10-09T12:14:58', User OID: 'PatientReportedOutcome (US3342200)', ODM File OID: 'ca8d0529-fdee-447a-889e-79fafc360864' User entered 'No interference with activity (1)'	System	09 Oct 2020 17:15:06
	System	09 Oct 2020 17:15:06

US3342200

Folder: Diary Dose 2 (1)

Form: MuscleAche_Day(10)

Generated On: 09 Jun 2021 17:05:26

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:04:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2D2D1647-7C35-4DCA-ADA3-8E1DAA921DDC)', Time: '2020-10-09T12:15:01', User OID: 'PatientReportedOutcome (US3342200)', ODM File OID: 'ca8d0529-fdee-447a-889e-79fafc360864' User entered '09 Oct 2020 12:15'	System	09 Oct 2020 17:15:06
	System	09 Oct 2020 17:15:06

US3342200

Folder: Diary Dose 2 (1)

Form: MuscleAche_Day(10)

Generated On: 09 Jun 2021 17:05:26

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:04:20
User entered '09 Oct 2020 12:00'	System	07 Oct 2020 21:48:50

US3342200

Folder: Diary Dose 2 (1)

Form: MuscleAche_Day(10)

Generated On: 09 Jun 2021 17:05:26

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:04:20
User entered '10 Oct 2020 11:59'	System	07 Oct 2020 21:48:50

US3342200

Folder: Diary Dose 2 (1)

Form: MuscleAche_Day(11)

Generated On: 09 Jun 2021 17:05:26

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:04:20
Data entry locked.	System	08 Oct 2020 17:00:47
User entered 'Day 11'	System	08 Oct 2020 17:00:47

US3342200

Folder: Diary Dose 2 (1)

Form: MuscleAche_Day(11)

Generated On: 09 Jun 2021 17:05:26

Select one response below to indicate the intensity of your **MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:04:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2D2D1647-7C35-4DCA-ADA3-8E1DAA921DDC)', Time: '2020-10-10T12:04:16', User OID: 'PatientReportedOutcome (US3342200)', ODM File OID: '3519342f-8f58-4f80-b9f0-6f7826f5d178' User entered 'Some interference with activity (2)'	System	10 Oct 2020 17:04:22
	System	10 Oct 2020 17:04:22

US3342200

Folder: Diary Dose 2 (1)

Form: MuscleAche_Day(11)

Generated On: 09 Jun 2021 17:05:26

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:04:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2D2D1647-7C35-4DCA-ADA3-8E1DAA921DDC)', Time: '2020-10-10T12:04:19', User OID: 'PatientReportedOutcome (US3342200)', ODM File OID: '3519342f-8f58-4f80-b9f0-6f7826f5d178' User entered '10 Oct 2020 12:04'	System	10 Oct 2020 17:04:22
	System	10 Oct 2020 17:04:22

US3342200

Folder: Diary Dose 2 (1)

Form: MuscleAche_Day(11)

Generated On: 09 Jun 2021 17:05:26

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:04:20
User entered '10 Oct 2020 12:00'	System	08 Oct 2020 17:00:47

US3342200

Folder: Diary Dose 2 (1)

Form: MuscleAche_Day(11)

Generated On: 09 Jun 2021 17:05:26

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:04:20
User entered '11 Oct 2020 11:59'	System	08 Oct 2020 17:00:47

US3342200

Folder: Diary Dose 2 (1)

Form: MuscleAche_Day(12)

Generated On: 09 Jun 2021 17:05:26

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:04:20
Data entry locked.	System	09 Oct 2020 17:15:06
User entered 'Day 12'	System	09 Oct 2020 17:15:06

US3342200

Folder: Diary Dose 2 (1)

Form: MuscleAche_Day(12)

Generated On: 09 Jun 2021 17:05:26

Select one response below to indicate the intensity of your **MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:04:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2D2D1647-7C35-4DCA-ADA3-8E1DAA921DDC)', Time: '2020-10-11T17:26:47', User OID: 'PatientReportedOutcome (US3342200)', ODM File OID: '5e50f26c-9da8-4488-ab28-e017d57040c9'	System	11 Oct 2020 22:26:52
User entered 'No interference with activity (1)'	System	11 Oct 2020 22:26:52

US3342200

Folder: Diary Dose 2 (1)

Form: MuscleAche_Day(12)

Generated On: 09 Jun 2021 17:05:26

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:04:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2D2D1647-7C35-4DCA-ADA3-8E1DAA921DDC)', Time: '2020-10-11T17:26:50', User OID: 'PatientReportedOutcome (US3342200)', ODM File OID: '5e50f26c-9da8-4488-ab28-e017d57040c9' User entered '11 Oct 2020 17:26'	System	11 Oct 2020 22:26:52
	System	11 Oct 2020 22:26:52

US3342200

Folder: Diary Dose 2 (1)

Form: MuscleAche_Day(12)

Generated On: 09 Jun 2021 17:05:26

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:04:20
User entered '11 Oct 2020 12:00'	System	09 Oct 2020 17:15:06

US3342200

Folder: Diary Dose 2 (1)

Form: MuscleAche_Day(12)

Generated On: 09 Jun 2021 17:05:26

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:04:20
User entered '12 Oct 2020 11:59'	System	09 Oct 2020 17:15:06

US3342200

Folder: Diary Dose 2 (1)

Form: MuscleAche_Day(13)

Generated On: 09 Jun 2021 17:05:26

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:04:20
Data entry locked.	System	10 Oct 2020 17:04:22
User entered 'Day 13'	System	10 Oct 2020 17:04:22

US3342200

Folder: Diary Dose 2 (1)

Form: MuscleAche_Day(13)

Generated On: 09 Jun 2021 17:05:26

Select one response below to indicate the intensity of your **MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:04:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2D2D1647-7C35-4DCA-ADA3-8E1DAA921DDC)', Time: '2020-10-12T16:02:24', User OID: 'PatientReportedOutcome (US3342200)', ODM File OID: 'da303063-927a-43b4-85f8-591e7e3463ac' User entered 'No interference with activity (1)'	System	12 Oct 2020 21:02:30
	System	12 Oct 2020 21:02:30

US3342200

Folder: Diary Dose 2 (1)

Form: MuscleAche_Day(13)

Generated On: 09 Jun 2021 17:05:26

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:04:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2D2D1647-7C35-4DCA-ADA3-8E1DAA921DDC)', Time: '2020-10-12T16:02:27', User OID: 'PatientReportedOutcome (US3342200)', ODM File OID: 'da303063-927a-43b4-85f8-591e7e3463ac' User entered '12 Oct 2020 16:02'	System	12 Oct 2020 21:02:30
	System	12 Oct 2020 21:02:30

US3342200

Folder: Diary Dose 2 (1)

Form: MuscleAche_Day(13)

Generated On: 09 Jun 2021 17:05:26

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:04:20
User entered '12 Oct 2020 12:00'	System	10 Oct 2020 17:04:22

US3342200

Folder: Diary Dose 2 (1)

Form: MuscleAche_Day(13)

Generated On: 09 Jun 2021 17:05:26

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:04:20
User entered '13 Oct 2020 11:59'	System	10 Oct 2020 17:04:22

US3342200

Folder: Diary Dose 2 (1)

Form: MuscleAche_Day(14)

Generated On: 09 Jun 2021 17:05:26

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:04:20
Data entry locked.	System	11 Oct 2020 22:26:52
User entered 'Day 14'	System	11 Oct 2020 22:26:52

US3342200

Folder: Diary Dose 2 (1)

Form: MuscleAche_Day(14)

Generated On: 09 Jun 2021 17:05:26

Select one response below to indicate the intensity of your **MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:04:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2D2D1647-7C35-4DCA-ADA3-8E1DAA921DDC)', Time: '2020-10-14T06:26:28', User OID: 'PatientReportedOutcome (US3342200)', ODM File OID: '74a6ee fb-25d8-4180-a9bc-b2848e26fe55'	System	14 Oct 2020 11:26:35
User entered 'No interference with activity (1)'	System	14 Oct 2020 11:26:35

US3342200

Folder: Diary Dose 2 (1)

Form: MuscleAche_Day(14)

Generated On: 09 Jun 2021 17:05:26

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:04:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2D2D1647-7C35-4DCA-ADA3-8E1DAA921DDC)', Time: '2020-10-14T06:26:32', User OID: 'PatientReportedOutcome (US3342200)', ODM File OID: '74a6eefb-25d8-4180-a9bc-b2848e26fe55' User entered '14 Oct 2020 06:26'	System	14 Oct 2020 11:26:35
	System	14 Oct 2020 11:26:35

US3342200

Folder: Diary Dose 2 (1)

Form: MuscleAche_Day(14)

Generated On: 09 Jun 2021 17:05:26

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:04:20
User entered '13 Oct 2020 12:00'	System	11 Oct 2020 22:26:52

US3342200

Folder: Diary Dose 2 (1)

Form: MuscleAche_Day(14)

Generated On: 09 Jun 2021 17:05:26

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:04:20
User entered '14 Oct 2020 11:59'	System	11 Oct 2020 22:26:52

US3342200

Folder: Diary Dose 2 (1)

Form: MuscleAche_Day(15)

Generated On: 09 Jun 2021 17:05:26

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:04:20
Data entry locked.	System	12 Oct 2020 21:02:30
User entered 'Day 15'	System	12 Oct 2020 21:02:30

US3342200

Folder: Diary Dose 2 (1)

Form: MuscleAche_Day(15)

Generated On: 09 Jun 2021 17:05:26

Select one response below to indicate the intensity of your **MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:04:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2D2D1647-7C35-4DCA-ADA3-8E1DAA921DDC)', Time: '2020-10-14T13:40:54', User OID: 'PatientReportedOutcome (US3342200)', ODM File OID: '7fb59d8e-bf3d-41c1-9520-afabe1a8434c' User entered 'No interference with activity (1)'	System	14 Oct 2020 18:40:59
	System	14 Oct 2020 18:40:59

US3342200

Folder: Diary Dose 2 (1)

Form: MuscleAche_Day(15)

Generated On: 09 Jun 2021 17:05:26

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:04:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2D2D1647-7C35-4DCA-ADA3-8E1DAA921DDC)', Time: '2020-10-14T13:40:56', User OID: 'PatientReportedOutcome (US3342200)', ODM File OID: '7fb59d8e-bf3d-41c1-9520-afabe1a8434c' User entered '14 Oct 2020 13:40'	System	14 Oct 2020 18:40:59
	System	14 Oct 2020 18:40:59

US3342200

Folder: Diary Dose 2 (1)

Form: MuscleAche_Day(15)

Generated On: 09 Jun 2021 17:05:26

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:04:20
User entered '14 Oct 2020 12:00'	System	12 Oct 2020 21:02:30

US3342200

Folder: Diary Dose 2 (1)

Form: MuscleAche_Day(15)

Generated On: 09 Jun 2021 17:05:26

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:04:20
User entered '15 Oct 2020 11:59'	System	12 Oct 2020 21:02:30

US3342200

Folder: Diary Dose 2 (1)

Form: MuscleAche_Day(16)

Generated On: 09 Jun 2021 17:05:26

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:04:20
Data entry locked.	System	14 Oct 2020 11:26:35
User entered 'Day 16'	System	14 Oct 2020 11:26:35

US3342200

Folder: Diary Dose 2 (1)

Form: MuscleAche_Day(16)

Generated On: 09 Jun 2021 17:05:26

Select one response below to indicate the intensity of your **MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:04:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2D2D1647-7C35-4DCA-ADA3-8E1DAA921DDC)', Time: '2020-10-16T02:16:55', User OID: 'PatientReportedOutcome (US3342200)', ODM File OID: 'd9304d65-e7e8-4f50-bda3-a19811369314' User entered 'No interference with activity (1)'	System	16 Oct 2020 07:17:00
	System	16 Oct 2020 07:17:00

US3342200

Folder: Diary Dose 2 (1)

Form: MuscleAche_Day(16)

Generated On: 09 Jun 2021 17:05:26

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:04:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2D2D1647-7C35-4DCA-ADA3-8E1DAA921DDC)', Time: '2020-10-16T02:16:58', User OID: 'PatientReportedOutcome (US3342200)', ODM File OID: 'd9304d65-e7e8-4f50-bda3-a19811369314' User entered '16 Oct 2020 02:16'	System	16 Oct 2020 07:17:00
	System	16 Oct 2020 07:17:00

US3342200

Folder: Diary Dose 2 (1)

Form: MuscleAche_Day(16)

Generated On: 09 Jun 2021 17:05:26

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:04:20
User entered '15 Oct 2020 12:00'	System	14 Oct 2020 11:26:35

US3342200

Folder: Diary Dose 2 (1)

Form: MuscleAche_Day(16)

Generated On: 09 Jun 2021 17:05:26

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:04:20
User entered '16 Oct 2020 11:59'	System	14 Oct 2020 11:26:35

US3342200

Folder: Diary Dose 2 (1)

Form: MuscleAche_Day(17)

Generated On: 09 Jun 2021 17:05:26

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:04:20
Data entry locked.	System	14 Oct 2020 18:40:59
User entered 'Day 17'	System	14 Oct 2020 18:40:59

US3342200

Folder: Diary Dose 2 (1)

Form: MuscleAche_Day(17)

Generated On: 09 Jun 2021 17:05:26

Select one response below to indicate the intensity of your **MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:04:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2D2D1647-7C35-4DCA-ADA3-8E1DAA921DDC)', Time: '2020-10-16T12:08:35', User OID: 'PatientReportedOutcome (US3342200)', ODM File OID: '9ba3081d-ce42-4e7d-8985-a621d4b00f61' User entered 'None (0)'	System	16 Oct 2020 17:08:42
	System	16 Oct 2020 17:08:42

US3342200

Folder: Diary Dose 2 (1)

Form: MuscleAche_Day(17)

Generated On: 09 Jun 2021 17:05:26

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:04:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2D2D1647-7C35-4DCA-ADA3-8E1DAA921DDC)', Time: '2020-10-16T12:08:38', User OID: 'PatientReportedOutcome (US3342200)', ODM File OID: '9ba3081d-ce42-4e7d-8985-a621d4b00f61' User entered '16 Oct 2020 12:08'	System	16 Oct 2020 17:08:42
	System	16 Oct 2020 17:08:42

US3342200

Folder: Diary Dose 2 (1)

Form: MuscleAche_Day(17)

Generated On: 09 Jun 2021 17:05:26

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:04:20
User entered '16 Oct 2020 12:00'	System	14 Oct 2020 18:40:59

US3342200

Folder: Diary Dose 2 (1)

Form: MuscleAche_Day(17)

Generated On: 09 Jun 2021 17:05:26

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:04:20
User entered '17 Oct 2020 11:59'	System	14 Oct 2020 18:40:59

US3342200

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(8)

Generated On: 09 Jun 2021 17:05:26

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:04:20
Data entry locked.	System	06 Oct 2020 07:37:46
User entered 'Day 8'	System	06 Oct 2020 07:37:46

US3342200

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(8)

Generated On: 09 Jun 2021 17:05:26

Select one response below to indicate the intensity of your **JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:04:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2D2D1647-7C35-4DCA-ADA3-8E1DAA921DDC)', Time: '2020-10-07T16:48:52', User OID: 'PatientReportedOutcome (US3342200)', ODM File OID: '2a09029f-574b-4a93-ba96-c4361624c270'	System	07 Oct 2020 21:48:59
User entered 'Some interference with activity (2)'	System	07 Oct 2020 21:48:59

US3342200

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(8)

Generated On: 09 Jun 2021 17:05:26

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:04:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2D2D1647-7C35-4DCA-ADA3-8E1DAA921DDC)', Time: '2020-10-07T16:48:56', User OID: 'PatientReportedOutcome (US3342200)', ODM File OID: '2a09029f-574b-4a93-ba96-c4361624c270' User entered '07 Oct 2020 16:48'	System	07 Oct 2020 21:48:59
	System	07 Oct 2020 21:48:59

US3342200

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(8)

Generated On: 09 Jun 2021 17:05:26

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:04:20
User entered '07 Oct 2020 12:00'	System	06 Oct 2020 07:37:46

US3342200

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(8)

Generated On: 09 Jun 2021 17:05:26

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:04:20
User entered '08 Oct 2020 11:59'	System	06 Oct 2020 07:37:46

US3342200

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(9)

Generated On: 09 Jun 2021 17:05:26

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:04:20
Data entry locked.	System	07 Oct 2020 09:30:27
User entered 'Day 9'	System	07 Oct 2020 09:30:27

US3342200

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(9)

Generated On: 09 Jun 2021 17:05:26

Select one response below to indicate the intensity of your **JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:04:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2D2D1647-7C35-4DCA-ADA3-8E1DAA921DDC)', Time: '2020-10-08T12:00:33', User OID: 'PatientReportedOutcome (US3342200)', ODM File OID: '955d25dc-9925-431b-b588-28bc7c629aa9' User entered 'Some interference with activity (2)'	System	08 Oct 2020 17:00:50
	System	08 Oct 2020 17:00:50

US3342200

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(9)

Generated On: 09 Jun 2021 17:05:26

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:04:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2D2D1647-7C35-4DCA-ADA3-8E1DAA921DDC)', Time: '2020-10-08T12:00:35', User OID: 'PatientReportedOutcome (US3342200)', ODM File OID: '955d25dc-9925-431b-b588-28bc7c629aa9' User entered '08 Oct 2020 12:00'	System	08 Oct 2020 17:00:50
	System	08 Oct 2020 17:00:50

US3342200

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(9)

Generated On: 09 Jun 2021 17:05:26

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:04:20
User entered '08 Oct 2020 12:00'	System	07 Oct 2020 09:30:27

US3342200

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(9)

Generated On: 09 Jun 2021 17:05:26

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:04:20
User entered '09 Oct 2020 11:59'	System	07 Oct 2020 09:30:27

US3342200

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(10)

Generated On: 09 Jun 2021 17:05:26

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:04:20
Data entry locked.	System	07 Oct 2020 21:48:59
User entered 'Day 10'	System	07 Oct 2020 21:48:59

US3342200

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(10)

Generated On: 09 Jun 2021 17:05:26

Select one response below to indicate the intensity of your **JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:04:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2D2D1647-7C35-4DCA-ADA3-8E1DAA921DDC)', Time: '2020-10-09T12:15:10', User OID: 'PatientReportedOutcome (US3342200)', ODM File OID: '92c1c0f8-adcb-477e-a77a-b3396eb33f58'	System	09 Oct 2020 17:15:19
User entered 'Some interference with activity (2)'	System	09 Oct 2020 17:15:19

US3342200

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(10)

Generated On: 09 Jun 2021 17:05:26

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:04:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2D2D1647-7C35-4DCA-ADA3-8E1DAA921DDC)', Time: '2020-10-09T12:15:14', User OID: 'PatientReportedOutcome (US3342200)', ODM File OID: '92c1c0f8-adcb-477e-a77a-b3396eb33f58' User entered '09 Oct 2020 12:15'	System	09 Oct 2020 17:15:19
	System	09 Oct 2020 17:15:19

US3342200

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(10)

Generated On: 09 Jun 2021 17:05:26

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:04:20
User entered '09 Oct 2020 12:00'	System	07 Oct 2020 21:48:59

US3342200

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(10)

Generated On: 09 Jun 2021 17:05:26

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:04:20
User entered '10 Oct 2020 11:59'	System	07 Oct 2020 21:48:59

US3342200

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(11)

Generated On: 09 Jun 2021 17:05:26

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:04:20
Data entry locked.	System	08 Oct 2020 17:00:50
User entered 'Day 11'	System	08 Oct 2020 17:00:50

US3342200

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(11)

Generated On: 09 Jun 2021 17:05:26

Select one response below to indicate the intensity of your **JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:04:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2D2D1647-7C35-4DCA-ADA3-8E1DAA921DDC)', Time: '2020-10-10T12:04:23', User OID: 'PatientReportedOutcome (US3342200)', ODM File OID: '7b4c8916-af48-4436-acc7-b1e9dc6880f1' User entered 'Some interference with activity (2)'	System	10 Oct 2020 17:04:28
	System	10 Oct 2020 17:04:28

US3342200

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(11)

Generated On: 09 Jun 2021 17:05:26

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:04:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2D2D1647-7C35-4DCA-ADA3-8E1DAA921DDC)', Time: '2020-10-10T12:04:26', User OID: 'PatientReportedOutcome (US3342200)', ODM File OID: '7b4c8916-af48-4436-acc7-b1e9dc6880f1' User entered '10 Oct 2020 12:04'	System	10 Oct 2020 17:04:28
	System	10 Oct 2020 17:04:28

US3342200

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(11)

Generated On: 09 Jun 2021 17:05:26

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:04:20
User entered '10 Oct 2020 12:00'	System	08 Oct 2020 17:00:50

US3342200

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(11)

Generated On: 09 Jun 2021 17:05:26

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:04:20
User entered '11 Oct 2020 11:59'	System	08 Oct 2020 17:00:50

US3342200

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(12)

Generated On: 09 Jun 2021 17:05:26

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:04:20
Data entry locked.	System	09 Oct 2020 17:15:19
User entered 'Day 12'	System	09 Oct 2020 17:15:19

US3342200

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(12)

Generated On: 09 Jun 2021 17:05:26

Select one response below to indicate the intensity of your **JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:04:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2D2D1647-7C35-4DCA-ADA3-8E1DAA921DDC)', Time: '2020-10-11T17:26:54', User OID: 'PatientReportedOutcome (US3342200)', ODM File OID: '3f950398-d7b3-48ad-9351-fbae712b66fc'	System	11 Oct 2020 22:27:01
User entered 'Some interference with activity (2)'	System	11 Oct 2020 22:27:01

US3342200

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(12)

Generated On: 09 Jun 2021 17:05:26

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:04:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2D2D1647-7C35-4DCA-ADA3-8E1DAA921DDC)', Time: '2020-10-11T17:26:58', User OID: 'PatientReportedOutcome (US3342200)', ODM File OID: '3f950398-d7b3-48ad-9351-fbae712b66fc' User entered '11 Oct 2020 17:26'	System	11 Oct 2020 22:27:01
	System	11 Oct 2020 22:27:01

US3342200

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(12)

Generated On: 09 Jun 2021 17:05:26

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:04:20
User entered '11 Oct 2020 12:00'	System	09 Oct 2020 17:15:19

US3342200

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(12)

Generated On: 09 Jun 2021 17:05:26

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:04:20
User entered '12 Oct 2020 11:59'	System	09 Oct 2020 17:15:19

US3342200

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(13)

Generated On: 09 Jun 2021 17:05:26

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:04:20
Data entry locked.	System	10 Oct 2020 17:04:28
User entered 'Day 13'	System	10 Oct 2020 17:04:28

US3342200

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(13)

Generated On: 09 Jun 2021 17:05:26

Select one response below to indicate the intensity of your **JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:04:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2D2D1647-7C35-4DCA-ADA3-8E1DAA921DDC)', Time: '2020-10-12T16:02:35', User OID: 'PatientReportedOutcome (US3342200)', ODM File OID: '1b65ab93-652a-4ccf-ab90-48d8fe91d59b' User entered 'Some interference with activity (2)'	System	12 Oct 2020 21:02:42
	System	12 Oct 2020 21:02:42

US3342200

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(13)

Generated On: 09 Jun 2021 17:05:26

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:04:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2D2D1647-7C35-4DCA-ADA3-8E1DAA921DDC)', Time: '2020-10-12T16:02:38', User OID: 'PatientReportedOutcome (US3342200)', ODM File OID: '1b65ab93-652a-4ccf-ab90-48d8fe91d59b' User entered '12 Oct 2020 16:02'	System	12 Oct 2020 21:02:42
	System	12 Oct 2020 21:02:42

US3342200

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(13)

Generated On: 09 Jun 2021 17:05:26

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:04:20
User entered '12 Oct 2020 12:00'	System	10 Oct 2020 17:04:28

US3342200

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(13)

Generated On: 09 Jun 2021 17:05:26

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:04:20
User entered '13 Oct 2020 11:59'	System	10 Oct 2020 17:04:28

US3342200

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(14)

Generated On: 09 Jun 2021 17:05:26

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:04:20
Data entry locked.	System	11 Oct 2020 22:27:01
User entered 'Day 14'	System	11 Oct 2020 22:27:01

US3342200

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(14)

Generated On: 09 Jun 2021 17:05:26

Select one response below to indicate the intensity of your **JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:04:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2D2D1647-7C35-4DCA-ADA3-8E1DAA921DDC)', Time: '2020-10-14T06:26:37', User OID: 'PatientReportedOutcome (US3342200)', ODM File OID: '62d9ea7a-d32e-439e-90b1-edbc061475d'	System	14 Oct 2020 11:26:43
User entered 'Some interference with activity (2)'	System	14 Oct 2020 11:26:43

US3342200

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(14)

Generated On: 09 Jun 2021 17:05:26

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:04:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2D2D1647-7C35-4DCA-ADA3-8E1DAA921DDC)', Time: '2020-10-14T06:26:41', User OID: 'PatientReportedOutcome (US3342200)', ODM File OID: '62d9ea7a-d32e-439e-90b1-edbc061475d' User entered '14 Oct 2020 06:26'	System	14 Oct 2020 11:26:43
	System	14 Oct 2020 11:26:43

US3342200

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(14)

Generated On: 09 Jun 2021 17:05:26

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:04:20
User entered '13 Oct 2020 12:00'	System	11 Oct 2020 22:27:01

US3342200

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(14)

Generated On: 09 Jun 2021 17:05:26

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:04:20
User entered '14 Oct 2020 11:59'	System	11 Oct 2020 22:27:01

US3342200

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(15)

Generated On: 09 Jun 2021 17:05:26

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:04:20
Data entry locked.	System	12 Oct 2020 21:02:42
User entered 'Day 15'	System	12 Oct 2020 21:02:42

US3342200

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(15)

Generated On: 09 Jun 2021 17:05:26

Select one response below to indicate the intensity of your **JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:04:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2D2D1647-7C35-4DCA-ADA3-8E1DAA921DDC)', Time: '2020-10-14T13:41:02', User OID: 'PatientReportedOutcome (US3342200)', ODM File OID: 'e9ff9e23-6a7e-4b38-95d0-6e4fff3422b7' User entered 'No interference with activity (1)'	System	14 Oct 2020 18:41:09
	System	14 Oct 2020 18:41:09

US3342200

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(15)

Generated On: 09 Jun 2021 17:05:26

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:04:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2D2D1647-7C35-4DCA-ADA3-8E1DAA921DDC)', Time: '2020-10-14T13:41:04', User OID: 'PatientReportedOutcome (US3342200)', ODM File OID: 'e9ff9e23-6a7e-4b38-95d0-6e4fff3422b7' User entered '14 Oct 2020 13:41'	System	14 Oct 2020 18:41:09
	System	14 Oct 2020 18:41:09

US3342200

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(15)

Generated On: 09 Jun 2021 17:05:26

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:04:20
User entered '14 Oct 2020 12:00'	System	12 Oct 2020 21:02:42

US3342200

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(15)

Generated On: 09 Jun 2021 17:05:26

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:04:20
User entered '15 Oct 2020 11:59'	System	12 Oct 2020 21:02:42

US3342200

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(16)

Generated On: 09 Jun 2021 17:05:26

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:04:20
Data entry locked.	System	14 Oct 2020 11:26:43
User entered 'Day 16'	System	14 Oct 2020 11:26:43

US3342200

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(16)

Generated On: 09 Jun 2021 17:05:26

Select one response below to indicate the intensity of your **JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:04:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2D2D1647-7C35-4DCA-ADA3-8E1DAA921DDC)', Time: '2020-10-16T02:17:05', User OID: 'PatientReportedOutcome (US3342200)', ODM File OID: '858ed4a9-5fc2-4060-8113-a1326101ae82'	System	16 Oct 2020 07:17:11
User entered 'Some interference with activity (2)'	System	16 Oct 2020 07:17:11

US3342200

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(16)

Generated On: 09 Jun 2021 17:05:26

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:04:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2D2D1647-7C35-4DCA-ADA3-8E1DAA921DDC)', Time: '2020-10-16T02:17:08', User OID: 'PatientReportedOutcome (US3342200)', ODM File OID: '858ed4a9-5fc2-4060-8113-a1326101ae82' User entered '16 Oct 2020 02:17'	System	16 Oct 2020 07:17:11
	System	16 Oct 2020 07:17:11

US3342200

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(16)

Generated On: 09 Jun 2021 17:05:26

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:04:20
User entered '15 Oct 2020 12:00'	System	14 Oct 2020 11:26:43

US3342200

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(16)

Generated On: 09 Jun 2021 17:05:26

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:04:20
User entered '16 Oct 2020 11:59'	System	14 Oct 2020 11:26:43

US3342200

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(17)

Generated On: 09 Jun 2021 17:05:26

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:04:20
Data entry locked.	System	14 Oct 2020 18:41:09
User entered 'Day 17'	System	14 Oct 2020 18:41:09

US3342200

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(17)

Generated On: 09 Jun 2021 17:05:26

Select one response below to indicate the intensity of your **JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:04:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2D2D1647-7C35-4DCA-ADA3-8E1DAA921DDC)', Time: '2020-10-16T12:08:42', User OID: 'PatientReportedOutcome (US3342200)', ODM File OID: '271050a6-4944-49c4-9a0d-8ef52d377375' User entered 'No interference with activity (1)'	System	16 Oct 2020 17:08:49
	System	16 Oct 2020 17:08:49

US3342200

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(17)

Generated On: 09 Jun 2021 17:05:26

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:04:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2D2D1647-7C35-4DCA-ADA3-8E1DAA921DDC)', Time: '2020-10-16T12:08:44', User OID: 'PatientReportedOutcome (US3342200)', ODM File OID: '271050a6-4944-49c4-9a0d-8ef52d377375' User entered '16 Oct 2020 12:08'	System	16 Oct 2020 17:08:49
	System	16 Oct 2020 17:08:49

US3342200

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(17)

Generated On: 09 Jun 2021 17:05:26

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:04:20
User entered '16 Oct 2020 12:00'	System	14 Oct 2020 18:41:09

US3342200

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(17)

Generated On: 09 Jun 2021 17:05:26

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:04:20
User entered '17 Oct 2020 11:59'	System	14 Oct 2020 18:41:09

US3342200

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(18)

Generated On: 09 Jun 2021 17:05:26

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:04:20
Data entry locked.	System	16 Oct 2020 07:17:11
User entered 'Day 18'	System	16 Oct 2020 07:17:11

US3342200

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(18)

Generated On: 09 Jun 2021 17:05:26

Select one response below to indicate the intensity of your **JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:04:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2D2D1647-7C35-4DCA-ADA3-8E1DAA921DDC)', Time: '2020-10-17T15:00:11', User OID: 'PatientReportedOutcome (US3342200)', ODM File OID: 'd57a0e06-e901-4385-ba24-a6f7a5f828ce' User entered 'Some interference with activity (2)'	System	17 Oct 2020 20:00:18
	System	17 Oct 2020 20:00:18

US3342200

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(18)

Generated On: 09 Jun 2021 17:05:26

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:04:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2D2D1647-7C35-4DCA-ADA3-8E1DAA921DDC)', Time: '2020-10-17T15:00:15', User OID: 'PatientReportedOutcome (US3342200)', ODM File OID: 'd57a0e06-e901-4385-ba24-a6f7a5f828ce' User entered '17 Oct 2020 15:00'	System	17 Oct 2020 20:00:18
	System	17 Oct 2020 20:00:18

US3342200

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(18)

Generated On: 09 Jun 2021 17:05:26

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:04:20
User entered '17 Oct 2020 12:00'	System	16 Oct 2020 07:17:11

US3342200

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(18)

Generated On: 09 Jun 2021 17:05:26

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:04:20
User entered '18 Oct 2020 11:59'	System	16 Oct 2020 07:17:11

US3342200

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(19)

Generated On: 09 Jun 2021 17:05:26

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:04:20
Data entry locked.	System	16 Oct 2020 17:08:49
User entered 'Day 19'	System	16 Oct 2020 17:08:49

US3342200

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(19)

Generated On: 09 Jun 2021 17:05:26

Select one response below to indicate the intensity of your **JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:04:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2D2D1647-7C35-4DCA-ADA3-8E1DAA921DDC)', Time: '2020-10-18T12:10:02', User OID: 'PatientReportedOutcome (US3342200)', ODM File OID: '01a46dbf-52ca-4e3a-af2a-79ad63693986'	System	18 Oct 2020 17:10:07
User entered 'No interference with activity (1)'	System	18 Oct 2020 17:10:07

US3342200

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(19)

Generated On: 09 Jun 2021 17:05:26

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:04:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2D2D1647-7C35-4DCA-ADA3-8E1DAA921DDC)', Time: '2020-10-18T12:10:05', User OID: 'PatientReportedOutcome (US3342200)', ODM File OID: '01a46dbf-52ca-4e3a-af2a-79ad63693986' User entered '18 Oct 2020 12:10'	System	18 Oct 2020 17:10:07
	System	18 Oct 2020 17:10:07

US3342200

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(19)

Generated On: 09 Jun 2021 17:05:26

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:04:20
User entered '18 Oct 2020 12:00'	System	16 Oct 2020 17:08:49

US3342200

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(19)

Generated On: 09 Jun 2021 17:05:26

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:04:20
User entered '19 Oct 2020 11:59'	System	16 Oct 2020 17:08:49

US3342200

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(20)

Generated On: 09 Jun 2021 17:05:26

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:04:20
Data entry locked.	System	17 Oct 2020 20:00:18
User entered 'Day 20'	System	17 Oct 2020 20:00:18

US3342200

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(20)

Generated On: 09 Jun 2021 17:05:26

Select one response below to indicate the intensity of your **JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:04:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2D2D1647-7C35-4DCA-ADA3-8E1DAA921DDC)', Time: '2020-10-19T16:38:47', User OID: 'PatientReportedOutcome (US3342200)', ODM File OID: 'd9773d79-39a2-4603-be88-18d042f9bdfd' User entered 'Some interference with activity (2)'	System	19 Oct 2020 21:38:54
	System	19 Oct 2020 21:38:54

US3342200

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(20)

Generated On: 09 Jun 2021 17:05:26

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:04:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2D2D1647-7C35-4DCA-ADA3-8E1DAA921DDC)', Time: '2020-10-19T16:38:51', User OID: 'PatientReportedOutcome (US3342200)', ODM File OID: 'd9773d79-39a2-4603-be88-18d042f9bdfd' User entered '19 Oct 2020 16:38'	System	19 Oct 2020 21:38:54
	System	19 Oct 2020 21:38:54

US3342200

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(20)

Generated On: 09 Jun 2021 17:05:26

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:04:20
User entered '19 Oct 2020 12:00'	System	17 Oct 2020 20:00:18

US3342200

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(20)

Generated On: 09 Jun 2021 17:05:26

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:04:20
User entered '20 Oct 2020 11:59'	System	17 Oct 2020 20:00:18

US3342200

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(21)

Generated On: 09 Jun 2021 17:05:26

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:04:20
Data entry locked.	System	18 Oct 2020 17:10:07
User entered 'Day 21'	System	18 Oct 2020 17:10:07

US3342200

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(21)

Generated On: 09 Jun 2021 17:05:26

Select one response below to indicate the intensity of your **JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:04:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2D2D1647-7C35-4DCA-ADA3-8E1DAA921DDC)', Time: '2020-10-20T12:39:11', User OID: 'PatientReportedOutcome (US3342200)', ODM File OID: '7a835e0c-798c-4f76-9577-37ae87501516'	System	20 Oct 2020 17:39:17
User entered 'Some interference with activity (2)'	System	20 Oct 2020 17:39:17

US3342200

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(21)

Generated On: 09 Jun 2021 17:05:26

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:04:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2D2D1647-7C35-4DCA-ADA3-8E1DAA921DDC)', Time: '2020-10-20T12:39:14', User OID: 'PatientReportedOutcome (US3342200)', ODM File OID: '7a835e0c-798c-4f76-9577-37ae87501516' User entered '20 Oct 2020 12:39'	System	20 Oct 2020 17:39:17
	System	20 Oct 2020 17:39:17

US3342200

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(21)

Generated On: 09 Jun 2021 17:05:26

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:04:20
User entered '20 Oct 2020 12:00'	System	18 Oct 2020 17:10:07

US3342200

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(21)

Generated On: 09 Jun 2021 17:05:26

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:04:20
User entered '21 Oct 2020 11:59'	System	18 Oct 2020 17:10:07

US3342200

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(22)

Generated On: 09 Jun 2021 17:05:26

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:04:20
Data entry locked.	System	19 Oct 2020 21:38:54
User entered 'Day 22'	System	19 Oct 2020 21:38:54

US3342200

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(22)

Generated On: 09 Jun 2021 17:05:26

Select one response below to indicate the intensity of your **JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:04:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2D2D1647-7C35-4DCA-ADA3-8E1DAA921DDC)', Time: '2020-10-21T12:04:29', User OID: 'PatientReportedOutcome (US3342200)', ODM File OID: '4ea81c96-cd95-418f-9792-aaa9d7b56c79' User entered 'Some interference with activity (2)'	System	21 Oct 2020 17:04:40
	System	21 Oct 2020 17:04:40

US3342200

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(22)

Generated On: 09 Jun 2021 17:05:26

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:04:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2D2D1647-7C35-4DCA-ADA3-8E1DAA921DDC)', Time: '2020-10-21T12:04:33', User OID: 'PatientReportedOutcome (US3342200)', ODM File OID: '4ea81c96-cd95-418f-9792-aaa9d7b56c79' User entered '21 Oct 2020 12:04'	System	21 Oct 2020 17:04:40
	System	21 Oct 2020 17:04:40

US3342200

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(22)

Generated On: 09 Jun 2021 17:05:26

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:04:20
User entered '21 Oct 2020 12:00'	System	19 Oct 2020 21:38:54

US3342200

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(22)

Generated On: 09 Jun 2021 17:05:26

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:04:20
User entered '22 Oct 2020 11:59'	System	19 Oct 2020 21:38:54

US3342200

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(23)

Generated On: 09 Jun 2021 17:05:26

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:04:20
Data entry locked.	System	20 Oct 2020 17:39:17
User entered 'Day 23'	System	20 Oct 2020 17:39:17

US3342200

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(23)

Generated On: 09 Jun 2021 17:05:26

Select one response below to indicate the intensity of your **JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:04:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2D2D1647-7C35-4DCA-ADA3-8E1DAA921DDC)', Time: '2020-10-22T12:08:21', User OID: 'PatientReportedOutcome (US3342200)', ODM File OID: '92af3dfd-03fa-4f2b-b489-236f70052ced' User entered 'Some interference with activity (2)'	System	22 Oct 2020 17:08:26
	System	22 Oct 2020 17:08:26

US3342200

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(23)

Generated On: 09 Jun 2021 17:05:26

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:04:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2D2D1647-7C35-4DCA-ADA3-8E1DAA921DDC)', Time: '2020-10-22T12:08:24', User OID: 'PatientReportedOutcome (US3342200)', ODM File OID: '92af3dfd-03fa-4f2b-b489-236f70052ced' User entered '22 Oct 2020 12:08'	System	22 Oct 2020 17:08:26
	System	22 Oct 2020 17:08:26

US3342200

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(23)

Generated On: 09 Jun 2021 17:05:26

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:04:20
User entered '22 Oct 2020 12:00'	System	20 Oct 2020 17:39:17

US3342200

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(23)

Generated On: 09 Jun 2021 17:05:26

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:04:20
User entered '23 Oct 2020 11:59'	System	20 Oct 2020 17:39:17

US3342200

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(24)

Generated On: 09 Jun 2021 17:05:26

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:04:20
Data entry locked.	System	21 Oct 2020 17:04:40
User entered 'Day 24'	System	21 Oct 2020 17:04:40

US3342200

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(24)

Generated On: 09 Jun 2021 17:05:26

Select one response below to indicate the intensity of your **JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:04:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2D2D1647-7C35-4DCA-ADA3-8E1DAA921DDC)', Time: '2020-10-23T12:00:21', User OID: 'PatientReportedOutcome (US3342200)', ODM File OID: '2aa1c910-3024-4836-8f2c-e5b1d2a8f759'	System	23 Oct 2020 17:00:29
User entered 'Some interference with activity (2)'	System	23 Oct 2020 17:00:29

US3342200

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(24)

Generated On: 09 Jun 2021 17:05:26

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:04:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2D2D1647-7C35-4DCA-ADA3-8E1DAA921DDC)', Time: '2020-10-23T12:00:25', User OID: 'PatientReportedOutcome (US3342200)', ODM File OID: '2aa1c910-3024-4836-8f2c-e5b1d2a8f759' User entered '23 Oct 2020 12:00'	System	23 Oct 2020 17:00:29
	System	23 Oct 2020 17:00:29

US3342200

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(24)

Generated On: 09 Jun 2021 17:05:26

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:04:20
User entered '23 Oct 2020 12:00'	System	21 Oct 2020 17:04:40

US3342200

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(24)

Generated On: 09 Jun 2021 17:05:26

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:04:20
User entered '24 Oct 2020 11:59'	System	21 Oct 2020 17:04:40

US3342200

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(25)

Generated On: 09 Jun 2021 17:05:26

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:04:20
Data entry locked.	System	22 Oct 2020 17:08:26
User entered 'Day 25'	System	22 Oct 2020 17:08:26

US3342200

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(25)

Generated On: 09 Jun 2021 17:05:26

Select one response below to indicate the intensity of your **JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:04:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2D2D1647-7C35-4DCA-ADA3-8E1DAA921DDC)', Time: '2020-10-24T17:55:15', User OID: 'PatientReportedOutcome (US3342200)', ODM File OID: '6aad7127-d1a5-4aa0-ab11-6682e06f0512'	System	24 Oct 2020 22:55:23
User entered 'No interference with activity (1)'	System	24 Oct 2020 22:55:23

US3342200

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(25)

Generated On: 09 Jun 2021 17:05:26

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:04:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2D2D1647-7C35-4DCA-ADA3-8E1DAA921DDC)', Time: '2020-10-24T17:55:21', User OID: 'PatientReportedOutcome (US3342200)', ODM File OID: '6aad7127-d1a5-4aa0-ab11-6682e06f0512' User entered '24 Oct 2020 17:55'	System	24 Oct 2020 22:55:23
	System	24 Oct 2020 22:55:23

US3342200

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(25)

Generated On: 09 Jun 2021 17:05:26

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:04:20
User entered '24 Oct 2020 12:00'	System	22 Oct 2020 17:08:26

US3342200

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(25)

Generated On: 09 Jun 2021 17:05:26

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:04:20
User entered '25 Oct 2020 11:59'	System	22 Oct 2020 17:08:26

US3342200

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(26)

Generated On: 09 Jun 2021 17:05:26

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:04:20
Data entry locked.	System	23 Oct 2020 17:00:29
User entered 'Day 26'	System	23 Oct 2020 17:00:29

US3342200

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(26)

Generated On: 09 Jun 2021 17:05:26

Select one response below to indicate the intensity of your **JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:04:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2D2D1647-7C35-4DCA-ADA3-8E1DAA921DDC)', Time: '2020-10-25T13:14:22', User OID: 'PatientReportedOutcome (US3342200)', ODM File OID: '3291dac1-c4ee-40c0-b405-064f1057cf15'	System	25 Oct 2020 18:14:52
User entered 'Some interference with activity (2)'	System	25 Oct 2020 18:14:52

US3342200

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(26)

Generated On: 09 Jun 2021 17:05:26

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:04:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2D2D1647-7C35-4DCA-ADA3-8E1DAA921DDC)', Time: '2020-10-25T13:14:49', User OID: 'PatientReportedOutcome (US3342200)', ODM File OID: '3291dac1-c4ee-40c0-b405-064f1057cf15' User entered '25 Oct 2020 13:14'	System	25 Oct 2020 18:14:52
	System	25 Oct 2020 18:14:52

US3342200

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(26)

Generated On: 09 Jun 2021 17:05:26

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:04:20
User entered '25 Oct 2020 12:00'	System	23 Oct 2020 17:00:29

US3342200

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(26)

Generated On: 09 Jun 2021 17:05:26

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:04:20
User entered '26 Oct 2020 11:59'	System	23 Oct 2020 17:00:29

US3342200

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(27)

Generated On: 09 Jun 2021 17:05:26

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:04:20
Data entry locked.	System	24 Oct 2020 22:55:23
User entered 'Day 27'	System	24 Oct 2020 22:55:23

US3342200

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(27)

Generated On: 09 Jun 2021 17:05:26

Select one response below to indicate the intensity of your **JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:04:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2D2D1647-7C35-4DCA-ADA3-8E1DAA921DDC)', Time: '2020-10-26T12:00:34', User OID: 'PatientReportedOutcome (US3342200)', ODM File OID: '772e1016-76bf-40fe-8acb-bcb43b60c30c' User entered 'No interference with activity (1)'	System	26 Oct 2020 17:01:15
	System	26 Oct 2020 17:01:15

US3342200

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(27)

Generated On: 09 Jun 2021 17:05:26

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:04:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2D2D1647-7C35-4DCA-ADA3-8E1DAA921DDC)', Time: '2020-10-26T12:00:38', User OID: 'PatientReportedOutcome (US3342200)', ODM File OID: '772e1016-76bf-40fe-8acb-bcb43b60c30c' User entered '26 Oct 2020 12:00'	System	26 Oct 2020 17:01:15
	System	26 Oct 2020 17:01:15

US3342200

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(27)

Generated On: 09 Jun 2021 17:05:26

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:04:20
User entered '26 Oct 2020 12:00'	System	24 Oct 2020 22:55:23

US3342200

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(27)

Generated On: 09 Jun 2021 17:05:26

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:04:20
User entered '27 Oct 2020 11:59'	System	24 Oct 2020 22:55:23

US3342200

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(28)

Generated On: 09 Jun 2021 17:05:26

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:04:20
Data entry locked.	System	25 Oct 2020 18:14:52
User entered 'Day 28'	System	25 Oct 2020 18:14:52

US3342200

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(28)

Generated On: 09 Jun 2021 17:05:26

Select one response below to indicate the intensity of your **JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:04:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2D2D1647-7C35-4DCA-ADA3-8E1DAA921DDC)', Time: '2020-10-27T12:15:46', User OID: 'PatientReportedOutcome (US3342200)', ODM File OID: '95bd0b31-b612-466b-8381-97288e44132b'	System	27 Oct 2020 17:15:53
User entered 'Some interference with activity (2)'	System	27 Oct 2020 17:15:53

US3342200

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(28)

Generated On: 09 Jun 2021 17:05:26

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:04:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2D2D1647-7C35-4DCA-ADA3-8E1DAA921DDC)', Time: '2020-10-27T12:15:49', User OID: 'PatientReportedOutcome (US3342200)', ODM File OID: '95bd0b31-b612-466b-8381-97288e44132b' User entered '27 Oct 2020 12:15'	System	27 Oct 2020 17:15:53
	System	27 Oct 2020 17:15:53

US3342200

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(28)

Generated On: 09 Jun 2021 17:05:26

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:04:20
User entered '27 Oct 2020 12:00'	System	25 Oct 2020 18:14:52

US3342200

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(28)

Generated On: 09 Jun 2021 17:05:26

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:04:20
User entered '28 Oct 2020 11:59'	System	25 Oct 2020 18:14:52

US3342200

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(29)

Generated On: 09 Jun 2021 17:05:26

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:04:20
Data entry locked.	System	26 Oct 2020 17:01:15
User entered 'Day 29'	System	26 Oct 2020 17:01:15

US3342200

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(29)

Generated On: 09 Jun 2021 17:05:26

Select one response below to indicate the intensity of your **JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:04:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2D2D1647-7C35-4DCA-ADA3-8E1DAA921DDC)', Time: '2020-10-28T13:15:01', User OID: 'PatientReportedOutcome (US3342200)', ODM File OID: '836916a1-5bf0-4d88-a6ac-07d13243cb2a'	System	28 Oct 2020 18:15:07
User entered 'Some interference with activity (2)'	System	28 Oct 2020 18:15:07

US3342200

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(29)

Generated On: 09 Jun 2021 17:05:26

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:04:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2D2D1647-7C35-4DCA-ADA3-8E1DAA921DDC)', Time: '2020-10-28T13:15:04', User OID: 'PatientReportedOutcome (US3342200)', ODM File OID: '836916a1-5bf0-4d88-a6ac-07d13243cb2a' User entered '28 Oct 2020 13:15'	System	28 Oct 2020 18:15:07
	System	28 Oct 2020 18:15:07

US3342200

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(29)

Generated On: 09 Jun 2021 17:05:26

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:04:20
User entered '28 Oct 2020 12:00'	System	26 Oct 2020 17:01:15

US3342200

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(29)

Generated On: 09 Jun 2021 17:05:26

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:04:20
User entered '29 Oct 2020 11:59'	System	26 Oct 2020 17:01:15

US3342200

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(30)

Generated On: 09 Jun 2021 17:05:26

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:04:20
Data entry locked.	System	27 Oct 2020 17:15:53
User entered 'Day 30'	System	27 Oct 2020 17:15:53

US3342200

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(30)

Generated On: 09 Jun 2021 17:05:26

Select one response below to indicate the intensity of your **JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:04:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2D2D1647-7C35-4DCA-ADA3-8E1DAA921DDC)', Time: '2020-10-29T13:11:39', User OID: 'PatientReportedOutcome (US3342200)', ODM File OID: 'ae0905f3-654d-46fe-81fa-faf91a5a4735'	System	29 Oct 2020 18:11:47
User entered 'Some interference with activity (2)'	System	29 Oct 2020 18:11:47

US3342200

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(30)

Generated On: 09 Jun 2021 17:05:26

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:04:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2D2D1647-7C35-4DCA-ADA3-8E1DAA921DDC)', Time: '2020-10-29T13:11:42', User OID: 'PatientReportedOutcome (US3342200)', ODM File OID: 'ae0905f3-654d-46fe-81fa-faf91a5a4735' User entered '29 Oct 2020 13:11'	System	29 Oct 2020 18:11:47
	System	29 Oct 2020 18:11:47

US3342200

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(30)

Generated On: 09 Jun 2021 17:05:26

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:04:20
User entered '29 Oct 2020 12:00'	System	27 Oct 2020 17:15:53

US3342200

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(30)

Generated On: 09 Jun 2021 17:05:26

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:04:20
User entered '30 Oct 2020 11:59'	System	27 Oct 2020 17:15:53

US3342200

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(31)

Generated On: 09 Jun 2021 17:05:26

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:04:20
Data entry locked.	System	28 Oct 2020 18:15:07
User entered 'Day 31'	System	28 Oct 2020 18:15:07

US3342200

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(31)

Generated On: 09 Jun 2021 17:05:26

Select one response below to indicate the intensity of your **JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:04:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2D2D1647-7C35-4DCA-ADA3-8E1DAA921DDC)', Time: '2020-10-30T12:00:34', User OID: 'PatientReportedOutcome (US3342200)', ODM File OID: '165ab8fd-6152-43e9-8a08-e00e50374b75' User entered 'Some interference with activity (2)'	System	30 Oct 2020 17:01:16
	System	30 Oct 2020 17:01:16

US3342200

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(31)

Generated On: 09 Jun 2021 17:05:26

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:04:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2D2D1647-7C35-4DCA-ADA3-8E1DAA921DDC)', Time: '2020-10-30T12:00:39', User OID: 'PatientReportedOutcome (US3342200)', ODM File OID: '165ab8fd-6152-43e9-8a08-e00e50374b75' User entered '30 Oct 2020 12:00'	System	30 Oct 2020 17:01:16
	System	30 Oct 2020 17:01:16

US3342200

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(31)

Generated On: 09 Jun 2021 17:05:26

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:04:20
User entered '30 Oct 2020 12:00'	System	28 Oct 2020 18:15:07

US3342200

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(31)

Generated On: 09 Jun 2021 17:05:26

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:04:20
User entered '31 Oct 2020 11:59'	System	28 Oct 2020 18:15:07

US3342200

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(32)

Generated On: 09 Jun 2021 17:05:26

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:04:20
Data entry locked.	System	29 Oct 2020 18:11:47
User entered 'Day 32'	System	29 Oct 2020 18:11:47

US3342200

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(32)

Generated On: 09 Jun 2021 17:05:26

Select one response below to indicate the intensity of your **JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:04:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2D2D1647-7C35-4DCA-ADA3-8E1DAA921DDC)', Time: '2020-10-31T16:56:53', User OID: 'PatientReportedOutcome (US3342200)', ODM File OID: 'f7b10f83-6f47-4acd-a407-01ad216bd7c5'	System	31 Oct 2020 21:56:59
User entered 'Some interference with activity (2)'	System	31 Oct 2020 21:56:59

US3342200

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(32)

Generated On: 09 Jun 2021 17:05:26

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:04:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2D2D1647-7C35-4DCA-ADA3-8E1DAA921DDC)', Time: '2020-10-31T16:56:56', User OID: 'PatientReportedOutcome (US3342200)', ODM File OID: 'f7b10f83-6f47-4acd-a407-01ad216bd7c5' User entered '31 Oct 2020 16:56'	System	31 Oct 2020 21:56:59
	System	31 Oct 2020 21:56:59

US3342200

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(32)

Generated On: 09 Jun 2021 17:05:26

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:04:20
User entered '31 Oct 2020 12:00'	System	29 Oct 2020 18:11:47

US3342200

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(32)

Generated On: 09 Jun 2021 17:05:26

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:04:20
User entered '01 Nov 2020 11:59'	System	29 Oct 2020 18:11:47

US3342200

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(33)

Generated On: 09 Jun 2021 17:05:26

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:04:20
Data entry locked.	System	30 Oct 2020 17:01:16
User entered 'Day 33'	System	30 Oct 2020 17:01:16

US3342200

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(33)

Generated On: 09 Jun 2021 17:05:26

Select one response below to indicate the intensity of your **JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:04:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2D2D1647-7C35-4DCA-ADA3-8E1DAA921DDC)', Time: '2020-11-01T14:03:25', User OID: 'PatientReportedOutcome (US3342200)', ODM File OID: 'fadecb0c-f7c8-488b-8c6f-3add290d3061' User entered 'Some interference with activity (2)'	System	01 Nov 2020 20:03:38
	System	01 Nov 2020 20:03:38

US3342200

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(33)

Generated On: 09 Jun 2021 17:05:26

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:04:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2D2D1647-7C35-4DCA-ADA3-8E1DAA921DDC)', Time: '2020-11-01T14:03:33', User OID: 'PatientReportedOutcome (US3342200)', ODM File OID: 'fadecb0c-f7c8-488b-8c6f-3add290d3061' User entered '01 Nov 2020 14:03'	System	01 Nov 2020 20:03:38
	System	01 Nov 2020 20:03:38

US3342200

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(33)

Generated On: 09 Jun 2021 17:05:26

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:04:20
User entered '01 Nov 2020 12:00'	System	30 Oct 2020 17:01:16

US3342200

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(33)

Generated On: 09 Jun 2021 17:05:26

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:04:20
User entered '02 Nov 2020 11:59'	System	30 Oct 2020 17:01:16

US3342200

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(34)

Generated On: 09 Jun 2021 17:05:26

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:04:20
Data entry locked.	System	31 Oct 2020 21:56:59
User entered 'Day 34'	System	31 Oct 2020 21:56:59

US3342200

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(34)

Generated On: 09 Jun 2021 17:05:26

Select one response below to indicate the intensity of your **JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:04:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2D2D1647-7C35-4DCA-ADA3-8E1DAA921DDC)', Time: '2020-11-02T17:31:53', User OID: 'PatientReportedOutcome (US3342200)', ODM File OID: 'e7ab827c-c69f-4a77-bbe7-78b3357f9e3a' User entered 'Some interference with activity (2)'	System	02 Nov 2020 23:31:59
	System	02 Nov 2020 23:31:59

US3342200

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(34)

Generated On: 09 Jun 2021 17:05:26

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:04:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2D2D1647-7C35-4DCA-ADA3-8E1DAA921DDC)', Time: '2020-11-02T17:31:57', User OID: 'PatientReportedOutcome (US3342200)', ODM File OID: 'e7ab827c-c69f-4a77-bbe7-78b3357f9e3a' User entered '02 Nov 2020 17:31'	System	02 Nov 2020 23:31:59
	System	02 Nov 2020 23:31:59

US3342200

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(34)

Generated On: 09 Jun 2021 17:05:26

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:04:20
User entered '02 Nov 2020 12:00'	System	31 Oct 2020 21:56:59

US3342200

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(34)

Generated On: 09 Jun 2021 17:05:26

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:04:20
User entered '03 Nov 2020 11:59'	System	31 Oct 2020 21:56:59

US3342200

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(35)

Generated On: 09 Jun 2021 17:05:26

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:04:20
Data entry locked.	System	01 Nov 2020 20:03:38
User entered 'Day 35'	System	01 Nov 2020 20:03:38

US3342200

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(35)

Generated On: 09 Jun 2021 17:05:26

Select one response below to indicate the intensity of your **JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:04:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2D2D1647-7C35-4DCA-ADA3-8E1DAA921DDC)', Time: '2020-11-03T18:01:54', User OID: 'PatientReportedOutcome (US3342200)', ODM File OID: '7e465ac8-ed24-40b2-9bc0-99a5d06377f0' User entered 'Some interference with activity (2)'	System	04 Nov 2020 00:02:03
	System	04 Nov 2020 00:02:03

US3342200

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(35)

Generated On: 09 Jun 2021 17:05:26

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:04:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2D2D1647-7C35-4DCA-ADA3-8E1DAA921DDC)', Time: '2020-11-03T18:01:59', User OID: 'PatientReportedOutcome (US3342200)', ODM File OID: '7e465ac8-ed24-40b2-9bc0-99a5d06377f0' User entered '03 Nov 2020 18:01'	System	04 Nov 2020 00:02:03
	System	04 Nov 2020 00:02:03

US3342200

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(35)

Generated On: 09 Jun 2021 17:05:26

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:04:20
User entered '03 Nov 2020 12:00'	System	01 Nov 2020 20:03:38

US3342200

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(35)

Generated On: 09 Jun 2021 17:05:26

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:04:20
User entered '04 Nov 2020 11:59'	System	01 Nov 2020 20:03:38

US3342200

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(36)

Generated On: 09 Jun 2021 17:05:26

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:04:20
Data entry locked.	System	02 Nov 2020 23:31:59
User entered 'Day 36'	System	02 Nov 2020 23:31:59

US3342200

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(36)

Generated On: 09 Jun 2021 17:05:26

Select one response below to indicate the intensity of your **JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:04:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2D2D1647-7C35-4DCA-ADA3-8E1DAA921DDC)', Time: '2020-11-05T06:41:30', User OID: 'PatientReportedOutcome (US3342200)', ODM File OID: '16f2f42c-9ab5-4c81-ac04-41cb1e6b9879' User entered 'Some interference with activity (2)'	System	05 Nov 2020 12:41:37
	System	05 Nov 2020 12:41:37

US3342200

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(36)

Generated On: 09 Jun 2021 17:05:26

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:04:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2D2D1647-7C35-4DCA-ADA3-8E1DAA921DDC)', Time: '2020-11-05T06:41:35', User OID: 'PatientReportedOutcome (US3342200)', ODM File OID: '16f2f42c-9ab5-4c81-ac04-41cb1e6b9879' User entered '05 Nov 2020 06:41'	System	05 Nov 2020 12:41:37
	System	05 Nov 2020 12:41:37

US3342200

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(36)

Generated On: 09 Jun 2021 17:05:26

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:04:20
User entered '04 Nov 2020 12:00'	System	02 Nov 2020 23:31:59

US3342200

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(36)

Generated On: 09 Jun 2021 17:05:26

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:04:20
User entered '05 Nov 2020 11:59'	System	02 Nov 2020 23:31:59

US3342200

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(37)

Generated On: 09 Jun 2021 17:05:26

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:04:20
Data entry locked.	System	04 Nov 2020 00:02:03
User entered 'Day 37'	System	04 Nov 2020 00:02:03

US3342200

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(37)

Generated On: 09 Jun 2021 17:05:26

Select one response below to indicate the intensity of your **JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:04:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2D2D1647-7C35-4DCA-ADA3-8E1DAA921DDC)', Time: '2020-11-05T12:13:31', User OID: 'PatientReportedOutcome (US3342200)', ODM File OID: '83e416d9-ed53-4153-9755-ab1757d2cd5a' User entered 'No interference with activity (1)'	System	05 Nov 2020 18:13:36
	System	05 Nov 2020 18:13:36

US3342200

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(37)

Generated On: 09 Jun 2021 17:05:26

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:04:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2D2D1647-7C35-4DCA-ADA3-8E1DAA921DDC)', Time: '2020-11-05T12:13:33', User OID: 'PatientReportedOutcome (US3342200)', ODM File OID: '83e416d9-ed53-4153-9755-ab1757d2cd5a' User entered '05 Nov 2020 12:13'	System	05 Nov 2020 18:13:36
	System	05 Nov 2020 18:13:36

US3342200

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(37)

Generated On: 09 Jun 2021 17:05:26

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:04:20
User entered '05 Nov 2020 12:00'	System	04 Nov 2020 00:02:03

US3342200

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(37)

Generated On: 09 Jun 2021 17:05:26

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:04:20
User entered '06 Nov 2020 11:59'	System	04 Nov 2020 00:02:03

US3342200

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(38)

Generated On: 09 Jun 2021 17:05:26

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:04:20
Data entry locked.	System	05 Nov 2020 12:41:37
User entered 'Day 38'	System	05 Nov 2020 12:41:37

US3342200

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(38)

Generated On: 09 Jun 2021 17:05:26

Select one response below to indicate the intensity of your **JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:04:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2D2D1647-7C35-4DCA-ADA3-8E1DAA921DDC)', Time: '2020-11-07T04:41:33', User OID: 'PatientReportedOutcome (US3342200)', ODM File OID: 'f1e2c6f1-cb47-43a8-b2d7-2f5139d1845a' User entered 'Some interference with activity (2)'	System	07 Nov 2020 10:41:41
	System	07 Nov 2020 10:41:41

US3342200

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(38)

Generated On: 09 Jun 2021 17:05:26

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:04:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2D2D1647-7C35-4DCA-ADA3-8E1DAA921DDC)', Time: '2020-11-07T04:41:38', User OID: 'PatientReportedOutcome (US3342200)', ODM File OID: 'f1e2c6f1-cb47-43a8-b2d7-2f5139d1845a' User entered '07 Nov 2020 04:41'	System	07 Nov 2020 10:41:41
	System	07 Nov 2020 10:41:41

US3342200

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(38)

Generated On: 09 Jun 2021 17:05:26

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:04:20
User entered '06 Nov 2020 12:00'	System	05 Nov 2020 12:41:37

US3342200

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(38)

Generated On: 09 Jun 2021 17:05:26

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:04:20
User entered '07 Nov 2020 11:59'	System	05 Nov 2020 12:41:37

US3342200

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(39)

Generated On: 09 Jun 2021 17:05:26

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:04:20
Data entry locked.	System	05 Nov 2020 18:13:36
User entered 'Day 39'	System	05 Nov 2020 18:13:36

Select one response below to indicate the intensity of your **JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:04:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2D2D1647-7C35-4DCA-ADA3-8E1DAA921DDC)', Time: '2020-11-07T12:30:29', User OID: 'PatientReportedOutcome (US3342200)', ODM File OID: '345d244c-116c-4aad-b80f-dea98179c269'	System	07 Nov 2020 18:30:37
User entered 'Some interference with activity (2)'	System	07 Nov 2020 18:30:37

US3342200

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(39)

Generated On: 09 Jun 2021 17:05:26

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:04:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2D2D1647-7C35-4DCA-ADA3-8E1DAA921DDC)', Time: '2020-11-07T12:30:32', User OID: 'PatientReportedOutcome (US3342200)', ODM File OID: '345d244c-116c-4aad-b80f-dea98179c269' User entered '07 Nov 2020 12:30'	System	07 Nov 2020 18:30:37
	System	07 Nov 2020 18:30:37

US3342200

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(39)

Generated On: 09 Jun 2021 17:05:26

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:04:20
User entered '07 Nov 2020 12:00'	System	05 Nov 2020 18:13:36

US3342200

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(39)

Generated On: 09 Jun 2021 17:05:26

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:04:20
User entered '08 Nov 2020 11:59'	System	05 Nov 2020 18:13:36

US3342200

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(40)

Generated On: 09 Jun 2021 17:05:26

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:04:20
Data entry locked.	System	07 Nov 2020 10:41:41
User entered 'Day 40'	System	07 Nov 2020 10:41:41

US3342200

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(40)

Generated On: 09 Jun 2021 17:05:26

Select one response below to indicate the intensity of your **JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:04:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2D2D1647-7C35-4DCA-ADA3-8E1DAA921DDC)', Time: '2020-11-08T12:00:49', User OID: 'PatientReportedOutcome (US3342200)', ODM File OID: 'e55514fb-9a34-4c44-8fe2-380f270e81ee' User entered 'Some interference with activity (2)'	System	08 Nov 2020 18:00:54
	System	08 Nov 2020 18:00:54

US3342200

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(40)

Generated On: 09 Jun 2021 17:05:26

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:04:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2D2D1647-7C35-4DCA-ADA3-8E1DAA921DDC)', Time: '2020-11-08T12:00:52', User OID: 'PatientReportedOutcome (US3342200)', ODM File OID: 'e55514fb-9a34-4c44-8fe2-380f270e81ee' User entered '08 Nov 2020 12:00'	System	08 Nov 2020 18:00:54
	System	08 Nov 2020 18:00:54

US3342200

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(40)

Generated On: 09 Jun 2021 17:05:26

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:04:20
User entered '08 Nov 2020 12:00'	System	07 Nov 2020 10:41:41

US3342200

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(40)

Generated On: 09 Jun 2021 17:05:26

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:04:20
User entered '09 Nov 2020 11:59'	System	07 Nov 2020 10:41:41

US3342200

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(41)

Generated On: 09 Jun 2021 17:05:26

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:04:20
Data entry locked.	System	07 Nov 2020 18:30:37
User entered 'Day 41'	System	07 Nov 2020 18:30:37

US3342200

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(41)

Generated On: 09 Jun 2021 17:05:26

Select one response below to indicate the intensity of your **JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:04:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2D2D1647-7C35-4DCA-ADA3-8E1DAA921DDC)', Time: '2020-11-09T21:21:22', User OID: 'PatientReportedOutcome (US3342200)', ODM File OID: 'ab73fa44-1c06-436c-b2d2-716a10769c15' User entered 'Some interference with activity (2)'	System	10 Nov 2020 03:21:29
	System	10 Nov 2020 03:21:29

US3342200

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(41)

Generated On: 09 Jun 2021 17:05:26

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:04:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2D2D1647-7C35-4DCA-ADA3-8E1DAA921DDC)', Time: '2020-11-09T21:21:25', User OID: 'PatientReportedOutcome (US3342200)', ODM File OID: 'ab73fa44-1c06-436c-b2d2-716a10769c15' User entered '09 Nov 2020 21:21'	System	10 Nov 2020 03:21:29
	System	10 Nov 2020 03:21:29

US3342200

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(41)

Generated On: 09 Jun 2021 17:05:26

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:04:20
User entered '09 Nov 2020 12:00'	System	07 Nov 2020 18:30:37

US3342200

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(41)

Generated On: 09 Jun 2021 17:05:26

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:04:20
User entered '10 Nov 2020 11:59'	System	07 Nov 2020 18:30:37

US3342200

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(42)

Generated On: 09 Jun 2021 17:05:26

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:04:20
Data entry locked.	System	08 Nov 2020 18:00:54
User entered 'Day 42'	System	08 Nov 2020 18:00:54

US3342200

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(42)

Generated On: 09 Jun 2021 17:05:26

Select one response below to indicate the intensity of your **JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:04:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2D2D1647-7C35-4DCA-ADA3-8E1DAA921DDC)', Time: '2020-11-11T04:15:33', User OID: 'PatientReportedOutcome (US3342200)', ODM File OID: '7a8db246-4b75-4ef7-8dc1-fa6008c29c0d' User entered 'Some interference with activity (2)'	System	11 Nov 2020 10:15:44
	System	11 Nov 2020 10:15:44

US3342200

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(42)

Generated On: 09 Jun 2021 17:05:26

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:04:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2D2D1647-7C35-4DCA-ADA3-8E1DAA921DDC)', Time: '2020-11-11T04:15:41', User OID: 'PatientReportedOutcome (US3342200)', ODM File OID: '7a8db246-4b75-4ef7-8dc1-fa6008c29c0d' User entered '11 Nov 2020 04:15'	System	11 Nov 2020 10:15:44
	System	11 Nov 2020 10:15:44

US3342200

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(42)

Generated On: 09 Jun 2021 17:05:26

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:04:20
User entered '10 Nov 2020 12:00'	System	08 Nov 2020 18:00:54

US3342200

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(42)

Generated On: 09 Jun 2021 17:05:26

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:04:20
User entered '11 Nov 2020 11:59'	System	08 Nov 2020 18:00:54

US3342200

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(43)

Generated On: 09 Jun 2021 17:05:26

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:04:20
Data entry locked.	System	10 Nov 2020 03:21:29
User entered 'Day 43'	System	10 Nov 2020 03:21:29

US3342200

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(43)

Generated On: 09 Jun 2021 17:05:26

Select one response below to indicate the intensity of your **JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:04:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2D2D1647-7C35-4DCA-ADA3-8E1DAA921DDC)', Time: '2020-11-11T17:04:55', User OID: 'PatientReportedOutcome (US3342200)', ODM File OID: 'e41b06a1-52fb-40e9-b2dc-2f5cfdcfd7e7' User entered 'Some interference with activity (2)'	System	11 Nov 2020 23:05:02
	System	11 Nov 2020 23:05:02

US3342200

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(43)

Generated On: 09 Jun 2021 17:05:26

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:04:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2D2D1647-7C35-4DCA-ADA3-8E1DAA921DDC)', Time: '2020-11-11T17:04:58', User OID: 'PatientReportedOutcome (US3342200)', ODM File OID: 'e41b06a1-52fb-40e9-b2dc-2f5cfdcfd7e7' User entered '11 Nov 2020 17:04'	System	11 Nov 2020 23:05:02
	System	11 Nov 2020 23:05:02

US3342200

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(43)

Generated On: 09 Jun 2021 17:05:26

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:04:20
User entered '11 Nov 2020 12:00'	System	10 Nov 2020 03:21:29

US3342200

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(43)

Generated On: 09 Jun 2021 17:05:26

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:04:20
User entered '12 Nov 2020 11:59'	System	10 Nov 2020 03:21:29

US3342200

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(44)

Generated On: 09 Jun 2021 17:05:26

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:04:20
Data entry locked.	System	11 Nov 2020 10:15:44
User entered 'Day 44'	System	11 Nov 2020 10:15:44

US3342200

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(44)

Generated On: 09 Jun 2021 17:05:26

Select one response below to indicate the intensity of your **JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:04:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2D2D1647-7C35-4DCA-ADA3-8E1DAA921DDC)', Time: '2020-11-12T14:39:46', User OID: 'PatientReportedOutcome (US3342200)', ODM File OID: '789ab4cf-1afd-4f8a-8771-09f3c1469354' User entered 'Some interference with activity (2)'	System	12 Nov 2020 20:39:53
	System	12 Nov 2020 20:39:53

US3342200

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(44)

Generated On: 09 Jun 2021 17:05:26

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:04:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2D2D1647-7C35-4DCA-ADA3-8E1DAA921DDC)', Time: '2020-11-12T14:39:50', User OID: 'PatientReportedOutcome (US3342200)', ODM File OID: '789ab4cf-1afd-4f8a-8771-09f3c1469354' User entered '12 Nov 2020 14:39'	System	12 Nov 2020 20:39:53
	System	12 Nov 2020 20:39:53

US3342200

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(44)

Generated On: 09 Jun 2021 17:05:26

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:04:20
User entered '12 Nov 2020 12:00'	System	11 Nov 2020 10:15:44

US3342200

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(44)

Generated On: 09 Jun 2021 17:05:26

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:04:20
User entered '13 Nov 2020 11:59'	System	11 Nov 2020 10:15:44

US3342200

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(45)

Generated On: 09 Jun 2021 17:05:26

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:04:20
Data entry locked.	System	11 Nov 2020 23:05:02
User entered 'Day 45'	System	11 Nov 2020 23:05:02

US3342200

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(45)

Generated On: 09 Jun 2021 17:05:26

Select one response below to indicate the intensity of your **JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:04:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2D2D1647-7C35-4DCA-ADA3-8E1DAA921DDC)', Time: '2020-11-13T18:17:21', User OID: 'PatientReportedOutcome (US3342200)', ODM File OID: 'f83663b0-98dd-4488-859a-2763496c3612'	System	14 Nov 2020 00:17:29
User entered 'Some interference with activity (2)'	System	14 Nov 2020 00:17:29

US3342200

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(45)

Generated On: 09 Jun 2021 17:05:26

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:04:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2D2D1647-7C35-4DCA-ADA3-8E1DAA921DDC)', Time: '2020-11-13T18:17:24', User OID: 'PatientReportedOutcome (US3342200)', ODM File OID: 'f83663b0-98dd-4488-859a-2763496c3612' User entered '13 Nov 2020 18:17'	System	14 Nov 2020 00:17:29
	System	14 Nov 2020 00:17:29

US3342200

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(45)

Generated On: 09 Jun 2021 17:05:26

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:04:20
User entered '13 Nov 2020 12:00'	System	11 Nov 2020 23:05:02

US3342200

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(45)

Generated On: 09 Jun 2021 17:05:26

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:04:20
User entered '14 Nov 2020 11:59'	System	11 Nov 2020 23:05:02

US3342200

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(46)

Generated On: 09 Jun 2021 17:05:26

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:04:20
Data entry locked.	System	12 Nov 2020 20:39:53
User entered 'Day 46'	System	12 Nov 2020 20:39:53

US3342200

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(46)

Generated On: 09 Jun 2021 17:05:26

Select one response below to indicate the intensity of your **JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:04:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2D2D1647-7C35-4DCA-ADA3-8E1DAA921DDC)', Time: '2020-11-15T04:11:29', User OID: 'PatientReportedOutcome (US3342200)', ODM File OID: 'e42b0613-6baf-4175-8097-04fd811bfa8b' User entered 'No interference with activity (1)'	System	15 Nov 2020 10:11:35
	System	15 Nov 2020 10:11:35

US3342200

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(46)

Generated On: 09 Jun 2021 17:05:26

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:04:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2D2D1647-7C35-4DCA-ADA3-8E1DAA921DDC)', Time: '2020-11-15T04:11:34', User OID: 'PatientReportedOutcome (US3342200)', ODM File OID: 'e42b0613-6baf-4175-8097-04fd811bfa8b' User entered '15 Nov 2020 04:11'	System	15 Nov 2020 10:11:35
	System	15 Nov 2020 10:11:35

US3342200

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(46)

Generated On: 09 Jun 2021 17:05:26

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:04:20
User entered '14 Nov 2020 12:00'	System	12 Nov 2020 20:39:53

US3342200

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(46)

Generated On: 09 Jun 2021 17:05:26

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:04:20
User entered '15 Nov 2020 11:59'	System	12 Nov 2020 20:39:53

US3342200

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(47)

Generated On: 09 Jun 2021 17:05:26

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:04:20
Data entry locked.	System	14 Nov 2020 00:17:29
User entered 'Day 47'	System	14 Nov 2020 00:17:29

US3342200

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(47)

Generated On: 09 Jun 2021 17:05:26

Select one response below to indicate the intensity of your **JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:04:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2D2D1647-7C35-4DCA-ADA3-8E1DAA921DDC)', Time: '2020-11-15T15:24:29', User OID: 'PatientReportedOutcome (US3342200)', ODM File OID: '8403c127-6409-4783-ae29-0777b766d778'	System	15 Nov 2020 21:24:36
User entered 'Some interference with activity (2)'	System	15 Nov 2020 21:24:36

US3342200

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(47)

Generated On: 09 Jun 2021 17:05:26

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:04:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2D2D1647-7C35-4DCA-ADA3-8E1DAA921DDC)', Time: '2020-11-15T15:24:33', User OID: 'PatientReportedOutcome (US3342200)', ODM File OID: '8403c127-6409-4783-ae29-0777b766d778' User entered '15 Nov 2020 15:24'	System	15 Nov 2020 21:24:36
	System	15 Nov 2020 21:24:36

US3342200

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(47)

Generated On: 09 Jun 2021 17:05:26

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:04:20
User entered '15 Nov 2020 12:00'	System	14 Nov 2020 00:17:29

US3342200

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(47)

Generated On: 09 Jun 2021 17:05:26

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:04:20
User entered '16 Nov 2020 11:59'	System	14 Nov 2020 00:17:29

US3342200

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(48)

Generated On: 09 Jun 2021 17:05:26

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:04:20
Data entry locked.	System	15 Nov 2020 10:11:35
User entered 'Day 48'	System	15 Nov 2020 10:11:35

US3342200

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(48)

Generated On: 09 Jun 2021 17:05:26

Select one response below to indicate the intensity of your **JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:04:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2D2D1647-7C35-4DCA-ADA3-8E1DAA921DDC)', Time: '2020-11-16T13:51:00', User OID: 'PatientReportedOutcome (US3342200)', ODM File OID: 'c28ebc46-cd29-48d8-b491-36de039ae35c' User entered 'Some interference with activity (2)'	System	16 Nov 2020 19:51:07
	System	16 Nov 2020 19:51:07

US3342200

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(48)

Generated On: 09 Jun 2021 17:05:26

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:04:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2D2D1647-7C35-4DCA-ADA3-8E1DAA921DDC)', Time: '2020-11-16T13:51:03', User OID: 'PatientReportedOutcome (US3342200)', ODM File OID: 'c28ebc46-cd29-48d8-b491-36de039ae35c' User entered '16 Nov 2020 13:51'	System	16 Nov 2020 19:51:07
	System	16 Nov 2020 19:51:07

US3342200

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(48)

Generated On: 09 Jun 2021 17:05:26

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:04:20
User entered '16 Nov 2020 12:00'	System	15 Nov 2020 10:11:35

US3342200

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(48)

Generated On: 09 Jun 2021 17:05:26

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:04:20
User entered '17 Nov 2020 11:59'	System	15 Nov 2020 10:11:35

US3342200

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(49)

Generated On: 09 Jun 2021 17:05:26

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:04:20
Data entry locked.	System	15 Nov 2020 21:24:36
User entered 'Day 49'	System	15 Nov 2020 21:24:36

US3342200

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(49)

Generated On: 09 Jun 2021 17:05:26

Select one response below to indicate the intensity of your **JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:04:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2D2D1647-7C35-4DCA-ADA3-8E1DAA921DDC)', Time: '2020-11-18T00:03:25', User OID: 'PatientReportedOutcome (US3342200)', ODM File OID: 'dca0ef93-08cf-4719-a42a-e26eb00763b6' User entered 'Some interference with activity (2)'	System	18 Nov 2020 06:03:36
	System	18 Nov 2020 06:03:36

US3342200

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(49)

Generated On: 09 Jun 2021 17:05:26

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:04:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2D2D1647-7C35-4DCA-ADA3-8E1DAA921DDC)', Time: '2020-11-18T00:03:32', User OID: 'PatientReportedOutcome (US3342200)', ODM File OID: 'dca0ef93-08cf-4719-a42a-e26eb00763b6' User entered '18 Nov 2020 00:03'	System	18 Nov 2020 06:03:36
	System	18 Nov 2020 06:03:36

US3342200

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(49)

Generated On: 09 Jun 2021 17:05:26

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:04:20
User entered '17 Nov 2020 12:00'	System	15 Nov 2020 21:24:36

US3342200

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(49)

Generated On: 09 Jun 2021 17:05:26

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:04:20
User entered '18 Nov 2020 11:59'	System	15 Nov 2020 21:24:36

US3342200

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(50)

Generated On: 09 Jun 2021 17:05:26

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:04:20
Data entry locked.	System	16 Nov 2020 19:51:07
User entered 'Day 50'	System	16 Nov 2020 19:51:07

US3342200

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(50)

Generated On: 09 Jun 2021 17:05:26

Select one response below to indicate the intensity of your **JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:04:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2D2D1647-7C35-4DCA-ADA3-8E1DAA921DDC)', Time: '2020-11-18T12:33:24', User OID: 'PatientReportedOutcome (US3342200)', ODM File OID: '0ec19178-b599-4afe-b338-70e92084a946'	System	18 Nov 2020 18:33:30
User entered 'Some interference with activity (2)'	System	18 Nov 2020 18:33:30

US3342200

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(50)

Generated On: 09 Jun 2021 17:05:26

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:04:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2D2D1647-7C35-4DCA-ADA3-8E1DAA921DDC)', Time: '2020-11-18T12:33:28', User OID: 'PatientReportedOutcome (US3342200)', ODM File OID: '0ec19178-b599-4afe-b338-70e92084a946' User entered '18 Nov 2020 12:33'	System	18 Nov 2020 18:33:30
	System	18 Nov 2020 18:33:30

US3342200

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(50)

Generated On: 09 Jun 2021 17:05:26

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:04:20
User entered '18 Nov 2020 12:00'	System	16 Nov 2020 19:51:07

US3342200

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(50)

Generated On: 09 Jun 2021 17:05:26

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:04:20
User entered '19 Nov 2020 11:59'	System	16 Nov 2020 19:51:07

US3342200

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(51)

Generated On: 09 Jun 2021 17:05:26

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:04:20
Data entry locked.	System	18 Nov 2020 06:03:36
User entered 'Day 51'	System	18 Nov 2020 06:03:36

US3342200

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(51)

Generated On: 09 Jun 2021 17:05:26

Select one response below to indicate the intensity of your **JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:04:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2D2D1647-7C35-4DCA-ADA3-8E1DAA921DDC)', Time: '2020-11-20T05:59:22', User OID: 'PatientReportedOutcome (US3342200)', ODM File OID: '8178f9ee-d7de-439e-8df2-09a8e93078cd' User entered 'Some interference with activity (2)'	System	20 Nov 2020 11:59:37

US3342200

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(51)

Generated On: 09 Jun 2021 17:05:26

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:04:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2D2D1647-7C35-4DCA-ADA3-8E1DAA921DDC)', Time: '2020-11-20T05:59:29', User OID: 'PatientReportedOutcome (US3342200)', ODM File OID: '8178f9ee-d7de-439e-8df2-09a8e93078cd' User entered '20 Nov 2020 05:59'	System	20 Nov 2020 11:59:37
	System	20 Nov 2020 11:59:37

US3342200

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(51)

Generated On: 09 Jun 2021 17:05:26

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:04:20
User entered '19 Nov 2020 12:00'	System	18 Nov 2020 06:03:36

US3342200

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(51)

Generated On: 09 Jun 2021 17:05:26

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:04:20
User entered '20 Nov 2020 11:59'	System	18 Nov 2020 06:03:36

US3342200

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(52)

Generated On: 09 Jun 2021 17:05:26

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:04:20
Data entry locked.	System	18 Nov 2020 18:33:30
User entered 'Day 52'	System	18 Nov 2020 18:33:30

US3342200

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(52)

Generated On: 09 Jun 2021 17:05:26

Select one response below to indicate the intensity of your **JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:04:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2D2D1647-7C35-4DCA-ADA3-8E1DAA921DDC)', Time: '2020-11-21T04:06:12', User OID: 'PatientReportedOutcome (US3342200)', ODM File OID: '48ecca37-a4dd-451f-8f07-fe03730a2e9f' User entered 'Some interference with activity (2)'	System	21 Nov 2020 10:06:20

US3342200

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(52)

Generated On: 09 Jun 2021 17:05:26

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:04:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2D2D1647-7C35-4DCA-ADA3-8E1DAA921DDC)', Time: '2020-11-21T04:06:17', User OID: 'PatientReportedOutcome (US3342200)', ODM File OID: '48ecca37-a4dd-451f-8f07-fe03730a2e9f' User entered '21 Nov 2020 04:06'	System	21 Nov 2020 10:06:20
	System	21 Nov 2020 10:06:20

US3342200

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(52)

Generated On: 09 Jun 2021 17:05:26

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:04:20
User entered '20 Nov 2020 12:00'	System	18 Nov 2020 18:33:30

US3342200

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(52)

Generated On: 09 Jun 2021 17:05:26

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:04:20
User entered '21 Nov 2020 11:59'	System	18 Nov 2020 18:33:30

US3342200

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(53)

Generated On: 09 Jun 2021 17:05:26

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:04:20
Data entry locked.	System	20 Nov 2020 11:59:37
User entered 'Day 53'	System	20 Nov 2020 11:59:37

US3342200

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(53)

Generated On: 09 Jun 2021 17:05:26

Select one response below to indicate the intensity of your **JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:04:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2D2D1647-7C35-4DCA-ADA3-8E1DAA921DDC)', Time: '2020-11-22T00:46:38', User OID: 'PatientReportedOutcome (US3342200)', ODM File OID: '75aeb4d9-08bb-44ba-8cb9-0b70abc36d3d' User entered 'No interference with activity (1)'	System	22 Nov 2020 06:46:43
	System	22 Nov 2020 06:46:43

US3342200

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(53)

Generated On: 09 Jun 2021 17:05:26

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:04:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2D2D1647-7C35-4DCA-ADA3-8E1DAA921DDC)', Time: '2020-11-22T00:46:41', User OID: 'PatientReportedOutcome (US3342200)', ODM File OID: '75aeb4d9-08bb-44ba-8cb9-0b70abc36d3d' User entered '22 Nov 2020 00:46'	System	22 Nov 2020 06:46:43
	System	22 Nov 2020 06:46:43

US3342200

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(53)

Generated On: 09 Jun 2021 17:05:26

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:04:20
User entered '21 Nov 2020 12:00'	System	20 Nov 2020 11:59:37

US3342200

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(53)

Generated On: 09 Jun 2021 17:05:26

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:04:20
User entered '22 Nov 2020 11:59'	System	20 Nov 2020 11:59:37

US3342200

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(54)

Generated On: 09 Jun 2021 17:05:26

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:04:20
Data entry locked.	System	21 Nov 2020 10:06:20
User entered 'Day 54'	System	21 Nov 2020 10:06:20

US3342200

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(54)

Generated On: 09 Jun 2021 17:05:26

Select one response below to indicate the intensity of your **JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:04:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2D2D1647-7C35-4DCA-ADA3-8E1DAA921DDC)', Time: '2020-11-22T17:30:20', User OID: 'PatientReportedOutcome (US3342200)', ODM File OID: 'dfdb2577-090f-4b38-88d7-8d7bbb55080e' User entered 'Some interference with activity (2)'	System	22 Nov 2020 23:30:27
	System	22 Nov 2020 23:30:27

US3342200

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(54)

Generated On: 09 Jun 2021 17:05:26

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:04:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2D2D1647-7C35-4DCA-ADA3-8E1DAA921DDC)', Time: '2020-11-22T17:30:23', User OID: 'PatientReportedOutcome (US3342200)', ODM File OID: 'dfdb2577-090f-4b38-88d7-8d7bbb55080e' User entered '22 Nov 2020 17:30'	System	22 Nov 2020 23:30:27
	System	22 Nov 2020 23:30:27

US3342200

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(54)

Generated On: 09 Jun 2021 17:05:26

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:04:20
User entered '22 Nov 2020 12:00'	System	21 Nov 2020 10:06:20

US3342200

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(54)

Generated On: 09 Jun 2021 17:05:26

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:04:20
User entered '23 Nov 2020 11:59'	System	21 Nov 2020 10:06:20

US3342200

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(55)

Generated On: 09 Jun 2021 17:05:26

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:04:20
Data entry locked.	System	22 Nov 2020 06:46:43
User entered 'Day 55'	System	22 Nov 2020 06:46:43

US3342200

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(55)

Generated On: 09 Jun 2021 17:05:26

Select one response below to indicate the intensity of your **JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:04:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2D2D1647-7C35-4DCA-ADA3-8E1DAA921DDC)', Time: '2020-11-23T12:02:04', User OID: 'PatientReportedOutcome (US3342200)', ODM File OID: '77ac41b4-755e-4a26-894c-43c4790ad7c5' User entered 'Some interference with activity (2)'	System	23 Nov 2020 18:02:09
	System	23 Nov 2020 18:02:09

US3342200

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(55)

Generated On: 09 Jun 2021 17:05:26

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:04:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2D2D1647-7C35-4DCA-ADA3-8E1DAA921DDC)', Time: '2020-11-23T12:02:07', User OID: 'PatientReportedOutcome (US3342200)', ODM File OID: '77ac41b4-755e-4a26-894c-43c4790ad7c5' User entered '23 Nov 2020 12:02'	System	23 Nov 2020 18:02:09
	System	23 Nov 2020 18:02:09

US3342200

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(55)

Generated On: 09 Jun 2021 17:05:26

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:04:20
User entered '23 Nov 2020 12:00'	System	22 Nov 2020 06:46:43

US3342200

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(55)

Generated On: 09 Jun 2021 17:05:26

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:04:20
User entered '24 Nov 2020 11:59'	System	22 Nov 2020 06:46:43

US3342200

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(56)

Generated On: 09 Jun 2021 17:05:26

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:04:20
Data entry locked.	System	22 Nov 2020 23:30:27
User entered 'Day 56'	System	22 Nov 2020 23:30:27

US3342200

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(56)

Generated On: 09 Jun 2021 17:05:26

Select one response below to indicate the intensity of your **JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:04:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2D2D1647-7C35-4DCA-ADA3-8E1DAA921DDC)', Time: '2020-11-24T13:09:57', User OID: 'PatientReportedOutcome (US3342200)', ODM File OID: '40df58ff-9d03-44b0-aa9b-39286ee6df62'	System	24 Nov 2020 19:10:04
User entered 'Some interference with activity (2)'	System	24 Nov 2020 19:10:04

US3342200

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(56)

Generated On: 09 Jun 2021 17:05:26

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:04:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2D2D1647-7C35-4DCA-ADA3-8E1DAA921DDC)', Time: '2020-11-24T13:09:59', User OID: 'PatientReportedOutcome (US3342200)', ODM File OID: '40df58ff-9d03-44b0-aa9b-39286ee6df62' User entered '24 Nov 2020 13:09'	System	24 Nov 2020 19:10:04
	System	24 Nov 2020 19:10:04

US3342200

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(56)

Generated On: 09 Jun 2021 17:05:26

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:04:20
User entered '24 Nov 2020 12:00'	System	22 Nov 2020 23:30:27

US3342200

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(56)

Generated On: 09 Jun 2021 17:05:26

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:04:20
User entered '25 Nov 2020 11:59'	System	22 Nov 2020 23:30:27

US3342200

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(57)

Generated On: 09 Jun 2021 17:05:26

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:04:20
Data entry locked.	System	23 Nov 2020 18:02:09
User entered 'Day 57'	System	23 Nov 2020 18:02:09

US3342200

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(57)

Generated On: 09 Jun 2021 17:05:26

Select one response below to indicate the intensity of your **JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:04:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2D2D1647-7C35-4DCA-ADA3-8E1DAA921DDC)', Time: '2020-11-25T16:13:00', User OID: 'PatientReportedOutcome (US3342200)', ODM File OID: 'f777e42b-cbf6-4057-a9af-a03a85b05bb2'	System	25 Nov 2020 22:13:05
User entered 'Some interference with activity (2)'	System	25 Nov 2020 22:13:05

US3342200

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(57)

Generated On: 09 Jun 2021 17:05:26

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:04:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2D2D1647-7C35-4DCA-ADA3-8E1DAA921DDC)', Time: '2020-11-25T16:13:03', User OID: 'PatientReportedOutcome (US3342200)', ODM File OID: 'f777e42b-cbf6-4057-a9af-a03a85b05bb2' User entered '25 Nov 2020 16:13'	System	25 Nov 2020 22:13:05
	System	25 Nov 2020 22:13:05

US3342200

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(57)

Generated On: 09 Jun 2021 17:05:26

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:04:20
User entered '25 Nov 2020 12:00'	System	23 Nov 2020 18:02:09

US3342200

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(57)

Generated On: 09 Jun 2021 17:05:26

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:04:20
User entered '26 Nov 2020 11:59'	System	23 Nov 2020 18:02:09

US3342200

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(58)

Generated On: 09 Jun 2021 17:05:26

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:04:20
Data entry locked.	System	24 Nov 2020 19:10:04
User entered 'Day 58'	System	24 Nov 2020 19:10:04

US3342200

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(58)

Generated On: 09 Jun 2021 17:05:26

Select one response below to indicate the intensity of your **JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:04:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2D2D1647-7C35-4DCA-ADA3-8E1DAA921DDC)', Time: '2020-11-26T12:17:02', User OID: 'PatientReportedOutcome (US3342200)', ODM File OID: '7f5d4c1c-a91f-4d1c-a634-16cc5c86d1f8' User entered 'Some interference with activity (2)'	System	26 Nov 2020 18:17:07
	System	26 Nov 2020 18:17:07

US3342200

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(58)

Generated On: 09 Jun 2021 17:05:26

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:04:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2D2D1647-7C35-4DCA-ADA3-8E1DAA921DDC)', Time: '2020-11-26T12:17:05', User OID: 'PatientReportedOutcome (US3342200)', ODM File OID: '7f5d4c1c-a91f-4d1c-a634-16cc5c86d1f8' User entered '26 Nov 2020 12:17'	System	26 Nov 2020 18:17:07
	System	26 Nov 2020 18:17:07

US3342200

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(58)

Generated On: 09 Jun 2021 17:05:26

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:04:20
User entered '26 Nov 2020 12:00'	System	24 Nov 2020 19:10:04

US3342200

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(58)

Generated On: 09 Jun 2021 17:05:26

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:04:20
User entered '27 Nov 2020 11:59'	System	24 Nov 2020 19:10:04

US3342200

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(59)

Generated On: 09 Jun 2021 17:05:26

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:04:20
Data entry locked.	System	25 Nov 2020 22:13:05
User entered 'Day 59'	System	25 Nov 2020 22:13:05

US3342200

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(59)

Generated On: 09 Jun 2021 17:05:26

Select one response below to indicate the intensity of your **JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:04:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2D2D1647-7C35-4DCA-ADA3-8E1DAA921DDC)', Time: '2020-11-27T12:04:45', User OID: 'PatientReportedOutcome (US3342200)', ODM File OID: '4e893d6f-6828-4c55-826b-65bc9e869e4a' User entered 'Some interference with activity (2)'	System	27 Nov 2020 18:04:52

US3342200

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(59)

Generated On: 09 Jun 2021 17:05:26

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:04:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2D2D1647-7C35-4DCA-ADA3-8E1DAA921DDC)', Time: '2020-11-27T12:04:47', User OID: 'PatientReportedOutcome (US3342200)', ODM File OID: '4e893d6f-6828-4c55-826b-65bc9e869e4a' User entered '27 Nov 2020 12:04'	System	27 Nov 2020 18:04:52
	System	27 Nov 2020 18:04:52

US3342200

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(59)

Generated On: 09 Jun 2021 17:05:26

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:04:20
User entered '27 Nov 2020 12:00'	System	25 Nov 2020 22:13:05

US3342200

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(59)

Generated On: 09 Jun 2021 17:05:26

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:04:20
User entered '28 Nov 2020 11:59'	System	25 Nov 2020 22:13:05

US3342200

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(60)

Generated On: 09 Jun 2021 17:05:26

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:04:20
Data entry locked.	System	26 Nov 2020 18:17:07
User entered 'Day 60'	System	26 Nov 2020 18:17:07

US3342200

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(60)

Generated On: 09 Jun 2021 17:05:26

Select one response below to indicate the intensity of your **JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:04:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2D2D1647-7C35-4DCA-ADA3-8E1DAA921DDC)', Time: '2020-11-28T13:17:25', User OID: 'PatientReportedOutcome (US3342200)', ODM File OID: '11aba61f-9c48-4d8c-91c4-a742fc28d825'	System	28 Nov 2020 19:17:32
User entered 'Some interference with activity (2)'	System	28 Nov 2020 19:17:32

US3342200

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(60)

Generated On: 09 Jun 2021 17:05:26

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:04:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2D2D1647-7C35-4DCA-ADA3-8E1DAA921DDC)', Time: '2020-11-28T13:17:29', User OID: 'PatientReportedOutcome (US3342200)', ODM File OID: '11aba61f-9c48-4d8c-91c4-a742fc28d825' User entered '28 Nov 2020 13:17'	System	28 Nov 2020 19:17:32
	System	28 Nov 2020 19:17:32

US3342200

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(60)

Generated On: 09 Jun 2021 17:05:26

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:04:20
User entered '28 Nov 2020 12:00'	System	26 Nov 2020 18:17:07

US3342200

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(60)

Generated On: 09 Jun 2021 17:05:26

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:04:20
User entered '29 Nov 2020 11:59'	System	26 Nov 2020 18:17:07

US3342200

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(61)

Generated On: 09 Jun 2021 17:05:26

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:04:20
Data entry locked.	System	27 Nov 2020 18:04:52
User entered 'Day 61'	System	27 Nov 2020 18:04:52

US3342200

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(61)

Generated On: 09 Jun 2021 17:05:26

Select one response below to indicate the intensity of your **JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:04:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2D2D1647-7C35-4DCA-ADA3-8E1DAA921DDC)', Time: '2020-11-29T12:13:44', User OID: 'PatientReportedOutcome (US3342200)', ODM File OID: '19db3db5-ae7a-4d08-aad6-e81c4661d4ab' User entered 'Some interference with activity (2)'	System	29 Nov 2020 18:13:51
	System	29 Nov 2020 18:13:51

US3342200

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(61)

Generated On: 09 Jun 2021 17:05:26

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:04:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2D2D1647-7C35-4DCA-ADA3-8E1DAA921DDC)', Time: '2020-11-29T12:13:48', User OID: 'PatientReportedOutcome (US3342200)', ODM File OID: '19db3db5-ae7a-4d08-aad6-e81c4661d4ab' User entered '29 Nov 2020 12:13'	System	29 Nov 2020 18:13:51
	System	29 Nov 2020 18:13:51

US3342200

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(61)

Generated On: 09 Jun 2021 17:05:26

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:04:20
User entered '29 Nov 2020 12:00'	System	27 Nov 2020 18:04:52

US3342200

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(61)

Generated On: 09 Jun 2021 17:05:26

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:04:20
User entered '30 Nov 2020 11:59'	System	27 Nov 2020 18:04:52

US3342200

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(62)

Generated On: 09 Jun 2021 17:05:26

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:04:20
Data entry locked.	System	28 Nov 2020 19:17:32
User entered 'Day 62'	System	28 Nov 2020 19:17:32

US3342200

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(62)

Generated On: 09 Jun 2021 17:05:26

Select one response below to indicate the intensity of your **JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:04:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2D2D1647-7C35-4DCA-ADA3-8E1DAA921DDC)', Time: '2020-11-30T13:17:21', User OID: 'PatientReportedOutcome (US3342200)', ODM File OID: '998d5292-81fd-461d-9e72-c64c89dae84f' User entered 'Some interference with activity (2)'	System	30 Nov 2020 19:17:27
	System	30 Nov 2020 19:17:27

US3342200

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(62)

Generated On: 09 Jun 2021 17:05:26

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:04:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2D2D1647-7C35-4DCA-ADA3-8E1DAA921DDC)', Time: '2020-11-30T13:17:24', User OID: 'PatientReportedOutcome (US3342200)', ODM File OID: '998d5292-81fd-461d-9e72-c64c89dae84f' User entered '30 Nov 2020 13:17'	System	30 Nov 2020 19:17:27
	System	30 Nov 2020 19:17:27

US3342200

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(62)

Generated On: 09 Jun 2021 17:05:26

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:04:20
User entered '30 Nov 2020 12:00'	System	28 Nov 2020 19:17:32

US3342200

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(62)

Generated On: 09 Jun 2021 17:05:26

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:04:20
User entered '01 Dec 2020 11:59'	System	28 Nov 2020 19:17:32

US3342200

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(63)

Generated On: 09 Jun 2021 17:05:26

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:04:20
Data entry locked.	System	29 Nov 2020 18:13:51
User entered 'Day 63'	System	29 Nov 2020 18:13:51

US3342200

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(63)

Generated On: 09 Jun 2021 17:05:26

Select one response below to indicate the intensity of your **JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:04:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2D2D1647-7C35-4DCA-ADA3-8E1DAA921DDC)', Time: '2020-12-02T04:51:31', User OID: 'PatientReportedOutcome (US3342200)', ODM File OID: '430c51d8-f91c-417e-b546-bf7ce6a3b068' User entered 'Some interference with activity (2)'	System	02 Dec 2020 10:51:38
	System	02 Dec 2020 10:51:38

US3342200

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(63)

Generated On: 09 Jun 2021 17:05:26

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:04:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2D2D1647-7C35-4DCA-ADA3-8E1DAA921DDC)', Time: '2020-12-02T04:51:35', User OID: 'PatientReportedOutcome (US3342200)', ODM File OID: '430c51d8-f91c-417e-b546-bf7ce6a3b068' User entered '02 Dec 2020 04:51'	System	02 Dec 2020 10:51:38
	System	02 Dec 2020 10:51:38

US3342200

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(63)

Generated On: 09 Jun 2021 17:05:26

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:04:20
User entered '01 Dec 2020 12:00'	System	29 Nov 2020 18:13:51

US3342200

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(63)

Generated On: 09 Jun 2021 17:05:26

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:04:20
User entered '02 Dec 2020 11:59'	System	29 Nov 2020 18:13:51

US3342200

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(64)

Generated On: 09 Jun 2021 17:05:26

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:04:20
Data entry locked.	System	30 Nov 2020 19:17:27
User entered 'Day 64'	System	30 Nov 2020 19:17:27

US3342200

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(64)

Generated On: 09 Jun 2021 17:05:26

Select one response below to indicate the intensity of your **JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:04:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2D2D1647-7C35-4DCA-ADA3-8E1DAA921DDC)', Time: '2020-12-02T12:00:52', User OID: 'PatientReportedOutcome (US3342200)', ODM File OID: '3fc39e7a-29c6-4e20-bdb5-cddd09806eb7'	System	02 Dec 2020 18:00:57
User entered 'Some interference with activity (2)'	System	02 Dec 2020 18:00:57

US3342200

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(64)

Generated On: 09 Jun 2021 17:05:26

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:04:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2D2D1647-7C35-4DCA-ADA3-8E1DAA921DDC)', Time: '2020-12-02T12:00:54', User OID: 'PatientReportedOutcome (US3342200)', ODM File OID: '3fc39e7a-29c6-4e20-bdb5-cddd09806eb7' User entered '02 Dec 2020 12:00'	System	02 Dec 2020 18:00:57
	System	02 Dec 2020 18:00:57

US3342200

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(64)

Generated On: 09 Jun 2021 17:05:26

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:04:20
User entered '02 Dec 2020 12:00'	System	30 Nov 2020 19:17:27

US3342200

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(64)

Generated On: 09 Jun 2021 17:05:26

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:04:20
User entered '03 Dec 2020 11:59'	System	30 Nov 2020 19:17:27

US3342200

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(65)

Generated On: 09 Jun 2021 17:05:26

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:04:20
Data entry locked.	System	02 Dec 2020 10:51:38
User entered 'Day 65'	System	02 Dec 2020 10:51:38

US3342200

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(65)

Generated On: 09 Jun 2021 17:05:26

Select one response below to indicate the intensity of your **JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:04:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2D2D1647-7C35-4DCA-ADA3-8E1DAA921DDC)', Time: '2020-12-03T13:03:19', User OID: 'PatientReportedOutcome (US3342200)', ODM File OID: '1dc1670b-63ea-4a8c-95ec-1386aba3a244'	System	03 Dec 2020 19:03:26
User entered 'Some interference with activity (2)'	System	03 Dec 2020 19:03:26

US3342200

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(65)

Generated On: 09 Jun 2021 17:05:26

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:04:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2D2D1647-7C35-4DCA-ADA3-8E1DAA921DDC)', Time: '2020-12-03T13:03:21', User OID: 'PatientReportedOutcome (US3342200)', ODM File OID: '1dc1670b-63ea-4a8c-95ec-1386aba3a244' User entered '03 Dec 2020 13:03'	System	03 Dec 2020 19:03:26
	System	03 Dec 2020 19:03:26

US3342200

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(65)

Generated On: 09 Jun 2021 17:05:26

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:04:20
User entered '03 Dec 2020 12:00'	System	02 Dec 2020 10:51:38

US3342200

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(65)

Generated On: 09 Jun 2021 17:05:26

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:04:20
User entered '04 Dec 2020 11:59'	System	02 Dec 2020 10:51:38

US3342200

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(66)

Generated On: 09 Jun 2021 17:05:26

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:04:20
Data entry locked.	System	02 Dec 2020 18:00:57
User entered 'Day 66'	System	02 Dec 2020 18:00:57

US3342200

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(66)

Generated On: 09 Jun 2021 17:05:26

Select one response below to indicate the intensity of your **JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:04:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2D2D1647-7C35-4DCA-ADA3-8E1DAA921DDC)', Time: '2020-12-04T12:00:20', User OID: 'PatientReportedOutcome (US3342200)', ODM File OID: '2a069e39-0729-4115-8daa-de756b058946'	System	04 Dec 2020 18:00:34
User entered 'Some interference with activity (2)'	System	04 Dec 2020 18:00:34

US3342200

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(66)

Generated On: 09 Jun 2021 17:05:26

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:04:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2D2D1647-7C35-4DCA-ADA3-8E1DAA921DDC)', Time: '2020-12-04T12:00:25', User OID: 'PatientReportedOutcome (US3342200)', ODM File OID: '2a069e39-0729-4115-8daa-de756b058946' User entered '04 Dec 2020 12:00'	System	04 Dec 2020 18:00:34
	System	04 Dec 2020 18:00:34

US3342200

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(66)

Generated On: 09 Jun 2021 17:05:26

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:04:20
User entered '04 Dec 2020 12:00'	System	02 Dec 2020 18:00:57

US3342200

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(66)

Generated On: 09 Jun 2021 17:05:26

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:04:20
User entered '05 Dec 2020 11:59'	System	02 Dec 2020 18:00:57

US3342200

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(67)

Generated On: 09 Jun 2021 17:05:26

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:04:20
Data entry locked.	System	03 Dec 2020 19:03:26
User entered 'Day 67'	System	03 Dec 2020 19:03:26

US3342200

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(67)

Generated On: 09 Jun 2021 17:05:26

Select one response below to indicate the intensity of your **JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:04:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2D2D1647-7C35-4DCA-ADA3-8E1DAA921DDC)', Time: '2020-12-05T19:56:14', User OID: 'PatientReportedOutcome (US3342200)', ODM File OID: '8610a726-7738-4053-9786-20050a132914' User entered 'Some interference with activity (2)'	System	06 Dec 2020 01:56:19
	System	06 Dec 2020 01:56:19

US3342200

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(67)

Generated On: 09 Jun 2021 17:05:26

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:04:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2D2D1647-7C35-4DCA-ADA3-8E1DAA921DDC)', Time: '2020-12-05T19:56:16', User OID: 'PatientReportedOutcome (US3342200)', ODM File OID: '8610a726-7738-4053-9786-20050a132914' User entered '05 Dec 2020 19:56'	System	06 Dec 2020 01:56:19
	System	06 Dec 2020 01:56:19

US3342200

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(67)

Generated On: 09 Jun 2021 17:05:26

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:04:20
User entered '05 Dec 2020 12:00'	System	03 Dec 2020 19:03:26

US3342200

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(67)

Generated On: 09 Jun 2021 17:05:26

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:04:20
User entered '06 Dec 2020 11:59'	System	03 Dec 2020 19:03:26

US3342200

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(68)

Generated On: 09 Jun 2021 17:05:26

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:04:20
Data entry locked.	System	04 Dec 2020 18:00:34
User entered 'Day 68'	System	04 Dec 2020 18:00:34

US3342200

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(68)

Generated On: 09 Jun 2021 17:05:26

Select one response below to indicate the intensity of your **JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:04:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2D2D1647-7C35-4DCA-ADA3-8E1DAA921DDC)', Time: '2020-12-06T12:50:11', User OID: 'PatientReportedOutcome (US3342200)', ODM File OID: '57c0d0a7-e82c-4390-8027-354577870a26'	System	06 Dec 2020 18:50:15
User entered 'Some interference with activity (2)'	System	06 Dec 2020 18:50:15

US3342200

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(68)

Generated On: 09 Jun 2021 17:05:26

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:04:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2D2D1647-7C35-4DCA-ADA3-8E1DAA921DDC)', Time: '2020-12-06T12:50:14', User OID: 'PatientReportedOutcome (US3342200)', ODM File OID: '57c0d0a7-e82c-4390-8027-354577870a26' User entered '06 Dec 2020 12:50'	System	06 Dec 2020 18:50:15
	System	06 Dec 2020 18:50:15

US3342200

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(68)

Generated On: 09 Jun 2021 17:05:26

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:04:20
User entered '06 Dec 2020 12:00'	System	04 Dec 2020 18:00:34

US3342200

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(68)

Generated On: 09 Jun 2021 17:05:26

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:04:20
User entered '07 Dec 2020 11:59'	System	04 Dec 2020 18:00:34

US3342200

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(69)

Generated On: 09 Jun 2021 17:05:26

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:04:20
Data entry locked.	System	06 Dec 2020 01:56:19
User entered 'Day 69'	System	06 Dec 2020 01:56:19

US3342200

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(69)

Generated On: 09 Jun 2021 17:05:26

Select one response below to indicate the intensity of your **JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:04:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2D2D1647-7C35-4DCA-ADA3-8E1DAA921DDC)', Time: '2020-12-07T12:07:02', User OID: 'PatientReportedOutcome (US3342200)', ODM File OID: 'd96b1522-31f4-4935-9b24-ebb3841d9'	System	07 Dec 2020 18:07:09
User entered 'Some interference with activity (2)'	System	07 Dec 2020 18:07:09

US3342200

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(69)

Generated On: 09 Jun 2021 17:05:26

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:04:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2D2D1647-7C35-4DCA-ADA3-8E1DAA921DDC)', Time: '2020-12-07T12:07:04', User OID: 'PatientReportedOutcome (US3342200)', ODM File OID: 'd96b1522-31f4-4935-9b24-ebbebe3841d9' User entered '07 Dec 2020 12:07'	System	07 Dec 2020 18:07:09
	System	07 Dec 2020 18:07:09

US3342200

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(69)

Generated On: 09 Jun 2021 17:05:26

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:04:20
User entered '07 Dec 2020 12:00'	System	06 Dec 2020 01:56:19

US3342200

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(69)

Generated On: 09 Jun 2021 17:05:26

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:04:20
User entered '08 Dec 2020 11:59'	System	06 Dec 2020 01:56:19

US3342200

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(70)

Generated On: 09 Jun 2021 17:05:26

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:04:20
Data entry locked.	System	06 Dec 2020 18:50:15
User entered 'Day 70'	System	06 Dec 2020 18:50:15

US3342200

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(70)

Generated On: 09 Jun 2021 17:05:26

Select one response below to indicate the intensity of your **JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:04:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2D2D1647-7C35-4DCA-ADA3-8E1DAA921DDC)', Time: '2020-12-08T13:05:34', User OID: 'PatientReportedOutcome (US3342200)', ODM File OID: '1fab6b95-b910-40b8-b6b1-d7923a80b2ad' User entered 'Some interference with activity (2)'	System	08 Dec 2020 19:05:39
	System	08 Dec 2020 19:05:39

US3342200

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(70)

Generated On: 09 Jun 2021 17:05:26

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:04:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2D2D1647-7C35-4DCA-ADA3-8E1DAA921DDC)', Time: '2020-12-08T13:05:36', User OID: 'PatientReportedOutcome (US3342200)', ODM File OID: '1fab6b95-b910-40b8-b6b1-d7923a80b2ad' User entered '08 Dec 2020 13:05'	System	08 Dec 2020 19:05:39
	System	08 Dec 2020 19:05:39

US3342200

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(70)

Generated On: 09 Jun 2021 17:05:26

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:04:20
User entered '08 Dec 2020 12:00'	System	06 Dec 2020 18:50:15

US3342200

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(70)

Generated On: 09 Jun 2021 17:05:26

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:04:20
User entered '09 Dec 2020 11:59'	System	06 Dec 2020 18:50:15

US3342200

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(71)

Generated On: 09 Jun 2021 17:05:26

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:04:20
Data entry locked.	System	07 Dec 2020 18:07:09
User entered 'Day 71'	System	07 Dec 2020 18:07:09

US3342200

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(71)

Generated On: 09 Jun 2021 17:05:26

Select one response below to indicate the intensity of your **JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:04:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2D2D1647-7C35-4DCA-ADA3-8E1DAA921DDC)', Time: '2020-12-09T13:54:29', User OID: 'PatientReportedOutcome (US3342200)', ODM File OID: 'f87d1195-15c0-4f44-9b5d-4476eb51d3f6'	System	09 Dec 2020 19:54:37
User entered 'No interference with activity (1)'	System	09 Dec 2020 19:54:37

US3342200

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(71)

Generated On: 09 Jun 2021 17:05:26

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:04:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2D2D1647-7C35-4DCA-ADA3-8E1DAA921DDC)', Time: '2020-12-09T13:54:32', User OID: 'PatientReportedOutcome (US3342200)', ODM File OID: 'f87d1195-15c0-4f44-9b5d-4476eb51d3f6' User entered '09 Dec 2020 13:54'	System	09 Dec 2020 19:54:37
	System	09 Dec 2020 19:54:37

US3342200

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(71)

Generated On: 09 Jun 2021 17:05:26

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:04:20
User entered '09 Dec 2020 12:00'	System	07 Dec 2020 18:07:09

US3342200

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(71)

Generated On: 09 Jun 2021 17:05:26

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:04:20
User entered '10 Dec 2020 11:59'	System	07 Dec 2020 18:07:09

US3342200

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(72)

Generated On: 09 Jun 2021 17:05:26

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:04:20
Data entry locked.	System	08 Dec 2020 19:05:39
User entered 'Day 72'	System	08 Dec 2020 19:05:39

US3342200

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(72)

Generated On: 09 Jun 2021 17:05:26

Select one response below to indicate the intensity of your **JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:04:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2D2D1647-7C35-4DCA-ADA3-8E1DAA921DDC)', Time: '2020-12-10T12:39:01', User OID: 'PatientReportedOutcome (US3342200)', ODM File OID: '8948eea5-e284-4839-a4de-c77850627b04' User entered 'Some interference with activity (2)'	System	10 Dec 2020 18:39:09
	System	10 Dec 2020 18:39:09

US3342200

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(72)

Generated On: 09 Jun 2021 17:05:26

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:04:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2D2D1647-7C35-4DCA-ADA3-8E1DAA921DDC)', Time: '2020-12-10T12:39:04', User OID: 'PatientReportedOutcome (US3342200)', ODM File OID: '8948eea5-e284-4839-a4de-c77850627b04' User entered '10 Dec 2020 12:39'	System	10 Dec 2020 18:39:09
	System	10 Dec 2020 18:39:09

US3342200

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(72)

Generated On: 09 Jun 2021 17:05:26

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:04:20
User entered '10 Dec 2020 12:00'	System	08 Dec 2020 19:05:39

US3342200

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(72)

Generated On: 09 Jun 2021 17:05:26

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:04:20
User entered '11 Dec 2020 11:59'	System	08 Dec 2020 19:05:39

US3342200

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(73)

Generated On: 09 Jun 2021 17:05:26

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:04:20
Data entry locked.	System	09 Dec 2020 19:54:37
User entered 'Day 73'	System	09 Dec 2020 19:54:37

US3342200

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(73)

Generated On: 09 Jun 2021 17:05:26

Select one response below to indicate the intensity of your **JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:04:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2D2D1647-7C35-4DCA-ADA3-8E1DAA921DDC)', Time: '2020-12-11T12:19:01', User OID: 'PatientReportedOutcome (US3342200)', ODM File OID: '87f19f01-b496-4d8a-86e1-6f45089e48de' User entered 'Some interference with activity (2)'	System	11 Dec 2020 18:19:07
	System	11 Dec 2020 18:19:07

US3342200

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(73)

Generated On: 09 Jun 2021 17:05:26

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:04:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2D2D1647-7C35-4DCA-ADA3-8E1DAA921DDC)', Time: '2020-12-11T12:19:04', User OID: 'PatientReportedOutcome (US3342200)', ODM File OID: '87f19f01-b496-4d8a-86e1-6f45089e48de' User entered '11 Dec 2020 12:19'	System	11 Dec 2020 18:19:07
	System	11 Dec 2020 18:19:07

US3342200

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(73)

Generated On: 09 Jun 2021 17:05:26

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:04:20
User entered '11 Dec 2020 12:00'	System	09 Dec 2020 19:54:37

US3342200

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(73)

Generated On: 09 Jun 2021 17:05:26

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:04:20
User entered '12 Dec 2020 11:59'	System	09 Dec 2020 19:54:37

US3342200

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(74)

Generated On: 09 Jun 2021 17:05:26

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:04:20
Data entry locked.	System	10 Dec 2020 18:39:09
User entered 'Day 74'	System	10 Dec 2020 18:39:09

US3342200

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(74)

Generated On: 09 Jun 2021 17:05:26

Select one response below to indicate the intensity of your **JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:04:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2D2D1647-7C35-4DCA-ADA3-8E1DAA921DDC)', Time: '2020-12-13T00:06:00', User OID: 'PatientReportedOutcome (US3342200)', ODM File OID: 'e0246854-6be7-41ff-9084-c4e23a36d45a' User entered 'Some interference with activity (2)'	System	13 Dec 2020 06:06:11
	System	13 Dec 2020 06:06:11

US3342200

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(74)

Generated On: 09 Jun 2021 17:05:26

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:04:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2D2D1647-7C35-4DCA-ADA3-8E1DAA921DDC)', Time: '2020-12-13T00:06:07', User OID: 'PatientReportedOutcome (US3342200)', ODM File OID: 'e0246854-6be7-41ff-9084-c4e23a36d45a' User entered '13 Dec 2020 00:06'	System	13 Dec 2020 06:06:11
	System	13 Dec 2020 06:06:11

US3342200

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(74)

Generated On: 09 Jun 2021 17:05:26

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:04:20
User entered '12 Dec 2020 12:00'	System	10 Dec 2020 18:39:09

US3342200

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(74)

Generated On: 09 Jun 2021 17:05:26

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:04:20
User entered '13 Dec 2020 11:59'	System	10 Dec 2020 18:39:09

US3342200

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(75)

Generated On: 09 Jun 2021 17:05:26

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:04:20
Data entry locked.	System	11 Dec 2020 18:19:07
User entered 'Day 75'	System	11 Dec 2020 18:19:07

US3342200

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(75)

Generated On: 09 Jun 2021 17:05:26

Select one response below to indicate the intensity of your **JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:04:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2D2D1647-7C35-4DCA-ADA3-8E1DAA921DDC)', Time: '2020-12-14T03:28:45', User OID: 'PatientReportedOutcome (US3342200)', ODM File OID: 'ea00114f-6535-43fe-8dbb-c4345c487369' User entered 'Some interference with activity (2)'	System	14 Dec 2020 09:28:52
	System	14 Dec 2020 09:28:52

US3342200

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(75)

Generated On: 09 Jun 2021 17:05:26

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:04:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2D2D1647-7C35-4DCA-ADA3-8E1DAA921DDC)', Time: '2020-12-14T03:28:48', User OID: 'PatientReportedOutcome (US3342200)', ODM File OID: 'ea00114f-6535-43fe-8dbb-c4345c487369' User entered '14 Dec 2020 03:28'	System	14 Dec 2020 09:28:52
	System	14 Dec 2020 09:28:52

US3342200

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(75)

Generated On: 09 Jun 2021 17:05:26

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:04:20
User entered '13 Dec 2020 12:00'	System	11 Dec 2020 18:19:07

US3342200

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(75)

Generated On: 09 Jun 2021 17:05:26

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:04:20
User entered '14 Dec 2020 11:59'	System	11 Dec 2020 18:19:07

US3342200

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(76)

Generated On: 09 Jun 2021 17:05:26

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:04:20
Data entry locked.	System	13 Dec 2020 06:06:11
User entered 'Day 76'	System	13 Dec 2020 06:06:11

US3342200

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(76)

Generated On: 09 Jun 2021 17:05:26

Select one response below to indicate the intensity of your **JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:04:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2D2D1647-7C35-4DCA-ADA3-8E1DAA921DDC)', Time: '2020-12-14T13:29:50', User OID: 'PatientReportedOutcome (US3342200)', ODM File OID: '71343d9e-6c67-4948-b5ef-f889a80f15e9'	System	14 Dec 2020 19:29:56
User entered 'Some interference with activity (2)'	System	14 Dec 2020 19:29:56

US3342200

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(76)

Generated On: 09 Jun 2021 17:05:26

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:04:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2D2D1647-7C35-4DCA-ADA3-8E1DAA921DDC)', Time: '2020-12-14T13:29:52', User OID: 'PatientReportedOutcome (US3342200)', ODM File OID: '71343d9e-6c67-4948-b5ef-f889a80f15e9' User entered '14 Dec 2020 13:29'	System	14 Dec 2020 19:29:56
	System	14 Dec 2020 19:29:56

US3342200

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(76)

Generated On: 09 Jun 2021 17:05:26

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:04:20
User entered '14 Dec 2020 12:00'	System	13 Dec 2020 06:06:11

US3342200

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(76)

Generated On: 09 Jun 2021 17:05:26

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:04:20
User entered '15 Dec 2020 11:59'	System	13 Dec 2020 06:06:11

US3342200

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(77)

Generated On: 09 Jun 2021 17:05:26

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:04:20
Data entry locked.	System	14 Dec 2020 09:28:52
User entered 'Day 77'	System	14 Dec 2020 09:28:52

US3342200

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(77)

Generated On: 09 Jun 2021 17:05:26

Select one response below to indicate the intensity of your **JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:04:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2D2D1647-7C35-4DCA-ADA3-8E1DAA921DDC)', Time: '2020-12-15T15:07:10', User OID: 'PatientReportedOutcome (US3342200)', ODM File OID: 'd5c7d751-9260-4d0e-8b22-167c3167a10c' User entered 'Some interference with activity (2)'	System	15 Dec 2020 21:07:17
	System	15 Dec 2020 21:07:17

US3342200

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(77)

Generated On: 09 Jun 2021 17:05:26

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:04:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2D2D1647-7C35-4DCA-ADA3-8E1DAA921DDC)', Time: '2020-12-15T15:07:13', User OID: 'PatientReportedOutcome (US3342200)', ODM File OID: 'd5c7d751-9260-4d0e-8b22-167c3167a10c' User entered '15 Dec 2020 15:07'	System	15 Dec 2020 21:07:17
	System	15 Dec 2020 21:07:17

US3342200

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(77)

Generated On: 09 Jun 2021 17:05:26

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:04:20
User entered '15 Dec 2020 12:00'	System	14 Dec 2020 09:28:52

US3342200

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(77)

Generated On: 09 Jun 2021 17:05:26

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:04:20
User entered '16 Dec 2020 11:59'	System	14 Dec 2020 09:28:52

US3342200

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(78)

Generated On: 09 Jun 2021 17:05:26

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:04:20
Data entry locked.	System	14 Dec 2020 19:29:56
User entered 'Day 78'	System	14 Dec 2020 19:29:56

US3342200

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(78)

Generated On: 09 Jun 2021 17:05:26

Select one response below to indicate the intensity of your **JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:04:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2D2D1647-7C35-4DCA-ADA3-8E1DAA921DDC)', Time: '2020-12-16T15:44:13', User OID: 'PatientReportedOutcome (US3342200)', ODM File OID: '487a1abc-b7e4-4efd-8f21-930cf19f7db0' User entered 'Some interference with activity (2)'	System	16 Dec 2020 21:44:20
	System	16 Dec 2020 21:44:20

US3342200

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(78)

Generated On: 09 Jun 2021 17:05:26

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:04:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2D2D1647-7C35-4DCA-ADA3-8E1DAA921DDC)', Time: '2020-12-16T15:44:17', User OID: 'PatientReportedOutcome (US3342200)', ODM File OID: '487a1abc-b7e4-4efd-8f21-930cf19f7db0' User entered '16 Dec 2020 15:44'	System	16 Dec 2020 21:44:20
	System	16 Dec 2020 21:44:20

US3342200

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(78)

Generated On: 09 Jun 2021 17:05:26

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:04:20
User entered '16 Dec 2020 12:00'	System	14 Dec 2020 19:29:56

US3342200

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(78)

Generated On: 09 Jun 2021 17:05:26

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:04:20
User entered '17 Dec 2020 11:59'	System	14 Dec 2020 19:29:56

US3342200

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(79)

Generated On: 09 Jun 2021 17:05:26

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:04:20
Data entry locked.	System	15 Dec 2020 21:07:17
User entered 'Day 79'	System	15 Dec 2020 21:07:17

US3342200

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(79)

Generated On: 09 Jun 2021 17:05:26

Select one response below to indicate the intensity of your **JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:04:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2D2D1647-7C35-4DCA-ADA3-8E1DAA921DDC)', Time: '2020-12-17T12:39:40', User OID: 'PatientReportedOutcome (US3342200)', ODM File OID: 'c134464f-4844-4855-80eb-a63ed01e190b' User entered 'Some interference with activity (2)'	System	17 Dec 2020 18:39:48
	System	17 Dec 2020 18:39:48

US3342200

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(79)

Generated On: 09 Jun 2021 17:05:26

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:04:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2D2D1647-7C35-4DCA-ADA3-8E1DAA921DDC)', Time: '2020-12-17T12:39:44', User OID: 'PatientReportedOutcome (US3342200)', ODM File OID: 'c134464f-4844-4855-80eb-a63ed01e190b' User entered '17 Dec 2020 12:39'	System	17 Dec 2020 18:39:48
	System	17 Dec 2020 18:39:48

US3342200

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(79)

Generated On: 09 Jun 2021 17:05:26

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:04:20
User entered '17 Dec 2020 12:00'	System	15 Dec 2020 21:07:17

US3342200

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(79)

Generated On: 09 Jun 2021 17:05:26

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:04:20
User entered '18 Dec 2020 11:59'	System	15 Dec 2020 21:07:17

US3342200

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(80)

Generated On: 09 Jun 2021 17:05:26

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:04:20
Data entry locked.	System	16 Dec 2020 21:44:20
User entered 'Day 80'	System	16 Dec 2020 21:44:20

US3342200

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(80)

Generated On: 09 Jun 2021 17:05:26

Select one response below to indicate the intensity of your **JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:04:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2D2D1647-7C35-4DCA-ADA3-8E1DAA921DDC)', Time: '2020-12-18T12:21:33', User OID: 'PatientReportedOutcome (US3342200)', ODM File OID: 'a600243b-0fdf-4404-8e17-a0b297909552'	System	18 Dec 2020 18:21:41
User entered 'Some interference with activity (2)'	System	18 Dec 2020 18:21:41

US3342200

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(80)

Generated On: 09 Jun 2021 17:05:26

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:04:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2D2D1647-7C35-4DCA-ADA3-8E1DAA921DDC)', Time: '2020-12-18T12:21:38', User OID: 'PatientReportedOutcome (US3342200)', ODM File OID: 'a600243b-0fdf-4404-8e17-a0b297909552' User entered '18 Dec 2020 12:21'	System	18 Dec 2020 18:21:41
	System	18 Dec 2020 18:21:41

US3342200

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(80)

Generated On: 09 Jun 2021 17:05:26

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:04:20
User entered '18 Dec 2020 12:00'	System	16 Dec 2020 21:44:20

US3342200

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(80)

Generated On: 09 Jun 2021 17:05:26

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:04:20
User entered '19 Dec 2020 11:59'	System	16 Dec 2020 21:44:20

US3342200

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(81)

Generated On: 09 Jun 2021 17:05:26

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:04:20
Data entry locked.	System	17 Dec 2020 18:39:48
User entered 'Day 81'	System	17 Dec 2020 18:39:48

US3342200

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(81)

Generated On: 09 Jun 2021 17:05:26

Select one response below to indicate the intensity of your **JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:04:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2D2D1647-7C35-4DCA-ADA3-8E1DAA921DDC)', Time: '2020-12-19T15:04:36', User OID: 'PatientReportedOutcome (US3342200)', ODM File OID: 'f35b730b-b57a-41be-b767-cf1c3a936e8d' User entered 'Some interference with activity (2)'	System	19 Dec 2020 21:04:41
	System	19 Dec 2020 21:04:41

US3342200

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(81)

Generated On: 09 Jun 2021 17:05:26

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:04:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2D2D1647-7C35-4DCA-ADA3-8E1DAA921DDC)', Time: '2020-12-19T15:04:38', User OID: 'PatientReportedOutcome (US3342200)', ODM File OID: 'f35b730b-b57a-41be-b767-cf1c3a936e8d' User entered '19 Dec 2020 15:04'	System	19 Dec 2020 21:04:41
	System	19 Dec 2020 21:04:41

US3342200

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(81)

Generated On: 09 Jun 2021 17:05:26

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:04:20
User entered '19 Dec 2020 12:00'	System	17 Dec 2020 18:39:48

US3342200

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(81)

Generated On: 09 Jun 2021 17:05:26

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:04:20
User entered '20 Dec 2020 11:59'	System	17 Dec 2020 18:39:48

US3342200

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(82)

Generated On: 09 Jun 2021 17:05:26

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:04:20
Data entry locked.	System	18 Dec 2020 18:21:41
User entered 'Day 82'	System	18 Dec 2020 18:21:41

US3342200

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(82)

Generated On: 09 Jun 2021 17:05:26

Select one response below to indicate the intensity of your **JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:04:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2D2D1647-7C35-4DCA-ADA3-8E1DAA921DDC)', Time: '2020-12-20T12:00:12', User OID: 'PatientReportedOutcome (US3342200)', ODM File OID: '9e6b542f-85f4-443f-a981-04272fce810b' User entered 'Some interference with activity (2)'	System	20 Dec 2020 18:00:21
	System	20 Dec 2020 18:00:21

US3342200

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(82)

Generated On: 09 Jun 2021 17:05:26

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:04:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2D2D1647-7C35-4DCA-ADA3-8E1DAA921DDC)', Time: '2020-12-20T12:00:15', User OID: 'PatientReportedOutcome (US3342200)', ODM File OID: '9e6b542f-85f4-443f-a981-04272fce810b' User entered '20 Dec 2020 12:00'	System	20 Dec 2020 18:00:21
	System	20 Dec 2020 18:00:21

US3342200

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(82)

Generated On: 09 Jun 2021 17:05:26

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:04:20
User entered '20 Dec 2020 12:00'	System	18 Dec 2020 18:21:41

US3342200

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(82)

Generated On: 09 Jun 2021 17:05:26

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:04:20
User entered '21 Dec 2020 11:59'	System	18 Dec 2020 18:21:41

US3342200

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(83)

Generated On: 09 Jun 2021 17:05:26

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:04:20
Data entry locked.	System	19 Dec 2020 21:04:41
User entered 'Day 83'	System	19 Dec 2020 21:04:41

US3342200

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(83)

Generated On: 09 Jun 2021 17:05:26

Select one response below to indicate the intensity of your **JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:04:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2D2D1647-7C35-4DCA-ADA3-8E1DAA921DDC)', Time: '2020-12-21T17:43:49', User OID: 'PatientReportedOutcome (US3342200)', ODM File OID: 'f922ff6c-d173-42fb-955f-bf8bf92f5a4a' User entered 'Some interference with activity (2)'	System	21 Dec 2020 23:43:56
	System	21 Dec 2020 23:43:56

US3342200

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(83)

Generated On: 09 Jun 2021 17:05:26

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:04:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2D2D1647-7C35-4DCA-ADA3-8E1DAA921DDC)', Time: '2020-12-21T17:43:52', User OID: 'PatientReportedOutcome (US3342200)', ODM File OID: 'f922ff6c-d173-42fb-955f-bf8bf92f5a4a' User entered '21 Dec 2020 17:43'	System	21 Dec 2020 23:43:56
	System	21 Dec 2020 23:43:56

US3342200

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(83)

Generated On: 09 Jun 2021 17:05:26

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:04:20
User entered '21 Dec 2020 12:00'	System	19 Dec 2020 21:04:41

US3342200

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(83)

Generated On: 09 Jun 2021 17:05:26

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:04:20
User entered '22 Dec 2020 11:59'	System	19 Dec 2020 21:04:41

US3342200

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(84)

Generated On: 09 Jun 2021 17:05:26

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:04:20
Data entry locked.	System	20 Dec 2020 18:00:21
User entered 'Day 84'	System	20 Dec 2020 18:00:21

US3342200

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(84)

Generated On: 09 Jun 2021 17:05:26

Select one response below to indicate the intensity of your **JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:04:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2D2D1647-7C35-4DCA-ADA3-8E1DAA921DDC)', Time: '2020-12-22T13:31:55', User OID: 'PatientReportedOutcome (US3342200)', ODM File OID: 'ceff30a0-9a05-4690-8a8c-840977c7b872'	System	22 Dec 2020 19:32:01
User entered 'Some interference with activity (2)'	System	22 Dec 2020 19:32:01

US3342200

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(84)

Generated On: 09 Jun 2021 17:05:26

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:04:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2D2D1647-7C35-4DCA-ADA3-8E1DAA921DDC)', Time: '2020-12-22T13:31:58', User OID: 'PatientReportedOutcome (US3342200)', ODM File OID: 'ceff30a0-9a05-4690-8a8c-840977c7b872' User entered '22 Dec 2020 13:31'	System	22 Dec 2020 19:32:01
	System	22 Dec 2020 19:32:01

US3342200

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(84)

Generated On: 09 Jun 2021 17:05:26

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:04:20
User entered '22 Dec 2020 12:00'	System	20 Dec 2020 18:00:21

US3342200

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(84)

Generated On: 09 Jun 2021 17:05:26

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:04:20
User entered '23 Dec 2020 11:59'	System	20 Dec 2020 18:00:21

US3342200

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(85)

Generated On: 09 Jun 2021 17:05:26

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:04:20
Data entry locked.	System	21 Dec 2020 23:43:56
User entered 'Day 85'	System	21 Dec 2020 23:43:56

US3342200

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(85)

Generated On: 09 Jun 2021 17:05:26

Select one response below to indicate the intensity of your **JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:04:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2D2D1647-7C35-4DCA-ADA3-8E1DAA921DDC)', Time: '2020-12-23T19:04:14', User OID: 'PatientReportedOutcome (US3342200)', ODM File OID: '1a2467ee-2c3e-4b96-a656-c0766dd5ffab' User entered 'Some interference with activity (2)'	System	24 Dec 2020 01:04:23
	System	24 Dec 2020 01:04:23

US3342200

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(85)

Generated On: 09 Jun 2021 17:05:26

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:04:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2D2D1647-7C35-4DCA-ADA3-8E1DAA921DDC)', Time: '2020-12-23T19:04:17', User OID: 'PatientReportedOutcome (US3342200)', ODM File OID: '1a2467ee-2c3e-4b96-a656-c0766dd5ffab' User entered '23 Dec 2020 19:04'	System	24 Dec 2020 01:04:23
	System	24 Dec 2020 01:04:23

US3342200

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(85)

Generated On: 09 Jun 2021 17:05:26

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:04:20
User entered '23 Dec 2020 12:00'	System	21 Dec 2020 23:43:56

US3342200

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(85)

Generated On: 09 Jun 2021 17:05:26

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:04:20
User entered '24 Dec 2020 11:59'	System	21 Dec 2020 23:43:56

US3342200

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(86)

Generated On: 09 Jun 2021 17:05:26

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:04:20
Data entry locked.	System	22 Dec 2020 19:32:01
User entered 'Day 86'	System	22 Dec 2020 19:32:01

US3342200

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(86)

Generated On: 09 Jun 2021 17:05:26

Select one response below to indicate the intensity of your **JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:04:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2D2D1647-7C35-4DCA-ADA3-8E1DAA921DDC)', Time: '2020-12-24T19:14:00', User OID: 'PatientReportedOutcome (US3342200)', ODM File OID: '7b2f1840-5e46-46f8-9b6c-ee2695c80e90'	System	25 Dec 2020 01:14:07
User entered 'Some interference with activity (2)'	System	25 Dec 2020 01:14:07

US3342200

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(86)

Generated On: 09 Jun 2021 17:05:26

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:04:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2D2D1647-7C35-4DCA-ADA3-8E1DAA921DDC)', Time: '2020-12-24T19:14:04', User OID: 'PatientReportedOutcome (US3342200)', ODM File OID: '7b2f1840-5e46-46f8-9b6c-ee2695c80e90' User entered '24 Dec 2020 19:14'	System	25 Dec 2020 01:14:07
	System	25 Dec 2020 01:14:07

US3342200

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(86)

Generated On: 09 Jun 2021 17:05:26

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:04:20
User entered '24 Dec 2020 12:00'	System	22 Dec 2020 19:32:01

US3342200

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(86)

Generated On: 09 Jun 2021 17:05:26

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:04:20
User entered '25 Dec 2020 11:59'	System	22 Dec 2020 19:32:01

US3342200

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(87)

Generated On: 09 Jun 2021 17:05:26

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:04:20
Data entry locked.	System	24 Dec 2020 01:04:23
User entered 'Day 87'	System	24 Dec 2020 01:04:23

US3342200

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(87)

Generated On: 09 Jun 2021 17:05:26

Select one response below to indicate the intensity of your **JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:04:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2D2D1647-7C35-4DCA-ADA3-8E1DAA921DDC)', Time: '2020-12-25T12:18:01', User OID: 'PatientReportedOutcome (US3342200)', ODM File OID: '2f12f0fc-c658-4c96-ba28-279aa8d55694'	System	25 Dec 2020 18:18:07
User entered 'Some interference with activity (2)'	System	25 Dec 2020 18:18:07

US3342200

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(87)

Generated On: 09 Jun 2021 17:05:26

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:04:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2D2D1647-7C35-4DCA-ADA3-8E1DAA921DDC)', Time: '2020-12-25T12:18:05', User OID: 'PatientReportedOutcome (US3342200)', ODM File OID: '2f12f0fc-c658-4c96-ba28-279aa8d55694' User entered '25 Dec 2020 12:18'	System	25 Dec 2020 18:18:07
	System	25 Dec 2020 18:18:07

US3342200

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(87)

Generated On: 09 Jun 2021 17:05:26

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:04:20
User entered '25 Dec 2020 12:00'	System	24 Dec 2020 01:04:23

US3342200

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(87)

Generated On: 09 Jun 2021 17:05:26

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:04:20
User entered '26 Dec 2020 11:59'	System	24 Dec 2020 01:04:23

US3342200

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(88)

Generated On: 09 Jun 2021 17:05:26

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:04:20
Data entry locked.	System	25 Dec 2020 01:14:07
User entered 'Day 88'	System	25 Dec 2020 01:14:07

US3342200

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(88)

Generated On: 09 Jun 2021 17:05:26

Select one response below to indicate the intensity of your **JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:04:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2D2D1647-7C35-4DCA-ADA3-8E1DAA921DDC)', Time: '2020-12-26T12:45:52', User OID: 'PatientReportedOutcome (US3342200)', ODM File OID: '050ac727-7712-4530-88ba-d0bae9ab138a' User entered 'Some interference with activity (2)'	System	26 Dec 2020 18:45:57
	System	26 Dec 2020 18:45:57

US3342200

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(88)

Generated On: 09 Jun 2021 17:05:26

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:04:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2D2D1647-7C35-4DCA-ADA3-8E1DAA921DDC)', Time: '2020-12-26T12:45:54', User OID: 'PatientReportedOutcome (US3342200)', ODM File OID: '050ac727-7712-4530-88ba-d0bae9ab138a' User entered '26 Dec 2020 12:45'	System	26 Dec 2020 18:45:57
	System	26 Dec 2020 18:45:57

US3342200

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(88)

Generated On: 09 Jun 2021 17:05:26

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:04:20
User entered '26 Dec 2020 12:00'	System	25 Dec 2020 01:14:07

US3342200

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(88)

Generated On: 09 Jun 2021 17:05:26

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:04:20
User entered '27 Dec 2020 11:59'	System	25 Dec 2020 01:14:07

US3342200

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(89)

Generated On: 09 Jun 2021 17:05:26

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:04:20
Data entry locked.	System	25 Dec 2020 18:18:07
User entered 'Day 89'	System	25 Dec 2020 18:18:07

US3342200

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(89)

Generated On: 09 Jun 2021 17:05:26

Select one response below to indicate the intensity of your **JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:04:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2D2D1647-7C35-4DCA-ADA3-8E1DAA921DDC)', Time: '2020-12-27T12:00:22', User OID: 'PatientReportedOutcome (US3342200)', ODM File OID: '7459e052-5c9f-4242-b3a0-1703ddbca6d1' User entered 'Some interference with activity (2)'	System	27 Dec 2020 18:00:32
	System	27 Dec 2020 18:00:32

US3342200

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(89)

Generated On: 09 Jun 2021 17:05:26

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:04:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2D2D1647-7C35-4DCA-ADA3-8E1DAA921DDC)', Time: '2020-12-27T12:00:24', User OID: 'PatientReportedOutcome (US3342200)', ODM File OID: '7459e052-5c9f-4242-b3a0-1703ddbca6d1' User entered '27 Dec 2020 12:00'	System	27 Dec 2020 18:00:32
	System	27 Dec 2020 18:00:32

US3342200

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(89)

Generated On: 09 Jun 2021 17:05:26

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:04:20
User entered '27 Dec 2020 12:00'	System	25 Dec 2020 18:18:07

US3342200

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(89)

Generated On: 09 Jun 2021 17:05:26

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:04:20
User entered '28 Dec 2020 11:59'	System	25 Dec 2020 18:18:07

US3342200

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(90)

Generated On: 09 Jun 2021 17:05:26

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:04:20
Data entry locked.	System	26 Dec 2020 18:45:57
User entered 'Day 90'	System	26 Dec 2020 18:45:57

US3342200

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(90)

Generated On: 09 Jun 2021 17:05:26

Select one response below to indicate the intensity of your **JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:04:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2D2D1647-7C35-4DCA-ADA3-8E1DAA921DDC)', Time: '2020-12-29T03:14:57', User OID: 'PatientReportedOutcome (US3342200)', ODM File OID: 'b58c5eaf-dc10-43c2-b9ff-8b0ff289b8ea' User entered 'Some interference with activity (2)'	System	29 Dec 2020 09:15:03
	System	29 Dec 2020 09:15:03

US3342200

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(90)

Generated On: 09 Jun 2021 17:05:26

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:04:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2D2D1647-7C35-4DCA-ADA3-8E1DAA921DDC)', Time: '2020-12-29T03:15:00', User OID: 'PatientReportedOutcome (US3342200)', ODM File OID: 'b58c5eaf-dc10-43c2-b9ff-8b0ff289b8ea' User entered '29 Dec 2020 03:15'	System	29 Dec 2020 09:15:03
	System	29 Dec 2020 09:15:03

US3342200

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(90)

Generated On: 09 Jun 2021 17:05:26

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:04:20
User entered '28 Dec 2020 12:00'	System	26 Dec 2020 18:45:57

US3342200

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(90)

Generated On: 09 Jun 2021 17:05:26

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:04:20
User entered '29 Dec 2020 11:59'	System	26 Dec 2020 18:45:57

US3342200

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(91)

Generated On: 09 Jun 2021 17:05:26

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:04:20
Data entry locked.	System	27 Dec 2020 18:00:32
User entered 'Day 91'	System	27 Dec 2020 18:00:32

US3342200

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(91)

Generated On: 09 Jun 2021 17:05:26

Select one response below to indicate the intensity of your **JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:04:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2D2D1647-7C35-4DCA-ADA3-8E1DAA921DDC)', Time: '2020-12-29T16:08:05', User OID: 'PatientReportedOutcome (US3342200)', ODM File OID: '7a2ec185-ffb3-4794-87b0-d5f802f50ab7' User entered 'Some interference with activity (2)'	System	29 Dec 2020 22:08:23
	System	29 Dec 2020 22:08:23

US3342200

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(91)

Generated On: 09 Jun 2021 17:05:26

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:04:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2D2D1647-7C35-4DCA-ADA3-8E1DAA921DDC)', Time: '2020-12-29T16:08:08', User OID: 'PatientReportedOutcome (US3342200)', ODM File OID: '7a2ec185-ffb3-4794-87b0-d5f802f50ab7' User entered '29 Dec 2020 16:08'	System	29 Dec 2020 22:08:23
	System	29 Dec 2020 22:08:23

US3342200

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(91)

Generated On: 09 Jun 2021 17:05:26

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:04:20
User entered '29 Dec 2020 12:00'	System	27 Dec 2020 18:00:32

US3342200

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(91)

Generated On: 09 Jun 2021 17:05:26

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:04:20
User entered '30 Dec 2020 11:59'	System	27 Dec 2020 18:00:32

US3342200

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(92)

Generated On: 09 Jun 2021 17:05:26

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:04:20
Data entry locked.	System	29 Dec 2020 09:15:03
User entered 'Day 92'	System	29 Dec 2020 09:15:03

US3342200

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(92)

Generated On: 09 Jun 2021 17:05:26

Select one response below to indicate the intensity of your **JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:04:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2D2D1647-7C35-4DCA-ADA3-8E1DAA921DDC)', Time: '2020-12-30T12:34:11', User OID: 'PatientReportedOutcome (US3342200)', ODM File OID: '11e0e7eb-728f-4dd8-9ea6-4f934a172308'	System	30 Dec 2020 18:34:16
User entered 'Some interference with activity (2)'	System	30 Dec 2020 18:34:16

US3342200

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(92)

Generated On: 09 Jun 2021 17:05:26

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:04:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2D2D1647-7C35-4DCA-ADA3-8E1DAA921DDC)', Time: '2020-12-30T12:34:14', User OID: 'PatientReportedOutcome (US3342200)', ODM File OID: '11e0e7eb-728f-4dd8-9ea6-4f934a172308' User entered '30 Dec 2020 12:34'	System	30 Dec 2020 18:34:16
	System	30 Dec 2020 18:34:16

US3342200

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(92)

Generated On: 09 Jun 2021 17:05:26

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:04:20
User entered '30 Dec 2020 12:00'	System	29 Dec 2020 09:15:03

US3342200

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(92)

Generated On: 09 Jun 2021 17:05:26

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:04:20
User entered '31 Dec 2020 11:59'	System	29 Dec 2020 09:15:03

US3342200

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(93)

Generated On: 09 Jun 2021 17:05:26

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:04:20
Data entry locked.	System	29 Dec 2020 22:08:23
User entered 'Day 93'	System	29 Dec 2020 22:08:23

US3342200

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(93)

Generated On: 09 Jun 2021 17:05:26

Select one response below to indicate the intensity of your **JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:04:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2D2D1647-7C35-4DCA-ADA3-8E1DAA921DDC)', Time: '2020-12-31T19:26:36', User OID: 'PatientReportedOutcome (US3342200)', ODM File OID: 'c6a9dd06-ee82-41c5-91c5-0c9f94ea610e'	System	01 Jan 2021 01:26:45
User entered 'Some interference with activity (2)'	System	01 Jan 2021 01:26:45

US3342200

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(93)

Generated On: 09 Jun 2021 17:05:26

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:04:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2D2D1647-7C35-4DCA-ADA3-8E1DAA921DDC)', Time: '2020-12-31T19:26:41', User OID: 'PatientReportedOutcome (US3342200)', ODM File OID: 'c6a9dd06-ee82-41c5-91c5-0c9f94ea610e' User entered '31 Dec 2020 19:26'	System	01 Jan 2021 01:26:45
	System	01 Jan 2021 01:26:45

US3342200

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(93)

Generated On: 09 Jun 2021 17:05:26

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:04:20
User entered '31 Dec 2020 12:00'	System	29 Dec 2020 22:08:23

US3342200

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(93)

Generated On: 09 Jun 2021 17:05:26

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:04:20
User entered '01 Jan 2021 11:59'	System	29 Dec 2020 22:08:23

US3342200

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(94)

Generated On: 09 Jun 2021 17:05:26

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:04:20
Data entry locked.	System	30 Dec 2020 18:34:16
User entered 'Day 94'	System	30 Dec 2020 18:34:16

US3342200

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(94)

Generated On: 09 Jun 2021 17:05:26

Select one response below to indicate the intensity of your **JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:04:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2D2D1647-7C35-4DCA-ADA3-8E1DAA921DDC)', Time: '2021-01-01T21:03:36', User OID: 'PatientReportedOutcome (US3342200)', ODM File OID: '70050b72-dde2-4742-901b-3387735ec999'	System	02 Jan 2021 03:03:45
User entered 'Some interference with activity (2)'	System	02 Jan 2021 03:03:45

US3342200

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(94)

Generated On: 09 Jun 2021 17:05:26

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:04:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2D2D1647-7C35-4DCA-ADA3-8E1DAA921DDC)', Time: '2021-01-01T21:03:41', User OID: 'PatientReportedOutcome (US3342200)', ODM File OID: '70050b72-dde2-4742-901b-3387735ec999' User entered '01 Jan 2021 21:03'	System	02 Jan 2021 03:03:45
	System	02 Jan 2021 03:03:45

US3342200

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(94)

Generated On: 09 Jun 2021 17:05:26

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:04:20
User entered '01 Jan 2021 12:00'	System	30 Dec 2020 18:34:16

US3342200

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(94)

Generated On: 09 Jun 2021 17:05:26

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:04:20
User entered '02 Jan 2021 11:59'	System	30 Dec 2020 18:34:16

US3342200

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(95)

Generated On: 09 Jun 2021 17:05:26

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:04:20
Data entry locked.	System	01 Jan 2021 01:26:45
User entered 'Day 95'	System	01 Jan 2021 01:26:45

US3342200

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(95)

Generated On: 09 Jun 2021 17:05:26

Select one response below to indicate the intensity of your **JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:04:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2D2D1647-7C35-4DCA-ADA3-8E1DAA921DDC)', Time: '2021-01-02T15:51:45', User OID: 'PatientReportedOutcome (US3342200)', ODM File OID: '7e783c3c-5e52-41c4-b20b-6a5033ba0136'	System	02 Jan 2021 21:51:51
User entered 'Some interference with activity (2)'	System	02 Jan 2021 21:51:51

US3342200

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(95)

Generated On: 09 Jun 2021 17:05:26

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:04:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2D2D1647-7C35-4DCA-ADA3-8E1DAA921DDC)', Time: '2021-01-02T15:51:48', User OID: 'PatientReportedOutcome (US3342200)', ODM File OID: '7e783c3c-5e52-41c4-b20b-6a5033ba0136'	System	02 Jan 2021 21:51:51
User entered '02 Jan 2021 15:51'	System	02 Jan 2021 21:51:51

US3342200

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(95)

Generated On: 09 Jun 2021 17:05:26

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:04:20
User entered '02 Jan 2021 12:00'	System	01 Jan 2021 01:26:45

US3342200

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(95)

Generated On: 09 Jun 2021 17:05:26

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:04:20
User entered '03 Jan 2021 11:59'	System	01 Jan 2021 01:26:45

US3342200

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(96)

Generated On: 09 Jun 2021 17:05:26

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:04:20
Data entry locked.	System	02 Jan 2021 03:03:45
User entered 'Day 96'	System	02 Jan 2021 03:03:45

US3342200

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(96)

Generated On: 09 Jun 2021 17:05:26

Select one response below to indicate the intensity of your **JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:04:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2D2D1647-7C35-4DCA-ADA3-8E1DAA921DDC)', Time: '2021-01-03T20:32:48', User OID: 'PatientReportedOutcome (US3342200)', ODM File OID: 'fb8d3930-b3fc-402a-9915-e67a75b9cb42'	System	04 Jan 2021 02:32:57
User entered 'Some interference with activity (2)'	System	04 Jan 2021 02:32:57

US3342200

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(96)

Generated On: 09 Jun 2021 17:05:26

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:04:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2D2D1647-7C35-4DCA-ADA3-8E1DAA921DDC)', Time: '2021-01-03T20:32:54', User OID: 'PatientReportedOutcome (US3342200)', ODM File OID: 'fb8d3930-b3fc-402a-9915-e67a75b9cb42' User entered '03 Jan 2021 20:32'	System	04 Jan 2021 02:32:57
	System	04 Jan 2021 02:32:57

US3342200

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(96)

Generated On: 09 Jun 2021 17:05:26

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:04:20
User entered '03 Jan 2021 12:00'	System	02 Jan 2021 03:03:45

US3342200

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(96)

Generated On: 09 Jun 2021 17:05:26

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:04:20
User entered '04 Jan 2021 11:59'	System	02 Jan 2021 03:03:45

US3342200

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(97)

Generated On: 09 Jun 2021 17:05:26

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:04:20
Data entry locked.	System	02 Jan 2021 21:51:51
User entered 'Day 97'	System	02 Jan 2021 21:51:51

US3342200

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(97)

Generated On: 09 Jun 2021 17:05:26

Select one response below to indicate the intensity of your **JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:04:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2D2D1647-7C35-4DCA-ADA3-8E1DAA921DDC)', Time: '2021-01-04T14:45:35', User OID: 'PatientReportedOutcome (US3342200)', ODM File OID: '431614b2-bd55-4fb0-bcb5-47c8ac90fc60'	System	04 Jan 2021 20:45:40
User entered 'Some interference with activity (2)'	System	04 Jan 2021 20:45:40

US3342200

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(97)

Generated On: 09 Jun 2021 17:05:26

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:04:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2D2D1647-7C35-4DCA-ADA3-8E1DAA921DDC)', Time: '2021-01-04T14:45:38', User OID: 'PatientReportedOutcome (US3342200)', ODM File OID: '431614b2-bd55-4fb0-bcb5-47c8ac90fc60' User entered '04 Jan 2021 14:45'	System	04 Jan 2021 20:45:40
	System	04 Jan 2021 20:45:40

US3342200

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(97)

Generated On: 09 Jun 2021 17:05:26

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:04:20
User entered '04 Jan 2021 12:00'	System	02 Jan 2021 21:51:51

US3342200

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(97)

Generated On: 09 Jun 2021 17:05:26

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:04:20
User entered '05 Jan 2021 11:59'	System	02 Jan 2021 21:51:51

US3342200

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(98)

Generated On: 09 Jun 2021 17:05:26

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:04:20
Data entry locked.	System	04 Jan 2021 02:32:57
User entered 'Day 98'	System	04 Jan 2021 02:32:57

US3342200

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(98)

Generated On: 09 Jun 2021 17:05:26

Select one response below to indicate the intensity of your **JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:04:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2D2D1647-7C35-4DCA-ADA3-8E1DAA921DDC)', Time: '2021-01-05T12:09:31', User OID: 'PatientReportedOutcome (US3342200)', ODM File OID: 'ddc622df-dd3b-4b80-acfc-b3767a1785c7'	System	05 Jan 2021 18:09:45
User entered 'Some interference with activity (2)'	System	05 Jan 2021 18:09:45

US3342200

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(98)

Generated On: 09 Jun 2021 17:05:26

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:04:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2D2D1647-7C35-4DCA-ADA3-8E1DAA921DDC)', Time: '2021-01-05T12:09:33', User OID: 'PatientReportedOutcome (US3342200)', ODM File OID: 'ddc622df-dd3b-4b80-acfc-b3767a1785c7' User entered '05 Jan 2021 12:09'	System	05 Jan 2021 18:09:45
	System	05 Jan 2021 18:09:45

US3342200

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(98)

Generated On: 09 Jun 2021 17:05:26

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:04:20
User entered '05 Jan 2021 12:00'	System	04 Jan 2021 02:32:57

US3342200

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(98)

Generated On: 09 Jun 2021 17:05:26

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:04:20
User entered '06 Jan 2021 11:59'	System	04 Jan 2021 02:32:57

US3342200

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(99)

Generated On: 09 Jun 2021 17:05:26

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:04:20
Data entry locked.	System	04 Jan 2021 20:45:40
User entered 'Day 99'	System	04 Jan 2021 20:45:40

US3342200

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(99)

Generated On: 09 Jun 2021 17:05:26

Select one response below to indicate the intensity of your **JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:04:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2D2D1647-7C35-4DCA-ADA3-8E1DAA921DDC)', Time: '2021-01-06T13:05:17', User OID: 'PatientReportedOutcome (US3342200)', ODM File OID: 'aa5c8dde-b02c-4fba-8251-4a3321aa90e4' User entered 'Some interference with activity (2)'	System	06 Jan 2021 19:05:28
	System	06 Jan 2021 19:05:28

US3342200

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(99)

Generated On: 09 Jun 2021 17:05:26

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:04:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2D2D1647-7C35-4DCA-ADA3-8E1DAA921DDC)', Time: '2021-01-06T13:05:23', User OID: 'PatientReportedOutcome (US3342200)', ODM File OID: 'aa5c8dde-b02c-4fba-8251-4a3321aa90e4' User entered '06 Jan 2021 13:05'	System	06 Jan 2021 19:05:28
	System	06 Jan 2021 19:05:28

US3342200

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(99)

Generated On: 09 Jun 2021 17:05:26

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:04:20
User entered '06 Jan 2021 12:00'	System	04 Jan 2021 20:45:40

US3342200

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(99)

Generated On: 09 Jun 2021 17:05:26

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:04:20
User entered '07 Jan 2021 11:59'	System	04 Jan 2021 20:45:40

US3342200

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(100)

Generated On: 09 Jun 2021 17:05:26

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:04:20
Data entry locked.	System	05 Jan 2021 18:09:45
User entered 'Day 100'	System	05 Jan 2021 18:09:45

US3342200

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(100)

Generated On: 09 Jun 2021 17:05:26

Select one response below to indicate the intensity of your **JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:04:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2D2D1647-7C35-4DCA-ADA3-8E1DAA921DDC)', Time: '2021-01-07T12:00:41', User OID: 'PatientReportedOutcome (US3342200)', ODM File OID: '83a0cf8a-eccd-41c5-92fe-8b25b4a23398'	System	07 Jan 2021 18:00:51
User entered 'Some interference with activity (2)'	System	07 Jan 2021 18:00:51

US3342200

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(100)

Generated On: 09 Jun 2021 17:05:26

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:04:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2D2D1647-7C35-4DCA-ADA3-8E1DAA921DDC)', Time: '2021-01-07T12:00:45', User OID: 'PatientReportedOutcome (US3342200)', ODM File OID: '83a0cf8a-eccd-41c5-92fe-8b25b4a23398' User entered '07 Jan 2021 12:00'	System	07 Jan 2021 18:00:51
	System	07 Jan 2021 18:00:51

US3342200

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(100)

Generated On: 09 Jun 2021 17:05:26

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:04:20
User entered '07 Jan 2021 12:00'	System	05 Jan 2021 18:09:45

US3342200

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(100)

Generated On: 09 Jun 2021 17:05:26

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:04:20
User entered '08 Jan 2021 11:59'	System	05 Jan 2021 18:09:45

US3342200

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(101)

Generated On: 09 Jun 2021 17:05:26

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:04:20
Data entry locked.	System	06 Jan 2021 19:05:28
User entered 'Day 101'	System	06 Jan 2021 19:05:28

US3342200

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(101)

Generated On: 09 Jun 2021 17:05:26

Select one response below to indicate the intensity of your **JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:04:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2D2D1647-7C35-4DCA-ADA3-8E1DAA921DDC)', Time: '2021-01-08T23:59:27', User OID: 'PatientReportedOutcome (US3342200)', ODM File OID: 'f630b4e9-4c6e-4157-9cfa-bdacf66b5413'	System	09 Jan 2021 05:59:34
User entered 'Some interference with activity (2)'	System	09 Jan 2021 05:59:34

US3342200

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(101)

Generated On: 09 Jun 2021 17:05:26

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:04:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2D2D1647-7C35-4DCA-ADA3-8E1DAA921DDC)', Time: '2021-01-08T23:59:31', User OID: 'PatientReportedOutcome (US3342200)', ODM File OID: 'f630b4e9-4c6e-4157-9cfa-bdacf66b5413' User entered '08 Jan 2021 23:59'	System	09 Jan 2021 05:59:34
	System	09 Jan 2021 05:59:34

US3342200

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(101)

Generated On: 09 Jun 2021 17:05:26

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:04:20
User entered '08 Jan 2021 12:00'	System	06 Jan 2021 19:05:28

US3342200

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(101)

Generated On: 09 Jun 2021 17:05:26

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:04:20
User entered '09 Jan 2021 11:59'	System	06 Jan 2021 19:05:28

US3342200

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(102)

Generated On: 09 Jun 2021 17:05:26

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:04:20
Data entry locked.	System	07 Jan 2021 18:00:51
User entered 'Day 102'	System	07 Jan 2021 18:00:51

US3342200

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(102)

Generated On: 09 Jun 2021 17:05:26

Select one response below to indicate the intensity of your **JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:04:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2D2D1647-7C35-4DCA-ADA3-8E1DAA921DDC)', Time: '2021-01-09T12:05:31', User OID: 'PatientReportedOutcome (US3342200)', ODM File OID: '6e1ed7c4-3a31-454e-8d1a-d5d6475a9d17'	System	09 Jan 2021 18:05:39
User entered 'Some interference with activity (2)'	System	09 Jan 2021 18:05:39

US3342200

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(102)

Generated On: 09 Jun 2021 17:05:26

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:04:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2D2D1647-7C35-4DCA-ADA3-8E1DAA921DDC)', Time: '2021-01-09T12:05:36', User OID: 'PatientReportedOutcome (US3342200)', ODM File OID: '6e1ed7c4-3a31-454e-8d1a-d5d6475a9d17' User entered '09 Jan 2021 12:05'	System	09 Jan 2021 18:05:39
	System	09 Jan 2021 18:05:39

US3342200

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(102)

Generated On: 09 Jun 2021 17:05:26

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:04:20
User entered '09 Jan 2021 12:00'	System	07 Jan 2021 18:00:51

US3342200

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(102)

Generated On: 09 Jun 2021 17:05:26

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:04:20
User entered '10 Jan 2021 11:59'	System	07 Jan 2021 18:00:51

US3342200

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(103)

Generated On: 09 Jun 2021 17:05:26

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:04:20
Data entry locked.	System	09 Jan 2021 05:59:34
User entered 'Day 103'	System	09 Jan 2021 05:59:34

US3342200

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(103)

Generated On: 09 Jun 2021 17:05:26

Select one response below to indicate the intensity of your **JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:04:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2D2D1647-7C35-4DCA-ADA3-8E1DAA921DDC)', Time: '2021-01-10T16:49:25', User OID: 'PatientReportedOutcome (US3342200)', ODM File OID: '56b01dd0-c3df-42dc-8368-b20da117c1db' User entered 'Some interference with activity (2)'	System	10 Jan 2021 22:49:30
	System	10 Jan 2021 22:49:30

US3342200

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(103)

Generated On: 09 Jun 2021 17:05:26

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:04:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2D2D1647-7C35-4DCA-ADA3-8E1DAA921DDC)', Time: '2021-01-10T16:49:27', User OID: 'PatientReportedOutcome (US3342200)', ODM File OID: '56b01dd0-c3df-42dc-8368-b20da117c1db' User entered '10 Jan 2021 16:49'	System	10 Jan 2021 22:49:30
	System	10 Jan 2021 22:49:30

US3342200

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(103)

Generated On: 09 Jun 2021 17:05:26

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:04:20
User entered '10 Jan 2021 12:00'	System	09 Jan 2021 05:59:34

US3342200

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(103)

Generated On: 09 Jun 2021 17:05:26

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:04:20
User entered '11 Jan 2021 11:59'	System	09 Jan 2021 05:59:34

US3342200

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(104)

Generated On: 09 Jun 2021 17:05:26

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:04:20
Data entry locked.	System	09 Jan 2021 18:05:39
User entered 'Day 104'	System	09 Jan 2021 18:05:39

US3342200

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(104)

Generated On: 09 Jun 2021 17:05:26

Select one response below to indicate the intensity of your **JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:04:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2D2D1647-7C35-4DCA-ADA3-8E1DAA921DDC)', Time: '2021-01-11T12:01:53', User OID: 'PatientReportedOutcome (US3342200)', ODM File OID: '5739d6ef-8700-4c80-bc95-4b973752a63e' User entered 'Some interference with activity (2)'	System	11 Jan 2021 18:02:26
	System	11 Jan 2021 18:02:26

US3342200

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(104)

Generated On: 09 Jun 2021 17:05:26

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:04:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2D2D1647-7C35-4DCA-ADA3-8E1DAA921DDC)', Time: '2021-01-11T12:01:56', User OID: 'PatientReportedOutcome (US3342200)', ODM File OID: '5739d6ef-8700-4c80-bc95-4b973752a63e' User entered '11 Jan 2021 12:01'	System	11 Jan 2021 18:02:26
	System	11 Jan 2021 18:02:26

US3342200

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(104)

Generated On: 09 Jun 2021 17:05:26

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:04:20
User entered '11 Jan 2021 12:00'	System	09 Jan 2021 18:05:39

US3342200

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(104)

Generated On: 09 Jun 2021 17:05:26

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:04:20
User entered '12 Jan 2021 11:59'	System	09 Jan 2021 18:05:39

US3342200

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(105)

Generated On: 09 Jun 2021 17:05:26

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:04:20
Data entry locked.	System	10 Jan 2021 22:49:30
User entered 'Day 105'	System	10 Jan 2021 22:49:30

US3342200

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(105)

Generated On: 09 Jun 2021 17:05:26

Select one response below to indicate the intensity of your **JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:04:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2D2D1647-7C35-4DCA-ADA3-8E1DAA921DDC)', Time: '2021-01-12T13:03:16', User OID: 'PatientReportedOutcome (US3342200)', ODM File OID: '3736ddde-4c9e-40e3-8d16-d0ccd353f7a2'	System	12 Jan 2021 19:03:35
User entered 'Some interference with activity (2)'	System	12 Jan 2021 19:03:35

US3342200

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(105)

Generated On: 09 Jun 2021 17:05:26

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:04:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2D2D1647-7C35-4DCA-ADA3-8E1DAA921DDC)', Time: '2021-01-12T13:03:18', User OID: 'PatientReportedOutcome (US3342200)', ODM File OID: '3736ddde-4c9e-40e3-8d16-d0ccd353f7a2' User entered '12 Jan 2021 13:03'	System	12 Jan 2021 19:03:35
	System	12 Jan 2021 19:03:35

US3342200

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(105)

Generated On: 09 Jun 2021 17:05:26

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:04:20
User entered '12 Jan 2021 12:00'	System	10 Jan 2021 22:49:30

US3342200

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(105)

Generated On: 09 Jun 2021 17:05:26

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:04:20
User entered '13 Jan 2021 11:59'	System	10 Jan 2021 22:49:30

US3342200

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(106)

Generated On: 09 Jun 2021 17:05:26

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:04:20
Data entry locked.	System	11 Jan 2021 18:02:26
User entered 'Day 106'	System	11 Jan 2021 18:02:26

US3342200

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(106)

Generated On: 09 Jun 2021 17:05:26

Select one response below to indicate the intensity of your **JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:04:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2D2D1647-7C35-4DCA-ADA3-8E1DAA921DDC)', Time: '2021-01-14T03:41:31', User OID: 'PatientReportedOutcome (US3342200)', ODM File OID: 'e5608e59-f422-4f52-a1d1-86c342338b51' User entered 'Some interference with activity (2)'	System	14 Jan 2021 09:41:41
	System	14 Jan 2021 09:41:41

US3342200

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(106)

Generated On: 09 Jun 2021 17:05:26

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:04:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2D2D1647-7C35-4DCA-ADA3-8E1DAA921DDC)', Time: '2021-01-14T03:41:35', User OID: 'PatientReportedOutcome (US3342200)', ODM File OID: 'e5608e59-f422-4f52-a1d1-86c342338b51' User entered '14 Jan 2021 03:41'	System	14 Jan 2021 09:41:41
	System	14 Jan 2021 09:41:41

US3342200

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(106)

Generated On: 09 Jun 2021 17:05:26

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:04:20
User entered '13 Jan 2021 12:00'	System	11 Jan 2021 18:02:26

US3342200

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(106)

Generated On: 09 Jun 2021 17:05:26

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:04:20
User entered '14 Jan 2021 11:59'	System	11 Jan 2021 18:02:26

US3342200

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(107)

Generated On: 09 Jun 2021 17:05:26

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:04:20
Data entry locked.	System	12 Jan 2021 19:03:35
User entered 'Day 107'	System	12 Jan 2021 19:03:35

US3342200

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(107)

Generated On: 09 Jun 2021 17:05:26

Select one response below to indicate the intensity of your **JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:04:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2D2D1647-7C35-4DCA-ADA3-8E1DAA921DDC)', Time: '2021-01-14T16:03:10', User OID: 'PatientReportedOutcome (US3342200)', ODM File OID: '52a6a925-4d54-4c00-a5ef-06a9d25e12b3'	System	14 Jan 2021 22:03:17
User entered 'Some interference with activity (2)'	System	14 Jan 2021 22:03:17

US3342200

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(107)

Generated On: 09 Jun 2021 17:05:26

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:04:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2D2D1647-7C35-4DCA-ADA3-8E1DAA921DDC)', Time: '2021-01-14T16:03:14', User OID: 'PatientReportedOutcome (US3342200)', ODM File OID: '52a6a925-4d54-4c00-a5ef-06a9d25e12b3' User entered '14 Jan 2021 16:03'	System	14 Jan 2021 22:03:17
	System	14 Jan 2021 22:03:17

US3342200

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(107)

Generated On: 09 Jun 2021 17:05:26

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:04:20
User entered '14 Jan 2021 12:00'	System	12 Jan 2021 19:03:35

US3342200

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(107)

Generated On: 09 Jun 2021 17:05:26

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:04:20
User entered '15 Jan 2021 11:59'	System	12 Jan 2021 19:03:35

US3342200

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(108)

Generated On: 09 Jun 2021 17:05:26

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:04:20
Data entry locked.	System	14 Jan 2021 09:41:41
User entered 'Day 108'	System	14 Jan 2021 09:41:41

US3342200

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(108)

Generated On: 09 Jun 2021 17:05:26

Select one response below to indicate the intensity of your **JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:04:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2D2D1647-7C35-4DCA-ADA3-8E1DAA921DDC)', Time: '2021-01-16T03:13:39', User OID: 'PatientReportedOutcome (US3342200)', ODM File OID: '6818df12-971f-49a1-af99-2da7832fbbcd' User entered 'Some interference with activity (2)'	System	16 Jan 2021 09:13:53
	System	16 Jan 2021 09:13:53

US3342200

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(108)

Generated On: 09 Jun 2021 17:05:26

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:04:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2D2D1647-7C35-4DCA-ADA3-8E1DAA921DDC)', Time: '2021-01-16T03:13:48', User OID: 'PatientReportedOutcome (US3342200)', ODM File OID: '6818df12-971f-49a1-af99-2da7832fbbcd' User entered '16 Jan 2021 03:13'	System	16 Jan 2021 09:13:53
	System	16 Jan 2021 09:13:53

US3342200

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(108)

Generated On: 09 Jun 2021 17:05:26

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:04:20
User entered '15 Jan 2021 12:00'	System	14 Jan 2021 09:41:41

US3342200

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(108)

Generated On: 09 Jun 2021 17:05:26

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:04:20
User entered '16 Jan 2021 11:59'	System	14 Jan 2021 09:41:41

US3342200

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(109)

Generated On: 09 Jun 2021 17:05:26

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:04:20
Data entry locked.	System	14 Jan 2021 22:03:17
User entered 'Day 109'	System	14 Jan 2021 22:03:17

US3342200

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(109)

Generated On: 09 Jun 2021 17:05:26

Select one response below to indicate the intensity of your **JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:04:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2D2D1647-7C35-4DCA-ADA3-8E1DAA921DDC)', Time: '2021-01-16T12:36:58', User OID: 'PatientReportedOutcome (US3342200)', ODM File OID: '7932d6a3-afa2-48dc-b86d-df0aa23003d0' User entered 'Some interference with activity (2)'	System	16 Jan 2021 18:37:03
	System	16 Jan 2021 18:37:03

US3342200

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(109)

Generated On: 09 Jun 2021 17:05:26

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:04:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2D2D1647-7C35-4DCA-ADA3-8E1DAA921DDC)', Time: '2021-01-16T12:37:01', User OID: 'PatientReportedOutcome (US3342200)', ODM File OID: '7932d6a3-afa2-48dc-b86d-df0aa23003d0' User entered '16 Jan 2021 12:37'	System	16 Jan 2021 18:37:03
	System	16 Jan 2021 18:37:03

US3342200

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(109)

Generated On: 09 Jun 2021 17:05:26

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:04:20
User entered '16 Jan 2021 12:00'	System	14 Jan 2021 22:03:17

US3342200

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(109)

Generated On: 09 Jun 2021 17:05:26

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:04:20
User entered '17 Jan 2021 11:59'	System	14 Jan 2021 22:03:17

US3342200

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(110)

Generated On: 09 Jun 2021 17:05:26

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:04:20
Data entry locked.	System	16 Jan 2021 09:13:53
User entered 'Day 110'	System	16 Jan 2021 09:13:53

US3342200

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(110)

Generated On: 09 Jun 2021 17:05:26

Select one response below to indicate the intensity of your **JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:04:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2D2D1647-7C35-4DCA-ADA3-8E1DAA921DDC)', Time: '2021-01-18T00:19:33', User OID: 'PatientReportedOutcome (US3342200)', ODM File OID: '26d5ef99-a456-425f-85fb-715a3883166b' User entered 'Some interference with activity (2)'	System	18 Jan 2021 06:19:39
	System	18 Jan 2021 06:19:39

US3342200

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(110)

Generated On: 09 Jun 2021 17:05:26

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:04:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2D2D1647-7C35-4DCA-ADA3-8E1DAA921DDC)', Time: '2021-01-18T00:19:37', User OID: 'PatientReportedOutcome (US3342200)', ODM File OID: '26d5ef99-a456-425f-85fb-715a3883166b' User entered '18 Jan 2021 00:19'	System	18 Jan 2021 06:19:39
	System	18 Jan 2021 06:19:39

US3342200

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(110)

Generated On: 09 Jun 2021 17:05:26

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:04:20
User entered '17 Jan 2021 12:00'	System	16 Jan 2021 09:13:53

US3342200

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(110)

Generated On: 09 Jun 2021 17:05:26

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:04:20
User entered '18 Jan 2021 11:59'	System	16 Jan 2021 09:13:53

US3342200

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(111)

Generated On: 09 Jun 2021 17:05:26

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:04:20
Data entry locked.	System	16 Jan 2021 18:37:03
User entered 'Day 111'	System	16 Jan 2021 18:37:03

US3342200

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(111)

Generated On: 09 Jun 2021 17:05:26

Select one response below to indicate the intensity of your **JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:04:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2D2D1647-7C35-4DCA-ADA3-8E1DAA921DDC)', Time: '2021-01-19T03:08:11', User OID: 'PatientReportedOutcome (US3342200)', ODM File OID: 'febdb9b0-6b03-41ad-9044-adafb33f8e37'	System	19 Jan 2021 09:08:17
User entered 'Some interference with activity (2)'	System	19 Jan 2021 09:08:17

US3342200

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(111)

Generated On: 09 Jun 2021 17:05:26

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:04:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2D2D1647-7C35-4DCA-ADA3-8E1DAA921DDC)', Time: '2021-01-19T03:08:14', User OID: 'PatientReportedOutcome (US3342200)', ODM File OID: 'febdb9b0-6b03-41ad-9044-adafb33f8e37' User entered '19 Jan 2021 03:08'	System	19 Jan 2021 09:08:17
	System	19 Jan 2021 09:08:17

US3342200

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(111)

Generated On: 09 Jun 2021 17:05:26

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:04:20
User entered '18 Jan 2021 12:00'	System	16 Jan 2021 18:37:03

US3342200

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(111)

Generated On: 09 Jun 2021 17:05:26

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:04:20
User entered '19 Jan 2021 11:59'	System	16 Jan 2021 18:37:03

US3342200

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(112)

Generated On: 09 Jun 2021 17:05:26

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:04:20
Data entry locked.	System	18 Jan 2021 06:19:39
User entered 'Day 112'	System	18 Jan 2021 06:19:39

US3342200

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(112)

Generated On: 09 Jun 2021 17:05:26

Select one response below to indicate the intensity of your **JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:04:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2D2D1647-7C35-4DCA-ADA3-8E1DAA921DDC)', Time: '2021-01-19T12:01:43', User OID: 'PatientReportedOutcome (US3342200)', ODM File OID: '2fd9e728-21d3-4ec4-9ee9-665239f841ef' User entered 'Some interference with activity (2)'	System	19 Jan 2021 18:02:00
	System	19 Jan 2021 18:02:00

US3342200

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(112)

Generated On: 09 Jun 2021 17:05:26

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:04:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2D2D1647-7C35-4DCA-ADA3-8E1DAA921DDC)', Time: '2021-01-19T12:01:46', User OID: 'PatientReportedOutcome (US3342200)', ODM File OID: '2fd9e728-21d3-4ec4-9ee9-665239f841ef' User entered '19 Jan 2021 12:01'	System	19 Jan 2021 18:02:00
	System	19 Jan 2021 18:02:00

US3342200

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(112)

Generated On: 09 Jun 2021 17:05:26

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:04:20
User entered '19 Jan 2021 12:00'	System	18 Jan 2021 06:19:39

US3342200

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(112)

Generated On: 09 Jun 2021 17:05:26

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:04:20
User entered '20 Jan 2021 11:59'	System	18 Jan 2021 06:19:39

US3342200

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(113)

Generated On: 09 Jun 2021 17:05:26

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:04:20
Data entry locked.	System	19 Jan 2021 09:08:17
User entered 'Day 113'	System	19 Jan 2021 09:08:17

US3342200

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(113)

Generated On: 09 Jun 2021 17:05:26

Select one response below to indicate the intensity of your **JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:04:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2D2D1647-7C35-4DCA-ADA3-8E1DAA921DDC)', Time: '2021-01-20T15:17:27', User OID: 'PatientReportedOutcome (US3342200)', ODM File OID: '8105984c-4045-4cfc-90de-12667c38d3da' User entered 'Some interference with activity (2)'	System	20 Jan 2021 21:17:34

US3342200

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(113)

Generated On: 09 Jun 2021 17:05:26

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:04:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2D2D1647-7C35-4DCA-ADA3-8E1DAA921DDC)', Time: '2021-01-20T15:17:30', User OID: 'PatientReportedOutcome (US3342200)', ODM File OID: '8105984c-4045-4cfc-90de-12667c38d3da' User entered '20 Jan 2021 15:17'	System	20 Jan 2021 21:17:34
	System	20 Jan 2021 21:17:34

US3342200

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(113)

Generated On: 09 Jun 2021 17:05:26

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:04:20
User entered '20 Jan 2021 12:00'	System	19 Jan 2021 09:08:17

US3342200

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(113)

Generated On: 09 Jun 2021 17:05:26

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:04:20
User entered '21 Jan 2021 11:59'	System	19 Jan 2021 09:08:17

US3342200

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(114)

Generated On: 09 Jun 2021 17:05:26

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:04:20
Data entry locked.	System	19 Jan 2021 18:02:00
User entered 'Day 114'	System	19 Jan 2021 18:02:00

US3342200

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(114)

Generated On: 09 Jun 2021 17:05:26

Select one response below to indicate the intensity of your **JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:04:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2D2D1647-7C35-4DCA-ADA3-8E1DAA921DDC)', Time: '2021-01-21T12:00:25', User OID: 'PatientReportedOutcome (US3342200)', ODM File OID: '954e8b21-7102-4f64-a09f-84e57515b45b' User entered 'Some interference with activity (2)'	System	21 Jan 2021 18:00:39
	System	21 Jan 2021 18:00:39

US3342200

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(114)

Generated On: 09 Jun 2021 17:05:26

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:04:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2D2D1647-7C35-4DCA-ADA3-8E1DAA921DDC)', Time: '2021-01-21T12:00:27', User OID: 'PatientReportedOutcome (US3342200)', ODM File OID: '954e8b21-7102-4f64-a09f-84e57515b45b' User entered '21 Jan 2021 12:00'	System	21 Jan 2021 18:00:39
	System	21 Jan 2021 18:00:39

US3342200

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(114)

Generated On: 09 Jun 2021 17:05:26

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:04:20
User entered '21 Jan 2021 12:00'	System	19 Jan 2021 18:02:00

US3342200

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(114)

Generated On: 09 Jun 2021 17:05:26

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:04:20
User entered '22 Jan 2021 11:59'	System	19 Jan 2021 18:02:00

US3342200

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(115)

Generated On: 09 Jun 2021 17:05:26

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:04:20
Data entry locked.	System	20 Jan 2021 21:17:34
User entered 'Day 115'	System	20 Jan 2021 21:17:34

US3342200

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(115)

Generated On: 09 Jun 2021 17:05:26

Select one response below to indicate the intensity of your **JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:04:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2D2D1647-7C35-4DCA-ADA3-8E1DAA921DDC)', Time: '2021-01-22T12:55:45', User OID: 'PatientReportedOutcome (US3342200)', ODM File OID: '0d486ec8-9904-4f0c-8618-96a1a32328b1' User entered 'Some interference with activity (2)'	System	22 Jan 2021 18:55:50
	System	22 Jan 2021 18:55:50

US3342200

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(115)

Generated On: 09 Jun 2021 17:05:26

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:04:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2D2D1647-7C35-4DCA-ADA3-8E1DAA921DDC)', Time: '2021-01-22T12:55:48', User OID: 'PatientReportedOutcome (US3342200)', ODM File OID: '0d486ec8-9904-4f0c-8618-96a1a32328b1' User entered '22 Jan 2021 12:55'	System	22 Jan 2021 18:55:50
	System	22 Jan 2021 18:55:50

US3342200

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(115)

Generated On: 09 Jun 2021 17:05:26

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:04:20
User entered '22 Jan 2021 12:00'	System	20 Jan 2021 21:17:34

US3342200

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(115)

Generated On: 09 Jun 2021 17:05:26

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:04:20
User entered '23 Jan 2021 11:59'	System	20 Jan 2021 21:17:34

US3342200

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(116)

Generated On: 09 Jun 2021 17:05:26

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:04:20
Data entry locked.	System	21 Jan 2021 18:00:39
User entered 'Day 116'	System	21 Jan 2021 18:00:39

US3342200

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(116)

Generated On: 09 Jun 2021 17:05:26

Select one response below to indicate the intensity of your **JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:04:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2D2D1647-7C35-4DCA-ADA3-8E1DAA921DDC)', Time: '2021-01-23T12:36:56', User OID: 'PatientReportedOutcome (US3342200)', ODM File OID: '03349dbe-2e6c-4cbd-9a80-223d8f7a141e' User entered 'Some interference with activity (2)'	System	23 Jan 2021 18:37:04
	System	23 Jan 2021 18:37:04

US3342200

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(116)

Generated On: 09 Jun 2021 17:05:26

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:04:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2D2D1647-7C35-4DCA-ADA3-8E1DAA921DDC)', Time: '2021-01-23T12:37:00', User OID: 'PatientReportedOutcome (US3342200)', ODM File OID: '03349dbe-2e6c-4cbd-9a80-223d8f7a141e' User entered '23 Jan 2021 12:37'	System	23 Jan 2021 18:37:04
	System	23 Jan 2021 18:37:04

US3342200

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(116)

Generated On: 09 Jun 2021 17:05:26

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:04:20
User entered '23 Jan 2021 12:00'	System	21 Jan 2021 18:00:39

US3342200

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(116)

Generated On: 09 Jun 2021 17:05:26

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:04:20
User entered '24 Jan 2021 11:59'	System	21 Jan 2021 18:00:39

US3342200

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(117)

Generated On: 09 Jun 2021 17:05:26

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:04:20
Data entry locked.	System	22 Jan 2021 18:55:50
User entered 'Day 117'	System	22 Jan 2021 18:55:50

US3342200

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(117)

Generated On: 09 Jun 2021 17:05:26

Select one response below to indicate the intensity of your **JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:04:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2D2D1647-7C35-4DCA-ADA3-8E1DAA921DDC)', Time: '2021-01-24T21:42:42', User OID: 'PatientReportedOutcome (US3342200)', ODM File OID: 'c33a7f5d-bccb-4034-9d9d-36e453244e84'	System	25 Jan 2021 03:42:50
User entered 'Some interference with activity (2)'	System	25 Jan 2021 03:42:50

US3342200

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(117)

Generated On: 09 Jun 2021 17:05:26

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:04:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2D2D1647-7C35-4DCA-ADA3-8E1DAA921DDC)', Time: '2021-01-24T21:42:45', User OID: 'PatientReportedOutcome (US3342200)', ODM File OID: 'c33a7f5d-bccb-4034-9d9d-36e453244e84' User entered '24 Jan 2021 21:42'	System	25 Jan 2021 03:42:50
	System	25 Jan 2021 03:42:50

US3342200

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(117)

Generated On: 09 Jun 2021 17:05:26

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:04:20
User entered '24 Jan 2021 12:00'	System	22 Jan 2021 18:55:50

US3342200

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(117)

Generated On: 09 Jun 2021 17:05:26

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:04:20
User entered '25 Jan 2021 11:59'	System	22 Jan 2021 18:55:50

US3342200

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(118)

Generated On: 09 Jun 2021 17:05:26

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:04:20
Data entry locked.	System	23 Jan 2021 18:37:04
User entered 'Day 118'	System	23 Jan 2021 18:37:04

US3342200

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(118)

Generated On: 09 Jun 2021 17:05:26

Select one response below to indicate the intensity of your **JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:04:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2D2D1647-7C35-4DCA-ADA3-8E1DAA921DDC)', Time: '2021-01-25T17:48:33', User OID: 'PatientReportedOutcome (US3342200)', ODM File OID: '2ce87151-26b5-41fe-ad28-e95a9279f1dc'	System	25 Jan 2021 23:48:47
User entered 'Some interference with activity (2)'	System	25 Jan 2021 23:48:47

US3342200

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(118)

Generated On: 09 Jun 2021 17:05:26

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:04:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2D2D1647-7C35-4DCA-ADA3-8E1DAA921DDC)', Time: '2021-01-25T17:48:36', User OID: 'PatientReportedOutcome (US3342200)', ODM File OID: '2ce87151-26b5-41fe-ad28-e95a9279f1dc' User entered '25 Jan 2021 17:48'	System	25 Jan 2021 23:48:47
	System	25 Jan 2021 23:48:47

US3342200

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(118)

Generated On: 09 Jun 2021 17:05:26

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:04:20
User entered '25 Jan 2021 12:00'	System	23 Jan 2021 18:37:04

US3342200

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(118)

Generated On: 09 Jun 2021 17:05:26

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:04:20
User entered '26 Jan 2021 11:59'	System	23 Jan 2021 18:37:04

US3342200

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(119)

Generated On: 09 Jun 2021 17:05:26

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:04:20
Data entry locked.	System	25 Jan 2021 03:42:50
User entered 'Day 119'	System	25 Jan 2021 03:42:50

US3342200

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(119)

Generated On: 09 Jun 2021 17:05:26

Select one response below to indicate the intensity of your **JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:04:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2D2D1647-7C35-4DCA-ADA3-8E1DAA921DDC)', Time: '2021-01-26T19:10:11', User OID: 'PatientReportedOutcome (US3342200)', ODM File OID: 'ba9db92c-2a1f-4688-8b26-ca15465edaa2'	System	27 Jan 2021 01:32:08
User entered 'Some interference with activity (2)'	System	27 Jan 2021 01:32:08

US3342200

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(119)

Generated On: 09 Jun 2021 17:05:26

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:04:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2D2D1647-7C35-4DCA-ADA3-8E1DAA921DDC)', Time: '2021-01-26T19:10:17', User OID: 'PatientReportedOutcome (US3342200)', ODM File OID: 'ba9db92c-2a1f-4688-8b26-ca15465edaa2' User entered '26 Jan 2021 19:10'	System	27 Jan 2021 01:32:08
	System	27 Jan 2021 01:32:08

US3342200

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(119)

Generated On: 09 Jun 2021 17:05:26

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:04:20
User entered '26 Jan 2021 12:00'	System	25 Jan 2021 03:42:50

US3342200

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(119)

Generated On: 09 Jun 2021 17:05:26

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:04:20
User entered '27 Jan 2021 11:59'	System	25 Jan 2021 03:42:50

US3342200

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(120)

Generated On: 09 Jun 2021 17:05:26

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:04:20
Data entry locked.	System	25 Jan 2021 23:48:47
User entered 'Day 120'	System	25 Jan 2021 23:48:47

US3342200

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(120)

Generated On: 09 Jun 2021 17:05:26

Select one response below to indicate the intensity of your **JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:04:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2D2D1647-7C35-4DCA-ADA3-8E1DAA921DDC)', Time: '2021-01-27T19:46:11', User OID: 'PatientReportedOutcome (US3342200)', ODM File OID: '0be46b7a-e395-43d7-ae95-060accecc0f5'	System	28 Jan 2021 01:46:16
User entered 'Some interference with activity (2)'	System	28 Jan 2021 01:46:16

US3342200

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(120)

Generated On: 09 Jun 2021 17:05:26

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:04:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2D2D1647-7C35-4DCA-ADA3-8E1DAA921DDC)', Time: '2021-01-27T19:46:14', User OID: 'PatientReportedOutcome (US3342200)', ODM File OID: '0be46b7a-e395-43d7-ae95-060accecc0f5' User entered '27 Jan 2021 19:46'	System	28 Jan 2021 01:46:16
	System	28 Jan 2021 01:46:16

US3342200

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(120)

Generated On: 09 Jun 2021 17:05:26

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:04:20
User entered '27 Jan 2021 12:00'	System	25 Jan 2021 23:48:47

US3342200

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(120)

Generated On: 09 Jun 2021 17:05:26

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:04:20
User entered '28 Jan 2021 11:59'	System	25 Jan 2021 23:48:47

US3342200

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(121)

Generated On: 09 Jun 2021 17:05:26

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:04:20
Data entry locked.	System	27 Jan 2021 01:32:08
User entered 'Day 121'	System	27 Jan 2021 01:32:08

US3342200

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(121)

Generated On: 09 Jun 2021 17:05:26

Select one response below to indicate the intensity of your **JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:04:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2D2D1647-7C35-4DCA-ADA3-8E1DAA921DDC)', Time: '2021-01-28T12:00:31', User OID: 'PatientReportedOutcome (US3342200)', ODM File OID: 'cb1914e9-f4fb-456e-8f3d-a53d9da926b4'	System	28 Jan 2021 18:00:51
User entered 'Some interference with activity (2)'	System	28 Jan 2021 18:00:51

US3342200

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(121)

Generated On: 09 Jun 2021 17:05:26

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:04:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2D2D1647-7C35-4DCA-ADA3-8E1DAA921DDC)', Time: '2021-01-28T12:00:33', User OID: 'PatientReportedOutcome (US3342200)', ODM File OID: 'cb1914e9-f4fb-456e-8f3d-a53d9da926b4' User entered '28 Jan 2021 12:00'	System	28 Jan 2021 18:00:51
	System	28 Jan 2021 18:00:51

US3342200

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(121)

Generated On: 09 Jun 2021 17:05:26

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:04:20
User entered '28 Jan 2021 12:00'	System	27 Jan 2021 01:32:08

US3342200

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(121)

Generated On: 09 Jun 2021 17:05:26

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:04:20
User entered '29 Jan 2021 11:59'	System	27 Jan 2021 01:32:08

US3342200

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(122)

Generated On: 09 Jun 2021 17:05:26

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:04:20
Data entry locked.	System	28 Jan 2021 01:46:16
User entered 'Day 122'	System	28 Jan 2021 01:46:16

US3342200

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(122)

Generated On: 09 Jun 2021 17:05:26

Select one response below to indicate the intensity of your **JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:04:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2D2D1647-7C35-4DCA-ADA3-8E1DAA921DDC)', Time: '2021-01-30T05:35:36', User OID: 'PatientReportedOutcome (US3342200)', ODM File OID: '63f1f83e-3da5-42bf-b6d6-37d0b912eb00' User entered 'Some interference with activity (2)'	System	30 Jan 2021 11:35:44
	System	30 Jan 2021 11:35:44

US3342200

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(122)

Generated On: 09 Jun 2021 17:05:26

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:04:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2D2D1647-7C35-4DCA-ADA3-8E1DAA921DDC)', Time: '2021-01-30T05:35:41', User OID: 'PatientReportedOutcome (US3342200)', ODM File OID: '63f1f83e-3da5-42bf-b6d6-37d0b912eb00' User entered '30 Jan 2021 05:35'	System	30 Jan 2021 11:35:44
	System	30 Jan 2021 11:35:44

US3342200

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(122)

Generated On: 09 Jun 2021 17:05:26

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:04:20
User entered '29 Jan 2021 12:00'	System	28 Jan 2021 01:46:16

US3342200

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(122)

Generated On: 09 Jun 2021 17:05:26

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:04:20
User entered '30 Jan 2021 11:59'	System	28 Jan 2021 01:46:16

US3342200

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(123)

Generated On: 09 Jun 2021 17:05:26

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:04:20
Data entry locked.	System	28 Jan 2021 18:00:51
User entered 'Day 123'	System	28 Jan 2021 18:00:51

US3342200

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(123)

Generated On: 09 Jun 2021 17:05:26

Select one response below to indicate the intensity of your **JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:04:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2D2D1647-7C35-4DCA-ADA3-8E1DAA921DDC)', Time: '2021-01-31T09:35:31', User OID: 'PatientReportedOutcome (US3342200)', ODM File OID: '8dc2ca76-96d0-426f-bf70-f5a86d9cf393' User entered 'Some interference with activity (2)'	System	31 Jan 2021 15:35:39
	System	31 Jan 2021 15:35:39

US3342200

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(123)

Generated On: 09 Jun 2021 17:05:26

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:04:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2D2D1647-7C35-4DCA-ADA3-8E1DAA921DDC)', Time: '2021-01-31T09:35:33', User OID: 'PatientReportedOutcome (US3342200)', ODM File OID: '8dc2ca76-96d0-426f-bf70-f5a86d9cf393' User entered '31 Jan 2021 09:35'	System	31 Jan 2021 15:35:39
	System	31 Jan 2021 15:35:39

US3342200

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(123)

Generated On: 09 Jun 2021 17:05:26

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:04:20
User entered '30 Jan 2021 12:00'	System	28 Jan 2021 18:00:51

US3342200

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(123)

Generated On: 09 Jun 2021 17:05:26

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:04:20
User entered '31 Jan 2021 11:59'	System	28 Jan 2021 18:00:51

US3342200

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(124)

Generated On: 09 Jun 2021 17:05:26

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:04:20
Data entry locked.	System	30 Jan 2021 11:35:44
User entered 'Day 124'	System	30 Jan 2021 11:35:44

US3342200

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(124)

Generated On: 09 Jun 2021 17:05:26

Select one response below to indicate the intensity of your **JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:04:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2D2D1647-7C35-4DCA-ADA3-8E1DAA921DDC)', Time: '2021-01-31T14:18:45', User OID: 'PatientReportedOutcome (US3342200)', ODM File OID: 'dc468e9f-d603-4ee4-a8ca-5b23f466862a' User entered 'Some interference with activity (2)'	System	31 Jan 2021 20:18:52
	System	31 Jan 2021 20:18:52

US3342200

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(124)

Generated On: 09 Jun 2021 17:05:26

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:04:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2D2D1647-7C35-4DCA-ADA3-8E1DAA921DDC)', Time: '2021-01-31T14:18:48', User OID: 'PatientReportedOutcome (US3342200)', ODM File OID: 'dc468e9f-d603-4ee4-a8ca-5b23f466862a' User entered '31 Jan 2021 14:18'	System	31 Jan 2021 20:18:52
	System	31 Jan 2021 20:18:52

US3342200

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(124)

Generated On: 09 Jun 2021 17:05:26

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:04:20
User entered '31 Jan 2021 12:00'	System	30 Jan 2021 11:35:44

US3342200

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(124)

Generated On: 09 Jun 2021 17:05:26

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:04:20
User entered '01 Feb 2021 11:59'	System	30 Jan 2021 11:35:44

US3342200

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(125)

Generated On: 09 Jun 2021 17:05:26

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:04:20
Data entry locked.	System	31 Jan 2021 15:35:39
User entered 'Day 125'	System	31 Jan 2021 15:35:39

US3342200

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(125)

Generated On: 09 Jun 2021 17:05:26

Select one response below to indicate the intensity of your **JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:04:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2D2D1647-7C35-4DCA-ADA3-8E1DAA921DDC)', Time: '2021-02-01T13:44:50', User OID: 'PatientReportedOutcome (US3342200)', ODM File OID: '10c23d6b-2ad8-4542-ac90-a3cda0ba2863'	System	01 Feb 2021 19:45:48
User entered 'Some interference with activity (2)'	System	01 Feb 2021 19:45:48

US3342200

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(125)

Generated On: 09 Jun 2021 17:05:26

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:04:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2D2D1647-7C35-4DCA-ADA3-8E1DAA921DDC)', Time: '2021-02-01T13:44:52', User OID: 'PatientReportedOutcome (US3342200)', ODM File OID: '10c23d6b-2ad8-4542-ac90-a3cda0ba2863' User entered '01 Feb 2021 13:44'	System	01 Feb 2021 19:45:48
	System	01 Feb 2021 19:45:48

US3342200

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(125)

Generated On: 09 Jun 2021 17:05:26

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:04:20
User entered '01 Feb 2021 12:00'	System	31 Jan 2021 15:35:39

US3342200

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(125)

Generated On: 09 Jun 2021 17:05:26

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:04:20
User entered '02 Feb 2021 11:59'	System	31 Jan 2021 15:35:39

US3342200

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(126)

Generated On: 09 Jun 2021 17:05:26

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:04:20
Data entry locked.	System	31 Jan 2021 20:18:52
User entered 'Day 126'	System	31 Jan 2021 20:18:52

US3342200

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(126)

Generated On: 09 Jun 2021 17:05:26

Select one response below to indicate the intensity of your **JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:04:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2D2D1647-7C35-4DCA-ADA3-8E1DAA921DDC)', Time: '2021-02-02T12:01:20', User OID: 'PatientReportedOutcome (US3342200)', ODM File OID: 'c9c47db2-56d0-4f35-934a-7dc70179e931'	System	02 Feb 2021 18:03:12
User entered 'Some interference with activity (2)'	System	02 Feb 2021 18:03:12

US3342200

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(126)

Generated On: 09 Jun 2021 17:05:26

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:04:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2D2D1647-7C35-4DCA-ADA3-8E1DAA921DDC)', Time: '2021-02-02T12:01:22', User OID: 'PatientReportedOutcome (US3342200)', ODM File OID: 'c9c47db2-56d0-4f35-934a-7dc70179e931' User entered '02 Feb 2021 12:01'	System	02 Feb 2021 18:03:12
	System	02 Feb 2021 18:03:12

US3342200

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(126)

Generated On: 09 Jun 2021 17:05:26

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:04:20
User entered '02 Feb 2021 12:00'	System	31 Jan 2021 20:18:52

US3342200

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(126)

Generated On: 09 Jun 2021 17:05:26

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:04:20
User entered '03 Feb 2021 11:59'	System	31 Jan 2021 20:18:52

US3342200

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(127)

Generated On: 09 Jun 2021 17:05:26

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:04:20
Data entry locked.	System	01 Feb 2021 19:45:48
User entered 'Day 127'	System	01 Feb 2021 19:45:48

US3342200

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(127)

Generated On: 09 Jun 2021 17:05:26

Select one response below to indicate the intensity of your **JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:04:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2D2D1647-7C35-4DCA-ADA3-8E1DAA921DDC)', Time: '2021-02-03T18:10:10', User OID: 'PatientReportedOutcome (US3342200)', ODM File OID: '5f1967c7-4e31-4dca-9d2c-3ea6a970de4e' User entered 'Some interference with activity (2)'	System	04 Feb 2021 00:10:25
	System	04 Feb 2021 00:10:25

US3342200

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(127)

Generated On: 09 Jun 2021 17:05:26

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:04:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2D2D1647-7C35-4DCA-ADA3-8E1DAA921DDC)', Time: '2021-02-03T18:10:13', User OID: 'PatientReportedOutcome (US3342200)', ODM File OID: '5f1967c7-4e31-4dca-9d2c-3ea6a970de4e' User entered '03 Feb 2021 18:10'	System	04 Feb 2021 00:10:25
	System	04 Feb 2021 00:10:25

US3342200

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(127)

Generated On: 09 Jun 2021 17:05:26

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:04:20
User entered '03 Feb 2021 12:00'	System	01 Feb 2021 19:45:48

US3342200

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(127)

Generated On: 09 Jun 2021 17:05:26

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:04:20
User entered '04 Feb 2021 11:59'	System	01 Feb 2021 19:45:48

US3342200

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(128)

Generated On: 09 Jun 2021 17:05:26

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:04:20
Data entry locked.	System	02 Feb 2021 18:03:12
User entered 'Day 128'	System	02 Feb 2021 18:03:12

US3342200

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(128)

Generated On: 09 Jun 2021 17:05:26

Select one response below to indicate the intensity of your **JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:04:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2D2D1647-7C35-4DCA-ADA3-8E1DAA921DDC)', Time: '2021-02-04T12:02:10', User OID: 'PatientReportedOutcome (US3342200)', ODM File OID: 'dfd2a0a9-6c86-44df-9b11-fc569ae147c1' User entered 'Some interference with activity (2)'	System	04 Feb 2021 18:04:09

US3342200

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(128)

Generated On: 09 Jun 2021 17:05:26

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:04:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2D2D1647-7C35-4DCA-ADA3-8E1DAA921DDC)', Time: '2021-02-04T12:02:14', User OID: 'PatientReportedOutcome (US3342200)', ODM File OID: 'dfd2a0a9-6c86-44df-9b11-fc569ae147c1' User entered '04 Feb 2021 12:02'	System	04 Feb 2021 18:04:09
	System	04 Feb 2021 18:04:09

US3342200

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(128)

Generated On: 09 Jun 2021 17:05:26

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:04:20
User entered '04 Feb 2021 12:00'	System	02 Feb 2021 18:03:12

US3342200

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(128)

Generated On: 09 Jun 2021 17:05:26

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:04:20
User entered '05 Feb 2021 11:59'	System	02 Feb 2021 18:03:12

US3342200

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(129)

Generated On: 09 Jun 2021 17:05:26

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:04:20
Data entry locked.	System	04 Feb 2021 00:10:25
User entered 'Day 129'	System	04 Feb 2021 00:10:25

US3342200

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(129)

Generated On: 09 Jun 2021 17:05:26

Select one response below to indicate the intensity of your **JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:04:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2D2D1647-7C35-4DCA-ADA3-8E1DAA921DDC)', Time: '2021-02-05T13:10:53', User OID: 'PatientReportedOutcome (US3342200)', ODM File OID: '5db1c080-69b0-454f-8424-6ad2d7ab8d4e' User entered 'Some interference with activity (2)'	System	05 Feb 2021 19:10:59
	System	05 Feb 2021 19:10:59

US3342200

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(129)

Generated On: 09 Jun 2021 17:05:26

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:04:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2D2D1647-7C35-4DCA-ADA3-8E1DAA921DDC)', Time: '2021-02-05T13:10:55', User OID: 'PatientReportedOutcome (US3342200)', ODM File OID: '5db1c080-69b0-454f-8424-6ad2d7ab8d4e' User entered '05 Feb 2021 13:10'	System	05 Feb 2021 19:10:59
	System	05 Feb 2021 19:10:59

US3342200

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(129)

Generated On: 09 Jun 2021 17:05:26

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:04:20
User entered '05 Feb 2021 12:00'	System	04 Feb 2021 00:10:25

US3342200

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(129)

Generated On: 09 Jun 2021 17:05:26

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:04:20
User entered '06 Feb 2021 11:59'	System	04 Feb 2021 00:10:25

US3342200

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(130)

Generated On: 09 Jun 2021 17:05:26

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:04:20
Data entry locked.	System	04 Feb 2021 18:04:09
User entered 'Day 130'	System	04 Feb 2021 18:04:09

US3342200

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(130)

Generated On: 09 Jun 2021 17:05:26

Select one response below to indicate the intensity of your **JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:04:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2D2D1647-7C35-4DCA-ADA3-8E1DAA921DDC)', Time: '2021-02-06T21:15:46', User OID: 'PatientReportedOutcome (US3342200)', ODM File OID: 'a06554ac-ea93-4df3-985d-b3b7fa46fd13'	System	07 Feb 2021 03:16:05
User entered 'Some interference with activity (2)'	System	07 Feb 2021 03:16:05

US3342200

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(130)

Generated On: 09 Jun 2021 17:05:26

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:04:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2D2D1647-7C35-4DCA-ADA3-8E1DAA921DDC)', Time: '2021-02-06T21:15:50', User OID: 'PatientReportedOutcome (US3342200)', ODM File OID: 'a06554ac-ea93-4df3-985d-b3b7fa46fd13' User entered '06 Feb 2021 21:15'	System	07 Feb 2021 03:16:05
	System	07 Feb 2021 03:16:05

US3342200

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(130)

Generated On: 09 Jun 2021 17:05:26

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:04:20
User entered '06 Feb 2021 12:00'	System	04 Feb 2021 18:04:09

US3342200

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(130)

Generated On: 09 Jun 2021 17:05:26

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:04:20
User entered '07 Feb 2021 11:59'	System	04 Feb 2021 18:04:09

US3342200

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(131)

Generated On: 09 Jun 2021 17:05:26

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:04:20
Data entry locked.	System	05 Feb 2021 19:10:59
User entered 'Day 131'	System	05 Feb 2021 19:10:59

US3342200

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(131)

Generated On: 09 Jun 2021 17:05:26

Select one response below to indicate the intensity of your **JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:04:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2D2D1647-7C35-4DCA-ADA3-8E1DAA921DDC)', Time: '2021-02-08T05:59:58', User OID: 'PatientReportedOutcome (US3342200)', ODM File OID: 'dc08174f-5927-40fe-9fdd-41d0615379b3'	System	08 Feb 2021 12:00:06
User entered 'Some interference with activity (2)'	System	08 Feb 2021 12:00:06

US3342200

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(131)

Generated On: 09 Jun 2021 17:05:26

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:04:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2D2D1647-7C35-4DCA-ADA3-8E1DAA921DDC)', Time: '2021-02-08T06:00:01', User OID: 'PatientReportedOutcome (US3342200)', ODM File OID: 'dc08174f-5927-40fe-9fdd-41d0615379b3' User entered '08 Feb 2021 06:00'	System	08 Feb 2021 12:00:06
	System	08 Feb 2021 12:00:06

US3342200

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(131)

Generated On: 09 Jun 2021 17:05:26

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:04:20
User entered '07 Feb 2021 12:00'	System	05 Feb 2021 19:10:59

US3342200

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(131)

Generated On: 09 Jun 2021 17:05:26

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:04:20
User entered '08 Feb 2021 11:59'	System	05 Feb 2021 19:10:59

US3342200

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(132)

Generated On: 09 Jun 2021 17:05:26

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:04:20
Data entry locked.	System	07 Feb 2021 03:16:05
User entered 'Day 132'	System	07 Feb 2021 03:16:05

US3342200

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(132)

Generated On: 09 Jun 2021 17:05:26

Select one response below to indicate the intensity of your **JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:04:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2D2D1647-7C35-4DCA-ADA3-8E1DAA921DDC)', Time: '2021-02-08T13:09:27', User OID: 'PatientReportedOutcome (US3342200)', ODM File OID: '9c21f226-b4f0-4e67-b0c4-3a2aba780323' User entered 'No interference with activity (1)'	System	08 Feb 2021 19:09:36
	System	08 Feb 2021 19:09:36

US3342200

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(132)

Generated On: 09 Jun 2021 17:05:26

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:04:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2D2D1647-7C35-4DCA-ADA3-8E1DAA921DDC)', Time: '2021-02-08T13:09:30', User OID: 'PatientReportedOutcome (US3342200)', ODM File OID: '9c21f226-b4f0-4e67-b0c4-3a2aba780323' User entered '08 Feb 2021 13:09'	System	08 Feb 2021 19:09:36
	System	08 Feb 2021 19:09:36

US3342200

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(132)

Generated On: 09 Jun 2021 17:05:26

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:04:20
User entered '08 Feb 2021 12:00'	System	07 Feb 2021 03:16:05

US3342200

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(132)

Generated On: 09 Jun 2021 17:05:26

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:04:20
User entered '09 Feb 2021 11:59'	System	07 Feb 2021 03:16:05

US3342200

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(133)

Generated On: 09 Jun 2021 17:05:26

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:04:20
Data entry locked.	System	08 Feb 2021 12:00:06
User entered 'Day 133'	System	08 Feb 2021 12:00:06

US3342200

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(133)

Generated On: 09 Jun 2021 17:05:26

Select one response below to indicate the intensity of your **JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:04:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2D2D1647-7C35-4DCA-ADA3-8E1DAA921DDC)', Time: '2021-02-09T16:43:12', User OID: 'PatientReportedOutcome (US3342200)', ODM File OID: '3a466f31-4a19-4276-9945-3ce1db730fc8' User entered 'Some interference with activity (2)'	System	09 Feb 2021 22:43:18
	System	09 Feb 2021 22:43:18

US3342200

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(133)

Generated On: 09 Jun 2021 17:05:26

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:04:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2D2D1647-7C35-4DCA-ADA3-8E1DAA921DDC)', Time: '2021-02-09T16:43:15', User OID: 'PatientReportedOutcome (US3342200)', ODM File OID: '3a466f31-4a19-4276-9945-3ce1db730fc8' User entered '09 Feb 2021 16:43'	System	09 Feb 2021 22:43:18
	System	09 Feb 2021 22:43:18

US3342200

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(133)

Generated On: 09 Jun 2021 17:05:26

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:04:20
User entered '09 Feb 2021 12:00'	System	08 Feb 2021 12:00:06

US3342200

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(133)

Generated On: 09 Jun 2021 17:05:26

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:04:20
User entered '10 Feb 2021 11:59'	System	08 Feb 2021 12:00:06

US3342200

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(134)

Generated On: 09 Jun 2021 17:05:26

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:04:20
Data entry locked.	System	08 Feb 2021 19:09:36
User entered 'Day 134'	System	08 Feb 2021 19:09:36

US3342200

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(134)

Generated On: 09 Jun 2021 17:05:26

Select one response below to indicate the intensity of your **JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:04:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2D2D1647-7C35-4DCA-ADA3-8E1DAA921DDC)', Time: '2021-02-11T03:47:47', User OID: 'PatientReportedOutcome (US3342200)', ODM File OID: 'a9717e25-71c3-4d6d-a45a-cb92dcf71e0e' User entered 'Some interference with activity (2)'	System	11 Feb 2021 09:47:57
	System	11 Feb 2021 09:47:57

US3342200

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(134)

Generated On: 09 Jun 2021 17:05:26

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:04:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2D2D1647-7C35-4DCA-ADA3-8E1DAA921DDC)', Time: '2021-02-11T03:47:50', User OID: 'PatientReportedOutcome (US3342200)', ODM File OID: 'a9717e25-71c3-4d6d-a45a-cb92dcf71e0e' User entered '11 Feb 2021 03:47'	System	11 Feb 2021 09:47:57
	System	11 Feb 2021 09:47:57

US3342200

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(134)

Generated On: 09 Jun 2021 17:05:26

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:04:20
User entered '10 Feb 2021 12:00'	System	08 Feb 2021 19:09:36

US3342200

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(134)

Generated On: 09 Jun 2021 17:05:26

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:04:20
User entered '11 Feb 2021 11:59'	System	08 Feb 2021 19:09:36

US3342200

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(135)

Generated On: 09 Jun 2021 17:05:26

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:04:20
Data entry locked.	System	09 Feb 2021 22:43:18
User entered 'Day 135'	System	09 Feb 2021 22:43:18

US3342200

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(135)

Generated On: 09 Jun 2021 17:05:26

Select one response below to indicate the intensity of your **JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:04:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2D2D1647-7C35-4DCA-ADA3-8E1DAA921DDC)', Time: '2021-02-11T12:37:07', User OID: 'PatientReportedOutcome (US3342200)', ODM File OID: '25c0cc7e-382b-48c5-9250-07c1936c1233'	System	11 Feb 2021 18:37:14
User entered 'Some interference with activity (2)'	System	11 Feb 2021 18:37:14

US3342200

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(135)

Generated On: 09 Jun 2021 17:05:26

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:04:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2D2D1647-7C35-4DCA-ADA3-8E1DAA921DDC)', Time: '2021-02-11T12:37:11', User OID: 'PatientReportedOutcome (US3342200)', ODM File OID: '25c0cc7e-382b-48c5-9250-07c1936c1233' User entered '11 Feb 2021 12:37'	System	11 Feb 2021 18:37:14
	System	11 Feb 2021 18:37:14

US3342200

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(135)

Generated On: 09 Jun 2021 17:05:26

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:04:20
User entered '11 Feb 2021 12:00'	System	09 Feb 2021 22:43:18

US3342200

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(135)

Generated On: 09 Jun 2021 17:05:26

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:04:20
User entered '12 Feb 2021 11:59'	System	09 Feb 2021 22:43:18

US3342200

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(136)

Generated On: 09 Jun 2021 17:05:26

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:04:20
Data entry locked.	System	11 Feb 2021 09:47:57
User entered 'Day 136'	System	11 Feb 2021 09:47:57

US3342200

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(136)

Generated On: 09 Jun 2021 17:05:26

Select one response below to indicate the intensity of your **JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:04:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2D2D1647-7C35-4DCA-ADA3-8E1DAA921DDC)', Time: '2021-02-12T12:56:52', User OID: 'PatientReportedOutcome (US3342200)', ODM File OID: '1a0de5c1-af6e-4080-a008-b5ade36c9a8f' User entered 'Some interference with activity (2)'	System	12 Feb 2021 18:56:58
	System	12 Feb 2021 18:56:58

US3342200

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(136)

Generated On: 09 Jun 2021 17:05:26

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:04:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2D2D1647-7C35-4DCA-ADA3-8E1DAA921DDC)', Time: '2021-02-12T12:56:55', User OID: 'PatientReportedOutcome (US3342200)', ODM File OID: '1a0de5c1-af6e-4080-a008-b5ade36c9a8f' User entered '12 Feb 2021 12:56'	System	12 Feb 2021 18:56:58
	System	12 Feb 2021 18:56:58

US3342200

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(136)

Generated On: 09 Jun 2021 17:05:26

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:04:20
User entered '12 Feb 2021 12:00'	System	11 Feb 2021 09:47:57

US3342200

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(136)

Generated On: 09 Jun 2021 17:05:26

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:04:20
User entered '13 Feb 2021 11:59'	System	11 Feb 2021 09:47:57

US3342200

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(137)

Generated On: 09 Jun 2021 17:05:26

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:04:20
Data entry locked.	System	11 Feb 2021 18:37:14
User entered 'Day 137'	System	11 Feb 2021 18:37:14

US3342200

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(137)

Generated On: 09 Jun 2021 17:05:26

Select one response below to indicate the intensity of your **JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:04:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2D2D1647-7C35-4DCA-ADA3-8E1DAA921DDC)', Time: '2021-02-13T12:28:39', User OID: 'PatientReportedOutcome (US3342200)', ODM File OID: '830bb9a2-c48d-4a79-87fc-696d2a0d1852'	System	13 Feb 2021 18:28:46
User entered 'Some interference with activity (2)'	System	13 Feb 2021 18:28:46

US3342200

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(137)

Generated On: 09 Jun 2021 17:05:26

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:04:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2D2D1647-7C35-4DCA-ADA3-8E1DAA921DDC)', Time: '2021-02-13T12:28:42', User OID: 'PatientReportedOutcome (US3342200)', ODM File OID: '830bb9a2-c48d-4a79-87fc-696d2a0d1852' User entered '13 Feb 2021 12:28'	System	13 Feb 2021 18:28:46
	System	13 Feb 2021 18:28:46

US3342200

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(137)

Generated On: 09 Jun 2021 17:05:26

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:04:20
User entered '13 Feb 2021 12:00'	System	11 Feb 2021 18:37:14

US3342200

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(137)

Generated On: 09 Jun 2021 17:05:26

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:04:20
User entered '14 Feb 2021 11:59'	System	11 Feb 2021 18:37:14

US3342200

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(138)

Generated On: 09 Jun 2021 17:05:26

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:04:20
Data entry locked.	System	12 Feb 2021 18:56:58
User entered 'Day 138'	System	12 Feb 2021 18:56:58

US3342200

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(138)

Generated On: 09 Jun 2021 17:05:26

Select one response below to indicate the intensity of your **JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:04:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2D2D1647-7C35-4DCA-ADA3-8E1DAA921DDC)', Time: '2021-02-14T13:07:59', User OID: 'PatientReportedOutcome (US3342200)', ODM File OID: '845a58f9-33c6-4cc3-89a8-7d640eefa432'	System	14 Feb 2021 19:08:06
User entered 'Some interference with activity (2)'	System	14 Feb 2021 19:08:06

US3342200

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(138)

Generated On: 09 Jun 2021 17:05:26

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:04:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2D2D1647-7C35-4DCA-ADA3-8E1DAA921DDC)', Time: '2021-02-14T13:08:02', User OID: 'PatientReportedOutcome (US3342200)', ODM File OID: '845a58f9-33c6-4cc3-89a8-7d640eefa432' User entered '14 Feb 2021 13:08'	System	14 Feb 2021 19:08:06
	System	14 Feb 2021 19:08:06

US3342200

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(138)

Generated On: 09 Jun 2021 17:05:26

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:04:20
User entered '14 Feb 2021 12:00'	System	12 Feb 2021 18:56:58

US3342200

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(138)

Generated On: 09 Jun 2021 17:05:26

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:04:20
User entered '15 Feb 2021 11:59'	System	12 Feb 2021 18:56:58

US3342200

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(139)

Generated On: 09 Jun 2021 17:05:26

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:04:20
Data entry locked.	System	13 Feb 2021 18:28:46
User entered 'Day 139'	System	13 Feb 2021 18:28:46

US3342200

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(139)

Generated On: 09 Jun 2021 17:05:26

Select one response below to indicate the intensity of your **JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:04:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2D2D1647-7C35-4DCA-ADA3-8E1DAA921DDC)', Time: '2021-02-15T12:00:41', User OID: 'PatientReportedOutcome (US3342200)', ODM File OID: 'ee3e85ee-f775-4567-b13f-b6c94ee5b4cf' User entered 'Some interference with activity (2)'	System	15 Feb 2021 18:02:31
	System	15 Feb 2021 18:02:31

US3342200

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(139)

Generated On: 09 Jun 2021 17:05:26

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:04:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2D2D1647-7C35-4DCA-ADA3-8E1DAA921DDC)', Time: '2021-02-15T12:00:43', User OID: 'PatientReportedOutcome (US3342200)', ODM File OID: 'ee3e85ee-f775-4567-b13f-b6c94ee5b4cf' User entered '15 Feb 2021 12:00'	System	15 Feb 2021 18:02:31
	System	15 Feb 2021 18:02:31

US3342200

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(139)

Generated On: 09 Jun 2021 17:05:26

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:04:20
User entered '15 Feb 2021 12:00'	System	13 Feb 2021 18:28:46

US3342200

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(139)

Generated On: 09 Jun 2021 17:05:26

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:04:20
User entered '16 Feb 2021 11:59'	System	13 Feb 2021 18:28:46

US3342200

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(140)

Generated On: 09 Jun 2021 17:05:26

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:04:20
Data entry locked.	System	14 Feb 2021 19:08:06
User entered 'Day 140'	System	14 Feb 2021 19:08:06

US3342200

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(140)

Generated On: 09 Jun 2021 17:05:26

Select one response below to indicate the intensity of your **JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:04:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2D2D1647-7C35-4DCA-ADA3-8E1DAA921DDC)', Time: '2021-02-16T18:19:00', User OID: 'PatientReportedOutcome (US3342200)', ODM File OID: 'e0ba1290-e057-4d12-a829-1f0ce9461fe7' User entered 'Some interference with activity (2)'	System	17 Feb 2021 00:20:09
	System	17 Feb 2021 00:20:09

US3342200

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(140)

Generated On: 09 Jun 2021 17:05:26

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:04:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2D2D1647-7C35-4DCA-ADA3-8E1DAA921DDC)', Time: '2021-02-16T18:19:02', User OID: 'PatientReportedOutcome (US3342200)', ODM File OID: 'e0ba1290-e057-4d12-a829-1f0ce9461fe7' User entered '16 Feb 2021 18:19'	System	17 Feb 2021 00:20:09
	System	17 Feb 2021 00:20:09

US3342200

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(140)

Generated On: 09 Jun 2021 17:05:26

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:04:20
User entered '16 Feb 2021 12:00'	System	14 Feb 2021 19:08:06

US3342200

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(140)

Generated On: 09 Jun 2021 17:05:26

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:04:20
User entered '17 Feb 2021 11:59'	System	14 Feb 2021 19:08:06

US3342200

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(141)

Generated On: 09 Jun 2021 17:05:26

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:04:20
Data entry locked.	System	15 Feb 2021 18:02:31
User entered 'Day 141'	System	15 Feb 2021 18:02:31

US3342200

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(141)

Generated On: 09 Jun 2021 17:05:26

Select one response below to indicate the intensity of your **JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:04:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2D2D1647-7C35-4DCA-ADA3-8E1DAA921DDC)', Time: '2021-02-17T12:34:21', User OID: 'PatientReportedOutcome (US3342200)', ODM File OID: 'ab4878a1-3ec5-4172-9a94-e0732bb809c5' User entered 'Some interference with activity (2)'	System	17 Feb 2021 18:34:28
	System	17 Feb 2021 18:34:28

US3342200

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(141)

Generated On: 09 Jun 2021 17:05:26

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:04:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2D2D1647-7C35-4DCA-ADA3-8E1DAA921DDC)', Time: '2021-02-17T12:34:25', User OID: 'PatientReportedOutcome (US3342200)', ODM File OID: 'ab4878a1-3ec5-4172-9a94-e0732bb809c5' User entered '17 Feb 2021 12:34'	System	17 Feb 2021 18:34:28
	System	17 Feb 2021 18:34:28

US3342200

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(141)

Generated On: 09 Jun 2021 17:05:26

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:04:20
User entered '17 Feb 2021 12:00'	System	15 Feb 2021 18:02:31

US3342200

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(141)

Generated On: 09 Jun 2021 17:05:26

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:04:20
User entered '18 Feb 2021 11:59'	System	15 Feb 2021 18:02:31

US3342200

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(142)

Generated On: 09 Jun 2021 17:05:26

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:04:20
Data entry locked.	System	17 Feb 2021 00:20:09
User entered 'Day 142'	System	17 Feb 2021 00:20:09

US3342200

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(142)

Generated On: 09 Jun 2021 17:05:26

Select one response below to indicate the intensity of your **JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:04:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2D2D1647-7C35-4DCA-ADA3-8E1DAA921DDC)', Time: '2021-02-18T12:43:14', User OID: 'PatientReportedOutcome (US3342200)', ODM File OID: '927069eb-8447-46ae-a170-ddf8ade9a9d0' User entered 'Some interference with activity (2)'	System	18 Feb 2021 18:43:20
	System	18 Feb 2021 18:43:20

US3342200

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(142)

Generated On: 09 Jun 2021 17:05:26

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:04:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2D2D1647-7C35-4DCA-ADA3-8E1DAA921DDC)', Time: '2021-02-18T12:43:16', User OID: 'PatientReportedOutcome (US3342200)', ODM File OID: '927069eb-8447-46ae-a170-ddf8ade9a9d0' User entered '18 Feb 2021 12:43'	System	18 Feb 2021 18:43:20
	System	18 Feb 2021 18:43:20

US3342200

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(142)

Generated On: 09 Jun 2021 17:05:26

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:04:20
User entered '18 Feb 2021 12:00'	System	17 Feb 2021 00:20:09

US3342200

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(142)

Generated On: 09 Jun 2021 17:05:26

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:04:20
User entered '19 Feb 2021 11:59'	System	17 Feb 2021 00:20:09

US3342200

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(143)

Generated On: 09 Jun 2021 17:05:26

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:04:20
Data entry locked.	System	17 Feb 2021 18:34:28
User entered 'Day 143'	System	17 Feb 2021 18:34:28

US3342200

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(143)

Generated On: 09 Jun 2021 17:05:26

Select one response below to indicate the intensity of your **JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:04:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2D2D1647-7C35-4DCA-ADA3-8E1DAA921DDC)', Time: '2021-02-19T16:11:14', User OID: 'PatientReportedOutcome (US3342200)', ODM File OID: '0615ae85-952e-42ec-a257-e254131e8ecc' User entered 'Some interference with activity (2)'	System	19 Feb 2021 22:11:19
	System	19 Feb 2021 22:11:19

US3342200

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(143)

Generated On: 09 Jun 2021 17:05:26

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:04:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2D2D1647-7C35-4DCA-ADA3-8E1DAA921DDC)', Time: '2021-02-19T16:11:16', User OID: 'PatientReportedOutcome (US3342200)', ODM File OID: '0615ae85-952e-42ec-a257-e254131e8ecc' User entered '19 Feb 2021 16:11'	System	19 Feb 2021 22:11:19
	System	19 Feb 2021 22:11:19

US3342200

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(143)

Generated On: 09 Jun 2021 17:05:26

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:04:20
User entered '19 Feb 2021 12:00'	System	17 Feb 2021 18:34:28

US3342200

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(143)

Generated On: 09 Jun 2021 17:05:26

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:04:20
User entered '20 Feb 2021 11:59'	System	17 Feb 2021 18:34:28

US3342200

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(144)

Generated On: 09 Jun 2021 17:05:26

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:04:20
Data entry locked.	System	18 Feb 2021 18:43:20
User entered 'Day 144'	System	18 Feb 2021 18:43:20

US3342200

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(144)

Generated On: 09 Jun 2021 17:05:26

Select one response below to indicate the intensity of your **JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:04:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2D2D1647-7C35-4DCA-ADA3-8E1DAA921DDC)', Time: '2021-02-20T18:18:55', User OID: 'PatientReportedOutcome (US3342200)', ODM File OID: 'f4ae7e3e-6697-461b-9e5a-3f1cab011471' User entered 'Some interference with activity (2)'	System	21 Feb 2021 00:19:08

US3342200

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(144)

Generated On: 09 Jun 2021 17:05:26

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:04:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2D2D1647-7C35-4DCA-ADA3-8E1DAA921DDC)', Time: '2021-02-20T18:18:59', User OID: 'PatientReportedOutcome (US3342200)', ODM File OID: 'f4ae7e3e-6697-461b-9e5a-3f1cab011471' User entered '20 Feb 2021 18:18'	System	21 Feb 2021 00:19:08
	System	21 Feb 2021 00:19:08

US3342200

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(144)

Generated On: 09 Jun 2021 17:05:26

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:04:20
User entered '20 Feb 2021 12:00'	System	18 Feb 2021 18:43:20

US3342200

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(144)

Generated On: 09 Jun 2021 17:05:26

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:04:20
User entered '21 Feb 2021 11:59'	System	18 Feb 2021 18:43:20

US3342200

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(145)

Generated On: 09 Jun 2021 17:05:26

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:04:20
Data entry locked.	System	19 Feb 2021 22:11:19
User entered 'Day 145'	System	19 Feb 2021 22:11:19

US3342200

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(145)

Generated On: 09 Jun 2021 17:05:26

Select one response below to indicate the intensity of your **JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:04:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2D2D1647-7C35-4DCA-ADA3-8E1DAA921DDC)', Time: '2021-02-21T12:00:25', User OID: 'PatientReportedOutcome (US3342200)', ODM File OID: 'c90c7758-19b5-40a1-bd98-db8b9d66e28b' User entered 'Some interference with activity (2)'	System	21 Feb 2021 18:01:12
	System	21 Feb 2021 18:01:12

US3342200

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(145)

Generated On: 09 Jun 2021 17:05:26

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:04:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2D2D1647-7C35-4DCA-ADA3-8E1DAA921DDC)', Time: '2021-02-21T12:00:28', User OID: 'PatientReportedOutcome (US3342200)', ODM File OID: 'c90c7758-19b5-40a1-bd98-db8b9d66e28b' User entered '21 Feb 2021 12:00'	System	21 Feb 2021 18:01:12
	System	21 Feb 2021 18:01:12

US3342200

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(145)

Generated On: 09 Jun 2021 17:05:26

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:04:20
User entered '21 Feb 2021 12:00'	System	19 Feb 2021 22:11:19

US3342200

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(145)

Generated On: 09 Jun 2021 17:05:26

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:04:20
User entered '22 Feb 2021 11:59'	System	19 Feb 2021 22:11:19

US3342200

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(146)

Generated On: 09 Jun 2021 17:05:26

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:04:20
Data entry locked.	System	21 Feb 2021 00:19:08
User entered 'Day 146'	System	21 Feb 2021 00:19:08

US3342200

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(146)

Generated On: 09 Jun 2021 17:05:26

Select one response below to indicate the intensity of your **JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:04:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2D2D1647-7C35-4DCA-ADA3-8E1DAA921DDC)', Time: '2021-02-22T12:02:02', User OID: 'PatientReportedOutcome (US3342200)', ODM File OID: '0990260b-8e15-4d22-bdca-586fbcf9d551' User entered 'Some interference with activity (2)'	System	22 Feb 2021 18:06:57
	System	22 Feb 2021 18:06:57

US3342200

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(146)

Generated On: 09 Jun 2021 17:05:26

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:04:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2D2D1647-7C35-4DCA-ADA3-8E1DAA921DDC)', Time: '2021-02-22T12:02:06', User OID: 'PatientReportedOutcome (US3342200)', ODM File OID: '0990260b-8e15-4d22-bdca-586fbcf9d551' User entered '22 Feb 2021 12:02'	System	22 Feb 2021 18:06:57
	System	22 Feb 2021 18:06:57

US3342200

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(146)

Generated On: 09 Jun 2021 17:05:26

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:04:20
User entered '22 Feb 2021 12:00'	System	21 Feb 2021 00:19:08

US3342200

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(146)

Generated On: 09 Jun 2021 17:05:26

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:04:20
User entered '23 Feb 2021 11:59'	System	21 Feb 2021 00:19:08

US3342200

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(147)

Generated On: 09 Jun 2021 17:05:26

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:04:20
Data entry locked.	System	21 Feb 2021 18:01:12
User entered 'Day 147'	System	21 Feb 2021 18:01:12

US3342200

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(147)

Generated On: 09 Jun 2021 17:05:26

Select one response below to indicate the intensity of your **JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:04:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2D2D1647-7C35-4DCA-ADA3-8E1DAA921DDC)', Time: '2021-02-23T12:58:17-06:00', User OID: 'PatientReportedOutcome (US3342200)', ODM File OID: '70b31a80-ed50-41a3-8ffb-276cd5468080' User entered 'Some interference with activity (2)'	System	23 Feb 2021 18:58:26

US3342200

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(147)

Generated On: 09 Jun 2021 17:05:26

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:04:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2D2D1647-7C35-4DCA-ADA3-8E1DAA921DDC)', Time: '2021-02-23T12:58:22-06:00', User OID: 'PatientReportedOutcome (US3342200)', ODM File OID: '70b31a80-ed50-41a3-8ffb-276cd5468080' User entered '23 Feb 2021 18:58'	System	23 Feb 2021 18:58:26
	System	23 Feb 2021 18:58:26

US3342200

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(147)

Generated On: 09 Jun 2021 17:05:26

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:04:20
User entered '23 Feb 2021 12:00'	System	21 Feb 2021 18:01:12

US3342200

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(147)

Generated On: 09 Jun 2021 17:05:26

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:04:20
User entered '24 Feb 2021 11:59'	System	21 Feb 2021 18:01:12

US3342200

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(148)

Generated On: 09 Jun 2021 17:05:26

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:04:20
Data entry locked.	System	22 Feb 2021 18:06:57
User entered 'Day 148'	System	22 Feb 2021 18:06:57

US3342200

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(148)

Generated On: 09 Jun 2021 17:05:26

Select one response below to indicate the intensity of your **JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:04:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2D2D1647-7C35-4DCA-ADA3-8E1DAA921DDC)', Time: '2021-02-24T12:01:26-06:00', User OID: 'PatientReportedOutcome (US3342200)', ODM File OID: 'd18aaf51-6b10-4373-8bca-5f4f62009a5f' User entered 'Significant; prevents daily activity (3)'	System	24 Feb 2021 18:04:01

US3342200

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(148)

Generated On: 09 Jun 2021 17:05:26

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:04:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2D2D1647-7C35-4DCA-ADA3-8E1DAA921DDC)', Time: '2021-02-24T12:01:29-06:00', User OID: 'PatientReportedOutcome (US3342200)', ODM File OID: 'd18aaf51-6b10-4373-8bca-5f4f62009a5f' User entered '24 Feb 2021 18:01'	System	24 Feb 2021 18:04:01
	System	24 Feb 2021 18:04:01

US3342200

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(148)

Generated On: 09 Jun 2021 17:05:26

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:04:20
User entered '24 Feb 2021 12:00'	System	22 Feb 2021 18:06:57

US3342200

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(148)

Generated On: 09 Jun 2021 17:05:26

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:04:20
User entered '25 Feb 2021 11:59'	System	22 Feb 2021 18:06:57

US3342200

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(149)

Generated On: 09 Jun 2021 17:05:26

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:04:20
Data entry locked.	System	23 Feb 2021 18:58:26
User entered 'Day 149'	System	23 Feb 2021 18:58:26

US3342200

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(149)

Generated On: 09 Jun 2021 17:05:26

Select one response below to indicate the intensity of your **JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:04:20

US3342200

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(149)

Generated On: 09 Jun 2021 17:05:26

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:04:20

US3342200

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(149)

Generated On: 09 Jun 2021 17:05:26

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:04:20
User entered '25 Feb 2021 12:00'	System	23 Feb 2021 18:58:26

US3342200

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(149)

Generated On: 09 Jun 2021 17:05:26

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:04:20
User entered '26 Feb 2021 11:59'	System	23 Feb 2021 18:58:26

US3342200

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(150)

Generated On: 09 Jun 2021 17:05:26

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:04:20
Data entry locked.	System	24 Feb 2021 18:04:01
User entered 'Day 150'	System	24 Feb 2021 18:04:01

US3342200

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(150)

Generated On: 09 Jun 2021 17:05:26

Select one response below to indicate the intensity of your **JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:04:20

US3342200

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(150)

Generated On: 09 Jun 2021 17:05:26

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:04:20

US3342200

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(150)

Generated On: 09 Jun 2021 17:05:26

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:04:20
User entered '26 Feb 2021 12:00'	System	24 Feb 2021 18:04:01

US3342200

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(150)

Generated On: 09 Jun 2021 17:05:26

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:04:20
User entered '27 Feb 2021 11:59'	System	24 Feb 2021 18:04:01

US3342200

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(8)

Generated On: 09 Jun 2021 17:05:26

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:04:20
Data entry locked.	System	06 Oct 2020 07:37:46
User entered 'Day 8'	System	06 Oct 2020 07:37:46

US3342200

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(8)

Generated On: 09 Jun 2021 17:05:26

Did you receive any **MEDICAL ATTENTION** (doctor visit, other) for any illness or symptoms?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:04:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2D2D1647-7C35-4DCA-ADA3-8E1DAA921DDC)', Time: '2020-10-07T16:49:00', User OID: 'PatientReportedOutcome (US3342200)', ODM File OID: 'da6dad4-45e4-4da5-985d-579372c606af' User entered 'No (N)'	System	07 Oct 2020 21:49:05
	System	07 Oct 2020 21:49:05

US3342200

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(8)

Generated On: 09 Jun 2021 17:05:26

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:04:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2D2D1647-7C35-4DCA-ADA3-8E1DAA921DDC)', Time: '2020-10-07T16:49:03', User OID: 'PatientReportedOutcome (US3342200)', ODM File OID: 'da6dad4-45e4-4da5-985d-579372c606af' User entered '07 Oct 2020 16:49'	System	07 Oct 2020 21:49:05
	System	07 Oct 2020 21:49:05

US3342200

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(8)

Generated On: 09 Jun 2021 17:05:26

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:04:20
User entered '07 Oct 2020 12:00'	System	06 Oct 2020 07:37:46

US3342200

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(8)

Generated On: 09 Jun 2021 17:05:26

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:04:20
User entered '08 Oct 2020 11:59'	System	06 Oct 2020 07:37:46

US3342200

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(9)

Generated On: 09 Jun 2021 17:05:26

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:04:20
Data entry locked.	System	07 Oct 2020 09:30:27
User entered 'Day 9'	System	07 Oct 2020 09:30:27

US3342200

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(9)

Generated On: 09 Jun 2021 17:05:26

Did you receive any **MEDICAL ATTENTION** (doctor visit, other) for any illness or symptoms?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:04:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2D2D1647-7C35-4DCA-ADA3-8E1DAA921DDC)', Time: '2020-10-08T12:00:39', User OID: 'PatientReportedOutcome (US3342200)', ODM File OID: '3f706fe5-5ba8-467d-b383-8d645024f97d' User entered 'No (N)'	System	08 Oct 2020 17:01:08
	System	08 Oct 2020 17:01:08

US3342200

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(9)

Generated On: 09 Jun 2021 17:05:26

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:04:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2D2D1647-7C35-4DCA-ADA3-8E1DAA921DDC)', Time: '2020-10-08T12:00:42', User OID: 'PatientReportedOutcome (US3342200)', ODM File OID: '3f706fe5-5ba8-467d-b383-8d645024f97d' User entered '08 Oct 2020 12:00'	System	08 Oct 2020 17:01:08
	System	08 Oct 2020 17:01:08

US3342200

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(9)

Generated On: 09 Jun 2021 17:05:26

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:04:20
User entered '08 Oct 2020 12:00'	System	07 Oct 2020 09:30:27

US3342200

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(9)

Generated On: 09 Jun 2021 17:05:26

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:04:20
User entered '09 Oct 2020 11:59'	System	07 Oct 2020 09:30:27

US3342200

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(10)

Generated On: 09 Jun 2021 17:05:26

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:04:20
Data entry locked.	System	07 Oct 2020 21:48:31
User entered 'Day 10'	System	07 Oct 2020 21:48:31

US3342200

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(10)

Generated On: 09 Jun 2021 17:05:26

Did you receive any **MEDICAL ATTENTION** (doctor visit, other) for any illness or symptoms?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:04:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2D2D1647-7C35-4DCA-ADA3-8E1DAA921DDC)', Time: '2020-10-09T12:15:25', User OID: 'PatientReportedOutcome (US3342200)', ODM File OID: '75222927-1e4d-423a-ab77-a0fd504d9ef8' User entered 'No (N)'	System	09 Oct 2020 17:15:33
	System	09 Oct 2020 17:15:33

US3342200

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(10)

Generated On: 09 Jun 2021 17:05:26

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:04:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2D2D1647-7C35-4DCA-ADA3-8E1DAA921DDC)', Time: '2020-10-09T12:15:29', User OID: 'PatientReportedOutcome (US3342200)', ODM File OID: '75222927-1e4d-423a-ab77-a0fd504d9ef8' User entered '09 Oct 2020 12:15'	System	09 Oct 2020 17:15:33
	System	09 Oct 2020 17:15:33

US3342200

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(10)

Generated On: 09 Jun 2021 17:05:26

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:04:20
User entered '09 Oct 2020 12:00'	System	07 Oct 2020 21:48:31

US3342200

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(10)

Generated On: 09 Jun 2021 17:05:26

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:04:20
User entered '10 Oct 2020 11:59'	System	07 Oct 2020 21:48:31

US3342200

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(11)

Generated On: 09 Jun 2021 17:05:26

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:04:20
Data entry locked.	System	08 Oct 2020 17:00:27
User entered 'Day 11'	System	08 Oct 2020 17:00:27

US3342200

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(11)

Generated On: 09 Jun 2021 17:05:26

Did you receive any **MEDICAL ATTENTION** (doctor visit, other) for any illness or symptoms?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:04:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2D2D1647-7C35-4DCA-ADA3-8E1DAA921DDC)', Time: '2020-10-10T12:04:30', User OID: 'PatientReportedOutcome (US3342200)', ODM File OID: '3352a37d-fd33-4c2a-a1f5-c5c163bcbdb2' User entered 'No (N)'	System	10 Oct 2020 17:04:36
	System	10 Oct 2020 17:04:36

US3342200

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(11)

Generated On: 09 Jun 2021 17:05:26

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:04:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2D2D1647-7C35-4DCA-ADA3-8E1DAA921DDC)', Time: '2020-10-10T12:04:32', User OID: 'PatientReportedOutcome (US3342200)', ODM File OID: '3352a37d-fd33-4c2a-a1f5-c5c163bcbdb2' User entered '10 Oct 2020 12:04'	System	10 Oct 2020 17:04:36
	System	10 Oct 2020 17:04:36

US3342200

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(11)

Generated On: 09 Jun 2021 17:05:26

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:04:20
User entered '10 Oct 2020 12:00'	System	08 Oct 2020 17:00:27

US3342200

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(11)

Generated On: 09 Jun 2021 17:05:26

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:04:20
User entered '11 Oct 2020 11:59'	System	08 Oct 2020 17:00:27

US3342200

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(12)

Generated On: 09 Jun 2021 17:05:26

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:04:20
Data entry locked.	System	09 Oct 2020 17:14:47
User entered 'Day 12'	System	09 Oct 2020 17:14:47

US3342200

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(12)

Generated On: 09 Jun 2021 17:05:26

Did you receive any **MEDICAL ATTENTION** (doctor visit, other) for any illness or symptoms?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:04:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2D2D1647-7C35-4DCA-ADA3-8E1DAA921DDC)', Time: '2020-10-11T17:27:04', User OID: 'PatientReportedOutcome (US3342200)', ODM File OID: '9a8e1bf8-1b7d-4337-bf40-85ba360d6e02' User entered 'No (N)'	System	11 Oct 2020 22:27:08
	System	11 Oct 2020 22:27:08

US3342200

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(12)

Generated On: 09 Jun 2021 17:05:26

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:04:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2D2D1647-7C35-4DCA-ADA3-8E1DAA921DDC)', Time: '2020-10-11T17:27:06', User OID: 'PatientReportedOutcome (US3342200)', ODM File OID: '9a8e1bf8-1b7d-4337-bf40-85ba360d6e02' User entered '11 Oct 2020 17:27'	System	11 Oct 2020 22:27:08
	System	11 Oct 2020 22:27:08

US3342200

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(12)

Generated On: 09 Jun 2021 17:05:26

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:04:20
User entered '11 Oct 2020 12:00'	System	09 Oct 2020 17:14:47

US3342200

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(12)

Generated On: 09 Jun 2021 17:05:26

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:04:20
User entered '12 Oct 2020 11:59'	System	09 Oct 2020 17:14:47

US3342200

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(13)

Generated On: 09 Jun 2021 17:05:26

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:04:20
Data entry locked.	System	10 Oct 2020 17:04:11
User entered 'Day 13'	System	10 Oct 2020 17:04:11

US3342200

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(13)

Generated On: 09 Jun 2021 17:05:26

Did you receive any **MEDICAL ATTENTION** (doctor visit, other) for any illness or symptoms?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:04:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2D2D1647-7C35-4DCA-ADA3-8E1DAA921DDC)', Time: '2020-10-12T16:02:42', User OID: 'PatientReportedOutcome (US3342200)', ODM File OID: 'a93271d5-26c7-4043-9b47-e7af0390035d' User entered 'Yes (Y)'	System	12 Oct 2020 21:02:52
	System	12 Oct 2020 21:02:52

US3342200

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(13)

Generated On: 09 Jun 2021 17:05:26

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:04:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2D2D1647-7C35-4DCA-ADA3-8E1DAA921DDC)', Time: '2020-10-12T16:02:48', User OID: 'PatientReportedOutcome (US3342200)', ODM File OID: 'a93271d5-26c7-4043-9b47-e7af0390035d' User entered '12 Oct 2020 16:02'	System	12 Oct 2020 21:02:52
	System	12 Oct 2020 21:02:52

US3342200

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(13)

Generated On: 09 Jun 2021 17:05:26

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:04:20
User entered '12 Oct 2020 12:00'	System	10 Oct 2020 17:04:11

US3342200

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(13)

Generated On: 09 Jun 2021 17:05:26

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:04:20
User entered '13 Oct 2020 11:59'	System	10 Oct 2020 17:04:11

US3342200

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(14)

Generated On: 09 Jun 2021 17:05:26

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:04:20
Data entry locked.	System	11 Oct 2020 22:26:46
User entered 'Day 14'	System	11 Oct 2020 22:26:46

US3342200

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(14)

Generated On: 09 Jun 2021 17:05:26

Did you receive any **MEDICAL ATTENTION** (doctor visit, other) for any illness or symptoms?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:04:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2D2D1647-7C35-4DCA-ADA3-8E1DAA921DDC)', Time: '2020-10-14T06:26:52', User OID: 'PatientReportedOutcome (US3342200)', ODM File OID: 'bc665186-0351-4c0a-8c54-e2a967815cb7' User entered 'No (N)'	System	14 Oct 2020 11:26:58
	System	14 Oct 2020 11:26:58

US3342200

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(14)

Generated On: 09 Jun 2021 17:05:26

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:04:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2D2D1647-7C35-4DCA-ADA3-8E1DAA921DDC)', Time: '2020-10-14T06:26:56', User OID: 'PatientReportedOutcome (US3342200)', ODM File OID: 'bc665186-0351-4c0a-8c54-e2a967815cb7' User entered '14 Oct 2020 06:26'	System	14 Oct 2020 11:26:58
	System	14 Oct 2020 11:26:58

US3342200

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(14)

Generated On: 09 Jun 2021 17:05:26

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:04:20
User entered '13 Oct 2020 12:00'	System	11 Oct 2020 22:26:46

US3342200

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(14)

Generated On: 09 Jun 2021 17:05:26

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:04:20
User entered '14 Oct 2020 11:59'	System	11 Oct 2020 22:26:46

US3342200

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(15)

Generated On: 09 Jun 2021 17:05:26

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:04:20
Data entry locked.	System	12 Oct 2020 21:02:18
User entered 'Day 15'	System	12 Oct 2020 21:02:18

US3342200

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(15)

Generated On: 09 Jun 2021 17:05:26

Did you receive any **MEDICAL ATTENTION** (doctor visit, other) for any illness or symptoms?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:04:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2D2D1647-7C35-4DCA-ADA3-8E1DAA921DDC)', Time: '2020-10-14T13:41:09', User OID: 'PatientReportedOutcome (US3342200)', ODM File OID: '88236280-c53c-4fc7-b11e-ac1b71be33b5' User entered 'No (N)'	System	14 Oct 2020 18:41:36
	System	14 Oct 2020 18:41:36

US3342200

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(15)

Generated On: 09 Jun 2021 17:05:26

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:04:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2D2D1647-7C35-4DCA-ADA3-8E1DAA921DDC)', Time: '2020-10-14T13:41:29', User OID: 'PatientReportedOutcome (US3342200)', ODM File OID: '88236280-c53c-4fc7-b11e-ac1b71be33b5' User entered '14 Oct 2020 13:41'	System	14 Oct 2020 18:41:36
	System	14 Oct 2020 18:41:36

US3342200

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(15)

Generated On: 09 Jun 2021 17:05:26

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:04:20
User entered '14 Oct 2020 12:00'	System	12 Oct 2020 21:02:18

US3342200

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(15)

Generated On: 09 Jun 2021 17:05:26

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:04:20
User entered '15 Oct 2020 11:59'	System	12 Oct 2020 21:02:18

US3342200

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(16)

Generated On: 09 Jun 2021 17:05:26

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:04:20
Data entry locked.	System	14 Oct 2020 11:26:26
User entered 'Day 16'	System	14 Oct 2020 11:26:26

US3342200

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(16)

Generated On: 09 Jun 2021 17:05:26

Did you receive any **MEDICAL ATTENTION** (doctor visit, other) for any illness or symptoms?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:04:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2D2D1647-7C35-4DCA-ADA3-8E1DAA921DDC)', Time: '2020-10-16T02:17:14', User OID: 'PatientReportedOutcome (US3342200)', ODM File OID: '60aba033-6c86-49c5-9164-59d75598c608' User entered 'No (N)'	System	16 Oct 2020 07:17:22
	System	16 Oct 2020 07:17:22

US3342200

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(16)

Generated On: 09 Jun 2021 17:05:26

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:04:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2D2D1647-7C35-4DCA-ADA3-8E1DAA921DDC)', Time: '2020-10-16T02:17:19', User OID: 'PatientReportedOutcome (US3342200)', ODM File OID: '60aba033-6c86-49c5-9164-59d75598c608' User entered '16 Oct 2020 02:17'	System	16 Oct 2020 07:17:22
	System	16 Oct 2020 07:17:22

US3342200

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(16)

Generated On: 09 Jun 2021 17:05:26

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:04:20
User entered '15 Oct 2020 12:00'	System	14 Oct 2020 11:26:26

US3342200

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(16)

Generated On: 09 Jun 2021 17:05:26

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:04:20
User entered '16 Oct 2020 11:59'	System	14 Oct 2020 11:26:26

US3342200

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(17)

Generated On: 09 Jun 2021 17:05:26

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:04:20
Data entry locked.	System	14 Oct 2020 18:40:52
User entered 'Day 17'	System	14 Oct 2020 18:40:52

US3342200

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(17)

Generated On: 09 Jun 2021 17:05:26

Did you receive any **MEDICAL ATTENTION** (doctor visit, other) for any illness or symptoms?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:04:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2D2D1647-7C35-4DCA-ADA3-8E1DAA921DDC)', Time: '2020-10-16T12:08:47', User OID: 'PatientReportedOutcome (US3342200)', ODM File OID: 'badf3f43-a9e4-459f-a44e-5bf987330931' User entered 'No (N)'	System	16 Oct 2020 17:08:52
	System	16 Oct 2020 17:08:52

US3342200

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(17)

Generated On: 09 Jun 2021 17:05:26

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:04:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2D2D1647-7C35-4DCA-ADA3-8E1DAA921DDC)', Time: '2020-10-16T12:08:50', User OID: 'PatientReportedOutcome (US3342200)', ODM File OID: 'badf3f43-a9e4-459f-a44e-5bf987330931' User entered '16 Oct 2020 12:08'	System	16 Oct 2020 17:08:52
	System	16 Oct 2020 17:08:52

US3342200

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(17)

Generated On: 09 Jun 2021 17:05:26

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:04:20
User entered '16 Oct 2020 12:00'	System	14 Oct 2020 18:40:52

US3342200

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(17)

Generated On: 09 Jun 2021 17:05:26

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:04:20
User entered '17 Oct 2020 11:59'	System	14 Oct 2020 18:40:52

US3342200

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(18)

Generated On: 09 Jun 2021 17:05:26

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:04:20
DataPoint Activated.	System	16 Oct 2020 17:08:49
DataPoint Inactivated.	System	16 Oct 2020 17:08:42
Data entry locked.	System	16 Oct 2020 07:16:52
User entered 'Day 18'	System	16 Oct 2020 07:16:52

US3342200

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(18)

Generated On: 09 Jun 2021 17:05:26

Did you receive any **MEDICAL ATTENTION** (doctor visit, other) for any illness or symptoms?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:04:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2D2D1647-7C35-4DCA-ADA3-8E1DAA921DDC)', Time: '2020-10-17T15:00:19', User OID: 'PatientReportedOutcome (US3342200)', ODM File OID: '801347a2-8845-4bf0-a75e-bc277b5bf663'	System	17 Oct 2020 20:00:27
User entered 'No (N)'	System	17 Oct 2020 20:00:27
DataPoint Activated.	System	16 Oct 2020 17:08:49
DataPoint Inactivated.	System	16 Oct 2020 17:08:42

US3342200

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(18)

Generated On: 09 Jun 2021 17:05:26

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:04:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2D2D1647-7C35-4DCA-ADA3-8E1DAA921DDC)', Time: '2020-10-17T15:00:23', User OID: 'PatientReportedOutcome (US3342200)', ODM File OID: '801347a2-8845-4bf0-a75e-bc277b5bf663'	System	17 Oct 2020 20:00:27
User entered '17 Oct 2020 15:00'	System	17 Oct 2020 20:00:27
DataPoint Activated.	System	16 Oct 2020 17:08:49
DataPoint Inactivated.	System	16 Oct 2020 17:08:42

US3342200

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(18)

Generated On: 09 Jun 2021 17:05:26

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:04:20
DataPoint Activated.	System	16 Oct 2020 17:08:49
DataPoint Inactivated.	System	16 Oct 2020 17:08:42
User entered '17 Oct 2020 12:00'	System	16 Oct 2020 07:16:52

US3342200

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(18)

Generated On: 09 Jun 2021 17:05:26

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:04:20
DataPoint Activated.	System	16 Oct 2020 17:08:49
DataPoint Inactivated.	System	16 Oct 2020 17:08:42
User entered '18 Oct 2020 11:59'	System	16 Oct 2020 07:16:52

US3342200

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(19)

Generated On: 09 Jun 2021 17:05:26

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:04:20
Data entry locked.	System	16 Oct 2020 17:08:49
User entered 'Day 19'	System	16 Oct 2020 17:08:49

US3342200

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(19)

Generated On: 09 Jun 2021 17:05:26

Did you receive any **MEDICAL ATTENTION** (doctor visit, other) for any illness or symptoms?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:04:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2D2D1647-7C35-4DCA-ADA3-8E1DAA921DDC)', Time: '2020-10-18T12:10:09', User OID: 'PatientReportedOutcome (US3342200)', ODM File OID: '77c95a9d-94e8-4d0b-9e20-2605f4c87bba' User entered 'No (N)'	System	18 Oct 2020 17:10:20
	System	18 Oct 2020 17:10:20

US3342200

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(19)

Generated On: 09 Jun 2021 17:05:26

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:04:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2D2D1647-7C35-4DCA-ADA3-8E1DAA921DDC)', Time: '2020-10-18T12:10:12', User OID: 'PatientReportedOutcome (US3342200)', ODM File OID: '77c95a9d-94e8-4d0b-9e20-2605f4c87bba' User entered '18 Oct 2020 12:10'	System	18 Oct 2020 17:10:20
	System	18 Oct 2020 17:10:20

US3342200

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(19)

Generated On: 09 Jun 2021 17:05:26

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:04:20
User entered '18 Oct 2020 12:00'	System	16 Oct 2020 17:08:49

US3342200

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(19)

Generated On: 09 Jun 2021 17:05:26

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:04:20
User entered '19 Oct 2020 11:59'	System	16 Oct 2020 17:08:49

US3342200

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(20)

Generated On: 09 Jun 2021 17:05:26

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:04:20
Data entry locked.	System	17 Oct 2020 20:00:18
User entered 'Day 20'	System	17 Oct 2020 20:00:18

US3342200

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(20)

Generated On: 09 Jun 2021 17:05:26

Did you receive any **MEDICAL ATTENTION** (doctor visit, other) for any illness or symptoms?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:04:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2D2D1647-7C35-4DCA-ADA3-8E1DAA921DDC)', Time: '2020-10-19T16:38:55', User OID: 'PatientReportedOutcome (US3342200)', ODM File OID: '3164eb21-c5e1-44a5-8d90-1994d29a8db7' User entered 'No (N)'	System	19 Oct 2020 21:39:01
	System	19 Oct 2020 21:39:01

US3342200

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(20)

Generated On: 09 Jun 2021 17:05:26

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:04:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2D2D1647-7C35-4DCA-ADA3-8E1DAA921DDC)', Time: '2020-10-19T16:38:57', User OID: 'PatientReportedOutcome (US3342200)', ODM File OID: '3164eb21-c5e1-44a5-8d90-1994d29a8db7' User entered '19 Oct 2020 16:38'	System	19 Oct 2020 21:39:01
	System	19 Oct 2020 21:39:01

US3342200

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(20)

Generated On: 09 Jun 2021 17:05:26

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:04:20
User entered '19 Oct 2020 12:00'	System	17 Oct 2020 20:00:18

US3342200

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(20)

Generated On: 09 Jun 2021 17:05:26

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:04:20
User entered '20 Oct 2020 11:59'	System	17 Oct 2020 20:00:18

US3342200

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(21)

Generated On: 09 Jun 2021 17:05:26

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:04:20
Data entry locked.	System	18 Oct 2020 17:10:07
User entered 'Day 21'	System	18 Oct 2020 17:10:07

US3342200

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(21)

Generated On: 09 Jun 2021 17:05:26

Did you receive any **MEDICAL ATTENTION** (doctor visit, other) for any illness or symptoms?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:04:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2D2D1647-7C35-4DCA-ADA3-8E1DAA921DDC)', Time: '2020-10-20T12:39:18', User OID: 'PatientReportedOutcome (US3342200)', ODM File OID: '3186c849-261a-4d9c-83ba-c89fd6c1f974' User entered 'No (N)'	System	20 Oct 2020 17:39:24
	System	20 Oct 2020 17:39:24

US3342200

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(21)

Generated On: 09 Jun 2021 17:05:26

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:04:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2D2D1647-7C35-4DCA-ADA3-8E1DAA921DDC)', Time: '2020-10-20T12:39:21', User OID: 'PatientReportedOutcome (US3342200)', ODM File OID: '3186c849-261a-4d9c-83ba-c89fd6c1f974' User entered '20 Oct 2020 12:39'	System	20 Oct 2020 17:39:24
	System	20 Oct 2020 17:39:24

US3342200

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(21)

Generated On: 09 Jun 2021 17:05:26

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:04:20
User entered '20 Oct 2020 12:00'	System	18 Oct 2020 17:10:07

US3342200

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(21)

Generated On: 09 Jun 2021 17:05:26

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:04:20
User entered '21 Oct 2020 11:59'	System	18 Oct 2020 17:10:07

US3342200

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(22)

Generated On: 09 Jun 2021 17:05:26

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:04:20
Data entry locked.	System	19 Oct 2020 21:38:54
User entered 'Day 22'	System	19 Oct 2020 21:38:54

US3342200

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(22)

Generated On: 09 Jun 2021 17:05:26

Did you receive any **MEDICAL ATTENTION** (doctor visit, other) for any illness or symptoms?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:04:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2D2D1647-7C35-4DCA-ADA3-8E1DAA921DDC)', Time: '2020-10-21T12:04:37', User OID: 'PatientReportedOutcome (US3342200)', ODM File OID: '3d10fcf5-5f8f-466d-be3b-ea82fd03f8'	System	21 Oct 2020 17:04:42
User entered 'No (N)'	System	21 Oct 2020 17:04:42

US3342200

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(22)

Generated On: 09 Jun 2021 17:05:26

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:04:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2D2D1647-7C35-4DCA-ADA3-8E1DAA921DDC)', Time: '2020-10-21T12:04:40', User OID: 'PatientReportedOutcome (US3342200)', ODM File OID: '3d10fcf5-5f8f-466d-be3b-ea82fd03f8'	System	21 Oct 2020 17:04:42
User entered '21 Oct 2020 12:04'	System	21 Oct 2020 17:04:42

US3342200

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(22)

Generated On: 09 Jun 2021 17:05:26

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:04:20
User entered '21 Oct 2020 12:00'	System	19 Oct 2020 21:38:54

US3342200

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(22)

Generated On: 09 Jun 2021 17:05:26

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:04:20
User entered '22 Oct 2020 11:59'	System	19 Oct 2020 21:38:54

US3342200

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(23)

Generated On: 09 Jun 2021 17:05:26

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:04:20
Data entry locked.	System	20 Oct 2020 17:39:17
User entered 'Day 23'	System	20 Oct 2020 17:39:17

US3342200

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(23)

Generated On: 09 Jun 2021 17:05:26

Did you receive any **MEDICAL ATTENTION** (doctor visit, other) for any illness or symptoms?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:04:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2D2D1647-7C35-4DCA-ADA3-8E1DAA921DDC)', Time: '2020-10-22T12:08:31', User OID: 'PatientReportedOutcome (US3342200)', ODM File OID: '3274a2c1-a903-43b1-a0f5-16f18579d8da' User entered 'No (N)'	System	22 Oct 2020 17:08:38
	System	22 Oct 2020 17:08:38

US3342200

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(23)

Generated On: 09 Jun 2021 17:05:26

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:04:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2D2D1647-7C35-4DCA-ADA3-8E1DAA921DDC)', Time: '2020-10-22T12:08:34', User OID: 'PatientReportedOutcome (US3342200)', ODM File OID: '3274a2c1-a903-43b1-a0f5-16f18579d8da' User entered '22 Oct 2020 12:08'	System	22 Oct 2020 17:08:38
	System	22 Oct 2020 17:08:38

US3342200

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(23)

Generated On: 09 Jun 2021 17:05:26

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:04:20
User entered '22 Oct 2020 12:00'	System	20 Oct 2020 17:39:17

US3342200

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(23)

Generated On: 09 Jun 2021 17:05:26

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:04:20
User entered '23 Oct 2020 11:59'	System	20 Oct 2020 17:39:17

US3342200

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(24)

Generated On: 09 Jun 2021 17:05:26

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:04:20
Data entry locked.	System	21 Oct 2020 17:04:40
User entered 'Day 24'	System	21 Oct 2020 17:04:40

US3342200

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(24)

Generated On: 09 Jun 2021 17:05:26

Did you receive any **MEDICAL ATTENTION** (doctor visit, other) for any illness or symptoms?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:04:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2D2D1647-7C35-4DCA-ADA3-8E1DAA921DDC)', Time: '2020-10-23T12:00:29', User OID: 'PatientReportedOutcome (US3342200)', ODM File OID: '00ba9176-bf63-4ede-83dc-523d8982ddf3' User entered 'No (N)'	System	23 Oct 2020 17:00:46
	System	23 Oct 2020 17:00:46

US3342200

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(24)

Generated On: 09 Jun 2021 17:05:26

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:04:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2D2D1647-7C35-4DCA-ADA3-8E1DAA921DDC)', Time: '2020-10-23T12:00:36', User OID: 'PatientReportedOutcome (US3342200)', ODM File OID: '00ba9176-bf63-4ede-83dc-523d8982ddf3' User entered '23 Oct 2020 12:00'	System	23 Oct 2020 17:00:46
	System	23 Oct 2020 17:00:46

US3342200

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(24)

Generated On: 09 Jun 2021 17:05:26

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:04:20
User entered '23 Oct 2020 12:00'	System	21 Oct 2020 17:04:40

US3342200

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(24)

Generated On: 09 Jun 2021 17:05:26

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:04:20
User entered '24 Oct 2020 11:59'	System	21 Oct 2020 17:04:40

US3342200

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(25)

Generated On: 09 Jun 2021 17:05:26

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:04:20
Data entry locked.	System	22 Oct 2020 17:08:26
User entered 'Day 25'	System	22 Oct 2020 17:08:26

US3342200

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(25)

Generated On: 09 Jun 2021 17:05:26

Did you receive any **MEDICAL ATTENTION** (doctor visit, other) for any illness or symptoms?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:04:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2D2D1647-7C35-4DCA-ADA3-8E1DAA921DDC)', Time: '2020-10-24T18:10:37', User OID: 'PatientReportedOutcome (US3342200)', ODM File OID: '8bb575f3-c3ab-4f19-bccd-4f6b906bc0ed' User entered 'No (N)'	System	24 Oct 2020 23:10:45
	System	24 Oct 2020 23:10:45

US3342200

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(25)

Generated On: 09 Jun 2021 17:05:26

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:04:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2D2D1647-7C35-4DCA-ADA3-8E1DAA921DDC)', Time: '2020-10-24T18:10:42', User OID: 'PatientReportedOutcome (US3342200)', ODM File OID: '8bb575f3-c3ab-4f19-bccd-4f6b906bc0ed' User entered '24 Oct 2020 18:10'	System	24 Oct 2020 23:10:45
	System	24 Oct 2020 23:10:45

US3342200

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(25)

Generated On: 09 Jun 2021 17:05:26

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:04:20
User entered '24 Oct 2020 12:00'	System	22 Oct 2020 17:08:26

US3342200

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(25)

Generated On: 09 Jun 2021 17:05:26

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:04:20
User entered '25 Oct 2020 11:59'	System	22 Oct 2020 17:08:26

US3342200

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(26)

Generated On: 09 Jun 2021 17:05:26

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:04:20
Data entry locked.	System	23 Oct 2020 17:00:29
User entered 'Day 26'	System	23 Oct 2020 17:00:29

US3342200

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(26)

Generated On: 09 Jun 2021 17:05:26

Did you receive any **MEDICAL ATTENTION** (doctor visit, other) for any illness or symptoms?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:04:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2D2D1647-7C35-4DCA-ADA3-8E1DAA921DDC)', Time: '2020-10-25T13:14:57', User OID: 'PatientReportedOutcome (US3342200)', ODM File OID: '34caff0f-d529-4b93-8d2c-2f41d072be4f' User entered 'No (N)'	System	25 Oct 2020 18:15:09
	System	25 Oct 2020 18:15:09

US3342200

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(26)

Generated On: 09 Jun 2021 17:05:26

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:04:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2D2D1647-7C35-4DCA-ADA3-8E1DAA921DDC)', Time: '2020-10-25T13:15:07', User OID: 'PatientReportedOutcome (US3342200)', ODM File OID: '34caff0f-d529-4b93-8d2c-2f41d072be4f' User entered '25 Oct 2020 13:15'	System	25 Oct 2020 18:15:09
	System	25 Oct 2020 18:15:09

US3342200

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(26)

Generated On: 09 Jun 2021 17:05:26

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:04:20
User entered '25 Oct 2020 12:00'	System	23 Oct 2020 17:00:29

US3342200

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(26)

Generated On: 09 Jun 2021 17:05:26

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:04:20
User entered '26 Oct 2020 11:59'	System	23 Oct 2020 17:00:29

US3342200

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(27)

Generated On: 09 Jun 2021 17:05:26

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:04:20
Data entry locked.	System	24 Oct 2020 22:55:23
User entered 'Day 27'	System	24 Oct 2020 22:55:23

US3342200

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(27)

Generated On: 09 Jun 2021 17:05:26

Did you receive any **MEDICAL ATTENTION** (doctor visit, other) for any illness or symptoms?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:04:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2D2D1647-7C35-4DCA-ADA3-8E1DAA921DDC)', Time: '2020-10-26T12:00:46', User OID: 'PatientReportedOutcome (US3342200)', ODM File OID: '005541c2-3bfa-4ba1-9a23-e1372bfaa56e' User entered 'No (N)'	System	26 Oct 2020 17:01:29
	System	26 Oct 2020 17:01:29

US3342200

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(27)

Generated On: 09 Jun 2021 17:05:26

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:04:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2D2D1647-7C35-4DCA-ADA3-8E1DAA921DDC)', Time: '2020-10-26T12:00:49', User OID: 'PatientReportedOutcome (US3342200)', ODM File OID: '005541c2-3bfa-4ba1-9a23-e1372bfaa56e' User entered '26 Oct 2020 12:00'	System	26 Oct 2020 17:01:29
	System	26 Oct 2020 17:01:29

US3342200

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(27)

Generated On: 09 Jun 2021 17:05:26

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:04:20
User entered '26 Oct 2020 12:00'	System	24 Oct 2020 22:55:23

US3342200

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(27)

Generated On: 09 Jun 2021 17:05:26

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:04:20
User entered '27 Oct 2020 11:59'	System	24 Oct 2020 22:55:23

US3342200

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(28)

Generated On: 09 Jun 2021 17:05:26

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:04:20
Data entry locked.	System	25 Oct 2020 18:14:52
User entered 'Day 28'	System	25 Oct 2020 18:14:52

US3342200

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(28)

Generated On: 09 Jun 2021 17:05:26

Did you receive any **MEDICAL ATTENTION** (doctor visit, other) for any illness or symptoms?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:04:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2D2D1647-7C35-4DCA-ADA3-8E1DAA921DDC)', Time: '2020-10-27T12:15:55', User OID: 'PatientReportedOutcome (US3342200)', ODM File OID: '75bc9bfb-1af9-4d2f-b091-3aa6b0447778' User entered 'No (N)'	System	27 Oct 2020 17:16:01
	System	27 Oct 2020 17:16:01

US3342200

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(28)

Generated On: 09 Jun 2021 17:05:26

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:04:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2D2D1647-7C35-4DCA-ADA3-8E1DAA921DDC)', Time: '2020-10-27T12:15:58', User OID: 'PatientReportedOutcome (US3342200)', ODM File OID: '75bc9bfb-1af9-4d2f-b091-3aa6b0447778' User entered '27 Oct 2020 12:15'	System	27 Oct 2020 17:16:01
	System	27 Oct 2020 17:16:01

US3342200

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(28)

Generated On: 09 Jun 2021 17:05:26

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:04:20
User entered '27 Oct 2020 12:00'	System	25 Oct 2020 18:14:52

US3342200

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(28)

Generated On: 09 Jun 2021 17:05:26

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:04:20
User entered '28 Oct 2020 11:59'	System	25 Oct 2020 18:14:52

US3342200

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(29)

Generated On: 09 Jun 2021 17:05:26

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:04:20
Data entry locked.	System	26 Oct 2020 17:01:15
User entered 'Day 29'	System	26 Oct 2020 17:01:15

US3342200

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(29)

Generated On: 09 Jun 2021 17:05:26

Did you receive any **MEDICAL ATTENTION** (doctor visit, other) for any illness or symptoms?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:04:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2D2D1647-7C35-4DCA-ADA3-8E1DAA921DDC)', Time: '2020-10-28T13:15:09', User OID: 'PatientReportedOutcome (US3342200)', ODM File OID: 'eca6ad73-bebf-4633-aa9f-b8c1a847fc61' User entered 'No (N)'	System	28 Oct 2020 18:15:15
	System	28 Oct 2020 18:15:15

US3342200

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(29)

Generated On: 09 Jun 2021 17:05:26

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:04:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2D2D1647-7C35-4DCA-ADA3-8E1DAA921DDC)', Time: '2020-10-28T13:15:13', User OID: 'PatientReportedOutcome (US3342200)', ODM File OID: 'eca6ad73-bebf-4633-aa9f-b8c1a847fc61' User entered '28 Oct 2020 13:15'	System	28 Oct 2020 18:15:15
	System	28 Oct 2020 18:15:15

US3342200

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(29)

Generated On: 09 Jun 2021 17:05:26

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:04:20
User entered '28 Oct 2020 12:00'	System	26 Oct 2020 17:01:15

US3342200

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(29)

Generated On: 09 Jun 2021 17:05:26

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:04:20
User entered '29 Oct 2020 11:59'	System	26 Oct 2020 17:01:15

US3342200

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(30)

Generated On: 09 Jun 2021 17:05:26

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:04:20
Data entry locked.	System	27 Oct 2020 17:15:53
User entered 'Day 30'	System	27 Oct 2020 17:15:53

US3342200

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(30)

Generated On: 09 Jun 2021 17:05:26

Did you receive any **MEDICAL ATTENTION** (doctor visit, other) for any illness or symptoms?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:04:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2D2D1647-7C35-4DCA-ADA3-8E1DAA921DDC)', Time: '2020-10-29T13:11:49', User OID: 'PatientReportedOutcome (US3342200)', ODM File OID: '991495b1-8e47-4d31-ae54-2905fca5cdcb' User entered 'No (N)'	System	29 Oct 2020 18:11:58
	System	29 Oct 2020 18:11:58

US3342200

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(30)

Generated On: 09 Jun 2021 17:05:26

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:04:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2D2D1647-7C35-4DCA-ADA3-8E1DAA921DDC)', Time: '2020-10-29T13:11:54', User OID: 'PatientReportedOutcome (US3342200)', ODM File OID: '991495b1-8e47-4d31-ae54-2905fca5cdcb' User entered '29 Oct 2020 13:11'	System	29 Oct 2020 18:11:58
	System	29 Oct 2020 18:11:58

US3342200

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(30)

Generated On: 09 Jun 2021 17:05:26

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:04:20
User entered '29 Oct 2020 12:00'	System	27 Oct 2020 17:15:53

US3342200

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(30)

Generated On: 09 Jun 2021 17:05:26

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:04:20
User entered '30 Oct 2020 11:59'	System	27 Oct 2020 17:15:53

US3342200

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(31)

Generated On: 09 Jun 2021 17:05:26

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:04:20
Data entry locked.	System	28 Oct 2020 18:15:07
User entered 'Day 31'	System	28 Oct 2020 18:15:07

US3342200

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(31)

Generated On: 09 Jun 2021 17:05:26

Did you receive any **MEDICAL ATTENTION** (doctor visit, other) for any illness or symptoms?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:04:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2D2D1647-7C35-4DCA-ADA3-8E1DAA921DDC)', Time: '2020-10-30T12:00:46', User OID: 'PatientReportedOutcome (US3342200)', ODM File OID: '66325d47-a1c4-40d2-8051-2f41f7ac6240' User entered 'No (N)'	System	30 Oct 2020 17:01:40
	System	30 Oct 2020 17:01:40

US3342200

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(31)

Generated On: 09 Jun 2021 17:05:26

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:04:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2D2D1647-7C35-4DCA-ADA3-8E1DAA921DDC)', Time: '2020-10-30T12:00:50', User OID: 'PatientReportedOutcome (US3342200)', ODM File OID: '66325d47-a1c4-40d2-8051-2f41f7ac6240' User entered '30 Oct 2020 12:00'	System	30 Oct 2020 17:01:40
	System	30 Oct 2020 17:01:40

US3342200

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(31)

Generated On: 09 Jun 2021 17:05:26

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:04:20
User entered '30 Oct 2020 12:00'	System	28 Oct 2020 18:15:07

US3342200

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(31)

Generated On: 09 Jun 2021 17:05:26

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:04:20
User entered '31 Oct 2020 11:59'	System	28 Oct 2020 18:15:07

US3342200

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(32)

Generated On: 09 Jun 2021 17:05:26

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:04:20
Data entry locked.	System	29 Oct 2020 18:11:47
User entered 'Day 32'	System	29 Oct 2020 18:11:47

US3342200

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(32)

Generated On: 09 Jun 2021 17:05:26

Did you receive any **MEDICAL ATTENTION** (doctor visit, other) for any illness or symptoms?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:04:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2D2D1647-7C35-4DCA-ADA3-8E1DAA921DDC)', Time: '2020-10-31T16:57:03', User OID: 'PatientReportedOutcome (US3342200)', ODM File OID: 'e3319374-cdd5-40d9-81ee-f081e67298fc' User entered 'No (N)'	System	31 Oct 2020 21:57:08
	System	31 Oct 2020 21:57:08

US3342200

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(32)

Generated On: 09 Jun 2021 17:05:26

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:04:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2D2D1647-7C35-4DCA-ADA3-8E1DAA921DDC)', Time: '2020-10-31T16:57:06', User OID: 'PatientReportedOutcome (US3342200)', ODM File OID: 'e3319374-cdd5-40d9-81ee-f081e67298fc' User entered '31 Oct 2020 16:57'	System	31 Oct 2020 21:57:08
	System	31 Oct 2020 21:57:08

US3342200

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(32)

Generated On: 09 Jun 2021 17:05:26

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:04:20
User entered '31 Oct 2020 12:00'	System	29 Oct 2020 18:11:47

US3342200

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(32)

Generated On: 09 Jun 2021 17:05:26

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:04:20
User entered '01 Nov 2020 11:59'	System	29 Oct 2020 18:11:47

US3342200

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(33)

Generated On: 09 Jun 2021 17:05:26

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:04:20
Data entry locked.	System	30 Oct 2020 17:01:16
User entered 'Day 33'	System	30 Oct 2020 17:01:16

US3342200

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(33)

Generated On: 09 Jun 2021 17:05:26

Did you receive any **MEDICAL ATTENTION** (doctor visit, other) for any illness or symptoms?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:04:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2D2D1647-7C35-4DCA-ADA3-8E1DAA921DDC)', Time: '2020-11-01T14:20:16', User OID: 'PatientReportedOutcome (US3342200)', ODM File OID: 'd1752878-a351-49c3-a5ff-065485f58db7' User entered 'No (N)'	System	01 Nov 2020 20:20:24
	System	01 Nov 2020 20:20:24

US3342200

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(33)

Generated On: 09 Jun 2021 17:05:26

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:04:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2D2D1647-7C35-4DCA-ADA3-8E1DAA921DDC)', Time: '2020-11-01T14:20:22', User OID: 'PatientReportedOutcome (US3342200)', ODM File OID: 'd1752878-a351-49c3-a5ff-065485f58db7' User entered '01 Nov 2020 14:20'	System	01 Nov 2020 20:20:24
	System	01 Nov 2020 20:20:24

US3342200

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(33)

Generated On: 09 Jun 2021 17:05:26

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:04:20
User entered '01 Nov 2020 12:00'	System	30 Oct 2020 17:01:16

US3342200

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(33)

Generated On: 09 Jun 2021 17:05:26

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:04:20
User entered '02 Nov 2020 11:59'	System	30 Oct 2020 17:01:16

US3342200

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(34)

Generated On: 09 Jun 2021 17:05:26

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:04:20
Data entry locked.	System	31 Oct 2020 21:56:59
User entered 'Day 34'	System	31 Oct 2020 21:56:59

US3342200

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(34)

Generated On: 09 Jun 2021 17:05:26

Did you receive any **MEDICAL ATTENTION** (doctor visit, other) for any illness or symptoms?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:04:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2D2D1647-7C35-4DCA-ADA3-8E1DAA921DDC)', Time: '2020-11-02T17:32:07', User OID: 'PatientReportedOutcome (US3342200)', ODM File OID: 'e4a4a2cb-613b-4ef3-980b-514d2029cc25' User entered 'No (N)'	System	02 Nov 2020 23:32:17
	System	02 Nov 2020 23:32:17

US3342200

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(34)

Generated On: 09 Jun 2021 17:05:26

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:04:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2D2D1647-7C35-4DCA-ADA3-8E1DAA921DDC)', Time: '2020-11-02T17:32:13', User OID: 'PatientReportedOutcome (US3342200)', ODM File OID: 'e4a4a2cb-613b-4ef3-980b-514d2029cc25' User entered '02 Nov 2020 17:32'	System	02 Nov 2020 23:32:17
	System	02 Nov 2020 23:32:17

US3342200

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(34)

Generated On: 09 Jun 2021 17:05:26

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:04:20
User entered '02 Nov 2020 12:00'	System	31 Oct 2020 21:56:59

US3342200

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(34)

Generated On: 09 Jun 2021 17:05:26

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:04:20
User entered '03 Nov 2020 11:59'	System	31 Oct 2020 21:56:59

US3342200

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(35)

Generated On: 09 Jun 2021 17:05:26

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:04:20
Data entry locked.	System	01 Nov 2020 20:03:38
User entered 'Day 35'	System	01 Nov 2020 20:03:38

US3342200

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(35)

Generated On: 09 Jun 2021 17:05:26

Did you receive any **MEDICAL ATTENTION** (doctor visit, other) for any illness or symptoms?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:04:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2D2D1647-7C35-4DCA-ADA3-8E1DAA921DDC)', Time: '2020-11-03T18:02:03', User OID: 'PatientReportedOutcome (US3342200)', ODM File OID: '8b6d4c1e-765b-409e-becc-b066971b910b' User entered 'Yes (Y)'	System	04 Nov 2020 00:02:12
	System	04 Nov 2020 00:02:12

US3342200

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(35)

Generated On: 09 Jun 2021 17:05:26

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:04:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2D2D1647-7C35-4DCA-ADA3-8E1DAA921DDC)', Time: '2020-11-03T18:02:10', User OID: 'PatientReportedOutcome (US3342200)', ODM File OID: '8b6d4c1e-765b-409e-becc-b066971b910b' User entered '03 Nov 2020 18:02'	System	04 Nov 2020 00:02:12
	System	04 Nov 2020 00:02:12

US3342200

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(35)

Generated On: 09 Jun 2021 17:05:26

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:04:20
User entered '03 Nov 2020 12:00'	System	01 Nov 2020 20:03:38

US3342200

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(35)

Generated On: 09 Jun 2021 17:05:26

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:04:20
User entered '04 Nov 2020 11:59'	System	01 Nov 2020 20:03:38

US3342200

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(36)

Generated On: 09 Jun 2021 17:05:26

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:04:20
Data entry locked.	System	02 Nov 2020 23:31:59
User entered 'Day 36'	System	02 Nov 2020 23:31:59

US3342200

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(36)

Generated On: 09 Jun 2021 17:05:26

Did you receive any **MEDICAL ATTENTION** (doctor visit, other) for any illness or symptoms?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:04:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2D2D1647-7C35-4DCA-ADA3-8E1DAA921DDC)', Time: '2020-11-05T06:41:45', User OID: 'PatientReportedOutcome (US3342200)', ODM File OID: '19529384-8580-432b-bce7-932c5226bb6f' User entered 'Yes (Y)'	System	05 Nov 2020 12:41:56
	System	05 Nov 2020 12:41:56

US3342200

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(36)

Generated On: 09 Jun 2021 17:05:26

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:04:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2D2D1647-7C35-4DCA-ADA3-8E1DAA921DDC)', Time: '2020-11-05T06:41:53', User OID: 'PatientReportedOutcome (US3342200)', ODM File OID: '19529384-8580-432b-bce7-932c5226bb6f' User entered '05 Nov 2020 06:41'	System	05 Nov 2020 12:41:56
	System	05 Nov 2020 12:41:56

US3342200

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(36)

Generated On: 09 Jun 2021 17:05:26

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:04:20
User entered '04 Nov 2020 12:00'	System	02 Nov 2020 23:31:59

US3342200

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(36)

Generated On: 09 Jun 2021 17:05:26

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:04:20
User entered '05 Nov 2020 11:59'	System	02 Nov 2020 23:31:59

US3342200

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(37)

Generated On: 09 Jun 2021 17:05:26

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:04:20
Data entry locked.	System	04 Nov 2020 00:02:03
User entered 'Day 37'	System	04 Nov 2020 00:02:03

US3342200

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(37)

Generated On: 09 Jun 2021 17:05:26

Did you receive any **MEDICAL ATTENTION** (doctor visit, other) for any illness or symptoms?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:04:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2D2D1647-7C35-4DCA-ADA3-8E1DAA921DDC)', Time: '2020-11-05T12:13:37', User OID: 'PatientReportedOutcome (US3342200)', ODM File OID: '6669907d-3e63-4656-96a7-2a49b6ba6bf4' User entered 'No (N)'	System	05 Nov 2020 18:13:42
	System	05 Nov 2020 18:13:42

US3342200

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(37)

Generated On: 09 Jun 2021 17:05:26

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:04:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2D2D1647-7C35-4DCA-ADA3-8E1DAA921DDC)', Time: '2020-11-05T12:13:39', User OID: 'PatientReportedOutcome (US3342200)', ODM File OID: '6669907d-3e63-4656-96a7-2a49b6ba6bf4' User entered '05 Nov 2020 12:13'	System	05 Nov 2020 18:13:42
	System	05 Nov 2020 18:13:42

US3342200

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(37)

Generated On: 09 Jun 2021 17:05:26

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:04:20
User entered '05 Nov 2020 12:00'	System	04 Nov 2020 00:02:03

US3342200

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(37)

Generated On: 09 Jun 2021 17:05:26

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:04:20
User entered '06 Nov 2020 11:59'	System	04 Nov 2020 00:02:03

US3342200

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(38)

Generated On: 09 Jun 2021 17:05:26

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:04:20
Data entry locked.	System	05 Nov 2020 12:41:37
User entered 'Day 38'	System	05 Nov 2020 12:41:37

US3342200

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(38)

Generated On: 09 Jun 2021 17:05:26

Did you receive any **MEDICAL ATTENTION** (doctor visit, other) for any illness or symptoms?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:04:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2D2D1647-7C35-4DCA-ADA3-8E1DAA921DDC)', Time: '2020-11-07T04:41:56', User OID: 'PatientReportedOutcome (US3342200)', ODM File OID: '97267a9c-9211-42a9-9e80-3753eff45398' User entered 'Yes (Y)'	System	07 Nov 2020 10:42:05
	System	07 Nov 2020 10:42:05

US3342200

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(38)

Generated On: 09 Jun 2021 17:05:26

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:04:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2D2D1647-7C35-4DCA-ADA3-8E1DAA921DDC)', Time: '2020-11-07T04:42:02', User OID: 'PatientReportedOutcome (US3342200)', ODM File OID: '97267a9c-9211-42a9-9e80-3753eff45398' User entered '07 Nov 2020 04:42'	System	07 Nov 2020 10:42:05
	System	07 Nov 2020 10:42:05

US3342200

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(38)

Generated On: 09 Jun 2021 17:05:26

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:04:20
User entered '06 Nov 2020 12:00'	System	05 Nov 2020 12:41:37

US3342200

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(38)

Generated On: 09 Jun 2021 17:05:26

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:04:20
User entered '07 Nov 2020 11:59'	System	05 Nov 2020 12:41:37

US3342200

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(39)

Generated On: 09 Jun 2021 17:05:26

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:04:20
Data entry locked.	System	05 Nov 2020 18:13:36
User entered 'Day 39'	System	05 Nov 2020 18:13:36

US3342200

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(39)

Generated On: 09 Jun 2021 17:05:26

Did you receive any **MEDICAL ATTENTION** (doctor visit, other) for any illness or symptoms?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:04:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2D2D1647-7C35-4DCA-ADA3-8E1DAA921DDC)', Time: '2020-11-07T12:30:36', User OID: 'PatientReportedOutcome (US3342200)', ODM File OID: '5292d9e3-27f8-4b96-b091-ce10985a1cd9' User entered 'No (N)'	System	07 Nov 2020 18:30:44
	System	07 Nov 2020 18:30:44

US3342200

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(39)

Generated On: 09 Jun 2021 17:05:26

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:04:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2D2D1647-7C35-4DCA-ADA3-8E1DAA921DDC)', Time: '2020-11-07T12:30:39', User OID: 'PatientReportedOutcome (US3342200)', ODM File OID: '5292d9e3-27f8-4b96-b091-ce10985a1cd9' User entered '07 Nov 2020 12:30'	System	07 Nov 2020 18:30:44
	System	07 Nov 2020 18:30:44

US3342200

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(39)

Generated On: 09 Jun 2021 17:05:26

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:04:20
User entered '07 Nov 2020 12:00'	System	05 Nov 2020 18:13:36

US3342200

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(39)

Generated On: 09 Jun 2021 17:05:26

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:04:20
User entered '08 Nov 2020 11:59'	System	05 Nov 2020 18:13:36

US3342200

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(40)

Generated On: 09 Jun 2021 17:05:26

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:04:20
Data entry locked.	System	07 Nov 2020 10:41:41
User entered 'Day 40'	System	07 Nov 2020 10:41:41

US3342200

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(40)

Generated On: 09 Jun 2021 17:05:26

Did you receive any **MEDICAL ATTENTION** (doctor visit, other) for any illness or symptoms?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:04:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2D2D1647-7C35-4DCA-ADA3-8E1DAA921DDC)', Time: '2020-11-08T12:00:57', User OID: 'PatientReportedOutcome (US3342200)', ODM File OID: '23412317-6d48-487d-aed6-4263a3a9c59c' User entered 'No (N)'	System	08 Nov 2020 18:01:07
	System	08 Nov 2020 18:01:07

US3342200

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(40)

Generated On: 09 Jun 2021 17:05:26

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:04:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2D2D1647-7C35-4DCA-ADA3-8E1DAA921DDC)', Time: '2020-11-08T12:01:00', User OID: 'PatientReportedOutcome (US3342200)', ODM File OID: '23412317-6d48-487d-aed6-4263a3a9c59c' User entered '08 Nov 2020 12:01'	System	08 Nov 2020 18:01:07
	System	08 Nov 2020 18:01:07

US3342200

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(40)

Generated On: 09 Jun 2021 17:05:26

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:04:20
User entered '08 Nov 2020 12:00'	System	07 Nov 2020 10:41:41

US3342200

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(40)

Generated On: 09 Jun 2021 17:05:26

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:04:20
User entered '09 Nov 2020 11:59'	System	07 Nov 2020 10:41:41

US3342200

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(41)

Generated On: 09 Jun 2021 17:05:26

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:04:20
Data entry locked.	System	07 Nov 2020 18:30:37
User entered 'Day 41'	System	07 Nov 2020 18:30:37

US3342200

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(41)

Generated On: 09 Jun 2021 17:05:26

Did you receive any **MEDICAL ATTENTION** (doctor visit, other) for any illness or symptoms?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:04:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2D2D1647-7C35-4DCA-ADA3-8E1DAA921DDC)', Time: '2020-11-09T21:21:30', User OID: 'PatientReportedOutcome (US3342200)', ODM File OID: '1bde2b73-d9e3-42a0-9d2a-cfa6a31c4954' User entered 'Yes (Y)'	System	10 Nov 2020 03:21:46
	System	10 Nov 2020 03:21:46

US3342200

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(41)

Generated On: 09 Jun 2021 17:05:26

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:04:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2D2D1647-7C35-4DCA-ADA3-8E1DAA921DDC)', Time: '2020-11-09T21:21:38', User OID: 'PatientReportedOutcome (US3342200)', ODM File OID: '1bde2b73-d9e3-42a0-9d2a-cfa6a31c4954' User entered '09 Nov 2020 21:21'	System	10 Nov 2020 03:21:46
	System	10 Nov 2020 03:21:46

US3342200

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(41)

Generated On: 09 Jun 2021 17:05:26

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:04:20
User entered '09 Nov 2020 12:00'	System	07 Nov 2020 18:30:37

US3342200

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(41)

Generated On: 09 Jun 2021 17:05:26

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:04:20
User entered '10 Nov 2020 11:59'	System	07 Nov 2020 18:30:37

US3342200

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(42)

Generated On: 09 Jun 2021 17:05:26

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:04:20
Data entry locked.	System	08 Nov 2020 18:00:54
User entered 'Day 42'	System	08 Nov 2020 18:00:54

US3342200

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(42)

Generated On: 09 Jun 2021 17:05:26

Did you receive any **MEDICAL ATTENTION** (doctor visit, other) for any illness or symptoms?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:04:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2D2D1647-7C35-4DCA-ADA3-8E1DAA921DDC)', Time: '2020-11-11T04:16:05', User OID: 'PatientReportedOutcome (US3342200)', ODM File OID: 'fbe01394-905f-4d50-a3d2-9afd420a136a' User entered 'No (N)'	System	11 Nov 2020 10:16:16
	System	11 Nov 2020 10:16:16

US3342200

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(42)

Generated On: 09 Jun 2021 17:05:26

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:04:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2D2D1647-7C35-4DCA-ADA3-8E1DAA921DDC)', Time: '2020-11-11T04:16:12', User OID: 'PatientReportedOutcome (US3342200)', ODM File OID: 'fbe01394-905f-4d50-a3d2-9afd420a136a' User entered '11 Nov 2020 04:16'	System	11 Nov 2020 10:16:16
	System	11 Nov 2020 10:16:16

US3342200

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(42)

Generated On: 09 Jun 2021 17:05:26

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:04:20
User entered '10 Nov 2020 12:00'	System	08 Nov 2020 18:00:54

US3342200

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(42)

Generated On: 09 Jun 2021 17:05:26

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:04:20
User entered '11 Nov 2020 11:59'	System	08 Nov 2020 18:00:54

US3342200

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(43)

Generated On: 09 Jun 2021 17:05:26

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:04:20
Data entry locked.	System	10 Nov 2020 03:21:29
User entered 'Day 43'	System	10 Nov 2020 03:21:29

US3342200

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(43)

Generated On: 09 Jun 2021 17:05:26

Did you receive any **MEDICAL ATTENTION** (doctor visit, other) for any illness or symptoms?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:04:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2D2D1647-7C35-4DCA-ADA3-8E1DAA921DDC)', Time: '2020-11-11T17:05:02', User OID: 'PatientReportedOutcome (US3342200)', ODM File OID: '47bb3757-02e1-43d1-8623-ea0d96fa5d0c' User entered 'No (N)'	System	11 Nov 2020 23:05:08
	System	11 Nov 2020 23:05:08

US3342200

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(43)

Generated On: 09 Jun 2021 17:05:26

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:04:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2D2D1647-7C35-4DCA-ADA3-8E1DAA921DDC)', Time: '2020-11-11T17:05:05', User OID: 'PatientReportedOutcome (US3342200)', ODM File OID: '47bb3757-02e1-43d1-8623-ea0d96fa5d0c' User entered '11 Nov 2020 17:05'	System	11 Nov 2020 23:05:08
	System	11 Nov 2020 23:05:08

US3342200

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(43)

Generated On: 09 Jun 2021 17:05:26

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:04:20
User entered '11 Nov 2020 12:00'	System	10 Nov 2020 03:21:29

US3342200

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(43)

Generated On: 09 Jun 2021 17:05:26

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:04:20
User entered '12 Nov 2020 11:59'	System	10 Nov 2020 03:21:29

US3342200

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(44)

Generated On: 09 Jun 2021 17:05:26

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:04:20
Data entry locked.	System	11 Nov 2020 10:15:44
User entered 'Day 44'	System	11 Nov 2020 10:15:44

US3342200

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(44)

Generated On: 09 Jun 2021 17:05:26

Did you receive any **MEDICAL ATTENTION** (doctor visit, other) for any illness or symptoms?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:04:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2D2D1647-7C35-4DCA-ADA3-8E1DAA921DDC)', Time: '2020-11-12T14:39:55', User OID: 'PatientReportedOutcome (US3342200)', ODM File OID: 'a40d47e4-d58a-45e9-a20c-02cc650b3a5d' User entered 'No (N)'	System	12 Nov 2020 20:40:04
	System	12 Nov 2020 20:40:04

US3342200

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(44)

Generated On: 09 Jun 2021 17:05:26

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:04:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2D2D1647-7C35-4DCA-ADA3-8E1DAA921DDC)', Time: '2020-11-12T14:39:59', User OID: 'PatientReportedOutcome (US3342200)', ODM File OID: 'a40d47e4-d58a-45e9-a20c-02cc650b3a5d' User entered '12 Nov 2020 14:39'	System	12 Nov 2020 20:40:04
	System	12 Nov 2020 20:40:04

US3342200

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(44)

Generated On: 09 Jun 2021 17:05:26

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:04:20
User entered '12 Nov 2020 12:00'	System	11 Nov 2020 10:15:44

US3342200

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(44)

Generated On: 09 Jun 2021 17:05:26

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:04:20
User entered '13 Nov 2020 11:59'	System	11 Nov 2020 10:15:44

US3342200

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(45)

Generated On: 09 Jun 2021 17:05:26

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:04:20
Data entry locked.	System	11 Nov 2020 23:05:02
User entered 'Day 45'	System	11 Nov 2020 23:05:02

US3342200

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(45)

Generated On: 09 Jun 2021 17:05:26

Did you receive any **MEDICAL ATTENTION** (doctor visit, other) for any illness or symptoms?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:04:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2D2D1647-7C35-4DCA-ADA3-8E1DAA921DDC)', Time: '2020-11-13T18:17:28', User OID: 'PatientReportedOutcome (US3342200)', ODM File OID: 'c960046b-9811-481f-a142-b6b2d68f5c13' User entered 'No (N)'	System	14 Nov 2020 00:17:55
	System	14 Nov 2020 00:17:55

US3342200

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(45)

Generated On: 09 Jun 2021 17:05:26

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:04:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2D2D1647-7C35-4DCA-ADA3-8E1DAA921DDC)', Time: '2020-11-13T18:17:53', User OID: 'PatientReportedOutcome (US3342200)', ODM File OID: 'c960046b-9811-481f-a142-b6b2d68f5c13' User entered '13 Nov 2020 18:17'	System	14 Nov 2020 00:17:55
	System	14 Nov 2020 00:17:55

US3342200

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(45)

Generated On: 09 Jun 2021 17:05:26

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:04:20
User entered '13 Nov 2020 12:00'	System	11 Nov 2020 23:05:02

US3342200

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(45)

Generated On: 09 Jun 2021 17:05:26

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:04:20
User entered '14 Nov 2020 11:59'	System	11 Nov 2020 23:05:02

US3342200

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(46)

Generated On: 09 Jun 2021 17:05:26

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:04:20
Data entry locked.	System	12 Nov 2020 20:39:53
User entered 'Day 46'	System	12 Nov 2020 20:39:53

US3342200

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(46)

Generated On: 09 Jun 2021 17:05:26

Did you receive any **MEDICAL ATTENTION** (doctor visit, other) for any illness or symptoms?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:04:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2D2D1647-7C35-4DCA-ADA3-8E1DAA921DDC)', Time: '2020-11-15T04:11:42', User OID: 'PatientReportedOutcome (US3342200)', ODM File OID: 'c41858e8-86b4-4a86-9ce5-ec765f859e0f' User entered 'No (N)'	System	15 Nov 2020 10:11:47
	System	15 Nov 2020 10:11:47

US3342200

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(46)

Generated On: 09 Jun 2021 17:05:26

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:04:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2D2D1647-7C35-4DCA-ADA3-8E1DAA921DDC)', Time: '2020-11-15T04:11:45', User OID: 'PatientReportedOutcome (US3342200)', ODM File OID: 'c41858e8-86b4-4a86-9ce5-ec765f859e0f' User entered '15 Nov 2020 04:11'	System	15 Nov 2020 10:11:47
	System	15 Nov 2020 10:11:47

US3342200

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(46)

Generated On: 09 Jun 2021 17:05:26

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:04:20
User entered '14 Nov 2020 12:00'	System	12 Nov 2020 20:39:53

US3342200

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(46)

Generated On: 09 Jun 2021 17:05:26

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:04:20
User entered '15 Nov 2020 11:59'	System	12 Nov 2020 20:39:53

US3342200

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(47)

Generated On: 09 Jun 2021 17:05:26

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:04:20
Data entry locked.	System	14 Nov 2020 00:17:29
User entered 'Day 47'	System	14 Nov 2020 00:17:29

US3342200

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(47)

Generated On: 09 Jun 2021 17:05:26

Did you receive any **MEDICAL ATTENTION** (doctor visit, other) for any illness or symptoms?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:04:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2D2D1647-7C35-4DCA-ADA3-8E1DAA921DDC)', Time: '2020-11-15T15:24:36', User OID: 'PatientReportedOutcome (US3342200)', ODM File OID: '939fed1e-fe13-425b-9699-448d77b0cfbb' User entered 'No (N)'	System	15 Nov 2020 21:24:42
	System	15 Nov 2020 21:24:42

US3342200

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(47)

Generated On: 09 Jun 2021 17:05:26

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:04:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2D2D1647-7C35-4DCA-ADA3-8E1DAA921DDC)', Time: '2020-11-15T15:24:40', User OID: 'PatientReportedOutcome (US3342200)', ODM File OID: '939fed1e-fe13-425b-9699-448d77b0cfbb' User entered '15 Nov 2020 15:24'	System	15 Nov 2020 21:24:42
	System	15 Nov 2020 21:24:42

US3342200

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(47)

Generated On: 09 Jun 2021 17:05:26

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:04:20
User entered '15 Nov 2020 12:00'	System	14 Nov 2020 00:17:29

US3342200

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(47)

Generated On: 09 Jun 2021 17:05:26

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:04:20
User entered '16 Nov 2020 11:59'	System	14 Nov 2020 00:17:29

US3342200

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(48)

Generated On: 09 Jun 2021 17:05:26

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:04:20
Data entry locked.	System	15 Nov 2020 10:11:35
User entered 'Day 48'	System	15 Nov 2020 10:11:35

US3342200

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(48)

Generated On: 09 Jun 2021 17:05:26

Did you receive any **MEDICAL ATTENTION** (doctor visit, other) for any illness or symptoms?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:04:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2D2D1647-7C35-4DCA-ADA3-8E1DAA921DDC)', Time: '2020-11-16T13:51:13', User OID: 'PatientReportedOutcome (US3342200)', ODM File OID: '817b9019-07f1-4efd-9139-eac093a9f13f' User entered 'No (N)'	System	16 Nov 2020 19:51:18
	System	16 Nov 2020 19:51:18

US3342200

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(48)

Generated On: 09 Jun 2021 17:05:26

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:04:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2D2D1647-7C35-4DCA-ADA3-8E1DAA921DDC)', Time: '2020-11-16T13:51:15', User OID: 'PatientReportedOutcome (US3342200)', ODM File OID: '817b9019-07f1-4efd-9139-eac093a9f13f' User entered '16 Nov 2020 13:51'	System	16 Nov 2020 19:51:18
	System	16 Nov 2020 19:51:18

US3342200

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(48)

Generated On: 09 Jun 2021 17:05:26

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:04:20
User entered '16 Nov 2020 12:00'	System	15 Nov 2020 10:11:35

US3342200

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(48)

Generated On: 09 Jun 2021 17:05:26

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:04:20
User entered '17 Nov 2020 11:59'	System	15 Nov 2020 10:11:35

US3342200

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(49)

Generated On: 09 Jun 2021 17:05:26

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:04:20
Data entry locked.	System	15 Nov 2020 21:24:36
User entered 'Day 49'	System	15 Nov 2020 21:24:36

US3342200

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(49)

Generated On: 09 Jun 2021 17:05:26

Did you receive any **MEDICAL ATTENTION** (doctor visit, other) for any illness or symptoms?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:04:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2D2D1647-7C35-4DCA-ADA3-8E1DAA921DDC)', Time: '2020-11-18T00:03:41', User OID: 'PatientReportedOutcome (US3342200)', ODM File OID: '93a21e81-4336-4cbd-b8ed-1fca0abc61b6' User entered 'No (N)'	System	18 Nov 2020 06:04:10
	System	18 Nov 2020 06:04:10

US3342200

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(49)

Generated On: 09 Jun 2021 17:05:26

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:04:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2D2D1647-7C35-4DCA-ADA3-8E1DAA921DDC)', Time: '2020-11-18T00:04:08', User OID: 'PatientReportedOutcome (US3342200)', ODM File OID: '93a21e81-4336-4cbd-b8ed-1fca0abc61b6' User entered '18 Nov 2020 00:04'	System	18 Nov 2020 06:04:10
	System	18 Nov 2020 06:04:10

US3342200

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(49)

Generated On: 09 Jun 2021 17:05:26

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:04:20
User entered '17 Nov 2020 12:00'	System	15 Nov 2020 21:24:36

US3342200

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(49)

Generated On: 09 Jun 2021 17:05:26

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:04:20
User entered '18 Nov 2020 11:59'	System	15 Nov 2020 21:24:36

US3342200

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(50)

Generated On: 09 Jun 2021 17:05:26

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:04:20
Data entry locked.	System	16 Nov 2020 19:51:07
User entered 'Day 50'	System	16 Nov 2020 19:51:07

US3342200

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(50)

Generated On: 09 Jun 2021 17:05:26

Did you receive any **MEDICAL ATTENTION** (doctor visit, other) for any illness or symptoms?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:04:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2D2D1647-7C35-4DCA-ADA3-8E1DAA921DDC)', Time: '2020-11-18T12:33:37', User OID: 'PatientReportedOutcome (US3342200)', ODM File OID: '503afd3a-a247-434f-b14e-158a1a327c55'	System	18 Nov 2020 18:33:48
User entered 'Yes (Y)'	System	18 Nov 2020 18:33:48

US3342200

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(50)

Generated On: 09 Jun 2021 17:05:26

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:04:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2D2D1647-7C35-4DCA-ADA3-8E1DAA921DDC)', Time: '2020-11-18T12:33:43', User OID: 'PatientReportedOutcome (US3342200)', ODM File OID: '503afd3a-a247-434f-b14e-158a1a327c55' User entered '18 Nov 2020 12:33'	System	18 Nov 2020 18:33:48
	System	18 Nov 2020 18:33:48

US3342200

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(50)

Generated On: 09 Jun 2021 17:05:26

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:04:20
User entered '18 Nov 2020 12:00'	System	16 Nov 2020 19:51:07

US3342200

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(50)

Generated On: 09 Jun 2021 17:05:26

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:04:20
User entered '19 Nov 2020 11:59'	System	16 Nov 2020 19:51:07

US3342200

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(51)

Generated On: 09 Jun 2021 17:05:26

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:04:20
Data entry locked.	System	18 Nov 2020 06:03:36
User entered 'Day 51'	System	18 Nov 2020 06:03:36

US3342200

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(51)

Generated On: 09 Jun 2021 17:05:26

Did you receive any **MEDICAL ATTENTION** (doctor visit, other) for any illness or symptoms?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:04:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2D2D1647-7C35-4DCA-ADA3-8E1DAA921DDC)', Time: '2020-11-20T05:59:42', User OID: 'PatientReportedOutcome (US3342200)', ODM File OID: 'a549c540-4520-4eb5-8a17-136343f4310d' User entered 'No (N)'	System	20 Nov 2020 11:59:48
	System	20 Nov 2020 11:59:48

US3342200

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(51)

Generated On: 09 Jun 2021 17:05:26

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:04:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2D2D1647-7C35-4DCA-ADA3-8E1DAA921DDC)', Time: '2020-11-20T05:59:45', User OID: 'PatientReportedOutcome (US3342200)', ODM File OID: 'a549c540-4520-4eb5-8a17-136343f4310d' User entered '20 Nov 2020 05:59'	System	20 Nov 2020 11:59:48
	System	20 Nov 2020 11:59:48

US3342200

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(51)

Generated On: 09 Jun 2021 17:05:26

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:04:20
User entered '19 Nov 2020 12:00'	System	18 Nov 2020 06:03:36

US3342200

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(51)

Generated On: 09 Jun 2021 17:05:26

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:04:20
User entered '20 Nov 2020 11:59'	System	18 Nov 2020 06:03:36

US3342200

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(52)

Generated On: 09 Jun 2021 17:05:26

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:04:20
Data entry locked.	System	18 Nov 2020 18:33:30
User entered 'Day 52'	System	18 Nov 2020 18:33:30

US3342200

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(52)

Generated On: 09 Jun 2021 17:05:26

Did you receive any **MEDICAL ATTENTION** (doctor visit, other) for any illness or symptoms?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:04:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2D2D1647-7C35-4DCA-ADA3-8E1DAA921DDC)', Time: '2020-11-21T04:06:24', User OID: 'PatientReportedOutcome (US3342200)', ODM File OID: '56b4fdb8-1273-41bb-908f-cfa93b67b7ed' User entered 'No (N)'	System	21 Nov 2020 10:06:32
	System	21 Nov 2020 10:06:32

US3342200

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(52)

Generated On: 09 Jun 2021 17:05:26

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:04:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2D2D1647-7C35-4DCA-ADA3-8E1DAA921DDC)', Time: '2020-11-21T04:06:29', User OID: 'PatientReportedOutcome (US3342200)', ODM File OID: '56b4fdb8-1273-41bb-908f-cfa93b67b7ed' User entered '21 Nov 2020 04:06'	System	21 Nov 2020 10:06:32
	System	21 Nov 2020 10:06:32

US3342200

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(52)

Generated On: 09 Jun 2021 17:05:26

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:04:20
User entered '20 Nov 2020 12:00'	System	18 Nov 2020 18:33:30

US3342200

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(52)

Generated On: 09 Jun 2021 17:05:26

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:04:20
User entered '21 Nov 2020 11:59'	System	18 Nov 2020 18:33:30

US3342200

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(53)

Generated On: 09 Jun 2021 17:05:26

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:04:20
Data entry locked.	System	20 Nov 2020 11:59:37
User entered 'Day 53'	System	20 Nov 2020 11:59:37

US3342200

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(53)

Generated On: 09 Jun 2021 17:05:26

Did you receive any **MEDICAL ATTENTION** (doctor visit, other) for any illness or symptoms?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:04:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2D2D1647-7C35-4DCA-ADA3-8E1DAA921DDC)', Time: '2020-11-22T00:46:47', User OID: 'PatientReportedOutcome (US3342200)', ODM File OID: 'e62b8e12-8ef5-453e-bd41-cfa6f099b87e' User entered 'No (N)'	System	22 Nov 2020 06:46:53
	System	22 Nov 2020 06:46:53

US3342200

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(53)

Generated On: 09 Jun 2021 17:05:26

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:04:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2D2D1647-7C35-4DCA-ADA3-8E1DAA921DDC)', Time: '2020-11-22T00:46:51', User OID: 'PatientReportedOutcome (US3342200)', ODM File OID: 'e62b8e12-8ef5-453e-bd41-cfa6f099b87e' User entered '22 Nov 2020 00:46'	System	22 Nov 2020 06:46:53
	System	22 Nov 2020 06:46:53

US3342200

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(53)

Generated On: 09 Jun 2021 17:05:26

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:04:20
User entered '21 Nov 2020 12:00'	System	20 Nov 2020 11:59:37

US3342200

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(53)

Generated On: 09 Jun 2021 17:05:26

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:04:20
User entered '22 Nov 2020 11:59'	System	20 Nov 2020 11:59:37

US3342200

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(54)

Generated On: 09 Jun 2021 17:05:26

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:04:20
Data entry locked.	System	21 Nov 2020 10:06:20
User entered 'Day 54'	System	21 Nov 2020 10:06:20

US3342200

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(54)

Generated On: 09 Jun 2021 17:05:26

Did you receive any **MEDICAL ATTENTION** (doctor visit, other) for any illness or symptoms?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:04:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2D2D1647-7C35-4DCA-ADA3-8E1DAA921DDC)', Time: '2020-11-22T17:30:34', User OID: 'PatientReportedOutcome (US3342200)', ODM File OID: '9d25c0ac-6ffd-4a87-ae0e-88bf598f9a2a' User entered 'No (N)'	System	22 Nov 2020 23:30:39
	System	22 Nov 2020 23:30:39

US3342200

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(54)

Generated On: 09 Jun 2021 17:05:26

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:04:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2D2D1647-7C35-4DCA-ADA3-8E1DAA921DDC)', Time: '2020-11-22T17:30:37', User OID: 'PatientReportedOutcome (US3342200)', ODM File OID: '9d25c0ac-6ffd-4a87-ae0e-88bf598f9a2a' User entered '22 Nov 2020 17:30'	System	22 Nov 2020 23:30:39
	System	22 Nov 2020 23:30:39

US3342200

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(54)

Generated On: 09 Jun 2021 17:05:26

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:04:20
User entered '22 Nov 2020 12:00'	System	21 Nov 2020 10:06:20

US3342200

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(54)

Generated On: 09 Jun 2021 17:05:26

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:04:20
User entered '23 Nov 2020 11:59'	System	21 Nov 2020 10:06:20

US3342200

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(55)

Generated On: 09 Jun 2021 17:05:26

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:04:20
Data entry locked.	System	22 Nov 2020 06:46:43
User entered 'Day 55'	System	22 Nov 2020 06:46:43

US3342200

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(55)

Generated On: 09 Jun 2021 17:05:26

Did you receive any **MEDICAL ATTENTION** (doctor visit, other) for any illness or symptoms?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:04:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2D2D1647-7C35-4DCA-ADA3-8E1DAA921DDC)', Time: '2020-11-23T12:02:30', User OID: 'PatientReportedOutcome (US3342200)', ODM File OID: '29923e59-280b-41f4-a483-3bcaf2b8ab05' User entered 'Yes (Y)'	System	23 Nov 2020 18:02:38
	System	23 Nov 2020 18:02:38

US3342200

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(55)

Generated On: 09 Jun 2021 17:05:26

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:04:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2D2D1647-7C35-4DCA-ADA3-8E1DAA921DDC)', Time: '2020-11-23T12:02:34', User OID: 'PatientReportedOutcome (US3342200)', ODM File OID: '29923e59-280b-41f4-a483-3bcaf2b8ab05' User entered '23 Nov 2020 12:02'	System	23 Nov 2020 18:02:38
	System	23 Nov 2020 18:02:38

US3342200

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(55)

Generated On: 09 Jun 2021 17:05:26

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:04:20
User entered '23 Nov 2020 12:00'	System	22 Nov 2020 06:46:43

US3342200

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(55)

Generated On: 09 Jun 2021 17:05:26

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:04:20
User entered '24 Nov 2020 11:59'	System	22 Nov 2020 06:46:43

US3342200

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(56)

Generated On: 09 Jun 2021 17:05:26

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:04:20
Data entry locked.	System	22 Nov 2020 23:30:27
User entered 'Day 56'	System	22 Nov 2020 23:30:27

US3342200

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(56)

Generated On: 09 Jun 2021 17:05:26

Did you receive any **MEDICAL ATTENTION** (doctor visit, other) for any illness or symptoms?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:04:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2D2D1647-7C35-4DCA-ADA3-8E1DAA921DDC)', Time: '2020-11-24T13:10:56', User OID: 'PatientReportedOutcome (US3342200)', ODM File OID: '3ba5ab69-0561-4bd6-844c-30bb5c79c75d' User entered 'No (N)'	System	24 Nov 2020 19:11:01
	System	24 Nov 2020 19:11:01

US3342200

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(56)

Generated On: 09 Jun 2021 17:05:26

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:04:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2D2D1647-7C35-4DCA-ADA3-8E1DAA921DDC)', Time: '2020-11-24T13:10:58', User OID: 'PatientReportedOutcome (US3342200)', ODM File OID: '3ba5ab69-0561-4bd6-844c-30bb5c79c75d' User entered '24 Nov 2020 13:10'	System	24 Nov 2020 19:11:01
	System	24 Nov 2020 19:11:01

US3342200

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(56)

Generated On: 09 Jun 2021 17:05:26

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:04:20
User entered '24 Nov 2020 12:00'	System	22 Nov 2020 23:30:27

US3342200

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(56)

Generated On: 09 Jun 2021 17:05:26

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:04:20
User entered '25 Nov 2020 11:59'	System	22 Nov 2020 23:30:27

US3342200

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(57)

Generated On: 09 Jun 2021 17:05:26

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:04:20
Data entry locked.	System	23 Nov 2020 18:02:09
User entered 'Day 57'	System	23 Nov 2020 18:02:09

US3342200

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(57)

Generated On: 09 Jun 2021 17:05:26

Did you receive any **MEDICAL ATTENTION** (doctor visit, other) for any illness or symptoms?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:04:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2D2D1647-7C35-4DCA-ADA3-8E1DAA921DDC)', Time: '2020-11-25T16:13:20', User OID: 'PatientReportedOutcome (US3342200)', ODM File OID: '19a1c94d-cbde-4d0a-a3cc-e83ea9cdb2f0' User entered 'Yes (Y)'	System	25 Nov 2020 22:13:24
	System	25 Nov 2020 22:13:24

US3342200

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(57)

Generated On: 09 Jun 2021 17:05:26

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:04:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2D2D1647-7C35-4DCA-ADA3-8E1DAA921DDC)', Time: '2020-11-25T16:13:22', User OID: 'PatientReportedOutcome (US3342200)', ODM File OID: '19a1c94d-cbde-4d0a-a3cc-e83ea9cdb2f0' User entered '25 Nov 2020 16:13'	System	25 Nov 2020 22:13:24
	System	25 Nov 2020 22:13:24

US3342200

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(57)

Generated On: 09 Jun 2021 17:05:26

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:04:20
User entered '25 Nov 2020 12:00'	System	23 Nov 2020 18:02:09

US3342200

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(57)

Generated On: 09 Jun 2021 17:05:26

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:04:20
User entered '26 Nov 2020 11:59'	System	23 Nov 2020 18:02:09

US3342200

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(58)

Generated On: 09 Jun 2021 17:05:26

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:04:20
Data entry locked.	System	24 Nov 2020 19:10:04
User entered 'Day 58'	System	24 Nov 2020 19:10:04

US3342200

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(58)

Generated On: 09 Jun 2021 17:05:26

Did you receive any **MEDICAL ATTENTION** (doctor visit, other) for any illness or symptoms?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:04:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2D2D1647-7C35-4DCA-ADA3-8E1DAA921DDC)', Time: '2020-11-26T12:17:08', User OID: 'PatientReportedOutcome (US3342200)', ODM File OID: '50eec563-4950-47cc-9411-41f1f4878284' User entered 'No (N)'	System	26 Nov 2020 18:17:12
	System	26 Nov 2020 18:17:12

US3342200

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(58)

Generated On: 09 Jun 2021 17:05:26

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:04:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2D2D1647-7C35-4DCA-ADA3-8E1DAA921DDC)', Time: '2020-11-26T12:17:10', User OID: 'PatientReportedOutcome (US3342200)', ODM File OID: '50eec563-4950-47cc-9411-41f1f4878284' User entered '26 Nov 2020 12:17'	System	26 Nov 2020 18:17:12
	System	26 Nov 2020 18:17:12

US3342200

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(58)

Generated On: 09 Jun 2021 17:05:26

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:04:20
User entered '26 Nov 2020 12:00'	System	24 Nov 2020 19:10:04

US3342200

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(58)

Generated On: 09 Jun 2021 17:05:26

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:04:20
User entered '27 Nov 2020 11:59'	System	24 Nov 2020 19:10:04

US3342200

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(59)

Generated On: 09 Jun 2021 17:05:26

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:04:20
Data entry locked.	System	25 Nov 2020 22:13:05
User entered 'Day 59'	System	25 Nov 2020 22:13:05

US3342200

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(59)

Generated On: 09 Jun 2021 17:05:26

Did you receive any **MEDICAL ATTENTION** (doctor visit, other) for any illness or symptoms?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:04:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2D2D1647-7C35-4DCA-ADA3-8E1DAA921DDC)', Time: '2020-11-27T12:04:51', User OID: 'PatientReportedOutcome (US3342200)', ODM File OID: '59536820-42c6-44ef-9e65-97e8a72858c3' User entered 'No (N)'	System	27 Nov 2020 18:04:57
	System	27 Nov 2020 18:04:57

US3342200

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(59)

Generated On: 09 Jun 2021 17:05:26

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:04:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2D2D1647-7C35-4DCA-ADA3-8E1DAA921DDC)', Time: '2020-11-27T12:04:53', User OID: 'PatientReportedOutcome (US3342200)', ODM File OID: '59536820-42c6-44ef-9e65-97e8a72858c3' User entered '27 Nov 2020 12:04'	System	27 Nov 2020 18:04:57
	System	27 Nov 2020 18:04:57

US3342200

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(59)

Generated On: 09 Jun 2021 17:05:26

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:04:20
User entered '27 Nov 2020 12:00'	System	25 Nov 2020 22:13:05

US3342200

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(59)

Generated On: 09 Jun 2021 17:05:26

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:04:20
User entered '28 Nov 2020 11:59'	System	25 Nov 2020 22:13:05

US3342200

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(60)

Generated On: 09 Jun 2021 17:05:26

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:04:20
Data entry locked.	System	26 Nov 2020 18:17:07
User entered 'Day 60'	System	26 Nov 2020 18:17:07

US3342200

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(60)

Generated On: 09 Jun 2021 17:05:26

Did you receive any **MEDICAL ATTENTION** (doctor visit, other) for any illness or symptoms?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:04:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2D2D1647-7C35-4DCA-ADA3-8E1DAA921DDC)', Time: '2020-11-28T13:17:34', User OID: 'PatientReportedOutcome (US3342200)', ODM File OID: '900943c7-680e-4baf-ac60-614d49e0760b' User entered 'No (N)'	System	28 Nov 2020 19:17:44
	System	28 Nov 2020 19:17:44

US3342200

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(60)

Generated On: 09 Jun 2021 17:05:26

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:04:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2D2D1647-7C35-4DCA-ADA3-8E1DAA921DDC)', Time: '2020-11-28T13:17:37', User OID: 'PatientReportedOutcome (US3342200)', ODM File OID: '900943c7-680e-4baf-ac60-614d49e0760b' User entered '28 Nov 2020 13:17'	System	28 Nov 2020 19:17:44
	System	28 Nov 2020 19:17:44

US3342200

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(60)

Generated On: 09 Jun 2021 17:05:26

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:04:20
User entered '28 Nov 2020 12:00'	System	26 Nov 2020 18:17:07

US3342200

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(60)

Generated On: 09 Jun 2021 17:05:26

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:04:20
User entered '29 Nov 2020 11:59'	System	26 Nov 2020 18:17:07

US3342200

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(61)

Generated On: 09 Jun 2021 17:05:26

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:04:20
Data entry locked.	System	27 Nov 2020 18:04:52
User entered 'Day 61'	System	27 Nov 2020 18:04:52

US3342200

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(61)

Generated On: 09 Jun 2021 17:05:26

Did you receive any **MEDICAL ATTENTION** (doctor visit, other) for any illness or symptoms?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:04:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2D2D1647-7C35-4DCA-ADA3-8E1DAA921DDC)', Time: '2020-11-29T12:13:54', User OID: 'PatientReportedOutcome (US3342200)', ODM File OID: '5fbc85a9-e610-4e57-b0e9-0ad1a1d9e0c5' User entered 'No (N)'	System	29 Nov 2020 18:14:00
	System	29 Nov 2020 18:14:00

US3342200

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(61)

Generated On: 09 Jun 2021 17:05:26

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:04:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2D2D1647-7C35-4DCA-ADA3-8E1DAA921DDC)', Time: '2020-11-29T12:13:57', User OID: 'PatientReportedOutcome (US3342200)', ODM File OID: '5fbc85a9-e610-4e57-b0e9-0ad1a1d9e0c5' User entered '29 Nov 2020 12:13'	System	29 Nov 2020 18:14:00
	System	29 Nov 2020 18:14:00

US3342200

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(61)

Generated On: 09 Jun 2021 17:05:26

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:04:20
User entered '29 Nov 2020 12:00'	System	27 Nov 2020 18:04:52

US3342200

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(61)

Generated On: 09 Jun 2021 17:05:26

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:04:20
User entered '30 Nov 2020 11:59'	System	27 Nov 2020 18:04:52

US3342200

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(62)

Generated On: 09 Jun 2021 17:05:26

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:04:20
Data entry locked.	System	28 Nov 2020 19:17:32
User entered 'Day 62'	System	28 Nov 2020 19:17:32

US3342200

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(62)

Generated On: 09 Jun 2021 17:05:26

Did you receive any **MEDICAL ATTENTION** (doctor visit, other) for any illness or symptoms?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:04:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2D2D1647-7C35-4DCA-ADA3-8E1DAA921DDC)', Time: '2020-11-30T13:17:48', User OID: 'PatientReportedOutcome (US3342200)', ODM File OID: '748b9733-b4e8-4be9-8e6f-e04135be3e87' User entered 'Yes (Y)'	System	30 Nov 2020 19:17:58
	System	30 Nov 2020 19:17:58

US3342200

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(62)

Generated On: 09 Jun 2021 17:05:26

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:04:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2D2D1647-7C35-4DCA-ADA3-8E1DAA921DDC)', Time: '2020-11-30T13:17:54', User OID: 'PatientReportedOutcome (US3342200)', ODM File OID: '748b9733-b4e8-4be9-8e6f-e04135be3e87' User entered '30 Nov 2020 13:17'	System	30 Nov 2020 19:17:58
	System	30 Nov 2020 19:17:58

US3342200

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(62)

Generated On: 09 Jun 2021 17:05:26

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:04:20
User entered '30 Nov 2020 12:00'	System	28 Nov 2020 19:17:32

US3342200

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(62)

Generated On: 09 Jun 2021 17:05:26

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:04:20
User entered '01 Dec 2020 11:59'	System	28 Nov 2020 19:17:32

US3342200

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(63)

Generated On: 09 Jun 2021 17:05:26

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:04:20
Data entry locked.	System	29 Nov 2020 18:13:51
User entered 'Day 63'	System	29 Nov 2020 18:13:51

US3342200

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(63)

Generated On: 09 Jun 2021 17:05:26

Did you receive any **MEDICAL ATTENTION** (doctor visit, other) for any illness or symptoms?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:04:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2D2D1647-7C35-4DCA-ADA3-8E1DAA921DDC)', Time: '2020-12-02T04:51:44', User OID: 'PatientReportedOutcome (US3342200)', ODM File OID: 'aecbec4b-82bc-4269-89c4-256639fe34a8' User entered 'No (N)'	System	02 Dec 2020 10:51:52
	System	02 Dec 2020 10:51:52

US3342200

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(63)

Generated On: 09 Jun 2021 17:05:26

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:04:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2D2D1647-7C35-4DCA-ADA3-8E1DAA921DDC)', Time: '2020-12-02T04:51:51', User OID: 'PatientReportedOutcome (US3342200)', ODM File OID: 'aecbec4b-82bc-4269-89c4-256639fe34a8' User entered '02 Dec 2020 04:51'	System	02 Dec 2020 10:51:52
	System	02 Dec 2020 10:51:52

US3342200

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(63)

Generated On: 09 Jun 2021 17:05:26

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:04:20
User entered '01 Dec 2020 12:00'	System	29 Nov 2020 18:13:51

US3342200

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(63)

Generated On: 09 Jun 2021 17:05:26

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:04:20
User entered '02 Dec 2020 11:59'	System	29 Nov 2020 18:13:51

US3342200

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(64)

Generated On: 09 Jun 2021 17:05:26

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:04:20
Data entry locked.	System	30 Nov 2020 19:17:27
User entered 'Day 64'	System	30 Nov 2020 19:17:27

US3342200

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(64)

Generated On: 09 Jun 2021 17:05:26

Did you receive any **MEDICAL ATTENTION** (doctor visit, other) for any illness or symptoms?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:04:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2D2D1647-7C35-4DCA-ADA3-8E1DAA921DDC)', Time: '2020-12-02T12:01:03', User OID: 'PatientReportedOutcome (US3342200)', ODM File OID: '0385c6e2-a9d8-4fba-b475-146b6b5047ac' User entered 'Yes (Y)'	System	02 Dec 2020 18:01:12
	System	02 Dec 2020 18:01:12

US3342200

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(64)

Generated On: 09 Jun 2021 17:05:26

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:04:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2D2D1647-7C35-4DCA-ADA3-8E1DAA921DDC)', Time: '2020-12-02T12:01:08', User OID: 'PatientReportedOutcome (US3342200)', ODM File OID: '0385c6e2-a9d8-4fba-b475-146b6b5047ac' User entered '02 Dec 2020 12:01'	System	02 Dec 2020 18:01:12
	System	02 Dec 2020 18:01:12

US3342200

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(64)

Generated On: 09 Jun 2021 17:05:26

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:04:20
User entered '02 Dec 2020 12:00'	System	30 Nov 2020 19:17:27

US3342200

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(64)

Generated On: 09 Jun 2021 17:05:26

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:04:20
User entered '03 Dec 2020 11:59'	System	30 Nov 2020 19:17:27

US3342200

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(65)

Generated On: 09 Jun 2021 17:05:26

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:04:20
Data entry locked.	System	02 Dec 2020 10:51:38
User entered 'Day 65'	System	02 Dec 2020 10:51:38

US3342200

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(65)

Generated On: 09 Jun 2021 17:05:26

Did you receive any **MEDICAL ATTENTION** (doctor visit, other) for any illness or symptoms?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:04:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2D2D1647-7C35-4DCA-ADA3-8E1DAA921DDC)', Time: '2020-12-03T13:03:28', User OID: 'PatientReportedOutcome (US3342200)', ODM File OID: 'da08edc6-9edf-42ec-bcc9-1a53fbdcafdc' User entered 'Yes (Y)'	System	03 Dec 2020 19:03:40
	System	03 Dec 2020 19:03:40

US3342200

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(65)

Generated On: 09 Jun 2021 17:05:26

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:04:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2D2D1647-7C35-4DCA-ADA3-8E1DAA921DDC)', Time: '2020-12-03T13:03:31', User OID: 'PatientReportedOutcome (US3342200)', ODM File OID: 'da08edc6-9edf-42ec-bcc9-1a53fbdcafdc' User entered '03 Dec 2020 13:03'	System	03 Dec 2020 19:03:40
	System	03 Dec 2020 19:03:40

US3342200

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(65)

Generated On: 09 Jun 2021 17:05:26

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:04:20
User entered '03 Dec 2020 12:00'	System	02 Dec 2020 10:51:38

US3342200

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(65)

Generated On: 09 Jun 2021 17:05:26

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:04:20
User entered '04 Dec 2020 11:59'	System	02 Dec 2020 10:51:38

US3342200

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(66)

Generated On: 09 Jun 2021 17:05:26

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:04:20
Data entry locked.	System	02 Dec 2020 18:00:57
User entered 'Day 66'	System	02 Dec 2020 18:00:57

US3342200

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(66)

Generated On: 09 Jun 2021 17:05:26

Did you receive any **MEDICAL ATTENTION** (doctor visit, other) for any illness or symptoms?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:04:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2D2D1647-7C35-4DCA-ADA3-8E1DAA921DDC)', Time: '2020-12-04T12:00:47', User OID: 'PatientReportedOutcome (US3342200)', ODM File OID: '0bbc51be-1c0a-4a8d-b7be-92a0746f7e68' User entered 'No (N)'	System	04 Dec 2020 18:00:54
	System	04 Dec 2020 18:00:54

US3342200

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(66)

Generated On: 09 Jun 2021 17:05:26

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:04:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2D2D1647-7C35-4DCA-ADA3-8E1DAA921DDC)', Time: '2020-12-04T12:00:51', User OID: 'PatientReportedOutcome (US3342200)', ODM File OID: '0bbc51be-1c0a-4a8d-b7be-92a0746f7e68' User entered '04 Dec 2020 12:00'	System	04 Dec 2020 18:00:54
	System	04 Dec 2020 18:00:54

US3342200

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(66)

Generated On: 09 Jun 2021 17:05:26

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:04:20
User entered '04 Dec 2020 12:00'	System	02 Dec 2020 18:00:57

US3342200

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(66)

Generated On: 09 Jun 2021 17:05:26

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:04:20
User entered '05 Dec 2020 11:59'	System	02 Dec 2020 18:00:57

US3342200

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(67)

Generated On: 09 Jun 2021 17:05:26

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:04:20
Data entry locked.	System	03 Dec 2020 19:03:26
User entered 'Day 67'	System	03 Dec 2020 19:03:26

US3342200

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(67)

Generated On: 09 Jun 2021 17:05:26

Did you receive any **MEDICAL ATTENTION** (doctor visit, other) for any illness or symptoms?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:04:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2D2D1647-7C35-4DCA-ADA3-8E1DAA921DDC)', Time: '2020-12-05T19:56:21', User OID: 'PatientReportedOutcome (US3342200)', ODM File OID: 'bdef5081-9942-437e-abee-a071dcbb5af0' User entered 'No (N)'	System	06 Dec 2020 01:56:25
	System	06 Dec 2020 01:56:25

US3342200

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(67)

Generated On: 09 Jun 2021 17:05:26

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:04:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2D2D1647-7C35-4DCA-ADA3-8E1DAA921DDC)', Time: '2020-12-05T19:56:24', User OID: 'PatientReportedOutcome (US3342200)', ODM File OID: 'bdef5081-9942-437e-abee-a071dcbb5af0' User entered '05 Dec 2020 19:56'	System	06 Dec 2020 01:56:25
	System	06 Dec 2020 01:56:25

US3342200

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(67)

Generated On: 09 Jun 2021 17:05:26

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:04:20
User entered '05 Dec 2020 12:00'	System	03 Dec 2020 19:03:26

US3342200

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(67)

Generated On: 09 Jun 2021 17:05:26

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:04:20
User entered '06 Dec 2020 11:59'	System	03 Dec 2020 19:03:26

US3342200

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(68)

Generated On: 09 Jun 2021 17:05:26

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:04:20
Data entry locked.	System	04 Dec 2020 18:00:34
User entered 'Day 68'	System	04 Dec 2020 18:00:34

US3342200

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(68)

Generated On: 09 Jun 2021 17:05:26

Did you receive any **MEDICAL ATTENTION** (doctor visit, other) for any illness or symptoms?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:04:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2D2D1647-7C35-4DCA-ADA3-8E1DAA921DDC)', Time: '2020-12-06T12:50:20', User OID: 'PatientReportedOutcome (US3342200)', ODM File OID: '68eaa6e1-06a5-43e1-9aba-0943eaa677ac' User entered 'No (N)'	System	06 Dec 2020 18:50:26
	System	06 Dec 2020 18:50:26

US3342200

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(68)

Generated On: 09 Jun 2021 17:05:26

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:04:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2D2D1647-7C35-4DCA-ADA3-8E1DAA921DDC)', Time: '2020-12-06T12:50:23', User OID: 'PatientReportedOutcome (US3342200)', ODM File OID: '68eaa6e1-06a5-43e1-9aba-0943eaa677ac' User entered '06 Dec 2020 12:50'	System	06 Dec 2020 18:50:26
	System	06 Dec 2020 18:50:26

US3342200

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(68)

Generated On: 09 Jun 2021 17:05:26

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:04:20
User entered '06 Dec 2020 12:00'	System	04 Dec 2020 18:00:34

US3342200

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(68)

Generated On: 09 Jun 2021 17:05:26

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:04:20
User entered '07 Dec 2020 11:59'	System	04 Dec 2020 18:00:34

US3342200

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(69)

Generated On: 09 Jun 2021 17:05:26

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:04:20
Data entry locked.	System	06 Dec 2020 01:56:19
User entered 'Day 69'	System	06 Dec 2020 01:56:19

US3342200

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(69)

Generated On: 09 Jun 2021 17:05:26

Did you receive any **MEDICAL ATTENTION** (doctor visit, other) for any illness or symptoms?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:04:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2D2D1647-7C35-4DCA-ADA3-8E1DAA921DDC)', Time: '2020-12-07T12:07:11', User OID: 'PatientReportedOutcome (US3342200)', ODM File OID: 'e5fcd469-f30d-47ca-a2a8-88339a020bc5' User entered 'Yes (Y)'	System	07 Dec 2020 18:07:18
	System	07 Dec 2020 18:07:18

US3342200

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(69)

Generated On: 09 Jun 2021 17:05:26

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:04:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2D2D1647-7C35-4DCA-ADA3-8E1DAA921DDC)', Time: '2020-12-07T12:07:14', User OID: 'PatientReportedOutcome (US3342200)', ODM File OID: 'e5fcd469-f30d-47ca-a2a8-88339a020bc5' User entered '07 Dec 2020 12:07'	System	07 Dec 2020 18:07:18
	System	07 Dec 2020 18:07:18

US3342200

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(69)

Generated On: 09 Jun 2021 17:05:26

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:04:20
User entered '07 Dec 2020 12:00'	System	06 Dec 2020 01:56:19

US3342200

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(69)

Generated On: 09 Jun 2021 17:05:26

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:04:20
User entered '08 Dec 2020 11:59'	System	06 Dec 2020 01:56:19

US3342200

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(70)

Generated On: 09 Jun 2021 17:05:26

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:04:20
Data entry locked.	System	06 Dec 2020 18:50:15
User entered 'Day 70'	System	06 Dec 2020 18:50:15

US3342200

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(70)

Generated On: 09 Jun 2021 17:05:26

Did you receive any **MEDICAL ATTENTION** (doctor visit, other) for any illness or symptoms?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:04:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2D2D1647-7C35-4DCA-ADA3-8E1DAA921DDC)', Time: '2020-12-08T13:05:40', User OID: 'PatientReportedOutcome (US3342200)', ODM File OID: '892cfe0d-23b8-43c4-a468-20165f168a73' User entered 'No (N)'	System	08 Dec 2020 19:05:47
	System	08 Dec 2020 19:05:47

US3342200

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(70)

Generated On: 09 Jun 2021 17:05:26

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:04:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2D2D1647-7C35-4DCA-ADA3-8E1DAA921DDC)', Time: '2020-12-08T13:05:42', User OID: 'PatientReportedOutcome (US3342200)', ODM File OID: '892cfe0d-23b8-43c4-a468-20165f168a73' User entered '08 Dec 2020 13:05'	System	08 Dec 2020 19:05:47
	System	08 Dec 2020 19:05:47

US3342200

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(70)

Generated On: 09 Jun 2021 17:05:26

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:04:20
User entered '08 Dec 2020 12:00'	System	06 Dec 2020 18:50:15

US3342200

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(70)

Generated On: 09 Jun 2021 17:05:26

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:04:20
User entered '09 Dec 2020 11:59'	System	06 Dec 2020 18:50:15

US3342200

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(71)

Generated On: 09 Jun 2021 17:05:26

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:04:20
Data entry locked.	System	07 Dec 2020 18:07:09
User entered 'Day 71'	System	07 Dec 2020 18:07:09

US3342200

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(71)

Generated On: 09 Jun 2021 17:05:26

Did you receive any **MEDICAL ATTENTION** (doctor visit, other) for any illness or symptoms?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:04:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2D2D1647-7C35-4DCA-ADA3-8E1DAA921DDC)', Time: '2020-12-09T13:54:36', User OID: 'PatientReportedOutcome (US3342200)', ODM File OID: 'ba6458cb-3cd4-4426-8be2-f4c2a8b7573f' User entered 'No (N)'	System	09 Dec 2020 19:54:42
	System	09 Dec 2020 19:54:42

US3342200

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(71)

Generated On: 09 Jun 2021 17:05:26

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:04:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2D2D1647-7C35-4DCA-ADA3-8E1DAA921DDC)', Time: '2020-12-09T13:54:38', User OID: 'PatientReportedOutcome (US3342200)', ODM File OID: 'ba6458cb-3cd4-4426-8be2-f4c2a8b7573f' User entered '09 Dec 2020 13:54'	System	09 Dec 2020 19:54:42
	System	09 Dec 2020 19:54:42

US3342200

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(71)

Generated On: 09 Jun 2021 17:05:26

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:04:20
User entered '09 Dec 2020 12:00'	System	07 Dec 2020 18:07:09

US3342200

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(71)

Generated On: 09 Jun 2021 17:05:26

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:04:20
User entered '10 Dec 2020 11:59'	System	07 Dec 2020 18:07:09

US3342200

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(72)

Generated On: 09 Jun 2021 17:05:26

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:04:20
Data entry locked.	System	08 Dec 2020 19:05:39
User entered 'Day 72'	System	08 Dec 2020 19:05:39

US3342200

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(72)

Generated On: 09 Jun 2021 17:05:26

Did you receive any **MEDICAL ATTENTION** (doctor visit, other) for any illness or symptoms?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:04:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2D2D1647-7C35-4DCA-ADA3-8E1DAA921DDC)', Time: '2020-12-10T12:39:10', User OID: 'PatientReportedOutcome (US3342200)', ODM File OID: '5cb3444a-f458-48f9-af89-636174461f98' User entered 'No (N)'	System	10 Dec 2020 18:39:15
	System	10 Dec 2020 18:39:15

US3342200

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(72)

Generated On: 09 Jun 2021 17:05:26

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:04:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2D2D1647-7C35-4DCA-ADA3-8E1DAA921DDC)', Time: '2020-12-10T12:39:13', User OID: 'PatientReportedOutcome (US3342200)', ODM File OID: '5cb3444a-f458-48f9-af89-636174461f98' User entered '10 Dec 2020 12:39'	System	10 Dec 2020 18:39:15
	System	10 Dec 2020 18:39:15

US3342200

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(72)

Generated On: 09 Jun 2021 17:05:26

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:04:20
User entered '10 Dec 2020 12:00'	System	08 Dec 2020 19:05:39

US3342200

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(72)

Generated On: 09 Jun 2021 17:05:26

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:04:20
User entered '11 Dec 2020 11:59'	System	08 Dec 2020 19:05:39

US3342200

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(73)

Generated On: 09 Jun 2021 17:05:26

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:04:20
Data entry locked.	System	09 Dec 2020 19:54:37
User entered 'Day 73'	System	09 Dec 2020 19:54:37

US3342200

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(73)

Generated On: 09 Jun 2021 17:05:26

Did you receive any **MEDICAL ATTENTION** (doctor visit, other) for any illness or symptoms?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:04:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2D2D1647-7C35-4DCA-ADA3-8E1DAA921DDC)', Time: '2020-12-11T12:19:07', User OID: 'PatientReportedOutcome (US3342200)', ODM File OID: 'dd7f6427-e6e6-4b22-ba15-2ea0861cfaed' User entered 'No (N)'	System	11 Dec 2020 18:19:12
	System	11 Dec 2020 18:19:12

US3342200

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(73)

Generated On: 09 Jun 2021 17:05:26

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:04:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2D2D1647-7C35-4DCA-ADA3-8E1DAA921DDC)', Time: '2020-12-11T12:19:09', User OID: 'PatientReportedOutcome (US3342200)', ODM File OID: 'dd7f6427-e6e6-4b22-ba15-2ea0861cfaed' User entered '11 Dec 2020 12:19'	System	11 Dec 2020 18:19:12
	System	11 Dec 2020 18:19:12

US3342200

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(73)

Generated On: 09 Jun 2021 17:05:26

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:04:20
User entered '11 Dec 2020 12:00'	System	09 Dec 2020 19:54:37

US3342200

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(73)

Generated On: 09 Jun 2021 17:05:26

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:04:20
User entered '12 Dec 2020 11:59'	System	09 Dec 2020 19:54:37

US3342200

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(74)

Generated On: 09 Jun 2021 17:05:26

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:04:20
Data entry locked.	System	10 Dec 2020 18:39:09
User entered 'Day 74'	System	10 Dec 2020 18:39:09

US3342200

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(74)

Generated On: 09 Jun 2021 17:05:26

Did you receive any **MEDICAL ATTENTION** (doctor visit, other) for any illness or symptoms?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:04:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2D2D1647-7C35-4DCA-ADA3-8E1DAA921DDC)', Time: '2020-12-13T00:06:13', User OID: 'PatientReportedOutcome (US3342200)', ODM File OID: '784dc833-2550-4c06-b665-9ad4ea3f70f0' User entered 'No (N)'	System	13 Dec 2020 06:06:21
	System	13 Dec 2020 06:06:21

US3342200

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(74)

Generated On: 09 Jun 2021 17:05:26

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:04:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2D2D1647-7C35-4DCA-ADA3-8E1DAA921DDC)', Time: '2020-12-13T00:06:18', User OID: 'PatientReportedOutcome (US3342200)', ODM File OID: '784dc833-2550-4c06-b665-9ad4ea3f70f0' User entered '13 Dec 2020 00:06'	System	13 Dec 2020 06:06:21
	System	13 Dec 2020 06:06:21

US3342200

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(74)

Generated On: 09 Jun 2021 17:05:26

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:04:20
User entered '12 Dec 2020 12:00'	System	10 Dec 2020 18:39:09

US3342200

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(74)

Generated On: 09 Jun 2021 17:05:26

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:04:20
User entered '13 Dec 2020 11:59'	System	10 Dec 2020 18:39:09

US3342200

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(75)

Generated On: 09 Jun 2021 17:05:26

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:04:20
Data entry locked.	System	11 Dec 2020 18:19:07
User entered 'Day 75'	System	11 Dec 2020 18:19:07

US3342200

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(75)

Generated On: 09 Jun 2021 17:05:26

Did you receive any **MEDICAL ATTENTION** (doctor visit, other) for any illness or symptoms?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:04:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2D2D1647-7C35-4DCA-ADA3-8E1DAA921DDC)', Time: '2020-12-14T03:28:53', User OID: 'PatientReportedOutcome (US3342200)', ODM File OID: 'c38aed74-a4e7-4f74-b078-621ea2069416' User entered 'No (N)'	System	14 Dec 2020 09:28:58
	System	14 Dec 2020 09:28:58

US3342200

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(75)

Generated On: 09 Jun 2021 17:05:26

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:04:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2D2D1647-7C35-4DCA-ADA3-8E1DAA921DDC)', Time: '2020-12-14T03:28:55', User OID: 'PatientReportedOutcome (US3342200)', ODM File OID: 'c38aed74-a4e7-4f74-b078-621ea2069416' User entered '14 Dec 2020 03:28'	System	14 Dec 2020 09:28:58
	System	14 Dec 2020 09:28:58

US3342200

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(75)

Generated On: 09 Jun 2021 17:05:26

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:04:20
User entered '13 Dec 2020 12:00'	System	11 Dec 2020 18:19:07

US3342200

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(75)

Generated On: 09 Jun 2021 17:05:26

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:04:20
User entered '14 Dec 2020 11:59'	System	11 Dec 2020 18:19:07

US3342200

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(76)

Generated On: 09 Jun 2021 17:05:26

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:04:20
Data entry locked.	System	13 Dec 2020 06:06:11
User entered 'Day 76'	System	13 Dec 2020 06:06:11

US3342200

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(76)

Generated On: 09 Jun 2021 17:05:26

Did you receive any **MEDICAL ATTENTION** (doctor visit, other) for any illness or symptoms?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:04:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2D2D1647-7C35-4DCA-ADA3-8E1DAA921DDC)', Time: '2020-12-14T13:30:03', User OID: 'PatientReportedOutcome (US3342200)', ODM File OID: '6e1e0c7a-1cc9-425e-9fbe-73c87bf38c81' User entered 'No (N)'	System	14 Dec 2020 19:30:10
	System	14 Dec 2020 19:30:10

US3342200

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(76)

Generated On: 09 Jun 2021 17:05:26

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:04:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2D2D1647-7C35-4DCA-ADA3-8E1DAA921DDC)', Time: '2020-12-14T13:30:08', User OID: 'PatientReportedOutcome (US3342200)', ODM File OID: '6e1e0c7a-1cc9-425e-9fbe-73c87bf38c81' User entered '14 Dec 2020 13:30'	System	14 Dec 2020 19:30:10
	System	14 Dec 2020 19:30:10

US3342200

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(76)

Generated On: 09 Jun 2021 17:05:26

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:04:20
User entered '14 Dec 2020 12:00'	System	13 Dec 2020 06:06:11

US3342200

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(76)

Generated On: 09 Jun 2021 17:05:26

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:04:20
User entered '15 Dec 2020 11:59'	System	13 Dec 2020 06:06:11

US3342200

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(77)

Generated On: 09 Jun 2021 17:05:26

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:04:20
Data entry locked.	System	14 Dec 2020 09:28:52
User entered 'Day 77'	System	14 Dec 2020 09:28:52

US3342200

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(77)

Generated On: 09 Jun 2021 17:05:26

Did you receive any **MEDICAL ATTENTION** (doctor visit, other) for any illness or symptoms?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:04:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2D2D1647-7C35-4DCA-ADA3-8E1DAA921DDC)', Time: '2020-12-15T15:07:18', User OID: 'PatientReportedOutcome (US3342200)', ODM File OID: '70c6cc14-76ce-4d0b-831c-11129fc0802d' User entered 'No (N)'	System	15 Dec 2020 21:07:24
	System	15 Dec 2020 21:07:24

US3342200

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(77)

Generated On: 09 Jun 2021 17:05:26

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:04:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2D2D1647-7C35-4DCA-ADA3-8E1DAA921DDC)', Time: '2020-12-15T15:07:20', User OID: 'PatientReportedOutcome (US3342200)', ODM File OID: '70c6cc14-76ce-4d0b-831c-11129fc0802d' User entered '15 Dec 2020 15:07'	System	15 Dec 2020 21:07:24
	System	15 Dec 2020 21:07:24

US3342200

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(77)

Generated On: 09 Jun 2021 17:05:26

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:04:20
User entered '15 Dec 2020 12:00'	System	14 Dec 2020 09:28:52

US3342200

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(77)

Generated On: 09 Jun 2021 17:05:26

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:04:20
User entered '16 Dec 2020 11:59'	System	14 Dec 2020 09:28:52

US3342200

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(78)

Generated On: 09 Jun 2021 17:05:26

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:04:20
Data entry locked.	System	14 Dec 2020 19:29:56
User entered 'Day 78'	System	14 Dec 2020 19:29:56

US3342200

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(78)

Generated On: 09 Jun 2021 17:05:26

Did you receive any **MEDICAL ATTENTION** (doctor visit, other) for any illness or symptoms?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:04:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2D2D1647-7C35-4DCA-ADA3-8E1DAA921DDC)', Time: '2020-12-16T16:03:50', User OID: 'PatientReportedOutcome (US3342200)', ODM File OID: '6606fa90-6899-4fc0-85f1-28f8922247c0' User entered 'No (N)'	System	16 Dec 2020 22:05:56
	System	16 Dec 2020 22:05:56

US3342200

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(78)

Generated On: 09 Jun 2021 17:05:26

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:04:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2D2D1647-7C35-4DCA-ADA3-8E1DAA921DDC)', Time: '2020-12-16T16:05:54', User OID: 'PatientReportedOutcome (US3342200)', ODM File OID: '6606fa90-6899-4fc0-85f1-28f8922247c0' User entered '16 Dec 2020 16:05'	System	16 Dec 2020 22:05:56
	System	16 Dec 2020 22:05:56

US3342200

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(78)

Generated On: 09 Jun 2021 17:05:26

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:04:20
User entered '16 Dec 2020 12:00'	System	14 Dec 2020 19:29:56

US3342200

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(78)

Generated On: 09 Jun 2021 17:05:26

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:04:20
User entered '17 Dec 2020 11:59'	System	14 Dec 2020 19:29:56

US3342200

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(79)

Generated On: 09 Jun 2021 17:05:26

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:04:20
Data entry locked.	System	15 Dec 2020 21:07:17
User entered 'Day 79'	System	15 Dec 2020 21:07:17

US3342200

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(79)

Generated On: 09 Jun 2021 17:05:26

Did you receive any **MEDICAL ATTENTION** (doctor visit, other) for any illness or symptoms?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:04:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2D2D1647-7C35-4DCA-ADA3-8E1DAA921DDC)', Time: '2020-12-17T12:39:47', User OID: 'PatientReportedOutcome (US3342200)', ODM File OID: 'c417ad43-f0c3-49b3-907b-910690f22e66'	System	17 Dec 2020 18:39:54
User entered 'No (N)'	System	17 Dec 2020 18:39:54

US3342200

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(79)

Generated On: 09 Jun 2021 17:05:26

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:04:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2D2D1647-7C35-4DCA-ADA3-8E1DAA921DDC)', Time: '2020-12-17T12:39:50', User OID: 'PatientReportedOutcome (US3342200)', ODM File OID: 'c417ad43-f0c3-49b3-907b-910690f22e66' User entered '17 Dec 2020 12:39'	System	17 Dec 2020 18:39:54
	System	17 Dec 2020 18:39:54

US3342200

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(79)

Generated On: 09 Jun 2021 17:05:26

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:04:20
User entered '17 Dec 2020 12:00'	System	15 Dec 2020 21:07:17

US3342200

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(79)

Generated On: 09 Jun 2021 17:05:26

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:04:20
User entered '18 Dec 2020 11:59'	System	15 Dec 2020 21:07:17

US3342200

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(80)

Generated On: 09 Jun 2021 17:05:26

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:04:20
Data entry locked.	System	16 Dec 2020 21:44:20
User entered 'Day 80'	System	16 Dec 2020 21:44:20

US3342200

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(80)

Generated On: 09 Jun 2021 17:05:26

Did you receive any **MEDICAL ATTENTION** (doctor visit, other) for any illness or symptoms?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:04:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2D2D1647-7C35-4DCA-ADA3-8E1DAA921DDC)', Time: '2020-12-18T12:21:41', User OID: 'PatientReportedOutcome (US3342200)', ODM File OID: '19f56957-9917-4d4d-a84e-77d05031f130' User entered 'No (N)'	System	18 Dec 2020 18:21:47
	System	18 Dec 2020 18:21:47

US3342200

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(80)

Generated On: 09 Jun 2021 17:05:26

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:04:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2D2D1647-7C35-4DCA-ADA3-8E1DAA921DDC)', Time: '2020-12-18T12:21:43', User OID: 'PatientReportedOutcome (US3342200)', ODM File OID: '19f56957-9917-4d4d-a84e-77d05031f130' User entered '18 Dec 2020 12:21'	System	18 Dec 2020 18:21:47
	System	18 Dec 2020 18:21:47

US3342200

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(80)

Generated On: 09 Jun 2021 17:05:26

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:04:20
User entered '18 Dec 2020 12:00'	System	16 Dec 2020 21:44:20

US3342200

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(80)

Generated On: 09 Jun 2021 17:05:26

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:04:20
User entered '19 Dec 2020 11:59'	System	16 Dec 2020 21:44:20

US3342200

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(81)

Generated On: 09 Jun 2021 17:05:26

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:04:20
Data entry locked.	System	17 Dec 2020 18:39:48
User entered 'Day 81'	System	17 Dec 2020 18:39:48

US3342200

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(81)

Generated On: 09 Jun 2021 17:05:26

Did you receive any **MEDICAL ATTENTION** (doctor visit, other) for any illness or symptoms?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:04:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2D2D1647-7C35-4DCA-ADA3-8E1DAA921DDC)', Time: '2020-12-19T15:04:42', User OID: 'PatientReportedOutcome (US3342200)', ODM File OID: '86e71b48-8541-4151-a3e8-c576e41772f3' User entered 'No (N)'	System	19 Dec 2020 21:04:48
	System	19 Dec 2020 21:04:48

US3342200

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(81)

Generated On: 09 Jun 2021 17:05:26

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:04:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2D2D1647-7C35-4DCA-ADA3-8E1DAA921DDC)', Time: '2020-12-19T15:04:44', User OID: 'PatientReportedOutcome (US3342200)', ODM File OID: '86e71b48-8541-4151-a3e8-c576e41772f3' User entered '19 Dec 2020 15:04'	System	19 Dec 2020 21:04:48
	System	19 Dec 2020 21:04:48

US3342200

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(81)

Generated On: 09 Jun 2021 17:05:26

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:04:20
User entered '19 Dec 2020 12:00'	System	17 Dec 2020 18:39:48

US3342200

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(81)

Generated On: 09 Jun 2021 17:05:26

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:04:20
User entered '20 Dec 2020 11:59'	System	17 Dec 2020 18:39:48

US3342200

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(82)

Generated On: 09 Jun 2021 17:05:26

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:04:20
Data entry locked.	System	18 Dec 2020 18:21:41
User entered 'Day 82'	System	18 Dec 2020 18:21:41

US3342200

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(82)

Generated On: 09 Jun 2021 17:05:26

Did you receive any **MEDICAL ATTENTION** (doctor visit, other) for any illness or symptoms?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:04:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2D2D1647-7C35-4DCA-ADA3-8E1DAA921DDC)', Time: '2020-12-20T12:00:33', User OID: 'PatientReportedOutcome (US3342200)', ODM File OID: '150f3006-9b34-450c-b0cb-1fdd035672f1' User entered 'No (N)'	System	20 Dec 2020 18:00:42
	System	20 Dec 2020 18:00:42

US3342200

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(82)

Generated On: 09 Jun 2021 17:05:26

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:04:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2D2D1647-7C35-4DCA-ADA3-8E1DAA921DDC)', Time: '2020-12-20T12:00:38', User OID: 'PatientReportedOutcome (US3342200)', ODM File OID: '150f3006-9b34-450c-b0cb-1fdd035672f1' User entered '20 Dec 2020 12:00'	System	20 Dec 2020 18:00:42
	System	20 Dec 2020 18:00:42

US3342200

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(82)

Generated On: 09 Jun 2021 17:05:26

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:04:20
User entered '20 Dec 2020 12:00'	System	18 Dec 2020 18:21:41

US3342200

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(82)

Generated On: 09 Jun 2021 17:05:26

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:04:20
User entered '21 Dec 2020 11:59'	System	18 Dec 2020 18:21:41

US3342200

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(83)

Generated On: 09 Jun 2021 17:05:26

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:04:20
Data entry locked.	System	19 Dec 2020 21:04:41
User entered 'Day 83'	System	19 Dec 2020 21:04:41

US3342200

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(83)

Generated On: 09 Jun 2021 17:05:26

Did you receive any **MEDICAL ATTENTION** (doctor visit, other) for any illness or symptoms?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:04:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2D2D1647-7C35-4DCA-ADA3-8E1DAA921DDC)', Time: '2020-12-21T17:44:19', User OID: 'PatientReportedOutcome (US3342200)', ODM File OID: '75f22e7b-4c30-4de9-9b3f-0c74fc70741e' User entered 'No (N)'	System	21 Dec 2020 23:44:41
	System	21 Dec 2020 23:44:41

US3342200

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(83)

Generated On: 09 Jun 2021 17:05:26

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:04:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2D2D1647-7C35-4DCA-ADA3-8E1DAA921DDC)', Time: '2020-12-21T17:44:39', User OID: 'PatientReportedOutcome (US3342200)', ODM File OID: '75f22e7b-4c30-4de9-9b3f-0c74fc70741e' User entered '21 Dec 2020 17:44'	System	21 Dec 2020 23:44:41
	System	21 Dec 2020 23:44:41

US3342200

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(83)

Generated On: 09 Jun 2021 17:05:26

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:04:20
User entered '21 Dec 2020 12:00'	System	19 Dec 2020 21:04:41

US3342200

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(83)

Generated On: 09 Jun 2021 17:05:26

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:04:20
User entered '22 Dec 2020 11:59'	System	19 Dec 2020 21:04:41

US3342200

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(84)

Generated On: 09 Jun 2021 17:05:26

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:04:20
Data entry locked.	System	20 Dec 2020 18:00:21
User entered 'Day 84'	System	20 Dec 2020 18:00:21

US3342200

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(84)

Generated On: 09 Jun 2021 17:05:26

Did you receive any **MEDICAL ATTENTION** (doctor visit, other) for any illness or symptoms?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:04:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2D2D1647-7C35-4DCA-ADA3-8E1DAA921DDC)', Time: '2020-12-22T13:32:02', User OID: 'PatientReportedOutcome (US3342200)', ODM File OID: '678b2cdc-5e22-4aac-9e37-3555e6cbd588' User entered 'No (N)'	System	22 Dec 2020 19:32:08
	System	22 Dec 2020 19:32:08

US3342200

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(84)

Generated On: 09 Jun 2021 17:05:26

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:04:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2D2D1647-7C35-4DCA-ADA3-8E1DAA921DDC)', Time: '2020-12-22T13:32:04', User OID: 'PatientReportedOutcome (US3342200)', ODM File OID: '678b2cdc-5e22-4aac-9e37-3555e6cbd588' User entered '22 Dec 2020 13:32'	System	22 Dec 2020 19:32:08
	System	22 Dec 2020 19:32:08

US3342200

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(84)

Generated On: 09 Jun 2021 17:05:26

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:04:20
User entered '22 Dec 2020 12:00'	System	20 Dec 2020 18:00:21

US3342200

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(84)

Generated On: 09 Jun 2021 17:05:26

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:04:20
User entered '23 Dec 2020 11:59'	System	20 Dec 2020 18:00:21

US3342200

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(85)

Generated On: 09 Jun 2021 17:05:26

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:04:20
Data entry locked.	System	21 Dec 2020 23:43:56
User entered 'Day 85'	System	21 Dec 2020 23:43:56

US3342200

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(85)

Generated On: 09 Jun 2021 17:05:26

Did you receive any **MEDICAL ATTENTION** (doctor visit, other) for any illness or symptoms?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:04:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2D2D1647-7C35-4DCA-ADA3-8E1DAA921DDC)', Time: '2020-12-23T19:04:20', User OID: 'PatientReportedOutcome (US3342200)', ODM File OID: '20dc6bce-6611-419e-828f-b69bacade826' User entered 'No (N)'	System	24 Dec 2020 01:04:25
	System	24 Dec 2020 01:04:25

US3342200

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(85)

Generated On: 09 Jun 2021 17:05:26

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:04:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2D2D1647-7C35-4DCA-ADA3-8E1DAA921DDC)', Time: '2020-12-23T19:04:23', User OID: 'PatientReportedOutcome (US3342200)', ODM File OID: '20dc6bce-6611-419e-828f-b69bacade826' User entered '23 Dec 2020 19:04'	System	24 Dec 2020 01:04:25
	System	24 Dec 2020 01:04:25

US3342200

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(85)

Generated On: 09 Jun 2021 17:05:26

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:04:20
User entered '23 Dec 2020 12:00'	System	21 Dec 2020 23:43:56

US3342200

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(85)

Generated On: 09 Jun 2021 17:05:26

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:04:20
User entered '24 Dec 2020 11:59'	System	21 Dec 2020 23:43:56

US3342200

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(86)

Generated On: 09 Jun 2021 17:05:26

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:04:20
Data entry locked.	System	22 Dec 2020 19:32:01
User entered 'Day 86'	System	22 Dec 2020 19:32:01

US3342200

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(86)

Generated On: 09 Jun 2021 17:05:26

Did you receive any **MEDICAL ATTENTION** (doctor visit, other) for any illness or symptoms?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:04:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2D2D1647-7C35-4DCA-ADA3-8E1DAA921DDC)', Time: '2020-12-24T19:14:08', User OID: 'PatientReportedOutcome (US3342200)', ODM File OID: '4884f43c-26f1-49c7-901c-db5ccdb1ef7b' User entered 'No (N)'	System	25 Dec 2020 01:14:30
	System	25 Dec 2020 01:14:30

US3342200

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(86)

Generated On: 09 Jun 2021 17:05:26

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:04:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2D2D1647-7C35-4DCA-ADA3-8E1DAA921DDC)', Time: '2020-12-24T19:14:28', User OID: 'PatientReportedOutcome (US3342200)', ODM File OID: '4884f43c-26f1-49c7-901c-db5ccdb1ef7b' User entered '24 Dec 2020 19:14'	System	25 Dec 2020 01:14:30
	System	25 Dec 2020 01:14:30

US3342200

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(86)

Generated On: 09 Jun 2021 17:05:26

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:04:20
User entered '24 Dec 2020 12:00'	System	22 Dec 2020 19:32:01

US3342200

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(86)

Generated On: 09 Jun 2021 17:05:26

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:04:20
User entered '25 Dec 2020 11:59'	System	22 Dec 2020 19:32:01

US3342200

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(87)

Generated On: 09 Jun 2021 17:05:26

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:04:20
Data entry locked.	System	24 Dec 2020 01:04:23
User entered 'Day 87'	System	24 Dec 2020 01:04:23

US3342200

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(87)

Generated On: 09 Jun 2021 17:05:26

Did you receive any **MEDICAL ATTENTION** (doctor visit, other) for any illness or symptoms?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:04:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2D2D1647-7C35-4DCA-ADA3-8E1DAA921DDC)', Time: '2020-12-25T12:18:09', User OID: 'PatientReportedOutcome (US3342200)', ODM File OID: '512d5fec-c4a7-4efd-a44c-94396819b910' User entered 'No (N)'	System	25 Dec 2020 18:18:17
	System	25 Dec 2020 18:18:17

US3342200

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(87)

Generated On: 09 Jun 2021 17:05:26

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:04:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2D2D1647-7C35-4DCA-ADA3-8E1DAA921DDC)', Time: '2020-12-25T12:18:12', User OID: 'PatientReportedOutcome (US3342200)', ODM File OID: '512d5fec-c4a7-4efd-a44c-94396819b910' User entered '25 Dec 2020 12:18'	System	25 Dec 2020 18:18:17
	System	25 Dec 2020 18:18:17

US3342200

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(87)

Generated On: 09 Jun 2021 17:05:26

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:04:20
User entered '25 Dec 2020 12:00'	System	24 Dec 2020 01:04:23

US3342200

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(87)

Generated On: 09 Jun 2021 17:05:26

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:04:20
User entered '26 Dec 2020 11:59'	System	24 Dec 2020 01:04:23

US3342200

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(88)

Generated On: 09 Jun 2021 17:05:26

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:04:20
Data entry locked.	System	25 Dec 2020 01:14:07
User entered 'Day 88'	System	25 Dec 2020 01:14:07

US3342200

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(88)

Generated On: 09 Jun 2021 17:05:26

Did you receive any **MEDICAL ATTENTION** (doctor visit, other) for any illness or symptoms?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:04:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2D2D1647-7C35-4DCA-ADA3-8E1DAA921DDC)', Time: '2020-12-26T12:46:01', User OID: 'PatientReportedOutcome (US3342200)', ODM File OID: 'b2c5a145-a496-4122-9c51-aaf81fa686dd' User entered 'No (N)'	System	26 Dec 2020 18:46:07
	System	26 Dec 2020 18:46:07

US3342200

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(88)

Generated On: 09 Jun 2021 17:05:26

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:04:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2D2D1647-7C35-4DCA-ADA3-8E1DAA921DDC)', Time: '2020-12-26T12:46:03', User OID: 'PatientReportedOutcome (US3342200)', ODM File OID: 'b2c5a145-a496-4122-9c51-aaf81fa686dd' User entered '26 Dec 2020 12:46'	System	26 Dec 2020 18:46:07
	System	26 Dec 2020 18:46:07

US3342200

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(88)

Generated On: 09 Jun 2021 17:05:26

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:04:20
User entered '26 Dec 2020 12:00'	System	25 Dec 2020 01:14:07

US3342200

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(88)

Generated On: 09 Jun 2021 17:05:26

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:04:20
User entered '27 Dec 2020 11:59'	System	25 Dec 2020 01:14:07

US3342200

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(89)

Generated On: 09 Jun 2021 17:05:26

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:04:20
Data entry locked.	System	25 Dec 2020 18:18:07
User entered 'Day 89'	System	25 Dec 2020 18:18:07

US3342200

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(89)

Generated On: 09 Jun 2021 17:05:26

Did you receive any **MEDICAL ATTENTION** (doctor visit, other) for any illness or symptoms?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:04:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2D2D1647-7C35-4DCA-ADA3-8E1DAA921DDC)', Time: '2020-12-27T12:00:28', User OID: 'PatientReportedOutcome (US3342200)', ODM File OID: 'fe8f04f7-2001-48e5-96a2-03166c979fc1' User entered 'No (N)'	System	27 Dec 2020 18:00:40
	System	27 Dec 2020 18:00:40

US3342200

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(89)

Generated On: 09 Jun 2021 17:05:26

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:04:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2D2D1647-7C35-4DCA-ADA3-8E1DAA921DDC)', Time: '2020-12-27T12:00:30', User OID: 'PatientReportedOutcome (US3342200)', ODM File OID: 'fe8f04f7-2001-48e5-96a2-03166c979fc1' User entered '27 Dec 2020 12:00'	System	27 Dec 2020 18:00:40
	System	27 Dec 2020 18:00:40

US3342200

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(89)

Generated On: 09 Jun 2021 17:05:26

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:04:20
User entered '27 Dec 2020 12:00'	System	25 Dec 2020 18:18:07

US3342200

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(89)

Generated On: 09 Jun 2021 17:05:26

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:04:20
User entered '28 Dec 2020 11:59'	System	25 Dec 2020 18:18:07

US3342200

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(90)

Generated On: 09 Jun 2021 17:05:26

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:04:20
Data entry locked.	System	26 Dec 2020 18:45:57
User entered 'Day 90'	System	26 Dec 2020 18:45:57

US3342200

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(90)

Generated On: 09 Jun 2021 17:05:26

Did you receive any **MEDICAL ATTENTION** (doctor visit, other) for any illness or symptoms?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:04:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2D2D1647-7C35-4DCA-ADA3-8E1DAA921DDC)', Time: '2020-12-29T03:15:05', User OID: 'PatientReportedOutcome (US3342200)', ODM File OID: 'c8f6fe33-f622-415d-99f2-84bf2001df84' User entered 'No (N)'	System	29 Dec 2020 09:15:10
	System	29 Dec 2020 09:15:10

US3342200

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(90)

Generated On: 09 Jun 2021 17:05:26

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:04:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2D2D1647-7C35-4DCA-ADA3-8E1DAA921DDC)', Time: '2020-12-29T03:15:08', User OID: 'PatientReportedOutcome (US3342200)', ODM File OID: 'c8f6fe33-f622-415d-99f2-84bf2001df84' User entered '29 Dec 2020 03:15'	System	29 Dec 2020 09:15:10
	System	29 Dec 2020 09:15:10

US3342200

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(90)

Generated On: 09 Jun 2021 17:05:26

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:04:20
User entered '28 Dec 2020 12:00'	System	26 Dec 2020 18:45:57

US3342200

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(90)

Generated On: 09 Jun 2021 17:05:26

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:04:20
User entered '29 Dec 2020 11:59'	System	26 Dec 2020 18:45:57

US3342200

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(91)

Generated On: 09 Jun 2021 17:05:26

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:04:20
Data entry locked.	System	27 Dec 2020 18:00:32
User entered 'Day 91'	System	27 Dec 2020 18:00:32

US3342200

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(91)

Generated On: 09 Jun 2021 17:05:26

Did you receive any **MEDICAL ATTENTION** (doctor visit, other) for any illness or symptoms?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:04:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2D2D1647-7C35-4DCA-ADA3-8E1DAA921DDC)', Time: '2020-12-29T16:08:15', User OID: 'PatientReportedOutcome (US3342200)', ODM File OID: '6f3234cc-7ea7-4872-b341-ddd20eaf3aba' User entered 'No (N)'	System	29 Dec 2020 22:08:25
	System	29 Dec 2020 22:08:25

US3342200

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(91)

Generated On: 09 Jun 2021 17:05:26

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:04:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2D2D1647-7C35-4DCA-ADA3-8E1DAA921DDC)', Time: '2020-12-29T16:08:18', User OID: 'PatientReportedOutcome (US3342200)', ODM File OID: '6f3234cc-7ea7-4872-b341-ddd20eaf3aba' User entered '29 Dec 2020 16:08'	System	29 Dec 2020 22:08:25
	System	29 Dec 2020 22:08:25

US3342200

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(91)

Generated On: 09 Jun 2021 17:05:26

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:04:20
User entered '29 Dec 2020 12:00'	System	27 Dec 2020 18:00:32

US3342200

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(91)

Generated On: 09 Jun 2021 17:05:26

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:04:20
User entered '30 Dec 2020 11:59'	System	27 Dec 2020 18:00:32

US3342200

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(92)

Generated On: 09 Jun 2021 17:05:26

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:04:20
Data entry locked.	System	29 Dec 2020 09:15:03
User entered 'Day 92'	System	29 Dec 2020 09:15:03

US3342200

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(92)

Generated On: 09 Jun 2021 17:05:26

Did you receive any **MEDICAL ATTENTION** (doctor visit, other) for any illness or symptoms?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:04:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2D2D1647-7C35-4DCA-ADA3-8E1DAA921DDC)', Time: '2020-12-30T12:34:18', User OID: 'PatientReportedOutcome (US3342200)', ODM File OID: '976c1ea1-17a0-4818-92fd-25ad4d77495f' User entered 'No (N)'	System	30 Dec 2020 18:34:27
	System	30 Dec 2020 18:34:27

US3342200

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(92)

Generated On: 09 Jun 2021 17:05:26

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:04:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2D2D1647-7C35-4DCA-ADA3-8E1DAA921DDC)', Time: '2020-12-30T12:34:24', User OID: 'PatientReportedOutcome (US3342200)', ODM File OID: '976c1ea1-17a0-4818-92fd-25ad4d77495f' User entered '30 Dec 2020 12:34'	System	30 Dec 2020 18:34:27
	System	30 Dec 2020 18:34:27

US3342200

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(92)

Generated On: 09 Jun 2021 17:05:26

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:04:20
User entered '30 Dec 2020 12:00'	System	29 Dec 2020 09:15:03

US3342200

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(92)

Generated On: 09 Jun 2021 17:05:26

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:04:20
User entered '31 Dec 2020 11:59'	System	29 Dec 2020 09:15:03

US3342200

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(93)

Generated On: 09 Jun 2021 17:05:26

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:04:20
Data entry locked.	System	29 Dec 2020 22:08:23
User entered 'Day 93'	System	29 Dec 2020 22:08:23

US3342200

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(93)

Generated On: 09 Jun 2021 17:05:26

Did you receive any **MEDICAL ATTENTION** (doctor visit, other) for any illness or symptoms?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:04:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2D2D1647-7C35-4DCA-ADA3-8E1DAA921DDC)', Time: '2020-12-31T19:26:44', User OID: 'PatientReportedOutcome (US3342200)', ODM File OID: 'cfb6626a-6c95-4c61-93e4-9b495b3b94e4' User entered 'No (N)'	System	01 Jan 2021 01:26:51
	System	01 Jan 2021 01:26:51

US3342200

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(93)

Generated On: 09 Jun 2021 17:05:26

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:04:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2D2D1647-7C35-4DCA-ADA3-8E1DAA921DDC)', Time: '2020-12-31T19:26:47', User OID: 'PatientReportedOutcome (US3342200)', ODM File OID: 'cfb6626a-6c95-4c61-93e4-9b495b3b94e4' User entered '31 Dec 2020 19:26'	System	01 Jan 2021 01:26:51
	System	01 Jan 2021 01:26:51

US3342200

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(93)

Generated On: 09 Jun 2021 17:05:26

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:04:20
User entered '31 Dec 2020 12:00'	System	29 Dec 2020 22:08:23

US3342200

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(93)

Generated On: 09 Jun 2021 17:05:26

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:04:20
User entered '01 Jan 2021 11:59'	System	29 Dec 2020 22:08:23

US3342200

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(94)

Generated On: 09 Jun 2021 17:05:26

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:04:20
Data entry locked.	System	30 Dec 2020 18:34:16
User entered 'Day 94'	System	30 Dec 2020 18:34:16

US3342200

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(94)

Generated On: 09 Jun 2021 17:05:26

Did you receive any **MEDICAL ATTENTION** (doctor visit, other) for any illness or symptoms?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:04:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2D2D1647-7C35-4DCA-ADA3-8E1DAA921DDC)', Time: '2021-01-01T21:03:46', User OID: 'PatientReportedOutcome (US3342200)', ODM File OID: 'da0ae1ce-034e-4c6b-b27e-a8886a727fc5' User entered 'No (N)'	System	02 Jan 2021 03:03:59
	System	02 Jan 2021 03:03:59

US3342200

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(94)

Generated On: 09 Jun 2021 17:05:26

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:04:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2D2D1647-7C35-4DCA-ADA3-8E1DAA921DDC)', Time: '2021-01-01T21:03:56', User OID: 'PatientReportedOutcome (US3342200)', ODM File OID: 'da0ae1ce-034e-4c6b-b27e-a8886a727fc5' User entered '01 Jan 2021 21:03'	System	02 Jan 2021 03:03:59
	System	02 Jan 2021 03:03:59

US3342200

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(94)

Generated On: 09 Jun 2021 17:05:26

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:04:20
User entered '01 Jan 2021 12:00'	System	30 Dec 2020 18:34:16

US3342200

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(94)

Generated On: 09 Jun 2021 17:05:26

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:04:20
User entered '02 Jan 2021 11:59'	System	30 Dec 2020 18:34:16

US3342200

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(95)

Generated On: 09 Jun 2021 17:05:26

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:04:20
Data entry locked.	System	01 Jan 2021 01:26:45
User entered 'Day 95'	System	01 Jan 2021 01:26:45

US3342200

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(95)

Generated On: 09 Jun 2021 17:05:26

Did you receive any **MEDICAL ATTENTION** (doctor visit, other) for any illness or symptoms?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:04:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2D2D1647-7C35-4DCA-ADA3-8E1DAA921DDC)', Time: '2021-01-02T15:52:02', User OID: 'PatientReportedOutcome (US3342200)', ODM File OID: '654f0e7a-72be-44fe-8599-cd1fd86532ef' User entered 'No (N)'	System	02 Jan 2021 21:52:10
	System	02 Jan 2021 21:52:10

US3342200

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(95)

Generated On: 09 Jun 2021 17:05:26

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:04:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2D2D1647-7C35-4DCA-ADA3-8E1DAA921DDC)', Time: '2021-01-02T15:52:05', User OID: 'PatientReportedOutcome (US3342200)', ODM File OID: '654f0e7a-72be-44fe-8599-cd1fd86532ef' User entered '02 Jan 2021 15:52'	System	02 Jan 2021 21:52:10
	System	02 Jan 2021 21:52:10

US3342200

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(95)

Generated On: 09 Jun 2021 17:05:26

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:04:20
User entered '02 Jan 2021 12:00'	System	01 Jan 2021 01:26:45

US3342200

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(95)

Generated On: 09 Jun 2021 17:05:26

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:04:20
User entered '03 Jan 2021 11:59'	System	01 Jan 2021 01:26:45

US3342200

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(96)

Generated On: 09 Jun 2021 17:05:26

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:04:20
Data entry locked.	System	02 Jan 2021 03:03:45
User entered 'Day 96'	System	02 Jan 2021 03:03:45

US3342200

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(96)

Generated On: 09 Jun 2021 17:05:26

Did you receive any **MEDICAL ATTENTION** (doctor visit, other) for any illness or symptoms?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:04:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2D2D1647-7C35-4DCA-ADA3-8E1DAA921DDC)', Time: '2021-01-03T20:33:00', User OID: 'PatientReportedOutcome (US3342200)', ODM File OID: '7e5efe93-b9f9-4cbf-8c3e-f72efa64908d' User entered 'No (N)'	System	04 Jan 2021 02:33:05
	System	04 Jan 2021 02:33:05

US3342200

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(96)

Generated On: 09 Jun 2021 17:05:26

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:04:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2D2D1647-7C35-4DCA-ADA3-8E1DAA921DDC)', Time: '2021-01-03T20:33:03', User OID: 'PatientReportedOutcome (US3342200)', ODM File OID: '7e5efe93-b9f9-4cbf-8c3e-f72efa64908d' User entered '03 Jan 2021 20:33'	System	04 Jan 2021 02:33:05
	System	04 Jan 2021 02:33:05

US3342200

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(96)

Generated On: 09 Jun 2021 17:05:26

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:04:20
User entered '03 Jan 2021 12:00'	System	02 Jan 2021 03:03:45

US3342200

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(96)

Generated On: 09 Jun 2021 17:05:26

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:04:20
User entered '04 Jan 2021 11:59'	System	02 Jan 2021 03:03:45

US3342200

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(97)

Generated On: 09 Jun 2021 17:05:26

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:04:20
Data entry locked.	System	02 Jan 2021 21:51:51
User entered 'Day 97'	System	02 Jan 2021 21:51:51

US3342200

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(97)

Generated On: 09 Jun 2021 17:05:26

Did you receive any **MEDICAL ATTENTION** (doctor visit, other) for any illness or symptoms?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:04:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2D2D1647-7C35-4DCA-ADA3-8E1DAA921DDC)', Time: '2021-01-04T14:57:16', User OID: 'PatientReportedOutcome (US3342200)', ODM File OID: '5c824776-e4d5-4dbb-8229-5184c18fd3ad' User entered 'No (N)'	System	05 Jan 2021 18:09:27
	System	05 Jan 2021 18:09:27

US3342200

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(97)

Generated On: 09 Jun 2021 17:05:26

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:04:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2D2D1647-7C35-4DCA-ADA3-8E1DAA921DDC)', Time: '2021-01-04T14:57:19', User OID: 'PatientReportedOutcome (US3342200)', ODM File OID: '5c824776-e4d5-4dbb-8229-5184c18fd3ad' User entered '04 Jan 2021 14:57'	System	05 Jan 2021 18:09:27
	System	05 Jan 2021 18:09:27

US3342200

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(97)

Generated On: 09 Jun 2021 17:05:26

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:04:20
User entered '04 Jan 2021 12:00'	System	02 Jan 2021 21:51:51

US3342200

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(97)

Generated On: 09 Jun 2021 17:05:26

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:04:20
User entered '05 Jan 2021 11:59'	System	02 Jan 2021 21:51:51

US3342200

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(98)

Generated On: 09 Jun 2021 17:05:26

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:04:20
Data entry locked.	System	04 Jan 2021 02:32:57
User entered 'Day 98'	System	04 Jan 2021 02:32:57

US3342200

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(98)

Generated On: 09 Jun 2021 17:05:26

Did you receive any **MEDICAL ATTENTION** (doctor visit, other) for any illness or symptoms?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:04:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2D2D1647-7C35-4DCA-ADA3-8E1DAA921DDC)', Time: '2021-01-05T12:09:38', User OID: 'PatientReportedOutcome (US3342200)', ODM File OID: '27b3ac72-7f98-4f23-ba6e-ec65cb392d26' User entered 'No (N)'	System	05 Jan 2021 18:09:46
	System	05 Jan 2021 18:09:46

US3342200

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(98)

Generated On: 09 Jun 2021 17:05:26

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:04:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2D2D1647-7C35-4DCA-ADA3-8E1DAA921DDC)', Time: '2021-01-05T12:09:42', User OID: 'PatientReportedOutcome (US3342200)', ODM File OID: '27b3ac72-7f98-4f23-ba6e-ec65cb392d26' User entered '05 Jan 2021 12:09'	System	05 Jan 2021 18:09:46
	System	05 Jan 2021 18:09:46

US3342200

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(98)

Generated On: 09 Jun 2021 17:05:26

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:04:20
User entered '05 Jan 2021 12:00'	System	04 Jan 2021 02:32:57

US3342200

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(98)

Generated On: 09 Jun 2021 17:05:26

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:04:20
User entered '06 Jan 2021 11:59'	System	04 Jan 2021 02:32:57

US3342200

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(99)

Generated On: 09 Jun 2021 17:05:26

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:04:20
Data entry locked.	System	04 Jan 2021 20:45:40
User entered 'Day 99'	System	04 Jan 2021 20:45:40

US3342200

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(99)

Generated On: 09 Jun 2021 17:05:26

Did you receive any **MEDICAL ATTENTION** (doctor visit, other) for any illness or symptoms?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:04:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2D2D1647-7C35-4DCA-ADA3-8E1DAA921DDC)', Time: '2021-01-06T13:05:40', User OID: 'PatientReportedOutcome (US3342200)', ODM File OID: '3c49699b-2b93-45af-a11a-019f377875b9' User entered 'No (N)'	System	06 Jan 2021 19:05:52
	System	06 Jan 2021 19:05:52

US3342200

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(99)

Generated On: 09 Jun 2021 17:05:26

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:04:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2D2D1647-7C35-4DCA-ADA3-8E1DAA921DDC)', Time: '2021-01-06T13:05:46', User OID: 'PatientReportedOutcome (US3342200)', ODM File OID: '3c49699b-2b93-45af-a11a-019f377875b9' User entered '06 Jan 2021 13:05'	System	06 Jan 2021 19:05:52
	System	06 Jan 2021 19:05:52

US3342200

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(99)

Generated On: 09 Jun 2021 17:05:26

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:04:20
User entered '06 Jan 2021 12:00'	System	04 Jan 2021 20:45:40

US3342200

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(99)

Generated On: 09 Jun 2021 17:05:26

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:04:20
User entered '07 Jan 2021 11:59'	System	04 Jan 2021 20:45:40

US3342200

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(100)

Generated On: 09 Jun 2021 17:05:26

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:04:20
Data entry locked.	System	05 Jan 2021 18:09:45
User entered 'Day 100'	System	05 Jan 2021 18:09:45

US3342200

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(100)

Generated On: 09 Jun 2021 17:05:26

Did you receive any **MEDICAL ATTENTION** (doctor visit, other) for any illness or symptoms?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:04:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2D2D1647-7C35-4DCA-ADA3-8E1DAA921DDC)', Time: '2021-01-07T12:00:53', User OID: 'PatientReportedOutcome (US3342200)', ODM File OID: 'ab7e2f65-ed47-4e88-a185-021c16c2c8fc' User entered 'No (N)'	System	07 Jan 2021 18:00:58
	System	07 Jan 2021 18:00:58

US3342200

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(100)

Generated On: 09 Jun 2021 17:05:26

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:04:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2D2D1647-7C35-4DCA-ADA3-8E1DAA921DDC)', Time: '2021-01-07T12:00:55', User OID: 'PatientReportedOutcome (US3342200)', ODM File OID: 'ab7e2f65-ed47-4e88-a185-021c16c2c8fc' User entered '07 Jan 2021 12:00'	System	07 Jan 2021 18:00:58
	System	07 Jan 2021 18:00:58

US3342200

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(100)

Generated On: 09 Jun 2021 17:05:26

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:04:20
User entered '07 Jan 2021 12:00'	System	05 Jan 2021 18:09:45

US3342200

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(100)

Generated On: 09 Jun 2021 17:05:26

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:04:20
User entered '08 Jan 2021 11:59'	System	05 Jan 2021 18:09:45

US3342200

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(101)

Generated On: 09 Jun 2021 17:05:26

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:04:20
Data entry locked.	System	06 Jan 2021 19:05:28
User entered 'Day 101'	System	06 Jan 2021 19:05:28

US3342200

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(101)

Generated On: 09 Jun 2021 17:05:26

Did you receive any **MEDICAL ATTENTION** (doctor visit, other) for any illness or symptoms?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:04:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2D2D1647-7C35-4DCA-ADA3-8E1DAA921DDC)', Time: '2021-01-08T23:59:42', User OID: 'PatientReportedOutcome (US3342200)', ODM File OID: '7b01c415-5e9c-434e-80ef-964bb42c51ca' User entered 'No (N)'	System	09 Jan 2021 05:59:48
	System	09 Jan 2021 05:59:48

US3342200

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(101)

Generated On: 09 Jun 2021 17:05:26

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:04:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2D2D1647-7C35-4DCA-ADA3-8E1DAA921DDC)', Time: '2021-01-08T23:59:47', User OID: 'PatientReportedOutcome (US3342200)', ODM File OID: '7b01c415-5e9c-434e-80ef-964bb42c51ca' User entered '08 Jan 2021 23:59'	System	09 Jan 2021 05:59:48
	System	09 Jan 2021 05:59:48

US3342200

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(101)

Generated On: 09 Jun 2021 17:05:26

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:04:20
User entered '08 Jan 2021 12:00'	System	06 Jan 2021 19:05:28

US3342200

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(101)

Generated On: 09 Jun 2021 17:05:26

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:04:20
User entered '09 Jan 2021 11:59'	System	06 Jan 2021 19:05:28

US3342200

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(102)

Generated On: 09 Jun 2021 17:05:26

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:04:20
Data entry locked.	System	07 Jan 2021 18:00:51
User entered 'Day 102'	System	07 Jan 2021 18:00:51

US3342200

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(102)

Generated On: 09 Jun 2021 17:05:26

Did you receive any **MEDICAL ATTENTION** (doctor visit, other) for any illness or symptoms?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:04:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2D2D1647-7C35-4DCA-ADA3-8E1DAA921DDC)', Time: '2021-01-09T12:05:50', User OID: 'PatientReportedOutcome (US3342200)', ODM File OID: '08ab8844-6447-43be-90ad-94d7288c625d' User entered 'No (N)'	System	09 Jan 2021 18:05:56
	System	09 Jan 2021 18:05:56

US3342200

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(102)

Generated On: 09 Jun 2021 17:05:26

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:04:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2D2D1647-7C35-4DCA-ADA3-8E1DAA921DDC)', Time: '2021-01-09T12:05:54', User OID: 'PatientReportedOutcome (US3342200)', ODM File OID: '08ab8844-6447-43be-90ad-94d7288c625d' User entered '09 Jan 2021 12:05'	System	09 Jan 2021 18:05:56
	System	09 Jan 2021 18:05:56

US3342200

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(102)

Generated On: 09 Jun 2021 17:05:26

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:04:20
User entered '09 Jan 2021 12:00'	System	07 Jan 2021 18:00:51

US3342200

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(102)

Generated On: 09 Jun 2021 17:05:26

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:04:20
User entered '10 Jan 2021 11:59'	System	07 Jan 2021 18:00:51

US3342200

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(103)

Generated On: 09 Jun 2021 17:05:26

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:04:20
Data entry locked.	System	09 Jan 2021 05:59:34
User entered 'Day 103'	System	09 Jan 2021 05:59:34

US3342200

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(103)

Generated On: 09 Jun 2021 17:05:26

Did you receive any **MEDICAL ATTENTION** (doctor visit, other) for any illness or symptoms?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:04:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2D2D1647-7C35-4DCA-ADA3-8E1DAA921DDC)', Time: '2021-01-10T16:56:38', User OID: 'PatientReportedOutcome (US3342200)', ODM File OID: '43306b09-1815-45b2-9963-0e4917fee783' User entered 'No (N)'	System	10 Jan 2021 22:56:44
	System	10 Jan 2021 22:56:44

US3342200

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(103)

Generated On: 09 Jun 2021 17:05:26

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:04:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2D2D1647-7C35-4DCA-ADA3-8E1DAA921DDC)', Time: '2021-01-10T16:56:40', User OID: 'PatientReportedOutcome (US3342200)', ODM File OID: '43306b09-1815-45b2-9963-0e4917fee783' User entered '10 Jan 2021 16:56'	System	10 Jan 2021 22:56:44
	System	10 Jan 2021 22:56:44

US3342200

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(103)

Generated On: 09 Jun 2021 17:05:26

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:04:20
User entered '10 Jan 2021 12:00'	System	09 Jan 2021 05:59:34

US3342200

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(103)

Generated On: 09 Jun 2021 17:05:26

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:04:20
User entered '11 Jan 2021 11:59'	System	09 Jan 2021 05:59:34

US3342200

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(104)

Generated On: 09 Jun 2021 17:05:26

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:04:20
Data entry locked.	System	09 Jan 2021 18:05:39
User entered 'Day 104'	System	09 Jan 2021 18:05:39

US3342200

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(104)

Generated On: 09 Jun 2021 17:05:26

Did you receive any **MEDICAL ATTENTION** (doctor visit, other) for any illness or symptoms?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:04:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2D2D1647-7C35-4DCA-ADA3-8E1DAA921DDC)', Time: '2021-01-11T12:02:03', User OID: 'PatientReportedOutcome (US3342200)', ODM File OID: '2d63d8a0-0d8c-42c8-93ff-2154087a2c0a' User entered 'No (N)'	System	12 Jan 2021 18:58:44
	System	12 Jan 2021 18:58:44

US3342200

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(104)

Generated On: 09 Jun 2021 17:05:26

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:04:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2D2D1647-7C35-4DCA-ADA3-8E1DAA921DDC)', Time: '2021-01-11T12:02:06', User OID: 'PatientReportedOutcome (US3342200)', ODM File OID: '2d63d8a0-0d8c-42c8-93ff-2154087a2c0a' User entered '11 Jan 2021 12:02'	System	12 Jan 2021 18:58:44
	System	12 Jan 2021 18:58:44

US3342200

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(104)

Generated On: 09 Jun 2021 17:05:26

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:04:20
User entered '11 Jan 2021 12:00'	System	09 Jan 2021 18:05:39

US3342200

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(104)

Generated On: 09 Jun 2021 17:05:26

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:04:20
User entered '12 Jan 2021 11:59'	System	09 Jan 2021 18:05:39

US3342200

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(105)

Generated On: 09 Jun 2021 17:05:26

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:04:20
Data entry locked.	System	10 Jan 2021 22:49:30
User entered 'Day 105'	System	10 Jan 2021 22:49:30

US3342200

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(105)

Generated On: 09 Jun 2021 17:05:26

Did you receive any **MEDICAL ATTENTION** (doctor visit, other) for any illness or symptoms?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:04:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2D2D1647-7C35-4DCA-ADA3-8E1DAA921DDC)', Time: '2021-01-12T13:03:24', User OID: 'PatientReportedOutcome (US3342200)', ODM File OID: '3584ef9a-d389-41cc-a501-50e340df8f3e' User entered 'No (N)'	System	12 Jan 2021 19:03:38
	System	12 Jan 2021 19:03:38

US3342200

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(105)

Generated On: 09 Jun 2021 17:05:26

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:04:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2D2D1647-7C35-4DCA-ADA3-8E1DAA921DDC)', Time: '2021-01-12T13:03:26', User OID: 'PatientReportedOutcome (US3342200)', ODM File OID: '3584ef9a-d389-41cc-a501-50e340df8f3e' User entered '12 Jan 2021 13:03'	System	12 Jan 2021 19:03:38
	System	12 Jan 2021 19:03:38

US3342200

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(105)

Generated On: 09 Jun 2021 17:05:26

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:04:20
User entered '12 Jan 2021 12:00'	System	10 Jan 2021 22:49:30

US3342200

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(105)

Generated On: 09 Jun 2021 17:05:26

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:04:20
User entered '13 Jan 2021 11:59'	System	10 Jan 2021 22:49:30

US3342200

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(106)

Generated On: 09 Jun 2021 17:05:26

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:04:20
Data entry locked.	System	11 Jan 2021 18:02:26
User entered 'Day 106'	System	11 Jan 2021 18:02:26

US3342200

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(106)

Generated On: 09 Jun 2021 17:05:26

Did you receive any **MEDICAL ATTENTION** (doctor visit, other) for any illness or symptoms?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:04:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2D2D1647-7C35-4DCA-ADA3-8E1DAA921DDC)', Time: '2021-01-14T03:41:44', User OID: 'PatientReportedOutcome (US3342200)', ODM File OID: 'c0a25c37-10ed-4e15-8eab-e1c2c4d3a340' User entered 'No (N)'	System	14 Jan 2021 09:41:51
	System	14 Jan 2021 09:41:51

US3342200

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(106)

Generated On: 09 Jun 2021 17:05:26

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:04:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2D2D1647-7C35-4DCA-ADA3-8E1DAA921DDC)', Time: '2021-01-14T03:41:48', User OID: 'PatientReportedOutcome (US3342200)', ODM File OID: 'c0a25c37-10ed-4e15-8eab-e1c2c4d3a340' User entered '14 Jan 2021 03:41'	System	14 Jan 2021 09:41:51
	System	14 Jan 2021 09:41:51

US3342200

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(106)

Generated On: 09 Jun 2021 17:05:26

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:04:20
User entered '13 Jan 2021 12:00'	System	11 Jan 2021 18:02:26

US3342200

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(106)

Generated On: 09 Jun 2021 17:05:26

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:04:20
User entered '14 Jan 2021 11:59'	System	11 Jan 2021 18:02:26

US3342200

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(107)

Generated On: 09 Jun 2021 17:05:26

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:04:20
Data entry locked.	System	12 Jan 2021 19:03:35
User entered 'Day 107'	System	12 Jan 2021 19:03:35

US3342200

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(107)

Generated On: 09 Jun 2021 17:05:26

Did you receive any **MEDICAL ATTENTION** (doctor visit, other) for any illness or symptoms?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:04:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2D2D1647-7C35-4DCA-ADA3-8E1DAA921DDC)', Time: '2021-01-14T16:03:20', User OID: 'PatientReportedOutcome (US3342200)', ODM File OID: '90fe3e86-64ee-495d-b69d-e168a32759a8' User entered 'No (N)'	System	14 Jan 2021 22:03:29
	System	14 Jan 2021 22:03:29

US3342200

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(107)

Generated On: 09 Jun 2021 17:05:26

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:04:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2D2D1647-7C35-4DCA-ADA3-8E1DAA921DDC)', Time: '2021-01-14T16:03:25', User OID: 'PatientReportedOutcome (US3342200)', ODM File OID: '90fe3e86-64ee-495d-b69d-e168a32759a8' User entered '14 Jan 2021 16:03'	System	14 Jan 2021 22:03:29
	System	14 Jan 2021 22:03:29

US3342200

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(107)

Generated On: 09 Jun 2021 17:05:26

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:04:20
User entered '14 Jan 2021 12:00'	System	12 Jan 2021 19:03:35

US3342200

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(107)

Generated On: 09 Jun 2021 17:05:26

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:04:20
User entered '15 Jan 2021 11:59'	System	12 Jan 2021 19:03:35

US3342200

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(108)

Generated On: 09 Jun 2021 17:05:26

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:04:20
Data entry locked.	System	14 Jan 2021 09:41:41
User entered 'Day 108'	System	14 Jan 2021 09:41:41

US3342200

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(108)

Generated On: 09 Jun 2021 17:05:26

Did you receive any **MEDICAL ATTENTION** (doctor visit, other) for any illness or symptoms?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:04:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2D2D1647-7C35-4DCA-ADA3-8E1DAA921DDC)', Time: '2021-01-16T03:13:58', User OID: 'PatientReportedOutcome (US3342200)', ODM File OID: 'a33070d7-4773-4839-b299-ce1756d3990c' User entered 'No (N)'	System	16 Jan 2021 09:14:18
	System	16 Jan 2021 09:14:18

US3342200

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(108)

Generated On: 09 Jun 2021 17:05:26

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:04:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2D2D1647-7C35-4DCA-ADA3-8E1DAA921DDC)', Time: '2021-01-16T03:14:15', User OID: 'PatientReportedOutcome (US3342200)', ODM File OID: 'a33070d7-4773-4839-b299-ce1756d3990c' User entered '16 Jan 2021 03:14'	System	16 Jan 2021 09:14:18
	System	16 Jan 2021 09:14:18

US3342200

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(108)

Generated On: 09 Jun 2021 17:05:26

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:04:20
User entered '15 Jan 2021 12:00'	System	14 Jan 2021 09:41:41

US3342200

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(108)

Generated On: 09 Jun 2021 17:05:26

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:04:20
User entered '16 Jan 2021 11:59'	System	14 Jan 2021 09:41:41

US3342200

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(109)

Generated On: 09 Jun 2021 17:05:26

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:04:20
Data entry locked.	System	14 Jan 2021 22:03:17
User entered 'Day 109'	System	14 Jan 2021 22:03:17

US3342200

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(109)

Generated On: 09 Jun 2021 17:05:26

Did you receive any **MEDICAL ATTENTION** (doctor visit, other) for any illness or symptoms?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:04:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2D2D1647-7C35-4DCA-ADA3-8E1DAA921DDC)', Time: '2021-01-16T12:37:07', User OID: 'PatientReportedOutcome (US3342200)', ODM File OID: '2c028e64-fb89-40c3-9e17-a7b5c9a07d7a' User entered 'No (N)'	System	16 Jan 2021 18:37:13
	System	16 Jan 2021 18:37:13

US3342200

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(109)

Generated On: 09 Jun 2021 17:05:26

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:04:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2D2D1647-7C35-4DCA-ADA3-8E1DAA921DDC)', Time: '2021-01-16T12:37:10', User OID: 'PatientReportedOutcome (US3342200)', ODM File OID: '2c028e64-fb89-40c3-9e17-a7b5c9a07d7a' User entered '16 Jan 2021 12:37'	System	16 Jan 2021 18:37:13
	System	16 Jan 2021 18:37:13

US3342200

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(109)

Generated On: 09 Jun 2021 17:05:26

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:04:20
User entered '16 Jan 2021 12:00'	System	14 Jan 2021 22:03:17

US3342200

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(109)

Generated On: 09 Jun 2021 17:05:26

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:04:20
User entered '17 Jan 2021 11:59'	System	14 Jan 2021 22:03:17

US3342200

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(110)

Generated On: 09 Jun 2021 17:05:26

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:04:20
Data entry locked.	System	16 Jan 2021 09:13:53
User entered 'Day 110'	System	16 Jan 2021 09:13:53

US3342200

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(110)

Generated On: 09 Jun 2021 17:05:26

Did you receive any **MEDICAL ATTENTION** (doctor visit, other) for any illness or symptoms?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:04:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2D2D1647-7C35-4DCA-ADA3-8E1DAA921DDC)', Time: '2021-01-18T00:19:43', User OID: 'PatientReportedOutcome (US3342200)', ODM File OID: '96b1040c-c423-4fe4-8f17-3bdb2ab68dc9' User entered 'No (N)'	System	18 Jan 2021 06:19:48
	System	18 Jan 2021 06:19:48

US3342200

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(110)

Generated On: 09 Jun 2021 17:05:26

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:04:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2D2D1647-7C35-4DCA-ADA3-8E1DAA921DDC)', Time: '2021-01-18T00:19:46', User OID: 'PatientReportedOutcome (US3342200)', ODM File OID: '96b1040c-c423-4fe4-8f17-3bdb2ab68dc9' User entered '18 Jan 2021 00:19'	System	18 Jan 2021 06:19:48
	System	18 Jan 2021 06:19:48

US3342200

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(110)

Generated On: 09 Jun 2021 17:05:26

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:04:20
User entered '17 Jan 2021 12:00'	System	16 Jan 2021 09:13:53

US3342200

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(110)

Generated On: 09 Jun 2021 17:05:26

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:04:20
User entered '18 Jan 2021 11:59'	System	16 Jan 2021 09:13:53

US3342200

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(111)

Generated On: 09 Jun 2021 17:05:26

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:04:20
Data entry locked.	System	16 Jan 2021 18:37:03
User entered 'Day 111'	System	16 Jan 2021 18:37:03

US3342200

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(111)

Generated On: 09 Jun 2021 17:05:26

Did you receive any **MEDICAL ATTENTION** (doctor visit, other) for any illness or symptoms?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:04:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2D2D1647-7C35-4DCA-ADA3-8E1DAA921DDC)', Time: '2021-01-19T03:08:18', User OID: 'PatientReportedOutcome (US3342200)', ODM File OID: 'afa01888-3ade-4831-bf77-7e00058913f9' User entered 'No (N)'	System	19 Jan 2021 09:08:24
	System	19 Jan 2021 09:08:24

US3342200

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(111)

Generated On: 09 Jun 2021 17:05:26

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:04:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2D2D1647-7C35-4DCA-ADA3-8E1DAA921DDC)', Time: '2021-01-19T03:08:22', User OID: 'PatientReportedOutcome (US3342200)', ODM File OID: 'afa01888-3ade-4831-bf77-7e00058913f9' User entered '19 Jan 2021 03:08'	System	19 Jan 2021 09:08:24
	System	19 Jan 2021 09:08:24

US3342200

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(111)

Generated On: 09 Jun 2021 17:05:26

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:04:20
User entered '18 Jan 2021 12:00'	System	16 Jan 2021 18:37:03

US3342200

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(111)

Generated On: 09 Jun 2021 17:05:26

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:04:20
User entered '19 Jan 2021 11:59'	System	16 Jan 2021 18:37:03

US3342200

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(112)

Generated On: 09 Jun 2021 17:05:26

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:04:20
Data entry locked.	System	18 Jan 2021 06:19:39
User entered 'Day 112'	System	18 Jan 2021 06:19:39

US3342200

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(112)

Generated On: 09 Jun 2021 17:05:26

Did you receive any **MEDICAL ATTENTION** (doctor visit, other) for any illness or symptoms?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:04:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2D2D1647-7C35-4DCA-ADA3-8E1DAA921DDC)', Time: '2021-01-19T12:01:50', User OID: 'PatientReportedOutcome (US3342200)', ODM File OID: '0f2dbf37-76b5-4c2e-bbb3-2e0c920ff6ba' User entered 'No (N)'	System	19 Jan 2021 18:02:42
	System	19 Jan 2021 18:02:42

US3342200

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(112)

Generated On: 09 Jun 2021 17:05:26

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:04:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2D2D1647-7C35-4DCA-ADA3-8E1DAA921DDC)', Time: '2021-01-19T12:01:52', User OID: 'PatientReportedOutcome (US3342200)', ODM File OID: '0f2dbf37-76b5-4c2e-bbb3-2e0c920ff6ba' User entered '19 Jan 2021 12:01'	System	19 Jan 2021 18:02:42
	System	19 Jan 2021 18:02:42

US3342200

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(112)

Generated On: 09 Jun 2021 17:05:26

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:04:20
User entered '19 Jan 2021 12:00'	System	18 Jan 2021 06:19:39

US3342200

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(112)

Generated On: 09 Jun 2021 17:05:26

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:04:20
User entered '20 Jan 2021 11:59'	System	18 Jan 2021 06:19:39

US3342200

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(113)

Generated On: 09 Jun 2021 17:05:26

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:04:20
Data entry locked.	System	19 Jan 2021 09:08:17
User entered 'Day 113'	System	19 Jan 2021 09:08:17

US3342200

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(113)

Generated On: 09 Jun 2021 17:05:26

Did you receive any **MEDICAL ATTENTION** (doctor visit, other) for any illness or symptoms?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:04:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2D2D1647-7C35-4DCA-ADA3-8E1DAA921DDC)', Time: '2021-01-20T15:17:35', User OID: 'PatientReportedOutcome (US3342200)', ODM File OID: '2d93d058-e980-4db0-a719-374b80d128de' User entered 'No (N)'	System	20 Jan 2021 21:17:41
	System	20 Jan 2021 21:17:41

US3342200

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(113)

Generated On: 09 Jun 2021 17:05:26

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:04:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2D2D1647-7C35-4DCA-ADA3-8E1DAA921DDC)', Time: '2021-01-20T15:17:38', User OID: 'PatientReportedOutcome (US3342200)', ODM File OID: '2d93d058-e980-4db0-a719-374b80d128de' User entered '20 Jan 2021 15:17'	System	20 Jan 2021 21:17:41
	System	20 Jan 2021 21:17:41

US3342200

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(113)

Generated On: 09 Jun 2021 17:05:26

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:04:20
User entered '20 Jan 2021 12:00'	System	19 Jan 2021 09:08:17

US3342200

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(113)

Generated On: 09 Jun 2021 17:05:26

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:04:20
User entered '21 Jan 2021 11:59'	System	19 Jan 2021 09:08:17

US3342200

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(114)

Generated On: 09 Jun 2021 17:05:26

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:04:20
Data entry locked.	System	19 Jan 2021 18:02:00
User entered 'Day 114'	System	19 Jan 2021 18:02:00

US3342200

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(114)

Generated On: 09 Jun 2021 17:05:26

Did you receive any **MEDICAL ATTENTION** (doctor visit, other) for any illness or symptoms?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:04:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2D2D1647-7C35-4DCA-ADA3-8E1DAA921DDC)', Time: '2021-01-21T12:00:33', User OID: 'PatientReportedOutcome (US3342200)', ODM File OID: '16523d68-96eb-48f1-a9db-a51b71e2a969' User entered 'No (N)'	System	21 Jan 2021 18:00:46
	System	21 Jan 2021 18:00:46

US3342200

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(114)

Generated On: 09 Jun 2021 17:05:26

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:04:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2D2D1647-7C35-4DCA-ADA3-8E1DAA921DDC)', Time: '2021-01-21T12:00:36', User OID: 'PatientReportedOutcome (US3342200)', ODM File OID: '16523d68-96eb-48f1-a9db-a51b71e2a969' User entered '21 Jan 2021 12:00'	System	21 Jan 2021 18:00:46
	System	21 Jan 2021 18:00:46

US3342200

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(114)

Generated On: 09 Jun 2021 17:05:26

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:04:20
User entered '21 Jan 2021 12:00'	System	19 Jan 2021 18:02:00

US3342200

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(114)

Generated On: 09 Jun 2021 17:05:26

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:04:20
User entered '22 Jan 2021 11:59'	System	19 Jan 2021 18:02:00

US3342200

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(115)

Generated On: 09 Jun 2021 17:05:26

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:04:20
Data entry locked.	System	20 Jan 2021 21:17:34
User entered 'Day 115'	System	20 Jan 2021 21:17:34

US3342200

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(115)

Generated On: 09 Jun 2021 17:05:26

Did you receive any **MEDICAL ATTENTION** (doctor visit, other) for any illness or symptoms?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:04:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2D2D1647-7C35-4DCA-ADA3-8E1DAA921DDC)', Time: '2021-01-22T12:55:53', User OID: 'PatientReportedOutcome (US3342200)', ODM File OID: 'd484aebd-9d27-475d-bd1a-d6b6fdbda49d' User entered 'No (N)'	System	22 Jan 2021 18:55:58
	System	22 Jan 2021 18:55:58

US3342200

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(115)

Generated On: 09 Jun 2021 17:05:26

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:04:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2D2D1647-7C35-4DCA-ADA3-8E1DAA921DDC)', Time: '2021-01-22T12:55:56', User OID: 'PatientReportedOutcome (US3342200)', ODM File OID: 'd484aebd-9d27-475d-bd1a-d6b6fdbda49d' User entered '22 Jan 2021 12:55'	System	22 Jan 2021 18:55:58
	System	22 Jan 2021 18:55:58

US3342200

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(115)

Generated On: 09 Jun 2021 17:05:26

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:04:20
User entered '22 Jan 2021 12:00'	System	20 Jan 2021 21:17:34

US3342200

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(115)

Generated On: 09 Jun 2021 17:05:26

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:04:20
User entered '23 Jan 2021 11:59'	System	20 Jan 2021 21:17:34

US3342200

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(116)

Generated On: 09 Jun 2021 17:05:26

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:04:20
Data entry locked.	System	21 Jan 2021 18:00:39
User entered 'Day 116'	System	21 Jan 2021 18:00:39

US3342200

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(116)

Generated On: 09 Jun 2021 17:05:26

Did you receive any **MEDICAL ATTENTION** (doctor visit, other) for any illness or symptoms?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:04:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2D2D1647-7C35-4DCA-ADA3-8E1DAA921DDC)', Time: '2021-01-23T12:37:05', User OID: 'PatientReportedOutcome (US3342200)', ODM File OID: '1546a02c-5c97-4552-ac03-ce142c23d115' User entered 'No (N)'	System	23 Jan 2021 18:37:10
	System	23 Jan 2021 18:37:10

US3342200

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(116)

Generated On: 09 Jun 2021 17:05:26

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:04:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2D2D1647-7C35-4DCA-ADA3-8E1DAA921DDC)', Time: '2021-01-23T12:37:07', User OID: 'PatientReportedOutcome (US3342200)', ODM File OID: '1546a02c-5c97-4552-ac03-ce142c23d115' User entered '23 Jan 2021 12:37'	System	23 Jan 2021 18:37:10
	System	23 Jan 2021 18:37:10

US3342200

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(116)

Generated On: 09 Jun 2021 17:05:26

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:04:20
User entered '23 Jan 2021 12:00'	System	21 Jan 2021 18:00:39

US3342200

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(116)

Generated On: 09 Jun 2021 17:05:26

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:04:20
User entered '24 Jan 2021 11:59'	System	21 Jan 2021 18:00:39

US3342200

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(117)

Generated On: 09 Jun 2021 17:05:26

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:04:20
Data entry locked.	System	22 Jan 2021 18:55:50
User entered 'Day 117'	System	22 Jan 2021 18:55:50

US3342200

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(117)

Generated On: 09 Jun 2021 17:05:26

Did you receive any **MEDICAL ATTENTION** (doctor visit, other) for any illness or symptoms?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:04:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2D2D1647-7C35-4DCA-ADA3-8E1DAA921DDC)', Time: '2021-01-24T21:42:52', User OID: 'PatientReportedOutcome (US3342200)', ODM File OID: 'da006e62-d677-4302-b906-583afff7e814' User entered 'No (N)'	System	25 Jan 2021 03:42:57
	System	25 Jan 2021 03:42:57

US3342200

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(117)

Generated On: 09 Jun 2021 17:05:26

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:04:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2D2D1647-7C35-4DCA-ADA3-8E1DAA921DDC)', Time: '2021-01-24T21:42:54', User OID: 'PatientReportedOutcome (US3342200)', ODM File OID: 'da006e62-d677-4302-b906-583afff7e814' User entered '24 Jan 2021 21:42'	System	25 Jan 2021 03:42:57
	System	25 Jan 2021 03:42:57

US3342200

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(117)

Generated On: 09 Jun 2021 17:05:26

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:04:20
User entered '24 Jan 2021 12:00'	System	22 Jan 2021 18:55:50

US3342200

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(117)

Generated On: 09 Jun 2021 17:05:26

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:04:20
User entered '25 Jan 2021 11:59'	System	22 Jan 2021 18:55:50

US3342200

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(118)

Generated On: 09 Jun 2021 17:05:26

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:04:20
Data entry locked.	System	23 Jan 2021 18:37:04
User entered 'Day 118'	System	23 Jan 2021 18:37:04

US3342200

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(118)

Generated On: 09 Jun 2021 17:05:26

Did you receive any **MEDICAL ATTENTION** (doctor visit, other) for any illness or symptoms?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:04:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2D2D1647-7C35-4DCA-ADA3-8E1DAA921DDC)', Time: '2021-01-25T17:48:43', User OID: 'PatientReportedOutcome (US3342200)', ODM File OID: 'c8288d84-8ba4-488a-b311-72e4a2613a89' User entered 'No (N)'	System	25 Jan 2021 23:48:49
	System	25 Jan 2021 23:48:49

US3342200

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(118)

Generated On: 09 Jun 2021 17:05:26

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:04:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2D2D1647-7C35-4DCA-ADA3-8E1DAA921DDC)', Time: '2021-01-25T17:48:45', User OID: 'PatientReportedOutcome (US3342200)', ODM File OID: 'c8288d84-8ba4-488a-b311-72e4a2613a89' User entered '25 Jan 2021 17:48'	System	25 Jan 2021 23:48:49
	System	25 Jan 2021 23:48:49

US3342200

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(118)

Generated On: 09 Jun 2021 17:05:26

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:04:20
User entered '25 Jan 2021 12:00'	System	23 Jan 2021 18:37:04

US3342200

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(118)

Generated On: 09 Jun 2021 17:05:26

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:04:20
User entered '26 Jan 2021 11:59'	System	23 Jan 2021 18:37:04

US3342200

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(119)

Generated On: 09 Jun 2021 17:05:26

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:04:20
Data entry locked.	System	25 Jan 2021 03:42:50
User entered 'Day 119'	System	25 Jan 2021 03:42:50

US3342200

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(119)

Generated On: 09 Jun 2021 17:05:26

Did you receive any **MEDICAL ATTENTION** (doctor visit, other) for any illness or symptoms?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:04:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2D2D1647-7C35-4DCA-ADA3-8E1DAA921DDC)', Time: '2021-01-26T19:10:22', User OID: 'PatientReportedOutcome (US3342200)', ODM File OID: 'b431e45c-f509-432d-a57a-dcea4eeb0ad6' User entered 'No (N)'	System	27 Jan 2021 01:32:08
	System	27 Jan 2021 01:32:08

US3342200

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(119)

Generated On: 09 Jun 2021 17:05:26

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:04:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2D2D1647-7C35-4DCA-ADA3-8E1DAA921DDC)', Time: '2021-01-26T19:10:29', User OID: 'PatientReportedOutcome (US3342200)', ODM File OID: 'b431e45c-f509-432d-a57a-dcea4eeb0ad6' User entered '26 Jan 2021 19:10'	System	27 Jan 2021 01:32:08
	System	27 Jan 2021 01:32:08

US3342200

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(119)

Generated On: 09 Jun 2021 17:05:26

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:04:20
User entered '26 Jan 2021 12:00'	System	25 Jan 2021 03:42:50

US3342200

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(119)

Generated On: 09 Jun 2021 17:05:26

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:04:20
User entered '27 Jan 2021 11:59'	System	25 Jan 2021 03:42:50

US3342200

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(120)

Generated On: 09 Jun 2021 17:05:26

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:04:20
Data entry locked.	System	25 Jan 2021 23:48:47
User entered 'Day 120'	System	25 Jan 2021 23:48:47

US3342200

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(120)

Generated On: 09 Jun 2021 17:05:26

Did you receive any **MEDICAL ATTENTION** (doctor visit, other) for any illness or symptoms?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:04:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2D2D1647-7C35-4DCA-ADA3-8E1DAA921DDC)', Time: '2021-01-27T19:46:23', User OID: 'PatientReportedOutcome (US3342200)', ODM File OID: '78386b3d-ce80-4f78-9ec9-57b227e4e837' User entered 'No (N)'	System	28 Jan 2021 01:46:31
	System	28 Jan 2021 01:46:31

US3342200

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(120)

Generated On: 09 Jun 2021 17:05:26

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:04:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2D2D1647-7C35-4DCA-ADA3-8E1DAA921DDC)', Time: '2021-01-27T19:46:26', User OID: 'PatientReportedOutcome (US3342200)', ODM File OID: '78386b3d-ce80-4f78-9ec9-57b227e4e837' User entered '27 Jan 2021 19:46'	System	28 Jan 2021 01:46:31
	System	28 Jan 2021 01:46:31

US3342200

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(120)

Generated On: 09 Jun 2021 17:05:26

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:04:20
User entered '27 Jan 2021 12:00'	System	25 Jan 2021 23:48:47

US3342200

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(120)

Generated On: 09 Jun 2021 17:05:26

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:04:20
User entered '28 Jan 2021 11:59'	System	25 Jan 2021 23:48:47

US3342200

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(121)

Generated On: 09 Jun 2021 17:05:26

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:04:20
Data entry locked.	System	27 Jan 2021 01:32:08
User entered 'Day 121'	System	27 Jan 2021 01:32:08

US3342200

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(121)

Generated On: 09 Jun 2021 17:05:26

Did you receive any **MEDICAL ATTENTION** (doctor visit, other) for any illness or symptoms?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:04:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2D2D1647-7C35-4DCA-ADA3-8E1DAA921DDC)', Time: '2021-01-28T12:00:38', User OID: 'PatientReportedOutcome (US3342200)', ODM File OID: 'b08c24f0-d72d-4011-b6bb-f47e25b1219d' User entered 'No (N)'	System	28 Jan 2021 18:00:57
	System	28 Jan 2021 18:00:57

US3342200

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(121)

Generated On: 09 Jun 2021 17:05:26

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:04:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2D2D1647-7C35-4DCA-ADA3-8E1DAA921DDC)', Time: '2021-01-28T12:00:42', User OID: 'PatientReportedOutcome (US3342200)', ODM File OID: 'b08c24f0-d72d-4011-b6bb-f47e25b1219d' User entered '28 Jan 2021 12:00'	System	28 Jan 2021 18:00:57
	System	28 Jan 2021 18:00:57

US3342200

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(121)

Generated On: 09 Jun 2021 17:05:26

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:04:20
User entered '28 Jan 2021 12:00'	System	27 Jan 2021 01:32:08

US3342200

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(121)

Generated On: 09 Jun 2021 17:05:26

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:04:20
User entered '29 Jan 2021 11:59'	System	27 Jan 2021 01:32:08

US3342200

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(122)

Generated On: 09 Jun 2021 17:05:26

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:04:20
Data entry locked.	System	28 Jan 2021 01:46:16
User entered 'Day 122'	System	28 Jan 2021 01:46:16

US3342200

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(122)

Generated On: 09 Jun 2021 17:05:26

Did you receive any **MEDICAL ATTENTION** (doctor visit, other) for any illness or symptoms?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:04:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2D2D1647-7C35-4DCA-ADA3-8E1DAA921DDC)', Time: '2021-01-30T05:35:46', User OID: 'PatientReportedOutcome (US3342200)', ODM File OID: 'bce120be-1cb3-4af3-8426-a25918ef1991' User entered 'No (N)'	System	30 Jan 2021 11:35:51
	System	30 Jan 2021 11:35:51

US3342200

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(122)

Generated On: 09 Jun 2021 17:05:26

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:04:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2D2D1647-7C35-4DCA-ADA3-8E1DAA921DDC)', Time: '2021-01-30T05:35:49', User OID: 'PatientReportedOutcome (US3342200)', ODM File OID: 'bce120be-1cb3-4af3-8426-a25918ef1991' User entered '30 Jan 2021 05:35'	System	30 Jan 2021 11:35:51
	System	30 Jan 2021 11:35:51

US3342200

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(122)

Generated On: 09 Jun 2021 17:05:26

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:04:20
User entered '29 Jan 2021 12:00'	System	28 Jan 2021 01:46:16

US3342200

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(122)

Generated On: 09 Jun 2021 17:05:26

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:04:20
User entered '30 Jan 2021 11:59'	System	28 Jan 2021 01:46:16

US3342200

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(123)

Generated On: 09 Jun 2021 17:05:26

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:04:20
Data entry locked.	System	28 Jan 2021 18:00:51
User entered 'Day 123'	System	28 Jan 2021 18:00:51

US3342200

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(123)

Generated On: 09 Jun 2021 17:05:26

Did you receive any **MEDICAL ATTENTION** (doctor visit, other) for any illness or symptoms?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:04:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2D2D1647-7C35-4DCA-ADA3-8E1DAA921DDC)', Time: '2021-01-31T09:35:39', User OID: 'PatientReportedOutcome (US3342200)', ODM File OID: '14e82be8-5489-46b9-9a5b-c56b600624f9' User entered 'No (N)'	System	31 Jan 2021 15:35:42
	System	31 Jan 2021 15:35:42

US3342200

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(123)

Generated On: 09 Jun 2021 17:05:26

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:04:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2D2D1647-7C35-4DCA-ADA3-8E1DAA921DDC)', Time: '2021-01-31T09:35:41', User OID: 'PatientReportedOutcome (US3342200)', ODM File OID: '14e82be8-5489-46b9-9a5b-c56b600624f9' User entered '31 Jan 2021 09:35'	System	31 Jan 2021 15:35:42
	System	31 Jan 2021 15:35:42

US3342200

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(123)

Generated On: 09 Jun 2021 17:05:26

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:04:20
User entered '30 Jan 2021 12:00'	System	28 Jan 2021 18:00:51

US3342200

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(123)

Generated On: 09 Jun 2021 17:05:26

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:04:20
User entered '31 Jan 2021 11:59'	System	28 Jan 2021 18:00:51

US3342200

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(124)

Generated On: 09 Jun 2021 17:05:26

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:04:20
Data entry locked.	System	30 Jan 2021 11:35:44
User entered 'Day 124'	System	30 Jan 2021 11:35:44

US3342200

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(124)

Generated On: 09 Jun 2021 17:05:26

Did you receive any **MEDICAL ATTENTION** (doctor visit, other) for any illness or symptoms?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:04:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2D2D1647-7C35-4DCA-ADA3-8E1DAA921DDC)', Time: '2021-01-31T14:18:54', User OID: 'PatientReportedOutcome (US3342200)', ODM File OID: '28fc90eb-b030-4837-9dfe-6a5c954072a3' User entered 'No (N)'	System	01 Feb 2021 19:45:47
	System	01 Feb 2021 19:45:47

US3342200

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(124)

Generated On: 09 Jun 2021 17:05:26

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:04:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2D2D1647-7C35-4DCA-ADA3-8E1DAA921DDC)', Time: '2021-01-31T14:18:57', User OID: 'PatientReportedOutcome (US3342200)', ODM File OID: '28fc90eb-b030-4837-9dfe-6a5c954072a3' User entered '31 Jan 2021 14:18'	System	01 Feb 2021 19:45:47
	System	01 Feb 2021 19:45:47

US3342200

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(124)

Generated On: 09 Jun 2021 17:05:26

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:04:20
User entered '31 Jan 2021 12:00'	System	30 Jan 2021 11:35:44

US3342200

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(124)

Generated On: 09 Jun 2021 17:05:26

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:04:20
User entered '01 Feb 2021 11:59'	System	30 Jan 2021 11:35:44

US3342200

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(125)

Generated On: 09 Jun 2021 17:05:26

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:04:20
Data entry locked.	System	31 Jan 2021 15:35:39
User entered 'Day 125'	System	31 Jan 2021 15:35:39

US3342200

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(125)

Generated On: 09 Jun 2021 17:05:26

Did you receive any **MEDICAL ATTENTION** (doctor visit, other) for any illness or symptoms?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:04:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2D2D1647-7C35-4DCA-ADA3-8E1DAA921DDC)', Time: '2021-02-01T13:44:56', User OID: 'PatientReportedOutcome (US3342200)', ODM File OID: 'e70d8bd9-cdf5-4eaf-a2b7-7c0251f034eb' User entered 'No (N)'	System	01 Feb 2021 19:45:49
	System	01 Feb 2021 19:45:49

US3342200

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(125)

Generated On: 09 Jun 2021 17:05:26

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:04:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2D2D1647-7C35-4DCA-ADA3-8E1DAA921DDC)', Time: '2021-02-01T13:44:58', User OID: 'PatientReportedOutcome (US3342200)', ODM File OID: 'e70d8bd9-cdf5-4eaf-a2b7-7c0251f034eb' User entered '01 Feb 2021 13:44'	System	01 Feb 2021 19:45:49
	System	01 Feb 2021 19:45:49

US3342200

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(125)

Generated On: 09 Jun 2021 17:05:26

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:04:20
User entered '01 Feb 2021 12:00'	System	31 Jan 2021 15:35:39

US3342200

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(125)

Generated On: 09 Jun 2021 17:05:26

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:04:20
User entered '02 Feb 2021 11:59'	System	31 Jan 2021 15:35:39

US3342200

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(126)

Generated On: 09 Jun 2021 17:05:26

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:04:20
Data entry locked.	System	31 Jan 2021 20:18:52
User entered 'Day 126'	System	31 Jan 2021 20:18:52

US3342200

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(126)

Generated On: 09 Jun 2021 17:05:26

Did you receive any **MEDICAL ATTENTION** (doctor visit, other) for any illness or symptoms?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:04:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2D2D1647-7C35-4DCA-ADA3-8E1DAA921DDC)', Time: '2021-02-02T12:01:30', User OID: 'PatientReportedOutcome (US3342200)', ODM File OID: 'dcc45219-98d5-416f-a32b-ba05b7141673' User entered 'No (N)'	System	04 Feb 2021 00:10:20
	System	04 Feb 2021 00:10:20

US3342200

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(126)

Generated On: 09 Jun 2021 17:05:26

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:04:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2D2D1647-7C35-4DCA-ADA3-8E1DAA921DDC)', Time: '2021-02-02T12:01:33', User OID: 'PatientReportedOutcome (US3342200)', ODM File OID: 'dcc45219-98d5-416f-a32b-ba05b7141673' User entered '02 Feb 2021 12:01'	System	04 Feb 2021 00:10:20
	System	04 Feb 2021 00:10:20

US3342200

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(126)

Generated On: 09 Jun 2021 17:05:26

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:04:20
User entered '02 Feb 2021 12:00'	System	31 Jan 2021 20:18:52

US3342200

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(126)

Generated On: 09 Jun 2021 17:05:26

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:04:20
User entered '03 Feb 2021 11:59'	System	31 Jan 2021 20:18:52

US3342200

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(127)

Generated On: 09 Jun 2021 17:05:26

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:04:20
Data entry locked.	System	01 Feb 2021 19:45:48
User entered 'Day 127'	System	01 Feb 2021 19:45:48

US3342200

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(127)

Generated On: 09 Jun 2021 17:05:26

Did you receive any **MEDICAL ATTENTION** (doctor visit, other) for any illness or symptoms?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:04:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2D2D1647-7C35-4DCA-ADA3-8E1DAA921DDC)', Time: '2021-02-03T18:10:19', User OID: 'PatientReportedOutcome (US3342200)', ODM File OID: '5e6e8bbd-617f-4581-90aa-7d21e64acba'	System	04 Feb 2021 00:10:25
User entered 'No (N)'	System	04 Feb 2021 00:10:25

US3342200

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(127)

Generated On: 09 Jun 2021 17:05:26

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:04:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2D2D1647-7C35-4DCA-ADA3-8E1DAA921DDC)', Time: '2021-02-03T18:10:21', User OID: 'PatientReportedOutcome (US3342200)', ODM File OID: '5e6e8bbd-617f-4581-90aa-7d21e64acba'	System	04 Feb 2021 00:10:25
User entered '03 Feb 2021 18:10'	System	04 Feb 2021 00:10:25

US3342200

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(127)

Generated On: 09 Jun 2021 17:05:26

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:04:20
User entered '03 Feb 2021 12:00'	System	01 Feb 2021 19:45:48

US3342200

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(127)

Generated On: 09 Jun 2021 17:05:26

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:04:20
User entered '04 Feb 2021 11:59'	System	01 Feb 2021 19:45:48

US3342200

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(128)

Generated On: 09 Jun 2021 17:05:26

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:04:20
Data entry locked.	System	02 Feb 2021 18:03:12
User entered 'Day 128'	System	02 Feb 2021 18:03:12

US3342200

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(128)

Generated On: 09 Jun 2021 17:05:26

Did you receive any **MEDICAL ATTENTION** (doctor visit, other) for any illness or symptoms?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:04:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2D2D1647-7C35-4DCA-ADA3-8E1DAA921DDC)', Time: '2021-02-04T12:02:19', User OID: 'PatientReportedOutcome (US3342200)', ODM File OID: 'a9cb4d4c-0e20-42b6-ab72-6c149009611e' User entered 'No (N)'	System	04 Feb 2021 18:04:47
	System	04 Feb 2021 18:04:47

US3342200

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(128)

Generated On: 09 Jun 2021 17:05:26

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:04:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2D2D1647-7C35-4DCA-ADA3-8E1DAA921DDC)', Time: '2021-02-04T12:02:22', User OID: 'PatientReportedOutcome (US3342200)', ODM File OID: 'a9cb4d4c-0e20-42b6-ab72-6c149009611e' User entered '04 Feb 2021 12:02'	System	04 Feb 2021 18:04:47
	System	04 Feb 2021 18:04:47

US3342200

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(128)

Generated On: 09 Jun 2021 17:05:26

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:04:20
User entered '04 Feb 2021 12:00'	System	02 Feb 2021 18:03:12

US3342200

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(128)

Generated On: 09 Jun 2021 17:05:26

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:04:20
User entered '05 Feb 2021 11:59'	System	02 Feb 2021 18:03:12

US3342200

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(129)

Generated On: 09 Jun 2021 17:05:26

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:04:20
Data entry locked.	System	04 Feb 2021 00:10:25
User entered 'Day 129'	System	04 Feb 2021 00:10:25

US3342200

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(129)

Generated On: 09 Jun 2021 17:05:26

Did you receive any **MEDICAL ATTENTION** (doctor visit, other) for any illness or symptoms?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:04:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2D2D1647-7C35-4DCA-ADA3-8E1DAA921DDC)', Time: '2021-02-05T13:11:03', User OID: 'PatientReportedOutcome (US3342200)', ODM File OID: '29516475-049a-4d3d-9979-bd3552f35430' User entered 'No (N)'	System	05 Feb 2021 19:11:13
	System	05 Feb 2021 19:11:13

US3342200

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(129)

Generated On: 09 Jun 2021 17:05:26

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:04:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2D2D1647-7C35-4DCA-ADA3-8E1DAA921DDC)', Time: '2021-02-05T13:11:09', User OID: 'PatientReportedOutcome (US3342200)', ODM File OID: '29516475-049a-4d3d-9979-bd3552f35430' User entered '05 Feb 2021 13:11'	System	05 Feb 2021 19:11:13
	System	05 Feb 2021 19:11:13

US3342200

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(129)

Generated On: 09 Jun 2021 17:05:26

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:04:20
User entered '05 Feb 2021 12:00'	System	04 Feb 2021 00:10:25

US3342200

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(129)

Generated On: 09 Jun 2021 17:05:26

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:04:20
User entered '06 Feb 2021 11:59'	System	04 Feb 2021 00:10:25

US3342200

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(130)

Generated On: 09 Jun 2021 17:05:26

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:04:20
Data entry locked.	System	04 Feb 2021 18:04:09
User entered 'Day 130'	System	04 Feb 2021 18:04:09

US3342200

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(130)

Generated On: 09 Jun 2021 17:05:26

Did you receive any **MEDICAL ATTENTION** (doctor visit, other) for any illness or symptoms?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:04:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2D2D1647-7C35-4DCA-ADA3-8E1DAA921DDC)', Time: '2021-02-06T21:15:57', User OID: 'PatientReportedOutcome (US3342200)', ODM File OID: '03fc99a6-f5a7-424a-8232-dc9c8d219cbd' User entered 'No (N)'	System	07 Feb 2021 03:16:06
	System	07 Feb 2021 03:16:06

US3342200

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(130)

Generated On: 09 Jun 2021 17:05:26

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:04:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2D2D1647-7C35-4DCA-ADA3-8E1DAA921DDC)', Time: '2021-02-06T21:16:00', User OID: 'PatientReportedOutcome (US3342200)', ODM File OID: '03fc99a6-f5a7-424a-8232-dc9c8d219cbd' User entered '06 Feb 2021 21:16'	System	07 Feb 2021 03:16:06
	System	07 Feb 2021 03:16:06

US3342200

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(130)

Generated On: 09 Jun 2021 17:05:26

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:04:20
User entered '06 Feb 2021 12:00'	System	04 Feb 2021 18:04:09

US3342200

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(130)

Generated On: 09 Jun 2021 17:05:26

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:04:20
User entered '07 Feb 2021 11:59'	System	04 Feb 2021 18:04:09

US3342200

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(131)

Generated On: 09 Jun 2021 17:05:26

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:04:20
Data entry locked.	System	05 Feb 2021 19:10:59
User entered 'Day 131'	System	05 Feb 2021 19:10:59

US3342200

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(131)

Generated On: 09 Jun 2021 17:05:26

Did you receive any **MEDICAL ATTENTION** (doctor visit, other) for any illness or symptoms?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:04:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2D2D1647-7C35-4DCA-ADA3-8E1DAA921DDC)', Time: '2021-02-08T06:00:05', User OID: 'PatientReportedOutcome (US3342200)', ODM File OID: 'fa6e154c-d818-4952-b434-17ec035d640e' User entered 'No (N)'	System	08 Feb 2021 12:00:10
	System	08 Feb 2021 12:00:10

US3342200

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(131)

Generated On: 09 Jun 2021 17:05:26

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:04:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2D2D1647-7C35-4DCA-ADA3-8E1DAA921DDC)', Time: '2021-02-08T06:00:08', User OID: 'PatientReportedOutcome (US3342200)', ODM File OID: 'fa6e154c-d818-4952-b434-17ec035d640e' User entered '08 Feb 2021 06:00'	System	08 Feb 2021 12:00:10
	System	08 Feb 2021 12:00:10

US3342200

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(131)

Generated On: 09 Jun 2021 17:05:26

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:04:20
User entered '07 Feb 2021 12:00'	System	05 Feb 2021 19:10:59

US3342200

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(131)

Generated On: 09 Jun 2021 17:05:26

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:04:20
User entered '08 Feb 2021 11:59'	System	05 Feb 2021 19:10:59

US3342200

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(132)

Generated On: 09 Jun 2021 17:05:26

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:04:20
Data entry locked.	System	07 Feb 2021 03:16:05
User entered 'Day 132'	System	07 Feb 2021 03:16:05

US3342200

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(132)

Generated On: 09 Jun 2021 17:05:26

Did you receive any **MEDICAL ATTENTION** (doctor visit, other) for any illness or symptoms?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:04:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2D2D1647-7C35-4DCA-ADA3-8E1DAA921DDC)', Time: '2021-02-08T13:09:33', User OID: 'PatientReportedOutcome (US3342200)', ODM File OID: 'b220faeb-143c-4eff-b7cc-bd9089cf8a09' User entered 'No (N)'	System	08 Feb 2021 19:09:39
	System	08 Feb 2021 19:09:39

US3342200

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(132)

Generated On: 09 Jun 2021 17:05:26

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:04:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2D2D1647-7C35-4DCA-ADA3-8E1DAA921DDC)', Time: '2021-02-08T13:09:36', User OID: 'PatientReportedOutcome (US3342200)', ODM File OID: 'b220faeb-143c-4eff-b7cc-bd9089cf8a09' User entered '08 Feb 2021 13:09'	System	08 Feb 2021 19:09:39
	System	08 Feb 2021 19:09:39

US3342200

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(132)

Generated On: 09 Jun 2021 17:05:26

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:04:20
User entered '08 Feb 2021 12:00'	System	07 Feb 2021 03:16:05

US3342200

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(132)

Generated On: 09 Jun 2021 17:05:26

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:04:20
User entered '09 Feb 2021 11:59'	System	07 Feb 2021 03:16:05

US3342200

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(133)

Generated On: 09 Jun 2021 17:05:26

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:04:20
Data entry locked.	System	08 Feb 2021 12:00:06
User entered 'Day 133'	System	08 Feb 2021 12:00:06

US3342200

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(133)

Generated On: 09 Jun 2021 17:05:26

Did you receive any **MEDICAL ATTENTION** (doctor visit, other) for any illness or symptoms?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:04:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2D2D1647-7C35-4DCA-ADA3-8E1DAA921DDC)', Time: '2021-02-09T16:43:22', User OID: 'PatientReportedOutcome (US3342200)', ODM File OID: '57daf6c6-6b1d-480e-bec4-f1442600d55c' User entered 'No (N)'	System	09 Feb 2021 22:43:37
	System	09 Feb 2021 22:43:37

US3342200

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(133)

Generated On: 09 Jun 2021 17:05:26

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:04:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2D2D1647-7C35-4DCA-ADA3-8E1DAA921DDC)', Time: '2021-02-09T16:43:34', User OID: 'PatientReportedOutcome (US3342200)', ODM File OID: '57daf6c6-6b1d-480e-bec4-f1442600d55c' User entered '09 Feb 2021 16:43'	System	09 Feb 2021 22:43:37
	System	09 Feb 2021 22:43:37

US3342200

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(133)

Generated On: 09 Jun 2021 17:05:26

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:04:20
User entered '09 Feb 2021 12:00'	System	08 Feb 2021 12:00:06

US3342200

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(133)

Generated On: 09 Jun 2021 17:05:26

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:04:20
User entered '10 Feb 2021 11:59'	System	08 Feb 2021 12:00:06

US3342200

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(134)

Generated On: 09 Jun 2021 17:05:26

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:04:20
Data entry locked.	System	08 Feb 2021 19:09:36
User entered 'Day 134'	System	08 Feb 2021 19:09:36

US3342200

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(134)

Generated On: 09 Jun 2021 17:05:26

Did you receive any **MEDICAL ATTENTION** (doctor visit, other) for any illness or symptoms?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:04:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2D2D1647-7C35-4DCA-ADA3-8E1DAA921DDC)', Time: '2021-02-11T03:47:55', User OID: 'PatientReportedOutcome (US3342200)', ODM File OID: '47f33627-9a42-4c23-a168-dd4453bff49c' User entered 'No (N)'	System	11 Feb 2021 09:48:01
	System	11 Feb 2021 09:48:01

US3342200

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(134)

Generated On: 09 Jun 2021 17:05:26

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:04:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2D2D1647-7C35-4DCA-ADA3-8E1DAA921DDC)', Time: '2021-02-11T03:47:58', User OID: 'PatientReportedOutcome (US3342200)', ODM File OID: '47f33627-9a42-4c23-a168-dd4453bff49c' User entered '11 Feb 2021 03:47'	System	11 Feb 2021 09:48:01
	System	11 Feb 2021 09:48:01

US3342200

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(134)

Generated On: 09 Jun 2021 17:05:26

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:04:20
User entered '10 Feb 2021 12:00'	System	08 Feb 2021 19:09:36

US3342200

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(134)

Generated On: 09 Jun 2021 17:05:26

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:04:20
User entered '11 Feb 2021 11:59'	System	08 Feb 2021 19:09:36

US3342200

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(135)

Generated On: 09 Jun 2021 17:05:26

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:04:20
Data entry locked.	System	09 Feb 2021 22:43:18
User entered 'Day 135'	System	09 Feb 2021 22:43:18

US3342200

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(135)

Generated On: 09 Jun 2021 17:05:26

Did you receive any **MEDICAL ATTENTION** (doctor visit, other) for any illness or symptoms?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:04:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2D2D1647-7C35-4DCA-ADA3-8E1DAA921DDC)', Time: '2021-02-11T12:37:20', User OID: 'PatientReportedOutcome (US3342200)', ODM File OID: 'bb1619f5-28f7-4673-a254-b8ace83eb3d4' User entered 'No (N)'	System	11 Feb 2021 18:37:29
	System	11 Feb 2021 18:37:29

US3342200

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(135)

Generated On: 09 Jun 2021 17:05:26

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:04:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2D2D1647-7C35-4DCA-ADA3-8E1DAA921DDC)', Time: '2021-02-11T12:37:23', User OID: 'PatientReportedOutcome (US3342200)', ODM File OID: 'bb1619f5-28f7-4673-a254-b8ace83eb3d4' User entered '11 Feb 2021 12:37'	System	11 Feb 2021 18:37:29
	System	11 Feb 2021 18:37:29

US3342200

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(135)

Generated On: 09 Jun 2021 17:05:26

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:04:20
User entered '11 Feb 2021 12:00'	System	09 Feb 2021 22:43:18

US3342200

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(135)

Generated On: 09 Jun 2021 17:05:26

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:04:20
User entered '12 Feb 2021 11:59'	System	09 Feb 2021 22:43:18

US3342200

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(136)

Generated On: 09 Jun 2021 17:05:26

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:04:20
Data entry locked.	System	11 Feb 2021 09:47:57
User entered 'Day 136'	System	11 Feb 2021 09:47:57

US3342200

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(136)

Generated On: 09 Jun 2021 17:05:26

Did you receive any **MEDICAL ATTENTION** (doctor visit, other) for any illness or symptoms?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:04:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2D2D1647-7C35-4DCA-ADA3-8E1DAA921DDC)', Time: '2021-02-12T12:57:00', User OID: 'PatientReportedOutcome (US3342200)', ODM File OID: '815eaf52-3563-48ba-8953-f8b73a4e7834' User entered 'No (N)'	System	12 Feb 2021 18:57:07
	System	12 Feb 2021 18:57:07

US3342200

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(136)

Generated On: 09 Jun 2021 17:05:26

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:04:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2D2D1647-7C35-4DCA-ADA3-8E1DAA921DDC)', Time: '2021-02-12T12:57:03', User OID: 'PatientReportedOutcome (US3342200)', ODM File OID: '815eaf52-3563-48ba-8953-f8b73a4e7834' User entered '12 Feb 2021 12:57'	System	12 Feb 2021 18:57:07
	System	12 Feb 2021 18:57:07

US3342200

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(136)

Generated On: 09 Jun 2021 17:05:26

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:04:20
User entered '12 Feb 2021 12:00'	System	11 Feb 2021 09:47:57

US3342200

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(136)

Generated On: 09 Jun 2021 17:05:26

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:04:20
User entered '13 Feb 2021 11:59'	System	11 Feb 2021 09:47:57

US3342200

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(137)

Generated On: 09 Jun 2021 17:05:26

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:04:20
Data entry locked.	System	11 Feb 2021 18:37:14
User entered 'Day 137'	System	11 Feb 2021 18:37:14

US3342200

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(137)

Generated On: 09 Jun 2021 17:05:26

Did you receive any **MEDICAL ATTENTION** (doctor visit, other) for any illness or symptoms?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:04:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2D2D1647-7C35-4DCA-ADA3-8E1DAA921DDC)', Time: '2021-02-13T12:28:46', User OID: 'PatientReportedOutcome (US3342200)', ODM File OID: 'a7f44095-6b45-4850-bb06-5c35fbced318' User entered 'No (N)'	System	13 Feb 2021 18:28:53
	System	13 Feb 2021 18:28:53

US3342200

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(137)

Generated On: 09 Jun 2021 17:05:26

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:04:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2D2D1647-7C35-4DCA-ADA3-8E1DAA921DDC)', Time: '2021-02-13T12:28:49', User OID: 'PatientReportedOutcome (US3342200)', ODM File OID: 'a7f44095-6b45-4850-bb06-5c35fbced318' User entered '13 Feb 2021 12:28'	System	13 Feb 2021 18:28:53
	System	13 Feb 2021 18:28:53

US3342200

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(137)

Generated On: 09 Jun 2021 17:05:26

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:04:20
User entered '13 Feb 2021 12:00'	System	11 Feb 2021 18:37:14

US3342200

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(137)

Generated On: 09 Jun 2021 17:05:26

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:04:20
User entered '14 Feb 2021 11:59'	System	11 Feb 2021 18:37:14

US3342200

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(138)

Generated On: 09 Jun 2021 17:05:26

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:04:20
Data entry locked.	System	12 Feb 2021 18:56:58
User entered 'Day 138'	System	12 Feb 2021 18:56:58

US3342200

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(138)

Generated On: 09 Jun 2021 17:05:26

Did you receive any **MEDICAL ATTENTION** (doctor visit, other) for any illness or symptoms?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:04:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2D2D1647-7C35-4DCA-ADA3-8E1DAA921DDC)', Time: '2021-02-14T13:08:07', User OID: 'PatientReportedOutcome (US3342200)', ODM File OID: '6c07b53b-9a6d-42cf-b09f-cbcc9dcd13ae' User entered 'No (N)'	System	14 Feb 2021 19:08:13
	System	14 Feb 2021 19:08:13

US3342200

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(138)

Generated On: 09 Jun 2021 17:05:26

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:04:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2D2D1647-7C35-4DCA-ADA3-8E1DAA921DDC)', Time: '2021-02-14T13:08:10', User OID: 'PatientReportedOutcome (US3342200)', ODM File OID: '6c07b53b-9a6d-42cf-b09f-cbcc9dcd13ae' User entered '14 Feb 2021 13:08'	System	14 Feb 2021 19:08:13
	System	14 Feb 2021 19:08:13

US3342200

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(138)

Generated On: 09 Jun 2021 17:05:26

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:04:20
User entered '14 Feb 2021 12:00'	System	12 Feb 2021 18:56:58

US3342200

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(138)

Generated On: 09 Jun 2021 17:05:26

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:04:20
User entered '15 Feb 2021 11:59'	System	12 Feb 2021 18:56:58

US3342200

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(139)

Generated On: 09 Jun 2021 17:05:26

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:04:20
Data entry locked.	System	13 Feb 2021 18:28:46
User entered 'Day 139'	System	13 Feb 2021 18:28:46

US3342200

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(139)

Generated On: 09 Jun 2021 17:05:26

Did you receive any **MEDICAL ATTENTION** (doctor visit, other) for any illness or symptoms?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:04:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2D2D1647-7C35-4DCA-ADA3-8E1DAA921DDC)', Time: '2021-02-15T12:00:49', User OID: 'PatientReportedOutcome (US3342200)', ODM File OID: 'd940eaed-971a-4a20-9487-d1f7900c292b' User entered 'No (N)'	System	17 Feb 2021 00:20:06
	System	17 Feb 2021 00:20:06

US3342200

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(139)

Generated On: 09 Jun 2021 17:05:26

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:04:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2D2D1647-7C35-4DCA-ADA3-8E1DAA921DDC)', Time: '2021-02-15T12:00:52', User OID: 'PatientReportedOutcome (US3342200)', ODM File OID: 'd940eaed-971a-4a20-9487-d1f7900c292b' User entered '15 Feb 2021 12:00'	System	17 Feb 2021 00:20:06
	System	17 Feb 2021 00:20:06

US3342200

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(139)

Generated On: 09 Jun 2021 17:05:26

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:04:20
User entered '15 Feb 2021 12:00'	System	13 Feb 2021 18:28:46

US3342200

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(139)

Generated On: 09 Jun 2021 17:05:26

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:04:20
User entered '16 Feb 2021 11:59'	System	13 Feb 2021 18:28:46

US3342200

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(140)

Generated On: 09 Jun 2021 17:05:26

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:04:20
Data entry locked.	System	14 Feb 2021 19:08:06
User entered 'Day 140'	System	14 Feb 2021 19:08:06

US3342200

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(140)

Generated On: 09 Jun 2021 17:05:26

Did you receive any **MEDICAL ATTENTION** (doctor visit, other) for any illness or symptoms?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:04:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2D2D1647-7C35-4DCA-ADA3-8E1DAA921DDC)', Time: '2021-02-16T18:19:07', User OID: 'PatientReportedOutcome (US3342200)', ODM File OID: '19d84317-48f3-4397-974f-996e0c3185f7' User entered 'No (N)'	System	17 Feb 2021 00:20:10
	System	17 Feb 2021 00:20:10

US3342200

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(140)

Generated On: 09 Jun 2021 17:05:26

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:04:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2D2D1647-7C35-4DCA-ADA3-8E1DAA921DDC)', Time: '2021-02-16T18:19:09', User OID: 'PatientReportedOutcome (US3342200)', ODM File OID: '19d84317-48f3-4397-974f-996e0c3185f7' User entered '16 Feb 2021 18:19'	System	17 Feb 2021 00:20:10
	System	17 Feb 2021 00:20:10

US3342200

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(140)

Generated On: 09 Jun 2021 17:05:26

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:04:20
User entered '16 Feb 2021 12:00'	System	14 Feb 2021 19:08:06

US3342200

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(140)

Generated On: 09 Jun 2021 17:05:26

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:04:20
User entered '17 Feb 2021 11:59'	System	14 Feb 2021 19:08:06

US3342200

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(141)

Generated On: 09 Jun 2021 17:05:26

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:04:20
Data entry locked.	System	15 Feb 2021 18:02:31
User entered 'Day 141'	System	15 Feb 2021 18:02:31

US3342200

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(141)

Generated On: 09 Jun 2021 17:05:26

Did you receive any **MEDICAL ATTENTION** (doctor visit, other) for any illness or symptoms?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:04:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2D2D1647-7C35-4DCA-ADA3-8E1DAA921DDC)', Time: '2021-02-17T12:34:28', User OID: 'PatientReportedOutcome (US3342200)', ODM File OID: 'a96ffa3c-a79f-4e53-ae49-0813407e2cad' User entered 'No (N)'	System	17 Feb 2021 18:34:37
	System	17 Feb 2021 18:34:37

US3342200

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(141)

Generated On: 09 Jun 2021 17:05:26

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:04:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2D2D1647-7C35-4DCA-ADA3-8E1DAA921DDC)', Time: '2021-02-17T12:34:31', User OID: 'PatientReportedOutcome (US3342200)', ODM File OID: 'a96ffa3c-a79f-4e53-ae49-0813407e2cad' User entered '17 Feb 2021 12:34'	System	17 Feb 2021 18:34:37
	System	17 Feb 2021 18:34:37

US3342200

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(141)

Generated On: 09 Jun 2021 17:05:26

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:04:20
User entered '17 Feb 2021 12:00'	System	15 Feb 2021 18:02:31

US3342200

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(141)

Generated On: 09 Jun 2021 17:05:26

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:04:20
User entered '18 Feb 2021 11:59'	System	15 Feb 2021 18:02:31

US3342200

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(142)

Generated On: 09 Jun 2021 17:05:26

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:04:20
Data entry locked.	System	17 Feb 2021 00:20:09
User entered 'Day 142'	System	17 Feb 2021 00:20:09

US3342200

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(142)

Generated On: 09 Jun 2021 17:05:26

Did you receive any **MEDICAL ATTENTION** (doctor visit, other) for any illness or symptoms?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:04:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2D2D1647-7C35-4DCA-ADA3-8E1DAA921DDC)', Time: '2021-02-18T12:43:20', User OID: 'PatientReportedOutcome (US3342200)', ODM File OID: '1ecf982b-f01d-425f-8ad2-f3845f3cb516' User entered 'No (N)'	System	18 Feb 2021 18:43:27
	System	18 Feb 2021 18:43:27

US3342200

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(142)

Generated On: 09 Jun 2021 17:05:26

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:04:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2D2D1647-7C35-4DCA-ADA3-8E1DAA921DDC)', Time: '2021-02-18T12:43:23', User OID: 'PatientReportedOutcome (US3342200)', ODM File OID: '1ecf982b-f01d-425f-8ad2-f3845f3cb516' User entered '18 Feb 2021 12:43'	System	18 Feb 2021 18:43:27
	System	18 Feb 2021 18:43:27

US3342200

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(142)

Generated On: 09 Jun 2021 17:05:26

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:04:20
User entered '18 Feb 2021 12:00'	System	17 Feb 2021 00:20:09

US3342200

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(142)

Generated On: 09 Jun 2021 17:05:26

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:04:20
User entered '19 Feb 2021 11:59'	System	17 Feb 2021 00:20:09

US3342200

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(143)

Generated On: 09 Jun 2021 17:05:26

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:04:20
Data entry locked.	System	17 Feb 2021 18:34:28
User entered 'Day 143'	System	17 Feb 2021 18:34:28

US3342200

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(143)

Generated On: 09 Jun 2021 17:05:26

Did you receive any **MEDICAL ATTENTION** (doctor visit, other) for any illness or symptoms?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:04:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2D2D1647-7C35-4DCA-ADA3-8E1DAA921DDC)', Time: '2021-02-19T16:11:22', User OID: 'PatientReportedOutcome (US3342200)', ODM File OID: 'e7924e7c-6eac-4c44-9567-5119bdf318cf' User entered 'No (N)'	System	19 Feb 2021 22:13:10
	System	19 Feb 2021 22:13:10

US3342200

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(143)

Generated On: 09 Jun 2021 17:05:26

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:04:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2D2D1647-7C35-4DCA-ADA3-8E1DAA921DDC)', Time: '2021-02-19T16:12:35', User OID: 'PatientReportedOutcome (US3342200)', ODM File OID: 'e7924e7c-6eac-4c44-9567-5119bdf318cf' User entered '19 Feb 2021 16:12'	System	19 Feb 2021 22:13:10
	System	19 Feb 2021 22:13:10

US3342200

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(143)

Generated On: 09 Jun 2021 17:05:26

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:04:20
User entered '19 Feb 2021 12:00'	System	17 Feb 2021 18:34:28

US3342200

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(143)

Generated On: 09 Jun 2021 17:05:26

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:04:20
User entered '20 Feb 2021 11:59'	System	17 Feb 2021 18:34:28

US3342200

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(144)

Generated On: 09 Jun 2021 17:05:26

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:04:20
Data entry locked.	System	18 Feb 2021 18:43:20
User entered 'Day 144'	System	18 Feb 2021 18:43:20

US3342200

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(144)

Generated On: 09 Jun 2021 17:05:26

Did you receive any **MEDICAL ATTENTION** (doctor visit, other) for any illness or symptoms?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:04:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2D2D1647-7C35-4DCA-ADA3-8E1DAA921DDC)', Time: '2021-02-20T18:19:04', User OID: 'PatientReportedOutcome (US3342200)', ODM File OID: 'c4458b7c-573d-400a-aea1-e7ed1438d364' User entered 'No (N)'	System	21 Feb 2021 00:19:11
	System	21 Feb 2021 00:19:11

US3342200

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(144)

Generated On: 09 Jun 2021 17:05:26

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:04:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2D2D1647-7C35-4DCA-ADA3-8E1DAA921DDC)', Time: '2021-02-20T18:19:06', User OID: 'PatientReportedOutcome (US3342200)', ODM File OID: 'c4458b7c-573d-400a-aea1-e7ed1438d364' User entered '20 Feb 2021 18:19'	System	21 Feb 2021 00:19:11
	System	21 Feb 2021 00:19:11

US3342200

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(144)

Generated On: 09 Jun 2021 17:05:26

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:04:20
User entered '20 Feb 2021 12:00'	System	18 Feb 2021 18:43:20

US3342200

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(144)

Generated On: 09 Jun 2021 17:05:26

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:04:20
User entered '21 Feb 2021 11:59'	System	18 Feb 2021 18:43:20

US3342200

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(145)

Generated On: 09 Jun 2021 17:05:26

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:04:20
Data entry locked.	System	19 Feb 2021 22:11:19
User entered 'Day 145'	System	19 Feb 2021 22:11:19

US3342200

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(145)

Generated On: 09 Jun 2021 17:05:26

Did you receive any **MEDICAL ATTENTION** (doctor visit, other) for any illness or symptoms?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:04:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2D2D1647-7C35-4DCA-ADA3-8E1DAA921DDC)', Time: '2021-02-21T12:00:32', User OID: 'PatientReportedOutcome (US3342200)', ODM File OID: 'f0f1c3e2-a407-4b03-956f-d71b09ffa206' User entered 'No (N)'	System	21 Feb 2021 18:01:28
	System	21 Feb 2021 18:01:28

US3342200

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(145)

Generated On: 09 Jun 2021 17:05:26

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:04:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2D2D1647-7C35-4DCA-ADA3-8E1DAA921DDC)', Time: '2021-02-21T12:00:35', User OID: 'PatientReportedOutcome (US3342200)', ODM File OID: 'f0f1c3e2-a407-4b03-956f-d71b09ffa206' User entered '21 Feb 2021 12:00'	System	21 Feb 2021 18:01:28
	System	21 Feb 2021 18:01:28

US3342200

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(145)

Generated On: 09 Jun 2021 17:05:26

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:04:20
User entered '21 Feb 2021 12:00'	System	19 Feb 2021 22:11:19

US3342200

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(145)

Generated On: 09 Jun 2021 17:05:26

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:04:20
User entered '22 Feb 2021 11:59'	System	19 Feb 2021 22:11:19

US3342200

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(146)

Generated On: 09 Jun 2021 17:05:26

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:04:20
Data entry locked.	System	21 Feb 2021 00:19:08
User entered 'Day 146'	System	21 Feb 2021 00:19:08

US3342200

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(146)

Generated On: 09 Jun 2021 17:05:26

Did you receive any **MEDICAL ATTENTION** (doctor visit, other) for any illness or symptoms?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:04:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2D2D1647-7C35-4DCA-ADA3-8E1DAA921DDC)', Time: '2021-02-22T12:02:14', User OID: 'PatientReportedOutcome (US3342200)', ODM File OID: '0e2dc6c2-9a50-45ec-a76a-fb2020c3ac1e' User entered 'No (N)'	System	23 Feb 2021 18:58:02
	System	23 Feb 2021 18:58:02

US3342200

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(146)

Generated On: 09 Jun 2021 17:05:26

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:04:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2D2D1647-7C35-4DCA-ADA3-8E1DAA921DDC)', Time: '2021-02-22T12:02:25', User OID: 'PatientReportedOutcome (US3342200)', ODM File OID: '0e2dc6c2-9a50-45ec-a76a-fb2020c3ac1e' User entered '22 Feb 2021 12:02'	System	23 Feb 2021 18:58:02
	System	23 Feb 2021 18:58:02

US3342200

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(146)

Generated On: 09 Jun 2021 17:05:26

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:04:20
User entered '22 Feb 2021 12:00'	System	21 Feb 2021 00:19:08

US3342200

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(146)

Generated On: 09 Jun 2021 17:05:26

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:04:20
User entered '23 Feb 2021 11:59'	System	21 Feb 2021 00:19:08

US3342200

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(147)

Generated On: 09 Jun 2021 17:05:26

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:04:20
Data entry locked.	System	21 Feb 2021 18:01:12
User entered 'Day 147'	System	21 Feb 2021 18:01:12

US3342200

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(147)

Generated On: 09 Jun 2021 17:05:26

Did you receive any **MEDICAL ATTENTION** (doctor visit, other) for any illness or symptoms?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:04:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2D2D1647-7C35-4DCA-ADA3-8E1DAA921DDC)', Time: '2021-02-23T12:58:28-06:00', User OID: 'PatientReportedOutcome (US3342200)', ODM File OID: 'cab3e62-77a4-4ee0-bf50-ffac82906f89' User entered 'No (N)'	System	23 Feb 2021 18:58:44
	System	23 Feb 2021 18:58:44

US3342200

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(147)

Generated On: 09 Jun 2021 17:05:26

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:04:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2D2D1647-7C35-4DCA-ADA3-8E1DAA921DDC)', Time: '2021-02-23T12:58:41-06:00', User OID: 'PatientReportedOutcome (US3342200)', ODM File OID: 'cab3e62-77a4-4ee0-bf50-ffac82906f89' User entered '23 Feb 2021 18:58'	System	23 Feb 2021 18:58:44
	System	23 Feb 2021 18:58:44

US3342200

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(147)

Generated On: 09 Jun 2021 17:05:26

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:04:20
User entered '23 Feb 2021 12:00'	System	21 Feb 2021 18:01:12

US3342200

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(147)

Generated On: 09 Jun 2021 17:05:26

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:04:20
User entered '24 Feb 2021 11:59'	System	21 Feb 2021 18:01:12

US3342200

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(148)

Generated On: 09 Jun 2021 17:05:26

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:04:20
Data entry locked.	System	22 Feb 2021 18:06:57
User entered 'Day 148'	System	22 Feb 2021 18:06:57

US3342200

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(148)

Generated On: 09 Jun 2021 17:05:26

Did you receive any **MEDICAL ATTENTION** (doctor visit, other) for any illness or symptoms?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:04:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2D2D1647-7C35-4DCA-ADA3-8E1DAA921DDC)', Time: '2021-02-24T12:01:35-06:00', User OID: 'PatientReportedOutcome (US3342200)', ODM File OID: 'a50f1376-5764-47b9-b8f1-be8366d86c2f' User entered 'No (N)'	System	24 Feb 2021 18:04:03
	System	24 Feb 2021 18:04:03

US3342200

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(148)

Generated On: 09 Jun 2021 17:05:26

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:04:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2D2D1647-7C35-4DCA-ADA3-8E1DAA921DDC)', Time: '2021-02-24T12:01:37-06:00', User OID: 'PatientReportedOutcome (US3342200)', ODM File OID: 'a50f1376-5764-47b9-b8f1-be8366d86c2f' User entered '24 Feb 2021 18:01'	System	24 Feb 2021 18:04:03
	System	24 Feb 2021 18:04:03

US3342200

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(148)

Generated On: 09 Jun 2021 17:05:26

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:04:20
User entered '24 Feb 2021 12:00'	System	22 Feb 2021 18:06:57

US3342200

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(148)

Generated On: 09 Jun 2021 17:05:26

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:04:20
User entered '25 Feb 2021 11:59'	System	22 Feb 2021 18:06:57

US3342200

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(149)

Generated On: 09 Jun 2021 17:05:26

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:04:20
Data entry locked.	System	23 Feb 2021 18:58:26
User entered 'Day 149'	System	23 Feb 2021 18:58:26

US3342200

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(149)

Generated On: 09 Jun 2021 17:05:26

Did you receive any **MEDICAL ATTENTION** (doctor visit, other) for any illness or symptoms?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:04:20

US3342200

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(149)

Generated On: 09 Jun 2021 17:05:26

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:04:20

US3342200

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(149)

Generated On: 09 Jun 2021 17:05:26

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:04:20
User entered '25 Feb 2021 12:00'	System	23 Feb 2021 18:58:26

US3342200

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(149)

Generated On: 09 Jun 2021 17:05:26

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:04:20
User entered '26 Feb 2021 11:59'	System	23 Feb 2021 18:58:26

US3342200

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(150)

Generated On: 09 Jun 2021 17:05:26

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:04:20
Data entry locked.	System	24 Feb 2021 18:04:01
User entered 'Day 150'	System	24 Feb 2021 18:04:01

US3342200

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(150)

Generated On: 09 Jun 2021 17:05:26

Did you receive any **MEDICAL ATTENTION** (doctor visit, other) for any illness or symptoms?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:04:20

US3342200

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(150)

Generated On: 09 Jun 2021 17:05:26

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:04:20

US3342200

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(150)

Generated On: 09 Jun 2021 17:05:26

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:04:20
User entered '26 Feb 2021 12:00'	System	24 Feb 2021 18:04:01

US3342200

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(150)

Generated On: 09 Jun 2021 17:05:26

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:04:20
User entered '27 Feb 2021 11:59'	System	24 Feb 2021 18:04:01

US3342200

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:05:26

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 09:47:07
User signature succeeded.	Paul Pickrell (b) (4)	12 Feb 2021 23:50:36
User entered 'Yes (Y)'	Ethan Shotton (b) (4)	07 Oct 2020 19:11:41

US3342200

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:05:26

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 09:47:07
User signature succeeded.	Paul Pickrell (b) (4)	12 Feb 2021 23:50:36
User entered '7 Oct 2020'	Ethan Shotton (b) (4)	07 Oct 2020 19:11:41

US3342200

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:05:26

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 09:47:07
User signature succeeded.	Paul Pickrell (b) (4)	12 Feb 2021 23:50:36
User entered 'Contact Made (CONTACT MADE)'	Ethan Shotton (b) (4)	07 Oct 2020 19:11:41

US3342200

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:05:26

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 09:47:07
User signature succeeded.	Paul Pickrell (b) (4)	12 Feb 2021 23:50:36
User entered empty.	Ethan Shotton (b) (4)	07 Oct 2020 19:11:41

US3342200

Folder: Safety Call Day 36 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:05:26

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 09:47:07
User signature succeeded.	Paul Pickrell (b) (4)	12 Feb 2021 23:50:36
User entered 'Yes (Y)'	Ethan Shotton (b) (4)	07 Oct 2020 19:11:45

US3342200

Folder: Safety Call Day 36 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:05:26

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 09:47:07
User entered 'I'	System	07 Oct 2020 19:11:45

US3342200

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:05:26

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 09:47:07
User signature succeeded.	Paul Pickrell (b) (4)	12 Feb 2021 23:50:36
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	14 Oct 2020 19:47:12

US3342200

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:05:26

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 09:47:07
User signature succeeded.	Paul Pickrell (b) (4)	12 Feb 2021 23:50:36
User entered '14 Oct 2020'	(b) (4) (b) (4), (b) (6)	14 Oct 2020 19:47:12

US3342200

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:05:26

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 09:47:07
User signature succeeded.	Paul Pickrell (b) (4)	12 Feb 2021 23:50:36
User entered 'Contact Made (CONTACT MADE)'	(b) (4) (b) (4), (b) (6)	14 Oct 2020 19:47:12

US3342200

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:05:26

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 09:47:07
User signature succeeded.	Paul Pickrell (b) (4)	12 Feb 2021 23:50:36
User entered empty.	(b) (4) (b) (4), (b) (6)	14 Oct 2020 19:47:12

US3342200

Folder: Safety Call Day 43 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:05:26

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 09:47:07
User signature succeeded.	Paul Pickrell (b) (4)	12 Feb 2021 23:50:36
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	14 Oct 2020 19:47:25

US3342200

Folder: Safety Call Day 43 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:05:26

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 09:47:07
User entered 'I'	System	14 Oct 2020 19:47:25

US3342200

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:05:26

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 09:47:07
User signature succeeded.	Paul Pickrell (b) (4)	12 Feb 2021 23:50:36
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	26 Oct 2020 22:08:18

US3342200

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:05:26

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 09:47:07
User signature succeeded.	Paul Pickrell (b) (4)	12 Feb 2021 23:50:36
User entered '21 Oct 2020'	(b) (4) (b) (4), (b) (6)	26 Oct 2020 22:08:18

US3342200

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:05:26

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 09:47:07
User signature succeeded.	Paul Pickrell (b) (4)	12 Feb 2021 23:50:36
User entered 'Contact Made (CONTACT MADE)'	(b) (4) (b) (4), (b) (6)	26 Oct 2020 22:08:18

US3342200

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:05:26

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 09:47:07
User signature succeeded.	Paul Pickrell (b) (4)	12 Feb 2021 23:50:36
User entered empty.	(b) (4), (b) (6)	26 Oct 2020 22:08:18

US3342200

Folder: Safety Call Day 50 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:05:26

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 09:47:07
User signature succeeded.	Paul Pickrell (b) (4)	12 Feb 2021 23:50:36
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	26 Oct 2020 22:08:22

US3342200

Folder: Safety Call Day 50 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:05:26

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 09:47:07
User entered 'I'	System	26 Oct 2020 22:08:22

US3342200

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 09 Jun 2021 17:05:26

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 09:47:07
User signature succeeded.	Paul Pickrell (b) (4)	12 Feb 2021 23:50:36
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	26 Oct 2020 22:08:41

US3342200

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 09 Jun 2021 17:05:26

[Visit date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 09:47:07
User signature succeeded.	Paul Pickrell (b) (4)	12 Feb 2021 23:50:36
User entered '26 Oct 2020'	(b) (4) (b) (4), (b) (6)	26 Oct 2020 22:08:41

US3342200

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 09 Jun 2021 17:05:26

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 09:47:07
User signature succeeded.	Paul Pickrell (b) (4)	12 Feb 2021 23:50:36
User entered 'Clinic (Clinic)'	(b) (4) (b) (4), (b) (6)	26 Oct 2020 22:08:41

US3342200

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 09 Jun 2021 17:05:26

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 09:47:07
User entered 'VISIT3'	System	26 Oct 2020 22:08:41

US3342200

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:05:26

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 09:47:07
User signature succeeded.	Paul Pickrell (b) (4)	12 Feb 2021 23:50:36
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	26 Oct 2020 22:09:31

US3342200

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:05:26

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 09:47:07
User signature succeeded.	Paul Pickrell (b) (4)	12 Feb 2021 23:50:36
User entered '26 Oct 2020'	(b) (4) (b) (4), (b) (6)	26 Oct 2020 22:09:31

US3342200

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:05:26

Time of assessment (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 09:47:07
User signature succeeded.	Paul Pickrell (b) (4)	12 Feb 2021 23:50:36
User entered '15:30'	(b) (4) (b) (4), (b) (6)	26 Oct 2020 22:09:31

US3342200

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:05:26

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 09:47:07
User entered '26 Oct 2020 15:30'	System	26 Oct 2020 22:09:31

US3342200

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:05:26

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 09:47:07
User signature succeeded.	Paul Pickrell (b) (4)	12 Feb 2021 23:50:36
User entered '98.8' F	(b) (4) (b) (4), (b) (6)	26 Oct 2020 22:09:31

US3342200

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:05:26

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 09:47:07
User signature succeeded.	Paul Pickrell (b) (4)	12 Feb 2021 23:50:36
User entered 'Oral (Oral)'	(b) (4) (b) (4), (b) (6)	26 Oct 2020 22:09:31

US3342200

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:05:26

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 09:47:07
User signature succeeded.	Paul Pickrell (b) (4)	12 Feb 2021 23:50:36
User entered empty.	(b) (4) (b) (4), (b) (6)	26 Oct 2020 22:09:31

US3342200

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:05:26

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 09:47:07
User signature succeeded.	Paul Pickrell (b) (4)	12 Feb 2021 23:50:36
User entered '71'	(b) (4) (b) (4), (b) (6)	26 Oct 2020 22:09:31

US3342200

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:05:26

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 09:47:07
User entered 'bpm'	System	26 Oct 2020 22:09:31

US3342200

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:05:26

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 09:47:07
User signature succeeded.	Paul Pickrell (b) (4)	12 Feb 2021 23:50:36
User entered '14'	(b) (4) (b) (4), (b) (6)	26 Oct 2020 22:09:31

US3342200

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:05:26

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 09:47:07
User entered 'breaths/min'	System	26 Oct 2020 22:09:31

US3342200

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:05:26

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 09:47:07
User signature succeeded.	Paul Pickrell (b) (4)	12 Feb 2021 23:50:36
User entered '117'	(b) (4) (b) (4), (b) (6)	26 Oct 2020 22:09:31

US3342200

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:05:26

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 09:47:07
User entered 'mmHg'	System	26 Oct 2020 22:09:31

US3342200

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:05:26

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 09:47:07
User signature succeeded.	Paul Pickrell (b) (4)	12 Feb 2021 23:50:36
User entered '77'	(b) (4) (b) (4), (b) (6)	26 Oct 2020 22:09:31

US3342200

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:05:26

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 09:47:07
User entered 'mmHg'	System	26 Oct 2020 22:09:31

US3342200

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:05:26

Height (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 09:47:07

US3342200

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:05:26

Weight (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 09:47:07

US3342200

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 17:05:26

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 09:47:07
User signature succeeded.	Paul Pickrell (b) (4)	12 Feb 2021 23:50:36
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	26 Oct 2020 22:09:42

US3342200

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 17:05:26

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 09:47:07
User signature succeeded.	Paul Pickrell (b) (4)	12 Feb 2021 23:50:36
User entered '26 Oct 2020'	(b) (4) (b) (4), (b) (6)	26 Oct 2020 22:09:42

US3342200

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:05:26

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 09:47:07
User signature succeeded.	Paul Pickrell (b) (4)	12 Feb 2021 23:50:36
User entered 'Yes (Y)'	(b) (4) Tiffany Lemuz (b) (4)	28 Oct 2020 19:40:05

US3342200

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:05:26

Collection date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 09:47:07
User signature succeeded.	Paul Pickrell (b) (4)	12 Feb 2021 23:50:36
User closed query 'Per GCL Lab recon: Immunogenicity- Sample collection date for Visit 3 Day 57 is recorded as 26-OCT-2020. However, collection date is missing in GCL. Please confirm if 26-OCT-2020 is correct date to update in GCL records.' (Site from DM).	(b) (4) (b) (4), (b) (6)	30 Nov 2020 09:02:48
Query 'Per GCL Lab recon: Immunogenicity- Sample collection date for Visit 3 Day 57 is recorded as 26-OCT-2020. However, collection date is missing in GCL. Please confirm if 26-OCT-2020 is correct date to update in GCL records.' answered with 'Visit 3 Day 57 collection date confirmed as 26-OCT-2020.' (Site from DM).	Andrew Bell (b) (4) (b) (4)	12 Nov 2020 15:59:20
User opened query 'Per GCL Lab recon: Immunogenicity- Sample collection date for Visit 3 Day 57 is recorded as 26-OCT-2020. However, collection date is missing in GCL. Please confirm if 26-OCT-2020 is correct date to update in GCL records.' (Site from DM).	(b) (4), (b) (6)	10 Nov 2020 10:00:52
User entered '26 Oct 2020'	Tiffany Lemuz (b) (4)	28 Oct 2020 19:40:05

US3342200

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:05:26

Collection time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 09:47:07
User signature succeeded.	Paul Pickrell (b) (4)	12 Feb 2021 23:50:36
User entered '17:06'	(b) (4) Tiffany Lemuz (b) (4)	28 Oct 2020 19:40:05

US3342200

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:05:26

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 09:47:07
User entered '26 Oct 2020 17:06'	System	28 Oct 2020 19:40:05

US3342200

Folder: Visit 3 Day 57 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:05:26

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 09:47:07
User signature succeeded.	Paul Pickrell (b) (4)	12 Feb 2021 23:50:36
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	26 Oct 2020 22:09:45

US3342200

Folder: Visit 3 Day 57 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:05:26

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 09:47:07
User entered 'I'	System	26 Oct 2020 22:09:45

US3342200

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:05:26

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:04:20
Data entry locked.	System	04 Sep 2020 21:55:03
User entered 'Day 64'	System	04 Sep 2020 21:55:03

US3342200

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:05:26

Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:04:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2D2D1647-7C35-4DCA-ADA3-8E1DAA921DDC)', Time: '2020-11-04T09:43:12', User OID: 'PatientReportedOutcome (US3342200)', ODM File OID: '59aa734d-2e59-4249-8202-46633a3278b1' User entered 'No (N)'	System	04 Nov 2020 15:43:34
	System	04 Nov 2020 15:43:34

US3342200

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:05:26

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:04:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2D2D1647-7C35-4DCA-ADA3-8E1DAA921DDC)', Time: '2020-11-04T09:43:16', User OID: 'PatientReportedOutcome (US3342200)', ODM File OID: '59aa734d-2e59-4249-8202-46633a3278b1' User entered 'No (N)'	System	04 Nov 2020 15:43:34
	System	04 Nov 2020 15:43:34

US3342200

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:05:26

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:04:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2D2D1647-7C35-4DCA-ADA3-8E1DAA921DDC)', Time: '2020-11-04T09:43:22', User OID: 'PatientReportedOutcome (US3342200)', ODM File OID: '59aa734d-2e59-4249-8202-46633a3278b1' User entered '04 Nov 2020 09:43:22'	System	04 Nov 2020 15:43:34
	System	04 Nov 2020 15:43:34

US3342200

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:05:26

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:04:20
Data entry locked.	System	04 Sep 2020 21:55:03
User entered '04 Nov 2020 00:01'	System	04 Sep 2020 21:55:03

US3342200

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:05:26

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:04:20
Data entry locked.	System	04 Sep 2020 21:55:03
User entered '08 Nov 2020 23:59'	System	04 Sep 2020 21:55:03

US3342200

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:05:26

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:04:20
Data entry locked.	System	04 Sep 2020 21:55:03
User entered 'Day 71'	System	04 Sep 2020 21:55:03

US3342200

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:05:26

[Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:04:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2D2D1647-7C35-4DCA-ADA3-8E1DAA921DDC)', Time: '2020-11-11T04:16:29', User OID: 'PatientReportedOutcome (US3342200)', ODM File OID: 'aaf2db1b-3936-4384-a2ae-e34fd9787e0c' User entered 'No (N)'	System	11 Nov 2020 10:16:52
	System	11 Nov 2020 10:16:52

US3342200

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:05:26

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:04:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2D2D1647-7C35-4DCA-ADA3-8E1DAA921DDC)', Time: '2020-11-11T04:16:36', User OID: 'PatientReportedOutcome (US3342200)', ODM File OID: 'aaf2db1b-3936-4384-a2ae-e34fd9787e0c'	System	11 Nov 2020 10:16:52
User entered 'No (N)'	System	11 Nov 2020 10:16:52

US3342200

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:05:26

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:04:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2D2D1647-7C35-4DCA-ADA3-8E1DAA921DDC)', Time: '2020-11-11T04:16:48', User OID: 'PatientReportedOutcome (US3342200)', ODM File OID: 'aaf2db1b-3936-4384-a2ae-e34fd9787e0c' User entered '11 Nov 2020 04:16:48'	System	11 Nov 2020 10:16:52
	System	11 Nov 2020 10:16:52

US3342200

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:05:26

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:04:20
Data entry locked.	System	04 Sep 2020 21:55:03
User entered '11 Nov 2020 00:01'	System	04 Sep 2020 21:55:03

US3342200

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:05:26

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:04:20
Data entry locked.	System	04 Sep 2020 21:55:03
User entered '15 Nov 2020 23:59'	System	04 Sep 2020 21:55:03

US3342200

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:05:26

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:04:20
Data entry locked.	System	04 Sep 2020 21:55:03
User entered 'Day 78'	System	04 Sep 2020 21:55:03

US3342200

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:05:26

[Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:04:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2D2D1647-7C35-4DCA-ADA3-8E1DAA921DDC)', Time: '2020-11-18T00:04:21', User OID: 'PatientReportedOutcome (US3342200)', ODM File OID: 'd0745912-b708-4f26-bcb8-ef2f184fdacc'	System	18 Nov 2020 06:04:44
User entered 'No (N)'	System	18 Nov 2020 06:04:44

US3342200

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:05:26

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:04:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2D2D1647-7C35-4DCA-ADA3-8E1DAA921DDC)', Time: '2020-11-18T00:04:33', User OID: 'PatientReportedOutcome (US3342200)', ODM File OID: 'd0745912-b708-4f26-bcb8-ef2f184fdacc'	System	18 Nov 2020 06:04:44
User entered 'No (N)'	System	18 Nov 2020 06:04:44

US3342200

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:05:26

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:04:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2D2D1647-7C35-4DCA-ADA3-8E1DAA921DDC)', Time: '2020-11-18T00:04:41', User OID: 'PatientReportedOutcome (US3342200)', ODM File OID: 'd0745912-b708-4f26-bcb8-ef2f184fdacc' User entered '18 Nov 2020 00:04:41'	System	18 Nov 2020 06:04:44
	System	18 Nov 2020 06:04:44

US3342200

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:05:26

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:04:20
Data entry locked.	System	04 Sep 2020 21:55:03
User entered '18 Nov 2020 00:01'	System	04 Sep 2020 21:55:03

US3342200

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:05:26

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:04:20
Data entry locked.	System	04 Sep 2020 21:55:03
User entered '22 Nov 2020 23:59'	System	04 Sep 2020 21:55:03

US3342200

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:05:26

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:39:53
Amendment Manager: User entered 'Day 82'	System	20 Nov 2020 05:39:53

US3342200

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:05:26

[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 (2D2D1647-7C35-4DCA-ADA3-8E1DAA921DDC)', Time: '2020-11-22T00:47:12', User OID: 'PatientReportedOutcome (US3342200)', ODM File OID: '2263e1aa-6deb-4eaf-b19a-688c6ca1830c' User entered 'Yes (Y)'	System	22 Nov 2020 06:48:17
	System	22 Nov 2020 06:48:17

US3342200

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:05:26

Have you been exposed to someone with 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 (2D2D1647-7C35-4DCA-ADA3-8E1DAA921DDC)', Time: '2020-11-22T00:47:35', User OID: 'PatientReportedOutcome (US3342200)', ODM File OID: '2263e1aa-6deb-4eaf-b19a-688c6ca1830c' User entered 'No (N)'	System	22 Nov 2020 06:48:17

US3342200

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:05:26

[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 (2D2D1647-7C35-4DCA-ADA3-8E1DAA921DDC)', Time: '2020-11-22T00:47:45', User OID: 'PatientReportedOutcome (US3342200)', ODM File OID: '2263e1aa-6deb-4eaf-b19a-688c6ca1830c' User entered 'No (N)'	System	22 Nov 2020 06:48:17
	System	22 Nov 2020 06:48:17

US3342200

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:05:26

[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 (2D2D1647-7C35-4DCA-ADA3-8E1DAA921DDC)', Time: '2020-11-22T00:48:07', User OID: 'PatientReportedOutcome (US3342200)', ODM File OID: '2263e1aa-6deb-4eaf-b19a-688c6ca1830c'	System	22 Nov 2020 06:48:17
User entered 'No (N)'	System	22 Nov 2020 06:48:17

US3342200

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:05:26

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2D2D1647-7C35-4DCA-ADA3-8E1DAA921DDC)', Time: '2020-11-22T00:48:10', User OID: 'PatientReportedOutcome (US3342200)', ODM File OID: '2263e1aa-6deb-4eaf-b19a-688c6ca1830c' User entered '22 Nov 2020 00:48:10'	System	22 Nov 2020 06:48:17
	System	22 Nov 2020 06:48:17

US3342200

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:05:26

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:39:53
Amendment Manager: User entered '22 Nov 2020 00:01'	System	20 Nov 2020 05:39:53

US3342200

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:05:26

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:39:53
Amendment Manager: User entered '26 Nov 2020 23:59'	System	20 Nov 2020 05:39:53

US3342200

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:05:26

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:39:53
Amendment Manager: User entered 'Day 89'	System	20 Nov 2020 05:39:53

US3342200

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:05:26

[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 (2D2D1647-7C35-4DCA-ADA3-8E1DAA921DDC)', Time: '2020-11-29T00:36:13', User OID: 'PatientReportedOutcome (US3342200)', ODM File OID: 'a12e5441-2e15-4cf9-87b1-dbaabeea3efb' User entered 'No (N)'	System	29 Nov 2020 06:36:30
	System	29 Nov 2020 06:36:30

US3342200

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:05:26

Have you been exposed to someone with 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 (2D2D1647-7C35-4DCA-ADA3-8E1DAA921DDC)', Time: '2020-11-29T00:36:21', User OID: 'PatientReportedOutcome (US3342200)', ODM File OID: 'a12e5441-2e15-4cf9-87b1-dbaabeea3efb' User entered 'No (N)'	System	29 Nov 2020 06:36:30
	System	29 Nov 2020 06:36:30

US3342200

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:05:26

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2D2D1647-7C35-4DCA-ADA3-8E1DAA921DDC)', Time: '2020-11-29T00:36:27', User OID: 'PatientReportedOutcome (US3342200)', ODM File OID: 'a12e5441-2e15-4cf9-87b1-dbaabeea3efb' User entered '29 Nov 2020 00:36:27'	System	29 Nov 2020 06:36:30
	System	29 Nov 2020 06:36:30

US3342200

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:05:26

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:39:53
Amendment Manager: User entered '29 Nov 2020 00:01'	System	20 Nov 2020 05:39:53

US3342200

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:05:26

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:39:53
Amendment Manager: User entered '03 Dec 2020 23:59'	System	20 Nov 2020 05:39:53

US3342200

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:05:26

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:39:53
Amendment Manager: User entered 'Day 96'	System	20 Nov 2020 05:39:53

US3342200

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:05:26

[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 (2D2D1647-7C35-4DCA-ADA3-8E1DAA921DDC)', Time: '2020-12-06T10:44:53', User OID: 'PatientReportedOutcome (US3342200)', ODM File OID: 'dd9df7ed-63b5-450f-8c30-155343882ab3' User entered 'No (N)'	System	06 Dec 2020 16:45:04
	System	06 Dec 2020 16:45:04

US3342200

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:05:26

Have you been exposed to someone with 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 (2D2D1647-7C35-4DCA-ADA3-8E1DAA921DDC)', Time: '2020-12-06T10:44:59', User OID: 'PatientReportedOutcome (US3342200)', ODM File OID: 'dd9df7ed-63b5-450f-8c30-155343882ab3' User entered 'No (N)'	System	06 Dec 2020 16:45:04
	System	06 Dec 2020 16:45:04

US3342200

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:05:26

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2D2D1647-7C35-4DCA-ADA3-8E1DAA921DDC)', Time: '2020-12-06T10:45:02', User OID: 'PatientReportedOutcome (US3342200)', ODM File OID: 'dd9df7ed-63b5-450f-8c30-155343882ab3' User entered '06 Dec 2020 10:45:02'	System	06 Dec 2020 16:45:04
	System	06 Dec 2020 16:45:04

US3342200

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:05:26

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:39:53
Amendment Manager: User entered '06 Dec 2020 00:01'	System	20 Nov 2020 05:39:53

US3342200

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:05:26

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:39:53
Amendment Manager: User entered '10 Dec 2020 23:59'	System	20 Nov 2020 05:39:53

US3342200

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:05:26

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:39:53
Amendment Manager: User entered 'Day 103'	System	20 Nov 2020 05:39:53

US3342200

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:05:26

[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 (2D2D1647-7C35-4DCA-ADA3-8E1DAA921DDC)', Time: '2020-12-13T00:06:29', User OID: 'PatientReportedOutcome (US3342200)', ODM File OID: 'd09def28-4983-4d6a-b58b-75879cfc0728' User entered 'Yes (Y)'	System	13 Dec 2020 06:07:07
	System	13 Dec 2020 06:07:07

US3342200

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:05:26

Have you been exposed to someone with 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 (2D2D1647-7C35-4DCA-ADA3-8E1DAA921DDC)', Time: '2020-12-13T00:06:40', User OID: 'PatientReportedOutcome (US3342200)', ODM File OID: 'd09def28-4983-4d6a-b58b-75879cfc0728' User entered 'No (N)'	System	13 Dec 2020 06:07:07
	System	13 Dec 2020 06:07:07

US3342200

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:05:26

[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 (2D2D1647-7C35-4DCA-ADA3-8E1DAA921DDC)', Time: '2020-12-13T00:06:47', User OID: 'PatientReportedOutcome (US3342200)', ODM File OID: 'd09def28-4983-4d6a-b58b-75879cfc0728' User entered 'No (N)'	System	13 Dec 2020 06:07:07
	System	13 Dec 2020 06:07:07

US3342200

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:05:26

[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 (2D2D1647-7C35-4DCA-ADA3-8E1DAA921DDC)', Time: '2020-12-13T00:06:56', User OID: 'PatientReportedOutcome (US3342200)', ODM File OID: 'd09def28-4983-4d6a-b58b-75879cfc0728' User entered 'No (N)'	System	13 Dec 2020 06:07:07
	System	13 Dec 2020 06:07:07

US3342200

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:05:26

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2D2D1647-7C35-4DCA-ADA3-8E1DAA921DDC)', Time: '2020-12-13T00:07:01', User OID: 'PatientReportedOutcome (US3342200)', ODM File OID: 'd09def28-4983-4d6a-b58b-75879cfc0728' User entered '13 Dec 2020 00:07:01'	System	13 Dec 2020 06:07:07
	System	13 Dec 2020 06:07:07

US3342200

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:05:26

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:39:53
Amendment Manager: User entered '13 Dec 2020 00:01'	System	20 Nov 2020 05:39:53

US3342200

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:05:26

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:39:53
Amendment Manager: User entered '17 Dec 2020 23:59'	System	20 Nov 2020 05:39:53

US3342200

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:05:26

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:39:53
Amendment Manager: User entered 'Day 110'	System	20 Nov 2020 05:39:53

US3342200

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:05:26

[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 (2D2D1647-7C35-4DCA-ADA3-8E1DAA921DDC)', Time: '2020-12-20T12:00:21', User OID: 'PatientReportedOutcome (US3342200)', ODM File OID: '96439d4a-eefc-4992-ae80-52a4b3960d84' User entered 'No (N)'	System	20 Dec 2020 18:00:34
	System	20 Dec 2020 18:00:34

US3342200

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:05:26

Have you been exposed to someone with 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 (2D2D1647-7C35-4DCA-ADA3-8E1DAA921DDC)', Time: '2020-12-20T12:00:25', User OID: 'PatientReportedOutcome (US3342200)', ODM File OID: '96439d4a-eefc-4992-ae80-52a4b3960d84' User entered 'No (N)'	System	20 Dec 2020 18:00:34
	System	20 Dec 2020 18:00:34

US3342200

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:05:26

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2D2D1647-7C35-4DCA-ADA3-8E1DAA921DDC)', Time: '2020-12-20T12:00:28', User OID: 'PatientReportedOutcome (US3342200)', ODM File OID: '96439d4a-eefc-4992-ae80-52a4b3960d84' User entered '20 Dec 2020 12:00:28'	System	20 Dec 2020 18:00:34
	System	20 Dec 2020 18:00:34

US3342200

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:05:26

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:39:53
Amendment Manager: User entered '20 Dec 2020 00:01'	System	20 Nov 2020 05:39:53

US3342200

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:05:26

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:39:53
Amendment Manager: User entered '24 Dec 2020 23:59'	System	20 Nov 2020 05:39:53

US3342200

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:05:26

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:39:53
Amendment Manager: User entered 'Day 117'	System	20 Nov 2020 05:39:53

US3342200

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:05:26

[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 (2D2D1647-7C35-4DCA-ADA3-8E1DAA921DDC)', Time: '2020-12-27T02:50:30', User OID: 'PatientReportedOutcome (US3342200)', ODM File OID: '3afd5e84-52cc-41c8-9e73-6301b9b5b730' User entered 'No (N)'	System	27 Dec 2020 08:51:08
	System	27 Dec 2020 08:51:08

US3342200

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:05:26

Have you been exposed to someone with 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 (2D2D1647-7C35-4DCA-ADA3-8E1DAA921DDC)', Time: '2020-12-27T02:50:57', User OID: 'PatientReportedOutcome (US3342200)', ODM File OID: '3afd5e84-52cc-41c8-9e73-6301b9b5b730' User entered 'No (N)'	System	27 Dec 2020 08:51:08
	System	27 Dec 2020 08:51:08

US3342200

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:05:26

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2D2D1647-7C35-4DCA-ADA3-8E1DAA921DDC)', Time: '2020-12-27T02:51:03', User OID: 'PatientReportedOutcome (US3342200)', ODM File OID: '3afd5e84-52cc-41c8-9e73-6301b9b5b730' User entered '27 Dec 2020 02:51:03'	System	27 Dec 2020 08:51:08
	System	27 Dec 2020 08:51:08

US3342200

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:05:26

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:39:53
Amendment Manager: User entered '27 Dec 2020 00:01'	System	20 Nov 2020 05:39:53

US3342200

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:05:26

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:39:53
Amendment Manager: User entered '31 Dec 2020 23:59'	System	20 Nov 2020 05:39:53

US3342200

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:05:26

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:39:53
Amendment Manager: User entered 'Day 124'	System	20 Nov 2020 05:39:53

US3342200

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:05:26

[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 (2D2D1647-7C35-4DCA-ADA3-8E1DAA921DDC)', Time: '2021-01-03T04:01:35', User OID: 'PatientReportedOutcome (US3342200)', ODM File OID: '368556ff-6bdf-4d96-9eb1-0daab480a7f9' User entered 'No (N)'	System	03 Jan 2021 10:01:56
	System	03 Jan 2021 10:01:56

US3342200

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:05:26

Have you been exposed to someone with 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 (2D2D1647-7C35-4DCA-ADA3-8E1DAA921DDC)', Time: '2021-01-03T04:01:49', User OID: 'PatientReportedOutcome (US3342200)', ODM File OID: '368556ff-6bdf-4d96-9eb1-0daab480a7f9'	System	03 Jan 2021 10:01:56
User entered 'No (N)'	System	03 Jan 2021 10:01:56

US3342200

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:05:26

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2D2D1647-7C35-4DCA-ADA3-8E1DAA921DDC)', Time: '2021-01-03T04:01:54', User OID: 'PatientReportedOutcome (US3342200)', ODM File OID: '368556ff-6bdf-4d96-9eb1-0daab480a7f9' User entered '03 Jan 2021 04:01:54'	System	03 Jan 2021 10:01:56
	System	03 Jan 2021 10:01:56

US3342200

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:05:26

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:39:53
Amendment Manager: User entered '03 Jan 2021 00:01'	System	20 Nov 2020 05:39:53

US3342200

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:05:26

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:39:53
Amendment Manager: User entered '07 Jan 2021 23:59'	System	20 Nov 2020 05:39:53

US3342200

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:05:26

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:39:53
Amendment Manager: User entered 'Day 131'	System	20 Nov 2020 05:39:53

US3342200

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:05:26

[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 (2D2D1647-7C35-4DCA-ADA3-8E1DAA921DDC)', Time: '2021-01-10T05:03:02', User OID: 'PatientReportedOutcome (US3342200)', ODM File OID: '004dd5a4-f78c-4307-b651-f24c69124e53'	System	10 Jan 2021 11:03:28
User entered 'No (N)'	System	10 Jan 2021 11:03:28

US3342200

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:05:26

Have you been exposed to someone with 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 (2D2D1647-7C35-4DCA-ADA3-8E1DAA921DDC)', Time: '2021-01-10T05:03:22', User OID: 'PatientReportedOutcome (US3342200)', ODM File OID: '004dd5a4-f78c-4307-b651-f24c69124e53' User entered 'No (N)'	System	10 Jan 2021 11:03:28

US3342200

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:05:26

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2D2D1647-7C35-4DCA-ADA3-8E1DAA921DDC)', Time: '2021-01-10T05:03:27', User OID: 'PatientReportedOutcome (US3342200)', ODM File OID: '004dd5a4-f78c-4307-b651-f24c69124e53' User entered '10 Jan 2021 05:03:27'	System	10 Jan 2021 11:03:28
	System	10 Jan 2021 11:03:28

US3342200

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:05:26

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:39:53
Amendment Manager: User entered '10 Jan 2021 00:01'	System	20 Nov 2020 05:39:53

US3342200

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:05:26

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:39:53
Amendment Manager: User entered '14 Jan 2021 23:59'	System	20 Nov 2020 05:39:53

US3342200

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:05:26

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:39:53
Amendment Manager: User entered 'Day 138'	System	20 Nov 2020 05:39:53

US3342200

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:05:26

[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 (2D2D1647-7C35-4DCA-ADA3-8E1DAA921DDC)', Time: '2021-01-17T00:03:48', User OID: 'PatientReportedOutcome (US3342200)', ODM File OID: 'efedc4ac-29b0-4cf2-9f82-ba04b27ae6e3' User entered 'No (N)'	System	17 Jan 2021 06:04:16
	System	17 Jan 2021 06:04:16

US3342200

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:05:26

Have you been exposed to someone with 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 (2D2D1647-7C35-4DCA-ADA3-8E1DAA921DDC)', Time: '2021-01-17T00:04:01', User OID: 'PatientReportedOutcome (US3342200)', ODM File OID: 'efedc4ac-29b0-4cf2-9f82-ba04b27ae6e3' User entered 'No (N)'	System	17 Jan 2021 06:04:16
	System	17 Jan 2021 06:04:16

US3342200

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:05:26

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2D2D1647-7C35-4DCA-ADA3-8E1DAA921DDC)', Time: '2021-01-17T00:04:13', User OID: 'PatientReportedOutcome (US3342200)', ODM File OID: 'efedc4ac-29b0-4cf2-9f82-ba04b27ae6e3' User entered '17 Jan 2021 00:04:13'	System	17 Jan 2021 06:04:16

US3342200

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:05:26

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:39:53
Amendment Manager: User entered '17 Jan 2021 00:01'	System	20 Nov 2020 05:39:53

US3342200

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:05:26

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:39:53
Amendment Manager: User entered '21 Jan 2021 23:59'	System	20 Nov 2020 05:39:53

US3342200

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:05:26

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:39:53
Amendment Manager: User entered 'Day 145'	System	20 Nov 2020 05:39:53

US3342200

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:05:26

[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 (2D2D1647-7C35-4DCA-ADA3-8E1DAA921DDC)', Time: '2021-01-24T00:01:30', User OID: 'PatientReportedOutcome (US3342200)', ODM File OID: '42a455a2-a45f-4481-ae97-eb3b2bd76bef'	System	24 Jan 2021 06:01:50
User entered 'No (N)'	System	24 Jan 2021 06:01:50

US3342200

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:05:26

Have you been exposed to someone with 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 (2D2D1647-7C35-4DCA-ADA3-8E1DAA921DDC)', Time: '2021-01-24T00:01:36', User OID: 'PatientReportedOutcome (US3342200)', ODM File OID: '42a455a2-a45f-4481-ae97-eb3b2bd76bef'	System	24 Jan 2021 06:01:50
User entered 'No (N)'	System	24 Jan 2021 06:01:50

US3342200

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:05:26

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2D2D1647-7C35-4DCA-ADA3-8E1DAA921DDC)', Time: '2021-01-24T00:01:39', User OID: 'PatientReportedOutcome (US3342200)', ODM File OID: '42a455a2-a45f-4481-ae97-eb3b2bd76bef' User entered '24 Jan 2021 00:01:39'	System	24 Jan 2021 06:01:50
	System	24 Jan 2021 06:01:50

US3342200

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:05:26

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:39:53
Amendment Manager: User entered '24 Jan 2021 00:01'	System	20 Nov 2020 05:39:53

US3342200

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:05:26

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:39:53
Amendment Manager: User entered '28 Jan 2021 23:59'	System	20 Nov 2020 05:39:53

US3342200

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:05:26

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:39:53
Amendment Manager: User entered 'Day 152'	System	20 Nov 2020 05:39:53

US3342200

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:05:26

[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 (2D2D1647-7C35-4DCA-ADA3-8E1DAA921DDC)', Time: '2021-01-31T09:35:46', User OID: 'PatientReportedOutcome (US3342200)', ODM File OID: 'edced0d4-aeeb-4849-9152-db62b50bc400' User entered 'No (N)'	System	31 Jan 2021 15:35:57
	System	31 Jan 2021 15:35:57

US3342200

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:05:26

Have you been exposed to someone with 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 (2D2D1647-7C35-4DCA-ADA3-8E1DAA921DDC)', Time: '2021-01-31T09:35:51', User OID: 'PatientReportedOutcome (US3342200)', ODM File OID: 'edced0d4-aeeb-4849-9152-db62b50bc400' User entered 'No (N)'	System	31 Jan 2021 15:35:57

US3342200

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:05:26

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2D2D1647-7C35-4DCA-ADA3-8E1DAA921DDC)', Time: '2021-01-31T09:35:54', User OID: 'PatientReportedOutcome (US3342200)', ODM File OID: 'edced0d4-aeeb-4849-9152-db62b50bc400' User entered '31 Jan 2021 09:35:54'	System	31 Jan 2021 15:35:57

US3342200

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:05:26

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:39:53
Amendment Manager: User entered '31 Jan 2021 00:01'	System	20 Nov 2020 05:39:53

US3342200

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:05:26

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:39:53
Amendment Manager: User entered '04 Feb 2021 23:59'	System	20 Nov 2020 05:39:53

US3342200

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:05:26

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:39:53
Amendment Manager: User entered 'Day 159'	System	20 Nov 2020 05:39:53

US3342200

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:05:26

[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 (2D2D1647-7C35-4DCA-ADA3-8E1DAA921DDC)', Time: '2021-02-07T04:32:36', User OID: 'PatientReportedOutcome (US3342200)', ODM File OID: '07c62193-a3bc-431a-9fe3-4b61dc144ef3' User entered 'No (N)'	System	07 Feb 2021 10:32:54
	System	07 Feb 2021 10:32:54

US3342200

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:05:26

Have you been exposed to someone with 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 (2D2D1647-7C35-4DCA-ADA3-8E1DAA921DDC)', Time: '2021-02-07T04:32:45', User OID: 'PatientReportedOutcome (US3342200)', ODM File OID: '07c62193-a3bc-431a-9fe3-4b61dc144ef3' User entered 'No (N)'	System	07 Feb 2021 10:32:54

US3342200

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:05:26

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2D2D1647-7C35-4DCA-ADA3-8E1DAA921DDC)', Time: '2021-02-07T04:32:51', User OID: 'PatientReportedOutcome (US3342200)', ODM File OID: '07c62193-a3bc-431a-9fe3-4b61dc144ef3' User entered '07 Feb 2021 04:32:51'	System	07 Feb 2021 10:32:54
	System	07 Feb 2021 10:32:54

US3342200

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:05:26

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:39:53
Amendment Manager: User entered '07 Feb 2021 00:01'	System	20 Nov 2020 05:39:53

US3342200

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:05:26

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:39:53
Amendment Manager: User entered '11 Feb 2021 23:59'	System	20 Nov 2020 05:39:53

US3342200

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:05:26

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:39:53
Amendment Manager: User entered 'Day 166'	System	20 Nov 2020 05:39:53

US3342200

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:05:26

[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 (2D2D1647-7C35-4DCA-ADA3-8E1DAA921DDC)', Time: '2021-02-14T04:42:50', User OID: 'PatientReportedOutcome (US3342200)', ODM File OID: '3f90baac-13b5-416b-becd-276ab2e55950'	System	14 Feb 2021 10:43:12
User entered 'No (N)'	System	14 Feb 2021 10:43:12

US3342200

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:05:26

Have you been exposed to someone with 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 (2D2D1647-7C35-4DCA-ADA3-8E1DAA921DDC)', Time: '2021-02-14T04:43:06', User OID: 'PatientReportedOutcome (US3342200)', ODM File OID: '3f90baac-13b5-416b-becd-276ab2e55950'	System	14 Feb 2021 10:43:12
User entered 'No (N)'	System	14 Feb 2021 10:43:12

US3342200

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:05:26

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2D2D1647-7C35-4DCA-ADA3-8E1DAA921DDC)', Time: '2021-02-14T04:43:10', User OID: 'PatientReportedOutcome (US3342200)', ODM File OID: '3f90baac-13b5-416b-becd-276ab2e55950' User entered '14 Feb 2021 04:43:10'	System	14 Feb 2021 10:43:12
	System	14 Feb 2021 10:43:12

US3342200

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:05:26

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:39:53
Amendment Manager: User entered '14 Feb 2021 00:01'	System	20 Nov 2020 05:39:53

US3342200

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:05:26

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:39:53
Amendment Manager: User entered '18 Feb 2021 23:59'	System	20 Nov 2020 05:39:53

US3342200

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:05:26

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:39:53
Amendment Manager: User entered 'Day 173'	System	20 Nov 2020 05:39:53

US3342200

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:05:26

[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 (2D2D1647-7C35-4DCA-ADA3-8E1DAA921DDC)', Time: '2021-02-21T09:37:35', User OID: 'PatientReportedOutcome (US3342200)', ODM File OID: '4868331a-bcd3-4b16-9019-da38b7f27cf0' User entered 'No (N)'	System	21 Feb 2021 15:38:20
	System	21 Feb 2021 15:38:20

US3342200

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:05:26

Have you been exposed to someone with 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 (2D2D1647-7C35-4DCA-ADA3-8E1DAA921DDC)', Time: '2021-02-21T09:38:13', User OID: 'PatientReportedOutcome (US3342200)', ODM File OID: '4868331a-bcd3-4b16-9019-da38b7f27cf0' User entered 'No (N)'	System	21 Feb 2021 15:38:20
	System	21 Feb 2021 15:38:20

US3342200

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:05:26

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2D2D1647-7C35-4DCA-ADA3-8E1DAA921DDC)', Time: '2021-02-21T09:38:17', User OID: 'PatientReportedOutcome (US3342200)', ODM File OID: '4868331a-bcd3-4b16-9019-da38b7f27cf0' User entered '21 Feb 2021 09:38:17'	System	21 Feb 2021 15:38:20
	System	21 Feb 2021 15:38:20

US3342200

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:05:26

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:39:53
Amendment Manager: User entered '21 Feb 2021 00:01'	System	20 Nov 2020 05:39:53

US3342200

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:05:26

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:39:53
Amendment Manager: User entered '25 Feb 2021 23:59'	System	20 Nov 2020 05:39:53

US3342200

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:05:26

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:39:53
Amendment Manager: User entered 'Day 180'	System	20 Nov 2020 05:39:53

US3342200

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:05:26

[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 (2D2D1647-7C35-4DCA-ADA3-8E1DAA921DDC)', Time: '2021-02-28T00:32:03-06:00', User OID: 'PatientReportedOutcome (US3342200)', ODM File OID: 'a4f1eaa3-f80d-4c14-8a84-87bdf7e5c181' User entered 'No (N)'	System	28 Feb 2021 06:32:15
	System	28 Feb 2021 06:32:15

US3342200

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:05:26

Have you been exposed to someone with 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 (2D2D1647-7C35-4DCA-ADA3-8E1DAA921DDC)', Time: '2021-02-28T00:32:08-06:00', User OID: 'PatientReportedOutcome (US3342200)', ODM File OID: 'a4f1eaa3-f80d-4c14-8a84-87bdf7e5c181' User entered 'No (N)'	System	28 Feb 2021 06:32:15

US3342200

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:05:26

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2D2D1647-7C35-4DCA-ADA3-8E1DAA921DDC)', Time: '2021-02-28T00:32:13-06:00', User OID: 'PatientReportedOutcome (US3342200)', ODM File OID: 'a4f1eaa3-f80d-4c14-8a84-87bdf7e5c181' User entered '28 Feb 2021 06:32:13'	System	28 Feb 2021 06:32:15
	System	28 Feb 2021 06:32:15

US3342200

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:05:26

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:39:53
Amendment Manager: User entered '28 Feb 2021 00:01'	System	20 Nov 2020 05:39:53

US3342200

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:05:26

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:39:53
Amendment Manager: User entered '04 Mar 2021 23:59'	System	20 Nov 2020 05:39:53

US3342200

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:05:26

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:39:53
Amendment Manager: User entered 'Day 187'	System	20 Nov 2020 05:39:53

US3342200

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:05:26

[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 (2D2D1647-7C35-4DCA-ADA3-8E1DAA921DDC)', Time: '2021-03-07T02:54:57-06:00', User OID: 'PatientReportedOutcome (US3342200)', ODM File OID: '3daca871-b7cf-4ab9-95ab-8880db0476a8' User entered 'No (N)'	System	07 Mar 2021 08:55:12
	System	07 Mar 2021 08:55:12

US3342200

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:05:26

Have you been exposed to someone with 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 (2D2D1647-7C35-4DCA-ADA3-8E1DAA921DDC)', Time: '2021-03-07T02:55:03-06:00', User OID: 'PatientReportedOutcome (US3342200)', ODM File OID: '3daca871-b7cf-4ab9-95ab-8880db0476a8'	System	07 Mar 2021 08:55:12
User entered 'No (N)'	System	07 Mar 2021 08:55:12

US3342200

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:05:26

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2D2D1647-7C35-4DCA-ADA3-8E1DAA921DDC)', Time: '2021-03-07T02:55:07-06:00', User OID: 'PatientReportedOutcome (US3342200)', ODM File OID: '3daca871-b7cf-4ab9-95ab-8880db0476a8' User entered '07 Mar 2021 02:55:07'	System	07 Mar 2021 08:55:12
	System	07 Mar 2021 08:55:12

US3342200

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:05:26

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:39:53
Amendment Manager: User entered '07 Mar 2021 00:01'	System	20 Nov 2020 05:39:53

US3342200

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:05:26

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:39:53
Amendment Manager: User entered '11 Mar 2021 23:59'	System	20 Nov 2020 05:39:53

US3342200

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:05:26

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:39:53
Amendment Manager: User entered 'Day 194'	System	20 Nov 2020 05:39:53

US3342200

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:05:26

[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 (2D2D1647-7C35-4DCA-ADA3-8E1DAA921DDC)', Time: '2021-03-14T05:56:06-05:00', User OID: 'PatientReportedOutcome (US3342200)', ODM File OID: 'd472106c-899e-4e02-9069-61a812899a61'	System	14 Mar 2021 10:56:21
User entered 'No (N)'	System	14 Mar 2021 10:56:21

US3342200

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:05:26

Have you been exposed to someone with 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 (2D2D1647-7C35-4DCA-ADA3-8E1DAA921DDC)', Time: '2021-03-14T05:56:12-05:00', User OID: 'PatientReportedOutcome (US3342200)', ODM File OID: 'd472106c-899e-4e02-9069-61a812899a61'	System	14 Mar 2021 10:56:21
User entered 'No (N)'	System	14 Mar 2021 10:56:21

US3342200

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:05:26

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2D2D1647-7C35-4DCA-ADA3-8E1DAA921DDC)', Time: '2021-03-14T05:56:17-05:00', User OID: 'PatientReportedOutcome (US3342200)', ODM File OID: 'd472106c-899e-4e02-9069-61a812899a61' User entered '14 Mar 2021 05:56:17'	System	14 Mar 2021 10:56:21
	System	14 Mar 2021 10:56:21

US3342200

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:05:26

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:39:53
Amendment Manager: User entered '14 Mar 2021 00:01'	System	20 Nov 2020 05:39:53

US3342200

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:05:26

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:39:53
Amendment Manager: User entered '18 Mar 2021 23:59'	System	20 Nov 2020 05:39:53

US3342200

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:05:26

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:39:53
Amendment Manager: User entered 'Day 201'	System	20 Nov 2020 05:39:53

US3342200

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:05:26

[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 (2D2D1647-7C35-4DCA-ADA3-8E1DAA921DDC)', Time: '2021-03-21T12:30:51-05:00', User OID: 'PatientReportedOutcome (US3342200)', ODM File OID: '17edb01e-1904-4152-bd2d-d194b93485dd'	System	21 Mar 2021 17:31:00
User entered 'No (N)'	System	21 Mar 2021 17:31:00

US3342200

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:05:26

Have you been exposed to someone with 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 (2D2D1647-7C35-4DCA-ADA3-8E1DAA921DDC)', Time: '2021-03-21T12:30:55-05:00', User OID: 'PatientReportedOutcome (US3342200)', ODM File OID: '17edb01e-1904-4152-bd2d-d194b93485dd' User entered 'No (N)'	System	21 Mar 2021 17:31:00

US3342200

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:05:26

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2D2D1647-7C35-4DCA-ADA3-8E1DAA921DDC)', Time: '2021-03-21T12:30:58-05:00', User OID: 'PatientReportedOutcome (US3342200)', ODM File OID: '17edb01e-1904-4152-bd2d-d194b93485dd' User entered '21 Mar 2021 12:30:58'	System	21 Mar 2021 17:31:00
	System	21 Mar 2021 17:31:00

US3342200

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:05:26

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:39:53
Amendment Manager: User entered '21 Mar 2021 00:01'	System	20 Nov 2020 05:39:53

US3342200

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:05:26

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:39:53
Amendment Manager: User entered '25 Mar 2021 23:59'	System	20 Nov 2020 05:39:53

US3342200

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:05:26

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:39:53
Amendment Manager: User entered 'Day 208'	System	20 Nov 2020 05:39:53

US3342200

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:05:26

[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 (2D2D1647-7C35-4DCA-ADA3-8E1DAA921DDC)', Time: '2021-03-28T05:11:38-05:00', User OID: 'PatientReportedOutcome (US3342200)', ODM File OID: '18ad4e7d-065a-4dac-9263-23abec0f9484' User entered 'No (N)'	System	28 Mar 2021 10:11:49

US3342200

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:05:26

Have you been exposed to someone with 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 (2D2D1647-7C35-4DCA-ADA3-8E1DAA921DDC)', Time: '2021-03-28T05:11:44-05:00', User OID: 'PatientReportedOutcome (US3342200)', ODM File OID: '18ad4e7d-065a-4dac-9263-23abec0f9484' User entered 'No (N)'	System	28 Mar 2021 10:11:49

US3342200

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:05:26

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2D2D1647-7C35-4DCA-ADA3-8E1DAA921DDC)', Time: '2021-03-28T05:11:47-05:00', User OID: 'PatientReportedOutcome (US3342200)', ODM File OID: '18ad4e7d-065a-4dac-9263-23abec0f9484' User entered '28 Mar 2021 05:11:47'	System	28 Mar 2021 10:11:49
	System	28 Mar 2021 10:11:49

US3342200

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:05:26

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:39:53
Amendment Manager: User entered '28 Mar 2021 00:01'	System	20 Nov 2020 05:39:53

US3342200

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:05:26

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:39:53
Amendment Manager: User entered '01 Apr 2021 23:59'	System	20 Nov 2020 05:39:53

US3342200

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:05:26

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:39:53
Amendment Manager: User entered 'Day 215'	System	20 Nov 2020 05:39:53

US3342200

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:05:26

[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 (2D2D1647-7C35-4DCA-ADA3-8E1DAA921DDC)', Time: '2021-04-04T03:46:33-05:00', User OID: 'PatientReportedOutcome (US3342200)', ODM File OID: '9744c04f-e9e3-4589-a52d-77f65439e1a8'	System	04 Apr 2021 08:46:47
User entered 'No (N)'	System	04 Apr 2021 08:46:47

US3342200

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:05:26

Have you been exposed to someone with 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 (2D2D1647-7C35-4DCA-ADA3-8E1DAA921DDC)', Time: '2021-04-04T03:46:39-05:00', User OID: 'PatientReportedOutcome (US3342200)', ODM File OID: '9744c04f-e9e3-4589-a52d-77f65439e1a8' User entered 'No (N)'	System	04 Apr 2021 08:46:47
	System	04 Apr 2021 08:46:47

US3342200

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:05:26

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2D2D1647-7C35-4DCA-ADA3-8E1DAA921DDC)', Time: '2021-04-04T03:46:44-05:00', User OID: 'PatientReportedOutcome (US3342200)', ODM File OID: '9744c04f-e9e3-4589-a52d-77f65439e1a8' User entered '04 Apr 2021 03:46:44'	System	04 Apr 2021 08:46:47
	System	04 Apr 2021 08:46:47

US3342200

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:05:26

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:39:53
Amendment Manager: User entered '04 Apr 2021 00:01'	System	20 Nov 2020 05:39:53

US3342200

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:05:26

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:39:53
Amendment Manager: User entered '08 Apr 2021 23:59'	System	20 Nov 2020 05:39:53

US3342200

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:05:26

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:39:53
Amendment Manager: User entered 'Day 222'	System	20 Nov 2020 05:39:53

US3342200

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:05:26

[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 (2D2D1647-7C35-4DCA-ADA3-8E1DAA921DDC)', Time: '2021-04-11T02:29:14-05:00', User OID: 'PatientReportedOutcome (US3342200)', ODM File OID: 'e38e4a96-462d-4767-a5fb-d604a1df11a6'	System	11 Apr 2021 07:29:54
User entered 'Yes (Y)'	System	11 Apr 2021 07:29:54

US3342200

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:05:26

Have you been exposed to someone with 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 (2D2D1647-7C35-4DCA-ADA3-8E1DAA921DDC)', Time: '2021-04-11T02:29:28-05:00', User OID: 'PatientReportedOutcome (US3342200)', ODM File OID: 'e38e4a96-462d-4767-a5fb-d604a1df11a6'	System	11 Apr 2021 07:29:54
User entered 'No (N)'	System	11 Apr 2021 07:29:54

US3342200

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:05:26

[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 (2D2D1647-7C35-4DCA-ADA3-8E1DAA921DDC)', Time: '2021-04-11T02:29:33-05:00', User OID: 'PatientReportedOutcome (US3342200)', ODM File OID: 'e38e4a96-462d-4767-a5fb-d604a1df11a6' User entered 'No (N)'	System	11 Apr 2021 07:29:54
	System	11 Apr 2021 07:29:54

US3342200

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:05:26

[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 (2D2D1647-7C35-4DCA-ADA3-8E1DAA921DDC)', Time: '2021-04-11T02:29:44-05:00', User OID: 'PatientReportedOutcome (US3342200)', ODM File OID: 'e38e4a96-462d-4767-a5fb-d604a1df11a6' User entered 'No (N)'	System	11 Apr 2021 07:29:54
	System	11 Apr 2021 07:29:54

US3342200

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:05:26

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2D2D1647-7C35-4DCA-ADA3-8E1DAA921DDC)', Time: '2021-04-11T02:29:48-05:00', User OID: 'PatientReportedOutcome (US3342200)', ODM File OID: 'e38e4a96-462d-4767-a5fb-d604a1df11a6'	System	11 Apr 2021 07:29:54
User entered '11 Apr 2021 02:29:48'	System	11 Apr 2021 07:29:54

US3342200

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:05:26

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:39:53
Amendment Manager: User entered '11 Apr 2021 00:01'	System	20 Nov 2020 05:39:53

US3342200

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:05:26

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:39:53
Amendment Manager: User entered '15 Apr 2021 23:59'	System	20 Nov 2020 05:39:53

US3342200

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:05:26

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:39:53
Amendment Manager: User entered 'Day 229'	System	20 Nov 2020 05:39:53

US3342200

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:05:26

[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 (2D2D1647-7C35-4DCA-ADA3-8E1DAA921DDC)', Time: '2021-04-18T06:57:13-05:00', User OID: 'PatientReportedOutcome (US3342200)', ODM File OID: 'e9e0a607-f89b-4bf6-81dc-cea8b93cb4eb'	System	18 Apr 2021 11:57:39
User entered 'Yes (Y)'	System	18 Apr 2021 11:57:39

US3342200

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:05:26

[Have you been exposed to someone with 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 (2D2D1647-7C35-4DCA-ADA3-8E1DAA921DDC)', Time: '2021-04-18T06:57:22-05:00', User OID: 'PatientReportedOutcome (US3342200)', ODM File OID: 'e9e0a607-f89b-4bf6-81dc-cea8b93cb4eb'	System	18 Apr 2021 11:57:39
User entered 'No (N)'	System	18 Apr 2021 11:57:39

US3342200

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:05:26

[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 (2D2D1647-7C35-4DCA-ADA3-8E1DAA921DDC)', Time: '2021-04-18T06:57:26-05:00', User OID: 'PatientReportedOutcome (US3342200)', ODM File OID: 'e9e0a607-f89b-4bf6-81dc-cea8b93cb4eb' User entered 'No (N)'	System	18 Apr 2021 11:57:39
	System	18 Apr 2021 11:57:39

US3342200

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:05:26

[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 (2D2D1647-7C35-4DCA-ADA3-8E1DAA921DDC)', Time: '2021-04-18T06:57:32-05:00', User OID: 'PatientReportedOutcome (US3342200)', ODM File OID: 'e9e0a607-f89b-4bf6-81dc-cea8b93cb4eb' User entered 'No (N)'	System	18 Apr 2021 11:57:39
	System	18 Apr 2021 11:57:39

US3342200

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:05:26

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2D2D1647-7C35-4DCA-ADA3-8E1DAA921DDC)', Time: '2021-04-18T06:57:36-05:00', User OID: 'PatientReportedOutcome (US3342200)', ODM File OID: 'e9e0a607-f89b-4bf6-81dc-cea8b93cb4eb' User entered '18 Apr 2021 06:57:36'	System	18 Apr 2021 11:57:39
	System	18 Apr 2021 11:57:39

US3342200

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:05:26

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:39:53
Amendment Manager: User entered '18 Apr 2021 00:01'	System	20 Nov 2020 05:39:53

US3342200

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:05:26

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:39:53
Amendment Manager: User entered '22 Apr 2021 23:59'	System	20 Nov 2020 05:39:53

US3342200

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:05:26

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:39:53
Amendment Manager: User entered 'Day 236'	System	20 Nov 2020 05:39:53

US3342200

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:05:26

[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 (2D2D1647-7C35-4DCA-ADA3-8E1DAA921DDC)', Time: '2021-04-25T07:35:58-05:00', User OID: 'PatientReportedOutcome (US3342200)', ODM File OID: '128d034d-c007-4058-a530-30ea033234a2'	System	25 Apr 2021 12:36:38
User entered 'Yes (Y)'	System	25 Apr 2021 12:36:38

US3342200

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:05:26

Have you been exposed to someone with 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 (2D2D1647-7C35-4DCA-ADA3-8E1DAA921DDC)', Time: '2021-04-25T07:36:03-05:00', User OID: 'PatientReportedOutcome (US3342200)', ODM File OID: '128d034d-c007-4058-a530-30ea033234a2'	System	25 Apr 2021 12:36:38
User entered 'No (N)'	System	25 Apr 2021 12:36:38

US3342200

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:05:26

[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 (2D2D1647-7C35-4DCA-ADA3-8E1DAA921DDC)', Time: '2021-04-25T07:36:13-05:00', User OID: 'PatientReportedOutcome (US3342200)', ODM File OID: '128d034d-c007-4058-a530-30ea033234a2' User entered 'No (N)'	System	25 Apr 2021 12:36:38
	System	25 Apr 2021 12:36:38

US3342200

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:05:26

[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 (2D2D1647-7C35-4DCA-ADA3-8E1DAA921DDC)', Time: '2021-04-25T07:36:19-05:00', User OID: 'PatientReportedOutcome (US3342200)', ODM File OID: '128d034d-c007-4058-a530-30ea033234a2'	System	25 Apr 2021 12:36:38
User entered 'No (N)'	System	25 Apr 2021 12:36:38

US3342200

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:05:26

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2D2D1647-7C35-4DCA-ADA3-8E1DAA921DDC)', Time: '2021-04-25T07:36:33-05:00', User OID: 'PatientReportedOutcome (US3342200)', ODM File OID: '128d034d-c007-4058-a530-30ea033234a2'	System	25 Apr 2021 12:36:38
User entered '25 Apr 2021 07:36:33'	System	25 Apr 2021 12:36:38

US3342200

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:05:26

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:39:53
Amendment Manager: User entered '25 Apr 2021 00:01'	System	20 Nov 2020 05:39:53

US3342200

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:05:26

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:39:53
Amendment Manager: User entered '29 Apr 2021 23:59'	System	20 Nov 2020 05:39:53

US3342200

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:05:26

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:39:53
Amendment Manager: User entered 'Day 243'	System	20 Nov 2020 05:39:53

US3342200

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:05:26

[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 (2D2D1647-7C35-4DCA-ADA3-8E1DAA921DDC)', Time: '2021-05-02T06:48:27-05:00', User OID: 'PatientReportedOutcome (US3342200)', ODM File OID: '00d317e7-a8c7-4681-87f9-f595e3c0916e' User entered 'No (N)'	System	02 May 2021 11:48:40
	System	02 May 2021 11:48:40

US3342200

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:05:26

Have you been exposed to someone with 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 (2D2D1647-7C35-4DCA-ADA3-8E1DAA921DDC)', Time: '2021-05-02T06:48:33-05:00', User OID: 'PatientReportedOutcome (US3342200)', ODM File OID: '00d317e7-a8c7-4681-87f9-f595e3c0916e' User entered 'No (N)'	System	02 May 2021 11:48:40
	System	02 May 2021 11:48:40

US3342200

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:05:26

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2D2D1647-7C35-4DCA-ADA3-8E1DAA921DDC)', Time: '2021-05-02T06:48:36-05:00', User OID: 'PatientReportedOutcome (US3342200)', ODM File OID: '00d317e7-a8c7-4681-87f9-f595e3c0916e' User entered '02 May 2021 06:48:36'	System	02 May 2021 11:48:40
	System	02 May 2021 11:48:40

US3342200

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:05:26

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:39:53
Amendment Manager: User entered '02 May 2021 00:01'	System	20 Nov 2020 05:39:53

US3342200

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:05:26

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:39:53
Amendment Manager: User entered '06 May 2021 23:59'	System	20 Nov 2020 05:39:53

US3342200

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:05:26

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:39:53
Amendment Manager: User entered 'Day 250'	System	20 Nov 2020 05:39:53

US3342200

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:05:26

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:39:53
Amendment Manager: User entered '09 May 2021 00:01'	System	20 Nov 2020 05:39:53

US3342200

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:05:26

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:39:53
Amendment Manager: User entered '13 May 2021 23:59'	System	20 Nov 2020 05:39:53

US3342200

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:05:26

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:39:53
Amendment Manager: User entered 'Day 257'	System	20 Nov 2020 05:39:53

US3342200

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:05:26

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:39:53
Amendment Manager: User entered '16 May 2021 00:01'	System	20 Nov 2020 05:39:53

US3342200

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:05:26

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:39:53
Amendment Manager: User entered '20 May 2021 23:59'	System	20 Nov 2020 05:39:53

US3342200

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:05:26

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:39:53
Amendment Manager: User entered 'Day 264'	System	20 Nov 2020 05:39:53

US3342200

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:05:26

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:39:53
Amendment Manager: User entered '23 May 2021 00:01'	System	20 Nov 2020 05:39:53

US3342200

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:05:26

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:39:53
Amendment Manager: User entered '27 May 2021 23:59'	System	20 Nov 2020 05:39:53

US3342200

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:05:26

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:39:53
Amendment Manager: User entered 'Day 271'	System	20 Nov 2020 05:39:53

US3342200

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:05:26

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:39:53
Amendment Manager: User entered '30 May 2021 00:01'	System	20 Nov 2020 05:39:53

US3342200

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:05:26

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:39:53
Amendment Manager: User entered '03 Jun 2021 23:59'	System	20 Nov 2020 05:39:53

US3342200

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:05:26

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:39:53
Amendment Manager: User entered 'Day 278'	System	20 Nov 2020 05:39:53

US3342200

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:05:26

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:39:53
Amendment Manager: User entered '06 Jun 2021 00:01'	System	20 Nov 2020 05:39:53

US3342200

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:05:26

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:39:53
Amendment Manager: User entered '10 Jun 2021 23:59'	System	20 Nov 2020 05:39:53

US3342200

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:05:26

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:39:53
Amendment Manager: User entered 'Day 285'	System	20 Nov 2020 05:39:53

US3342200

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:05:26

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:39:53
Amendment Manager: User entered '13 Jun 2021 00:01'	System	20 Nov 2020 05:39:53

US3342200

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:05:26

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:39:53
Amendment Manager: User entered '17 Jun 2021 23:59'	System	20 Nov 2020 05:39:53

US3342200

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:05:26

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:39:53
Amendment Manager: User entered 'Day 292'	System	20 Nov 2020 05:39:53

US3342200

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:05:26

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:39:53
Amendment Manager: User entered '20 Jun 2021 00:01'	System	20 Nov 2020 05:39:53

US3342200

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:05:26

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:39:53
Amendment Manager: User entered '24 Jun 2021 23:59'	System	20 Nov 2020 05:39:53

US3342200

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:05:26

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:39:53
Amendment Manager: User entered 'Day 299'	System	20 Nov 2020 05:39:53

US3342200

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:05:26

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:39:53
Amendment Manager: User entered '27 Jun 2021 00:01'	System	20 Nov 2020 05:39:53

US3342200

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:05:26

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:39:53
Amendment Manager: User entered '01 Jul 2021 23:59'	System	20 Nov 2020 05:39:53

US3342200

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:05:26

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:39:53
Amendment Manager: User entered 'Day 306'	System	20 Nov 2020 05:39:53

US3342200

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:05:26

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:39:53
Amendment Manager: User entered '04 Jul 2021 00:01'	System	20 Nov 2020 05:39:53

US3342200

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:05:26

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:39:53
Amendment Manager: User entered '08 Jul 2021 23:59'	System	20 Nov 2020 05:39:53

US3342200

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:05:26

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:39:53
Amendment Manager: User entered 'Day 313'	System	20 Nov 2020 05:39:53

US3342200

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:05:26

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:39:53
Amendment Manager: User entered '11 Jul 2021 00:01'	System	20 Nov 2020 05:39:53

US3342200

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:05:26

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:39:53
Amendment Manager: User entered '15 Jul 2021 23:59'	System	20 Nov 2020 05:39:53

US3342200

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:05:26

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:39:53
Amendment Manager: User entered 'Day 320'	System	20 Nov 2020 05:39:53

US3342200

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:05:26

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:39:53
Amendment Manager: User entered '18 Jul 2021 00:01'	System	20 Nov 2020 05:39:53

US3342200

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:05:26

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:39:53
Amendment Manager: User entered '22 Jul 2021 23:59'	System	20 Nov 2020 05:39:53

US3342200

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:05:26

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:39:53
Amendment Manager: User entered 'Day 327'	System	20 Nov 2020 05:39:53

US3342200

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:05:26

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:39:53
Amendment Manager: User entered '25 Jul 2021 00:01'	System	20 Nov 2020 05:39:53

US3342200

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:05:26

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:39:53
Amendment Manager: User entered '29 Jul 2021 23:59'	System	20 Nov 2020 05:39:53

US3342200

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:05:26

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:39:53
Amendment Manager: User entered 'Day 334'	System	20 Nov 2020 05:39:53

US3342200

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:05:26

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:39:53
Amendment Manager: User entered '01 Aug 2021 00:01'	System	20 Nov 2020 05:39:53

US3342200

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:05:26

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:39:53
Amendment Manager: User entered '05 Aug 2021 23:59'	System	20 Nov 2020 05:39:53

US3342200

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:05:26

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:39:53
Amendment Manager: User entered 'Day 341'	System	20 Nov 2020 05:39:53

US3342200

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:05:26

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:39:53
Amendment Manager: User entered '08 Aug 2021 00:01'	System	20 Nov 2020 05:39:53

US3342200

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:05:26

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:39:53
Amendment Manager: User entered '12 Aug 2021 23:59'	System	20 Nov 2020 05:39:53

US3342200

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:05:26

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:39:53
Amendment Manager: User entered 'Day 348'	System	20 Nov 2020 05:39:53

US3342200

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:05:26

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:39:53
Amendment Manager: User entered '15 Aug 2021 00:01'	System	20 Nov 2020 05:39:53

US3342200

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:05:26

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:39:53
Amendment Manager: User entered '19 Aug 2021 23:59'	System	20 Nov 2020 05:39:53

US3342200

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:05:26

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:39:53
Amendment Manager: User entered 'Day 355'	System	20 Nov 2020 05:39:53

US3342200

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:05:26

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:39:53
Amendment Manager: User entered '22 Aug 2021 00:01'	System	20 Nov 2020 05:39:53

US3342200

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:05:26

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:39:53
Amendment Manager: User entered '26 Aug 2021 23:59'	System	20 Nov 2020 05:39:53

US3342200

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:05:26

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:39:53
Amendment Manager: User entered 'Day 362'	System	20 Nov 2020 05:39:53

US3342200

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:05:26

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:39:53
Amendment Manager: User entered '29 Aug 2021 00:01'	System	20 Nov 2020 05:39:53

US3342200

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:05:26

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:39:53
Amendment Manager: User entered '02 Sep 2021 23:59'	System	20 Nov 2020 05:39:53

US3342200

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:05:26

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:39:53
Amendment Manager: User entered 'Day 369'	System	20 Nov 2020 05:39:53

US3342200

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:05:26

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:39:53
Amendment Manager: User entered '05 Sep 2021 00:01'	System	20 Nov 2020 05:39:53

US3342200

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:05:26

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:39:53
Amendment Manager: User entered '09 Sep 2021 23:59'	System	20 Nov 2020 05:39:53

US3342200

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:05:26

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:39:53
Amendment Manager: User entered 'Day 376'	System	20 Nov 2020 05:39:53

US3342200

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:05:26

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:39:53
Amendment Manager: User entered '12 Sep 2021 00:01'	System	20 Nov 2020 05:39:53

US3342200

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:05:26

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:39:53
Amendment Manager: User entered '16 Sep 2021 23:59'	System	20 Nov 2020 05:39:53

US3342200

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:05:26

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:39:53
Amendment Manager: User entered 'Day 383'	System	20 Nov 2020 05:39:53

US3342200

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:05:26

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:39:53
Amendment Manager: User entered '19 Sep 2021 00:01'	System	20 Nov 2020 05:39:53

US3342200

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:05:26

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:39:53
Amendment Manager: User entered '23 Sep 2021 23:59'	System	20 Nov 2020 05:39:53

US3342200

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:05:26

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:39:53
Amendment Manager: User entered 'Day 390'	System	20 Nov 2020 05:39:53

US3342200

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:05:26

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:39:53
Amendment Manager: User entered '26 Sep 2021 00:01'	System	20 Nov 2020 05:39:53

US3342200

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:05:26

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:39:53
Amendment Manager: User entered '30 Sep 2021 23:59'	System	20 Nov 2020 05:39:53

US3342200

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:05:26

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:39:53
Amendment Manager: User entered 'Day 397'	System	20 Nov 2020 05:39:53

US3342200

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:05:26

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:39:53
Amendment Manager: User entered '03 Oct 2021 00:01'	System	20 Nov 2020 05:39:53

US3342200

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:05:26

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:39:53
Amendment Manager: User entered '07 Oct 2021 23:59'	System	20 Nov 2020 05:39:53

US3342200

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:05:26

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:39:53
Amendment Manager: User entered 'Day 404'	System	20 Nov 2020 05:39:53

US3342200

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:05:26

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:39:53
Amendment Manager: User entered '10 Oct 2021 00:01'	System	20 Nov 2020 05:39:53

US3342200

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:05:26

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:39:53
Amendment Manager: User entered '14 Oct 2021 23:59'	System	20 Nov 2020 05:39:53

US3342200

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:05:26

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:39:53
Amendment Manager: User entered 'Day 411'	System	20 Nov 2020 05:39:53

US3342200

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:05:26

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:39:53
Amendment Manager: User entered '17 Oct 2021 00:01'	System	20 Nov 2020 05:39:53

US3342200

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:05:26

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:39:53
Amendment Manager: User entered '21 Oct 2021 23:59'	System	20 Nov 2020 05:39:53

US3342200

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:05:26

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:39:53
Amendment Manager: User entered 'Day 418'	System	20 Nov 2020 05:39:53

US3342200

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:05:26

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:39:53
Amendment Manager: User entered '24 Oct 2021 00:01'	System	20 Nov 2020 05:39:53

US3342200

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:05:26

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:39:53
Amendment Manager: User entered '28 Oct 2021 23:59'	System	20 Nov 2020 05:39:53

US3342200

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:05:26

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:39:53
Amendment Manager: User entered 'Day 425'	System	20 Nov 2020 05:39:53

US3342200

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:05:26

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:39:53
Amendment Manager: User entered '31 Oct 2021 00:01'	System	20 Nov 2020 05:39:53

US3342200

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:05:26

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:39:53
Amendment Manager: User entered '04 Nov 2021 23:59'	System	20 Nov 2020 05:39:53

US3342200

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:05:26

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:39:53
Amendment Manager: User entered 'Day 432'	System	20 Nov 2020 05:39:53

US3342200

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:05:26

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:39:53
Amendment Manager: User entered '07 Nov 2021 00:01'	System	20 Nov 2020 05:39:53

US3342200

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:05:26

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:39:53
Amendment Manager: User entered '11 Nov 2021 23:59'	System	20 Nov 2020 05:39:53

US3342200

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:05:26

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:39:53
Amendment Manager: User entered 'Day 439'	System	20 Nov 2020 05:39:53

US3342200

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:05:26

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:39:53
Amendment Manager: User entered '14 Nov 2021 00:01'	System	20 Nov 2020 05:39:53

US3342200

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:05:26

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:39:53
Amendment Manager: User entered '18 Nov 2021 23:59'	System	20 Nov 2020 05:39:53

US3342200

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:05:26

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:39:53
Amendment Manager: User entered 'Day 446'	System	20 Nov 2020 05:39:53

US3342200

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:05:26

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:39:53
Amendment Manager: User entered '21 Nov 2021 00:01'	System	20 Nov 2020 05:39:53

US3342200

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:05:26

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:39:53
Amendment Manager: User entered '25 Nov 2021 23:59'	System	20 Nov 2020 05:39:53

US3342200

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:05:26

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:39:53
Amendment Manager: User entered 'Day 453'	System	20 Nov 2020 05:39:53

US3342200

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:05:26

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:39:53
Amendment Manager: User entered '28 Nov 2021 00:01'	System	20 Nov 2020 05:39:53

US3342200

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:05:26

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:39:53
Amendment Manager: User entered '02 Dec 2021 23:59'	System	20 Nov 2020 05:39:53

US3342200

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:05:26

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:39:53
Amendment Manager: User entered 'Day 460'	System	20 Nov 2020 05:39:53

US3342200

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:05:26

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:39:53
Amendment Manager: User entered '05 Dec 2021 00:01'	System	20 Nov 2020 05:39:53

US3342200

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:05:26

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:39:53
Amendment Manager: User entered '09 Dec 2021 23:59'	System	20 Nov 2020 05:39:53

US3342200

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:05:26

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:39:53
Amendment Manager: User entered 'Day 467'	System	20 Nov 2020 05:39:53

US3342200

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:05:26

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:39:53
Amendment Manager: User entered '12 Dec 2021 00:01'	System	20 Nov 2020 05:39:53

US3342200

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:05:26

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:39:53
Amendment Manager: User entered '16 Dec 2021 23:59'	System	20 Nov 2020 05:39:53

US3342200

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:05:26

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:39:53
Amendment Manager: User entered 'Day 474'	System	20 Nov 2020 05:39:53

US3342200

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:05:26

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:39:53
Amendment Manager: User entered '19 Dec 2021 00:01'	System	20 Nov 2020 05:39:53

US3342200

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:05:26

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:39:53
Amendment Manager: User entered '23 Dec 2021 23:59'	System	20 Nov 2020 05:39:53

US3342200

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:05:26

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:39:53
Amendment Manager: User entered 'Day 481'	System	20 Nov 2020 05:39:53

US3342200

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:05:26

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:39:53
Amendment Manager: User entered '26 Dec 2021 00:01'	System	20 Nov 2020 05:39:53

US3342200

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:05:26

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:39:53
Amendment Manager: User entered '30 Dec 2021 23:59'	System	20 Nov 2020 05:39:53

US3342200

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:05:26

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:39:53
Amendment Manager: User entered 'Day 488'	System	20 Nov 2020 05:39:53

US3342200

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:05:26

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:39:53
Amendment Manager: User entered '02 Jan 2022 00:01'	System	20 Nov 2020 05:39:53

US3342200

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:05:26

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:39:53
Amendment Manager: User entered '06 Jan 2022 23:59'	System	20 Nov 2020 05:39:53

US3342200

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:05:26

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:39:53
Amendment Manager: User entered 'Day 495'	System	20 Nov 2020 05:39:53

US3342200

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:05:26

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:39:53
Amendment Manager: User entered '09 Jan 2022 00:01'	System	20 Nov 2020 05:39:53

US3342200

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:05:26

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:39:53
Amendment Manager: User entered '13 Jan 2022 23:59'	System	20 Nov 2020 05:39:53

US3342200

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:05:26

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:39:53
Amendment Manager: User entered 'Day 502'	System	20 Nov 2020 05:39:53

US3342200

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:05:26

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:39:53
Amendment Manager: User entered '16 Jan 2022 00:01'	System	20 Nov 2020 05:39:53

US3342200

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:05:26

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:39:53
Amendment Manager: User entered '20 Jan 2022 23:59'	System	20 Nov 2020 05:39:53

US3342200

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:05:26

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:39:53
Amendment Manager: User entered 'Day 509'	System	20 Nov 2020 05:39:53

US3342200

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:05:26

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:39:53
Amendment Manager: User entered '23 Jan 2022 00:01'	System	20 Nov 2020 05:39:53

US3342200

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:05:26

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:39:53
Amendment Manager: User entered '27 Jan 2022 23:59'	System	20 Nov 2020 05:39:53

US3342200

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:05:26

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:39:53
Amendment Manager: User entered 'Day 516'	System	20 Nov 2020 05:39:53

US3342200

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:05:26

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:39:53
Amendment Manager: User entered '30 Jan 2022 00:01'	System	20 Nov 2020 05:39:53

US3342200

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:05:26

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:39:53
Amendment Manager: User entered '03 Feb 2022 23:59'	System	20 Nov 2020 05:39:53

US3342200

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:05:26

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:39:53
Amendment Manager: User entered 'Day 523'	System	20 Nov 2020 05:39:53

US3342200

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:05:26

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:39:53
Amendment Manager: User entered '06 Feb 2022 00:01'	System	20 Nov 2020 05:39:53

US3342200

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:05:26

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:39:53
Amendment Manager: User entered '10 Feb 2022 23:59'	System	20 Nov 2020 05:39:53

US3342200

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:05:26

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:39:53
Amendment Manager: User entered 'Day 530'	System	20 Nov 2020 05:39:53

US3342200

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:05:26

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:39:53
Amendment Manager: User entered '13 Feb 2022 00:01'	System	20 Nov 2020 05:39:53

US3342200

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:05:26

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:39:53
Amendment Manager: User entered '17 Feb 2022 23:59'	System	20 Nov 2020 05:39:53

US3342200

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:05:26

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:39:53
Amendment Manager: User entered 'Day 537'	System	20 Nov 2020 05:39:53

US3342200

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:05:26

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:39:53
Amendment Manager: User entered '20 Feb 2022 00:01'	System	20 Nov 2020 05:39:53

US3342200

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:05:26

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:39:53
Amendment Manager: User entered '24 Feb 2022 23:59'	System	20 Nov 2020 05:39:53

US3342200

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:05:26

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:39:53
Amendment Manager: User entered 'Day 544'	System	20 Nov 2020 05:39:53

US3342200

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:05:26

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:39:53
Amendment Manager: User entered '27 Feb 2022 00:01'	System	20 Nov 2020 05:39:53

US3342200

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:05:26

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:39:53
Amendment Manager: User entered '03 Mar 2022 23:59'	System	20 Nov 2020 05:39:53

US3342200

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:05:26

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:39:53
Amendment Manager: User entered 'Day 551'	System	20 Nov 2020 05:39:53

US3342200

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:05:26

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:39:53
Amendment Manager: User entered '06 Mar 2022 00:01'	System	20 Nov 2020 05:39:53

US3342200

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:05:26

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:39:53
Amendment Manager: User entered '10 Mar 2022 23:59'	System	20 Nov 2020 05:39:53

US3342200

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:05:26

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:39:53
Amendment Manager: User entered 'Day 558'	System	20 Nov 2020 05:39:53

US3342200

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:05:26

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:39:53
Amendment Manager: User entered '13 Mar 2022 00:01'	System	20 Nov 2020 05:39:53

US3342200

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:05:26

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:39:53
Amendment Manager: User entered '17 Mar 2022 23:59'	System	20 Nov 2020 05:39:53

US3342200

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:05:26

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:39:53
Amendment Manager: User entered 'Day 565'	System	20 Nov 2020 05:39:53

US3342200

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:05:26

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:39:53
Amendment Manager: User entered '20 Mar 2022 00:01'	System	20 Nov 2020 05:39:53

US3342200

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:05:26

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:39:53
Amendment Manager: User entered '24 Mar 2022 23:59'	System	20 Nov 2020 05:39:53

US3342200

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:05:26

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:39:53
Amendment Manager: User entered 'Day 572'	System	20 Nov 2020 05:39:53

US3342200

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:05:26

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:39:53
Amendment Manager: User entered '27 Mar 2022 00:01'	System	20 Nov 2020 05:39:53

US3342200

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:05:26

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:39:53
Amendment Manager: User entered '31 Mar 2022 23:59'	System	20 Nov 2020 05:39:53

US3342200

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:05:26

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:39:53
Amendment Manager: User entered 'Day 579'	System	20 Nov 2020 05:39:53

US3342200

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:05:26

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:39:53
Amendment Manager: User entered '03 Apr 2022 00:01'	System	20 Nov 2020 05:39:53

US3342200

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:05:26

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:39:53
Amendment Manager: User entered '07 Apr 2022 23:59'	System	20 Nov 2020 05:39:53

US3342200

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:05:26

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:39:53
Amendment Manager: User entered 'Day 586'	System	20 Nov 2020 05:39:53

US3342200

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:05:26

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:39:53
Amendment Manager: User entered '10 Apr 2022 00:01'	System	20 Nov 2020 05:39:53

US3342200

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:05:26

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:39:53
Amendment Manager: User entered '14 Apr 2022 23:59'	System	20 Nov 2020 05:39:53

US3342200

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:05:26

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:39:53
Amendment Manager: User entered 'Day 593'	System	20 Nov 2020 05:39:53

US3342200

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:05:26

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:39:53
Amendment Manager: User entered '17 Apr 2022 00:01'	System	20 Nov 2020 05:39:53

US3342200

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:05:26

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:39:53
Amendment Manager: User entered '21 Apr 2022 23:59'	System	20 Nov 2020 05:39:53

US3342200

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:05:26

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:39:53
Amendment Manager: User entered 'Day 600'	System	20 Nov 2020 05:39:53

US3342200

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:05:26

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:39:53
Amendment Manager: User entered '24 Apr 2022 00:01'	System	20 Nov 2020 05:39:53

US3342200

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:05:26

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:39:53
Amendment Manager: User entered '28 Apr 2022 23:59'	System	20 Nov 2020 05:39:53

US3342200

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:05:26

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:39:53
Amendment Manager: User entered 'Day 607'	System	20 Nov 2020 05:39:53

US3342200

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:05:26

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:39:53
Amendment Manager: User entered '01 May 2022 00:01'	System	20 Nov 2020 05:39:53

US3342200

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:05:26

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:39:53
Amendment Manager: User entered '05 May 2022 23:59'	System	20 Nov 2020 05:39:53

US3342200

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:05:26

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:39:53
Amendment Manager: User entered 'Day 614'	System	20 Nov 2020 05:39:53

US3342200

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:05:26

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:39:53
Amendment Manager: User entered '08 May 2022 00:01'	System	20 Nov 2020 05:39:53

US3342200

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:05:26

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:39:53
Amendment Manager: User entered '12 May 2022 23:59'	System	20 Nov 2020 05:39:53

US3342200

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:05:26

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:39:53
Amendment Manager: User entered 'Day 621'	System	20 Nov 2020 05:39:53

US3342200

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:05:26

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:39:53
Amendment Manager: User entered '15 May 2022 00:01'	System	20 Nov 2020 05:39:53

US3342200

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:05:26

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:39:53
Amendment Manager: User entered '19 May 2022 23:59'	System	20 Nov 2020 05:39:53

US3342200

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:05:26

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:39:53
Amendment Manager: User entered 'Day 628'	System	20 Nov 2020 05:39:53

US3342200

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:05:26

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:39:53
Amendment Manager: User entered '22 May 2022 00:01'	System	20 Nov 2020 05:39:53

US3342200

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:05:26

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:39:53
Amendment Manager: User entered '26 May 2022 23:59'	System	20 Nov 2020 05:39:53

US3342200

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:05:26

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:39:53
Amendment Manager: User entered 'Day 635'	System	20 Nov 2020 05:39:53

US3342200

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:05:26

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:39:53
Amendment Manager: User entered '29 May 2022 00:01'	System	20 Nov 2020 05:39:53

US3342200

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:05:26

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:39:53
Amendment Manager: User entered '02 Jun 2022 23:59'	System	20 Nov 2020 05:39:53

US3342200

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:05:26

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:39:53
Amendment Manager: User entered 'Day 642'	System	20 Nov 2020 05:39:53

US3342200

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:05:26

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:39:53
Amendment Manager: User entered '05 Jun 2022 00:01'	System	20 Nov 2020 05:39:53

US3342200

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:05:26

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:39:53
Amendment Manager: User entered '09 Jun 2022 23:59'	System	20 Nov 2020 05:39:53

US3342200

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:05:26

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:39:53
Amendment Manager: User entered 'Day 649'	System	20 Nov 2020 05:39:53

US3342200

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:05:26

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:39:53
Amendment Manager: User entered '12 Jun 2022 00:01'	System	20 Nov 2020 05:39:53

US3342200

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:05:26

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:39:53
Amendment Manager: User entered '16 Jun 2022 23:59'	System	20 Nov 2020 05:39:53

US3342200

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:05:26

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:39:53
Amendment Manager: User entered 'Day 656'	System	20 Nov 2020 05:39:53

US3342200

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:05:26

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:39:53
Amendment Manager: User entered '19 Jun 2022 00:01'	System	20 Nov 2020 05:39:53

US3342200

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:05:26

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:39:53
Amendment Manager: User entered '23 Jun 2022 23:59'	System	20 Nov 2020 05:39:53

US3342200

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:05:26

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:39:53
Amendment Manager: User entered 'Day 663'	System	20 Nov 2020 05:39:53

US3342200

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:05:26

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:39:53
Amendment Manager: User entered '26 Jun 2022 00:01'	System	20 Nov 2020 05:39:53

US3342200

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:05:26

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:39:53
Amendment Manager: User entered '30 Jun 2022 23:59'	System	20 Nov 2020 05:39:53

US3342200

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:05:26

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:39:53
Amendment Manager: User entered 'Day 670'	System	20 Nov 2020 05:39:53

US3342200

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:05:26

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:39:53
Amendment Manager: User entered '03 Jul 2022 00:01'	System	20 Nov 2020 05:39:53

US3342200

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:05:26

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:39:53
Amendment Manager: User entered '07 Jul 2022 23:59'	System	20 Nov 2020 05:39:53

US3342200

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:05:26

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:39:53
Amendment Manager: User entered 'Day 677'	System	20 Nov 2020 05:39:53

US3342200

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:05:26

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:39:53
Amendment Manager: User entered '10 Jul 2022 00:01'	System	20 Nov 2020 05:39:53

US3342200

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:05:26

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:39:53
Amendment Manager: User entered '14 Jul 2022 23:59'	System	20 Nov 2020 05:39:53

US3342200

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:05:26

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:39:53
Amendment Manager: User entered 'Day 684'	System	20 Nov 2020 05:39:53

US3342200

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:05:26

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:39:53
Amendment Manager: User entered '17 Jul 2022 00:01'	System	20 Nov 2020 05:39:53

US3342200

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:05:26

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:39:53
Amendment Manager: User entered '21 Jul 2022 23:59'	System	20 Nov 2020 05:39:53

US3342200

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:05:26

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:39:53
Amendment Manager: User entered 'Day 691'	System	20 Nov 2020 05:39:53

US3342200

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:05:26

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:39:53
Amendment Manager: User entered '24 Jul 2022 00:01'	System	20 Nov 2020 05:39:53

US3342200

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:05:26

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:39:53
Amendment Manager: User entered '28 Jul 2022 23:59'	System	20 Nov 2020 05:39:53

US3342200

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:05:26

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:39:53
Amendment Manager: User entered 'Day 698'	System	20 Nov 2020 05:39:53

US3342200

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:05:26

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:39:53
Amendment Manager: User entered '31 Jul 2022 00:01'	System	20 Nov 2020 05:39:53

US3342200

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:05:26

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:39:53
Amendment Manager: User entered '04 Aug 2022 23:59'	System	20 Nov 2020 05:39:53

US3342200

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:05:26

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:39:53
Amendment Manager: User entered 'Day 705'	System	20 Nov 2020 05:39:53

US3342200

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:05:26

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:39:53
Amendment Manager: User entered '07 Aug 2022 00:01'	System	20 Nov 2020 05:39:53

US3342200

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:05:26

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:39:53
Amendment Manager: User entered '11 Aug 2022 23:59'	System	20 Nov 2020 05:39:53

US3342200

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:05:26

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:39:53
Amendment Manager: User entered 'Day 712'	System	20 Nov 2020 05:39:53

US3342200

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:05:26

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:39:53
Amendment Manager: User entered '14 Aug 2022 00:01'	System	20 Nov 2020 05:39:53

US3342200

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:05:26

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:39:53
Amendment Manager: User entered '18 Aug 2022 23:59'	System	20 Nov 2020 05:39:53

US3342200

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:05:26

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:39:53
Amendment Manager: User entered 'Day 719'	System	20 Nov 2020 05:39:53

US3342200

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:05:26

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:39:53
Amendment Manager: User entered '21 Aug 2022 00:01'	System	20 Nov 2020 05:39:53

US3342200

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:05:26

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:39:53
Amendment Manager: User entered '25 Aug 2022 23:59'	System	20 Nov 2020 05:39:53

US3342200

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:05:26

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:39:53
Amendment Manager: User entered 'Day 726'	System	20 Nov 2020 05:39:53

US3342200

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:05:26

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:39:53
Amendment Manager: User entered '28 Aug 2022 00:01'	System	20 Nov 2020 05:39:53

US3342200

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:05:26

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:39:53
Amendment Manager: User entered '01 Sep 2022 23:59'	System	20 Nov 2020 05:39:53

US3342200

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:05:26

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:39:53
Amendment Manager: User entered 'Day 733'	System	20 Nov 2020 05:39:53

US3342200

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:05:26

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:39:53
Amendment Manager: User entered '04 Sep 2022 00:01'	System	20 Nov 2020 05:39:53

US3342200

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:05:26

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:39:53
Amendment Manager: User entered '08 Sep 2022 23:59'	System	20 Nov 2020 05:39:53

US3342200

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:05:26

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:39:53
Amendment Manager: User entered 'Day 740'	System	20 Nov 2020 05:39:53

US3342200

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:05:26

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:39:53
Amendment Manager: User entered '11 Sep 2022 00:01'	System	20 Nov 2020 05:39:53

US3342200

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:05:26

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:39:53
Amendment Manager: User entered '15 Sep 2022 23:59'	System	20 Nov 2020 05:39:53

US3342200

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:05:26

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:39:53
Amendment Manager: User entered 'Day 747'	System	20 Nov 2020 05:39:53

US3342200

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:05:26

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:39:53
Amendment Manager: User entered '18 Sep 2022 00:01'	System	20 Nov 2020 05:39:53

US3342200

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:05:26

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:39:53
Amendment Manager: User entered '22 Sep 2022 23:59'	System	20 Nov 2020 05:39:53

US3342200

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:05:26

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:39:53
Amendment Manager: User entered 'Day 754'	System	20 Nov 2020 05:39:53

US3342200

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:05:26

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:39:53
Amendment Manager: User entered '25 Sep 2022 00:01'	System	20 Nov 2020 05:39:53

US3342200

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:05:26

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:39:53
Amendment Manager: User entered '29 Sep 2022 23:59'	System	20 Nov 2020 05:39:53

US3342200

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:05:26

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:39:53
Amendment Manager: User entered 'Day 761'	System	20 Nov 2020 05:39:53

US3342200

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:05:26

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:39:53
Amendment Manager: User entered '02 Oct 2022 00:01'	System	20 Nov 2020 05:39:53

US3342200

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:05:26

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:39:53
Amendment Manager: User entered '06 Oct 2022 23:59'	System	20 Nov 2020 05:39:53

US3342200

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:05:26

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:39:53
Amendment Manager: User entered 'Day 768'	System	20 Nov 2020 05:39:53

US3342200

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:05:26

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:39:53
Amendment Manager: User entered '09 Oct 2022 00:01'	System	20 Nov 2020 05:39:53

US3342200

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:05:26

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:39:53
Amendment Manager: User entered '13 Oct 2022 23:59'	System	20 Nov 2020 05:39:53

US3342200

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:05:26

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:39:53
Amendment Manager: User entered 'Day 775'	System	20 Nov 2020 05:39:53

US3342200

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:05:26

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:39:53
Amendment Manager: User entered '16 Oct 2022 00:01'	System	20 Nov 2020 05:39:53

US3342200

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:05:26

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:39:53
Amendment Manager: User entered '20 Oct 2022 23:59'	System	20 Nov 2020 05:39:53

US3342200

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:05:26

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:39:53
Amendment Manager: User entered 'Day 782'	System	20 Nov 2020 05:39:53

US3342200

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:05:26

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:39:53
Amendment Manager: User entered '23 Oct 2022 00:01'	System	20 Nov 2020 05:39:53

US3342200

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:05:26

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:39:53
Amendment Manager: User entered '27 Oct 2022 23:59'	System	20 Nov 2020 05:39:53

US3342200

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:05:26

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:39:53
Amendment Manager: User entered 'Day 789'	System	20 Nov 2020 05:39:53

US3342200

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:05:26

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:39:53
Amendment Manager: User entered '30 Oct 2022 00:01'	System	20 Nov 2020 05:39:53

US3342200

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:05:26

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:39:53
Amendment Manager: User entered '03 Nov 2022 23:59'	System	20 Nov 2020 05:39:53

US3342200

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:05:26

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:39:53
Amendment Manager: User entered 'Day 796'	System	20 Nov 2020 05:39:53

US3342200

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:05:26

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:39:53
Amendment Manager: User entered '06 Nov 2022 00:01'	System	20 Nov 2020 05:39:53

US3342200

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:05:26

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:39:53
Amendment Manager: User entered '10 Nov 2022 23:59'	System	20 Nov 2020 05:39:53

US3342200

Folder: Cosmetic Injections and Dermal Fillers

Form: Cosmetic Injection_ Dermal Filler eDiary (1)

Generated On: 09 Jun 2021 17:05:26

Have you ever received facial cosmetic injections, such as Juvederm, Voluma, Radiesse, Restylane, Botox or other?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 02:06:47
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2D2D1647-7C35-4DCA-ADA3-8E1DAA921DDC)', Time: '2021-02-28T00:32:22-06:00', User OID: 'PatientReportedOutcome (US3342200)', ODM File OID: '5551672f-ec29-466a-b69d-d8757cdcecd0'	System	28 Feb 2021 06:32:28
User entered 'No (N)'	System	28 Feb 2021 06:32:28

US3342200

Folder: Cosmetic Injections and Dermal Fillers

Form: Cosmetic Injection_ Dermal Filler eDiary (1)

Generated On: 09 Jun 2021 17:05:26

[Date & Time of Submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 02:06:47
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2D2D1647-7C35-4DCA-ADA3-8E1DAA921DDC)', Time: '2021-02-28T00:32:26-06:00', User OID: 'PatientReportedOutcome (US3342200)', ODM File OID: '5551672f-ec29-466a-b69d-d8757cdcecd0' User entered '28 Feb 2021 06:32:26'	System	28 Feb 2021 06:32:28
	System	28 Feb 2021 06:32:28

US3342200

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:05:26

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 16:42:07
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 16:12:04
User entered 'Yes (Y)'	(b) (4) Stefanie Mott (b) (4)	23 Nov 2020 22:50:24

US3342200

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:05:26

Date of Contact or Contact Attempt (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 16:42:07
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 16:12:04
User entered '23 Nov 2020'	(b) (4) Stefanie Mott (b) (4)	23 Nov 2020 22:50:24

US3342200

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:05:26

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 16:42:07
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 16:12:04
User entered 'Contact Made (CONTACT MADE)'	(b) (4) Stefanie Mott (b) (4)	23 Nov 2020 22:50:24

US3342200

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:05:26

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 16:42:07
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 16:12:04
User entered empty.	(b) (4) Stefanie Mott (b) (4)	23 Nov 2020 22:50:24

US3342200

Folder: Safety Call Day 85 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:05:26

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 16:42:07
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:24:15
User entered 'Yes (Y)'	(b) (4) Stefanie Mott (b) (4)	23 Nov 2020 22:50:29

US3342200

Folder: Safety Call Day 85 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:05:26

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 16:42:07
User entered 'I'	System	23 Nov 2020 22:50:29

US3342200

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:05:26

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:52:03
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:24:15
User entered 'Yes (Y)'	Ethan Shotton (b) (4)	30 Dec 2020 22:04:39

US3342200

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:05:26

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:52:03
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:24:15
User entered '30 Dec 2020'	Ethan Shotton (b) (4)	30 Dec 2020 22:04:39

US3342200

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:05:26

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:52:03
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:24:15
User entered 'Contact Made (CONTACT MADE)'	Ethan Shotton (b) (4)	30 Dec 2020 22:04:39

US3342200

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:05:26

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:52:03
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:24:15
User entered empty.	Ethan Shotton (b) (4)	30 Dec 2020 22:04:39

US3342200

Folder: Safety Call Day 119 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:05:26

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:52:03
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:24:15
User entered 'Yes (Y)'	Ethan Shotton (b) (4)	30 Dec 2020 22:04:44

US3342200

Folder: Safety Call Day 119 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:05:26

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:52:03
User entered 'I'	System	30 Dec 2020 22:04:44

US3342200

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:05:26

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:52:03
User signature succeeded.	Paul Pickrell (b) (4)	29 Mar 2021 15:07:52
User entered 'Yes (Y)'	Ethan Shotton (b) (4)	17 Mar 2021 21:22:56

US3342200

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:05:26

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:52:03
User signature succeeded.	Paul Pickrell (b) (4)	29 Mar 2021 15:07:52
User entered '25 Jan 2021'	Ethan Shotton (b) (4)	17 Mar 2021 21:22:56

US3342200

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:05:26

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:52:03
User signature succeeded.	Paul Pickrell (b) (4)	29 Mar 2021 15:07:52
User entered 'Contact Made (CONTACT MADE)'	Ethan Shotton (b) (4)	17 Mar 2021 21:22:56

US3342200

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:05:26

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:52:03
User signature succeeded.	Paul Pickrell (b) (4)	29 Mar 2021 15:07:52
User entered empty.	Ethan Shotton (b) (4)	17 Mar 2021 21:22:56

US3342200

Folder: Safety Call Day 149 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:05:26

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:52:03
User signature succeeded.	Paul Pickrell (b) (4)	29 Mar 2021 15:07:52
User entered 'Yes (Y)'	Ethan Shotton (b) (4)	17 Mar 2021 21:23:02

US3342200

Folder: Safety Call Day 149 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:05:26

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:52:03
User entered 'I'	System	17 Mar 2021 21:23:02

US3342200

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:05:26

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:52:03
User signature succeeded.	Paul Pickrell (b) (4)	29 Mar 2021 15:07:52
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	19 Mar 2021 13:22:00

US3342200

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:05:26

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:52:03
User signature succeeded.	Paul Pickrell (b) (4)	29 Mar 2021 15:07:52
User entered empty.	(b) (4) (b) (4), (b) (6)	19 Mar 2021 13:22:00

US3342200

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:05:26

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:52:03
User signature succeeded.	Paul Pickrell (b) (4)	29 Mar 2021 15:07:52
User entered empty.	(b) (4) (b) (4), (b) (6)	19 Mar 2021 13:22:00

US3342200

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:05:26

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:52:03
User signature succeeded.	Paul Pickrell (b) (4)	29 Mar 2021 15:07:52
User entered 'Visit was cancelled due to site closure (winter storm uri). PD noted.'	(b) (4) (b) (4), (b) (6)	19 Mar 2021 13:22:00

US3342200

Folder: Safety Call Day 179 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:05:26

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:52:03
User signature succeeded.	Paul Pickrell (b) (4)	29 Mar 2021 15:07:52
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	19 Mar 2021 13:22:13

US3342200

Folder: Safety Call Day 179 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:05:26

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:52:03
User entered 'I'	System	19 Mar 2021 13:22:13

US3342200

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Generated On: 09 Jun 2021 17:05:26

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:18:40
User signature succeeded.	Paul Pickrell (b) (4)	29 Mar 2021 15:07:52
User entered 'Yes (Y)'	John Luna (b) (4)	26 Mar 2021 21:49:22

US3342200

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Generated On: 09 Jun 2021 17:05:26

[Visit date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:18:40
User signature succeeded.	Paul Pickrell (b) (4)	29 Mar 2021 15:07:52
User entered '26 Mar 2021'	John Luna (b) (4)	26 Mar 2021 21:49:22

US3342200

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Generated On: 09 Jun 2021 17:05:26

[Was visit performed at the participant's home or at the clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:18:40
User signature succeeded.	Paul Pickrell (b) (4)	29 Mar 2021 15:07:52
User entered 'Clinic (Clinic)'	John Luna (b) (4)	26 Mar 2021 21:49:22

US3342200

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Generated On: 09 Jun 2021 17:05:26

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:18:40
User entered 'VISIT4'	System	26 Mar 2021 21:49:22

US3342200

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:05:26

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:18:40
User signature succeeded.	Paul Pickrell (b) (4)	12 Apr 2021 15:51:34
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	31 Mar 2021 20:38:41

US3342200

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:05:26

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:18:40
User signature succeeded.	Paul Pickrell (b) (4)	12 Apr 2021 15:51:34
User entered '26 Mar 2021'	(b) (4) (b) (4), (b) (6)	31 Mar 2021 20:38:41

US3342200

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:05:26

Time of assessment (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:18:40
User signature succeeded.	Paul Pickrell (b) (4)	12 Apr 2021 15:51:34
User entered '15:50'	(b) (4) (b) (4), (b) (6)	31 Mar 2021 20:38:41

US3342200

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:05:26

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:18:40
User entered '26 Mar 2021 15:50'	System	31 Mar 2021 20:38:41

US3342200

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:05:26

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:18:40
User signature succeeded.	Paul Pickrell (b) (4)	12 Apr 2021 15:51:34
User entered '98.2' F	(b) (4) (b) (4), (b) (6)	31 Mar 2021 20:38:41

US3342200

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:05:26

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:18:40
User signature succeeded.	Paul Pickrell (b) (4)	12 Apr 2021 15:51:34
User entered 'Oral (Oral)'	(b) (4) (b) (4), (b) (6)	31 Mar 2021 20:38:41

US3342200

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:05:26

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:18:40
User signature succeeded.	Paul Pickrell (b) (4)	12 Apr 2021 15:51:34
User entered empty.	(b) (4) (b) (4), (b) (6)	31 Mar 2021 20:38:41

US3342200

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:05:26

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:18:40
User signature succeeded.	Paul Pickrell (b) (4)	12 Apr 2021 15:51:34
User entered '76'	(b) (4) (b) (4), (b) (6)	31 Mar 2021 20:38:41

US3342200

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:05:26

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:18:40
User entered 'bpm'	System	31 Mar 2021 20:38:41

US3342200

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:05:26

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:18:40
User signature succeeded.	Paul Pickrell (b) (4)	12 Apr 2021 15:51:34
User entered '12'	(b) (4) (b) (4), (b) (6)	31 Mar 2021 20:38:41

US3342200

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:05:26

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:18:40
User entered 'breaths/min'	System	31 Mar 2021 20:38:41

US3342200

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:05:26

[Systolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:18:40
User signature succeeded.	Paul Pickrell (b) (4)	12 Apr 2021 15:51:34
User entered '112'	(b) (4) (b) (4), (b) (6)	31 Mar 2021 20:38:41

US3342200

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:05:26

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:18:40
User entered 'mmHg'	System	31 Mar 2021 20:38:41

US3342200

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:05:26

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:18:40
User signature succeeded.	Paul Pickrell (b) (4)	12 Apr 2021 15:51:34
User entered '75'	(b) (4) (b) (4), (b) (6)	31 Mar 2021 20:38:41

US3342200

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:05:26

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:18:40
User entered 'mmHg'	System	31 Mar 2021 20:38:41

US3342200

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:05:26

Height (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:18:40

US3342200

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:05:26

[Weight \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:18:40

US3342200

Folder: Visit 4 Day 209 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 17:05:26

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:18:40
User signature succeeded.	Paul Pickrell (b) (4)	29 Mar 2021 15:07:52
User entered 'Yes (Y)'	John Luna (b) (4)	26 Mar 2021 21:49:36

US3342200

Folder: Visit 4 Day 209 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 17:05:26

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:18:40
User signature succeeded.	Paul Pickrell (b) (4)	29 Mar 2021 15:07:52
User entered '26 Mar 2021'	John Luna (b) (4)	26 Mar 2021 21:49:36

US3342200

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:05:26

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:18:40
User signature succeeded.	Paul Pickrell (b) (4)	12 Apr 2021 15:51:34
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	31 Mar 2021 20:43:39

US3342200

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:05:26

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:18:40
User signature succeeded.	Paul Pickrell (b) (4)	12 Apr 2021 15:51:34
User entered '26 Mar 2021'	(b) (4) (b) (4), (b) (6)	31 Mar 2021 20:43:39

US3342200

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:05:26

[Collection time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:18:40
User signature succeeded.	Paul Pickrell (b) (4)	12 Apr 2021 15:51:34
User entered '16:33'	(b) (4) (b) (4), (b) (6)	31 Mar 2021 20:43:39

US3342200

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:05:26

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:18:40
User entered '26 Mar 2021 16:33'	System	31 Mar 2021 20:43:39

US3342200

Folder: Visit 4 Day 209 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:05:26

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:18:40
User signature succeeded.	Paul Pickrell (b) (4)	29 Mar 2021 15:07:52
User entered 'Yes (Y)'	John Luna (b) (4)	26 Mar 2021 21:49:46

US3342200

Folder: Visit 4 Day 209 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:05:26

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:18:40
User entered 'I'	System	26 Mar 2021 21:49:46

US3342200

Folder: Safety Call Day 239 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:05:26

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Pickrell (b) (4)	28 Apr 2021 22:33:29
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	28 Apr 2021 17:33:20

US3342200

Folder: Safety Call Day 239 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:05:26

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Paul Pickrell (b) (4)	28 Apr 2021 22:33:29
User entered '28 Apr 2021'	(b) (4) (b) (4), (b) (6)	28 Apr 2021 17:33:20

US3342200

Folder: Safety Call Day 239 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:05:26

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Pickrell (b) (4)	28 Apr 2021 22:33:29
User entered 'Contact Made (CONTACT MADE)'	(b) (4) (b) (4), (b) (6)	28 Apr 2021 17:33:20

US3342200

Folder: Safety Call Day 239 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:05:26

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
User signature succeeded.	Paul Pickrell (b) (4)	28 Apr 2021 22:33:29
User entered empty.	(b) (4) (b) (4), (b) (6)	28 Apr 2021 17:33:20

US3342200

Folder: Safety Call Day 239 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:05:26

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Pickrell (b) (4)	28 Apr 2021 22:33:29
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	28 Apr 2021 17:33:12

US3342200

Folder: Safety Call Day 239 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:05:26

[Continuing Flag](#)

Audit	User	Time (GMT)
User entered 'I'	System	28 Apr 2021 17:33:12

US3342200

Folder: Participant Decision Visit / OL-D1 (1)

Form: Visit Date

Generated On: 09 Jun 2021 17:05:26

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 00:12:35
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:24:15
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	15 Jan 2021 21:29:38

US3342200

Folder: Participant Decision Visit / OL-D1 (1)

Form: Visit Date

Generated On: 09 Jun 2021 17:05:26

[Visit date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 00:12:35
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:24:15
User entered '15 Jan 2021'	(b) (4) (b) (4), (b) (6)	15 Jan 2021 21:29:38

US3342200

Folder: Participant Decision Visit / OL-D1 (1)

Form: Visit Date

Generated On: 09 Jun 2021 17:05:26

[Was visit performed at the participant's home or at the clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 00:12:35
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:24:15
User entered 'Clinic (Clinic)'	(b) (4) (b) (4), (b) (6)	15 Jan 2021 21:29:38

US3342200

Folder: Participant Decision Visit / OL-D1 (1)

Form: Visit Date

Generated On: 09 Jun 2021 17:05:26

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 00:12:35
User entered 'UNBLND_DECIDE'	System	15 Jan 2021 21:29:38

US3342200

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 09 Jun 2021 17:05:26

Date of updated informed consent (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 00:12:35
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:24:15
User entered '15 Jan 2021'	(b) (4) (b) (4), (b) (6)	15 Jan 2021 21:30:02

US3342200

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 09 Jun 2021 17:05:26

[N/A - Subject Unblinded under Amendment 5 and Discontinued from Study](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 00:12:35
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:24:15
User entered '0'	Ethan Shotton (b) (4)	09 Mar 2021 13:44:13
Amendment Manager inserted this DataPoint.	System	06 Mar 2021 18:42:02

US3342200

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 09 Jun 2021 17:05:26

[Was the participant unblinded?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 00:12:35
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:24:15
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	15 Jan 2021 21:30:02

US3342200

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 09 Jun 2021 17:05:26

[Under what version of the Protocol was the Participant unblinded?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 00:12:35
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:24:15
User entered 'Amendment 6 or later (Amendment 6 or later)'	Ethan Shotton (b) (4)	09 Mar 2021 13:44:13
Amendment Manager inserted this DataPoint.	System	06 Mar 2021 18:42:02

US3342200

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 09 Jun 2021 17:05:26

Date of unblinding (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 00:12:35
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:24:15
User entered '15 Jan 2021'	(b) (4) (b) (4), (b) (6)	15 Jan 2021 21:30:02

US3342200

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 09 Jun 2021 17:05:26

[Participant randomization assignment](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 00:12:35
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:24:15
User entered 'Placebo (Placebo)'	(b) (4) (b) (4), (b) (6)	15 Jan 2021 21:30:02

US3342200

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 09 Jun 2021 17:05:26

[Actual Dose 1](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 00:12:35
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:24:15
Amendment Manager: User entered 'Placebo (Placebo)'	(b) (4)	20 Jan 2021 14:13:35
User entered 'Placebo (Placebo)'	(b) (4), (b) (6)	15 Jan 2021 21:30:02

US3342200

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 09 Jun 2021 17:05:26

[Actual Dose 2](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 00:12:35
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:24:15
Amendment Manager: User entered 'Placebo (Placebo)'	(b) (4)	20 Jan 2021 14:13:35
User entered 'Placebo (Placebo)'	(b) (4), (b) (6)	15 Jan 2021 21:30:02

US3342200

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 09 Jun 2021 17:05:26

[Will participant receive mRNA-1273?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 00:12:35
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:24:15
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	15 Jan 2021 21:30:02

US3342200

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 09 Jun 2021 17:05:26

[Placebo Only Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 00:12:35
User entered '1'	System	15 Jan 2021 21:30:02

US3342200

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 09 Jun 2021 17:05:26

[Continuing with mRNA-1273](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 00:12:35
User entered 'I'	System	15 Jan 2021 21:30:02

US3342200

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 17:05:26

[Height](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 00:12:35
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:24:15
User entered '163.5' cm	(b) (4) (b) (4), (b) (6)	15 Jan 2021 21:38:57

US3342200

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 17:05:26

Weight

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 00:12:35
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:24:15
User entered '65.4' kg	(b) (4) (b) (4), (b) (6)	15 Jan 2021 21:38:57

US3342200

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 17:05:26

BMI (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 00:12:35
User entered '24.46483'	System	15 Jan 2021 21:38:57
DataPoint set to visible.	System	15 Jan 2021 21:30:02

US3342200

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 17:05:26

[Height](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 00:12:35
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:24:15
User entered '163.5' cm	(b) (4) (b) (4), (b) (6)	15 Jan 2021 21:38:57

US3342200

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 17:05:26

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 00:12:35
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:24:15
User entered '65.4' kg	(b) (4) (b) (4), (b) (6)	15 Jan 2021 21:38:57

US3342200

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 17:05:26

BMI (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 00:12:35
User entered '24.46483'	System	15 Jan 2021 21:38:57
DataPoint set to visible.	System	15 Jan 2021 21:30:02

US3342200

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:05:26

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 00:12:35
User accepted default value 'Pre-Dose (PREDOSE)'	(b) (4), (b) (6)	15 Jan 2021 21:38:57

US3342200

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:05:26

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 00:12:35
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:24:15
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	15 Jan 2021 21:38:57

US3342200

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:05:26

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 00:12:35
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:24:15
User entered '15 Jan 2021'	(b) (4) (b) (4), (b) (6)	15 Jan 2021 21:38:57

US3342200

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:05:26

[Time of assessment \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 00:12:35
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:24:15
User entered '13:52'	(b) (4) (b) (4), (b) (6)	15 Jan 2021 21:38:57

US3342200

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:05:26

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 00:12:35
User entered '15 Jan 2021 13:52'	System	15 Jan 2021 21:38:57

US3342200

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:05:26

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 00:12:35
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:24:15
User entered '97.9' F	(b) (4) (b) (4), (b) (6)	15 Jan 2021 21:38:57

US3342200

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:05:26

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 00:12:35
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:24:15
User entered 'Oral (Oral)'	(b) (4) (b) (4), (b) (6)	15 Jan 2021 21:38:57

US3342200

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:05:26

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 00:12:35
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:24:15
User entered empty.	(b) (4) (b) (4), (b) (6)	15 Jan 2021 21:38:57

US3342200

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:05:26

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 00:12:35
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:24:15
User entered '79'	(b) (4) (b) (4), (b) (6)	15 Jan 2021 21:38:57

US3342200

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:05:26

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 00:12:35
User entered 'bpm'	System	15 Jan 2021 21:38:57

US3342200

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:05:26

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 00:12:35
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:24:15
User entered '14'	(b) (4) (b) (4), (b) (6)	15 Jan 2021 21:38:57

US3342200

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:05:26

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 00:12:35
User entered 'breaths/min'	System	15 Jan 2021 21:38:57

US3342200

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:05:26

[Systolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 00:12:35
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:24:15
User entered '127'	(b) (4) (b) (4), (b) (6)	15 Jan 2021 21:38:57

US3342200

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:05:26

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 00:12:35
User entered 'mmHg'	System	15 Jan 2021 21:38:57

US3342200

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:05:26

[Diastolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 00:12:35
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:24:15
User entered '85'	(b) (4) (b) (4), (b) (6)	15 Jan 2021 21:38:57

US3342200

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:05:26

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 00:12:35
User entered 'mmHg'	System	15 Jan 2021 21:38:57

US3342200

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 17:05:26

[Height](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 00:12:35
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:24:15
User entered '163.5' cm	(b) (4) (b) (4), (b) (6)	15 Jan 2021 21:38:57

US3342200

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 17:05:26

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 00:12:35
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:24:15
User entered '65.4' kg	(b) (4) (b) (4), (b) (6)	15 Jan 2021 21:38:57

US3342200

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 17:05:26

BMI (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 00:12:35
User entered '24.46483'	System	15 Jan 2021 21:38:57
DataPoint set to visible.	System	15 Jan 2021 21:30:02

US3342200

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:05:26

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 00:12:35
User accepted default value 'Post-Dose (POSTDOSE)'	(b) (4), (b) (6)	15 Jan 2021 21:38:57

US3342200

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:05:26

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 00:12:35
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:24:15
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	15 Jan 2021 21:38:57

US3342200

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:05:26

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 00:12:35
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:24:15
User entered '15 Jan 2021'	(b) (4) (b) (4), (b) (6)	15 Jan 2021 21:38:57

US3342200

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:05:26

Time of assessment (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 00:12:35
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:24:15
User entered '15:33'	(b) (4) (b) (4), (b) (6)	15 Jan 2021 21:38:57

US3342200

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:05:26

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 00:12:35
User entered '15 Jan 2021 15:33'	System	15 Jan 2021 21:38:57

US3342200

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:05:26

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 00:12:35
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:24:15
User entered '97.0' F	(b) (4) (b) (4), (b) (6)	15 Jan 2021 21:38:57

US3342200

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:05:26

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 00:12:35
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:24:15
User entered 'Oral (Oral)'	(b) (4) (b) (4), (b) (6)	15 Jan 2021 21:38:57

US3342200

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:05:26

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 00:12:35
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:24:15
User entered empty.	(b) (4) (b) (4), (b) (6)	15 Jan 2021 21:38:57

US3342200

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:05:26

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 00:12:35
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:24:15
User entered '74'	(b) (4) (b) (4), (b) (6)	15 Jan 2021 21:38:57

US3342200

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:05:26

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 00:12:35
User entered 'bpm'	System	15 Jan 2021 21:38:57

US3342200

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:05:26

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 00:12:35
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:24:15
User entered '16'	(b) (4) (b) (4), (b) (6)	15 Jan 2021 21:38:57

US3342200

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:05:26

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 00:12:35
User entered 'breaths/min'	System	15 Jan 2021 21:38:57

US3342200

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:05:26

[Systolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 00:12:35
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:24:15
User entered '123'	(b) (4) (b) (4), (b) (6)	15 Jan 2021 21:38:57

US3342200

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:05:26

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 00:12:35
User entered 'mmHg'	System	15 Jan 2021 21:38:57

US3342200

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:05:26

[Diastolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 00:12:35
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:24:15
User entered '83'	(b) (4) (b) (4), (b) (6)	15 Jan 2021 21:38:57

US3342200

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:05:26

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 00:12:35
User entered 'mmHg'	System	15 Jan 2021 21:38:57

US3342200

Folder: Participant Decision Visit / OL-D1 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 17:05:26

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 00:12:35
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:24:15
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	15 Jan 2021 21:46:05

US3342200

Folder: Participant Decision Visit / OL-D1 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 17:05:26

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 00:12:35
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:24:15
User entered '15 Jan 2021'	(b) (4) (b) (4), (b) (6)	15 Jan 2021 21:46:05

US3342200

Folder: Participant Decision Visit / OL-D1 (1)

Form: Exposure

Generated On: 09 Jun 2021 17:05:26

[Was study treatment given?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 00:12:35
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:24:15
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Mar 2021 18:05:41
User entered 'Yes (Y)'	(b) (4), (b) (6)	15 Jan 2021 21:46:31

US3342200

Folder: Participant Decision Visit / OL-D1 (1)

Form: Exposure

Generated On: 09 Jun 2021 17:05:26

[If No, reason not given](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 00:12:35
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:24:15
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Mar 2021 18:05:41
User entered empty.	(b) (4), (b) (6)	15 Jan 2021 21:46:31

US3342200

Folder: Participant Decision Visit / OL-D1 (1)

Form: Exposure

Generated On: 09 Jun 2021 17:05:26

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)	26 Apr 2021 00:12:35
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:24:15
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Mar 2021 18:05:41
User entered empty.	(b) (4), (b) (6)	15 Jan 2021 21:46:31

US3342200

Folder: Participant Decision Visit / OL-D1 (1)

Form: Exposure

Generated On: 09 Jun 2021 17:05:26

[What was the study treatment? \(Unblinded\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 00:12:35
User entered 'mRNA-1273'	System	15 Jan 2021 21:46:31
DataPoint set to visible.	System	15 Jan 2021 21:30:02

US3342200

Folder: Participant Decision Visit / OL-D1 (1)

Form: Exposure

Generated On: 09 Jun 2021 17:05:26

What was the treatment date? (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 00:12:35
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:24:15
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Mar 2021 18:05:41
User entered '15 Jan 2021'	(b) (4), (b) (6)	15 Jan 2021 21:46:31

US3342200

Folder: Participant Decision Visit / OL-D1 (1)

Form: Exposure

Generated On: 09 Jun 2021 17:05:26

[What was the treatment time? \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 00:12:35
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:24:15
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Mar 2021 18:05:41
User entered '15:03'	(b) (4), (b) (6)	15 Jan 2021 21:46:31

US3342200

Folder: Participant Decision Visit / OL-D1 (1)

Form: Exposure

Generated On: 09 Jun 2021 17:05:26

[Treatment Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 00:12:35
User entered '15 Jan 2021 15:03'	System	15 Jan 2021 21:46:31

US3342200

Folder: Participant Decision Visit / OL-D1 (1)

Form: Exposure

Generated On: 09 Jun 2021 17:05:26

[Which arm was used to give treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 00:12:35
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:24:15
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Mar 2021 18:05:41
User entered 'Left Arm (LEFT ARM)'	(b) (4), (b) (6)	15 Jan 2021 21:46:31

US3342200

Folder: Participant Decision Visit / OL-D1 (1)

Form: Exposure

Generated On: 09 Jun 2021 17:05:26

[What was the frequency of the study treatment dosing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 00:12:35
DataPoint Verified.	(b) (4), (b) (6)	03 Mar 2021 18:05:41
User entered 'ONCE'	System	15 Jan 2021 21:46:31

US3342200

Folder: Participant Decision Visit / OL-D1 (1)

Form: Exposure

Generated On: 09 Jun 2021 17:05:26

What was the route of administration for the study treatment?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 00:12:35
User entered 'INTRAMUSCULAR'	System	15 Jan 2021 21:46:31

US3342200

Folder: Participant Decision Visit / OL-D1 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:05:26

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 00:12:35
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:24:15
User entered 'Yes (Y)'	Morgan Schulle (b) (4)	19 Jan 2021 20:31:13

US3342200

Folder: Participant Decision Visit / OL-D1 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:05:26

Collection date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 00:12:35
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:24:15
User closed query 'Per GCL Lab Reconciliation: Antibody-mediated Immunogenicity: Per GCL, no immunogenicity sample was received for the Participant Decision Visit/ OL-D1 on 15Jan2021. Please provide accession number and tracking or clarify. Thank you.' (Site from DM). Query 'Per GCL Lab Reconciliation: Antibody-mediated Immunogenicity: Per GCL, no immunogenicity sample was received for the Participant Decision Visit/ OL-D1 on 15Jan2021. Please provide accession number and tracking or clarify. Thank you.' answered with 'all immuno samples accessioned in req 1F621467741' (Site from DM).	(b) (4) (b) (4), (b) (6)	15 Feb 2021 14:37:28
User opened query 'Per GCL Lab Reconciliation: Antibody-mediated Immunogenicity: Per GCL, no immunogenicity sample was received for the Participant Decision Visit/ OL-D1 on 15Jan2021. Please provide accession number and tracking or clarify. Thank you.' (Site from DM).	Eileen Euperio (b) (4) (b) (4)	05 Feb 2021 16:52:33
User entered '15 Jan 2021'	(b) (4), (b) (6)	04 Feb 2021 18:43:00
	Morgan Schulle (b) (4) (b) (4)	19 Jan 2021 20:31:13

US3342200

Folder: Participant Decision Visit / OL-D1 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:05:26

[Collection time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 00:12:35
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:24:15
User entered '14:30'	Morgan Schulle (b) (4)	19 Jan 2021 20:31:13

US3342200

Folder: Participant Decision Visit / OL-D1 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:05:26

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 00:12:35
User entered '15 Jan 2021 14:30'	System	19 Jan 2021 20:31:13

US3342200

Folder: Participant Decision Visit / OL-D1 (1)

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 09 Jun 2021 17:05:26

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 00:12:35
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:24:15
User entered 'Yes (Y)'	Morgan Schulle (b) (4)	19 Jan 2021 20:31:03

US3342200

Folder: Participant Decision Visit / OL-D1 (1)

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 09 Jun 2021 17:05:26

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 00:12:35
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:24:15
User entered '15 Jan 2021'	Morgan Schulle (b) (4)	19 Jan 2021 20:31:03

US3342200

Folder: Participant Decision Visit / OL-D1 (1)

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 09 Jun 2021 17:05:26

[Collection time \(00:00 - 23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 00:12:35
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:24:15
User entered '14:31'	Morgan Schulle (b) (4)	19 Jan 2021 20:31:03

US3342200

Folder: Participant Decision Visit / OL-D1 (1)

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 09 Jun 2021 17:05:26

[Collection Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 00:12:35
User entered '15 Jan 2021 14:31'	System	19 Jan 2021 20:31:03

US3342200

Folder: Participant Decision Visit / OL-D1 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:05:26

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 00:12:35
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:24:15
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	15 Jan 2021 21:47:01

US3342200

Folder: Participant Decision Visit / OL-D1 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:05:26

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 00:12:35
User entered 'I'	System	15 Jan 2021 21:47:01

US3342200

Folder: Safety Call OL-D8 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:05:26

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 00:12:35
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 16:12:04
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	22 Jan 2021 22:45:52

US3342200

Folder: Safety Call OL-D8 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:05:26

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 00:12:35
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 16:12:04
User entered '22 Jan 2021'	(b) (4) (b) (4), (b) (6)	22 Jan 2021 22:45:52

US3342200

Folder: Safety Call OL-D8 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:05:26

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 00:12:35
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 16:12:04
User entered 'Contact Made (CONTACT MADE)'	(b) (4) (b) (4), (b) (6)	22 Jan 2021 22:45:52

US3342200

Folder: Safety Call OL-D8 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:05:26

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 00:12:35
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 16:12:04
User entered empty.	(b) (4), (b) (6)	22 Jan 2021 22:45:52

US3342200

Folder: Safety Call OL-D8 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:05:26

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 00:12:35
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 16:12:04
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	22 Jan 2021 22:45:57

US3342200

Folder: Safety Call OL-D8 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:05:26

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 00:12:35
User entered 'I'	System	22 Jan 2021 22:45:57

US3342200

Folder: Safety Call OL-D8 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:05:26

[OLD29 Placebo Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 00:12:35
User entered '1'	System	22 Jan 2021 22:45:57
DataPoint set to visible.	System	22 Jan 2021 22:45:57

US3342200

Folder: OL-D29 (1)

Form: Visit Date

Generated On: 09 Jun 2021 17:05:26

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 00:12:35
User signature succeeded.	Paul Pickrell (b) (4)	29 Mar 2021 15:07:52
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	23 Feb 2021 16:40:32

US3342200

Folder: OL-D29 (1)

Form: Visit Date

Generated On: 09 Jun 2021 17:05:26

Visit date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 00:12:35
User signature succeeded.	Paul Pickrell (b) (4)	29 Mar 2021 15:07:52
User closed query 'Per GCL Lab Reconciliation: Antibody-mediated Immunogenicity: Sample dated 23FEB2021 is recorded under Participant Decision Visit OL-D29/OL-2 visit in PPD Central Lab, however the same is missing in EDC. Please review and update the sample data in EDC per CCGs V.5.0 page 34-35 by initiating Immunogenicity Assessment eCRF under this folder as appropriate. Else Clarify, Thank you' (Site from DM).	(b) (4), (b) (6)	16 Mar 2021 14:14:20
Query 'Per GCL Lab Reconciliation: Antibody-mediated Immunogenicity: Sample dated 23FEB2021 is recorded under Participant Decision Visit OL-D29/OL-2 visit in PPD Central Lab, however the same is missing in EDC. Please review and update the sample data in EDC per CCGs V.5.0 page 34-35 by initiating Immunogenicity Assessment eCRF under this folder as appropriate. Else Clarify, Thank you' answered with 'please clarify as this lab data has been entered as "unscheduled 23Feb2021" below in EDC. unable to enter info under OL-D29 folder, which is why unscheduled visit was created for immunogenicity assessment.' (Site from DM).	Olivia Hapanowicz (b) (4)	15 Mar 2021 13:34:23
User opened query 'Per GCL Lab Reconciliation: Antibody-mediated Immunogenicity: Sample dated 23FEB2021 is recorded under Participant Decision Visit OL-D29/OL-2 visit in PPD Central Lab, however the same is missing in EDC. Please review and update the sample data in EDC per CCGs V.5.0 page 34-35 by initiating Immunogenicity Assessment eCRF under this folder as appropriate. Else Clarify, Thank you' (Site from DM).	(b) (4), (b) (6)	08 Mar 2021 09:31:22
User entered '23 Feb 2021'	(b) (4), (b) (6)	23 Feb 2021 16:40:32

US3342200

Folder: OL-D29 (1)

Form: Visit Date

Generated On: 09 Jun 2021 17:05:26

[Was visit performed at the participant's home or at the clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 00:12:35
User signature succeeded.	Paul Pickrell (b) (4)	29 Mar 2021 15:07:52
User entered 'Clinic (Clinic)'	(b) (4) (b) (4), (b) (6)	23 Feb 2021 16:40:32

US3342200

Folder: OL-D29 (1)

Form: Visit Date

Generated On: 09 Jun 2021 17:05:26

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 00:12:35
User entered 'OLD29'	System	23 Feb 2021 16:40:32

US3342200

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:05:26

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 00:12:35
User accepted default value 'Pre-Dose (PREDOSE)'	(b) (4), (b) (6)	23 Feb 2021 16:43:20

US3342200

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:05:26

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 00:12:35
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:24:15
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	23 Feb 2021 16:43:20

US3342200

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:05:26

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 00:12:35
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:24:15
User entered '23 Feb 2021'	(b) (4) (b) (4), (b) (6)	23 Feb 2021 16:43:20

US3342200

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:05:26

[Time of assessment \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 00:12:35
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:24:15
User entered '08:46'	(b) (4) (b) (4), (b) (6)	23 Feb 2021 16:43:20

US3342200

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:05:26

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 00:12:35
User entered '23 Feb 2021 08:46'	System	23 Feb 2021 16:43:20

US3342200

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:05:26

[Temperature \(xxx.x\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 00:12:35
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:24:15
User entered '98.3' F	(b) (4) (b) (4), (b) (6)	23 Feb 2021 16:43:20

US3342200

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:05:26

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 00:12:35
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:24:15
User entered 'Oral (Oral)'	(b) (4) (b) (4), (b) (6)	23 Feb 2021 16:43:20

US3342200

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:05:26

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 00:12:35
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:24:15
User entered empty.	(b) (4) (b) (4), (b) (6)	23 Feb 2021 16:43:20

US3342200

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:05:26

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 00:12:35
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:24:15
User entered '81'	(b) (4) (b) (4), (b) (6)	23 Feb 2021 16:43:20

US3342200

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:05:26

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 00:12:35
User entered 'bpm'	System	23 Feb 2021 16:43:20

US3342200

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:05:26

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 00:12:35
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:24:15
User entered '16'	(b) (4) (b) (4), (b) (6)	23 Feb 2021 16:43:20

US3342200

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:05:26

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 00:12:35
User entered 'breaths/min'	System	23 Feb 2021 16:43:20

US3342200

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:05:26

[Systolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 00:12:35
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:24:15
User entered '121'	(b) (4) (b) (4), (b) (6)	23 Feb 2021 16:43:20

US3342200

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:05:26

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 00:12:35
User entered 'mmHg'	System	23 Feb 2021 16:43:20

US3342200

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:05:26

[Diastolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 00:12:35
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:24:15
User entered '79'	(b) (4) (b) (4), (b) (6)	23 Feb 2021 16:43:20

US3342200

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:05:26

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 00:12:35
User entered 'mmHg'	System	23 Feb 2021 16:43:20

US3342200

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:05:26

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 00:12:35
User accepted default value 'Post-Dose (POSTDOSE)'	(b) (4), (b) (6)	23 Feb 2021 16:43:20

US3342200

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:05:26

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 00:12:35
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:24:15
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	23 Feb 2021 16:43:20

US3342200

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:05:26

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 00:12:35
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:24:15
User entered '23 Feb 2021'	(b) (4) (b) (4), (b) (6)	23 Feb 2021 16:43:20

US3342200

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:05:26

Time of assessment (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 00:12:35
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:24:15
User entered '10:12'	(b) (4) (b) (4), (b) (6)	23 Feb 2021 16:43:20

US3342200

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:05:26

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 00:12:35
User entered '23 Feb 2021 10:12'	System	23 Feb 2021 16:43:20

US3342200

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:05:26

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 00:12:35
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:24:15
User entered '98.4' F	(b) (4) (b) (4), (b) (6)	23 Feb 2021 16:43:20

US3342200

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:05:26

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 00:12:35
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:24:15
User entered 'Oral (Oral)'	(b) (4) (b) (4), (b) (6)	23 Feb 2021 16:43:20

US3342200

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:05:26

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 00:12:35
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:24:15
User entered empty.	(b) (4) (b) (4), (b) (6)	23 Feb 2021 16:43:20

US3342200

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:05:26

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 00:12:35
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:24:15
User entered '76'	(b) (4) (b) (4), (b) (6)	23 Feb 2021 16:43:20

US3342200

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:05:26

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 00:12:35
User entered 'bpm'	System	23 Feb 2021 16:43:20

US3342200

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:05:26

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 00:12:35
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:24:15
User entered '14'	(b) (4) (b) (4), (b) (6)	23 Feb 2021 16:43:20

US3342200

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:05:26

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 00:12:35
User entered 'breaths/min'	System	23 Feb 2021 16:43:20

US3342200

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:05:26

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 00:12:35
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:24:15
User entered '128'	(b) (4) (b) (4), (b) (6)	23 Feb 2021 16:43:20

US3342200

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:05:26

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 00:12:35
User entered 'mmHg'	System	23 Feb 2021 16:43:20

US3342200

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:05:26

[Diastolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 00:12:35
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:24:15
User entered '84'	(b) (4) (b) (4), (b) (6)	23 Feb 2021 16:43:20

US3342200

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:05:26

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 00:12:35
User entered 'mmHg'	System	23 Feb 2021 16:43:20

US3342200

Folder: OL-D29 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 17:05:26

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 00:12:35
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:24:15
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	23 Feb 2021 16:42:06

US3342200

Folder: OL-D29 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 17:05:26

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 00:12:35
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:24:15
User entered empty.	(b) (4) (b) (4), (b) (6)	23 Feb 2021 16:42:06

US3342200

Folder: OL-D29 (1)

Form: Exposure

Generated On: 09 Jun 2021 17:05:26

[Was study treatment given?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 00:12:35
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:24:15
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	23 Feb 2021 16:41:44

US3342200

Folder: OL-D29 (1)

Form: Exposure

Generated On: 09 Jun 2021 17:05:26

[If No, reason not given](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 00:12:35
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:24:15
User entered empty.	(b) (4) (b) (4), (b) (6)	23 Feb 2021 16:41:44

US3342200

Folder: OL-D29 (1)

Form: Exposure

Generated On: 09 Jun 2021 17:05:26

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)	26 Apr 2021 00:12:35
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:24:15
User entered empty.	(b) (4) (b) (4), (b) (6)	23 Feb 2021 16:41:44

US3342200

Folder: OL-D29 (1)

Form: Exposure

Generated On: 09 Jun 2021 17:05:26

[What was the study treatment? \(Unblinded\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 00:12:35
User entered 'mRNA-1273'	System	23 Feb 2021 16:41:44
DataPoint set to visible.	System	22 Jan 2021 22:45:57

US3342200

Folder: OL-D29 (1)

Form: Exposure

Generated On: 09 Jun 2021 17:05:26

[What was the treatment date? \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 00:12:35
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:24:15
User entered '23 Feb 2021'	(b) (4) (b) (4), (b) (6)	23 Feb 2021 16:41:44

US3342200

Folder: OL-D29 (1)

Form: Exposure

Generated On: 09 Jun 2021 17:05:26

[What was the treatment time? \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 00:12:35
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:24:15
User entered '09:42'	(b) (4) (b) (4), (b) (6)	23 Feb 2021 16:41:44

US3342200

Folder: OL-D29 (1)

Form: Exposure

Generated On: 09 Jun 2021 17:05:26

[Treatment Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 00:12:35
User entered '23 Feb 2021 09:42'	System	23 Feb 2021 16:41:44

US3342200

Folder: OL-D29 (1)

Form: Exposure

Generated On: 09 Jun 2021 17:05:26

[Which arm was used to give treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 00:12:35
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:24:15
User entered 'Left Arm (LEFT ARM)'	(b) (4) (b) (4), (b) (6)	23 Feb 2021 16:41:44

US3342200

Folder: OL-D29 (1)

Form: Exposure

Generated On: 09 Jun 2021 17:05:26

[What was the frequency of the study treatment dosing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 00:12:35
User entered 'ONCE'	System	23 Feb 2021 16:41:44

US3342200

Folder: OL-D29 (1)

Form: Exposure

Generated On: 09 Jun 2021 17:05:26

What was the route of administration for the study treatment?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 00:12:35
User entered 'INTRAMUSCULAR'	System	23 Feb 2021 16:41:44

US3342200

Folder: OL-D29 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:05:26

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 00:12:35
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:24:15
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	23 Feb 2021 16:41:11

US3342200

Folder: OL-D29 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:05:26

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 00:12:35
User entered 'I'	System	23 Feb 2021 16:41:11

US3342200

Folder: Safety Call OL-D36 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:05:26

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 00:12:35
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 16:12:04
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	02 Mar 2021 15:11:09

US3342200

Folder: Safety Call OL-D36 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:05:26

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 00:12:35
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 16:12:04
User entered '02 Mar 2021'	(b) (4) (b) (4), (b) (6)	02 Mar 2021 15:11:09

US3342200

Folder: Safety Call OL-D36 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:05:26

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 00:12:35
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 16:12:04
User entered 'Contact Made (CONTACT MADE)'	(b) (4) (b) (4), (b) (6)	02 Mar 2021 15:11:09

US3342200

Folder: Safety Call OL-D36 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:05:26

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 00:12:35
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 16:12:04
User entered empty.	(b) (4) (b) (4), (b) (6)	02 Mar 2021 15:11:09

US3342200

Folder: Safety Call OL-D36 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:05:26

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 00:12:35
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 16:12:04
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	02 Mar 2021 15:11:14

US3342200

Folder: Safety Call OL-D36 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:05:26

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 00:12:35
User entered 'I'	System	02 Mar 2021 15:11:14

US3342200

Folder: OL-D57 (1)

Form: Visit Date

Generated On: 09 Jun 2021 17:05:26

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 00:12:35
User signature succeeded.	Paul Pickrell (b) (4)	29 Mar 2021 15:07:52
User entered 'Yes (Y)'	John Luna (b) (4)	26 Mar 2021 21:50:46

US3342200

Folder: OL-D57 (1)

Form: Visit Date

Generated On: 09 Jun 2021 17:05:26

[Visit date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 00:12:35
User signature succeeded.	Paul Pickrell (b) (4)	29 Mar 2021 15:07:52
User entered '26 Mar 2021'	John Luna (b) (4)	26 Mar 2021 21:50:46

US3342200

Folder: OL-D57 (1)

Form: Visit Date

Generated On: 09 Jun 2021 17:05:26

[Was visit performed at the participant's home or at the clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 00:12:35
User signature succeeded.	Paul Pickrell (b) (4)	29 Mar 2021 15:07:52
User entered 'Clinic (Clinic)'	John Luna (b) (4)	26 Mar 2021 21:50:46

US3342200

Folder: OL-D57 (1)

Form: Visit Date

Generated On: 09 Jun 2021 17:05:26

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 00:12:35
User entered 'OLD57'	System	26 Mar 2021 21:50:46

US3342200

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:05:26

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 00:12:35
User signature succeeded.	Paul Pickrell (b) (4)	29 Mar 2021 15:07:52
User entered 'Yes (Y)'	John Luna (b) (4)	26 Mar 2021 21:51:19

US3342200

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:05:26

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 00:12:35
User signature succeeded.	Paul Pickrell (b) (4)	29 Mar 2021 15:07:52
User entered '26 Mar 2021'	John Luna (b) (4)	26 Mar 2021 21:51:19

US3342200

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:05:26

Time of assessment (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 00:12:35
User signature succeeded.	Paul Pickrell (b) (4)	29 Mar 2021 15:07:52
User entered '15:50'	John Luna (b) (4)	26 Mar 2021 21:51:19

US3342200

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:05:26

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 00:12:35
User entered '26 Mar 2021 15:50'	System	26 Mar 2021 21:51:19

US3342200

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:05:26

[Temperature \(xxx.x\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 00:12:35
User signature succeeded.	Paul Pickrell (b) (4)	29 Mar 2021 15:07:52
User entered '98.2' F	John Luna (b) (4)	26 Mar 2021 21:51:19

US3342200

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:05:26

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 00:12:35
User signature succeeded.	Paul Pickrell (b) (4)	29 Mar 2021 15:07:52
User entered 'Oral (Oral)'	John Luna (b) (4)	26 Mar 2021 21:51:19

US3342200

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:05:26

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 00:12:35
User signature succeeded.	Paul Pickrell (b) (4)	29 Mar 2021 15:07:52
User entered empty.	John Luna (b) (4)	26 Mar 2021 21:51:19

US3342200

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:05:26

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 00:12:35
User signature succeeded.	Paul Pickrell (b) (4)	29 Mar 2021 15:07:52
User entered '76'	John Luna (b) (4)	26 Mar 2021 21:51:19

US3342200

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:05:26

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 00:12:35
User entered 'bpm'	System	26 Mar 2021 21:51:19

US3342200

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:05:26

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 00:12:35
User signature succeeded.	Paul Pickrell (b) (4)	29 Mar 2021 15:07:52
User entered '12'	John Luna (b) (4)	26 Mar 2021 21:51:19

US3342200

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:05:26

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 00:12:35
User entered 'breaths/min'	System	26 Mar 2021 21:51:19

US3342200

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:05:26

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 00:12:35
User signature succeeded.	Paul Pickrell (b) (4)	29 Mar 2021 15:07:52
User entered '112'	John Luna (b) (4)	26 Mar 2021 21:51:19

US3342200

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:05:26

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 00:12:35
User entered 'mmHg'	System	26 Mar 2021 21:51:19

US3342200

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:05:26

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 00:12:35
User signature succeeded.	Paul Pickrell (b) (4)	29 Mar 2021 15:07:52
User entered '75'	John Luna (b) (4)	26 Mar 2021 21:51:19

US3342200

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:05:26

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 00:12:35
User entered 'mmHg'	System	26 Mar 2021 21:51:19

US3342200

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:05:26

[Height \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 00:12:35

US3342200

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:05:26

[Weight \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 00:12:35

US3342200

Folder: OL-D57 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 17:05:26

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 00:12:35
User signature succeeded.	Paul Pickrell (b) (4)	29 Mar 2021 15:07:52
User entered 'Yes (Y)'	John Luna (b) (4)	26 Mar 2021 21:51:28

US3342200

Folder: OL-D57 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 17:05:26

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 00:12:35
User signature succeeded.	Paul Pickrell (b) (4)	29 Mar 2021 15:07:52
User entered '26 Mar 2021'	John Luna (b) (4)	26 Mar 2021 21:51:28

US3342200

Folder: OL-D57 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:05:26

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 00:12:35
User signature succeeded.	Paul Pickrell (b) (4)	12 Apr 2021 15:51:34
User entered 'Yes (Y)'	Ethan Shotton (b) (4)	31 Mar 2021 15:37:20

US3342200

Folder: OL-D57 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:05:26

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 00:12:35
User signature succeeded.	Paul Pickrell (b) (4)	12 Apr 2021 15:51:34
User entered '26 Mar 2021'	Ethan Shotton (b) (4)	31 Mar 2021 15:37:20

US3342200

Folder: OL-D57 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:05:26

[Collection time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 00:12:35
User signature succeeded.	Paul Pickrell (b) (4)	12 Apr 2021 15:51:34
User entered '16:33'	Ethan Shotton (b) (4)	31 Mar 2021 15:37:20

US3342200

Folder: OL-D57 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:05:26

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 00:12:35
User entered '26 Mar 2021 16:33'	System	31 Mar 2021 15:37:20

US3342200

Folder: Unscheduled 23 Feb 2021

Form: Unscheduled Visit Assessment

Generated On: 09 Jun 2021 17:05:26

[Visit Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 23:50:59
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 16:12:04
User entered '23 Feb 2021'	(b) (4) Ethan Shotton (b) (4)	12 Mar 2021 13:46:01

US3342200

Folder: Unscheduled 23 Feb 2021

Form: Unscheduled Visit Assessment

Generated On: 09 Jun 2021 17:05:26

[Physical Exam](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 23:50:59
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 16:12:04
User entered '0'	Ethan Shotton (b) (4)	12 Mar 2021 13:46:01

US3342200

Folder: Unscheduled 23 Feb 2021

Form: Unscheduled Visit Assessment

Generated On: 09 Jun 2021 17:05:26

[Vital Signs](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 23:50:59
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 16:12:04
User entered '0'	Ethan Shotton (b) (4)	12 Mar 2021 13:46:01

US3342200

Folder: **Unscheduled 23 Feb 2021**

Form: **Unscheduled Visit Assessment**

Generated On: **09 Jun 2021 17:05:26**

[Immunogenicity Assessment](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 23:50:59
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 16:12:04
User entered 'I'	Ethan Shotton (b) (4)	12 Mar 2021 13:46:01

US3342200

Folder: Unscheduled 23 Feb 2021

Form: Unscheduled Visit Assessment

Generated On: 09 Jun 2021 17:05:26

[Pregnancy Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 23:50:59
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 16:12:04
User entered '0'	Ethan Shotton (b) (4)	12 Mar 2021 13:46:01

US3342200

Folder: Unscheduled 23 Feb 2021

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:05:26

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 23:51:07
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 16:12:04
User entered 'Yes (Y)'	Ethan Shotton (b) (4)	12 Mar 2021 13:46:14

US3342200

Folder: Unscheduled 23 Feb 2021

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:05:26

Collection date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 23:51:07
User closed query 'Per GCL Lab Reconciliation: Immunogenicity Assessment: Sample dated 23FEB2021 is recorded under Participant Unscheduled Visit in EDC, however the same is reported under OL-D29/OL-2 visit in PPD Central lab. Please reconcile the correct Visit and confirm in query response. Else clarify, Thank you' (Site from DM).	(b) (4), (b) (6)	24 Mar 2021 09:20:31
Query 'Per GCL Lab Reconciliation: Immunogenicity Assessment: Sample dated 23FEB2021 is recorded under Participant Unscheduled Visit in EDC, however the same is reported under OL-D29/OL-2 visit in PPD Central lab. Please reconcile the correct Visit and confirm in query response. Else clarify, Thank you' answered with 'immunogenicity sample collected in error at OL-D29. unable to put in EDC under OL-D29 folder and an unscheduled visit had to be created to add data.' (Site from DM).	Olivia Hapanowicz (b) (4)	22 Mar 2021 12:46:02
User opened query 'Per GCL Lab Reconciliation: Immunogenicity Assessment: Sample dated 23FEB2021 is recorded under Participant Unscheduled Visit in EDC, however the same is reported under OL-D29/OL-2 visit in PPD Central lab. Please reconcile the correct Visit and confirm in query response. Else clarify, Thank you' (Site from DM).	(b) (4), (b) (6)	22 Mar 2021 05:04:17
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 16:12:04
User entered '23 Feb 2021'	Ethan Shotton (b) (4)	12 Mar 2021 13:46:14

US3342200

Folder: Unscheduled 23 Feb 2021

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:05:26

[Collection time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 23:51:07
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 16:12:04
User entered '09:03'	Ethan Shotton (b) (4)	12 Mar 2021 13:46:14

US3342200

Folder: Unscheduled 23 Feb 2021

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:05:26

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 23:51:07
User entered '23 Feb 2021 09:03'	System	12 Mar 2021 13:46:14

US3342200

Folder: Adverse Events

Form: Adverse Events Summary

Generated On: 09 Jun 2021 17:05:26

[Did the participant experience any adverse events?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 05:46:33
User closed query 'Per DM CLR: Medical Attention was checked for DAY 13 on Diary Dose 2. However, there is no Solicited Adverse Reaction (recorded as AE) with "Was this a medically-attended AE?" = YES. Please review and ensure that this Solicited Adverse reaction is captured as an Adverse event and response to "Was this a medically-attended AE?" is YES. Review and update eCRF as appropriate. ' (Site from DM).	(b) (4), (b) (6)	21 Apr 2021 12:24:53
Query 'Per DM CLR: Medical Attention was checked for DAY 13 on Diary Dose 2. However, there is no Solicited Adverse Reaction (recorded as AE) with "Was this a medically-attended AE?" = YES. Please review and ensure that this Solicited Adverse reaction is captured as an Adverse event and response to "Was this a medically-attended AE?" is YES. Review and update eCRF as appropriate. ' answered with 'Subject did not have a MAAE. Subject reported having an annual physical on 12Oct2020. No dx was reported.' (Site from DM).	Ethan Shotton (b) (4) (b) (4)	20 Apr 2021 14:25:56
User closed query 'Per protocol any Solicited local or systemic AR lasting beyond 7 days post-injection must be entered into the participant's source document and must also be recorded as an AE in the participant's Adverse Event eCRF. Per subject's diary, Medical Attention lasted beyond day 7 post injection. Please reconcile and enter event as needed per Completion Guidelines (page 47/48) and ensure SAR box is checked. ' (Site from DM).	(b) (4), (b) (6)	20 Apr 2021 13:17:50
User closed query 'Per protocol any Solicited local or systemic AR lasting beyond 7 days post-injection must be entered into the participant's source document and must also be recorded as an AE in the participant's Adverse Event eCRF. Per subject's diary, Joint aches in several joints lasted beyond day 7 post injection. Please reconcile and enter event as needed per Completion Guidelines (page 47/48) and ensure SAR box is checked. ' (Site from DM).	(b) (4), (b) (6)	20 Apr 2021 13:17:41

US3342200

Folder: Adverse Events

Form: Adverse Events Summary

Generated On: 09 Jun 2021 17:05:26

[Did the participant experience any adverse events?](#)

Audit	User	Time (GMT)
User opened query 'Per DM CLR: Medical Attention was checked for DAY 13 on Diary Dose 2. However, there is no Solicited Adverse Reaction (recorded as AE) with "Was this a medically-attended AE?" = YES. Please review and ensure that this Solicited Adverse reaction is captured as an Adverse event and response to "Was this a medically-attended AE?" is YES. Review and update eCRF as appropriate. ' (Site from DM).	(b) (4), (b) (6)	20 Apr 2021 00:51:42
Query 'Per protocol any Solicited local or systemic AR lasting beyond 7 days post-injection must be entered into the participant's source document and must also be recorded as an AE in the participant's Adverse Event eCRF. Per subject's diary, Medical Attention lasted beyond day 7 post injection. Please reconcile and enter event as needed per Completion Guidelines (page 47/48) and ensure SAR box is checked. ' answered with 'Medical attention related to AE #4. AE source and subject's chart includes events and procedures relating to this AE that correlate with dates of medical attention put in this e-Diary.' (Site from DM).	Ethan Shotton (b) (4) (b) (4)	19 Apr 2021 18:09:55
Query 'Per protocol any Solicited local or systemic AR lasting beyond 7 days post-injection must be entered into the participant's source document and must also be recorded as an AE in the participant's Adverse Event eCRF. Per subject's diary, Joint aches in several joints lasted beyond day 7 post injection. Please reconcile and enter event as needed per Completion Guidelines (page 47/48) and ensure SAR box is checked. ' answered with 'Joint aches not pertinent to vaccine. Pt reported these sx in error and was retrained on correct diary entries. Joint aches are recorded in subject's MH.' (Site from DM).	Ethan Shotton (b) (4) (b) (4)	19 Apr 2021 18:05:49

US3342200

Folder: Adverse Events

Form: Adverse Events Summary

Generated On: 09 Jun 2021 17:05:26

[Did the participant experience any adverse events?](#)

Audit	User	Time (GMT)
User opened query 'Per protocol any Solicited local or systemic AR lasting beyond 7 days post-injection must be entered into the participant's source document and must also be recorded as an AE in the participant's Adverse Event eCRF. Per subject's diary, Medical Attention lasted beyond day 7 post injection. Please reconcile and enter event as needed per Completion Guidelines (page 47/48) and ensure SAR box is checked. ' (Site from DM).	(b) (4), (b) (6)	17 Apr 2021 09:18:01
User opened query 'Per protocol any Solicited local or systemic AR lasting beyond 7 days post-injection must be entered into the participant's source document and must also be recorded as an AE in the participant's Adverse Event eCRF. Per subject's diary, Joint aches in several joints lasted beyond day 7 post injection. Please reconcile and enter event as needed per Completion Guidelines (page 47/48) and ensure SAR box is checked.	(b) (4), (b) (6)	17 Apr 2021 09:17:29
' (Site from DM). User signature succeeded.	Paul Pickrell (b) (4)	22 Mar 2021 13:29:43
User closed query 'Per DM CLR: Please note, Per Diary Dose 2 Record, symptom of JOINT ACHES persist beyond Day 7 (start date: Day 1 - 30SEP2020; end date: Day 135 - 11FEB2020). Review if this should be recorded as a Solicited Adverse Reaction per protocol 8.3.4 and update AE eCRF as appropriate. Else, provide clarification.	(b) (4) (b) (4), (b) (6)	16 Mar 2021 02:33:52
' (Site from DM). Query 'Per DM CLR: Please note, Per Diary Dose 2 Record, symptom of JOINT ACHES persist beyond Day 7 (start date: Day 1 - 30SEP2020; end date: Day 135 - 11FEB2020). Review if this should be recorded as a Solicited Adverse Reaction per protocol 8.3.4 and update AE eCRF as appropriate. Else, provide clarification.	Olivia Hapanowicz (b) (4) (b) (4)	15 Mar 2021 14:22:29
' answered with 'joint aches not pertinent to vaccine, pt reported in error. joint aches recorded on MH.' (Site from DM).		

US3342200

Folder: Adverse Events

Form: Adverse Events Summary

Generated On: 09 Jun 2021 17:05:26

[Did the participant experience any adverse events?](#)

Audit	User	Time (GMT)
User opened query 'Per DM CLR: Please note, Per Diary Dose 2 Record, symptom of JOINT ACHES persist beyond Day 7 (start date: Day 1 - 30SEP2020; end date: Day 135 - 11FEB2020). Review if this should be recorded as a Solicited Adverse Reaction per protocol 8.3.4 and update AE eCRF as appropriate. Else, provide clarification. ' (Site from DM). DataPoint Verified.	(b) (4), (b) (6) (b) (4)	12 Feb 2021 01:36:09
	(b) (4), (b) (6) (b) (4)	09 Dec 2020 18:09:01
User entered 'Yes (Y)'	Morgan Schulle (b) (4) (b) (4)	05 Oct 2020 19:28:06

US3342200

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:05:26

[AEID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:04:04

US3342200

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:05:26

[Adverse event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:04:04
User signature succeeded.	Paul Pickrell (b) (4)	29 Mar 2021 15:07:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Dec 2020 18:12:19
User closed query 'Per DM CLR: Please review AE and please update to specify the type of Rash (e.g. Maculopapular, Pustular, etc.) and if this is URTICARIAL or NON-URTICARIAL. Please update and reconcile with applicable eCRFs so there would be an appropriate match. Otherwise, clarify.' (Site from DM).	(b) (4), (b) (6)	24 Nov 2020 13:49:39
User coded data point as SOC: Skin and subcutaneous tissue disorders, HLGT: Epidermal and dermal conditions, HLT: Dermatitis and eczema, PT: Dermatitis atopic, LLT: Dermatitis atopic aggravated - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	23 Nov 2020 23:01:15
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 23:01:15
Data point term sent to Coder	System	23 Nov 2020 22:10:24
Query 'Per DM CLR: Please review AE and please update to specify the type of Rash (e.g. Maculopapular, Pustular, etc.) and if this is URTICARIAL or NON-URTICARIAL. Please update and reconcile with applicable eCRFs so there would be an appropriate match. Otherwise, clarify.' answered with 'updated term' (Site from DM).	Eileen Euperio (b) (4) (b) (4)	23 Nov 2020 22:10:23
Coding entries removed.	Eileen Euperio (b) (4) (b) (4)	23 Nov 2020 22:10:18
User entered 'atopic dermatitis exacerbation' reason for change: Data Entry Error	Eileen Euperio (b) (4) (b) (4)	23 Nov 2020 22:10:18
User coded data point as SOC: Skin and subcutaneous tissue disorders, HLGT: Epidermal and dermal conditions, HLT: Rashes, eruptions and exanthems NEC, PT: Rash, LLT: Rash on legs & arms - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	11 Nov 2020 16:14:34
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	11 Nov 2020 16:14:34

US3342200

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:05:26

[Adverse event](#)

Audit	User	Time (GMT)
User opened query 'Per DM CLR: Please review AE and please update to specify the type of Rash (e.g. Maculopapular, Pustular, etc.) and if this is URTICARIAL or NON-URTICARIAL. Please update and reconcile with applicable eCRFs so there would be an appropriate match. Otherwise, clarify.' (Site from DM).	(b) (4), (b) (6)	11 Nov 2020 10:39:56
User closed query 'Per MM: Specify location of rash' (Site from DM).	(b) (4), (b) (6)	09 Nov 2020 16:47:06
Query 'Per MM: Specify location of rash' answered with 'Location specified in description and narrative.' (Site from DM).	Andrew Bell (b) (4)	06 Nov 2020 17:01:02
Data point term sent to Coder	System	06 Nov 2020 17:00:44
Coding entries removed.	Andrew Bell (b) (4)	06 Nov 2020 17:00:39
User entered 'RASH (BOTH ARMS AND LEGS)' reason for change: Data Entry Error	(b) (4)	
User opened query 'Per MM: Specify location of rash' (Site from DM).	Andrew Bell (b) (4)	06 Nov 2020 17:00:39
User coded data point as SOC: Skin and subcutaneous tissue disorders, HLGT: Epidermal and dermal conditions, HLT: Rashes, eruptions and exanthems NEC, PT: Rash, LLT: Rash - version MedDRA\23.0.	(b) (4), (b) (6)	30 Oct 2020 16:53:08
User coded data point as Term Coded data point by User: Coder System - version MedDRA\23.0.	Coder Import (b) (4)	05 Oct 2020 19:33:20
Data point term sent to Coder	(b) (4)	
User entered 'RASH'	System	05 Oct 2020 19:32:42
	Morgan Schulle (b) (4)	05 Oct 2020 19:32:19
	(b) (4)	

US3342200

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:05:26

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:04:04
User signature succeeded.	Paul Pickrell (b) (4)	29 Mar 2021 15:07:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Dec 2020 18:12:19
User entered 'No (N)'	Morgan Schulle (b) (4) (b) (4)	05 Oct 2020 19:32:19

US3342200

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:05:26

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:04:04
User signature succeeded.	Paul Pickrell (b) (4)	29 Mar 2021 15:07:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Dec 2020 18:12:19
User entered 'No (N)'	Morgan Schulle (b) (4) (b) (4)	05 Oct 2020 19:32:19

US3342200

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:05:26

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:04:04
User signature succeeded.	Paul Pickrell (b) (4)	29 Mar 2021 15:07:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Dec 2020 18:12:19
User entered 'No (N)'	Morgan Schulle (b) (4) (b) (4)	05 Oct 2020 19:32:19

US3342200

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:05:26

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:04:04
User signature succeeded.	Paul Pickrell (b) (4)	29 Mar 2021 15:07:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Dec 2020 18:12:19
User entered '04 Sep 2020'	Morgan Schulle (b) (4) (b) (4)	05 Oct 2020 19:32:19

US3342200

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:05:26

[Start time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:04:04
User signature succeeded.	Paul Pickrell (b) (4)	29 Mar 2021 15:07:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Dec 2020 18:12:19
User entered '22:00'	Morgan Schulle (b) (4) (b) (4)	05 Oct 2020 19:32:19

US3342200

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:05:26

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:04:04
User entered '04 Sep 2020 22:00'	System	05 Oct 2020 19:32:19

US3342200

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:05:26

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:04:04
User signature succeeded.	Paul Pickrell (b) (4)	29 Mar 2021 15:07:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Mar 2021 16:15:49
User closed query 'Ongoing is Yes, but End Date is provided. Please correct.' (Site from System).	System	18 Mar 2021 18:07:54
DataPoint Un-verified.	Ethan Shotton (b) (4)	18 Mar 2021 18:07:54
User entered 'No (N)' reason for change: Data Entry Error	(b) (4) Ethan Shotton (b) (4)	18 Mar 2021 18:07:54
User opened query 'Ongoing is Yes, but End Date is provided. Please correct.' (Site from System).	(b) (4) System	18 Mar 2021 18:07:47
DataPoint Verified.	(b) (4), (b) (6)	09 Dec 2020 18:12:19
User closed query 'Per DM CLR: Please review the status of this AE and verify if this already resolved and end date is already available. If yes, please update eCRF as appropriate. Otherwise, confirm if it is still ongoing. ' (Site from DM).	(b) (4), (b) (6)	01 Dec 2020 15:40:24
Query 'Per DM CLR: Please review the status of this AE and verify if this already resolved and end date is already available. If yes, please update eCRF as appropriate. Otherwise, confirm if it is still ongoing. ' answered with 'As to limit patient inconvenience, updates regarding AE condition will be discussed at Safety Call Day 119. Any changes will be entered at that time.' (Site from DM).	Morgan Schulle (b) (4) (b) (4)	30 Nov 2020 18:30:21
User opened query 'Per DM CLR: Please review the status of this AE and verify if this already resolved and end date is already available. If yes, please update eCRF as appropriate. Otherwise, confirm if it is still ongoing. ' (Site from DM).	(b) (4), (b) (6)	27 Nov 2020 10:21:49
User entered 'Yes (Y)'	Morgan Schulle (b) (4) (b) (4)	05 Oct 2020 19:32:19

US3342200

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:05:26

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:04:04
User signature succeeded.	Paul Pickrell (b) (4)	29 Mar 2021 15:07:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Mar 2021 16:15:49
User closed query 'Outcome is Recovered/Resolved, Recovered/Resolved with Sequelae or Fatal, but End Date is missing. Please provide.' (Site from System).	System	18 Mar 2021 18:07:47
Query 'Outcome is Recovered/Resolved, Recovered/Resolved with Sequelae or Fatal, but End Date is missing. Please provide.' answered by data change (Site from System).	System	18 Mar 2021 18:07:47
DataPoint Un-verified.	Ethan Shotton (b) (4)	18 Mar 2021 18:07:47
User entered '16 Oct 2020' reason for change: Data Entry Error	(b) (4) Ethan Shotton (b) (4)	18 Mar 2021 18:07:47
User opened query 'Outcome is Recovered/Resolved, Recovered/Resolved with Sequelae or Fatal, but End Date is missing. Please provide.' (Site from System).	(b) (4)	18 Mar 2021 18:07:16
DataPoint Verified.	(b) (4), (b) (6)	09 Dec 2020 18:12:19
User entered empty.	Morgan Schulle (b) (4) (b) (4)	05 Oct 2020 19:32:19

US3342200

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:05:26

End time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:04:04
User signature succeeded.	Paul Pickrell (b) (4)	29 Mar 2021 15:07:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Mar 2021 16:15:49
User closed query 'Data entered is non-conformant. Please correct.' (Site from System).	System	18 Mar 2021 18:14:57
User entered '09:00' reason for change: Data Entry Error	Ethan Shotton (b) (4) (b) (4)	18 Mar 2021 18:14:57
User opened query 'Data entered is non-conformant. Please correct.' (Site from System).	System	18 Mar 2021 18:08:31
User closed query 'Data is required. Please provide.' (Site from System).	System	18 Mar 2021 18:08:31
DataPoint Un-verified.	Ethan Shotton (b) (4) (b) (4)	18 Mar 2021 18:08:31
User entered 'UN:UN' (non-conformant).	Ethan Shotton (b) (4) (b) (4)	18 Mar 2021 18:08:31
User opened query 'Data is required. Please provide.' (Site from System).	System	18 Mar 2021 18:07:54
DataPoint Verified.	(b) (4), (b) (6)	09 Dec 2020 18:12:19
User entered empty.	Morgan Schulle (b) (4) (b) (4)	05 Oct 2020 19:32:19

US3342200

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:05:26

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:04:04
User entered '16 Oct 2020 09:00'	System	18 Mar 2021 18:14:57
User entered '16 Oct 2020 UN:UN' (non-conformant).	System	18 Mar 2021 18:08:31
User entered empty.	System	05 Oct 2020 19:32:19

US3342200

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:05:26

Severity

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:04:04
User signature succeeded.	Paul Pickrell (b) (4)	29 Mar 2021 15:07:52
User closed query 'Per DM CLR: AE Grade = 1, as this condition is listed as ongoing in the Med History and the AE term indicates worsening, it is unexpected that a worsening event would = Grade 1. Please review and update the grade or provide clarification.' (Site from DM).	(b) (4) (b) (4), (b) (6)	08 Feb 2021 16:26:48
Query 'Per DM CLR: AE Grade = 1, as this condition is listed as ongoing in the Med History and the AE term indicates worsening, it is unexpected that a worsening event would = Grade 1. Please review and update the grade or provide clarification.' answered with 'exacerbation of existing AD considered to be a mild exacerbation' (Site from DM).	Eileen Euperio (b) (4) (b) (4)	05 Feb 2021 16:56:32
User opened query 'Per DM CLR: AE Grade = 1, as this condition is listed as ongoing in the Med History and the AE term indicates worsening, it is unexpected that a worsening event would = Grade 1. Please review and update the grade or provide clarification.' (Site from DM).	(b) (4), (b) (6)	19 Jan 2021 12:08:50
DataPoint Verified.	(b) (4), (b) (6)	09 Dec 2020 18:12:19
User entered 'Grade 1/Mild (Grade 1/Mild)'	Morgan Schulle (b) (4) (b) (4)	05 Oct 2020 19:32:19

US3342200

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:05:26

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:04:04
User signature succeeded.	Paul Pickrell (b) (4)	29 Mar 2021 15:07:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Dec 2020 18:12:19
User entered 'No (N)'	Morgan Schulle (b) (4) (b) (4)	05 Oct 2020 19:32:19

US3342200

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:05:26

[Death](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:04:04
User signature succeeded.	Paul Pickrell (b) (4)	29 Mar 2021 15:07:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Dec 2020 18:12:19
User entered '0'	Morgan Schulle (b) (4) (b) (4)	05 Oct 2020 19:32:19

US3342200

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:05:26

[Life threatening](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:04:04
User signature succeeded.	Paul Pickrell (b) (4)	29 Mar 2021 15:07:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Dec 2020 18:12:19
User entered '0'	Morgan Schulle (b) (4) (b) (4)	05 Oct 2020 19:32:19

US3342200

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:05:26

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:04:04
User signature succeeded.	Paul Pickrell (b) (4)	29 Mar 2021 15:07:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Dec 2020 18:12:19
User entered '0'	Morgan Schulle (b) (4) (b) (4)	05 Oct 2020 19:32:19

US3342200

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:05:26

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:04:04
User signature succeeded.	Paul Pickrell (b) (4)	29 Mar 2021 15:07:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Dec 2020 18:12:19
User entered empty.	Morgan Schulle (b) (4) (b) (4)	05 Oct 2020 19:32:19

US3342200

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:05:26

Hospital Discharge Date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:04:04
User signature succeeded.	Paul Pickrell (b) (4)	29 Mar 2021 15:07:52
Reviewed for Data Management.	(b) (4) (b) (4), (b) (6)	08 Feb 2021 16:26:55
DataPoint Verified.	(b) (4), (b) (6)	09 Dec 2020 18:12:19
User entered empty.	Morgan Schulle (b) (4) (b) (4)	05 Oct 2020 19:32:19

US3342200

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:05:26

[Admitted to ICU?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:04:04
User signature succeeded.	Paul Pickrell (b) (4)	29 Mar 2021 15:07:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Dec 2020 18:12:19
User entered empty.	Morgan Schulle (b) (4) (b) (4)	05 Oct 2020 19:32:19

US3342200

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:05:26

[Number of Days in ICU](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:04:04
User signature succeeded.	Paul Pickrell (b) (4)	29 Mar 2021 15:07:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Dec 2020 18:12:19
User entered empty.	Morgan Schulle (b) (4) (b) (4)	05 Oct 2020 19:32:19

US3342200

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:05:26

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:04:04
User signature succeeded.	Paul Pickrell (b) (4)	29 Mar 2021 15:07:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Dec 2020 18:12:19
User entered '0'	Morgan Schulle (b) (4) (b) (4)	05 Oct 2020 19:32:19

US3342200

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:05:26

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:04:04
User signature succeeded.	Paul Pickrell (b) (4)	29 Mar 2021 15:07:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Dec 2020 18:12:19
User entered '0'	Morgan Schulle (b) (4) (b) (4)	05 Oct 2020 19:32:19

US3342200

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:05:26

[Other medically important event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:04:04
User signature succeeded.	Paul Pickrell (b) (4)	29 Mar 2021 15:07:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Dec 2020 18:12:19
User entered '0'	Morgan Schulle (b) (4) (b) (4)	05 Oct 2020 19:32:19

US3342200

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:05:26

[Relationship to investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:04:04
User signature succeeded.	Paul Pickrell (b) (4)	29 Mar 2021 15:07:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Dec 2020 18:12:19
User entered 'Not Related (NOT RELATED)'	Morgan Schulle (b) (4) (b) (4)	05 Oct 2020 19:32:19

US3342200

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:05:26

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:04:04
User signature succeeded.	Paul Pickrell (b) (4)	29 Mar 2021 15:07:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Dec 2020 18:12:19
User entered 'Not Related (NOT RELATED)'	Morgan Schulle (b) (4) (b) (4)	05 Oct 2020 19:32:19

US3342200

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:05:26

[Action taken with investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:04:04
User signature succeeded.	Paul Pickrell (b) (4)	29 Mar 2021 15:07:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Dec 2020 18:12:19
User entered 'None (NONE)'	Morgan Schulle (b) (4) (b) (4)	05 Oct 2020 19:32:19

US3342200

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:05:26

[None](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:04:04
User signature succeeded.	Paul Pickrell (b) (4)	29 Mar 2021 15:07:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Dec 2020 18:12:19
User entered '0'	Morgan Schulle (b) (4) (b) (4)	05 Oct 2020 19:32:19

US3342200

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:05:26

[Concomitant Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:04:04
User signature succeeded.	Paul Pickrell (b) (4)	29 Mar 2021 15:07:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Dec 2020 18:12:19
User closed query 'Per DM CLR: Other Action Taken = Concomitant Medication, however there is no Concomitant Medication recorded that matches this AE during this timeframe. Per SAE narrative, "using Triamcinolone as needed". If this medication was also given for this AE, please include this AE as one of the CM's indication, so there will be an appropriate match. Otherwise, please review and add a Con Medication as appropriate or update action taken.' (Site from DM).	(b) (4), (b) (6)	24 Nov 2020 13:49:53
Query 'Per DM CLR: Other Action Taken = Concomitant Medication, however there is no Concomitant Medication recorded that matches this AE during this timeframe. Per SAE narrative, "using Triamcinolone as needed". If this medication was also given for this AE, please include this AE as one of the CM's indication, so there will be an appropriate match. Otherwise, please review and add a Con Medication as appropriate or update action taken.' answered with 'triamcinolone added to con med for this AE' (Site from DM).	Stefanie Mott (b) (4)	23 Nov 2020 22:16:05
User opened query 'Per DM CLR: Other Action Taken = Concomitant Medication, however there is no Concomitant Medication recorded that matches this AE during this timeframe. Per SAE narrative, "using Triamcinolone as needed". If this medication was also given for this AE, please include this AE as one of the CM's indication, so there will be an appropriate match. Otherwise, please review and add a Con Medication as appropriate or update action taken.' (Site from DM).	(b) (4), (b) (6)	11 Nov 2020 10:40:19
User entered 'I'	Morgan Schulle (b) (4) (b) (4)	05 Oct 2020 19:32:19

US3342200

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:05:26

[Concomitant Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:04:04
User signature succeeded.	Paul Pickrell (b) (4)	29 Mar 2021 15:07:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Dec 2020 18:12:19
User entered '0'	Morgan Schulle (b) (4) (b) (4)	05 Oct 2020 19:32:19

US3342200

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:05:26

[Outcome](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:04:04
User signature succeeded.	Paul Pickrell (b) (4)	29 Mar 2021 15:07:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Mar 2021 16:15:49
DataPoint Un-verified.	Ethan Shotton (b) (4)	18 Mar 2021 18:07:16
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)' reason for change:	(b) (4) Ethan Shotton (b) (4)	18 Mar 2021 18:07:16
Data Entry Error	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	09 Dec 2020 18:12:19
User entered 'Recovering/Resolving (RECOVERING/RESOLVING)'	Morgan Schulle (b) (4) (b) (4)	05 Oct 2020 19:32:19

US3342200

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:05:26

[If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:04:04
User signature succeeded.	Paul Pickrell (b) (4)	29 Mar 2021 15:07:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Dec 2020 18:12:19
User entered empty.	Morgan Schulle (b) (4) (b) (4)	05 Oct 2020 19:32:19

US3342200

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:05:26

[Narrative](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:04:04
User signature succeeded.	Paul Pickrell (b) (4)	29 Mar 2021 15:07:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Dec 2020 18:12:19
User entered empty; reason for change Data Entry Error	Stefanie Mott (b) (4)	23 Nov 2020 22:16:10
User entered 'RASH - BILATERAL ARMS AND LEGS. USING Triamcinolone AS NEEDED.'	Morgan Schulle (b) (4) (b) (4)	05 Oct 2020 19:32:19

US3342200

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:05:26

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:04:04
User entered '0'	System	05 Oct 2020 19:32:19

US3342200

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:05:26

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:04:04
User entered '0'	System	05 Oct 2020 19:32:19

US3342200

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:05:26

[Admitted to ICU Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:04:04

US3342200

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:05:26

[AEID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:04:09

US3342200

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:05:26

[Adverse event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:04:09
User signature succeeded.	Paul Pickrell (b) (4)	29 Mar 2021 15:07:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Mar 2021 16:15:49
User coded data point as SOC: Musculoskeletal and connective tissue disorders, HLG: Muscle disorders, HLT: Muscle pains, PT: Myalgia, LLT: Myalgia - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	18 Mar 2021 14:29:38
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	18 Mar 2021 14:29:38
User closed query 'Per CDM Re-query: Since this solicited event met AE reporting criteria, please provide the location of muscle pain. Thank you' (Site from DM).	(b) (4), (b) (6)	16 Mar 2021 16:32:20
Data point term sent to Coder	System	15 Mar 2021 14:13:03
Query 'Per CDM Re-query: Since this solicited event met AE reporting criteria, please provide the location of muscle pain. Thank you' answered with 'updated' (Site from DM).	Olivia Hapanowicz (b) (4) (b) (4)	15 Mar 2021 14:12:21
DataPoint Un-verified.	Olivia Hapanowicz (b) (4) (b) (4)	15 Mar 2021 14:12:16
Coding entries removed.	Olivia Hapanowicz (b) (4) (b) (4)	15 Mar 2021 14:12:16
User entered 'MYALGIA bilateral upper arms and hips' reason for change: New Information	Olivia Hapanowicz (b) (4) (b) (4)	15 Mar 2021 14:12:16
User opened query 'Per CDM Re-query: Since this solicited event met AE reporting criteria, please provide the location of muscle pain. Thank you' (Site from DM).	(b) (4), (b) (6)	08 Feb 2021 16:28:43
User closed query 'Per DM CLR: Please provide the specific location of muscle pain (eg, generalized myalgia, back muscle pain, arms, etc). Review and update Adverse Event condition as appropriate and ensure update is reconciled with any corresponding ConMed entries, if applicable.' (Site from DM).	(b) (4), (b) (6)	08 Feb 2021 16:28:43
Comment added 'Myalgia in upper arms and hips BL per source'.	Eileen Euperio (b) (4) (b) (4)	05 Feb 2021 16:58:09

US3342200

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:05:26

[Adverse event](#)

Audit	User	Time (GMT)
Query 'Per DM CLR: Please provide the specific location of muscle pain (eg, generalized myalgia, back muscle pain, arms, etc). Review and update Adverse Event condition as appropriate and ensure update is reconciled with any corresponding ConMed entries, if applicable.' answered with 'myalgia reported per eDiary which does not ask for specific location' (Site from DM).	Eileen Euperio (b) (4)	05 Feb 2021 16:57:01
User opened query 'Per DM CLR: Please provide the specific location of muscle pain (eg, generalized myalgia, back muscle pain, arms, etc). Review and update Adverse Event condition as appropriate and ensure update is reconciled with any corresponding ConMed entries, if applicable.' (Site from DM).	(b) (4), (b) (6)	17 Dec 2020 12:47:56
DataPoint Verified.	(b) (4), (b) (6)	09 Dec 2020 18:12:19
User coded data point as SOC: Musculoskeletal and connective tissue disorders, HLGT: Muscle disorders, HLT: Muscle pains, PT: Myalgia, LLT: Myalgia - version MedDRA\\23.0.	Coder Import (b) (4)	26 Oct 2020 22:08:27
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	26 Oct 2020 22:08:27
Data point term sent to Coder	System	26 Oct 2020 22:07:11
User entered 'Myalgia'	(b) (4), (b) (6)	26 Oct 2020 22:06:14

US3342200

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:05:26

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:04:09
User signature succeeded.	Paul Pickrell (b) (4)	29 Mar 2021 15:07:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Dec 2020 18:12:19
User entered 'No (N)'	(b) (4), (b) (6)	26 Oct 2020 22:06:14

US3342200

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:05:26

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:04:09
User signature succeeded.	Paul Pickrell (b) (4)	29 Mar 2021 15:07:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Dec 2020 18:12:19
User entered 'Yes (Y)'	(b) (4), (b) (6)	26 Oct 2020 22:06:14

US3342200

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:05:26

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:04:09
User signature succeeded.	Paul Pickrell (b) (4)	29 Mar 2021 15:07:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Dec 2020 18:12:19
User entered 'No (N)'	(b) (4), (b) (6)	26 Oct 2020 22:06:14

US3342200

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:05:26

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:04:09
User signature succeeded.	Paul Pickrell (b) (4)	29 Mar 2021 15:07:52
User closed query 'Per DM CLR: Please note that this AE start date does not match the Diary initial start date of Solicited Symptom Muscle aches all over on 30 SEP 2020. Please review if this should be reconciled. Else, provide clarification on dates.' (Site from DM).	(b) (4) (b) (4), (b) (6)	08 Feb 2021 16:27:29
Query 'Per DM CLR: Please note that this AE start date does not match the Diary initial start date of Solicited Symptom Muscle aches all over on 30 SEP 2020. Please review if this should be reconciled. Else, provide clarification on dates.' answered with 'this is the date reported AFTER 7 days following vaccine' (Site from DM).	Eileen Euperio (b) (4) (b) (4)	05 Feb 2021 16:58:34
User opened query 'Per DM CLR: Please note that this AE start date does not match the Diary initial start date of Solicited Symptom Muscle aches all over on 30 SEP 2020. Please review if this should be reconciled. Else, provide clarification on dates.' (Site from DM).	(b) (4), (b) (6)	17 Dec 2020 12:48:20
DataPoint Verified.	(b) (4), (b) (6)	09 Dec 2020 18:12:19
User entered '5 Oct 2020'	(b) (4), (b) (6)	26 Oct 2020 22:06:14

US3342200

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:05:26

[Start time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:04:09
User signature succeeded.	Paul Pickrell (b) (4)	29 Mar 2021 15:07:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Dec 2020 18:12:19
User entered empty.	(b) (4), (b) (6)	26 Oct 2020 22:06:14

US3342200

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:05:26

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:04:09
User entered empty.	System	26 Oct 2020 22:06:14

US3342200

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:05:26

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:04:09
User signature succeeded.	Paul Pickrell (b) (4)	29 Mar 2021 15:07:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Dec 2020 18:12:19
User entered 'No (N)'	(b) (4), (b) (6)	26 Oct 2020 22:06:14

US3342200

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:05:26

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:04:09
User signature succeeded.	Paul Pickrell (b) (4)	29 Mar 2021 15:07:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Dec 2020 18:12:19
User entered '16 Oct 2020'	(b) (4), (b) (6)	26 Oct 2020 22:06:14

US3342200

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:05:26

End time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:04:09
User signature succeeded.	Paul Pickrell (b) (4)	29 Mar 2021 15:07:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Dec 2020 18:12:19
User entered empty.	(b) (4), (b) (6)	26 Oct 2020 22:06:14

US3342200

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:05:26

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:04:09
User entered empty.	System	26 Oct 2020 22:06:14

US3342200

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:05:26

[Severity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:04:09
User signature succeeded.	Paul Pickrell (b) (4)	29 Mar 2021 15:07:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Dec 2020 18:12:19
User entered 'Grade 1/Mild (Grade 1/Mild)'	(b) (4), (b) (6)	26 Oct 2020 22:06:14

US3342200

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:05:26

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:04:09
User signature succeeded.	Paul Pickrell (b) (4)	29 Mar 2021 15:07:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Dec 2020 18:12:19
User entered 'No (N)'	(b) (4), (b) (6)	26 Oct 2020 22:06:14

US3342200

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:05:26

[Death](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:04:09
User signature succeeded.	Paul Pickrell (b) (4)	29 Mar 2021 15:07:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Dec 2020 18:12:19
User entered '0'	(b) (4), (b) (6)	26 Oct 2020 22:06:14

US3342200

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:05:26

[Life threatening](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:04:09
User signature succeeded.	Paul Pickrell (b) (4)	29 Mar 2021 15:07:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Dec 2020 18:12:19
User entered '0'	(b) (4), (b) (6)	26 Oct 2020 22:06:14

US3342200

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:05:26

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:04:09
User signature succeeded.	Paul Pickrell (b) (4)	29 Mar 2021 15:07:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Dec 2020 18:12:19
User entered '0'	(b) (4), (b) (6)	26 Oct 2020 22:06:14

US3342200

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:05:26

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:04:09
User signature succeeded.	Paul Pickrell (b) (4)	29 Mar 2021 15:07:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Dec 2020 18:12:19
User entered empty.	(b) (4), (b) (6)	26 Oct 2020 22:06:14

US3342200

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:05:26

Hospital Discharge Date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:04:09
User signature succeeded.	Paul Pickrell (b) (4)	29 Mar 2021 15:07:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Dec 2020 18:12:19
User entered empty.	(b) (4), (b) (6)	26 Oct 2020 22:06:14

US3342200

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:05:26

[Admitted to ICU?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:04:09
User signature succeeded.	Paul Pickrell (b) (4)	29 Mar 2021 15:07:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Dec 2020 18:12:19
User entered empty.	(b) (4), (b) (6)	26 Oct 2020 22:06:14

US3342200

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:05:26

[Number of Days in ICU](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:04:09
User signature succeeded.	Paul Pickrell (b) (4)	29 Mar 2021 15:07:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Dec 2020 18:12:19
User entered empty.	(b) (4), (b) (6)	26 Oct 2020 22:06:14

US3342200

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:05:26

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:04:09
User signature succeeded.	Paul Pickrell (b) (4)	29 Mar 2021 15:07:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Dec 2020 18:12:19
User entered '0'	(b) (4), (b) (6)	26 Oct 2020 22:06:14

US3342200

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:05:26

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:04:09
User signature succeeded.	Paul Pickrell (b) (4)	29 Mar 2021 15:07:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Dec 2020 18:12:19
User entered '0'	(b) (4), (b) (6)	26 Oct 2020 22:06:14

US3342200

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:05:26

[Other medically important event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:04:09
User signature succeeded.	Paul Pickrell (b) (4)	29 Mar 2021 15:07:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Dec 2020 18:12:19
User entered '0'	(b) (4), (b) (6)	26 Oct 2020 22:06:14

US3342200

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:05:26

[Relationship to investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:04:09
User signature succeeded.	Paul Pickrell (b) (4)	29 Mar 2021 15:07:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Dec 2020 18:12:19
User entered 'Related (RELATED)'	(b) (4), (b) (6)	26 Oct 2020 22:06:14

US3342200

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:05:26

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:04:09
User signature succeeded.	Paul Pickrell (b) (4)	29 Mar 2021 15:07:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Dec 2020 18:12:19
User entered 'Not Related (NOT RELATED)'	(b) (4), (b) (6)	26 Oct 2020 22:06:14

US3342200

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:05:26

Action taken with investigational product

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:04:09
User signature succeeded.	Paul Pickrell (b) (4)	29 Mar 2021 15:07:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Mar 2021 16:15:49
User closed query 'Per CDM: "Action taken with investigational product" is recorded as 'None', however if Adverse Event started after IP then it expected to be as "Not applicable" instead of "None". Thank you' (Site from DM).	(b) (4), (b) (6)	19 Mar 2021 13:12:02
Query 'Per CDM: "Action taken with investigational product" is recorded as 'None', however if Adverse Event started after IP then it expected to be as "Not applicable" instead of "None". Thank you' answered with 'Action taken updated on source and EDC.' (Site from DM).	Ethan Shotton (b) (4) (b) (4)	18 Mar 2021 20:43:23
DataPoint Un-verified.	Ethan Shotton (b) (4) (b) (4)	18 Mar 2021 20:43:03
User entered 'Not Applicable (NOT APPLICABLE)' reason for change: Data Entry Error	Ethan Shotton (b) (4) (b) (4)	18 Mar 2021 20:43:03
User opened query 'Per CDM: "Action taken with investigational product" is recorded as 'None', however if Adverse Event started after IP then it expected to be as "Not applicable" instead of "None". Thank you' (Site from DM).	(b) (4), (b) (6)	18 Mar 2021 20:06:19
DataPoint Verified.	(b) (4), (b) (6)	09 Dec 2020 18:12:19
User entered 'None (NONE)'	(b) (4), (b) (6)	26 Oct 2020 22:06:14

US3342200

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:05:26

[None](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:04:09
User signature succeeded.	Paul Pickrell (b) (4)	29 Mar 2021 15:07:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Dec 2020 18:12:19
User entered 'l'	(b) (4), (b) (6)	26 Oct 2020 22:06:14

US3342200

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:05:26

[Concomitant Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:04:09
User signature succeeded.	Paul Pickrell (b) (4)	29 Mar 2021 15:07:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Dec 2020 18:12:19
User entered '0'	(b) (4), (b) (6)	26 Oct 2020 22:06:14

US3342200

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:05:26

[Concomitant Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:04:09
User signature succeeded.	Paul Pickrell (b) (4)	29 Mar 2021 15:07:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Dec 2020 18:12:19
User entered '0'	(b) (4), (b) (6)	26 Oct 2020 22:06:14

US3342200

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:05:26

[Outcome](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:04:09
User signature succeeded.	Paul Pickrell (b) (4)	29 Mar 2021 15:07:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Dec 2020 18:12:19
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)'	(b) (4), (b) (6)	26 Oct 2020 22:06:14

US3342200

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:05:26

[If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:04:09
User signature succeeded.	Paul Pickrell (b) (4)	29 Mar 2021 15:07:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Dec 2020 18:12:19
User entered empty.	(b) (4), (b) (6)	26 Oct 2020 22:06:14

US3342200

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:05:26

[Narrative](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:04:09
User signature succeeded.	Paul Pickrell (b) (4)	29 Mar 2021 15:07:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Dec 2020 18:12:19
User entered empty.	(b) (4), (b) (6)	26 Oct 2020 22:06:14

US3342200

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:05:26

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:04:09
User entered '0'	System	26 Oct 2020 22:06:14

US3342200

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:05:26

Medically Attended AE Derived (CSA Programming Field Only)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:04:09
User entered '0'	System	26 Oct 2020 22:06:14

US3342200

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:05:26

[Admitted to ICU Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:04:09

US3342200

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:05:26

[AEID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:04:14

US3342200

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:05:26

[Adverse event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:04:14
User signature succeeded.	Paul Pickrell (b) (4)	29 Mar 2021 15:07:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Dec 2020 18:12:19
User coded data point as SOC: General disorders and administration site conditions, HLGT: General system disorders NEC, HLT: Asthenic conditions, PT: Fatigue, LLT: Fatigue - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	26 Oct 2020 22:08:28
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	26 Oct 2020 22:08:28
Data point term sent to Coder	System	26 Oct 2020 22:08:12
User entered 'Fatigue'	(b) (4), (b) (6)	26 Oct 2020 22:07:42

US3342200

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:05:26

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:04:14
User signature succeeded.	Paul Pickrell (b) (4)	29 Mar 2021 15:07:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Dec 2020 18:12:19
User entered 'No (N)'	(b) (4), (b) (6)	26 Oct 2020 22:07:42

US3342200

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:05:26

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:04:14
User signature succeeded.	Paul Pickrell (b) (4)	29 Mar 2021 15:07:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Dec 2020 18:12:19
User entered 'Yes (Y)'	(b) (4), (b) (6)	26 Oct 2020 22:07:42

US3342200

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:05:26

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:04:14
User signature succeeded.	Paul Pickrell (b) (4)	29 Mar 2021 15:07:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Dec 2020 18:12:19
User entered 'No (N)'	(b) (4), (b) (6)	26 Oct 2020 22:07:42

US3342200

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:05:26

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:04:14
User signature succeeded.	Paul Pickrell (b) (4)	29 Mar 2021 15:07:52
User closed query 'Per DM CLR: Please note that this AE start date does not match the Diary initial start date of Solicited Symptom Fatigue on 30 SEP 2020. Please review if this should be reconciled. Else, provide clarification on dates. ' (Site from DM).	(b) (4), (b) (6)	15 Jan 2021 16:05:30
Query 'Per DM CLR: Please note that this AE start date does not match the Diary initial start date of Solicited Symptom Fatigue on 30 SEP 2020. Please review if this should be reconciled. Else, provide clarification on dates. ' answered with 'No, the correct start date is 04OCT2020 because pt did not have symptoms consistently from 30SEP2020 to 04OCT2020.' (Site from DM).	Olivia Hapanowicz (b) (4)	14 Jan 2021 17:01:20
User opened query 'Per DM CLR: Please note that this AE start date does not match the Diary initial start date of Solicited Symptom Fatigue on 30 SEP 2020. Please review if this should be reconciled. Else, provide clarification on dates. ' (Site from DM).	(b) (4), (b) (6)	17 Dec 2020 12:48:28
DataPoint Verified.	(b) (4), (b) (6)	09 Dec 2020 18:12:19
User entered '4 Oct 2020'	(b) (4), (b) (6)	26 Oct 2020 22:07:42

US3342200

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:05:26

[Start time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:04:14
User signature succeeded.	Paul Pickrell (b) (4)	29 Mar 2021 15:07:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Dec 2020 18:12:19
User entered empty.	(b) (4), (b) (6)	26 Oct 2020 22:07:42

US3342200

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:05:26

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:04:14
User entered empty.	System	26 Oct 2020 22:07:42

US3342200

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:05:26

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:04:14
User signature succeeded.	Paul Pickrell (b) (4)	29 Mar 2021 15:07:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Dec 2020 18:12:19
User entered 'No (N)'	(b) (4), (b) (6)	26 Oct 2020 22:07:42

US3342200

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:05:26

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:04:14
User signature succeeded.	Paul Pickrell (b) (4)	29 Mar 2021 15:07:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Dec 2020 18:12:19
User entered '16 Oct 2020'	(b) (4), (b) (6)	26 Oct 2020 22:07:42

US3342200

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:05:26

End time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:04:14
User signature succeeded.	Paul Pickrell (b) (4)	29 Mar 2021 15:07:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Dec 2020 18:12:19
User entered empty.	(b) (4), (b) (6)	26 Oct 2020 22:07:42

US3342200

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:05:26

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:04:14
User entered empty.	System	26 Oct 2020 22:07:42

US3342200

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:05:26

[Severity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:04:14
User signature succeeded.	Paul Pickrell (b) (4)	29 Mar 2021 15:07:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Dec 2020 18:12:19
User entered 'Grade 1/Mild (Grade 1/Mild)'	(b) (4), (b) (6)	26 Oct 2020 22:07:42

US3342200

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:05:26

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:04:14
User signature succeeded.	Paul Pickrell (b) (4)	29 Mar 2021 15:07:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Dec 2020 18:12:19
User entered 'No (N)'	(b) (4), (b) (6)	26 Oct 2020 22:07:42

US3342200

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:05:26

[Death](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:04:14
User signature succeeded.	Paul Pickrell (b) (4)	29 Mar 2021 15:07:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Dec 2020 18:12:19
User entered '0'	(b) (4), (b) (6)	26 Oct 2020 22:07:42

US3342200

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:05:26

[Life threatening](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:04:14
User signature succeeded.	Paul Pickrell (b) (4)	29 Mar 2021 15:07:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Dec 2020 18:12:19
User entered '0'	(b) (4), (b) (6)	26 Oct 2020 22:07:42

US3342200

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:05:26

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:04:14
User signature succeeded.	Paul Pickrell (b) (4)	29 Mar 2021 15:07:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Dec 2020 18:12:19
User entered '0'	(b) (4), (b) (6)	26 Oct 2020 22:07:42

US3342200

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:05:26

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:04:14
User signature succeeded.	Paul Pickrell (b) (4)	29 Mar 2021 15:07:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Dec 2020 18:12:19
User entered empty.	(b) (4), (b) (6)	26 Oct 2020 22:07:42

US3342200

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:05:26

[Hospital Discharge Date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:04:14
User signature succeeded.	Paul Pickrell (b) (4)	29 Mar 2021 15:07:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Dec 2020 18:12:19
User entered empty.	(b) (4), (b) (6)	26 Oct 2020 22:07:42

US3342200

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:05:26

[Admitted to ICU?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:04:14
User signature succeeded.	Paul Pickrell (b) (4)	29 Mar 2021 15:07:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Dec 2020 18:12:19
User entered empty.	(b) (4), (b) (6)	26 Oct 2020 22:07:42

US3342200

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:05:26

[Number of Days in ICU](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:04:14
User signature succeeded.	Paul Pickrell (b) (4)	29 Mar 2021 15:07:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Dec 2020 18:12:19
User entered empty.	(b) (4), (b) (6)	26 Oct 2020 22:07:42

US3342200

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:05:26

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:04:14
User signature succeeded.	Paul Pickrell (b) (4)	29 Mar 2021 15:07:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Dec 2020 18:12:19
User entered '0'	(b) (4), (b) (6)	26 Oct 2020 22:07:42

US3342200

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:05:26

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:04:14
User signature succeeded.	Paul Pickrell (b) (4)	29 Mar 2021 15:07:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Dec 2020 18:12:19
User entered '0'	(b) (4), (b) (6)	26 Oct 2020 22:07:42

US3342200

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:05:26

[Other medically important event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:04:14
User signature succeeded.	Paul Pickrell (b) (4)	29 Mar 2021 15:07:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Dec 2020 18:12:19
User entered '0'	(b) (4), (b) (6)	26 Oct 2020 22:07:42

US3342200

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:05:26

[Relationship to investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:04:14
User signature succeeded.	Paul Pickrell (b) (4)	29 Mar 2021 15:07:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Dec 2020 18:12:19
User entered 'Related (RELATED)'	(b) (4), (b) (6)	26 Oct 2020 22:07:42

US3342200

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:05:26

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:04:14
User signature succeeded.	Paul Pickrell (b) (4)	29 Mar 2021 15:07:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Dec 2020 18:12:19
User entered 'Not Related (NOT RELATED)'	(b) (4), (b) (6)	26 Oct 2020 22:07:42

US3342200

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:05:26

[Action taken with investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:04:14
User signature succeeded.	Paul Pickrell (b) (4)	29 Mar 2021 15:07:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Dec 2020 18:12:19
User entered 'None (NONE)'	(b) (4), (b) (6)	26 Oct 2020 22:07:42

US3342200

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:05:26

[None](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:04:14
User signature succeeded.	Paul Pickrell (b) (4)	29 Mar 2021 15:07:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Dec 2020 18:12:19
User entered 'l'	(b) (4), (b) (6)	26 Oct 2020 22:07:42

US3342200

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:05:26

[Concomitant Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:04:14
User signature succeeded.	Paul Pickrell (b) (4)	29 Mar 2021 15:07:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Dec 2020 18:12:19
User entered '0'	(b) (4), (b) (6)	26 Oct 2020 22:07:42

US3342200

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:05:26

[Concomitant Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:04:14
User signature succeeded.	Paul Pickrell (b) (4)	29 Mar 2021 15:07:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Dec 2020 18:12:19
User entered '0'	(b) (4), (b) (6)	26 Oct 2020 22:07:42

US3342200

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:05:26

[Outcome](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:04:14
User signature succeeded.	Paul Pickrell (b) (4)	29 Mar 2021 15:07:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Dec 2020 18:12:19
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)'	(b) (4), (b) (6)	26 Oct 2020 22:07:42

US3342200

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:05:26

[If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:04:14
User signature succeeded.	Paul Pickrell (b) (4)	29 Mar 2021 15:07:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Dec 2020 18:12:19
User entered empty.	(b) (4), (b) (6)	26 Oct 2020 22:07:42

US3342200

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:05:26

[Narrative](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:04:14
User signature succeeded.	Paul Pickrell (b) (4)	29 Mar 2021 15:07:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Dec 2020 18:12:19
User entered empty.	(b) (4), (b) (6)	26 Oct 2020 22:07:42

US3342200

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:05:26

Serious Adverse Event Derived (CSA Programming Field Only)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:04:14
User entered '0'	System	26 Oct 2020 22:07:42

US3342200

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:05:26

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:04:14
User entered '0'	System	26 Oct 2020 22:07:42

US3342200

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:05:26

[Admitted to ICU Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:04:14

US3342200

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 17:05:26

[AEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Pickrell (b) (4)	29 Mar 2021 15:07:52
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	09 Dec 2020 18:12:19
Reviewed for Safety.	(b) (4), (b) (6)	24 Nov 2020 20:40:02
User entered		
'USA-US203-2020-mRNA-1273-P301000006'	System	24 Nov 2020 20:39:57
User entered 'New'	(b) (4), (b) (6)	24 Nov 2020 20:39:57

US3342200

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 17:05:26

[Adverse event](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Pickrell (b) (4)	29 Mar 2021 15:07:52
User closed query 'PV Query: Please confirm if event term should be updated based on diagnosis from oncologist.' (Site from Safety).	(b) (4) (b) (4), (b) (6)	08 Feb 2021 17:11:13
Query 'PV Query: Please confirm if event term should be updated based on diagnosis from oncologist.' answered with 'dx from med records show ductal carcinoma in situ' (Site from Safety).	Eileen Euperio (b) (4) (b) (4)	05 Feb 2021 16:59:37
User opened query 'PV Query: Please confirm if event term should be updated based on diagnosis from oncologist.' (Site from Safety).	(b) (4), (b) (6)	25 Jan 2021 17:54:34
DataPoint Verified.	(b) (4), (b) (6)	09 Dec 2020 18:12:19
User coded data point as SOC: Neoplasms benign, malignant and unspecified (incl cysts and polyps), HLGT: Breast neoplasms malignant and unspecified (incl nipple), HLT: Breast and nipple neoplasms malignant, PT: Intraductal proliferative breast lesion, LLT: Carcinoma in situ of breast ductal - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	23 Nov 2020 22:50:14
User coded data point as Term Coded data point by User: Coder System - version MedDRA\23.0.	Coder Import (b) (4)	23 Nov 2020 22:50:14
Data point term sent to Coder	System	23 Nov 2020 22:49:21
User entered 'DUCTAL CARCINOMA IN SITU RIGHT BREAST'	Stefanie Mott (b) (4)	23 Nov 2020 22:48:26

US3342200

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 17:05:26

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Pickrell (b) (4)	29 Mar 2021 15:07:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Dec 2020 18:12:19
User entered 'Yes (Y)'	Stefanie Mott (b) (4)	23 Nov 2020 22:48:26

US3342200

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 17:05:26

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Pickrell (b) (4)	29 Mar 2021 15:07:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Dec 2020 18:12:19
User entered 'No (N)'	Stefanie Mott (b) (4)	23 Nov 2020 22:48:26

US3342200

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 17:05:26

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Pickrell (b) (4)	29 Mar 2021 15:07:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Dec 2020 18:12:19
User entered 'No (N)'	Stefanie Mott (b) (4)	23 Nov 2020 22:48:26

US3342200

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 17:05:26

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Paul Pickrell (b) (4)	29 Mar 2021 15:07:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Dec 2020 18:12:19
User entered '20 Nov 2020'	Stefanie Mott (b) (4)	23 Nov 2020 22:48:26

US3342200

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 17:05:26

[Start time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Pickrell (b) (4)	29 Mar 2021 15:07:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Dec 2020 18:12:19
User entered empty.	Stefanie Mott (b) (4)	23 Nov 2020 22:48:26

US3342200

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 17:05:26

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	23 Nov 2020 22:48:26

US3342200

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 17:05:26

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Pickrell (b) (4)	29 Mar 2021 15:07:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Mar 2021 16:15:49
DataPoint Un-verified.	(b) (4), (b) (6)	15 Jan 2021 21:49:36
User entered 'No (N)' reason for change: Data Entry Error		15 Jan 2021 21:49:36
DataPoint Verified.	(b) (4), (b) (6)	09 Dec 2020 18:12:19
User entered 'Yes (Y)'	Stefanie Mott (b) (4)	23 Nov 2020 22:48:26

US3342200

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 17:05:26

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Paul Pickrell (b) (4)	29 Mar 2021 15:07:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Mar 2021 16:15:49
DataPoint Un-verified.	(b) (4), (b) (6)	15 Jan 2021 21:49:36
User entered '13 Jan 2021' reason for change: Data Entry Error		15 Jan 2021 21:49:36
DataPoint Verified.	(b) (4), (b) (6)	09 Dec 2020 18:12:19
User entered empty.	Stefanie Mott (b) (4)	23 Nov 2020 22:48:26

US3342200

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 17:05:26

End time (00:00-23:59)

Audit	User	Time (GMT)
User signature succeeded.	Paul Pickrell (b) (4)	29 Mar 2021 15:07:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Mar 2021 16:15:49
User closed query 'End time is present for an AE that did not start within 24 hours after dosing. Please remove the End time.' (Site from System).	System	15 Jan 2021 21:50:00
User closed query 'Data entered is non-conformant. Please correct.' (Site from System).	System	15 Jan 2021 21:50:00
User entered empty; reason for change Data Entry Error	(b) (4), (b) (6)	15 Jan 2021 21:50:00
User opened query 'Data entered is non-conformant. Please correct.' (Site from System).	System	15 Jan 2021 21:49:36
User opened query 'End time is present for an AE that did not start within 24 hours after dosing. Please remove the End time.' (Site from System).	System	15 Jan 2021 21:49:36
DataPoint Un-verified.	(b) (4), (b) (6)	15 Jan 2021 21:49:36
User entered 'un:un' (non-conformant).		15 Jan 2021 21:49:36
DataPoint Verified.	(b) (4), (b) (6)	09 Dec 2020 18:12:19
User entered empty.	Stefanie Mott (b) (4)	23 Nov 2020 22:48:26

US3342200

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 17:05:26

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Query 'PV Query: Please provide the event end date (recovered, returned to baseline, or, in the investigator's opinion, a new baseline has been achieved), when available. ' canceled (Site from Safety).	(b) (4), (b) (6)	15 Mar 2021 16:37:37
User entered empty.	System	15 Jan 2021 21:50:00
User entered '13 Jan 2021 UN:UN' (non-conformant).	System	15 Jan 2021 21:49:36
User opened query 'PV Query: Please provide the event end date (recovered, returned to baseline, or, in the investigator's opinion, a new baseline has been achieved), when available. ' (Site from Safety).	(b) (4), (b) (6)	03 Dec 2020 23:53:51
User entered empty.	System	23 Nov 2020 22:48:26

US3342200

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 17:05:26

[Severity](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Pickrell (b) (4)	29 Mar 2021 15:07:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Dec 2020 18:12:19
User entered 'Grade 3/Severe (Grade 3/Severe)'	Stefanie Mott (b) (4)	23 Nov 2020 22:48:26

US3342200

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 17:05:26

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Pickrell (b) (4)	29 Mar 2021 15:07:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Dec 2020 18:12:19
User entered 'Yes (Y)'	Stefanie Mott (b) (4) [REDACTED] [REDACTED]	23 Nov 2020 22:48:26

US3342200

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 17:05:26

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Pickrell (b) (4)	29 Mar 2021 15:07:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Dec 2020 18:12:19
User entered '0'	Stefanie Mott (b) (4)	23 Nov 2020 22:48:26

US3342200

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 17:05:26

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Pickrell (b) (4)	29 Mar 2021 15:07:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Dec 2020 18:12:19
User entered '0'	Stefanie Mott (b) (4)	23 Nov 2020 22:48:26

US3342200

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 17:05:26

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Pickrell (b) (4)	29 Mar 2021 15:07:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Dec 2020 18:12:19
User entered '0'	Stefanie Mott (b) (4)	23 Nov 2020 22:48:26

US3342200

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 17:05:26

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Paul Pickrell (b) (4)	29 Mar 2021 15:07:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Dec 2020 18:12:19
User entered empty.	Stefanie Mott (b) (4)	23 Nov 2020 22:48:26

US3342200

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 17:05:26

Hospital Discharge Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Paul Pickrell (b) (4)	29 Mar 2021 15:07:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Dec 2020 18:12:19
User entered empty.	Stefanie Mott (b) (4)	23 Nov 2020 22:48:26

US3342200

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 17:05:26

[Admitted to ICU?](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Pickrell (b) (4)	29 Mar 2021 15:07:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Dec 2020 18:12:19
User entered empty.	Stefanie Mott (b) (4)	23 Nov 2020 22:48:26

US3342200

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 17:05:26

[Number of Days in ICU](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Pickrell (b) (4)	29 Mar 2021 15:07:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Dec 2020 18:12:19
User entered empty.	Stefanie Mott (b) (4)	23 Nov 2020 22:48:26

US3342200

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 17:05:26

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Pickrell (b) (4)	29 Mar 2021 15:07:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Dec 2020 18:12:19
User entered '0'	Stefanie Mott (b) (4)	23 Nov 2020 22:48:26

US3342200

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 17:05:26

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Pickrell (b) (4)	29 Mar 2021 15:07:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Dec 2020 18:12:19
User entered '0'	Stefanie Mott (b) (4)	23 Nov 2020 22:48:26

US3342200

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 17:05:26

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Pickrell (b) (4)	29 Mar 2021 15:07:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Dec 2020 18:12:19
User entered 'I'	Stefanie Mott (b) (4)	23 Nov 2020 22:48:26

US3342200

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 17:05:26

[Relationship to investigational product](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Pickrell (b) (4)	29 Mar 2021 15:07:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Dec 2020 18:12:19
User entered 'Not Related (NOT RELATED)'	Stefanie Mott (b) (4)	23 Nov 2020 22:48:26

US3342200

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 17:05:26

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Pickrell (b) (4)	29 Mar 2021 15:07:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Dec 2020 18:12:19
User entered 'Not Related (NOT RELATED)'	Stefanie Mott (b) (4)	23 Nov 2020 22:48:26

US3342200

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 17:05:26

Action taken with investigational product

Audit	User	Time (GMT)
User signature succeeded.	Paul Pickrell (b) (4)	29 Mar 2021 15:07:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Dec 2020 18:12:19
User closed query 'Per CDM: Per CCGs p. 33, Relationship to investigational product is expected to be "Not Applicable" if clinical event is prior to first dose of investigational product. Kindly review and reconcile as appropriate. ' (Site from DM).	(b) (4), (b) (6)	04 Dec 2020 15:15:52
Query 'Per CDM: Per CCGs p. 33, Relationship to investigational product is expected to be "Not Applicable" if clinical event is prior to first dose of investigational product. Kindly review and reconcile as appropriate. ' answered with 'updated' (Site from DM).	Eileen Euperio (b) (4) (b) (4)	03 Dec 2020 18:17:15
User entered 'Not Applicable (NOT APPLICABLE)' reason for change: Data Entry Error	Eileen Euperio (b) (4) (b) (4)	03 Dec 2020 18:16:52
User opened query 'Per CDM: Per CCGs p. 33, Relationship to investigational product is expected to be "Not Applicable" if clinical event is prior to first dose of investigational product. Kindly review and reconcile as appropriate. ' (Site from DM).	(b) (4), (b) (6)	26 Nov 2020 06:59:32
User entered 'None (NONE)'	Stefanie Mott (b) (4)	23 Nov 2020 22:48:26

US3342200

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 17:05:26

None

Audit	User	Time (GMT)
User signature succeeded.	Paul Pickrell (b) (4)	29 Mar 2021 15:07:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Mar 2021 16:15:49
User closed query 'Per DM CLR: Other Action Taken = None, however there is a ConProc recorded that matches this AE during this timeframe. Please review and update AE eCRF as appropriate.' (Site from DM).	(b) (4), (b) (6)	12 Mar 2021 17:20:43
Query 'Per DM CLR: Other Action Taken = None, however there is a ConProc recorded that matches this AE during this timeframe. Please review and update AE eCRF as appropriate.' answered with 'Action Taken updated on EDC and source.' (Site from DM).	Ethan Shotton (b) (4) (b) (4)	11 Mar 2021 13:12:45
DataPoint Un-verified.	(b) (4), (b) (6)	02 Mar 2021 20:09:19
User entered '0' reason for change: Data Entry Error	(b) (4), (b) (6)	02 Mar 2021 20:09:19
User opened query 'Per DM CLR: Other Action Taken = None, however there is a ConProc recorded that matches this AE during this timeframe. Please review and update AE eCRF as appropriate.' (Site from DM).	(b) (4), (b) (6)	22 Feb 2021 01:51:30
DataPoint Verified.	(b) (4), (b) (6)	09 Dec 2020 18:12:19
User entered '1'	Stefanie Mott (b) (4)	23 Nov 2020 22:48:26

US3342200

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 17:05:26

[Concomitant Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Pickrell (b) (4)	29 Mar 2021 15:07:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Dec 2020 18:12:19
User entered '0'	Stefanie Mott (b) (4)	23 Nov 2020 22:48:26

US3342200

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 17:05:26

[Concomitant Procedure](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Pickrell (b) (4)	29 Mar 2021 15:07:52
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	19 Mar 2021 16:15:49
DataPoint Un-verified.	(b) (4), (b) (6)	02 Mar 2021 20:09:19
User entered '1' reason for change: Data Entry Error	(b) (4), (b) (6)	02 Mar 2021 20:09:19
DataPoint Verified.	(b) (4), (b) (6)	09 Dec 2020 18:12:19
User entered '0'	Stefanie Mott (b) (4)	23 Nov 2020 22:48:26

US3342200

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 17:05:26

[Outcome](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Pickrell (b) (4)	29 Mar 2021 15:07:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Mar 2021 16:15:49
User closed query 'PV Query: The event was reported as resolved with sequelae. Please provide the sequelae. ' (Site from Safety).	(b) (4), (b) (6)	12 Mar 2021 17:17:18
Query 'PV Query: The event was reported as resolved with sequelae. Please provide the sequelae. ' answered with 'Sequelae updated in EDC.' (Site from Safety).	Ethan Shotton (b) (4) (b) (4)	11 Mar 2021 13:14:44
User opened query 'PV Query: The event was reported as resolved with sequelae. Please provide the sequelae. ' (Site from Safety).	(b) (4), (b) (6)	09 Mar 2021 21:48:27
User entered 'Recovered/Resolved with Sequelae (RECOVERED/RESOLVED WITH SEQUELAE)' reason for change: Data Entry Error	(b) (4), (b) (6)	02 Mar 2021 20:08:48
DataPoint Un-verified.	(b) (4), (b) (6)	15 Jan 2021 21:49:36
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)' reason for change: Data Entry Error	(b) (4), (b) (6)	15 Jan 2021 21:49:36
User closed query 'PV Query: Please provide the final event outcome, when available. If not expected to resolve, please confirm in your response. If resolution is expected, please keep query open until achieved. ' (Site from Safety).	(b) (4), (b) (6)	10 Dec 2020 18:47:32
DataPoint Verified.	(b) (4), (b) (6)	09 Dec 2020 18:12:19
Query 'PV Query: Please provide the final event outcome, when available. If not expected to resolve, please confirm in your response. If resolution is expected, please keep query open until achieved. ' answered with 'RESOLUTION FOR DX IS NOT EXPECTED DURING THIS STUDY TIMEFRAME' (Site from Safety).	Eileen Euperio (b) (4) (b) (4)	09 Dec 2020 17:46:49
User opened query 'PV Query: Please provide the final event outcome, when available. If not expected to resolve, please confirm in your response. If resolution is expected, please keep query open until achieved. ' (Site from Safety).	(b) (4), (b) (6)	03 Dec 2020 23:53:31

PRODUCTION RELEASE (v12.003
EAB) (1725)

3852 of 4196

US3342200

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 17:05:26

[Outcome](#)

Audit	User	Time (GMT)
User entered 'Not Recovered/Not Resolved (NOT RECOVERED/NOT RESOLVED)'	Stefanie Mott (b) (4) [REDACTED] [REDACTED]	23 Nov 2020 22:48:26

US3342200

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 17:05:26

If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:

Audit	User	Time (GMT)
User signature succeeded.	Paul Pickrell (b) (4)	28 Apr 2021 22:33:29
	(b) (4)	
DataPoint Un-verified.	Ethan Shotton (b) (4)	28 Apr 2021 20:45:16
	(b) (4)	
Signature has been broken.	Ethan Shotton (b) (4)	28 Apr 2021 20:45:16
	(b) (4)	
User entered 'PATIENT REPORTS SHE WILL BE STARTING HORMONE BLOCKER MEDICATION THIS THURSDAY (04MAR2021) AS RECOMMENDED BY ONCOLOGIST FOR PREVENTION OF DUCTAL CARCINOMA RECURRENCE.' reason for change: Data Entry Error	Ethan Shotton (b) (4)	28 Apr 2021 20:45:16
	(b) (4)	
User signature succeeded.	Paul Pickrell (b) (4)	29 Mar 2021 15:07:52
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	19 Mar 2021 16:15:49
	(b) (4)	
User entered 'PATIENT REPOSRTS SHE WILL BE STARTING HORMONE BLOCKER MEDICATION THIS THURSDAY (04MAR2021) AS RECOMMENDED BY ONCOLOGIST FOR PREVENTION OF DUCTAL CARCINOMA RECURRENCE.' reason for change: Data Entry Error	Ethan Shotton (b) (4)	11 Mar 2021 13:15:35
	(b) (4)	
DataPoint Un-verified.	(b) (4), (b) (6)	02 Mar 2021 20:08:48
	(b) (4), (b) (6)	
User entered 'PATIENT REPOSRTS SHE WILL BE STARTING HORMONE BLOCKER MEDICATION THIS THURSDAY (04MAR2021) AS RECOMMENDED BY ONCOLOGIST FOR PREVENTION OF DUCTAL CARNONMA RECURRENCE.' reason for change: Data Entry Error	(b) (4), (b) (6)	02 Mar 2021 20:08:48
	(b) (4), (b) (6)	
DataPoint Verified.	(b) (4), (b) (6)	09 Dec 2020 18:12:19
	(b) (4), (b) (6)	
User entered empty.	Stefanie Mott (b) (4)	23 Nov 2020 22:48:26
	(b) (4)	

US3342200

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 17:05:26

[Narrative](#)

Audit	User	Time (GMT)
User closed query 'PV Query: Thank you for your recent response. However, please clarify as the results of U/S and mammogram from Oct 2020 were still not included in the narrative. It only stated that subject had annual exam and was told by provider to have another mammogram and U/S due to another right breast lump.' (Site from Safety). User signature succeeded.	(b) (4), (b) (6) (b) (4)	30 Mar 2021 15:11:23
DataPoint Un-verified.	Paul Pickrell (b) (4) (b) (4)	29 Mar 2021 15:07:52
	Eileen Euperio (b) (4) (b) (4)	29 Mar 2021 13:28:19
User entered 'PATIENT HAD AN ABNORMAL MAMMOGRAM JUL2020 RIGHT BREAST AND HAD A RIGHT BREAST BIOSPY. RESULTS FROM ULTRASOUND AND MAMMOGRAM SHOWED CATEGORY 3 LESION AT SITE OF MASS.RESULTS FROM AUG2020 BIOPSY WERE BENIGN WITH FIBROCYSTIC CHANGES AND CALCIFICATIONS. PATIENT HAD U/S NOV2020 AND THEN HAD A LUMPECTOMY OF RIGHT BREAST 18NOV2020. PATIENT WAS DIAGNOSED WITH DUCTAL CARCINOMA IN SITU OF THE RIGHT BREAST FOLLOWING BIOPSY ON 20NOV2020. PATHOLOGY REPORT SHOWED CATEGORY 3 LESION AT SITE OFMASS. PATHOLOGY REPORT IDENTIFIED DUCTAL CARCINOMA IN SITU GRADE 2-3 MEASURING YP YO 9 MM IN DIMESNION. PATIENT WILL BE SEEING BREAST CANCER SPECIALIST AND HAS NOT STARTED MEDICATION OR RADIATION AT THIS TIME. PATIENT SAW ONCOLOGIST 13JAN2021. TOLD HER LESION WAS "PRE-CANCER" AND THAT SHE WOULD NOT NEED ANY FURTHER RADIATION OR MEDICATION AT THIS TIME.' reason for change: Data Entry Error	Eileen Euperio (b) (4) (b) (4)	29 Mar 2021 13:28:19

US3342200

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 17:05:26

[Narrative](#)

Audit	User	Time (GMT)
Query 'PV Query: Thank you for your recent response. However, please clarify as the results of U/S and mammogram from Oct 2020 were still not included in the narrative. It only stated that subject had annual exam and was told by provider to have another mammogram and U/S due to another right breast lump.' answered with 'u/s and mammogram were not done in OCT2020. confirmed with patient that U/S and lumpectomy were done NOV2020, no mammogram done reported' (Site from Safety).	Eileen Euperio (b) (4) (b) (4)	29 Mar 2021 13:27:43
User opened query 'PV Query: Thank you for your recent response. However, please clarify as the results of U/S and mammogram from Oct 2020 were still not included in the narrative. It only stated that subject had annual exam and was told by provider to have another mammogram and U/S due to another right breast lump.' (Site from Safety).	(b) (4), (b) (6) (b) (4)	19 Mar 2021 23:20:57
DataPoint Verified.	(b) (4), (b) (6) (b) (4)	19 Mar 2021 16:15:49
User closed query 'PV Query: Please provide results for U/S and mammogram from Oct 2020 . ' (Site from Safety).	(b) (4), (b) (6) (b) (4)	16 Mar 2021 16:47:31
User closed query 'Per DM CLR: SAE Narrative = BIOPSY OF RIGHT BREAST 18NOV2020. 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) (b) (4)	16 Mar 2021 16:31:53
User closed query 'Per DM CLR: Narrative = PATIENT HAD AN ABNORMAL MAMMOGRAM JUL2020. However, please review and verify if this should be recorded as part of the subject's Medical History. If yes, ensure to record this medical condition in the MH eCRF as appropriate.' (Site from DM).	(b) (4), (b) (6) (b) (4)	16 Mar 2021 16:31:26
Query 'Per DM CLR: SAE Narrative = BIOPSY OF RIGHT BREAST 18NOV2020. However, this is not recorded in the ConProc eCRF. Please review and ensure that this is captured in the appropriate eCRF. ' answered with 'LUMPECTOMY WAS PERFORMED ON THIS DATE, NOT BOPSY. THE BIOPSY OCCURED AUG2020, UPDATED' (Site from DM).	Eileen Euperio (b) (4) (b) (4)	15 Mar 2021 14:05:36

PRODUCTION RELEASE (v12.003
EAB) (1725)

3856 of 4196

US3342200

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 17:05:26

[Narrative](#)

Audit	User	Time (GMT)
User entered 'PATIENT HAD AN ABNORMAL MAMMOGRAM JUL2020 RIGHT BREAST AND HAD A RIGHT BREAST BIOSPY. RESULTS FROM ULTRASOUND AND MAMMOGRAM SHOWED CATEGORY 3 LESION AT SITE OF MASS.RESULTS FROM AUG2020 BIOPSY WERE BENIGN WITH FIBROCYSTIC CHANGES AND CALCIFICATIONS. PATIENT HAD ANNUAL EXAM OCT2020 AND WAS TOLD BY PROVIDER TO HAVE ANOTHER MAMMOGRAM AND U/S OF RIGHT BREAST DUE TO ANOTHER RIGHT BREAST LUMP. PATIENT HAD U/S NOV2020 AND THEN HAD A LUMPECTOMY OF RIGHT BREAST 18NOV2020. PATIENT WAS DIAGNOSED WITH DUCTAL CARCINOMA IN SITU OF THE RIGHT BREAST FOLLOWING BIOPSY ON 20NOV2020. PATHOLOGY REPORT SHOWED CATEGORY 3 LESION AT SITE OFMASS. PATHOLOGY REPORT IDENTIFIED DUCTAL CARCINOMA IN SITU GRADE 2-3 MEASURING YP YO 9 MM IN DIMESNION. PATIENT WILL BE SEEING BREAST CANCER SPECIALIST AND HAS NOT STARTED MEDICATION OR RADIATION AT THIS TIME. PATIENT SAW ONCOLOGIST 13JAN2021. TOLD HER LESION WAS "PRE-CANCER" AND THAT SHE WOULD NOT NEED ANY FURTHER RADIATION OR MEDICATION AT THIS TIME.' reason for change: Data Entry Error	Eileen Euperio (b) (4)	15 Mar 2021 14:04:51
Query 'Per DM CLR: Narrative = PATIENT HAD AN ABNORMAL MAMMOGRAM JUL2020. However, please review and verify if this should be recorded as part of the subject's Medical History. If yes, ensure to record this medical condition in the MH eCRF as appropriate.' answered with 'this has been moved to med hx CRF' (Site from DM).	Eileen Euperio (b) (4)	15 Mar 2021 14:01:23
Query 'PV Query: Please provide results for U/S and mammogram from Oct 2020 . ' answered with 'results are listed in the narrative' (Site from Safety).	Eileen Euperio (b) (4)	15 Mar 2021 13:53:03

PRODUCTION RELEASE (v12.003
EAB) (1725)

3857 of 4196

US3342200

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 17:05:26

[Narrative](#)

Audit	User	Time (GMT)
User opened query 'PV Query: Please provide results for U/S and mammogram from Oct 2020 . ' (Site from Safety).	(b) (4), (b) (6)	09 Mar 2021 21:49:16
User opened query 'Per DM CLR: Narrative = PATIENT HAD AN ABNORMAL MAMMOGRAM JUL2020. However, please review and verify if this should be recorded as part of the subject's Medical History. If yes, ensure to record this medical condition in the MH eCRF as appropriate.' (Site from DM).	(b) (4), (b) (6)	22 Feb 2021 01:51:41
User closed query 'PV Query: Please provide results for U/S and mammogram from Oct 2020' (Site from Safety).	(b) (4), (b) (6)	08 Feb 2021 17:11:20
User closed query 'Per DM CLR: SAE Narrative = PATIENT HAD MAMMOGRAM AND U/S OCT2020. However, these were 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)	08 Feb 2021 16:29:59
User opened query 'Per DM CLR: SAE Narrative = BIOPSY OF RIGHT BREAST 18NOV2020. 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)	07 Feb 2021 10:58:46

US3342200

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 17:05:26

[Narrative](#)

Audit	User	Time (GMT)
User entered 'PATIENT HAD AN ABNORMAL MAMMOGRAM JUL2020 RIGHT BREAST AND HAD A RIGHT BREAST BIOSPY. RESULTS FROM ULTRASOUND AND MAMMOGRAM SHOWED CATEGORY 3 LESION AT SITE OF MASS.RESULTS FROM AUG2020 BIOSPY WERE BENIGN WITH FIBROCYSTIC CHANGES AND CALCIFICATIONS. PATIENT HAD ANNUAL EXAM OCT2020 AND WAS TOLD BY PROVIDER TO HAVE ANOTHER MAMMOGRAM AND U/S OF RIGHT BREAST DUE TO ANOTHER RIGHT BREAST LUMP. PATIENT HAD U/S NOV2020 AND THEN HAD A BIOSPY OF RIGHT BREAST 18NOV2020. PATIENT WAS DIAGNOSED WITH DUCTAL CARCINOMA IN SITU OF THE RIGHT BREAST FOLLOWING BIOSPY ON 20NOV2020. PATHOLOGY REPORT SHOWED CATEGORY 3 LESION AT SITE OFMASS. PATHOLOGY REPORT IDENTIFIED DUCTAL CARCINOMA IN SITU GRADE 2-3 MEASURING YP YO 9 MM IN DIMESNION. PATIENT WILL BE SEEING BREAST CANCER SPECIALIST AND HAS NOT STARTED MEDICATION OR RADIATION AT THIS TIME. PATIENT SAW ONCOLOGIST 13JAN2021. TOLD HER LESION WAS "PRE-CANCER" AND THAT SHE WOULD NOT NEED ANY FURTHER RADIATION OR MEDICATION AT THIS TIME.' reason for change: New Information Query 'Per DM CLR: SAE Narrative = PATIENT HAD MAMMOGRAM AND U/S OCT2020. However, these were not recorded in the ConProc eCRF. Please review and ensure that this is captured in the appropriate eCRF. ' answered with 'MAMMOGRAM AND U/S DONE AFTER ANNUAL EXAM IN OCT2020-THESE ARE REPORTED IN ECRFS' (Site from DM).	Eileen Euperio (b) (4) (b) (4)	05 Feb 2021 17:14:43
	Eileen Euperio (b) (4) (b) (4)	05 Feb 2021 17:06:14

US3342200

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 17:05:26

[Narrative](#)

Audit	User	Time (GMT)
User entered 'PATIENT HAD AN ABNORMAL MAMMOGRAM JUL2020 RIGHT BREAST AND HAD A RIGHT BREAST BIOSPY. RESULTS FROM ULTRASOUND AND MAMMOGRAM SHOWED CATEGORY 3 LESION AT SITE OF MASS.RESULTS FROM AUG2020 BIOPSY WERE BENIGN WITH FIBROCYSTIC CHANGES AND CALCIFICATIONS. PATIENT HAD ANNUAL EXAM OCT2020 AND WAS TOLD BY PROVIDER TO HAVE ANOTHER MAMMOGRAM AND U/S OF RIGHT BREAST DUE TO ANOTHER RIGHT BREAST LUMP. PATIENT HAD MAMMOGRAM AND U/S OCT2020 AND THEN HAD A BIOPSY OF RIGHT BREAST 18NOV2020. PATIENT WAS DIAGNOSED WITH DUCTAL CARCINOMA IN SITU OF THE RIGHT BREAST FOLLOWING BIOPSY ON 20NOV2020. PATHOLOGY REPORT SHOWED CATEGORY 3 LESION AT SITE OFMASS. PATHOLOGY REPORT IDENTIFIED DUCTAL CARCINOMA IN SITU GRADE 2-3 MEASURING YP YO 9 MM IN DIMESNION. PATIENT WILL BE SEEING BREAST CANCER SPECIALIST AND HAS NOT STARTED MEDICATION OR RADIATION AT THIS TIME. PATIENT SAW ONCOLOGIST 13JAN2021. TOLD HER LESION WAS "PRE-CANCER" AND THAT SHE WOULD NOT NEED ANY FURTHER RADIATION OR MEDICATION AT THIS TIME.'	Eileen Euperio (b) (4) (b) (4)	05 Feb 2021 17:02:25
New Information		
Query 'PV Query: Please provide results for U/S and mammogram from Oct 2020' answered with 'results are included in narrative' (Site from Safety).	Eileen Euperio (b) (4) (b) (4)	05 Feb 2021 17:00:10
Query 'PV Query: Please confirm if event term should be updated based on diagnosis from oncologist.' canceled (Site from Safety).	(b) (4), (b) (6)	25 Jan 2021 17:54:28
User opened query 'PV Query: Please confirm if event term should be updated based on diagnosis from oncologist.' (Site from Safety).	(b) (4), (b) (6)	25 Jan 2021 17:54:04

US3342200

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 17:05:26

[Narrative](#)

Audit	User	Time (GMT)
User opened query 'Per DM CLR: SAE Narrative = PATIENT HAD MAMMOGRAM AND U/S OCT2020. However, these were not recorded in the ConProc eCRF. Please review and ensure that this is captured in the appropriate eCRF. ' (Site from DM). DataPoint Un-verified.	(b) (4), (b) (6)	19 Jan 2021 12:10:19
	(b) (4), (b) (6)	15 Jan 2021 21:49:36
User entered 'PATIENT HAD AN ABNORMAL MAMMOGRAM JUL2020 RIGHT BREAST AND HAD A RIGHT BREAST BIOSPY. RESULTS FROM ULTRASOUND AND MAMMOGRAM SHOWED CATEGORY 3 LESION AT SITE OF MASS.RESULTS FROM AUG2020 BIOPSY WERE BENIGN WITH FIBROCYSTIC CHANGES AND CALCIFICATIONS. PATIENT HAD ANNUAL EXAM OCT2020 AND WAS TOLD BY PROVIDER TO HAVE ANOTHER MAMMOGRAM AND U/S OF RIGHT BREAST DUE TO ANOTHER RIGHT BREAST LUMP. PATIENT HAD MAMMOGRAM AND U/S OCT2020 AND THEN HAD A BIOPSY OF RIGHT BREAST 18NOV2020. PATIENT WAS DIAGNOSED WITH DUCTAL CARCINOMA IN SITU OF THE RIGHT BREAST FOLLOWING BIOPSY ON 20NOV2020. PATIENT WILL BE SEEING BREAST CANCER SPECIALIST AND HAS NOT STARTED MEDICATION OR RADIATION AT THIS TIME. Patient saw oncologist 13Jan2021. Told her lesion was "pre-cancer" and that she would not need any further radiation or medication at this time.' reason for change: New Information		15 Jan 2021 21:49:36
User opened query 'PV Query: Please provide results for U/S and mammogram from Oct 2020' (Site from Safety).	(b) (4), (b) (6)	14 Dec 2020 18:58:58

US3342200

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 17:05:26

[Narrative](#)

Audit	User	Time (GMT)
User closed query 'PV Query: Please provide treatment given for the event including medical intervention and/or surgical treatments. 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)	10 Dec 2020 18:47:43
User closed query 'PV Query: Please provide the results of the mammogram and ultrasound. ' (Site from Safety).	(b) (4), (b) (6)	10 Dec 2020 18:47:39
DataPoint Verified.	(b) (4), (b) (6)	09 Dec 2020 18:12:19
Query 'PV Query: Please provide treatment given for the event including medical intervention and/or surgical treatments. 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 'CONCOMITANT PROCEDURES HAVE BEEN ADDED TO THE LOG. SUBJECT IS NOT CURRENTLY ON MEDICATIONS OR TREATMENT YET FOR THIS AE' (Site from Safety).	Eileen Euperio (b) (4) (b) (4)	09 Dec 2020 17:47:34

US3342200

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 17:05:26

[Narrative](#)

Audit	User	Time (GMT)
User entered 'PATIENT HAD AN ABNORMAL MAMMOGRAM JUL2020 RIGHT BREAST AND HAD A RIGHT BREAST BIOSPY. RESULTS FROM ULTRASOUND AND MAMMOGRAM SHOWED CATEGORY 3 LESION AT SITE OF MASS.RESULTS FROM AUG2020 BIOPSY WERE BENIGN WITH FIBROCYSTIC CHANGES AND CALCIFICATIONS. PATIENT HAD ANNUAL EXAM OCT2020 AND WAS TOLD BY PROVIDER TO HAVE ANOTHER MAMMOGRAM AND U/S OF RIGHT BREAST DUE TO ANOTHER RIGHT BREAST LUMP. PATIENT HAD MAMMOGRAM AND U/S OCT2020 AND THEN HAD A BIOPSY OF RIGHT BREAST 18NOV2020. PATIENT WAS DIAGNOSED WITH DUCTAL CARCINOMA IN SITU OF THE RIGHT BREAST FOLLOWING BIOPSY ON 20NOV2020. PATIENT WILL BE SEEING BREAST CANCER SPECIALIST AND HAS NOT STARTED MEDICATION OR RADIATION AT THIS TIME.' reason for change: New Information	Eileen Euperio (b) (4)	09 Dec 2020 17:46:25
Query 'PV Query: Please provide the results of the mammogram and ultrasound. ' answered with 'UPDATED IN NARRATIVE' (Site from Safety).	Eileen Euperio (b) (4)	09 Dec 2020 17:38:12

US3342200

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 17:05:26

[Narrative](#)

Audit	User	Time (GMT)
User entered 'PATIENT HAD AN ABNORMAL MAMMOGRAM JUL2020 RIGHT BREAST AND HAD A RIGHT BREAST BIOSPY. RESULTS FROM ULTRASOUND AND MAMMOGRAM SHOWED CATEGORY 3 LESION AT SITE OF MASS.DRESULTS FROM AUG2020 BIOPSY WERE BENIGN WITH FIBROCYSTIC CHANGES AND CALCIFICATIONS. PATIENT HAD ANNUAL EXAM OCT2020 AND WAS TOLD BY PROVIDER TO HAVE ANOTHER MAMMOGRAM AND U/S OF RIGHT BREAST DUE TO ANOTHER RIGHT BREAST LUMP. PATIENT HAD MAMMOGRAM AND U/S OCT2020 AND THEN HAD A BIOPSY OF RIGHT BREAST 18NOV2020. PATIENT WAS DIAGNOSED WITH DUCTAL CARCINOMA IN SITU OF THE RIGHT BREAST FOLLOWING BIOPSY ON 20NOV2020. PATIENT WILL BE SEEING BREAST CANCER SPECIALIST AND HAS NOT STARTED MEDICATION OR RADIATION AT THIS TIME.' reason for change: New Information	Eileen Euperio (b) (4) (b) (4)	09 Dec 2020 17:38:03
User opened query 'PV Query: Please provide treatment given for the event including medical intervention and/or surgical treatments. 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)	03 Dec 2020 23:54:14
User opened query 'PV Query: Please provide the results of the mammogram and ultrasound. ' (Site from Safety).	(b) (4), (b) (6)	03 Dec 2020 23:54:04

US3342200

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 17:05:26

[Narrative](#)

Audit	User	Time (GMT)
User entered 'patient had an abnormal mammogram Aug2020 right breast and had a right breast biopsy. results from Aug2020 biopsy were benign. Patient had annual exam Oct2020 and was told by provider to have another mammogram and u/s of right breast due to another right breast lump. Patient had mammogram and u/s Oct2020 and then had a biopsy of right breast 18Nov2020. Patient was diagnosed with ductal carcinoma in situ of the right breast following biopsy on 20Nov2020. Patient will be seeing breast cancer specialist and has not started medication or radiation at this time.'	Stefanie Mott (b) (4)	23 Nov 2020 22:48:26

US3342200

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 17:05:26

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered 'I'	System	23 Nov 2020 22:48:26

US3342200

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 17:05:26

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered 'I'	System	23 Nov 2020 22:48:26

US3342200

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 17:05:26

[AEID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:04:24

US3342200

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 17:05:26

[Adverse event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:04:24
User signature succeeded.	Paul Pickrell (b) (4)	29 Mar 2021 15:07:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Mar 2021 16:15:49
User coded data point as SOC: Injury, poisoning and procedural complications, HLGT: Injuries by physical agents, HLT: Radiation injuries, PT: Radiation skin injury, LLT: Dermatitis radiation - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	16 Mar 2021 09:57:49
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	16 Mar 2021 09:57:49
Data point term sent to Coder	System	15 Mar 2021 15:57:10
User entered 'radiation dermatitis'	Olivia Hapanowicz (b) (4) (b) (4)	15 Mar 2021 15:56:46

US3342200

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 17:05:26

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:04:24
User signature succeeded.	Paul Pickrell (b) (4)	29 Mar 2021 15:07:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Mar 2021 16:15:49
User entered 'Yes (Y)'	Olivia Hapanowicz (b) (4) (b) (4)	15 Mar 2021 15:56:46

US3342200

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 17:05:26

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:04:24
User signature succeeded.	Paul Pickrell (b) (4)	29 Mar 2021 15:07:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Mar 2021 16:15:49
User entered 'No (N)'	Olivia Hapanowicz (b) (4) (b) (4)	15 Mar 2021 15:56:46

US3342200

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 17:05:26

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:04:24
User signature succeeded.	Paul Pickrell (b) (4)	29 Mar 2021 15:07:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Mar 2021 16:15:49
User entered 'No (N)'	Olivia Hapanowicz (b) (4) (b) (4)	15 Mar 2021 15:56:46

US3342200

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 17:05:26

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:04:24
User signature succeeded.	Paul Pickrell (b) (4)	29 Mar 2021 15:07:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Mar 2021 16:15:49
User entered '21 Jan 2021'	Olivia Hapanowicz (b) (4) (b) (4)	15 Mar 2021 15:56:46

US3342200

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 17:05:26

[Start time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:04:24
User signature succeeded.	Paul Pickrell (b) (4)	29 Mar 2021 15:07:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Mar 2021 16:15:49
User entered empty.	Olivia Hapanowicz (b) (4) (b) (4)	15 Mar 2021 15:56:46

US3342200

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 17:05:26

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:04:24
User entered empty.	System	15 Mar 2021 15:56:46

US3342200

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 17:05:26

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:04:24
User signature succeeded.	Paul Pickrell (b) (4)	29 Mar 2021 15:07:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Mar 2021 16:15:49
User entered 'No (N)'	Olivia Hapanowicz (b) (4) (b) (4)	15 Mar 2021 15:56:46

US3342200

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 17:05:26

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:04:24
User signature succeeded.	Paul Pickrell (b) (4)	29 Mar 2021 15:07:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Mar 2021 16:15:49
User entered '11 Feb 2021'	Olivia Hapanowicz (b) (4) (b) (4)	15 Mar 2021 15:56:46

US3342200

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 17:05:26

End time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:04:24
User signature succeeded.	Paul Pickrell (b) (4)	29 Mar 2021 15:07:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Mar 2021 16:15:49
User entered empty.	Olivia Hapanowicz (b) (4) (b) (4)	15 Mar 2021 15:56:46

US3342200

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 17:05:26

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:04:24
User entered empty.	System	15 Mar 2021 15:56:46

US3342200

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 17:05:26

[Severity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:04:24
User signature succeeded.	Paul Pickrell (b) (4)	29 Mar 2021 15:07:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Mar 2021 16:15:49
User entered 'Grade 2/Moderate (Grade 2/Moderate)'	Olivia Hapanowicz (b) (4) (b) (4)	15 Mar 2021 15:56:46

US3342200

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 17:05:26

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:04:24
User signature succeeded.	Paul Pickrell (b) (4)	29 Mar 2021 15:07:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Mar 2021 16:15:49
User entered 'No (N)'	Olivia Hapanowicz (b) (4) (b) (4)	15 Mar 2021 15:56:46

US3342200

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 17:05:26

[Death](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:04:24
User signature succeeded.	Paul Pickrell (b) (4)	29 Mar 2021 15:07:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Mar 2021 16:15:49
User entered '0'	Olivia Hapanowicz (b) (4) (b) (4)	15 Mar 2021 15:56:46

US3342200

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 17:05:26

[Life threatening](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:04:24
User signature succeeded.	Paul Pickrell (b) (4)	29 Mar 2021 15:07:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Mar 2021 16:15:49
User entered '0'	Olivia Hapanowicz (b) (4) (b) (4)	15 Mar 2021 15:56:46

US3342200

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 17:05:26

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:04:24
User signature succeeded.	Paul Pickrell (b) (4)	29 Mar 2021 15:07:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Mar 2021 16:15:49
User entered '0'	Olivia Hapanowicz (b) (4) (b) (4)	15 Mar 2021 15:56:46

US3342200

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 17:05:26

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:04:24
User signature succeeded.	Paul Pickrell (b) (4)	29 Mar 2021 15:07:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Mar 2021 16:15:49
User entered empty.	Olivia Hapanowicz (b) (4) (b) (4)	15 Mar 2021 15:56:46

US3342200

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 17:05:26

Hospital Discharge Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:04:24
User signature succeeded.	Paul Pickrell (b) (4)	29 Mar 2021 15:07:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Mar 2021 16:15:49
User entered empty.	Olivia Hapanowicz (b) (4) (b) (4)	15 Mar 2021 15:56:46

US3342200

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 17:05:26

[Admitted to ICU?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:04:24
User signature succeeded.	Paul Pickrell (b) (4)	29 Mar 2021 15:07:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Mar 2021 16:15:49
User entered empty.	Olivia Hapanowicz (b) (4) (b) (4)	15 Mar 2021 15:56:46

US3342200

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 17:05:26

[Number of Days in ICU](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:04:24
User signature succeeded.	Paul Pickrell (b) (4)	29 Mar 2021 15:07:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Mar 2021 16:15:49
User entered empty.	Olivia Hapanowicz (b) (4) (b) (4)	15 Mar 2021 15:56:46

US3342200

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 17:05:26

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:04:24
User signature succeeded.	Paul Pickrell (b) (4)	29 Mar 2021 15:07:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Mar 2021 16:15:49
User entered '0'	Olivia Hapanowicz (b) (4) (b) (4)	15 Mar 2021 15:56:46

US3342200

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 17:05:26

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:04:24
User signature succeeded.	Paul Pickrell (b) (4)	29 Mar 2021 15:07:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Mar 2021 16:15:49
User entered '0'	Olivia Hapanowicz (b) (4) (b) (4)	15 Mar 2021 15:56:46

US3342200

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 17:05:26

[Other medically important event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:04:24
User signature succeeded.	Paul Pickrell (b) (4)	29 Mar 2021 15:07:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Mar 2021 16:15:49
User entered '0'	Olivia Hapanowicz (b) (4) (b) (4)	15 Mar 2021 15:56:46

US3342200

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 17:05:26

[Relationship to investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:04:24
User signature succeeded.	Paul Pickrell (b) (4)	29 Mar 2021 15:07:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Mar 2021 16:15:49
User entered 'Not Related (NOT RELATED)'	Olivia Hapanowicz (b) (4) (b) (4)	15 Mar 2021 15:56:46

US3342200

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 17:05:26

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:04:24
User signature succeeded.	Paul Pickrell (b) (4)	29 Mar 2021 15:07:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Mar 2021 16:15:49
User entered 'Not Related (NOT RELATED)'	Olivia Hapanowicz (b) (4) (b) (4)	15 Mar 2021 15:56:46

US3342200

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 17:05:26

[Action taken with investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:04:24
User signature succeeded.	Paul Pickrell (b) (4)	29 Mar 2021 15:07:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Mar 2021 16:15:49
User entered 'Not Applicable (NOT APPLICABLE)'	Olivia Hapanowicz (b) (4) (b) (4)	15 Mar 2021 15:56:46

US3342200

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 17:05:26

[None](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:04:24
User signature succeeded.	Paul Pickrell (b) (4)	29 Mar 2021 15:07:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Mar 2021 16:15:49
User entered '0'	Olivia Hapanowicz (b) (4) (b) (4)	15 Mar 2021 15:56:46

US3342200

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 17:05:26

[Concomitant Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:04:24
User signature succeeded.	Paul Pickrell (b) (4)	29 Mar 2021 15:07:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Mar 2021 16:15:49
User entered 'l'	Olivia Hapanowicz (b) (4) (b) (4)	15 Mar 2021 15:56:46

US3342200

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 17:05:26

[Concomitant Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:04:24
User signature succeeded.	Paul Pickrell (b) (4)	29 Mar 2021 15:07:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Mar 2021 16:15:49
User entered '0'	Olivia Hapanowicz (b) (4) (b) (4)	15 Mar 2021 15:56:46

US3342200

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 17:05:26

[Outcome](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:04:24
User signature succeeded.	Paul Pickrell (b) (4)	29 Mar 2021 15:07:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Mar 2021 16:15:49
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)'	Olivia Hapanowicz (b) (4) (b) (4)	15 Mar 2021 15:56:46

US3342200

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 17:05:26

[If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:04:24
User signature succeeded.	Paul Pickrell (b) (4)	29 Mar 2021 15:07:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Mar 2021 16:15:49
User entered empty.	Olivia Hapanowicz (b) (4) (b) (4)	15 Mar 2021 15:56:46

US3342200

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 17:05:26

[Narrative](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:04:24
User signature succeeded.	Paul Pickrell (b) (4)	29 Mar 2021 15:07:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Mar 2021 16:15:49
User entered empty.	Olivia Hapanowicz (b) (4) (b) (4)	15 Mar 2021 15:56:46

US3342200

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 17:05:26

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:04:24
User entered '0'	System	15 Mar 2021 15:56:46

US3342200

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 17:05:26

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:04:24
User entered 'I'	System	15 Mar 2021 15:56:46

US3342200

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 17:05:26

[Admitted to ICU Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:04:24

US3342200

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination Summary

Generated On: 09 Jun 2021 17:05:26

[Were any prior/concomitant medications and/or vaccinations taken?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 05:46:33
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:24:15
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Dec 2020 18:25:38
User entered 'Yes (Y)'	Stefanie Mott (b) (4)	04 Sep 2020 22:02:19

US3342200

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 17:05:26

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Pickrell (b) (4)	22 Mar 2021 13:32:48
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Dec 2020 18:26:05
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: VITAMIN D NOS, PRODUCTSYNONYM: VITAMIN D [VITAMIN D NOS] - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	04 Sep 2020 22:04:46
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	04 Sep 2020 22:04:46
Data point term sent to Coder	System	04 Sep 2020 22:03:52
User entered 'Vitamin D'	Stefanie Mott (b) (4) (b) (4) (b) (4)	04 Sep 2020 22:03:36

US3342200

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 17:05:26

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Pickrell (b) (4)	22 Mar 2021 13:32:48
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Mar 2021 16:19:32
User closed query 'Per DM CLR: Please review and verify if this can be updated to NO as there is a corresponding MH condition recorded. If yes, please update accordingly. ' (Site from DM).	(b) (4), (b) (6)	12 Mar 2021 10:05:24
Query 'Per DM CLR: Please review and verify if this can be updated to NO as there is a corresponding MH condition recorded. If yes, please update accordingly. ' answered with 'updated' (Site from DM).	Olivia Hapanowicz (b) (4) (b) (4)	11 Mar 2021 18:48:53
User entered 'No (N)' reason for change: Data Entry Error	Olivia Hapanowicz (b) (4) (b) (4)	11 Mar 2021 18:48:46
User opened query 'Per DM CLR: Please review and verify if this can be updated to NO as there is a corresponding MH condition recorded. If yes, please update accordingly. ' (Site from DM).	(b) (4), (b) (6)	23 Feb 2021 08:35:50
User closed query 'Per CDM: Please review prophylaxis because supplements/vitamins/contraceptives and vaccines are considered as prophylaxis. Update as appropriate or clarify otherwise. Thank you!' (Site from DM).	(b) (4), (b) (6)	08 Feb 2021 15:14:00
Query 'Per CDM: Please review prophylaxis because supplements/vitamins/contraceptives and vaccines are considered as prophylaxis. Update as appropriate or clarify otherwise. Thank you!' answered with 'UPDATED' (Site from DM).	Eileen Euperio (b) (4) (b) (4)	05 Feb 2021 17:15:17
DataPoint Un-verified.	Eileen Euperio (b) (4) (b) (4)	05 Feb 2021 17:15:10
User entered 'Yes (Y)' reason for change: Data Entry Error	Eileen Euperio (b) (4) (b) (4)	05 Feb 2021 17:15:10
User opened query 'Per CDM: Please review prophylaxis because supplements/vitamins/contraceptives and vaccines are considered as prophylaxis. Update as appropriate or clarify otherwise. Thank you!' (Site from DM).	(b) (4), (b) (6)	17 Dec 2020 10:45:01
DataPoint Verified.	(b) (4), (b) (6)	09 Dec 2020 18:26:05

US3342200

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 17:05:26

[Prophylaxis](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Stefanie Mott (b) (4) [REDACTED] [REDACTED]	04 Sep 2020 22:03:36

US3342200

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 17:05:26

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Pickrell (b) (4)	22 Mar 2021 13:32:48
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Dec 2020 18:26:05
User entered 'Vitamin D deficiency'	Stefanie Mott (b) (4)	04 Sep 2020 22:03:36

US3342200

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 17:05:26

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Pickrell (b) (4)	22 Mar 2021 13:32:48
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Dec 2020 18:26:05
User entered '5000'	Stefanie Mott (b) (4)	04 Sep 2020 22:03:36

US3342200

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 17:05:26

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Pickrell (b) (4)	22 Mar 2021 13:32:48
User closed query 'Per DM CLR: Please review the unit as this does not correspond to the given dose of this medication. Review and update as applicable. ' (Site from DM).	(b) (4) (b) (4), (b) (6)	11 Dec 2020 13:35:18
DataPoint Verified.	(b) (4), (b) (6)	09 Dec 2020 18:26:05
Query 'Per DM CLR: Please review the unit as this does not correspond to the given dose of this medication. Review and update as applicable. ' answered with 'UPDATED' (Site from DM).	Eileen Euperio (b) (4) (b) (4)	09 Dec 2020 17:45:36
User entered 'IU (IU)' reason for change: Data Entry Error	Eileen Euperio (b) (4) (b) (4)	09 Dec 2020 17:45:31
User opened query 'Per DM CLR: Please review the unit as this does not correspond to the given dose of this medication. Review and update as applicable. ' (Site from DM).	(b) (4), (b) (6)	02 Dec 2020 15:24:47
User entered 'mg (mg)'	Stefanie Mott (b) (4)	04 Sep 2020 22:03:36

US3342200

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 17:05:26

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Paul Pickrell (b) (4)	22 Mar 2021 13:32:48
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Dec 2020 18:26:05
User entered empty.	Stefanie Mott (b) (4)	04 Sep 2020 22:03:36

US3342200

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 17:05:26

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Pickrell (b) (4)	22 Mar 2021 13:32:48
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Dec 2020 18:26:05
User entered 'every week (QS)'	Stefanie Mott (b) (4)	04 Sep 2020 22:03:36

US3342200

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 17:05:26

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Pickrell (b) (4)	22 Mar 2021 13:32:48
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Dec 2020 18:26:05
User entered empty.	Stefanie Mott (b) (4)	04 Sep 2020 22:03:36

US3342200

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 17:05:26

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Pickrell (b) (4)	22 Mar 2021 13:32:48
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Dec 2020 18:26:05
User entered 'Oral (ORAL)'	Stefanie Mott (b) (4)	04 Sep 2020 22:03:36

US3342200

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 17:05:26

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Paul Pickrell (b) (4)	22 Mar 2021 13:32:48
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Dec 2020 18:26:05
User entered empty.	Stefanie Mott (b) (4)	04 Sep 2020 22:03:36

US3342200

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 17:05:26

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Paul Pickrell (b) (4)	22 Mar 2021 13:32:48
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Dec 2020 18:26:05
User entered 'UN UNK 2015'	Stefanie Mott (b) (4)	04 Sep 2020 22:03:36

US3342200

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 17:05:26

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Pickrell (b) (4)	22 Mar 2021 13:32:48
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Dec 2020 18:26:05
User entered '0'	Stefanie Mott (b) (4)	04 Sep 2020 22:03:36

US3342200

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 17:05:26

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Pickrell (b) (4)	22 Mar 2021 13:32:48
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Dec 2020 18:26:05
User entered 'Yes (Y)'	Stefanie Mott (b) (4)	04 Sep 2020 22:03:36

US3342200

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 17:05:26

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Paul Pickrell (b) (4)	22 Mar 2021 13:32:48
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Dec 2020 18:26:05
User entered empty.	Stefanie Mott (b) (4)	04 Sep 2020 22:03:36

US3342200

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 17:05:26

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Pickrell (b) (4)	22 Mar 2021 13:32:48
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Dec 2020 18:26:05
User entered 'No (N)'	Stefanie Mott (b) (4)	04 Sep 2020 22:03:36

US3342200

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 17:05:26

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	04 Sep 2020 22:03:36

US3342200

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 17:05:26

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	04 Sep 2020 22:03:36

US3342200

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 17:05:26

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '803 (803)'	System	04 Sep 2020 22:03:36

US3342200

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 17:05:26

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Pickrell (b) (4)	22 Mar 2021 13:32:48
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Dec 2020 18:26:05
User coded data point as ATC: RESPIRATORY SYSTEM, ATC: DRUGS FOR OBSTRUCTIVE AIRWAY DISEASES, ATC: OTHER SYSTEMIC DRUGS FOR OBSTRUCTIVE AIRWAY DISEASES, ATC: LEUKOTRIENE RECEPTOR ANTAGONISTS, PRODUCT: MONTELUKAST SODIUM, PRODUCTSYNONYM: SINGULAIR - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	04 Sep 2020 22:05:47
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	04 Sep 2020 22:05:47
Data point term sent to Coder	System	04 Sep 2020 22:04:52
User entered 'Singulair'	Stefanie Mott (b) (4)	04 Sep 2020 22:04:24

US3342200

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 17:05:26

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Pickrell (b) (4)	22 Mar 2021 13:32:48
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Dec 2020 18:26:05
User entered 'No (N)'	Stefanie Mott (b) (4)	04 Sep 2020 22:04:24

US3342200

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 17:05:26

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Pickrell (b) (4)	22 Mar 2021 13:32:48
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Dec 2020 18:26:05
User entered 'Seasonal allergies'	Stefanie Mott (b) (4)	04 Sep 2020 22:04:24

US3342200

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 17:05:26

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Pickrell (b) (4)	22 Mar 2021 13:32:48
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Dec 2020 18:26:05
User entered '10'	Stefanie Mott (b) (4)	04 Sep 2020 22:04:24

US3342200

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 17:05:26

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Pickrell (b) (4)	22 Mar 2021 13:32:48
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Dec 2020 18:26:05
User entered 'mg (mg)'	Stefanie Mott (b) (4)	04 Sep 2020 22:04:24

US3342200

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 17:05:26

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Paul Pickrell (b) (4)	22 Mar 2021 13:32:48
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Dec 2020 18:26:05
User entered empty.	Stefanie Mott (b) (4)	04 Sep 2020 22:04:24

US3342200

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 17:05:26

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Pickrell (b) (4)	22 Mar 2021 13:32:48
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Dec 2020 18:26:05
User entered 'as needed (PRN)'	Stefanie Mott (b) (4)	04 Sep 2020 22:04:24

US3342200

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 17:05:26

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Paul Pickrell (b) (4)	22 Mar 2021 13:32:48
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Dec 2020 18:26:05
User entered empty.	Stefanie Mott (b) (4)	04 Sep 2020 22:04:24

US3342200

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 17:05:26

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Pickrell (b) (4)	22 Mar 2021 13:32:48
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Dec 2020 18:26:05
User entered 'Oral (ORAL)'	Stefanie Mott (b) (4)	04 Sep 2020 22:04:24

US3342200

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 17:05:26

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Paul Pickrell (b) (4)	22 Mar 2021 13:32:48
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Dec 2020 18:26:05
User entered empty.	Stefanie Mott (b) (4)	04 Sep 2020 22:04:24

US3342200

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 17:05:26

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Paul Pickrell (b) (4)	22 Mar 2021 13:32:48
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Dec 2020 18:26:05
User entered 'UN UNK 2010'	Stefanie Mott (b) (4)	04 Sep 2020 22:04:24

US3342200

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 17:05:26

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Pickrell (b) (4)	22 Mar 2021 13:32:48
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Dec 2020 18:26:05
User entered '0'	Stefanie Mott (b) (4)	04 Sep 2020 22:04:24

US3342200

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 17:05:26

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Pickrell (b) (4)	22 Mar 2021 13:32:48
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Dec 2020 18:26:05
User entered 'Yes (Y)'	Stefanie Mott (b) (4)	04 Sep 2020 22:04:24

US3342200

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 17:05:26

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Paul Pickrell (b) (4)	22 Mar 2021 13:32:48
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Dec 2020 18:26:05
User entered empty.	Stefanie Mott (b) (4)	04 Sep 2020 22:04:24

US3342200

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 17:05:26

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Pickrell (b) (4)	22 Mar 2021 13:32:48
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Dec 2020 18:26:05
User entered 'No (N)'	Stefanie Mott (b) (4)	04 Sep 2020 22:04:24

US3342200

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 17:05:26

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	04 Sep 2020 22:04:24

US3342200

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 17:05:26

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	04 Sep 2020 22:04:24

US3342200

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 17:05:26

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	04 Sep 2020 22:04:24

US3342200

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 17:05:26

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 13:06:14
User signature succeeded.	Paul Pickrell (b) (4)	22 Mar 2021 13:32:48
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Dec 2020 18:26:05
User coded data point as ATC: ANTIINFECTIVES FOR SYSTEMIC USE, ATC: VACCINES, ATC: VIRAL VACCINES, ATC: INFLUENZA VACCINES, PRODUCT: INFLUENZA VACCINE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	05 Sep 2020 05:39:44
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	05 Sep 2020 05:39:44
Data point term sent to Coder	System	04 Sep 2020 22:05:54
User entered 'Flu vaccine'	Stefanie Mott (b) (4)	04 Sep 2020 22:05:41

US3342200

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 17:05:26

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 13:06:14
User signature succeeded.	Paul Pickrell (b) (4)	22 Mar 2021 13:32:48
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Dec 2020 18:26:05
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) (6)	03 Dec 2020 13:59:50
Query 'Per DM CLR: Please review response as supplements/vitamins/contraceptives and vaccines are considered as prophylaxis. Update as appropriate. ' answered with 'This has been updated.' (Site from DM).	Olivia Hapanowicz (b) (4) (b) (4)	02 Dec 2020 21:49:42
User entered 'Yes (Y)' reason for change: Data Entry Error	Olivia Hapanowicz (b) (4) (b) (4)	02 Dec 2020 21:49:33
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)	30 Nov 2020 13:48:14
User entered 'No (N)'	Stefanie Mott (b) (4)	04 Sep 2020 22:05:41

US3342200

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 17:05:26

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 13:06:14
User signature succeeded.	Paul Pickrell (b) (4)	22 Mar 2021 13:32:48
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Dec 2020 18:26:05
User entered 'influenza prevention'	Stefanie Mott (b) (4)	04 Sep 2020 22:05:41

US3342200

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 17:05:26

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 13:06:14
User signature succeeded.	Paul Pickrell (b) (4)	22 Mar 2021 13:32:48
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Dec 2020 18:26:05
User entered 'l'	Stefanie Mott (b) (4)	04 Sep 2020 22:05:41

US3342200

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 17:05:26

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 13:06:14
User signature succeeded.	Paul Pickrell (b) (4)	22 Mar 2021 13:32:48
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Dec 2020 18:26:05
User entered 'Other (OTHER)'	Stefanie Mott (b) (4)	04 Sep 2020 22:05:41

US3342200

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 17:05:26

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 13:06:14
User signature succeeded.	Paul Pickrell (b) (4)	22 Mar 2021 13:32:48
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Dec 2020 18:26:05
User closed query 'Per CDM: If dose unit is Other, specify is recorded as ' DOSE' which is unclear.Please consider to verify and update data appropriately else clarify.Thank you. ' (Site from DM).	(b) (4), (b) (6)	08 Oct 2020 06:25:00
Query 'Per CDM: If dose unit is Other, specify is recorded as ' DOSE' which is unclear.Please consider to verify and update data appropriately else clarify.Thank you. ' answered with 'Updated from "dose" to "injection" due to unknown exact dosage.' (Site from DM).	Andrew Bell (b) (4) (b) (4)	07 Oct 2020 14:34:07
User entered 'INJECTION' reason for change: Data Entry Error	Andrew Bell (b) (4) (b) (4)	07 Oct 2020 14:33:33
User opened query 'Per CDM: If dose unit is Other, specify is recorded as ' DOSE' which is unclear.Please consider to verify and update data appropriately else clarify.Thank you. ' (Site from DM).	(b) (4), (b) (6)	07 Oct 2020 06:24:49
User entered 'Dose'	Stefanie Mott (b) (4)	04 Sep 2020 22:05:41

US3342200

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 17:05:26

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 13:06:14
User signature succeeded.	Paul Pickrell (b) (4)	22 Mar 2021 13:32:48
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Dec 2020 18:26:05
User entered 'once (ONCE)'	Stefanie Mott (b) (4)	04 Sep 2020 22:05:41

US3342200

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 17:05:26

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 13:06:14
User signature succeeded.	Paul Pickrell (b) (4)	22 Mar 2021 13:32:48
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Dec 2020 18:26:05
User entered empty.	Stefanie Mott (b) (4)	04 Sep 2020 22:05:41

US3342200

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 17:05:26

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 13:06:14
User signature succeeded.	Paul Pickrell (b) (4)	22 Mar 2021 13:32:48
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Dec 2020 18:26:05
User entered 'Intramuscular (INTRAMUSCULAR)'	Stefanie Mott (b) (4)	04 Sep 2020 22:05:41

US3342200

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 17:05:26

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 13:06:14
User signature succeeded.	Paul Pickrell (b) (4)	22 Mar 2021 13:32:48
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Dec 2020 18:26:05
User entered empty.	Stefanie Mott (b) (4)	04 Sep 2020 22:05:41

US3342200

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 17:05:26

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 13:06:14
User signature succeeded.	Paul Pickrell (b) (4)	22 Mar 2021 13:32:48
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Dec 2020 18:26:05
User entered '05 Aug 2020'	Stefanie Mott (b) (4)	04 Sep 2020 22:05:41

US3342200

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 17:05:26

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 13:06:14
User signature succeeded.	Paul Pickrell (b) (4)	22 Mar 2021 13:32:48
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Dec 2020 18:26:05
User entered '0'	Stefanie Mott (b) (4)	04 Sep 2020 22:05:41

US3342200

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 17:05:26

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 13:06:14
User signature succeeded.	Paul Pickrell (b) (4)	22 Mar 2021 13:32:48
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Dec 2020 18:26:05
User entered 'No (N)'	Stefanie Mott (b) (4)	04 Sep 2020 22:05:41

US3342200

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 17:05:26

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 13:06:14
User signature succeeded.	Paul Pickrell (b) (4)	22 Mar 2021 13:32:48
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Dec 2020 18:26:05
User entered '05 Aug 2020'	Stefanie Mott (b) (4)	04 Sep 2020 22:05:41

US3342200

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 17:05:26

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 13:06:14
User signature succeeded.	Paul Pickrell (b) (4)	22 Mar 2021 13:32:48
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Dec 2020 18:26:05
User entered 'No (N)'	Stefanie Mott (b) (4)	04 Sep 2020 22:05:41

US3342200

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 17:05:26

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 13:06:14
User entered empty.	System	04 Sep 2020 22:05:41

US3342200

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 17:05:26

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 13:06:14
User entered empty.	System	04 Sep 2020 22:05:41

US3342200

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 17:05:26

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 13:06:14
User entered empty.	System	04 Sep 2020 22:05:41

US3342200

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 17:05:26

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Pickrell (b) (4)	22 Mar 2021 13:32:48
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Dec 2020 18:26:05
User coded data point as ATC: DERMATOLOGICALS, ATC: CORTICOSTEROIDS, DERMATOLOGICAL PREPARATIONS, ATC: CORTICOSTEROIDS, PLAIN, ATC: CORTICOSTEROIDS, MODERATELY POTENT (GROUP II), PRODUCT: TRIAMCINOLONE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	06 Oct 2020 05:45:29
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	06 Oct 2020 05:45:29
Data point term sent to Coder	System	05 Oct 2020 19:27:28
User entered 'Triamcinolone 1%'	Morgan Schulle (b) (4) (b) (4)	05 Oct 2020 19:26:55

US3342200

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 17:05:26

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Pickrell (b) (4)	22 Mar 2021 13:32:48
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Dec 2020 18:26:05
User entered 'No (N)'	Morgan Schulle (b) (4) (b) (4)	05 Oct 2020 19:26:55

US3342200

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 17:05:26

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Pickrell (b) (4)	22 Mar 2021 13:32:48
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Dec 2020 18:26:05
User entered 'ATOPIC DERMATITIS'	Morgan Schulle (b) (4) (b) (4)	05 Oct 2020 19:26:55

US3342200

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 17:05:26

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Pickrell (b) (4)	22 Mar 2021 13:32:48
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Dec 2020 18:26:05
User entered 'I'	Morgan Schulle (b) (4) (b) (4)	05 Oct 2020 19:26:55

US3342200

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 17:05:26

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Pickrell (b) (4)	22 Mar 2021 13:32:48
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Dec 2020 18:26:05
User entered 'Other (OTHER)'	Morgan Schulle (b) (4) (b) (4)	05 Oct 2020 19:26:55

US3342200

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 17:05:26

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Paul Pickrell (b) (4)	22 Mar 2021 13:32:48
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Dec 2020 18:26:05
User entered 'APPLICATION'	Morgan Schulle (b) (4) (b) (4)	05 Oct 2020 19:26:55

US3342200

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 17:05:26

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Pickrell (b) (4)	22 Mar 2021 13:32:48
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Dec 2020 18:26:05
User entered 'as needed (PRN)'	Morgan Schulle (b) (4) (b) (4)	05 Oct 2020 19:26:55

US3342200

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 17:05:26

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Pickrell (b) (4)	22 Mar 2021 13:32:48
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Dec 2020 18:26:05
User entered empty.	Morgan Schulle (b) (4) (b) (4)	05 Oct 2020 19:26:55

US3342200

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 17:05:26

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Pickrell (b) (4)	22 Mar 2021 13:32:48
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Dec 2020 18:26:05
User entered 'Topical (TOPICAL)'	Morgan Schulle (b) (4) (b) (4)	05 Oct 2020 19:26:55

US3342200

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 17:05:26

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Paul Pickrell (b) (4)	22 Mar 2021 13:32:48
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Dec 2020 18:26:05
User entered empty.	Morgan Schulle (b) (4) (b) (4)	05 Oct 2020 19:26:55

US3342200

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 17:05:26

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Paul Pickrell (b) (4)	22 Mar 2021 13:32:48
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Dec 2020 18:26:05
User entered 'UN UNK 2000'	Morgan Schulle (b) (4) (b) (4)	05 Oct 2020 19:26:55

US3342200

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 17:05:26

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Pickrell (b) (4)	22 Mar 2021 13:32:48
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Dec 2020 18:26:05
User entered '0'	Morgan Schulle (b) (4) (b) (4)	05 Oct 2020 19:26:55

US3342200

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 17:05:26

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Pickrell (b) (4)	22 Mar 2021 13:32:48
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Dec 2020 18:26:05
User entered 'Yes (Y)'	Morgan Schulle (b) (4) (b) (4)	05 Oct 2020 19:26:55

US3342200

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 17:05:26

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Paul Pickrell (b) (4)	22 Mar 2021 13:32:48
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Dec 2020 18:26:05
User entered empty.	Morgan Schulle (b) (4) (b) (4)	05 Oct 2020 19:26:55

US3342200

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 17:05:26

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Pickrell (b) (4)	22 Mar 2021 13:32:48
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Dec 2020 18:26:05
User entered 'No (N)'	Morgan Schulle (b) (4) (b) (4)	05 Oct 2020 19:26:55

US3342200

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 17:05:26

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	05 Oct 2020 19:26:55

US3342200

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 17:05:26

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	05 Oct 2020 19:26:55

US3342200

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 17:05:26

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	05 Oct 2020 19:26:55

US3342200

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 17:05:26

Name of Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 08:28:13
User signature succeeded.	Paul Pickrell (b) (4)	22 Mar 2021 13:32:48
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Dec 2020 18:26:05
User coded data point as ATC: NERVOUS SYSTEM, ATC: ANALGESICS, ATC: OTHER ANALGESICS AND ANTIPYRETICS, ATC: ANILIDES, PRODUCT: PARACETAMOL, PRODUCTSYNONYM: ACETAMINOPHEN EXTRA STRENGTH - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	07 Oct 2020 20:03:54
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 Oct 2020 20:03:54
Data point term sent to Coder	System	07 Oct 2020 19:15:18
User entered 'Acetaminophen extra strength'	Ethan Shotton (b) (4) (b) (4)	07 Oct 2020 19:14:49

US3342200

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 17:05:26

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 08:28:13
User signature succeeded.	Paul Pickrell (b) (4)	22 Mar 2021 13:32:48
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Dec 2020 18:26:05
User entered 'No (N)'	Ethan Shotton (b) (4) (b) (4)	07 Oct 2020 19:14:49

US3342200

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 17:05:26

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 08:28:13
User signature succeeded.	Paul Pickrell (b) (4)	22 Mar 2021 13:32:48
User closed query 'Per DM CLR: Please note that there is no AE or Dairy event that matches this Con med indication. Review if this should be recorded as an Adverse Event (unsolicited). Else, provide clarification if this will not be recorded on AE eCRF.' (Site from DM).	(b) (4) (b) (4), (b) (6)	11 Dec 2020 13:35:06
DataPoint Verified.	(b) (4), (b) (6)	09 Dec 2020 18:26:05
Query 'Per DM CLR: Please note that there is no AE or Dairy event that matches this Con med indication. Review if this should be recorded as an Adverse Event (unsolicited). Else, provide clarification if this will not be recorded on AE eCRF.' answered with 'ENTRY IS DAY 4 BUT SUBJECT REPORTS TAKING IT ON D3 POST 2ND VAX' (Site from DM).	Eileen Euperio (b) (4) (b) (4)	09 Dec 2020 17:44:42
User opened query 'Per DM CLR: Please note that there is no AE or Dairy event that matches this Con med indication. Review if this should be recorded as an Adverse Event (unsolicited). Else, provide clarification if this will not be recorded on AE eCRF.' (Site from DM).	(b) (4), (b) (6)	30 Nov 2020 13:49:46
User entered 'Headache (solicited reaction - Vaccine #2)'	Ethan Shotton (b) (4) (b) (4)	07 Oct 2020 19:14:49

US3342200

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 17:05:26

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 08:28:13
User signature succeeded.	Paul Pickrell (b) (4)	22 Mar 2021 13:32:48
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Dec 2020 18:26:05
User entered '500'	Ethan Shotton (b) (4) (b) (4)	07 Oct 2020 19:14:49

US3342200

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 17:05:26

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 08:28:13
User signature succeeded.	Paul Pickrell (b) (4)	22 Mar 2021 13:32:48
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Dec 2020 18:26:05
User entered 'mg (mg)'	Ethan Shotton (b) (4) (b) (4)	07 Oct 2020 19:14:49

US3342200

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 17:05:26

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 08:28:13
User signature succeeded.	Paul Pickrell (b) (4)	22 Mar 2021 13:32:48
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Dec 2020 18:26:05
User entered empty.	Ethan Shotton (b) (4) (b) (4)	07 Oct 2020 19:14:49

US3342200

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 17:05:26

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 08:28:13
User signature succeeded.	Paul Pickrell (b) (4)	22 Mar 2021 13:32:48
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Dec 2020 18:26:05
User closed query 'Data is required. Please complete.' (Site from System).	System	07 Oct 2020 19:14:57
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	07 Oct 2020 19:14:57
User entered 'once (ONCE)' reason for change: Data Entry Error	Ethan Shotton (b) (4) (b) (4)	07 Oct 2020 19:14:57
User opened query 'Data is required. Please complete.' (Site from System).	System	07 Oct 2020 19:14:49
User entered empty.	Ethan Shotton (b) (4) (b) (4)	07 Oct 2020 19:14:49

US3342200

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 17:05:26

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 08:28:13
User signature succeeded.	Paul Pickrell (b) (4)	22 Mar 2021 13:32:48
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Dec 2020 18:26:05
User entered empty.	Ethan Shotton (b) (4) (b) (4)	07 Oct 2020 19:14:49

US3342200

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 17:05:26

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 08:28:13
User signature succeeded.	Paul Pickrell (b) (4)	22 Mar 2021 13:32:48
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Dec 2020 18:26:05
User entered 'Oral (ORAL)'	Ethan Shotton (b) (4) (b) (4)	07 Oct 2020 19:14:49

US3342200

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 17:05:26

[If route of administration is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 08:28:13
User signature succeeded.	Paul Pickrell (b) (4)	22 Mar 2021 13:32:48
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Dec 2020 18:26:05
User entered empty.	Ethan Shotton (b) (4) (b) (4)	07 Oct 2020 19:14:49

US3342200

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 17:05:26

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 08:28:13
User signature succeeded.	Paul Pickrell (b) (4)	22 Mar 2021 13:32:48
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Dec 2020 18:26:05
User entered '03 Oct 2020'	Ethan Shotton (b) (4) (b) (4)	07 Oct 2020 19:14:49

US3342200

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 17:05:26

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 08:28:13
User signature succeeded.	Paul Pickrell (b) (4)	22 Mar 2021 13:32:48
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Dec 2020 18:26:05
User entered '0'	Ethan Shotton (b) (4) (b) (4)	07 Oct 2020 19:14:49

US3342200

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 17:05:26

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 08:28:13
User signature succeeded.	Paul Pickrell (b) (4)	22 Mar 2021 13:32:48
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Dec 2020 18:26:05
User entered 'No (N)'	Ethan Shotton (b) (4) (b) (4)	07 Oct 2020 19:14:49

US3342200

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 17:05:26

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 08:28:13
User signature succeeded.	Paul Pickrell (b) (4)	22 Mar 2021 13:32:48
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Dec 2020 18:26:05
User entered '03 Oct 2020'	Ethan Shotton (b) (4) (b) (4)	07 Oct 2020 19:14:49

US3342200

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 17:05:26

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 08:28:13
User signature succeeded.	Paul Pickrell (b) (4)	22 Mar 2021 13:32:48
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Dec 2020 18:26:05
User entered 'Yes (Y)'	Ethan Shotton (b) (4) (b) (4)	07 Oct 2020 19:14:49

US3342200

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 17:05:26

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 08:28:13
User entered empty.	System	07 Oct 2020 19:14:49

US3342200

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 17:05:26

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 08:28:13
User entered empty.	System	07 Oct 2020 19:14:49

US3342200

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 17:05:26

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 08:28:13
User entered empty.	System	07 Oct 2020 19:14:49

US3342200

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 17:05:26

Name of Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 06:46:14
User signature succeeded.	Paul Pickrell (b) (4)	22 Mar 2021 13:32:48
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Mar 2021 16:19:32
User coded data point as ATC: DERMATOLOGICALS, ATC: ANTIBIOTICS AND CHEMOTHERAPEUTICS FOR DERMATOLOGICAL USE, ATC: CHEMOTHERAPEUTICS FOR TOPICAL USE, ATC: SULFONAMIDES, PRODUCT: SULFADIAZINE SILVER, PRODUCTSYNONYM: SILVER SULFADIAZINE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	16 Mar 2021 11:13:49
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	16 Mar 2021 11:13:49
Data point term sent to Coder	System	15 Mar 2021 15:58:11
Coding entries removed.	Olivia Hapanowicz (b) (4) (b) (4)	15 Mar 2021 15:57:11
User coded data point as ATC: DERMATOLOGICALS, ATC: ANTIBIOTICS AND CHEMOTHERAPEUTICS FOR DERMATOLOGICAL USE, ATC: CHEMOTHERAPEUTICS FOR TOPICAL USE, ATC: SULFONAMIDES, PRODUCT: SULFADIAZINE SILVER, PRODUCTSYNONYM: SILVER SULFADIAZINE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	25 Jan 2021 07:38:11
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	25 Jan 2021 07:38:11
Data point term sent to Coder	System	22 Jan 2021 22:47:45
User entered 'Silver Sulfadiazine'	(b) (4), (b) (6)	22 Jan 2021 22:47:03

US3342200

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 17:05:26

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 06:46:14
User signature succeeded.	Paul Pickrell (b) (4)	22 Mar 2021 13:32:48
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Mar 2021 16:19:32
User entered 'No (N)'	(b) (4), (b) (6)	22 Jan 2021 22:47:03

US3342200

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 17:05:26

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 06:46:14
User signature succeeded.	Paul Pickrell (b) (4)	22 Mar 2021 13:32:48
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Mar 2021 16:19:32
User closed query 'Per DM CLR: Please update the indication to reflect the underlying medical condition that this medication is being used to prevent/treat. Please reconcile with AE or Med History eCRF so there is an appropriate match. Update eCRF as appropriate. (if indication is a mechanism of Action, Drug class, etc.) ' (Site from DM).	(b) (4), (b) (6)	16 Mar 2021 17:16:37
Query 'Per DM CLR: Please update the indication to reflect the underlying medical condition that this medication is being used to prevent/treat. Please reconcile with AE or Med History eCRF so there is an appropriate match. Update eCRF as appropriate. (if indication is a mechanism of Action, Drug class, etc.) ' answered with 'indication updated to correspond to AE.' (Site from DM).	Olivia Hapanowicz (b) (4) (b) (4)	15 Mar 2021 15:57:24
User entered 'radiation dermatitis' reason for change: Data Entry Error	Olivia Hapanowicz (b) (4) (b) (4)	15 Mar 2021 15:57:11
User opened query 'Per DM CLR: Please update the indication to reflect the underlying medical condition that this medication is being used to prevent/treat. Please reconcile with AE or Med History eCRF so there is an appropriate match. Update eCRF as appropriate. (if indication is a mechanism of Action, Drug class, etc.) ' (Site from DM).	(b) (4), (b) (6)	23 Feb 2021 08:36:21
User entered 'Breast Cancer Radiation'	(b) (4), (b) (6)	22 Jan 2021 22:47:03

US3342200

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 17:05:26

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 06:46:14
User signature succeeded.	Paul Pickrell (b) (4)	22 Mar 2021 13:32:48
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Mar 2021 16:19:32
User entered 'l'	(b) (4), (b) (6)	22 Jan 2021 22:47:03

US3342200

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 17:05:26

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 06:46:14
User signature succeeded.	Paul Pickrell (b) (4)	22 Mar 2021 13:32:48
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Mar 2021 16:19:32
User entered 'Other (OTHER)'	(b) (4), (b) (6)	22 Jan 2021 22:47:03

US3342200

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 17:05:26

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 06:46:14
User signature succeeded.	Paul Pickrell (b) (4)	22 Mar 2021 13:32:48
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Mar 2021 16:19:32
User entered 'application'	(b) (4), (b) (6)	22 Jan 2021 22:47:03

US3342200

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 17:05:26

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 06:46:14
User signature succeeded.	Paul Pickrell (b) (4)	22 Mar 2021 13:32:48
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Mar 2021 16:19:32
User entered 'twice daily (BID)'	(b) (4), (b) (6)	22 Jan 2021 22:47:03

US3342200

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 17:05:26

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 06:46:14
User signature succeeded.	Paul Pickrell (b) (4)	22 Mar 2021 13:32:48
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Mar 2021 16:19:32
User entered empty.	(b) (4), (b) (6)	22 Jan 2021 22:47:03

US3342200

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 17:05:26

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 06:46:14
User signature succeeded.	Paul Pickrell (b) (4)	22 Mar 2021 13:32:48
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Mar 2021 16:19:32
User entered 'Topical (TOPICAL)'	(b) (4), (b) (6)	22 Jan 2021 22:47:03

US3342200

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 17:05:26

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 06:46:14
User signature succeeded.	Paul Pickrell (b) (4)	22 Mar 2021 13:32:48
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Mar 2021 16:19:32
User entered empty.	(b) (4), (b) (6)	22 Jan 2021 22:47:03

US3342200

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 17:05:26

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 06:46:14
User signature succeeded.	Paul Pickrell (b) (4)	22 Mar 2021 13:32:48
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Mar 2021 16:19:32
User entered '21 Jan 2021'	(b) (4), (b) (6)	22 Jan 2021 22:47:03

US3342200

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 17:05:26

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 06:46:14
User signature succeeded.	Paul Pickrell (b) (4)	22 Mar 2021 13:32:48
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Mar 2021 16:19:32
User entered '0'	(b) (4), (b) (6)	22 Jan 2021 22:47:03

US3342200

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 17:05:26

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 06:46:14
User signature succeeded.	Paul Pickrell (b) (4)	22 Mar 2021 13:32:48
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Mar 2021 16:19:32
User entered 'No (N)' reason for change: New Information	Olivia Hapanowicz (b) (4)	15 Mar 2021 15:57:11
User entered 'Yes (Y)'	(b) (4), (b) (6)	22 Jan 2021 22:47:03

US3342200

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 17:05:26

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 06:46:14
User signature succeeded.	Paul Pickrell (b) (4)	22 Mar 2021 13:32:48
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Mar 2021 16:19:32
User entered '11 Feb 2021' reason for change: New Information	Olivia Hapanowicz (b) (4)	15 Mar 2021 15:57:11
User entered empty.	(b) (4) (b) (4), (b) (6)	22 Jan 2021 22:47:03

US3342200

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 17:05:26

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 06:46:14
User signature succeeded.	Paul Pickrell (b) (4)	22 Mar 2021 13:32:48
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Mar 2021 16:19:32
User entered 'No (N)'	(b) (4), (b) (6)	22 Jan 2021 22:47:03

US3342200

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 17:05:26

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 06:46:14
User entered '2'	System	22 Jan 2021 22:47:03

US3342200

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 17:05:26

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 06:46:14
User entered '1'	System	22 Jan 2021 22:47:03

US3342200

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 17:05:26

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 06:46:14
User entered '804 (804)'	System	22 Jan 2021 22:47:03

US3342200

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 17:05:26

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Pickrell (b) (4)	30 Apr 2021 22:17:54
User coded data point as ATC: ANTINEOPLASTIC AND IMMUNOMODULATING AGENTS, ATC: ENDOCRINE THERAPY, ATC: HORMONE ANTAGONISTS AND RELATED AGENTS, ATC: ANTI-ESTROGENS, PRODUCT: TAMOXIFEN - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4)	30 Apr 2021 06:17:15
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	30 Apr 2021 06:17:15
Data point term sent to Coder	System	29 Apr 2021 16:25:35
User entered 'TAMOXIFEN'	(b) (4), (b) (6)	29 Apr 2021 16:25:06

US3342200

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 17:05:26

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Pickrell (b) (4)	30 Apr 2021 22:17:54
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	29 Apr 2021 16:25:06

US3342200

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 17:05:26

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Pickrell (b) (4)	30 Apr 2021 22:17:54
User entered 'DUCTAL CARCINOMA IN SITU RIGHT BREAST'	(b) (4) (b) (4), (b) (6)	29 Apr 2021 16:25:06

US3342200

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 17:05:26

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Pickrell (b) (4)	30 Apr 2021 22:17:54
User entered '20'	(b) (4) (b) (4), (b) (6)	29 Apr 2021 16:25:06

US3342200

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 17:05:26

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Pickrell (b) (4)	30 Apr 2021 22:17:54
User entered 'mg (mg)'	(b) (4) (b) (4), (b) (6)	29 Apr 2021 16:25:06

US3342200

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 17:05:26

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Paul Pickrell (b) (4)	30 Apr 2021 22:17:54
User entered empty.	(b) (4) (b) (4), (b) (6)	29 Apr 2021 16:25:06

US3342200

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 17:05:26

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Pickrell (b) (4)	30 Apr 2021 22:17:54
User entered 'once daily (QD)'	(b) (4) (b) (4), (b) (6)	29 Apr 2021 16:25:06

US3342200

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 17:05:26

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Paul Pickrell (b) (4)	30 Apr 2021 22:17:54
User entered empty.	(b) (4) (b) (4), (b) (6)	29 Apr 2021 16:25:06

US3342200

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 17:05:26

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Pickrell (b) (4)	30 Apr 2021 22:17:54
User entered 'Oral (ORAL)'	(b) (4) (b) (4), (b) (6)	29 Apr 2021 16:25:06

US3342200

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 17:05:26

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Paul Pickrell (b) (4)	30 Apr 2021 22:17:54
User entered empty.	(b) (4) (b) (4), (b) (6)	29 Apr 2021 16:25:06

US3342200

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 17:05:26

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Paul Pickrell (b) (4)	30 Apr 2021 22:17:54
User entered '10 Apr 2021'	(b) (4) (b) (4), (b) (6)	29 Apr 2021 16:25:06

US3342200

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 17:05:26

Start date completely unknown

Audit	User	Time (GMT)
User signature succeeded.	Paul Pickrell (b) (4)	30 Apr 2021 22:17:54
User entered '0'	(b) (4) (b) (4), (b) (6)	29 Apr 2021 16:25:06

US3342200

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 17:05:26

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Pickrell (b) (4)	30 Apr 2021 22:17:54
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	29 Apr 2021 16:25:06

US3342200

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 17:05:26

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Paul Pickrell (b) (4)	30 Apr 2021 22:17:54
User entered empty.	(b) (4) (b) (4), (b) (6)	29 Apr 2021 16:25:06

US3342200

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 17:05:26

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Pickrell (b) (4)	30 Apr 2021 22:17:54
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	29 Apr 2021 16:25:06

US3342200

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 17:05:26

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	29 Apr 2021 16:25:06

US3342200

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 17:05:26

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	29 Apr 2021 16:25:06

US3342200

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 17:05:26

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	29 Apr 2021 16:25:06

US3342200

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures Summary

Generated On: 09 Jun 2021 17:05:26

[Were any concomitant procedures performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 05:46:33
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:24:15
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Dec 2020 18:27:21
User entered 'Yes (Y)'	Stefanie Mott (b) (4)	23 Nov 2020 23:01:56

US3342200

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (2)

Generated On: 09 Jun 2021 17:05:26

Procedure/Surgery date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Paul Pickrell (b) (4)	22 Mar 2021 13:32:48
	(b) (4)	
Signature has been broken.	Eileen Euperio (b) (4)	15 Mar 2021 13:51:00
	(b) (4)	
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:24:15
	(b) (4)	
User closed query 'Per CDM: Date of surgery/procedure (18Nov2020) is prior to Adverse Event (#4 20Nov2020). Please reconcile and update as needed, else provide clarification. ' (Site from DM).	(b) (4), (b) (6)	08 Feb 2021 15:17:11
Query 'Per CDM: Date of surgery/procedure (18Nov2020) is prior to Adverse Event (#4 20Nov2020). Please reconcile and update as needed, else provide clarification. ' answered with 'DIAGNOSIS WAS ON 20NOV2020 BUT LUMPECTOMY DONE 18NOV2020' (Site from DM).	Eileen Euperio (b) (4)	05 Feb 2021 17:05:08
	(b) (4)	
User opened query 'Per CDM: Date of surgery/procedure (18Nov2020) is prior to Adverse Event (#4 20Nov2020). Please reconcile and update as needed, else provide clarification. ' (Site from DM).	(b) (4), (b) (6)	16 Dec 2020 19:05:16
DataPoint Verified.	(b) (4), (b) (6)	09 Dec 2020 18:28:50
User entered '18 Nov 2020'	Eileen Euperio (b) (4)	09 Dec 2020 17:39:54
	(b) (4)	

US3342200

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (2)

Generated On: 09 Jun 2021 17:05:26

[Procedure/Surgery](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:24:15
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Dec 2020 18:28:50
User entered 'RIGHT BREAST LUMPECTOMY'	Eileen Euperio (b) (4) (b) (4)	09 Dec 2020 17:39:54

US3342200

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (2)

Generated On: 09 Jun 2021 17:05:26

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:24:15
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Dec 2020 18:28:50
User entered 'Adverse Event (AE)'	Eileen Euperio (b) (4) (b) (4)	09 Dec 2020 17:39:54

US3342200

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (2)

Generated On: 09 Jun 2021 17:05:26

If indication is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:24:15
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Dec 2020 18:28:50
User entered empty.	Eileen Euperio (b) (4) (b) (4)	09 Dec 2020 17:39:54

US3342200

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (3)

Generated On: 09 Jun 2021 17:05:26

Procedure/Surgery date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:26:11
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:24:15
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Dec 2020 18:28:50
User entered '06 Nov 2020'	Eileen Euperio (b) (4) (b) (4)	09 Dec 2020 17:40:15

US3342200

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (3)

Generated On: 09 Jun 2021 17:05:26

[Procedure/Surgery](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:26:11
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:24:15
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Dec 2020 18:28:50
User entered 'RIGHT BREAST ULTRASOUND'	Eileen Euperio (b) (4) (b) (4)	09 Dec 2020 17:40:15

US3342200

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (3)

Generated On: 09 Jun 2021 17:05:26

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:26:11
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:24:15
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Dec 2020 18:28:50
User entered 'Diagnostic (DIAGNOSTIC)'	Eileen Euperio (b) (4) (b) (4)	09 Dec 2020 17:40:15

US3342200

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (3)

Generated On: 09 Jun 2021 17:05:26

If indication is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:26:11
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:24:15
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Dec 2020 18:28:50
User entered empty.	Eileen Euperio (b) (4) (b) (4)	09 Dec 2020 17:40:15

US3342200

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (5)

Generated On: 09 Jun 2021 17:05:26

Procedure/Surgery date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:26:12
DataPoint Verified.	(b) (4), (b) (6)	19 Mar 2021 16:14:05
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:24:15
User entered '22 Dec 2020'	Ethan Shotton (b) (4)	30 Dec 2020 22:05:52

US3342200

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (5)

Generated On: 09 Jun 2021 17:05:26

[Procedure/Surgery](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:26:12
DataPoint Verified.	(b) (4), (b) (6)	19 Mar 2021 16:14:09
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:24:15
User entered 'Radiation Therapy'	Ethan Shotton (b) (4)	30 Dec 2020 22:05:52

US3342200

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (5)

Generated On: 09 Jun 2021 17:05:26

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:26:12
DataPoint Verified.	(b) (4), (b) (6)	19 Mar 2021 16:14:11
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:24:15
User closed query 'Per DM CLR: Please review if this procedure was done for AE#4 DUCTAL CARCINOMA IN SITU RIGHT BREAST. If so, ensure action taken reflects this procedure (ie, Other Action Taken=Concomitant Procedure). Else, there is no AE condition that matches this procedure. Review and update necessary ecrfs as appropriate. '(Site from DM).	(b) (4) (b) (4), (b) (6)	12 Mar 2021 10:07:11
Query 'Per DM CLR: Please review if this procedure was done for AE#4 DUCTAL CARCINOMA IN SITU RIGHT BREAST. If so, ensure action taken reflects this procedure (ie, Other Action Taken=Concomitant Procedure). Else, there is no AE condition that matches this procedure. Review and update necessary ecrfs as appropriate. ' answered with 'This procedure was done for AE #4 Ductal Carcinoma In Situ Right Breast. AE #4 EDC and Source updated to reflect this.' (Site from DM).	Ethan Shotton (b) (4) (b) (4)	11 Mar 2021 13:12:06
User opened query 'Per DM CLR: Please review if this procedure was done for AE#4 DUCTAL CARCINOMA IN SITU RIGHT BREAST. If so, ensure action taken reflects this procedure (ie, Other Action Taken=Concomitant Procedure). Else, there is no AE condition that matches this procedure. Review and update necessary ecrfs as appropriate. '(Site from DM).	(b) (4), (b) (6)	23 Feb 2021 10:16:22
User entered 'Adverse Event (AE)'	Ethan Shotton (b) (4) (b) (4)	30 Dec 2020 22:05:52

US3342200

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (5)

Generated On: 09 Jun 2021 17:05:26

If indication is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:26:12
DataPoint Verified.	(b) (4), (b) (6)	19 Mar 2021 16:14:14
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:24:15
User entered empty.	Ethan Shotton (b) (4)	30 Dec 2020 22:05:52

US3342200

Folder: SAE USA-US203-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 09 Jun 2021 17:05:26

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:24:15
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Dec 2020 18:01:36
Reviewed for Safety.	(b) (4), (b) (6)	24 Nov 2020 20:40:18
User entered 'USA-US203-2020-MRNA-1273-P301000006'	System	24 Nov 2020 20:39:57

US3342200

Folder: SAE USA-US203-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 09 Jun 2021 17:05:26

Serious

Audit	User	Time (GMT)
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:24:15
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Dec 2020 18:01:36
Reviewed for Safety.	(b) (4), (b) (6)	24 Nov 2020 20:40:18
User entered 'Yes (Y)'	System	24 Nov 2020 20:39:57

US3342200

Folder: SAE USA-US203-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 09 Jun 2021 17:05:26

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:24:15
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Dec 2020 18:01:36
Reviewed for Safety.	(b) (4), (b) (6)	24 Nov 2020 20:40:18
User entered 'No (N)'	System	24 Nov 2020 20:39:57

US3342200

Folder: SAE USA-US203-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 09 Jun 2021 17:05:26

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:24:15
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Dec 2020 18:01:36
Reviewed for Safety.	(b) (4), (b) (6)	24 Nov 2020 20:40:18
User entered 'No (N)'	System	24 Nov 2020 20:39:57

US3342200

Folder: SAE USA-US203-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 09 Jun 2021 17:05:26

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:24:15
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Dec 2020 18:01:36
Reviewed for Safety.	(b) (4), (b) (6)	24 Nov 2020 20:40:18
User entered 'No (N)'	System	24 Nov 2020 20:39:57

US3342200

Folder: SAE USA-US203-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 09 Jun 2021 17:05:26

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:24:15
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Dec 2020 18:01:36
Reviewed for Safety.	(b) (4), (b) (6)	24 Nov 2020 20:40:18
User entered 'No (N)'	System	24 Nov 2020 20:39:57

US3342200

Folder: SAE USA-US203-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 09 Jun 2021 17:05:26

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:24:15
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Dec 2020 18:01:36
Reviewed for Safety.	(b) (4), (b) (6)	24 Nov 2020 20:40:18
User entered 'No (N)'	System	24 Nov 2020 20:39:57

US3342200

Folder: SAE USA-US203-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 09 Jun 2021 17:05:26

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:24:15
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Dec 2020 18:01:36
Reviewed for Safety.	(b) (4), (b) (6)	24 Nov 2020 20:40:18
User entered 'Yes (Y)'	System	24 Nov 2020 20:39:57

US3342200

Folder: SAE USA-US203-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 09 Jun 2021 17:05:26

[Investigator's First Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 22:12:21
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:24:15
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	08 Feb 2021 17:17:17
User entered 'Paul'	System	08 Feb 2021 17:17:13

US3342200

Folder: SAE USA-US203-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 09 Jun 2021 17:05:26

[Investigator's Last Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 22:12:23
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:24:15
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	08 Feb 2021 17:17:17
User entered 'Pickrell'	System	08 Feb 2021 17:17:13

US3342200

Folder: SAE USA-US203-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 09 Jun 2021 17:05:26

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:24:15
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Dec 2020 18:01:36
Reviewed for Safety.	(b) (4), (b) (6)	04 Dec 2020 14:37:09
User entered 'US'	System	24 Nov 2020 20:40:28

US3342200

Folder: SAE USA-US203-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 09 Jun 2021 17:05:26

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '10'	System	29 Apr 2021 15:04:38
User entered '9'	System	30 Mar 2021 15:11:38
User entered '8'	System	15 Mar 2021 17:27:03
User entered '7'	System	12 Mar 2021 17:18:59
User entered '6'	System	03 Mar 2021 16:21:32
User entered '5'	System	08 Feb 2021 17:17:13
User entered '4'	System	19 Jan 2021 16:03:30
User entered '3'	System	10 Dec 2020 18:48:16
User entered '2'	System	04 Dec 2020 14:37:19
User entered '1'	System	24 Nov 2020 20:40:28

US3342200

Folder: SAE USA-US203-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 09 Jun 2021 17:05:26

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:24:15
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Dec 2020 18:01:36
Reviewed for Safety.	(b) (4), (b) (6)	24 Nov 2020 20:40:18
User entered 'USA-US203-2020-MRNA-1273-P301000006'	System	24 Nov 2020 20:39:57

US3342200

Folder: SAE USA-US203-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 09 Jun 2021 17:05:26

Serious

Audit	User	Time (GMT)
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:24:15
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Dec 2020 18:01:36
Reviewed for Safety.	(b) (4), (b) (6)	24 Nov 2020 20:40:18
User entered 'Yes (Y)'	System	24 Nov 2020 20:39:57

US3342200

Folder: SAE USA-US203-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 09 Jun 2021 17:05:26

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:24:15
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Dec 2020 18:01:36
Reviewed for Safety.	(b) (4), (b) (6)	24 Nov 2020 20:40:18
User entered 'No (N)'	System	24 Nov 2020 20:39:57

US3342200

Folder: SAE USA-US203-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 09 Jun 2021 17:05:26

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:24:15
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Dec 2020 18:01:36
Reviewed for Safety.	(b) (4), (b) (6)	24 Nov 2020 20:40:18
User entered 'No (N)'	System	24 Nov 2020 20:39:57

US3342200

Folder: SAE USA-US203-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 09 Jun 2021 17:05:26

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:24:15
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Dec 2020 18:01:36
Reviewed for Safety.	(b) (4), (b) (6)	24 Nov 2020 20:40:18
User entered 'No (N)'	System	24 Nov 2020 20:39:57

US3342200

Folder: SAE USA-US203-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 09 Jun 2021 17:05:26

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:24:15
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Dec 2020 18:01:36
Reviewed for Safety.	(b) (4), (b) (6)	24 Nov 2020 20:40:18
User entered 'No (N)'	System	24 Nov 2020 20:39:57

US3342200

Folder: SAE USA-US203-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 09 Jun 2021 17:05:26

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:24:15
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Dec 2020 18:01:36
Reviewed for Safety.	(b) (4), (b) (6)	24 Nov 2020 20:40:18
User entered 'No (N)'	System	24 Nov 2020 20:39:57

US3342200

Folder: SAE USA-US203-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 09 Jun 2021 17:05:26

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:24:15
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Dec 2020 18:01:36
Reviewed for Safety.	(b) (4), (b) (6)	24 Nov 2020 20:40:18
User entered 'Yes (Y)'	System	24 Nov 2020 20:39:57

US3342200

Folder: SAE USA-US203-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 09 Jun 2021 17:05:26

[Investigator's First Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 22:12:21
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:24:15
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	08 Feb 2021 17:17:17
User entered 'Paul'	System	08 Feb 2021 17:17:13

US3342200

Folder: SAE USA-US203-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 09 Jun 2021 17:05:26

[Investigator's Last Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 22:12:23
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:24:15
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	08 Feb 2021 17:17:17
User entered 'Pickrell'	System	08 Feb 2021 17:17:13

US3342200

Folder: SAE USA-US203-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 09 Jun 2021 17:05:26

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:24:15
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Dec 2020 18:01:36
Reviewed for Safety.	(b) (4), (b) (6)	04 Dec 2020 14:37:09
User entered 'US'	System	24 Nov 2020 20:40:28

US3342200

Folder: SAE USA-US203-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 09 Jun 2021 17:05:26

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '10'	System	29 Apr 2021 15:04:38
User entered '9'	System	30 Mar 2021 15:11:38
User entered '8'	System	15 Mar 2021 17:27:03
User entered '7'	System	12 Mar 2021 17:18:59
User entered '6'	System	03 Mar 2021 16:21:32
User entered '5'	System	08 Feb 2021 17:17:13
User entered '4'	System	19 Jan 2021 16:03:30
User entered '3'	System	10 Dec 2020 18:48:16
User entered '2'	System	04 Dec 2020 14:37:19
User entered '1'	System	24 Nov 2020 20:40:28

US3342200

Folder: SAE USA-US203-2020-MRNA-1273-P301000006

Form: Safety Report Form (1)

Generated On: 09 Jun 2021 17:05:26

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:24:15
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Dec 2020 18:01:36
User entered '24/Nov/2020 20:40'	System	24 Nov 2020 20:40:28

US3342200

Folder: SAE USA-US203-2020-MRNA-1273-P301000006

Form: Safety Report Form (1)

Generated On: 09 Jun 2021 17:05:26

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.	Paul Pickrell (b) (4)	13 Mar 2021 15:24:15
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Dec 2020 18:01:36
Reviewed for Safety.	(b) (4), (b) (6)	04 Dec 2020 14:37:09
User entered 'I'	(b) (4), (b) (6)	24 Nov 2020 20:40:28

US3342200

Folder: SAE USA-US203-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 09 Jun 2021 17:05:26

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:24:15
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Dec 2020 18:01:36
Reviewed for Safety.	(b) (4), (b) (6)	24 Nov 2020 20:40:18
User entered 'USA-US203-2020-MRNA-1273-P301000006'	System	24 Nov 2020 20:39:57

US3342200

Folder: SAE USA-US203-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 09 Jun 2021 17:05:26

Serious

Audit	User	Time (GMT)
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:24:15
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Dec 2020 18:01:36
Reviewed for Safety.	(b) (4), (b) (6)	24 Nov 2020 20:40:18
User entered 'Yes (Y)'	System	24 Nov 2020 20:39:57

US3342200

Folder: SAE USA-US203-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 09 Jun 2021 17:05:26

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:24:15
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Dec 2020 18:01:36
Reviewed for Safety.	(b) (4), (b) (6)	24 Nov 2020 20:40:18
User entered 'No (N)'	System	24 Nov 2020 20:39:57

US3342200

Folder: SAE USA-US203-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 09 Jun 2021 17:05:26

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:24:15
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Dec 2020 18:01:36
Reviewed for Safety.	(b) (4), (b) (6)	24 Nov 2020 20:40:18
User entered 'No (N)'	System	24 Nov 2020 20:39:57

US3342200

Folder: SAE USA-US203-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 09 Jun 2021 17:05:26

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:24:15
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Dec 2020 18:01:36
Reviewed for Safety.	(b) (4), (b) (6)	24 Nov 2020 20:40:18
User entered 'No (N)'	System	24 Nov 2020 20:39:57

US3342200

Folder: SAE USA-US203-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 09 Jun 2021 17:05:26

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:24:15
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Dec 2020 18:01:36
Reviewed for Safety.	(b) (4), (b) (6)	24 Nov 2020 20:40:18
User entered 'No (N)'	System	24 Nov 2020 20:39:57

US3342200

Folder: SAE USA-US203-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 09 Jun 2021 17:05:26

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:24:15
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Dec 2020 18:01:36
Reviewed for Safety.	(b) (4), (b) (6)	24 Nov 2020 20:40:18
User entered 'No (N)'	System	24 Nov 2020 20:39:57

US3342200

Folder: SAE USA-US203-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 09 Jun 2021 17:05:26

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:24:15
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Dec 2020 18:01:36
Reviewed for Safety.	(b) (4), (b) (6)	24 Nov 2020 20:40:18
User entered 'Yes (Y)'	System	24 Nov 2020 20:39:57

US3342200

Folder: SAE USA-US203-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 09 Jun 2021 17:05:26

[Investigator's First Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 22:12:21
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:24:15
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	08 Feb 2021 17:17:17
User entered 'Paul'	System	08 Feb 2021 17:17:13

US3342200

Folder: SAE USA-US203-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 09 Jun 2021 17:05:26

[Investigator's Last Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 22:12:23
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:24:15
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	08 Feb 2021 17:17:17
User entered 'Pickrell'	System	08 Feb 2021 17:17:13

US3342200

Folder: SAE USA-US203-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 09 Jun 2021 17:05:26

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:24:15
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Dec 2020 18:01:36
Reviewed for Safety.	(b) (4), (b) (6)	04 Dec 2020 14:37:09
User entered 'US'	System	24 Nov 2020 20:40:28

US3342200

Folder: SAE USA-US203-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 09 Jun 2021 17:05:26

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '10'	System	29 Apr 2021 15:04:38
User entered '9'	System	30 Mar 2021 15:11:38
User entered '8'	System	15 Mar 2021 17:27:03
User entered '7'	System	12 Mar 2021 17:18:59
User entered '6'	System	03 Mar 2021 16:21:32
User entered '5'	System	08 Feb 2021 17:17:13
User entered '4'	System	19 Jan 2021 16:03:30
User entered '3'	System	10 Dec 2020 18:48:16
User entered '2'	System	04 Dec 2020 14:37:19
User entered '1'	System	24 Nov 2020 20:40:28

US3342200

Folder: SAE USA-US203-2020-MRNA-1273-P301000006

Form: Safety Report Form (2)

Generated On: 09 Jun 2021 17:05:26

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:24:15
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Dec 2020 18:01:36
User entered '04/Dec/2020 09:37'	System	04 Dec 2020 14:37:19

US3342200

Folder: SAE USA-US203-2020-MRNA-1273-P301000006

Form: Safety Report Form (2)

Generated On: 09 Jun 2021 17:05:26

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.	Paul Pickrell (b) (4)	13 Mar 2021 15:24:15
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	10 Dec 2020 18:47:58
DataPoint Verified.	(b) (4), (b) (6)	09 Dec 2020 18:01:36
User entered 'I'	(b) (4), (b) (6)	04 Dec 2020 14:37:19

US3342200

Folder: SAE USA-US203-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 09 Jun 2021 17:05:26

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:24:15
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Dec 2020 18:01:36
Reviewed for Safety.	(b) (4), (b) (6)	24 Nov 2020 20:40:18
User entered 'USA-US203-2020-MRNA-1273-P301000006'	System	24 Nov 2020 20:39:57

US3342200

Folder: SAE USA-US203-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 09 Jun 2021 17:05:26

Serious

Audit	User	Time (GMT)
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:24:15
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Dec 2020 18:01:36
Reviewed for Safety.	(b) (4), (b) (6)	24 Nov 2020 20:40:18
User entered 'Yes (Y)'	System	24 Nov 2020 20:39:57

US3342200

Folder: SAE USA-US203-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 09 Jun 2021 17:05:26

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:24:15
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Dec 2020 18:01:36
Reviewed for Safety.	(b) (4), (b) (6)	24 Nov 2020 20:40:18
User entered 'No (N)'	System	24 Nov 2020 20:39:57

US3342200

Folder: SAE USA-US203-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 09 Jun 2021 17:05:26

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:24:15
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Dec 2020 18:01:36
Reviewed for Safety.	(b) (4), (b) (6)	24 Nov 2020 20:40:18
User entered 'No (N)'	System	24 Nov 2020 20:39:57

US3342200

Folder: SAE USA-US203-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 09 Jun 2021 17:05:26

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:24:15
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Dec 2020 18:01:36
Reviewed for Safety.	(b) (4), (b) (6)	24 Nov 2020 20:40:18
User entered 'No (N)'	System	24 Nov 2020 20:39:57

US3342200

Folder: SAE USA-US203-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 09 Jun 2021 17:05:26

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:24:15
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Dec 2020 18:01:36
Reviewed for Safety.	(b) (4), (b) (6)	24 Nov 2020 20:40:18
User entered 'No (N)'	System	24 Nov 2020 20:39:57

US3342200

Folder: SAE USA-US203-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 09 Jun 2021 17:05:26

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:24:15
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Dec 2020 18:01:36
Reviewed for Safety.	(b) (4), (b) (6)	24 Nov 2020 20:40:18
User entered 'No (N)'	System	24 Nov 2020 20:39:57

US3342200

Folder: SAE USA-US203-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 09 Jun 2021 17:05:26

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:24:15
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Dec 2020 18:01:36
Reviewed for Safety.	(b) (4), (b) (6)	24 Nov 2020 20:40:18
User entered 'Yes (Y)'	System	24 Nov 2020 20:39:57

US3342200

Folder: SAE USA-US203-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 09 Jun 2021 17:05:26

[Investigator's First Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 22:12:21
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:24:15
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	08 Feb 2021 17:17:17
User entered 'Paul'	System	08 Feb 2021 17:17:13

US3342200

Folder: SAE USA-US203-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 09 Jun 2021 17:05:26

[Investigator's Last Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 22:12:23
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:24:15
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	08 Feb 2021 17:17:17
User entered 'Pickrell'	System	08 Feb 2021 17:17:13

US3342200

Folder: SAE USA-US203-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 09 Jun 2021 17:05:26

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:24:15
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Dec 2020 18:01:36
Reviewed for Safety.	(b) (4), (b) (6)	04 Dec 2020 14:37:09
User entered 'US'	System	24 Nov 2020 20:40:28

US3342200

Folder: SAE USA-US203-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 09 Jun 2021 17:05:26

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '10'	System	29 Apr 2021 15:04:38
User entered '9'	System	30 Mar 2021 15:11:38
User entered '8'	System	15 Mar 2021 17:27:03
User entered '7'	System	12 Mar 2021 17:18:59
User entered '6'	System	03 Mar 2021 16:21:32
User entered '5'	System	08 Feb 2021 17:17:13
User entered '4'	System	19 Jan 2021 16:03:30
User entered '3'	System	10 Dec 2020 18:48:16
User entered '2'	System	04 Dec 2020 14:37:19
User entered '1'	System	24 Nov 2020 20:40:28

US3342200

Folder: SAE USA-US203-2020-MRNA-1273-P301000006

Form: Safety Report Form (3)

Generated On: 09 Jun 2021 17:05:26

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Mar 2021 15:56:17
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:24:15
User entered '10/Dec/2020 13:48'	(b) (4) System	10 Dec 2020 18:48:16

US3342200

Folder: SAE USA-US203-2020-MRNA-1273-P301000006

Form: Safety Report Form (3)

Generated On: 09 Jun 2021 17:05:26

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)	19 Mar 2021 15:56:17
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:24:15
Reviewed for Safety.	(b) (4), (b) (6)	19 Jan 2021 16:03:17
User entered 'I'	(b) (4), (b) (6)	10 Dec 2020 18:48:16

US3342200

Folder: SAE USA-US203-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 09 Jun 2021 17:05:26

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:24:15
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Dec 2020 18:01:36
Reviewed for Safety.	(b) (4), (b) (6)	24 Nov 2020 20:40:18
User entered 'USA-US203-2020-MRNA-1273-P301000006'	System	24 Nov 2020 20:39:57

US3342200

Folder: SAE USA-US203-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 09 Jun 2021 17:05:26

Serious

Audit	User	Time (GMT)
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:24:15
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Dec 2020 18:01:36
Reviewed for Safety.	(b) (4), (b) (6)	24 Nov 2020 20:40:18
User entered 'Yes (Y)'	System	24 Nov 2020 20:39:57

US3342200

Folder: SAE USA-US203-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 09 Jun 2021 17:05:26

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:24:15
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Dec 2020 18:01:36
Reviewed for Safety.	(b) (4), (b) (6)	24 Nov 2020 20:40:18
User entered 'No (N)'	System	24 Nov 2020 20:39:57

US3342200

Folder: SAE USA-US203-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 09 Jun 2021 17:05:26

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:24:15
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Dec 2020 18:01:36
Reviewed for Safety.	(b) (4), (b) (6)	24 Nov 2020 20:40:18
User entered 'No (N)'	System	24 Nov 2020 20:39:57

US3342200

Folder: SAE USA-US203-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 09 Jun 2021 17:05:26

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:24:15
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Dec 2020 18:01:36
Reviewed for Safety.	(b) (4), (b) (6)	24 Nov 2020 20:40:18
User entered 'No (N)'	System	24 Nov 2020 20:39:57

US3342200

Folder: SAE USA-US203-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 09 Jun 2021 17:05:26

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:24:15
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Dec 2020 18:01:36
Reviewed for Safety.	(b) (4), (b) (6)	24 Nov 2020 20:40:18
User entered 'No (N)'	System	24 Nov 2020 20:39:57

US3342200

Folder: SAE USA-US203-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 09 Jun 2021 17:05:26

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:24:15
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Dec 2020 18:01:36
Reviewed for Safety.	(b) (4), (b) (6)	24 Nov 2020 20:40:18
User entered 'No (N)'	System	24 Nov 2020 20:39:57

US3342200

Folder: SAE USA-US203-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 09 Jun 2021 17:05:26

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:24:15
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Dec 2020 18:01:36
Reviewed for Safety.	(b) (4), (b) (6)	24 Nov 2020 20:40:18
User entered 'Yes (Y)'	System	24 Nov 2020 20:39:57

US3342200

Folder: SAE USA-US203-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 09 Jun 2021 17:05:26

[Investigator's First Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 22:12:21
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:24:15
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	08 Feb 2021 17:17:17
User entered 'Paul'	System	08 Feb 2021 17:17:13

US3342200

Folder: SAE USA-US203-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 09 Jun 2021 17:05:26

[Investigator's Last Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 22:12:23
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:24:15
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	08 Feb 2021 17:17:17
User entered 'Pickrell'	System	08 Feb 2021 17:17:13

US3342200

Folder: SAE USA-US203-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 09 Jun 2021 17:05:26

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:24:15
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Dec 2020 18:01:36
Reviewed for Safety.	(b) (4), (b) (6)	04 Dec 2020 14:37:09
User entered 'US'	System	24 Nov 2020 20:40:28

US3342200

Folder: SAE USA-US203-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 09 Jun 2021 17:05:26

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '10'	System	29 Apr 2021 15:04:38
User entered '9'	System	30 Mar 2021 15:11:38
User entered '8'	System	15 Mar 2021 17:27:03
User entered '7'	System	12 Mar 2021 17:18:59
User entered '6'	System	03 Mar 2021 16:21:32
User entered '5'	System	08 Feb 2021 17:17:13
User entered '4'	System	19 Jan 2021 16:03:30
User entered '3'	System	10 Dec 2020 18:48:16
User entered '2'	System	04 Dec 2020 14:37:19
User entered '1'	System	24 Nov 2020 20:40:28

US3342200

Folder: SAE USA-US203-2020-MRNA-1273-P301000006

Form: Safety Report Form (4)

Generated On: 09 Jun 2021 17:05:26

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Mar 2021 15:56:17
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:24:15
User entered '19/Jan/2021 11:03'	(b) (4) System	19 Jan 2021 16:03:30

US3342200

Folder: SAE USA-US203-2020-MRNA-1273-P301000006

Form: Safety Report Form (4)

Generated On: 09 Jun 2021 17:05:26

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)	19 Mar 2021 15:56:17
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:24:15
Reviewed for Safety.	(b) (4), (b) (6)	08 Feb 2021 17:17:17
User entered 'I'	(b) (4), (b) (6)	19 Jan 2021 16:03:30

US3342200

Folder: SAE USA-US203-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 09 Jun 2021 17:05:26

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:24:15
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Dec 2020 18:01:36
Reviewed for Safety.	(b) (4), (b) (6)	24 Nov 2020 20:40:18
User entered 'USA-US203-2020-MRNA-1273-P301000006'	System	24 Nov 2020 20:39:57

US3342200

Folder: SAE USA-US203-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 09 Jun 2021 17:05:26

Serious

Audit	User	Time (GMT)
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:24:15
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Dec 2020 18:01:36
Reviewed for Safety.	(b) (4), (b) (6)	24 Nov 2020 20:40:18
User entered 'Yes (Y)'	System	24 Nov 2020 20:39:57

US3342200

Folder: SAE USA-US203-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 09 Jun 2021 17:05:26

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:24:15
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Dec 2020 18:01:36
Reviewed for Safety.	(b) (4), (b) (6)	24 Nov 2020 20:40:18
User entered 'No (N)'	System	24 Nov 2020 20:39:57

US3342200

Folder: SAE USA-US203-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 09 Jun 2021 17:05:26

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:24:15
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Dec 2020 18:01:36
Reviewed for Safety.	(b) (4), (b) (6)	24 Nov 2020 20:40:18
User entered 'No (N)'	System	24 Nov 2020 20:39:57

US3342200

Folder: SAE USA-US203-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 09 Jun 2021 17:05:26

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:24:15
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Dec 2020 18:01:36
Reviewed for Safety.	(b) (4), (b) (6)	24 Nov 2020 20:40:18
User entered 'No (N)'	System	24 Nov 2020 20:39:57

US3342200

Folder: SAE USA-US203-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 09 Jun 2021 17:05:26

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:24:15
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Dec 2020 18:01:36
Reviewed for Safety.	(b) (4), (b) (6)	24 Nov 2020 20:40:18
User entered 'No (N)'	System	24 Nov 2020 20:39:57

US3342200

Folder: SAE USA-US203-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 09 Jun 2021 17:05:26

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:24:15
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Dec 2020 18:01:36
Reviewed for Safety.	(b) (4), (b) (6)	24 Nov 2020 20:40:18
User entered 'No (N)'	System	24 Nov 2020 20:39:57

US3342200

Folder: SAE USA-US203-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 09 Jun 2021 17:05:26

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:24:15
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Dec 2020 18:01:36
Reviewed for Safety.	(b) (4), (b) (6)	24 Nov 2020 20:40:18
User entered 'Yes (Y)'	System	24 Nov 2020 20:39:57

US3342200

Folder: SAE USA-US203-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 09 Jun 2021 17:05:26

[Investigator's First Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 22:12:21
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:24:15
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	08 Feb 2021 17:17:17
User entered 'Paul'	System	08 Feb 2021 17:17:13

US3342200

Folder: SAE USA-US203-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 09 Jun 2021 17:05:26

[Investigator's Last Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 22:12:23
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:24:15
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	08 Feb 2021 17:17:17
User entered 'Pickrell'	System	08 Feb 2021 17:17:13

US3342200

Folder: SAE USA-US203-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 09 Jun 2021 17:05:26

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:24:15
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Dec 2020 18:01:36
Reviewed for Safety.	(b) (4), (b) (6)	04 Dec 2020 14:37:09
User entered 'US'	System	24 Nov 2020 20:40:28

US3342200

Folder: SAE USA-US203-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 09 Jun 2021 17:05:26

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '10'	System	29 Apr 2021 15:04:38
User entered '9'	System	30 Mar 2021 15:11:38
User entered '8'	System	15 Mar 2021 17:27:03
User entered '7'	System	12 Mar 2021 17:18:59
User entered '6'	System	03 Mar 2021 16:21:32
User entered '5'	System	08 Feb 2021 17:17:13
User entered '4'	System	19 Jan 2021 16:03:30
User entered '3'	System	10 Dec 2020 18:48:16
User entered '2'	System	04 Dec 2020 14:37:19
User entered '1'	System	24 Nov 2020 20:40:28

US3342200

Folder: SAE USA-US203-2020-MRNA-1273-P301000006

Form: Safety Report Form (5)

Generated On: 09 Jun 2021 17:05:26

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Mar 2021 15:56:17
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:24:15
User entered '08/Feb/2021 12:17'	(b) (4) System	08 Feb 2021 17:17:13

US3342200

Folder: SAE USA-US203-2020-MRNA-1273-P301000006

Form: Safety Report Form (5)

Generated On: 09 Jun 2021 17:05:26

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)	19 Mar 2021 15:56:17
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:24:15
Reviewed for Safety.	(b) (4), (b) (6)	08 Feb 2021 17:17:17
User entered '1'	(b) (4), (b) (6)	08 Feb 2021 17:17:13

US3342200

Folder: SAE USA-US203-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 09 Jun 2021 17:05:26

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:24:15
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Dec 2020 18:01:36
Reviewed for Safety.	(b) (4), (b) (6)	24 Nov 2020 20:40:18
User entered 'USA-US203-2020-MRNA-1273-P301000006'	System	24 Nov 2020 20:39:57

US3342200

Folder: SAE USA-US203-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 09 Jun 2021 17:05:26

Serious

Audit	User	Time (GMT)
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:24:15
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Dec 2020 18:01:36
Reviewed for Safety.	(b) (4), (b) (6)	24 Nov 2020 20:40:18
User entered 'Yes (Y)'	System	24 Nov 2020 20:39:57

US3342200

Folder: SAE USA-US203-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 09 Jun 2021 17:05:26

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:24:15
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Dec 2020 18:01:36
Reviewed for Safety.	(b) (4), (b) (6)	24 Nov 2020 20:40:18
User entered 'No (N)'	System	24 Nov 2020 20:39:57

US3342200

Folder: SAE USA-US203-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 09 Jun 2021 17:05:26

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:24:15
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Dec 2020 18:01:36
Reviewed for Safety.	(b) (4), (b) (6)	24 Nov 2020 20:40:18
User entered 'No (N)'	System	24 Nov 2020 20:39:57

US3342200

Folder: SAE USA-US203-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 09 Jun 2021 17:05:26

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:24:15
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Dec 2020 18:01:36
Reviewed for Safety.	(b) (4), (b) (6)	24 Nov 2020 20:40:18
User entered 'No (N)'	System	24 Nov 2020 20:39:57

US3342200

Folder: SAE USA-US203-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 09 Jun 2021 17:05:26

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:24:15
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Dec 2020 18:01:36
Reviewed for Safety.	(b) (4), (b) (6)	24 Nov 2020 20:40:18
User entered 'No (N)'	System	24 Nov 2020 20:39:57

US3342200

Folder: SAE USA-US203-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 09 Jun 2021 17:05:26

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:24:15
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Dec 2020 18:01:36
Reviewed for Safety.	(b) (4), (b) (6)	24 Nov 2020 20:40:18
User entered 'No (N)'	System	24 Nov 2020 20:39:57

US3342200

Folder: SAE USA-US203-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 09 Jun 2021 17:05:26

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:24:15
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Dec 2020 18:01:36
Reviewed for Safety.	(b) (4), (b) (6)	24 Nov 2020 20:40:18
User entered 'Yes (Y)'	System	24 Nov 2020 20:39:57

US3342200

Folder: SAE USA-US203-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 09 Jun 2021 17:05:26

[Investigator's First Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 22:12:21
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:24:15
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	08 Feb 2021 17:17:17
User entered 'Paul'	System	08 Feb 2021 17:17:13

US3342200

Folder: SAE USA-US203-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 09 Jun 2021 17:05:26

[Investigator's Last Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 22:12:23
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:24:15
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	08 Feb 2021 17:17:17
User entered 'Pickrell'	System	08 Feb 2021 17:17:13

US3342200

Folder: SAE USA-US203-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 09 Jun 2021 17:05:26

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:24:15
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Dec 2020 18:01:36
Reviewed for Safety.	(b) (4), (b) (6)	04 Dec 2020 14:37:09
User entered 'US'	System	24 Nov 2020 20:40:28

US3342200

Folder: SAE USA-US203-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 09 Jun 2021 17:05:26

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '10'	System	29 Apr 2021 15:04:38
User entered '9'	System	30 Mar 2021 15:11:38
User entered '8'	System	15 Mar 2021 17:27:03
User entered '7'	System	12 Mar 2021 17:18:59
User entered '6'	System	03 Mar 2021 16:21:32
User entered '5'	System	08 Feb 2021 17:17:13
User entered '4'	System	19 Jan 2021 16:03:30
User entered '3'	System	10 Dec 2020 18:48:16
User entered '2'	System	04 Dec 2020 14:37:19
User entered '1'	System	24 Nov 2020 20:40:28

US3342200

Folder: SAE USA-US203-2020-MRNA-1273-P301000006

Form: Safety Report Form (6)

Generated On: 09 Jun 2021 17:05:26

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Mar 2021 15:56:17
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:24:15
User entered '03/Mar/2021 11:21'	(b) (4) System	03 Mar 2021 16:21:32

US3342200

Folder: SAE USA-US203-2020-MRNA-1273-P301000006

Form: Safety Report Form (6)

Generated On: 09 Jun 2021 17:05:26

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)	19 Mar 2021 15:56:17
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:24:15
Reviewed for Safety.	(b) (4), (b) (6)	12 Mar 2021 17:19:03
User entered 'I'	(b) (4), (b) (6)	03 Mar 2021 16:21:32

US3342200

Folder: SAE USA-US203-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 09 Jun 2021 17:05:26

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:24:15
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Dec 2020 18:01:36
Reviewed for Safety.	(b) (4), (b) (6)	24 Nov 2020 20:40:18
User entered 'USA-US203-2020-MRNA-1273-P301000006'	System	24 Nov 2020 20:39:57

US3342200

Folder: SAE USA-US203-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 09 Jun 2021 17:05:26

Serious

Audit	User	Time (GMT)
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:24:15
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Dec 2020 18:01:36
Reviewed for Safety.	(b) (4), (b) (6)	24 Nov 2020 20:40:18
User entered 'Yes (Y)'	System	24 Nov 2020 20:39:57

US3342200

Folder: SAE USA-US203-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 09 Jun 2021 17:05:26

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:24:15
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Dec 2020 18:01:36
Reviewed for Safety.	(b) (4), (b) (6)	24 Nov 2020 20:40:18
User entered 'No (N)'	System	24 Nov 2020 20:39:57

US3342200

Folder: SAE USA-US203-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 09 Jun 2021 17:05:26

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:24:15
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Dec 2020 18:01:36
Reviewed for Safety.	(b) (4), (b) (6)	24 Nov 2020 20:40:18
User entered 'No (N)'	System	24 Nov 2020 20:39:57

US3342200

Folder: SAE USA-US203-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 09 Jun 2021 17:05:26

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:24:15
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Dec 2020 18:01:36
Reviewed for Safety.	(b) (4), (b) (6)	24 Nov 2020 20:40:18
User entered 'No (N)'	System	24 Nov 2020 20:39:57

US3342200

Folder: SAE USA-US203-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 09 Jun 2021 17:05:26

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:24:15
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Dec 2020 18:01:36
Reviewed for Safety.	(b) (4), (b) (6)	24 Nov 2020 20:40:18
User entered 'No (N)'	System	24 Nov 2020 20:39:57

US3342200

Folder: SAE USA-US203-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 09 Jun 2021 17:05:26

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:24:15
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Dec 2020 18:01:36
Reviewed for Safety.	(b) (4), (b) (6)	24 Nov 2020 20:40:18
User entered 'No (N)'	System	24 Nov 2020 20:39:57

US3342200

Folder: SAE USA-US203-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 09 Jun 2021 17:05:26

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:24:15
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Dec 2020 18:01:36
Reviewed for Safety.	(b) (4), (b) (6)	24 Nov 2020 20:40:18
User entered 'Yes (Y)'	System	24 Nov 2020 20:39:57

US3342200

Folder: SAE USA-US203-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 09 Jun 2021 17:05:26

[Investigator's First Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 22:12:21
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:24:15
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	08 Feb 2021 17:17:17
User entered 'Paul'	System	08 Feb 2021 17:17:13

US3342200

Folder: SAE USA-US203-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 09 Jun 2021 17:05:26

[Investigator's Last Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 22:12:23
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:24:15
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	08 Feb 2021 17:17:17
User entered 'Pickrell'	System	08 Feb 2021 17:17:13

US3342200

Folder: SAE USA-US203-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 09 Jun 2021 17:05:26

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:24:15
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Dec 2020 18:01:36
Reviewed for Safety.	(b) (4), (b) (6)	04 Dec 2020 14:37:09
User entered 'US'	System	24 Nov 2020 20:40:28

US3342200

Folder: SAE USA-US203-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 09 Jun 2021 17:05:26

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '10'	System	29 Apr 2021 15:04:38
User entered '9'	System	30 Mar 2021 15:11:38
User entered '8'	System	15 Mar 2021 17:27:03
User entered '7'	System	12 Mar 2021 17:18:59
User entered '6'	System	03 Mar 2021 16:21:32
User entered '5'	System	08 Feb 2021 17:17:13
User entered '4'	System	19 Jan 2021 16:03:30
User entered '3'	System	10 Dec 2020 18:48:16
User entered '2'	System	04 Dec 2020 14:37:19
User entered '1'	System	24 Nov 2020 20:40:28

US3342200

Folder: SAE USA-US203-2020-MRNA-1273-P301000006

Form: Safety Report Form (7)

Generated On: 09 Jun 2021 17:05:26

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Mar 2021 15:56:17
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:24:15
User entered '12/Mar/2021 12:18'	(b) (4) System	12 Mar 2021 17:18:59

US3342200

Folder: SAE USA-US203-2020-MRNA-1273-P301000006

Form: Safety Report Form (7)

Generated On: 09 Jun 2021 17:05:26

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)	19 Mar 2021 15:56:17
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:24:15
Reviewed for Safety.	(b) (4), (b) (6)	12 Mar 2021 17:19:03
User entered 'I'	(b) (4), (b) (6)	12 Mar 2021 17:18:59

US3342200

Folder: SAE USA-US203-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 09 Jun 2021 17:05:26

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:24:15
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Dec 2020 18:01:36
Reviewed for Safety.	(b) (4), (b) (6)	24 Nov 2020 20:40:18
User entered 'USA-US203-2020-MRNA-1273-P301000006'	System	24 Nov 2020 20:39:57

US3342200

Folder: SAE USA-US203-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 09 Jun 2021 17:05:26

Serious

Audit	User	Time (GMT)
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:24:15
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Dec 2020 18:01:36
Reviewed for Safety.	(b) (4), (b) (6)	24 Nov 2020 20:40:18
User entered 'Yes (Y)'	System	24 Nov 2020 20:39:57

US3342200

Folder: SAE USA-US203-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 09 Jun 2021 17:05:26

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:24:15
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Dec 2020 18:01:36
Reviewed for Safety.	(b) (4), (b) (6)	24 Nov 2020 20:40:18
User entered 'No (N)'	System	24 Nov 2020 20:39:57

US3342200

Folder: SAE USA-US203-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 09 Jun 2021 17:05:26

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:24:15
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Dec 2020 18:01:36
Reviewed for Safety.	(b) (4), (b) (6)	24 Nov 2020 20:40:18
User entered 'No (N)'	System	24 Nov 2020 20:39:57

US3342200

Folder: SAE USA-US203-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 09 Jun 2021 17:05:26

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:24:15
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Dec 2020 18:01:36
Reviewed for Safety.	(b) (4), (b) (6)	24 Nov 2020 20:40:18
User entered 'No (N)'	System	24 Nov 2020 20:39:57

US3342200

Folder: SAE USA-US203-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 09 Jun 2021 17:05:26

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:24:15
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Dec 2020 18:01:36
Reviewed for Safety.	(b) (4), (b) (6)	24 Nov 2020 20:40:18
User entered 'No (N)'	System	24 Nov 2020 20:39:57

US3342200

Folder: SAE USA-US203-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 09 Jun 2021 17:05:26

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:24:15
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Dec 2020 18:01:36
Reviewed for Safety.	(b) (4), (b) (6)	24 Nov 2020 20:40:18
User entered 'No (N)'	System	24 Nov 2020 20:39:57

US3342200

Folder: SAE USA-US203-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 09 Jun 2021 17:05:26

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:24:15
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Dec 2020 18:01:36
Reviewed for Safety.	(b) (4), (b) (6)	24 Nov 2020 20:40:18
User entered 'Yes (Y)'	System	24 Nov 2020 20:39:57

US3342200

Folder: SAE USA-US203-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 09 Jun 2021 17:05:26

[Investigator's First Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 22:12:21
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:24:15
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	08 Feb 2021 17:17:17
User entered 'Paul'	System	08 Feb 2021 17:17:13

US3342200

Folder: SAE USA-US203-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 09 Jun 2021 17:05:26

[Investigator's Last Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 22:12:23
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:24:15
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	08 Feb 2021 17:17:17
User entered 'Pickrell'	System	08 Feb 2021 17:17:13

US3342200

Folder: SAE USA-US203-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 09 Jun 2021 17:05:26

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:24:15
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Dec 2020 18:01:36
Reviewed for Safety.	(b) (4), (b) (6)	04 Dec 2020 14:37:09
User entered 'US'	System	24 Nov 2020 20:40:28

US3342200

Folder: SAE USA-US203-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 09 Jun 2021 17:05:26

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '10'	System	29 Apr 2021 15:04:38
User entered '9'	System	30 Mar 2021 15:11:38
User entered '8'	System	15 Mar 2021 17:27:03
User entered '7'	System	12 Mar 2021 17:18:59
User entered '6'	System	03 Mar 2021 16:21:32
User entered '5'	System	08 Feb 2021 17:17:13
User entered '4'	System	19 Jan 2021 16:03:30
User entered '3'	System	10 Dec 2020 18:48:16
User entered '2'	System	04 Dec 2020 14:37:19
User entered '1'	System	24 Nov 2020 20:40:28

US3342200

Folder: SAE USA-US203-2020-MRNA-1273-P301000006

Form: Safety Report Form (8)

Generated On: 09 Jun 2021 17:05:26

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Pickrell (b) (4)	29 Mar 2021 15:07:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Mar 2021 15:56:17
User entered '15/Mar/2021 13:27'	System	15 Mar 2021 17:27:03

US3342200

Folder: SAE USA-US203-2020-MRNA-1273-P301000006

Form: Safety Report Form (8)

Generated On: 09 Jun 2021 17:05:26

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.	Paul Pickrell (b) (4)	29 Mar 2021 15:07:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Mar 2021 15:56:17
Reviewed for Safety.	(b) (4), (b) (6)	15 Mar 2021 17:27:09
User entered 'I'	(b) (4), (b) (6)	15 Mar 2021 17:27:03

US3342200

Folder: SAE USA-US203-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 09 Jun 2021 17:05:26

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:24:15
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Dec 2020 18:01:36
Reviewed for Safety.	(b) (4), (b) (6)	24 Nov 2020 20:40:18
User entered 'USA-US203-2020-MRNA-1273-P301000006'	System	24 Nov 2020 20:39:57

US3342200

Folder: SAE USA-US203-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 09 Jun 2021 17:05:26

Serious

Audit	User	Time (GMT)
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:24:15
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Dec 2020 18:01:36
Reviewed for Safety.	(b) (4), (b) (6)	24 Nov 2020 20:40:18
User entered 'Yes (Y)'	System	24 Nov 2020 20:39:57

US3342200

Folder: SAE USA-US203-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 09 Jun 2021 17:05:26

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:24:15
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Dec 2020 18:01:36
Reviewed for Safety.	(b) (4), (b) (6)	24 Nov 2020 20:40:18
User entered 'No (N)'	System	24 Nov 2020 20:39:57

US3342200

Folder: SAE USA-US203-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 09 Jun 2021 17:05:26

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:24:15
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Dec 2020 18:01:36
Reviewed for Safety.	(b) (4), (b) (6)	24 Nov 2020 20:40:18
User entered 'No (N)'	System	24 Nov 2020 20:39:57

US3342200

Folder: SAE USA-US203-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 09 Jun 2021 17:05:26

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:24:15
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Dec 2020 18:01:36
Reviewed for Safety.	(b) (4), (b) (6)	24 Nov 2020 20:40:18
User entered 'No (N)'	System	24 Nov 2020 20:39:57

US3342200

Folder: SAE USA-US203-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 09 Jun 2021 17:05:26

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:24:15
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Dec 2020 18:01:36
Reviewed for Safety.	(b) (4), (b) (6)	24 Nov 2020 20:40:18
User entered 'No (N)'	System	24 Nov 2020 20:39:57

US3342200

Folder: SAE USA-US203-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 09 Jun 2021 17:05:26

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:24:15
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Dec 2020 18:01:36
Reviewed for Safety.	(b) (4), (b) (6)	24 Nov 2020 20:40:18
User entered 'No (N)'	System	24 Nov 2020 20:39:57

US3342200

Folder: SAE USA-US203-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 09 Jun 2021 17:05:26

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:24:15
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Dec 2020 18:01:36
Reviewed for Safety.	(b) (4), (b) (6)	24 Nov 2020 20:40:18
User entered 'Yes (Y)'	System	24 Nov 2020 20:39:57

US3342200

Folder: SAE USA-US203-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 09 Jun 2021 17:05:26

[Investigator's First Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 22:12:21
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:24:15
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	08 Feb 2021 17:17:17
User entered 'Paul'	System	08 Feb 2021 17:17:13

US3342200

Folder: SAE USA-US203-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 09 Jun 2021 17:05:26

[Investigator's Last Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 22:12:23
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:24:15
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	08 Feb 2021 17:17:17
User entered 'Pickrell'	System	08 Feb 2021 17:17:13

US3342200

Folder: SAE USA-US203-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 09 Jun 2021 17:05:26

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:24:15
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Dec 2020 18:01:36
Reviewed for Safety.	(b) (4), (b) (6)	04 Dec 2020 14:37:09
User entered 'US'	System	24 Nov 2020 20:40:28

US3342200

Folder: SAE USA-US203-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 09 Jun 2021 17:05:26

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '10'	System	29 Apr 2021 15:04:38
User entered '9'	System	30 Mar 2021 15:11:38
User entered '8'	System	15 Mar 2021 17:27:03
User entered '7'	System	12 Mar 2021 17:18:59
User entered '6'	System	03 Mar 2021 16:21:32
User entered '5'	System	08 Feb 2021 17:17:13
User entered '4'	System	19 Jan 2021 16:03:30
User entered '3'	System	10 Dec 2020 18:48:16
User entered '2'	System	04 Dec 2020 14:37:19
User entered '1'	System	24 Nov 2020 20:40:28

US3342200

Folder: SAE USA-US203-2020-MRNA-1273-P301000006

Form: Safety Report Form (9)

Generated On: 09 Jun 2021 17:05:26

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Pickrell (b) (4)	12 Apr 2021 15:51:34
User entered '30/Mar/2021 11:11'	(b) (4) System	30 Mar 2021 15:11:38

US3342200

Folder: SAE USA-US203-2020-MRNA-1273-P301000006

Form: Safety Report Form (9)

Generated On: 09 Jun 2021 17:05:26

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.	Paul Pickrell (b) (4)	12 Apr 2021 15:51:34
Reviewed for Safety.	(b) (4)	
	(b) (4), (b) (6)	30 Mar 2021 15:11:42
User entered 'I'	(b) (4), (b) (6)	30 Mar 2021 15:11:38

US3342200

Folder: SAE USA-US203-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 09 Jun 2021 17:05:26

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:24:15
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Dec 2020 18:01:36
Reviewed for Safety.	(b) (4), (b) (6)	24 Nov 2020 20:40:18
User entered 'USA-US203-2020-MRNA-1273-P301000006'	System	24 Nov 2020 20:39:57

US3342200

Folder: SAE USA-US203-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 09 Jun 2021 17:05:26

Serious

Audit	User	Time (GMT)
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:24:15
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Dec 2020 18:01:36
Reviewed for Safety.	(b) (4), (b) (6)	24 Nov 2020 20:40:18
User entered 'Yes (Y)'	System	24 Nov 2020 20:39:57

US3342200

Folder: SAE USA-US203-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 09 Jun 2021 17:05:26

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:24:15
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Dec 2020 18:01:36
Reviewed for Safety.	(b) (4), (b) (6)	24 Nov 2020 20:40:18
User entered 'No (N)'	System	24 Nov 2020 20:39:57

US3342200

Folder: SAE USA-US203-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 09 Jun 2021 17:05:26

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:24:15
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Dec 2020 18:01:36
Reviewed for Safety.	(b) (4), (b) (6)	24 Nov 2020 20:40:18
User entered 'No (N)'	System	24 Nov 2020 20:39:57

US3342200

Folder: SAE USA-US203-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 09 Jun 2021 17:05:26

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:24:15
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Dec 2020 18:01:36
Reviewed for Safety.	(b) (4), (b) (6)	24 Nov 2020 20:40:18
User entered 'No (N)'	System	24 Nov 2020 20:39:57

US3342200

Folder: SAE USA-US203-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 09 Jun 2021 17:05:26

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:24:15
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Dec 2020 18:01:36
Reviewed for Safety.	(b) (4), (b) (6)	24 Nov 2020 20:40:18
User entered 'No (N)'	System	24 Nov 2020 20:39:57

US3342200

Folder: SAE USA-US203-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 09 Jun 2021 17:05:26

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:24:15
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Dec 2020 18:01:36
Reviewed for Safety.	(b) (4), (b) (6)	24 Nov 2020 20:40:18
User entered 'No (N)'	System	24 Nov 2020 20:39:57

US3342200

Folder: SAE USA-US203-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 09 Jun 2021 17:05:26

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:24:15
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Dec 2020 18:01:36
Reviewed for Safety.	(b) (4), (b) (6)	24 Nov 2020 20:40:18
User entered 'Yes (Y)'	System	24 Nov 2020 20:39:57

US3342200

Folder: SAE USA-US203-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 09 Jun 2021 17:05:26

[Investigator's First Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 22:12:21
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:24:15
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	08 Feb 2021 17:17:17
User entered 'Paul'	System	08 Feb 2021 17:17:13

US3342200

Folder: SAE USA-US203-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 09 Jun 2021 17:05:26

[Investigator's Last Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 22:12:23
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:24:15
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	08 Feb 2021 17:17:17
User entered 'Pickrell'	System	08 Feb 2021 17:17:13

US3342200

Folder: SAE USA-US203-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 09 Jun 2021 17:05:26

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:24:15
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Dec 2020 18:01:36
Reviewed for Safety.	(b) (4), (b) (6)	04 Dec 2020 14:37:09
User entered 'US'	System	24 Nov 2020 20:40:28

US3342200

Folder: SAE USA-US203-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 09 Jun 2021 17:05:26

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '10'	System	29 Apr 2021 15:04:38
User entered '9'	System	30 Mar 2021 15:11:38
User entered '8'	System	15 Mar 2021 17:27:03
User entered '7'	System	12 Mar 2021 17:18:59
User entered '6'	System	03 Mar 2021 16:21:32
User entered '5'	System	08 Feb 2021 17:17:13
User entered '4'	System	19 Jan 2021 16:03:30
User entered '3'	System	10 Dec 2020 18:48:16
User entered '2'	System	04 Dec 2020 14:37:19
User entered '1'	System	24 Nov 2020 20:40:28

US3342200

Folder: SAE USA-US203-2020-MRNA-1273-P301000006

Form: Safety Report Form (10)

Generated On: 09 Jun 2021 17:05:26

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Pickrell (b) (4)	30 Apr 2021 22:17:54
User entered '29/Apr/2021 10:00'	(b) (4) System	29 Apr 2021 15:04:38

US3342200

Folder: SAE USA-US203-2020-MRNA-1273-P301000006

Form: Safety Report Form (10)

Generated On: 09 Jun 2021 17:05:26

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.	Paul Pickrell (b) (4)	30 Apr 2021 22:17:54
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	29 Apr 2021 15:15:56
User entered 'I'	(b) (4), (b) (6)	29 Apr 2021 15:04:38