

US3632052 (Prod: Grady Health System)

Generated By: KC Joubran

Generated On: 10 Jun 2021 09:13:35

All time stamps listed in this document are displayed in GMT

US3632052

Form: Participant Creation

Data signed: (b) (4) 02 Apr 2021 20:59:27

Generated On: 10 Jun 2021 09:13:35

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Participant ID

US3632052

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

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US3632052

Folder: Screening

Form: Visit Date

Data signed: (b) (4) 15 Mar 2021 12:20:23

Generated On: 10 Jun 2021 09:13:35

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	08 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

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Folder: Screening

Form: Demographics

Data signed: (b) (4) 15 Mar 2021 12:20:23

Generated On: 10 Jun 2021 09:13:35

Date of Birth (MMM yyyy)	(b) (6) 1959
Age	61
Age Units	YEARS
Age (Derived)	61
Sex	Female <input type="radio"/> Male <input checked="" type="radio"/>
Ethnicity	Hispanic or Latino <input type="radio"/> Not Hispanic or Latino <input checked="" type="radio"/> Not Reported <input type="radio"/> Unknown <input type="radio"/>
Race (Check All That Apply)	
White	False
Black	True
Asian	False
American Indian or Alaska Native	False
Native Hawaiian or other Pacific Islander	False
Other	False
If race is Other, specify _____	
Unknown	False
Not reported	False

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Folder: Screening

Form: Enrollment

Data signed: (b) (4) 15 Mar 2021 12:20:23

Generated On: 10 Jun 2021 09:13:35

Date of Informed Consent ( <i>dd MMM yyyy</i> )	08 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

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Folder: Screening

Form: Inclusion/Exclusion Criteria Summary

Data signed: (b) (4) 15 Mar 2021 12:20:23

Generated On: 10 Jun 2021 09:13:35

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Did the participant meet all eligibility criteria?

Yes ☒

No ☐

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Folder: Screening

Form: Medical History Summary

Data signed: (b) (4) 15 Mar 2021 12:20:23

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Were any significant conditions reported?

Yes ☒  
No ☐

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Folder: Screening

Form: Medical History (1)

Data signed: (b) (4) 15 Mar 2021 12:20:23

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Condition	HYPERTENSION
Start date (dd MMM yyyy)	01 UNK 2014
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 2014
Start Year (derived)	2014
Stop Month and Year (derived)	
Stop Year (derived)	



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Folder: Screening

Form: Medical History (2)

Data signed: (b) (4) 15 Mar 2021 12:20:23

Generated On: 10 Jun 2021 09:13:35

Condition	HYPERCHOLESTEROLEMIA
Start date (dd MMM yyyy)	01 UNK 2016
Start date completely unknown	False
Condition ongoing at study entry	Yes <input checked="" type="radio"/> No <input type="radio"/>
If No, please specify the stop date (dd MMM yyyy) _____	
Stop date completely unknown	False
Start Month and Year (derived)	JAN 2016
Start Year (derived)	2016
Stop Month and Year (derived)	_____
Stop Year (derived)	_____

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Folder: Screening

Form: Medical History (3)

Data signed: (b) (4) 15 Mar 2021 12:20:23

Generated On: 10 Jun 2021 09:13:35

Condition	BENIGN PROSTATIC HYPERTROPHY
Start date (dd MMM yyyy)	01 UNK 2018
Start date completely unknown	False
Condition ongoing at study entry	Yes <input checked="" type="radio"/> No <input type="radio"/>
If No, please specify the stop date (dd MMM yyyy) _____	
Stop date completely unknown	False
Start Month and Year (derived)	JAN 2018
Start Year (derived)	2018
Stop Month and Year (derived)	_____
Stop Year (derived)	_____

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Folder: Screening

Form: Medical History (4)

Data signed: (b) (4) 15 Mar 2021 12:20:23

Generated On: 10 Jun 2021 09:13:35

Condition	SEASONAL ALLERGIES
Start date (dd MMM yyyy)	01 UNK 2018
Start date completely unknown	False
Condition ongoing at study entry	Yes <input checked="" type="radio"/> No <input type="radio"/>
If No, please specify the stop date (dd MMM yyyy)	
Stop date completely unknown	False
Start Month and Year (derived)	JAN 2018
Start Year (derived)	2018
Stop Month and Year (derived)	
Stop Year (derived)	

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Folder: Screening

Form: Medical History (5)

Data signed: (b) (4) 15 Mar 2021 12:20:23

Generated On: 10 Jun 2021 09:13:35

Condition	TINNITUS IN BOTH EARS
Start date (dd MMM yyyy)	01 UNK 2016
Start date completely unknown	False
Condition ongoing at study entry	Yes <input checked="" type="radio"/> No <input type="radio"/>
If No, please specify the stop date (dd MMM yyyy) _____	
Stop date completely unknown	False
Start Month and Year (derived)	JAN 2016
Start Year (derived)	2016
Stop Month and Year (derived)	_____
Stop Year (derived)	_____

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Folder: Screening

Form: Medical History (6)

Data signed: (b) (4) 15 Mar 2021 12:20:23

Generated On: 10 Jun 2021 09:13:35

Condition	INSOMNIA
Start date (dd MMM yyyy)	01 UNK 2016
Start date completely unknown	False
Condition ongoing at study entry	Yes <input checked="" type="radio"/> No <input type="radio"/>
If No, please specify the stop date (dd MMM yyyy) _____	
Stop date completely unknown	False
Start Month and Year (derived)	JAN 2016
Start Year (derived)	2016
Stop Month and Year (derived)	_____
Stop Year (derived)	_____

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Folder: Screening

Form: Vital Signs

Data signed: (b) (4) 15 Mar 2021 12:20:23

Generated On: 10 Jun 2021 09:13:35

Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment ( <i>dd MMM yyyy</i> )	8 SEP 2020
Time of assessment ( <i>00:00-23:59</i> )	08:40 (24 HR)
Vital Signs Date and Time (derived)	8 SEP 2020 08:40
Height ( <i>xxx.x</i> )	176 cm
Weight ( <i>xxx.x</i> )	95 kg
BMI ( <i>xxx.x</i> )	30.66890 kg/m <sup>2</sup>
BMI units	KG/M2
Temperature ( <i>xxx.x</i> )	ND - Not Done
Route of measurement	Oral <input type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	
Pulse ( <i>xxx</i> )	ND - Not Done
Pulse units	BPM
Respiratory Rate ( <i>xxx</i> )	ND - Not Done
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure ( <i>xxx</i> )	ND - Not Done
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure ( <i>xxx</i> )	ND - Not Done
Diastolic Blood Pressure units	MMHG
Height (derived)	
Weight (derived)	

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Folder: Screening

Form: Physical Examination

Data signed: (b) (4) 15 Mar 2021 12:20:23

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Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

8 SEP 2020

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

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Folder: Screening

Form: Risk of Exposure

Data signed: (b) (4) 15 Mar 2021 12:20:23

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**Occupational Risk**

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

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

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

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

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

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

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

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

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

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

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

**Other** Yes ☐ No ☒

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**Specify**

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**Location and Living Circumstances Risk (check all that apply)**

**No Risk Identified** False

**Resides in Nursing Home or Assisted Living Facility** False



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Folder: Screening

Form: Risk of Exposure

Data signed: (b) (4) 15 Mar 2021 12:20:23

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

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Folder: Visit 1 Day 1

Form: Visit Date

Data signed: (b) (4) 08 Mar 2021 14:31:03

Generated On: 10 Jun 2021 09:13:35

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	08 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

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Folder: Visit 1 Day 1

Form: Randomization

Data signed: (b) (4) 08 Mar 2021 14:31:03

Generated On: 10 Jun 2021 09:13:35

What was the date of randomization? (dd MMM yyyy) 08 SEP 2020

What was the participant's randomization number? 111919

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

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

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

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

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

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

Liver Disease Yes ☐ No ☒

Human Immunodeficiency Virus (HIV) infection Yes ☐ No ☒

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Data signed: (b) (4) 08 Mar 2021 14:31:03

Generated On: 10 Jun 2021 09:13:35

Height	ND - Not Done
Weight	ND - Not Done

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Data signed: (b) (4) 08 Mar 2021 14:31:03

Generated On: 10 Jun 2021 09:13:35

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)	8 SEP 2020
Time of assessment (00:00-23:59)	08:40 (24 HR)
Vital Signs Date and Time (derived)	8 SEP 2020 08:40
Temperature (xxx.x)	36.9 C
Route of measurement	Oral <input checked="" type="radio"/> Axillary <input type="radio"/> Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	74 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	134 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	81 mmHg
Diastolic Blood Pressure units	MMHG

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Data signed: (b) (4) 08 Mar 2021 14:31:03

Generated On: 10 Jun 2021 09:13:35

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)	8 SEP 2020
Time of assessment (00:00-23:59)	11:38 (24 HR)
Vital Signs Date and Time (derived)	8 SEP 2020 11:38
Temperature (xxx.x)	35.6 C
Route of measurement	Oral <input checked="" type="radio"/> Axillary <input type="radio"/> Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	59 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	20 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	156 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	87 mmHg
Diastolic Blood Pressure units	MMHG

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Folder: Visit 1 Day 1

Form: Physical Examination

Data signed: (b) (4) 08 Mar 2021 14:31:03

Generated On: 10 Jun 2021 09:13:35

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

8 SEP 2020

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

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Folder: Visit 1 Day 1

Form: Exposure

Data signed: (b) (4) 08 Mar 2021 14:31:03

Generated On: 10 Jun 2021 09:13:35

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) 08 SEP 2020

What was the treatment time? (00:00-23:59) 11:02 (24 HR)

Treatment Date and Time (derived) 08 SEP 2020 11:02

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

What was the frequency of the study treatment dosing? ONCE

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



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Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Data signed: (b) (4) 08 Mar 2021 14:31:03

Generated On: 10 Jun 2021 09:13:35

Was the sample collected?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Collection date (dd MMM yyyy)	8 SEP 2020
Collection time (00:00-23:59)	10:02 (24 HR)
Collection date and time (derived)	8 SEP 2020 10:02

US3632052

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab

Data signed: (b) (4) 08 Mar 2021 14:31:03

Generated On: 10 Jun 2021 09:13:35

Collection date (dd MMM yyyy)			8 SEP 2020
Lab Test	Was the sample collected?	Collection time (00:00 - 23:59)	Collection date and time (derived)
Nasopharyngeal Swab 1	Yes	09:50	8 SEP 2020 09:50
Nasopharyngeal Swab 2	No		

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Folder: Visit 1 Day 1

Form: Continuing

Data signed: (b) (4) 08 Mar 2021 14:31:03

Generated On: 10 Jun 2021 09:13:35

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

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Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/1)

Generated On: 10 Jun 2021 09:13:35

**TIMEPOINT**

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

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

96.2 °F

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

Yes ☐

No ☒

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

PC Time Stamp

08 SEP 2020 11:41

PC Open Date & Time

08 SEP 2020 11:22

PC Close Date & Time

08 SEP 2020 13:52

US3632052

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/2)

Generated On: 10 Jun 2021 09:13:35

**TIMEPOINT**

DAY 1, AFTER VACCINATION  
(AT HOME)

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

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

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

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

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

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

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

Was **TEMPERATURE** taken? Yes ☒ No ☐

Please record your **TEMPERATURE** in °F 96.9 °F

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

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

PC Time Stamp 08 SEP 2020 15:35

PC Open Date & Time 08 SEP 2020 14:47

PC Close Date & Time 09 SEP 2020 11:59

US3632052

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(2)

Generated On: 10 Jun 2021 09:13:35

**TIMEPOINT**

DAY 2

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

96.8 °F

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

Yes ☐

No ☒

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

PC Time Stamp

09 SEP 2020 21:51

PC Open Date & Time

09 SEP 2020 12:00

PC Close Date & Time

10 SEP 2020 11:59

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Folder: Diary Dose 1 (1)

Form: Temperature\_Day(3)

Generated On: 10 Jun 2021 09:13:35

**TIMEPOINT**

DAY 3

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

96.8 °F

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

Yes ☐

No ☒

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

PC Time Stamp

10 SEP 2020 23:32

PC Open Date & Time

10 SEP 2020 12:00

PC Close Date & Time

11 SEP 2020 11:59

US3632052

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(4)

Generated On: 10 Jun 2021 09:13:35

**TIMEPOINT**

DAY 4

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.0 °F

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

Yes ☐

No ☒

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

PC Time Stamp

11 SEP 2020 22:25

PC Open Date & Time

11 SEP 2020 12:00

PC Close Date & Time

12 SEP 2020 11:59



US3632052

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(5)

Generated On: 10 Jun 2021 09:13:35

**TIMEPOINT**

DAY 5

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.0 °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

12 SEP 2020 23:40

PC Open Date & Time

12 SEP 2020 12:00

PC Close Date & Time

13 SEP 2020 11:59

US3632052

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(6)

Generated On: 10 Jun 2021 09:13:35

**TIMEPOINT**

DAY 6

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

96.7 °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

13 SEP 2020 22:37

PC Open Date & Time

13 SEP 2020 12:00

PC Close Date & Time

14 SEP 2020 11:59

US3632052

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(7)

Generated On: 10 Jun 2021 09:13:35

**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

97.5 °F

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

Yes ☐

No ☒

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

PC Time Stamp

14 SEP 2020 23:20

PC Open Date & Time

14 SEP 2020 12:00

PC Close Date & Time

15 SEP 2020 11:59

US3632052

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/1)

Generated On: 10 Jun 2021 09:13:35

**TIMEPOINT**

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

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

PC Time Stamp

08 SEP 2020 11:42

PC Open Date & Time

08 SEP 2020 11:22

PC Close Date & Time

08 SEP 2020 13:52

US3632052

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/2)

Generated On: 10 Jun 2021 09:13:35

**TIMEPOINT**

DAY 1, AFTER VACCINATION  
(AT HOME)

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

Please select one response below

None ☒

Does not interfere with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

Please select one response below

None ☒

Does not interfere with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

PC Time Stamp

08 SEP 2020 15:36

PC Open Date & Time

08 SEP 2020 14:47

PC Close Date & Time

09 SEP 2020 11:59

US3632052

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(2)

Generated On: 10 Jun 2021 09:13:35

**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

09 SEP 2020 21:52

PC Open Date & Time

09 SEP 2020 12:00

PC Close Date & Time

10 SEP 2020 11:59

US3632052

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(3)

Generated On: 10 Jun 2021 09:13:35

**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

10 SEP 2020 23:33

PC Open Date & Time

10 SEP 2020 12:00

PC Close Date & Time

11 SEP 2020 11:59

US3632052

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(4)

Generated On: 10 Jun 2021 09:13:35

**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

11 SEP 2020 22:25

PC Open Date & Time

11 SEP 2020 12:00

PC Close Date & Time

12 SEP 2020 11:59



US3632052

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(5)

Generated On: 10 Jun 2021 09:13:35

**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

12 SEP 2020 23:40

PC Open Date & Time

12 SEP 2020 12:00

PC Close Date & Time

13 SEP 2020 11:59

US3632052

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(6)

Generated On: 10 Jun 2021 09:13:35

**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

13 SEP 2020 22:37

PC Open Date & Time

13 SEP 2020 12:00

PC Close Date & Time

14 SEP 2020 11:59

US3632052

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(7)

Generated On: 10 Jun 2021 09:13:35

**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

14 SEP 2020 23:20

PC Open Date & Time

14 SEP 2020 12:00

PC Close Date & Time

15 SEP 2020 11:59

US3632052

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 10 Jun 2021 09:13:35

**TIMEPOINT**

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

**HEADACHE**

None ☒

No interference with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

**FATIGUE**

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

**MUSCLE ACHES ALL OVER BODY**

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

**JOINT ACHES IN SEVERAL JOINTS**

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

**NAUSEA/VOMITING**

None ☒

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

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

Prevents daily activity, requires  
outpatient IV hydration ☐

**CHILLS**

None ☒

No interference with activity ☐

Some interference with activity  
not requiring medical attention ☐

Prevents daily activity and  
requires medical attention ☐

US3632052

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 10 Jun 2021 09:13:35

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

No ☒

Yes ☐

PC Time stamp	08 SEP 2020 11:43
PC Open Date & Time	08 SEP 2020 11:22
PC Close Date & Time	08 SEP 2020 13:52

US3632052

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 10 Jun 2021 09:13:35

**TIMEPOINT**

DAY 1, AFTER VACCINATION  
(AT HOME)

**HEADACHE**

None ☒

No interference with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

**FATIGUE**

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

**MUSCLE ACHES ALL OVER BODY**

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

**JOINT ACHES IN SEVERAL JOINTS**

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

**NAUSEA/VOMITING**

None ☒

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

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

Prevents daily activity, requires  
outpatient IV hydration ☐

**CHILLS**

None ☒

No interference with activity ☐

Some interference with activity  
not requiring medical attention ☐

Prevents daily activity and  
requires medical attention ☐

US3632052

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 10 Jun 2021 09:13:35

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

No ☒

Yes ☐

PC Time stamp	08 SEP 2020 15:37
PC Open Date & Time	08 SEP 2020 14:47
PC Close Date & Time	09 SEP 2020 11:59

US3632052

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 10 Jun 2021 09:13:35

TIMEPOINT

DAY 2

HEADACHE

None ☒

No interference with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

FATIGUE

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☐

No interference with activity ☒

Some interference with activity ☐

Significant; prevents daily  
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

NAUSEA/VOMITING

None ☒

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

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

Prevents daily activity, requires  
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity  
not requiring medical attention ☐

Prevents daily activity and  
requires medical attention ☐

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

No ☒

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EAB) (1725)

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Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 10 Jun 2021 09:13:35

Yes <input type="checkbox"/>	
PC Time stamp	09 SEP 2020 21:52
PC Open Date & Time	09 SEP 2020 12:00
PC Close Date & Time	10 SEP 2020 11:59

US3632052

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 10 Jun 2021 09:13:35

TIMEPOINT

DAY 3

HEADACHE

None ☒

No interference with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

FATIGUE

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

NAUSEA/VOMITING

None ☒

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

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

Prevents daily activity, requires  
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity  
not requiring medical attention ☐

Prevents daily activity and  
requires medical attention ☐

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

No ☒

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EAB) (1725)

US3632052

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 10 Jun 2021 09:13:35

Yes <input type="checkbox"/>	
PC Time stamp	10 SEP 2020 23:33
PC Open Date & Time	10 SEP 2020 12:00
PC Close Date & Time	11 SEP 2020 11:59

US3632052

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 10 Jun 2021 09:13:35

TIMEPOINT

DAY 4

HEADACHE

None ☒

No interference with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

FATIGUE

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

NAUSEA/VOMITING

None ☒

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

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

Prevents daily activity, requires  
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity  
not requiring medical attention ☐

Prevents daily activity and  
requires medical attention ☐

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

No ☒

US3632052

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 10 Jun 2021 09:13:35

Yes <input type="checkbox"/>	
PC Time stamp	11 SEP 2020 22:26
PC Open Date & Time	11 SEP 2020 12:00
PC Close Date & Time	12 SEP 2020 11:59

US3632052

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 10 Jun 2021 09:13:35

TIMEPOINT

DAY 5

HEADACHE

None ☒

No interference with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

FATIGUE

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

NAUSEA/VOMITING

None ☒

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

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

Prevents daily activity, requires  
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity  
not requiring medical attention ☐

Prevents daily activity and  
requires medical attention ☐

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

No ☒

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EAB) (1725)

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Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 10 Jun 2021 09:13:35

Yes <input type="checkbox"/>	
PC Time stamp	12 SEP 2020 23:41
PC Open Date & Time	12 SEP 2020 12:00
PC Close Date & Time	13 SEP 2020 11:59

US3632052

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 10 Jun 2021 09:13:35

**TIMEPOINT**

DAY 6

**HEADACHE**

None ☐

No interference with activity ☒

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

Any use of prescription pain  
reliever or prevents daily activity ☐

**FATIGUE**

None ☐

No interference with activity ☒

Some interference with activity ☐

Significant; prevents daily  
activity ☐

**MUSCLE ACHES ALL OVER BODY**

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

**JOINT ACHES IN SEVERAL JOINTS**

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

**NAUSEA/VOMITING**

None ☒

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

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

Prevents daily activity, requires  
outpatient IV hydration ☐

**CHILLS**

None ☒

No interference with activity ☐

Some interference with activity  
not requiring medical attention ☐

Prevents daily activity and  
requires medical attention ☐

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

No ☒

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Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 10 Jun 2021 09:13:35

Yes <input type="checkbox"/>	
PC Time stamp	13 SEP 2020 22:38
PC Open Date & Time	13 SEP 2020 12:00
PC Close Date & Time	14 SEP 2020 11:59

US3632052

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 10 Jun 2021 09:13:35

**TIMEPOINT**

DAY 7

**HEADACHE**

None ☐

No interference with activity ☒

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

Any use of prescription pain  
reliever or prevents daily activity ☐

**FATIGUE**

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

**MUSCLE ACHES ALL OVER BODY**

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

**JOINT ACHES IN SEVERAL JOINTS**

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

**NAUSEA/VOMITING**

None ☒

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

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

Prevents daily activity, requires  
outpatient IV hydration ☐

**CHILLS**

None ☒

No interference with activity ☐

Some interference with activity  
not requiring medical attention ☐

Prevents daily activity and  
requires medical attention ☐

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

No ☒

US3632052

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 10 Jun 2021 09:13:35

Yes <input type="checkbox"/>	
PC Time stamp	14 SEP 2020 23:21
PC Open Date & Time	14 SEP 2020 12:00
PC Close Date & Time	15 SEP 2020 11:59

US3632052

Folder: Diary Dose 1 (1)

Form: Headache\_Day(8)

Generated On: 10 Jun 2021 09:13:35

**TIMEPOINT**

DAY 8

Select one response below to indicate the intensity of your

None ☒

**HEADACHE**

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 ☐

PC Time Stamp 15 SEP 2020 23:54

PC Open Date & Time 15 SEP 2020 12:00

PC Close Date & Time 16 SEP 2020 11:59

US3632052

Folder: Diary Dose 1 (1)

Form: Medical Attention\_Day(8)

Generated On: 10 Jun 2021 09:13:35

<b>TIMEPOINT</b>	DAY 8
Did you receive any <b>MEDICAL ATTENTION</b> (doctor visit, <b>other</b> ) for any illness or symptoms?	No <input checked="" type="radio"/> Yes <input type="radio"/>
PC Time stamp	15 SEP 2020 23:54
PC Open Date & Time	15 SEP 2020 12:00
PC Close Date & Time	16 SEP 2020 11:59

US3632052

Folder: Safety Call Day 8 (1)

Form: Safety Call

Data signed: (b) (4) 08 Mar 2021 14:31:03

Generated On: 10 Jun 2021 09:13:35

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

15 SEP 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

*If Contact Not Made, please provide Comments*

US3632052

Folder: Safety Call Day 8 (1)

Form: Continuing

Data signed: (b) (4) 08 Mar 2021 14:31:03

Generated On: 10 Jun 2021 09:13:35

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3632052

Folder: Safety Call Day 15 (1)

Form: Safety Call

Data signed: (b) (4) 08 Mar 2021 14:31:03

Generated On: 10 Jun 2021 09:13:35

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

22 SEP 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

*If Contact Not Made, please provide Comments*



US3632052

Folder: Safety Call Day 15 (1)

Form: Continuing

Data signed: (b) (4) 08 Mar 2021 14:31:03

Generated On: 10 Jun 2021 09:13:35

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3632052

Folder: Safety Call Day 22 (1)

Form: Safety Call

Data signed: (b) (4) 08 Mar 2021 14:31:03

Generated On: 10 Jun 2021 09:13:35

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

29 SEP 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

*If Contact Not Made, please provide Comments*

US3632052

Folder: Safety Call Day 22 (1)

Form: Continuing

Data signed: (b) (4) 08 Mar 2021 14:31:03

Generated On: 10 Jun 2021 09:13:35

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3632052

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Data signed: (b) (4) 08 Mar 2021 14:31:04

Generated On: 10 Jun 2021 09:13:35

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	6 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	VISIT2

US3632052

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Data signed: (b) (4) 08 Mar 2021 14:31:04

Generated On: 10 Jun 2021 09:13:35

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)	6 OCT 2020
Time of assessment (00:00-23:59)	10:14 (24 HR)
Vital Signs Date and Time (derived)	6 OCT 2020 10:14
Temperature (xxx.x)	97.6 F
Route of measurement	Oral <input checked="" type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	78 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	130 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	78 mmHg
Diastolic Blood Pressure units	MMHG

US3632052

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Data signed: (b) (4) 08 Mar 2021 14:31:04

Generated On: 10 Jun 2021 09:13:35

Timepoint	Pre-Dose <input type="checkbox"/>
	Post-Dose <input checked="" type="checkbox"/>
Were vital signs assessed?	Yes <input checked="" type="checkbox"/>
	No <input type="checkbox"/>
Date of assessment (dd MMM yyyy)	6 OCT 2020
Time of assessment (00:00-23:59)	12:05 (24 HR)
Vital Signs Date and Time (derived)	6 OCT 2020 12:05
Temperature (xxx.x)	97.4 F
Route of measurement	Oral <input checked="" type="checkbox"/>
	Axillary <input type="checkbox"/>
	Other <input type="checkbox"/>
If Other, specify	
Pulse (xxx)	72 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	20 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	143 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	81 mmHg
Diastolic Blood Pressure units	MMHG

US3632052

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Data signed: (b) (4) 08 Mar 2021 14:31:04

Generated On: 10 Jun 2021 09:13:35

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

6 OCT 2020

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

US3632052

Folder: Visit 2 Day 29 (1)

Form: Exposure

Data signed: (b) (4) 08 Mar 2021 14:31:03

Generated On: 10 Jun 2021 09:13:35

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) 6 OCT 2020

What was the treatment time? (00:00-23:59) 11:33 (24 HR)

Treatment Date and Time (derived) 6 OCT 2020 11:33

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



US3632052

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 08 Mar 2021 14:31:04

Generated On: 10 Jun 2021 09:13:35

Was the sample collected?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Collection date (dd MMM yyyy)	6 OCT 2020
Collection time (00:00-23:59)	10:46 (24 HR)
Collection date and time (derived)	6 OCT 2020 10:46

US3632052

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab

Data signed: (b) (4) 08 Mar 2021 14:31:03

Generated On: 10 Jun 2021 09:13:35

Collection date (dd MMM yyyy)			6 OCT 2020
Lab Test	Was the sample collected?	Collection time (00:00 - 23:59)	Collection date and time (derived)
Nasopharyngeal Swab 1	Yes	10:48	6 OCT 2020 10:48
Nasopharyngeal Swab 2	No		

US3632052

Folder: Visit 2 Day 29 (1)

Form: Continuing

Data signed: (b) (4) 08 Mar 2021 14:31:03

Generated On: 10 Jun 2021 09:13:35

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3632052

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/1)

Generated On: 10 Jun 2021 09:13:35

**TIMEPOINT**

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

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒  
No ☐

Please record your **TEMPERATURE** in °F

97.4 °F

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

Yes ☐  
No ☒

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

PC Time Stamp 06 OCT 2020 12:09

PC Open Date & Time 06 OCT 2020 11:53

PC Close Date & Time 06 OCT 2020 14:23

US3632052

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/2)

Generated On: 10 Jun 2021 09:13:35

**TIMEPOINT**

DAY 1, AFTER VACCINATION  
(AT HOME)

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

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

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

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

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

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

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

Was **TEMPERATURE** taken? Yes ☒ No ☐

Please record your **TEMPERATURE** in °F 96.9 °F

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

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

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

To **PREVENT** pain or fever from occurring False

PC Time Stamp 06 OCT 2020 21:57

PC Open Date & Time 06 OCT 2020 15:18

PC Close Date & Time 07 OCT 2020 11:59

US3632052

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(2)

Generated On: 10 Jun 2021 09:13:35

**TIMEPOINT**

DAY 2

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

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

07 OCT 2020 22:39

PC Open Date & Time

07 OCT 2020 12:00

PC Close Date & Time

08 OCT 2020 11:59

US3632052

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(3)

Generated On: 10 Jun 2021 09:13:35

**TIMEPOINT**

DAY 3

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

96.9 °F

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

Yes ☐

No ☒

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

PC Time Stamp

08 OCT 2020 23:03

PC Open Date & Time

08 OCT 2020 12:00

PC Close Date & Time

09 OCT 2020 11:59

US3632052

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(4)

Generated On: 10 Jun 2021 09:13:35

**TIMEPOINT**

DAY 4

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

96.6 °F

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

Yes ☐

No ☒

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

PC Time Stamp

09 OCT 2020 22:59

PC Open Date & Time

09 OCT 2020 12:00

PC Close Date & Time

10 OCT 2020 11:59



US3632052

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(5)

Generated On: 10 Jun 2021 09:13:35

**TIMEPOINT**

DAY 5

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.7 °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

10 OCT 2020 22:36

PC Open Date & Time

10 OCT 2020 12:00

PC Close Date & Time

11 OCT 2020 11:59

US3632052

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(6)

Generated On: 10 Jun 2021 09:13:35

**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

97.7 °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

11 OCT 2020 23:32

PC Open Date & Time

11 OCT 2020 12:00

PC Close Date & Time

12 OCT 2020 11:59

US3632052

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(7)

Generated On: 10 Jun 2021 09:13:35

**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.

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.5 °F

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

Yes ☐

No ☒

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

PC Time Stamp

12 OCT 2020 23:17

PC Open Date & Time

12 OCT 2020 12:00

PC Close Date & Time

13 OCT 2020 11:59

US3632052

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/1)

Generated On: 10 Jun 2021 09:13:35

**TIMEPOINT**

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

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

PC Time Stamp

06 OCT 2020 12:09

PC Open Date & Time

06 OCT 2020 11:53

PC Close Date & Time

06 OCT 2020 14:23

US3632052

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/2)

Generated On: 10 Jun 2021 09:13:35

**TIMEPOINT**

DAY 1, AFTER VACCINATION  
(AT HOME)

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

Please select one response below

None ☐

Does not interfere with activity ☒

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

Any use of prescription pain  
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

Please select one response below

None ☒

Does not interfere with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

PC Time Stamp

06 OCT 2020 21:58

PC Open Date & Time

06 OCT 2020 15:18

PC Close Date & Time

07 OCT 2020 11:59

US3632052

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(2)

Generated On: 10 Jun 2021 09:13:35

**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

07 OCT 2020 22:40

PC Open Date & Time

07 OCT 2020 12:00

PC Close Date & Time

08 OCT 2020 11:59

US3632052

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(3)

Generated On: 10 Jun 2021 09:13:35

**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

08 OCT 2020 23:03

PC Open Date & Time

08 OCT 2020 12:00

PC Close Date & Time

09 OCT 2020 11:59

US3632052

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(4)

Generated On: 10 Jun 2021 09:13:35

**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

09 OCT 2020 23:00

PC Open Date & Time

09 OCT 2020 12:00

PC Close Date & Time

10 OCT 2020 11:59



US3632052

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(5)

Generated On: 10 Jun 2021 09:13:35

**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

10 OCT 2020 22:36

PC Open Date & Time

10 OCT 2020 12:00

PC Close Date & Time

11 OCT 2020 11:59

US3632052

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(6)

Generated On: 10 Jun 2021 09:13:35

**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

11 OCT 2020 23:32

PC Open Date & Time

11 OCT 2020 12:00

PC Close Date & Time

12 OCT 2020 11:59

US3632052

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(7)

Generated On: 10 Jun 2021 09:13:35

**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

12 OCT 2020 23:17

PC Open Date & Time

12 OCT 2020 12:00

PC Close Date & Time

13 OCT 2020 11:59

US3632052

Folder: Diary Dose 2 (1)

Form: General\_Day(1/1)

Generated On: 10 Jun 2021 09:13:35

**TIMEPOINT**

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

**HEADACHE**

None ☒

No interference with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

**FATIGUE**

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

**MUSCLE ACHES ALL OVER BODY**

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

**JOINT ACHES IN SEVERAL JOINTS**

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

**NAUSEA/VOMITING**

None ☒

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

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

Prevents daily activity, requires  
outpatient IV hydration ☐

**CHILLS**

None ☒

No interference with activity ☐

Some interference with activity  
not requiring medical attention ☐

Prevents daily activity and  
requires medical attention ☐

US3632052

Folder: Diary Dose 2 (1)

Form: General\_Day(1/1)

Generated On: 10 Jun 2021 09:13:35

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

No ☒

Yes ☐

PC Time stamp	06 OCT 2020 12:10
PC Open Date & Time	06 OCT 2020 11:53
PC Close Date & Time	06 OCT 2020 14:23

US3632052

Folder: Diary Dose 2 (1)

Form: General\_Day(1/2)

Generated On: 10 Jun 2021 09:13:35

**TIMEPOINT**

DAY 1, AFTER VACCINATION  
(AT HOME)

**HEADACHE**

None ☒

No interference with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

**FATIGUE**

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

**MUSCLE ACHES ALL OVER BODY**

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

**JOINT ACHES IN SEVERAL JOINTS**

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

**NAUSEA/VOMITING**

None ☒

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

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

Prevents daily activity, requires  
outpatient IV hydration ☐

**CHILLS**

None ☒

No interference with activity ☐

Some interference with activity  
not requiring medical attention ☐

Prevents daily activity and  
requires medical attention ☐

US3632052

Folder: Diary Dose 2 (1)

Form: General\_Day(1/2)

Generated On: 10 Jun 2021 09:13:35

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

No ☒

Yes ☐

PC Time stamp	06 OCT 2020 21:59
PC Open Date & Time	06 OCT 2020 15:18
PC Close Date & Time	07 OCT 2020 11:59

US3632052

Folder: Diary Dose 2 (1)

Form: General\_Day(2)

Generated On: 10 Jun 2021 09:13:35

TIMEPOINT

DAY 2

HEADACHE

None ☒

No interference with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

FATIGUE

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

NAUSEA/VOMITING

None ☒

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

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

Prevents daily activity, requires  
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity  
not requiring medical attention ☐

Prevents daily activity and  
requires medical attention ☐

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

No ☒

PRODUCTION RELEASE (v12.003  
EAB) (1725)

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US3632052

Folder: Diary Dose 2 (1)

Form: General\_Day(2)

Generated On: 10 Jun 2021 09:13:35

Yes <input type="checkbox"/>	
PC Time stamp	07 OCT 2020 22:41
PC Open Date & Time	07 OCT 2020 12:00
PC Close Date & Time	08 OCT 2020 11:59

US3632052

Folder: Diary Dose 2 (1)

Form: General\_Day(3)

Generated On: 10 Jun 2021 09:13:35

TIMEPOINT

DAY 3

HEADACHE

None ☒

No interference with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

FATIGUE

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

NAUSEA/VOMITING

None ☒

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

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

Prevents daily activity, requires  
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity  
not requiring medical attention ☐

Prevents daily activity and  
requires medical attention ☐

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

No ☒

PRODUCTION RELEASE (v12.003

97 of 2398

EAB) (1725)

US3632052

Folder: Diary Dose 2 (1)

Form: General\_Day(3)

Generated On: 10 Jun 2021 09:13:35

Yes <input type="checkbox"/>	
PC Time stamp	08 OCT 2020 23:04
PC Open Date & Time	08 OCT 2020 12:00
PC Close Date & Time	09 OCT 2020 11:59

US3632052

Folder: Diary Dose 2 (1)

Form: General\_Day(4)

Generated On: 10 Jun 2021 09:13:35

**TIMEPOINT**

DAY 4

**HEADACHE**

None ☒

No interference with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

**FATIGUE**

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

**MUSCLE ACHES ALL OVER BODY**

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

**JOINT ACHES IN SEVERAL JOINTS**

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

**NAUSEA/VOMITING**

None ☒

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

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

Prevents daily activity, requires  
outpatient IV hydration ☐

**CHILLS**

None ☒

No interference with activity ☐

Some interference with activity  
not requiring medical attention ☐

Prevents daily activity and  
requires medical attention ☐

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

No ☒

PRODUCTION RELEASE (v12.003

99 of 2398

EAB) (1725)

US3632052

Folder: Diary Dose 2 (1)

Form: General\_Day(4)

Generated On: 10 Jun 2021 09:13:35

Yes <input type="checkbox"/>	
PC Time stamp	09 OCT 2020 23:00
PC Open Date & Time	09 OCT 2020 12:00
PC Close Date & Time	10 OCT 2020 11:59

US3632052

Folder: Diary Dose 2 (1)

Form: General\_Day(5)

Generated On: 10 Jun 2021 09:13:35

TIMEPOINT

DAY 5

HEADACHE

None ☒

No interference with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

FATIGUE

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

NAUSEA/VOMITING

None ☒

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

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

Prevents daily activity, requires  
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity  
not requiring medical attention ☐

Prevents daily activity and  
requires medical attention ☐

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

No ☒

US3632052

Folder: Diary Dose 2 (1)

Form: General\_Day(5)

Generated On: 10 Jun 2021 09:13:35

Yes <input type="checkbox"/>	
PC Time stamp	10 OCT 2020 22:37
PC Open Date & Time	10 OCT 2020 12:00
PC Close Date & Time	11 OCT 2020 11:59

US3632052

Folder: Diary Dose 2 (1)

Form: General\_Day(6)

Generated On: 10 Jun 2021 09:13:35

TIMEPOINT

DAY 6

HEADACHE

None ☒

No interference with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

FATIGUE

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

NAUSEA/VOMITING

None ☒

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

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

Prevents daily activity, requires  
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity  
not requiring medical attention ☐

Prevents daily activity and  
requires medical attention ☐

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

No ☒



US3632052

Folder: Diary Dose 2 (1)

Form: General\_Day(6)

Generated On: 10 Jun 2021 09:13:35

Yes <input type="checkbox"/>	
PC Time stamp	11 OCT 2020 23:32
PC Open Date & Time	11 OCT 2020 12:00
PC Close Date & Time	12 OCT 2020 11:59

US3632052

Folder: Diary Dose 2 (1)

Form: General\_Day(7)

Generated On: 10 Jun 2021 09:13:35

**TIMEPOINT**

DAY 7

**HEADACHE**

None ☒

No interference with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

**FATIGUE**

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

**MUSCLE ACHES ALL OVER BODY**

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

**JOINT ACHES IN SEVERAL JOINTS**

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

**NAUSEA/VOMITING**

None ☒

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

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

Prevents daily activity, requires  
outpatient IV hydration ☐

**CHILLS**

None ☒

No interference with activity ☐

Some interference with activity  
not requiring medical attention ☐

Prevents daily activity and  
requires medical attention ☐

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

No ☒

US3632052

Folder: Diary Dose 2 (1)

Form: General\_Day(7)

Generated On: 10 Jun 2021 09:13:35

Yes <input type="checkbox"/>	
PC Time stamp	12 OCT 2020 23:18
PC Open Date & Time	12 OCT 2020 12:00
PC Close Date & Time	13 OCT 2020 11:59

US3632052

Folder: Safety Call Day 36 (1)

Form: Safety Call

Data signed: (b) (4) 08 Mar 2021 14:31:03

Generated On: 10 Jun 2021 09:13:35

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

13 OCT 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

*If Contact Not Made, please provide Comments*

US3632052

Folder: Safety Call Day 36 (1)

Form: Continuing

Data signed: (b) (4) 08 Mar 2021 14:31:03

Generated On: 10 Jun 2021 09:13:35

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3632052

Folder: Safety Call Day 43 (1)

Form: Safety Call

Data signed: (b) (4) 08 Mar 2021 14:31:03

Generated On: 10 Jun 2021 09:13:35

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

20 OCT 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

*If Contact Not Made, please provide Comments*

US3632052

Folder: Safety Call Day 43 (1)

Form: Continuing

Data signed: (b) (4) 08 Mar 2021 14:31:03

Generated On: 10 Jun 2021 09:13:35

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3632052

Folder: Safety Call Day 50 (1)

Form: Safety Call

Data signed: (b) (4) 08 Mar 2021 14:31:03

Generated On: 10 Jun 2021 09:13:35

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

27 OCT 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

*If Contact Not Made, please provide Comments*



US3632052

Folder: Safety Call Day 50 (1)

Form: Continuing

Data signed: (b) (4) 08 Mar 2021 14:31:03

Generated On: 10 Jun 2021 09:13:35

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3632052

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Data signed: (b) (4) 08 Mar 2021 14:31:04

Generated On: 10 Jun 2021 09:13:35

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	2 NOV 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

US3632052

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Data signed: (b) (4) 08 Mar 2021 14:31:04

Generated On: 10 Jun 2021 09:13:35

Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (dd MMM yyyy)	2 NOV 2020
Time of assessment (00:00-23:59)	14:08 (24 HR)
Vital Signs Date and Time (derived)	2 NOV 2020 14:08
Temperature (xxx.x)	97.2 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)	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	125 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	79 mmHg
Diastolic Blood Pressure units	MMHG
Height (derived)	
Weight (derived)	

US3632052

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Data signed: (b) (4) 08 Mar 2021 14:31:04

Generated On: 10 Jun 2021 09:13:35

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.*

US3632052

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 08 Mar 2021 14:31:04

Generated On: 10 Jun 2021 09:13:35

Was the sample collected?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Collection date (dd MMM yyyy)	2 NOV 2020
Collection time (00:00-23:59)	14:38 (24 HR)
Collection date and time (derived)	2 NOV 2020 14:38

US3632052

Folder: Visit 3 Day 57 (1)

Form: Continuing

Data signed: (b) (4) 08 Mar 2021 14:31:04

Generated On: 10 Jun 2021 09:13:35

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3632052

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:13:35

<b>TIMEPOINT</b>	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 <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	08 NOV 2020 16:22:48
Patient Cloud Open Date & Time	08 NOV 2020 00:01
Patient Cloud Close Date & Time	12 NOV 2020 23:59

US3632052

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:13:35

**TIMEPOINT**

DAY 71

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

15 NOV 2020 11:01:47

Patient Cloud Open Date & Time

15 NOV 2020 00:01

Patient Cloud Close Date & Time

19 NOV 2020 23:59



US3632052

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:13:35

TIMEPOINT	DAY 75
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"/>

**US3632052**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:13:35**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
<a href="#">Patient Cloud Open Date &amp; Time</a>	19 NOV 2020 00:01
<a href="#">Patient Cloud Close Date &amp; Time</a>	23 NOV 2020 23:59

US3632052

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:13:35

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 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	27 NOV 2020 18:37:08
Patient Cloud Open Date & Time	26 NOV 2020 00:01
Patient Cloud Close Date & Time	30 NOV 2020 23:59

US3632052

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:13:35

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	03 DEC 2020 12:46:27
Patient Cloud Open Date & Time	03 DEC 2020 00:01
Patient Cloud Close Date & Time	07 DEC 2020 23:59

US3632052

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:13:35

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	10 DEC 2020 10:58:08
Patient Cloud Open Date & Time	10 DEC 2020 00:01
Patient Cloud Close Date & Time	14 DEC 2020 23:59

US3632052

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:13:35

**TIMEPOINT**

DAY 103

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

17 DEC 2020 09:11:38

Patient Cloud Open Date & Time

17 DEC 2020 00:01

Patient Cloud Close Date & Time

21 DEC 2020 23:59

US3632052

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:13:35

TIMEPOINT	DAY 110
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input 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"/>

**US3632052**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:13:35**

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

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<a href="#">Patient Cloud Open Date &amp; Time</a>	24 DEC 2020 00:01
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<a href="#">Patient Cloud Close Date &amp; Time</a>	28 DEC 2020 23:59
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US3632052

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:13:35

**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

02 JAN 2021 08:54:52

Patient Cloud Open Date & Time

31 DEC 2020 00:01

Patient Cloud Close Date & Time

04 JAN 2021 23:59

US3632052

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:13:35

TIMEPOINT	DAY 124
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	09 JAN 2021 07:34:01
Patient Cloud Open Date & Time	07 JAN 2021 00:01
Patient Cloud Close Date & Time	11 JAN 2021 23:59

US3632052

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:13:35

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	14 JAN 2021 12:16:28
Patient Cloud Open Date & Time	14 JAN 2021 00:01
Patient Cloud Close Date & Time	18 JAN 2021 23:59

US3632052

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:13:35

**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

21 JAN 2021 15:54:52

Patient Cloud Open Date & Time

21 JAN 2021 00:01

Patient Cloud Close Date & Time

25 JAN 2021 23:59

US3632052

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:13:35

<b>TIMEPOINT</b>	DAY 145
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input 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 JAN 2021 15:52:48
Patient Cloud Open Date & Time	28 JAN 2021 00:01
Patient Cloud Close Date & Time	01 FEB 2021 23:59

US3632052

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:13:35

**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

05 FEB 2021 19:42:17

Patient Cloud Open Date & Time

04 FEB 2021 00:01

Patient Cloud Close Date & Time

08 FEB 2021 23:59

US3632052

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:13:35

TIMEPOINT	DAY 159
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	11 FEB 2021 10:14:10
Patient Cloud Open Date & Time	11 FEB 2021 00:01
Patient Cloud Close Date & Time	15 FEB 2021 23:59

US3632052

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:13:35

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 type="radio"/> Yes <input checked="" type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input checked="" type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	18 FEB 2021 10:56:56
Patient Cloud Open Date & Time	18 FEB 2021 00:01
Patient Cloud Close Date & Time	22 FEB 2021 23:59



US3632052

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:13:35

**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

27 FEB 2021 10:26:51

Patient Cloud Open Date & Time

25 FEB 2021 00:01

Patient Cloud Close Date & Time

01 MAR 2021 23:59

US3632052

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:13:35

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	04 MAR 2021 11:18:16
Patient Cloud Open Date & Time	04 MAR 2021 00:01
Patient Cloud Close Date & Time	08 MAR 2021 23:59

US3632052

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:13:35

<b>TIMEPOINT</b>	DAY 187
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	15 MAR 2021 14:08:34
Patient Cloud Open Date & Time	11 MAR 2021 00:01
Patient Cloud Close Date & Time	15 MAR 2021 23:59

US3632052

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:13:35

<b>TIMEPOINT</b>	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	18 MAR 2021 10:05:11
Patient Cloud Open Date & Time	18 MAR 2021 00:01
Patient Cloud Close Date & Time	22 MAR 2021 23:59

US3632052

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:13:35

**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

25 MAR 2021 09:38:28

Patient Cloud Open Date & Time

25 MAR 2021 00:01

Patient Cloud Close Date & Time

29 MAR 2021 23:59

US3632052

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:13:35

**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

01 APR 2021 11:34:43

Patient Cloud Open Date & Time

01 APR 2021 00:01

Patient Cloud Close Date & Time

05 APR 2021 23:59

US3632052

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:13:35

**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

10 APR 2021 12:01:07

Patient Cloud Open Date & Time

08 APR 2021 00:01

Patient Cloud Close Date & Time

12 APR 2021 23:59

US3632052

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:13:35

**TIMEPOINT**

DAY 222

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

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

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



**US3632052**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:13:35**

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

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[Patient Cloud Open Date & Time](#)

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15 APR 2021 00:01

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[Patient Cloud Close Date & Time](#)

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19 APR 2021 23:59

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US3632052

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:13:35

**TIMEPOINT**

DAY 229

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

22 APR 2021 10:50:14

Patient Cloud Open Date & Time

22 APR 2021 00:01

Patient Cloud Close Date & Time

26 APR 2021 23:59

US3632052

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:13:35

**TIMEPOINT**

DAY 236

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

30 APR 2021 18:32:43

Patient Cloud Open Date & Time

29 APR 2021 00:01

Patient Cloud Close Date & Time

03 MAY 2021 23:59

US3632052

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:13:35

TIMEPOINT	DAY 243
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input 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"/>

**US3632052**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:13:35**

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

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[Patient Cloud Open Date & Time](#)

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06 MAY 2021 00:01

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[Patient Cloud Close Date & Time](#)

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10 MAY 2021 23:59

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US3632052

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:13:35

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"/>

**US3632052**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:13:35**

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

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[Patient Cloud Open Date & Time](#)

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13 MAY 2021 00:01

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[Patient Cloud Close Date & Time](#)

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17 MAY 2021 23:59

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US3632052

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:13:35

**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 ☐



**US3632052**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:13:35**

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

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[Patient Cloud Open Date & Time](#)

20 MAY 2021 00:01

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[Patient Cloud Close Date & Time](#)

24 MAY 2021 23:59

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US3632052

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:13:35

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"/>

**US3632052**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:13:35**

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

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[Patient Cloud Open Date & Time](#)

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27 MAY 2021 00:01

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[Patient Cloud Close Date & Time](#)

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31 MAY 2021 23:59

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US3632052

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:13:35

**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 ☐

**US3632052**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:13:35**

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

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[Patient Cloud Open Date & Time](#)

03 JUN 2021 00:01

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[Patient Cloud Close Date & Time](#)

07 JUN 2021 23:59

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US3632052

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:13:35

**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 ☐

**US3632052**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:13:35**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

10 JUN 2021 00:01

[Patient Cloud Close Date & Time](#)

14 JUN 2021 23:59

US3632052

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:13:35

**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 ☐



**US3632052**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:13:35**

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

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[Patient Cloud Open Date & Time](#)

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17 JUN 2021 00:01

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[Patient Cloud Close Date & Time](#)

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21 JUN 2021 23:59

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US3632052

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:13:35

**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 ☐

**US3632052**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:13:35**

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

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[Patient Cloud Open Date & Time](#)

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24 JUN 2021 00:01

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[Patient Cloud Close Date & Time](#)

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28 JUN 2021 23:59

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US3632052

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:13:35

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

**US3632052**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:13:35**

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

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[Patient Cloud Open Date & Time](#)

01 JUL 2021 00:01

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[Patient Cloud Close Date & Time](#)

05 JUL 2021 23:59

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US3632052

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:13:35

**TIMEPOINT**

DAY 306

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

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

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

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

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

Fever (Temperature  $\geq$  100.4°F/38°C) ☐

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

**US3632052**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:13:35**

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

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[Patient Cloud Open Date & Time](#)

08 JUL 2021 00:01

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[Patient Cloud Close Date & Time](#)

12 JUL 2021 23:59

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US3632052

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:13:35

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 <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"/>



**US3632052**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:13:35**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
<a href="#">Patient Cloud Open Date &amp; Time</a>	15 JUL 2021 00:01
<a href="#">Patient Cloud Close Date &amp; Time</a>	19 JUL 2021 23:59

US3632052

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:13:35

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="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"/>

**US3632052**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:13:35**

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

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[Patient Cloud Open Date & Time](#)

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22 JUL 2021 00:01

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[Patient Cloud Close Date & Time](#)

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26 JUL 2021 23:59

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US3632052

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:13:35

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 <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"/>

**US3632052**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:13:35**

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

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[Patient Cloud Open Date & Time](#)

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29 JUL 2021 00:01

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[Patient Cloud Close Date & Time](#)

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02 AUG 2021 23:59

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US3632052

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:13:35

**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 ☐

**US3632052**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:13:35**

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

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[Patient Cloud Open Date & Time](#)

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05 AUG 2021 00:01

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[Patient Cloud Close Date & Time](#)

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09 AUG 2021 23:59

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US3632052

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:13:35

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="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"/>



**US3632052**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:13:35**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
<a href="#">Patient Cloud Open Date &amp; Time</a>	12 AUG 2021 00:01
<a href="#">Patient Cloud Close Date &amp; Time</a>	16 AUG 2021 23:59

US3632052

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:13:35

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"/>

**US3632052**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:13:35**

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

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[Patient Cloud Open Date & Time](#)

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19 AUG 2021 00:01

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[Patient Cloud Close Date & Time](#)

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23 AUG 2021 23:59

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US3632052

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:13:35

**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 ☐

**US3632052**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:13:35**

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

US3632052

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:13:35

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"/>

**US3632052**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:13:35**

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

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[Patient Cloud Open Date & Time](#)

02 SEP 2021 00:01

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[Patient Cloud Close Date & Time](#)

06 SEP 2021 23:59

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US3632052

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:13:35

**TIMEPOINT**

DAY 369

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

No ☐

Yes ☐

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

No ☐

Yes ☐

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

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

Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?

No ☐

Yes ☐

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

Fever (Temperature  $\geq$  100.4°F/38°C) ☐

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?

No ☐

Yes ☐



**US3632052**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:13:35**

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

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[Patient Cloud Open Date & Time](#)

09 SEP 2021 00:01

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[Patient Cloud Close Date & Time](#)

13 SEP 2021 23:59

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US3632052

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:13:35

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 <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"/>

**US3632052**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:13:35**

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

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[Patient Cloud Open Date & Time](#)

16 SEP 2021 00:01

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[Patient Cloud Close Date & Time](#)

20 SEP 2021 23:59

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US3632052

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:13:35

**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 ☐

**US3632052**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:13:35**

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

[Patient Cloud Open Date & Time](#)

23 SEP 2021 00:01

[Patient Cloud Close Date & Time](#)

27 SEP 2021 23:59

US3632052

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:13:35

**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 ☐

**US3632052**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:13:35**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
<a href="#">Patient Cloud Open Date &amp; Time</a>	30 SEP 2021 00:01
<a href="#">Patient Cloud Close Date &amp; Time</a>	04 OCT 2021 23:59

US3632052

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:13:35

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 <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"/>



**US3632052**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:13:35**

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

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[Patient Cloud Open Date & Time](#)

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07 OCT 2021 00:01

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[Patient Cloud Close Date & Time](#)

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11 OCT 2021 23:59

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US3632052

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:13:35

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"/>

**US3632052**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:13:35**

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

14 OCT 2021 00:01

[Patient Cloud Close Date & Time](#)

18 OCT 2021 23:59

US3632052

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:13:35

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"/>

**US3632052**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:13:35**

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

US3632052

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:13:35

**TIMEPOINT**

DAY 418

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

**US3632052**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:13:35**

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

[Patient Cloud Open Date & Time](#)

28 OCT 2021 00:01

[Patient Cloud Close Date & Time](#)

01 NOV 2021 23:59

US3632052

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:13:35

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 <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"/>



**US3632052**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:13:35**

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

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[Patient Cloud Open Date & Time](#)

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04 NOV 2021 00:01

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[Patient Cloud Close Date & Time](#)

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08 NOV 2021 23:59

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US3632052

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:13:35

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 <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"/>

**US3632052**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:13:35**

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

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[Patient Cloud Open Date & Time](#)

11 NOV 2021 00:01

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[Patient Cloud Close Date & Time](#)

15 NOV 2021 23:59

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US3632052

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:13:35

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 <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"/>

**US3632052**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:13:35**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

18 NOV 2021 00:01

[Patient Cloud Close Date & Time](#)

22 NOV 2021 23:59

US3632052

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:13:35

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 <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"/>

**US3632052**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:13:35**

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

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<a href="#">Patient Cloud Open Date &amp; Time</a>	25 NOV 2021 00:01
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<a href="#">Patient Cloud Close Date &amp; Time</a>	29 NOV 2021 23:59
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US3632052

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:13:35

**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 ☐



**US3632052**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:13:35**

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

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[Patient Cloud Open Date & Time](#)

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02 DEC 2021 00:01

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[Patient Cloud Close Date & Time](#)

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06 DEC 2021 23:59

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US3632052

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:13:35

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"/>

**US3632052**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:13:35**

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

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[Patient Cloud Open Date & Time](#)

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09 DEC 2021 00:01

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[Patient Cloud Close Date & Time](#)

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13 DEC 2021 23:59

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US3632052

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:13:35

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 <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"/>

**US3632052**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:13:35**

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

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[Patient Cloud Open Date & Time](#)

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16 DEC 2021 00:01

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[Patient Cloud Close Date & Time](#)

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20 DEC 2021 23:59

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US3632052

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:13:35

**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 ☐

**US3632052**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:13:35**

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

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<a href="#">Patient Cloud Open Date &amp; Time</a>	23 DEC 2021 00:01
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<a href="#">Patient Cloud Close Date &amp; Time</a>	27 DEC 2021 23:59
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US3632052

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:13:35

**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 ☐



**US3632052**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:13:35**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
<a href="#">Patient Cloud Open Date &amp; Time</a>	30 DEC 2021 00:01
<a href="#">Patient Cloud Close Date &amp; Time</a>	03 JAN 2022 23:59

US3632052

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:13:35

TIMEPOINT	DAY 488
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="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"/>

**US3632052**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:13:35**

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

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[Patient Cloud Open Date & Time](#)

06 JAN 2022 00:01

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[Patient Cloud Close Date & Time](#)

10 JAN 2022 23:59

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US3632052

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:13:35

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 <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"/>

**US3632052**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:13:35**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
<a href="#">Patient Cloud Open Date &amp; Time</a>	13 JAN 2022 00:01
<a href="#">Patient Cloud Close Date &amp; Time</a>	17 JAN 2022 23:59

US3632052

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:13:35

**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 ☐

**US3632052**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:13:35**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

20 JAN 2022 00:01

[Patient Cloud Close Date & Time](#)

24 JAN 2022 23:59

US3632052

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:13:35

**TIMEPOINT**

DAY 509

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

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

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

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

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

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

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

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



**US3632052**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:13:35**

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

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[Patient Cloud Open Date & Time](#)

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27 JAN 2022 00:01

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[Patient Cloud Close Date & Time](#)

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31 JAN 2022 23:59

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US3632052

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:13:35

**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 ☐

**US3632052**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:13:35**

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

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[Patient Cloud Open Date & Time](#)

03 FEB 2022 00:01

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[Patient Cloud Close Date & Time](#)

07 FEB 2022 23:59

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US3632052

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:13:35

**TIMEPOINT**

DAY 523

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

**US3632052**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:13:35**

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

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[Patient Cloud Open Date & Time](#)

10 FEB 2022 00:01

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[Patient Cloud Close Date & Time](#)

14 FEB 2022 23:59

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US3632052

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:13:35

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"/>

**US3632052**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:13:35**

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

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[Patient Cloud Open Date & Time](#)

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17 FEB 2022 00:01

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21 FEB 2022 23:59

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US3632052

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:13:35

**TIMEPOINT**

DAY 537

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

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

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

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

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

Fever (Temperature  $\geq$  100.4°F/38°C) ☐

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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



**US3632052**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:13:35**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

24 FEB 2022 00:01

[Patient Cloud Close Date & Time](#)

28 FEB 2022 23:59

US3632052

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:13:35

**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 ☐

**US3632052**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:13:35**

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

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03 MAR 2022 00:01

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07 MAR 2022 23:59

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US3632052

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:13:35

**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 ☐

**US3632052**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:13:35**

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

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10 MAR 2022 00:01

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14 MAR 2022 23:59

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US3632052

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:13:35

**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 ☐

**US3632052**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:13:35**

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

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[Patient Cloud Open Date & Time](#)

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17 MAR 2022 00:01

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[Patient Cloud Close Date & Time](#)

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21 MAR 2022 23:59

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US3632052

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:13:35

**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 ☐



**US3632052**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:13:35**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

24 MAR 2022 00:01

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28 MAR 2022 23:59

US3632052

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:13:35

**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 ☐

**US3632052**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:13:35**

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

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31 MAR 2022 00:01

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[Patient Cloud Close Date & Time](#)

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04 APR 2022 23:59

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US3632052

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:13:35

**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 ☐

**US3632052**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:13:35**

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

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07 APR 2022 00:01

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[Patient Cloud Close Date & Time](#)

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11 APR 2022 23:59

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US3632052

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:13:35

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 <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"/>

**US3632052**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:13:35**

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

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[Patient Cloud Open Date & Time](#)

14 APR 2022 00:01

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[Patient Cloud Close Date & Time](#)

18 APR 2022 23:59

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US3632052

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:13:35

**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 ☐



**US3632052**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:13:35**

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

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[Patient Cloud Open Date & Time](#)

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21 APR 2022 00:01

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[Patient Cloud Close Date & Time](#)

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25 APR 2022 23:59

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US3632052

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:13:35

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"/>

**US3632052**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:13:35**

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

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[Patient Cloud Open Date & Time](#)

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28 APR 2022 00:01

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[Patient Cloud Close Date & Time](#)

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02 MAY 2022 23:59

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US3632052

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:13:35

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"/>

**US3632052**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:13:35**

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

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[Patient Cloud Open Date & Time](#)

05 MAY 2022 00:01

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[Patient Cloud Close Date & Time](#)

09 MAY 2022 23:59

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US3632052

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:13:35

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

**US3632052**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:13:35**

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

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[Patient Cloud Open Date & Time](#)

12 MAY 2022 00:01

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[Patient Cloud Close Date & Time](#)

16 MAY 2022 23:59

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US3632052

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:13:35

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"/>



**US3632052**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:13:35**

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

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[Patient Cloud Open Date & Time](#)

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19 MAY 2022 00:01

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[Patient Cloud Close Date & Time](#)

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23 MAY 2022 23:59

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US3632052

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:13:35

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 <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"/>

**US3632052**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:13:35**

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

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[Patient Cloud Open Date & Time](#)

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26 MAY 2022 00:01

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[Patient Cloud Close Date & Time](#)

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30 MAY 2022 23:59

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US3632052

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:13:35

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 <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"/>

**US3632052**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:13:35**

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

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[Patient Cloud Open Date & Time](#)

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02 JUN 2022 00:01

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[Patient Cloud Close Date & Time](#)

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06 JUN 2022 23:59

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US3632052

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:13:35

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 <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"/>

**US3632052**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:13:35**

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

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[Patient Cloud Open Date & Time](#)

09 JUN 2022 00:01

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[Patient Cloud Close Date & Time](#)

13 JUN 2022 23:59

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US3632052

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:13:35

**TIMEPOINT**

DAY 649

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

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

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

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

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

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



**US3632052**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:13:35**

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

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[Patient Cloud Open Date & Time](#)

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16 JUN 2022 00:01

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[Patient Cloud Close Date & Time](#)

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20 JUN 2022 23:59

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US3632052

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:13:35

**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 ☐

**US3632052**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:13:35**

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

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[Patient Cloud Open Date & Time](#)

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23 JUN 2022 00:01

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[Patient Cloud Close Date & Time](#)

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27 JUN 2022 23:59

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US3632052

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:13:35

**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 ☐

**US3632052**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:13:35**

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

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[Patient Cloud Open Date & Time](#)

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30 JUN 2022 00:01

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[Patient Cloud Close Date & Time](#)

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04 JUL 2022 23:59

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US3632052

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:13:35

TIMEPOINT	DAY 670
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="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"/>

**US3632052**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:13:35**

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

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[Patient Cloud Open Date & Time](#)

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07 JUL 2022 00:01

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[Patient Cloud Close Date & Time](#)

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11 JUL 2022 23:59

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US3632052

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:13:35

**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 ☐



**US3632052**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:13:35**

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

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[Patient Cloud Open Date & Time](#)

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14 JUL 2022 00:01

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[Patient Cloud Close Date & Time](#)

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18 JUL 2022 23:59

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US3632052

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:13:35

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

**US3632052**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:13:35**

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

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[Patient Cloud Open Date & Time](#)

21 JUL 2022 00:01

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[Patient Cloud Close Date & Time](#)

25 JUL 2022 23:59

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US3632052

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:13:35

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°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"/>

**US3632052**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:13:35**

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

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[Patient Cloud Open Date & Time](#)

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28 JUL 2022 00:01

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[Patient Cloud Close Date & Time](#)

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01 AUG 2022 23:59

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US3632052

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:13:35

**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 ☐

**US3632052**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:13:35**

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

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[Patient Cloud Open Date & Time](#)

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04 AUG 2022 00:01

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[Patient Cloud Close Date & Time](#)

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08 AUG 2022 23:59

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US3632052

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:13:35

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



**US3632052**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:13:35**

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

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[Patient Cloud Open Date & Time](#)

11 AUG 2022 00:01

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[Patient Cloud Close Date & Time](#)

15 AUG 2022 23:59

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US3632052

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:13:35

**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 ☐

**US3632052**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:13:35**

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

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[Patient Cloud Open Date & Time](#)

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18 AUG 2022 00:01

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[Patient Cloud Close Date & Time](#)

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22 AUG 2022 23:59

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US3632052

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:13:35

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="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"/>

**US3632052**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:13:35**

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

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[Patient Cloud Open Date & Time](#)

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25 AUG 2022 00:01

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[Patient Cloud Close Date & Time](#)

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29 AUG 2022 23:59

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US3632052

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:13:35

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 <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"/>

**US3632052**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:13:35**

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

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[Patient Cloud Open Date & Time](#)

01 SEP 2022 00:01

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[Patient Cloud Close Date & Time](#)

05 SEP 2022 23:59

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US3632052

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:13:35

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="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"/>



**US3632052**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:13:35**

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

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[Patient Cloud Open Date & Time](#)

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08 SEP 2022 00:01

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12 SEP 2022 23:59

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US3632052

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:13:35

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"/>

**US3632052**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:13:35**

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

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[Patient Cloud Open Date & Time](#)

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15 SEP 2022 00:01

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[Patient Cloud Close Date & Time](#)

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19 SEP 2022 23:59

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US3632052

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:13:35

TIMEPOINT	DAY 747
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$ )	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>

**US3632052**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:13:35**

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

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[Patient Cloud Open Date & Time](#)

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22 SEP 2022 00:01

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[Patient Cloud Close Date & Time](#)

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26 SEP 2022 23:59

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US3632052

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:13:35

**TIMEPOINT**

DAY 754

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

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

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

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

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

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

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

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

**US3632052**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:13:35**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

29 SEP 2022 00:01

[Patient Cloud Close Date & Time](#)

03 OCT 2022 23:59

US3632052

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:13:35

**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 ☐



**US3632052**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:13:35**

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

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[Patient Cloud Open Date & Time](#)

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06 OCT 2022 00:01

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[Patient Cloud Close Date & Time](#)

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10 OCT 2022 23:59

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US3632052

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:13:35

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 $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$ )	<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"/>

**US3632052**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:13:35**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
<a href="#">Patient Cloud Open Date &amp; Time</a>	13 OCT 2022 00:01
<a href="#">Patient Cloud Close Date &amp; Time</a>	17 OCT 2022 23:59

US3632052

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:13:35

**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 ☐

**US3632052**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:13:35**

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

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[Patient Cloud Open Date & Time](#)

20 OCT 2022 00:01

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[Patient Cloud Close Date & Time](#)

24 OCT 2022 23:59

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US3632052

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:13:35

**TIMEPOINT**

DAY 782

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

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

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

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

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

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

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

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

**US3632052**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:13:35**

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

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<a href="#">Patient Cloud Open Date &amp; Time</a>	27 OCT 2022 00:01
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<a href="#">Patient Cloud Close Date &amp; Time</a>	31 OCT 2022 23:59
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US3632052

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:13:35

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 <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"/>



**US3632052**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:13:35**

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

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[Patient Cloud Open Date & Time](#)

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03 NOV 2022 00:01

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[Patient Cloud Close Date & Time](#)

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07 NOV 2022 23:59

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US3632052

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:13:35

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="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"/>

**US3632052**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:13:35**

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

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[Patient Cloud Open Date & Time](#)

10 NOV 2022 00:01

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[Patient Cloud Close Date & Time](#)

14 NOV 2022 23:59

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US3632052

Folder: Cosmetic Injections and Dermal Fillers

Form: Cosmetic Injection\_ Dermal Filler eDiary

Generated On: 10 Jun 2021 09:13:35

Have you ever received facial cosmetic injections, such as Juvederm, Voluma, Radiesse, Restylane, Botox or other?	Have you ever received a dermal filler, such as Juvederm, Voluma, Radiesse, Restylane, or Botox or other for a medical indication such as a migraine headache?	Date & Time of Submission
No		27 FEB 2021 10:27:09

US3632052

Folder: Safety Call Day 85 (1)

Form: Safety Call

Data signed: (b) (4) 08 Mar 2021 14:31:03

Generated On: 10 Jun 2021 09:13:35

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

1 DEC 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

*If Contact Not Made, please provide Comments*

US3632052

Folder: Safety Call Day 85 (1)

Form: Continuing

Data signed: (b) (4) 08 Mar 2021 14:31:03

Generated On: 10 Jun 2021 09:13:35

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3632052

Folder: Safety Call Day 119 (1)

Form: Safety Call

Data signed: (b) (4) 02 Apr 2021 20:59:29

Generated On: 10 Jun 2021 09:13:35

Was Contact Attempted? Yes ☐  
No ☒

Date of Contact or Contact Attempt (dd MMM yyyy)

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

Comments PARTICIPANT WAS IN ILLNESS  
PROTOCOL DURING SC  
WINDOW.  
*If Contact Not Made, please provide Comments*

US3632052

Folder: Safety Call Day 119 (1)

Form: Continuing

Data signed: (b) (4) 02 Apr 2021 20:59:29

Generated On: 10 Jun 2021 09:13:35

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1



US3632052

Folder: Safety Call Day 149 (1)

Form: Safety Call

Data signed: (b) (4) 02 Apr 2021 20:59:29

Generated On: 10 Jun 2021 09:13:35

Was Contact Attempted? Yes ☒  
No ☐

Date of Contact or Contact Attempt (dd MMM yyyy) 3 FEB 2021

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

Comments

*If Contact Not Made, please provide Comments*

US3632052

Folder: Safety Call Day 149 (1)

Form: Continuing

Data signed: (b) (4) 02 Apr 2021 20:59:29

Generated On: 10 Jun 2021 09:13:35

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3632052

Folder: Safety Call Day 179 (1)

Form: Safety Call

Data signed: (b) (4) 02 Apr 2021 20:59:29

Generated On: 10 Jun 2021 09:13:35

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

5 MAR 2021

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

*If Contact Not Made, please provide Comments*

US3632052

Folder: Safety Call Day 179 (1)

Form: Continuing

Data signed: (b) (4) 02 Apr 2021 20:59:29

Generated On: 10 Jun 2021 09:13:35

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3632052

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Data signed: (b) (4) 02 Apr 2021 20:59:29

Generated On: 10 Jun 2021 09:13:35

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>

Visit date (dd MMM yyyy)	01 APR 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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US3632052

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Data signed: (b) (4) 02 Apr 2021 20:59:29

Generated On: 10 Jun 2021 09:13:35

Were vital signs assessed? Yes ☐  
No ☒

Date of assessment (dd MMM yyyy) \_\_\_\_\_

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

Vital Signs Date and Time (derived) \_\_\_\_\_

Temperature (xxx.x) \_\_\_\_\_

Route of measurement Oral ☐  
Axillary ☐  
Other ☐

If Other, specify \_\_\_\_\_

Pulse (xxx) \_\_\_\_\_

Pulse units \_\_\_\_\_

Respiratory Rate (xxx) \_\_\_\_\_

Respiratory Rate units \_\_\_\_\_

Systolic Blood Pressure (xxx) \_\_\_\_\_

Systolic Blood Pressure units \_\_\_\_\_

Diastolic Blood Pressure (xxx) \_\_\_\_\_

Diastolic Blood Pressure units \_\_\_\_\_

Height (derived) \_\_\_\_\_

Weight (derived) \_\_\_\_\_

US3632052

Folder: Visit 4 Day 209 (1)

Form: Physical Examination

Data signed: (b) (4) 02 Apr 2021 20:59:29

Generated On: 10 Jun 2021 09:13:35

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.*

US3632052

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 02 Apr 2021 20:59:29

Generated On: 10 Jun 2021 09:13:35

Was the sample collected?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Collection date (dd MMM yyyy)	01 APR 2021
Collection time (00:00-23:59)	13:58 (24 HR)
Collection date and time (derived)	01 APR 2021 13:58



US3632052

Folder: Visit 4 Day 209 (1)

Form: Continuing

Data signed: (b) (4) 02 Apr 2021 20:59:29

Generated On: 10 Jun 2021 09:13:35

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

**US3632052**

**Folder: Safety Call Day 239 (1)**

**Form: Safety Call**

**Generated On: 10 Jun 2021 09:13:35**

Was Contact Attempted? Yes ☐  
No ☐

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

Please select one status for the follow-up contact

Contact Made ☐

Contact Not Made ☐

Comments

*If Contact Not Made, please provide Comments*

**US3632052**

**Folder: Safety Call Day 239 (1)**

**Form: Continuing**

**Generated On: 10 Jun 2021 09:13:35**

Is the participant continuing to the next visit?

Yes ☐

No ☐

Continuing Flag

US3632052

Folder: Covid-19 Assessment 12 Nov 2020

Form: COVID-19 Contact

Data signed: (b) (4) 02 Apr 2021 20:59:29

Generated On: 10 Jun 2021 09:13:35

Date of Contact	12 NOV 2020
Time of Contact	14:00
Date and Time of Contact (derived)	12 NOV 2020 14:00
Type of Contact	<div>Clinic Visit - Scheduled<input type="checkbox"/></div> <div>Clinical Visit - Unscheduled<input checked="" type="checkbox"/></div> <div>Safety Call<input type="checkbox"/></div> <div>Convalescent Tele-visit<input type="checkbox"/></div>
Has the subject reported symptoms of SARS-COV-2?	<div>Yes<input checked="" type="checkbox"/></div> <div>No<input type="checkbox"/></div>

US3632052

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (1)

Data signed: (b) (4) 22 Apr 2021 15:40:43

Generated On: 10 Jun 2021 09:13:35

Symptom Day

Day 1	<input checked="" type="radio"/>
Day 2	<input type="radio"/>
Day 3	<input type="radio"/>
Day 4	<input type="radio"/>
Day 5	<input type="radio"/>
Day 6	<input type="radio"/>
Day 7	<input type="radio"/>
Day 8	<input type="radio"/>
Day 9	<input type="radio"/>
Day 10	<input type="radio"/>
Day 11	<input type="radio"/>
Day 12	<input type="radio"/>
Day 13	<input type="radio"/>
Day 14	<input type="radio"/>
Day 15	<input type="radio"/>
Day 16	<input type="radio"/>
Day 17	<input type="radio"/>
Day 18	<input type="radio"/>
Day 19	<input type="radio"/>
Day 20	<input type="radio"/>
Day 21	<input type="radio"/>
Day 22	<input type="radio"/>
Day 23	<input type="radio"/>
Day 24	<input type="radio"/>
Day 25	<input type="radio"/>
Day 26	<input type="radio"/>
Day 27	<input type="radio"/>
Day 28	<input type="radio"/>
Day 29	<input type="radio"/>
Day 30	<input type="radio"/>
Day 31	<input type="radio"/>
Day 32	<input type="radio"/>

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Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (1)

Data signed: (b) (4) 22 Apr 2021 15:40:43

Generated On: 10 Jun 2021 09:13:35

	Day 33	<input type="checkbox"/>
	Day 34	<input type="checkbox"/>
	Day 35	<input type="checkbox"/>
	Day 36	<input type="checkbox"/>
	Day 37	<input type="checkbox"/>
	Day 38	<input type="checkbox"/>
	Day 39	<input type="checkbox"/>
	Day 40	<input type="checkbox"/>
Date	10 NOV 2020	
Assessment Not Done	False	
O2 Saturation	ND - Not Done	
O2 Saturation Units	%	
Temperature	ND - Not Done	
Chills	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Cough	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Shortness of Breath	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Difficulty Breathing	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>

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Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (1)

Data signed: (b) (4) 22 Apr 2021 15:40:43

Generated On: 10 Jun 2021 09:13:35

	Not Done	<input type="radio"/>
Fatigue	None	<input type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input checked="" type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Muscle Aches (Myalgia)	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Body Aches	None	<input type="radio"/>
	Mild	<input checked="" type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Headache	None	<input type="radio"/>
	Mild	<input checked="" type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
New Loss of Taste	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
New Loss of Smell	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>

US3632052

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (1)

Data signed: (b) (4) 22 Apr 2021 15:40:43

Generated On: 10 Jun 2021 09:13:35

Nasal Congestion	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Runny Nose (Rhinorrhea)	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Nausea	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Vomiting	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Diarrhea	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Sore Throat	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>



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Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (2)

Data signed: (b) (4) 22 Apr 2021 15:40:43

Generated On: 10 Jun 2021 09:13:35

Symptom Day

Day 1	<input type="checkbox"/>
Day 2	<input checked="" type="checkbox"/>
Day 3	<input type="checkbox"/>
Day 4	<input type="checkbox"/>
Day 5	<input type="checkbox"/>
Day 6	<input type="checkbox"/>
Day 7	<input type="checkbox"/>
Day 8	<input type="checkbox"/>
Day 9	<input type="checkbox"/>
Day 10	<input type="checkbox"/>
Day 11	<input type="checkbox"/>
Day 12	<input type="checkbox"/>
Day 13	<input type="checkbox"/>
Day 14	<input type="checkbox"/>
Day 15	<input type="checkbox"/>
Day 16	<input type="checkbox"/>
Day 17	<input type="checkbox"/>
Day 18	<input type="checkbox"/>
Day 19	<input type="checkbox"/>
Day 20	<input type="checkbox"/>
Day 21	<input type="checkbox"/>
Day 22	<input type="checkbox"/>
Day 23	<input type="checkbox"/>
Day 24	<input type="checkbox"/>
Day 25	<input type="checkbox"/>
Day 26	<input type="checkbox"/>
Day 27	<input type="checkbox"/>
Day 28	<input type="checkbox"/>
Day 29	<input type="checkbox"/>
Day 30	<input type="checkbox"/>
Day 31	<input type="checkbox"/>
Day 32	<input type="checkbox"/>

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Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (2)

Data signed: (b) (4) 22 Apr 2021 15:40:43

Generated On: 10 Jun 2021 09:13:35

	Day 33	<input type="checkbox"/>
	Day 34	<input type="checkbox"/>
	Day 35	<input type="checkbox"/>
	Day 36	<input type="checkbox"/>
	Day 37	<input type="checkbox"/>
	Day 38	<input type="checkbox"/>
	Day 39	<input type="checkbox"/>
	Day 40	<input type="checkbox"/>
Date	11 NOV 2020	
Assessment Not Done	False	
O2 Saturation	ND - Not Done	
O2 Saturation Units	%	
Temperature	ND - Not Done	
Chills	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Cough	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Shortness of Breath	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Difficulty Breathing	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>

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Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (2)

Data signed: (b) (4) 22 Apr 2021 15:40:43

Generated On: 10 Jun 2021 09:13:35

	Not Done	<input type="radio"/>
Fatigue	None	<input type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input checked="" type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Muscle Aches (Myalgia)	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Body Aches	None	<input type="radio"/>
	Mild	<input checked="" type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Headache	None	<input type="radio"/>
	Mild	<input checked="" type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
New Loss of Taste	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
New Loss of Smell	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>

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Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (2)

Data signed: (b) (4) 22 Apr 2021 15:40:43

Generated On: 10 Jun 2021 09:13:35

Nasal Congestion	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Runny Nose (Rhinorrhea)	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Nausea	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Vomiting	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Diarrhea	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Sore Throat	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>

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Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (3)

Data signed: (b) (4) 22 Apr 2021 15:40:43

Generated On: 10 Jun 2021 09:13:35

Symptom Day

Day 1	<input type="checkbox"/>
Day 2	<input type="checkbox"/>
Day 3	<input checked="" type="checkbox"/>
Day 4	<input type="checkbox"/>
Day 5	<input type="checkbox"/>
Day 6	<input type="checkbox"/>
Day 7	<input type="checkbox"/>
Day 8	<input type="checkbox"/>
Day 9	<input type="checkbox"/>
Day 10	<input type="checkbox"/>
Day 11	<input type="checkbox"/>
Day 12	<input type="checkbox"/>
Day 13	<input type="checkbox"/>
Day 14	<input type="checkbox"/>
Day 15	<input type="checkbox"/>
Day 16	<input type="checkbox"/>
Day 17	<input type="checkbox"/>
Day 18	<input type="checkbox"/>
Day 19	<input type="checkbox"/>
Day 20	<input type="checkbox"/>
Day 21	<input type="checkbox"/>
Day 22	<input type="checkbox"/>
Day 23	<input type="checkbox"/>
Day 24	<input type="checkbox"/>
Day 25	<input type="checkbox"/>
Day 26	<input type="checkbox"/>
Day 27	<input type="checkbox"/>
Day 28	<input type="checkbox"/>
Day 29	<input type="checkbox"/>
Day 30	<input type="checkbox"/>
Day 31	<input type="checkbox"/>
Day 32	<input type="checkbox"/>

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Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (3)

Data signed: (b) (4) 22 Apr 2021 15:40:43

Generated On: 10 Jun 2021 09:13:35

	Day 33	<input type="checkbox"/>
	Day 34	<input type="checkbox"/>
	Day 35	<input type="checkbox"/>
	Day 36	<input type="checkbox"/>
	Day 37	<input type="checkbox"/>
	Day 38	<input type="checkbox"/>
	Day 39	<input type="checkbox"/>
	Day 40	<input type="checkbox"/>
Date	12 NOV 2020	
Assessment Not Done	False	
O2 Saturation	99 %	
O2 Saturation Units	%	
Temperature	97.2 F	
Chills	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Cough	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Shortness of Breath	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Difficulty Breathing	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
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Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (3)

Data signed: (b) (4) 22 Apr 2021 15:40:43

Generated On: 10 Jun 2021 09:13:35

	Not Done	<input type="radio"/>
Fatigue	None	<input type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input checked="" type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Muscle Aches (Myalgia)	None	<input type="radio"/>
	Mild	<input checked="" type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Body Aches	None	<input type="radio"/>
	Mild	<input checked="" type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Headache	None	<input type="radio"/>
	Mild	<input checked="" type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
New Loss of Taste	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
New Loss of Smell	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>

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Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (3)

Data signed: (b) (4) 22 Apr 2021 15:40:43

Generated On: 10 Jun 2021 09:13:35

Nasal Congestion	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Runny Nose (Rhinorrhea)	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Nausea	None	<input type="radio"/>
	Mild	<input checked="" type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Vomiting	None	<input type="radio"/>
	Mild	<input checked="" type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Diarrhea	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Sore Throat	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>



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Form: Symptom Log (4)

Data signed: (b) (4) 22 Apr 2021 15:40:43

Generated On: 10 Jun 2021 09:13:35

Symptom Day

Day 1	<input type="checkbox"/>
Day 2	<input type="checkbox"/>
Day 3	<input type="checkbox"/>
Day 4	<input checked="" type="checkbox"/>
Day 5	<input type="checkbox"/>
Day 6	<input type="checkbox"/>
Day 7	<input type="checkbox"/>
Day 8	<input type="checkbox"/>
Day 9	<input type="checkbox"/>
Day 10	<input type="checkbox"/>
Day 11	<input type="checkbox"/>
Day 12	<input type="checkbox"/>
Day 13	<input type="checkbox"/>
Day 14	<input type="checkbox"/>
Day 15	<input type="checkbox"/>
Day 16	<input type="checkbox"/>
Day 17	<input type="checkbox"/>
Day 18	<input type="checkbox"/>
Day 19	<input type="checkbox"/>
Day 20	<input type="checkbox"/>
Day 21	<input type="checkbox"/>
Day 22	<input type="checkbox"/>
Day 23	<input type="checkbox"/>
Day 24	<input type="checkbox"/>
Day 25	<input type="checkbox"/>
Day 26	<input type="checkbox"/>
Day 27	<input type="checkbox"/>
Day 28	<input type="checkbox"/>
Day 29	<input type="checkbox"/>
Day 30	<input type="checkbox"/>
Day 31	<input type="checkbox"/>
Day 32	<input type="checkbox"/>

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Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (4)

Data signed: (b) (4) 22 Apr 2021 15:40:43

Generated On: 10 Jun 2021 09:13:35

	Day 33	<input type="checkbox"/>
	Day 34	<input type="checkbox"/>
	Day 35	<input type="checkbox"/>
	Day 36	<input type="checkbox"/>
	Day 37	<input type="checkbox"/>
	Day 38	<input type="checkbox"/>
	Day 39	<input type="checkbox"/>
	Day 40	<input type="checkbox"/>
Date	13 NOV 2020	
Assessment Not Done	False	
O2 Saturation	98 %	
O2 Saturation Units	%	
Temperature	96.4 F	
Chills	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Cough	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Shortness of Breath	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Difficulty Breathing	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>

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Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (4)

Data signed: (b) (4) 22 Apr 2021 15:40:43

Generated On: 10 Jun 2021 09:13:35

	Not Done	<input type="radio"/>
Fatigue	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Muscle Aches (Myalgia)	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Body Aches	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Headache	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
New Loss of Taste	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
New Loss of Smell	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>

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Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (4)

Data signed: (b) (4) 22 Apr 2021 15:40:43

Generated On: 10 Jun 2021 09:13:35

Nasal Congestion	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Runny Nose (Rhinorrhea)	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Nausea	None	<input type="radio"/>
	Mild	<input checked="" type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Vomiting	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Diarrhea	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Sore Throat	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>

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Form: Symptom Log (5)

Data signed: (b) (4) 22 Apr 2021 15:40:43

Generated On: 10 Jun 2021 09:13:35

Symptom Day

Day 1	<input type="checkbox"/>
Day 2	<input type="checkbox"/>
Day 3	<input type="checkbox"/>
Day 4	<input type="checkbox"/>
Day 5	<input checked="" type="checkbox"/>
Day 6	<input type="checkbox"/>
Day 7	<input type="checkbox"/>
Day 8	<input type="checkbox"/>
Day 9	<input type="checkbox"/>
Day 10	<input type="checkbox"/>
Day 11	<input type="checkbox"/>
Day 12	<input type="checkbox"/>
Day 13	<input type="checkbox"/>
Day 14	<input type="checkbox"/>
Day 15	<input type="checkbox"/>
Day 16	<input type="checkbox"/>
Day 17	<input type="checkbox"/>
Day 18	<input type="checkbox"/>
Day 19	<input type="checkbox"/>
Day 20	<input type="checkbox"/>
Day 21	<input type="checkbox"/>
Day 22	<input type="checkbox"/>
Day 23	<input type="checkbox"/>
Day 24	<input type="checkbox"/>
Day 25	<input type="checkbox"/>
Day 26	<input type="checkbox"/>
Day 27	<input type="checkbox"/>
Day 28	<input type="checkbox"/>
Day 29	<input type="checkbox"/>
Day 30	<input type="checkbox"/>
Day 31	<input type="checkbox"/>
Day 32	<input type="checkbox"/>

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Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (5)

Data signed: (b) (4) 22 Apr 2021 15:40:43

Generated On: 10 Jun 2021 09:13:35

	Day 33	<input type="checkbox"/>
	Day 34	<input type="checkbox"/>
	Day 35	<input type="checkbox"/>
	Day 36	<input type="checkbox"/>
	Day 37	<input type="checkbox"/>
	Day 38	<input type="checkbox"/>
	Day 39	<input type="checkbox"/>
	Day 40	<input type="checkbox"/>
Date	14 NOV 2020	
Assessment Not Done	False	
O2 Saturation	98 %	
O2 Saturation Units	%	
Temperature	97.4 F	
Chills	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Cough	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Shortness of Breath	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Difficulty Breathing	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
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EAB) (1725)		

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Form: Symptom Log (5)

Data signed: (b) (4) 22 Apr 2021 15:40:43

Generated On: 10 Jun 2021 09:13:35

	Not Done	<input type="radio"/>
Fatigue	None	<input type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input checked="" type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Muscle Aches (Myalgia)	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Body Aches	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Headache	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
New Loss of Taste	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
New Loss of Smell	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>

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Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (5)

Data signed: (b) (4) 22 Apr 2021 15:40:43

Generated On: 10 Jun 2021 09:13:35

Nasal Congestion	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Runny Nose (Rhinorrhea)	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Nausea	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Vomiting	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Diarrhea	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Sore Throat	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>



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Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (6)

Data signed: (b) (4) 22 Apr 2021 15:40:43

Generated On: 10 Jun 2021 09:13:35

Symptom Day

Day 1	<input type="checkbox"/>
Day 2	<input type="checkbox"/>
Day 3	<input type="checkbox"/>
Day 4	<input type="checkbox"/>
Day 5	<input type="checkbox"/>
Day 6	<input checked="" type="checkbox"/>
Day 7	<input type="checkbox"/>
Day 8	<input type="checkbox"/>
Day 9	<input type="checkbox"/>
Day 10	<input type="checkbox"/>
Day 11	<input type="checkbox"/>
Day 12	<input type="checkbox"/>
Day 13	<input type="checkbox"/>
Day 14	<input type="checkbox"/>
Day 15	<input type="checkbox"/>
Day 16	<input type="checkbox"/>
Day 17	<input type="checkbox"/>
Day 18	<input type="checkbox"/>
Day 19	<input type="checkbox"/>
Day 20	<input type="checkbox"/>
Day 21	<input type="checkbox"/>
Day 22	<input type="checkbox"/>
Day 23	<input type="checkbox"/>
Day 24	<input type="checkbox"/>
Day 25	<input type="checkbox"/>
Day 26	<input type="checkbox"/>
Day 27	<input type="checkbox"/>
Day 28	<input type="checkbox"/>
Day 29	<input type="checkbox"/>
Day 30	<input type="checkbox"/>
Day 31	<input type="checkbox"/>
Day 32	<input type="checkbox"/>

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Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (6)

Data signed: (b) (4) 22 Apr 2021 15:40:43

Generated On: 10 Jun 2021 09:13:35

	Day 33	<input type="checkbox"/>
	Day 34	<input type="checkbox"/>
	Day 35	<input type="checkbox"/>
	Day 36	<input type="checkbox"/>
	Day 37	<input type="checkbox"/>
	Day 38	<input type="checkbox"/>
	Day 39	<input type="checkbox"/>
	Day 40	<input type="checkbox"/>
Date	15 NOV 2020	
Assessment Not Done	False	
O2 Saturation	98 %	
O2 Saturation Units	%	
Temperature	96.7 F	
Chills	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Cough	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Shortness of Breath	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Difficulty Breathing	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
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Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (6)

Data signed: (b) (4) 22 Apr 2021 15:40:43

Generated On: 10 Jun 2021 09:13:35

	Not Done	<input type="radio"/>
Fatigue	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Muscle Aches (Myalgia)	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Body Aches	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Headache	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
New Loss of Taste	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
New Loss of Smell	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>

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Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (6)

Data signed: (b) (4) 22 Apr 2021 15:40:43

Generated On: 10 Jun 2021 09:13:35

Nasal Congestion	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Runny Nose (Rhinorrhea)	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Nausea	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Vomiting	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Diarrhea	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Sore Throat	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>

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Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (7)

Data signed: (b) (4) 22 Apr 2021 15:40:43

Generated On: 10 Jun 2021 09:13:35

Symptom Day

Day 1	<input type="checkbox"/>
Day 2	<input type="checkbox"/>
Day 3	<input type="checkbox"/>
Day 4	<input type="checkbox"/>
Day 5	<input type="checkbox"/>
Day 6	<input type="checkbox"/>
Day 7	<input checked="" type="checkbox"/>
Day 8	<input type="checkbox"/>
Day 9	<input type="checkbox"/>
Day 10	<input type="checkbox"/>
Day 11	<input type="checkbox"/>
Day 12	<input type="checkbox"/>
Day 13	<input type="checkbox"/>
Day 14	<input type="checkbox"/>
Day 15	<input type="checkbox"/>
Day 16	<input type="checkbox"/>
Day 17	<input type="checkbox"/>
Day 18	<input type="checkbox"/>
Day 19	<input type="checkbox"/>
Day 20	<input type="checkbox"/>
Day 21	<input type="checkbox"/>
Day 22	<input type="checkbox"/>
Day 23	<input type="checkbox"/>
Day 24	<input type="checkbox"/>
Day 25	<input type="checkbox"/>
Day 26	<input type="checkbox"/>
Day 27	<input type="checkbox"/>
Day 28	<input type="checkbox"/>
Day 29	<input type="checkbox"/>
Day 30	<input type="checkbox"/>
Day 31	<input type="checkbox"/>
Day 32	<input type="checkbox"/>

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Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (7)

Data signed: (b) (4) 22 Apr 2021 15:40:43

Generated On: 10 Jun 2021 09:13:35

	Day 33	<input type="checkbox"/>
	Day 34	<input type="checkbox"/>
	Day 35	<input type="checkbox"/>
	Day 36	<input type="checkbox"/>
	Day 37	<input type="checkbox"/>
	Day 38	<input type="checkbox"/>
	Day 39	<input type="checkbox"/>
	Day 40	<input type="checkbox"/>
Date	16 NOV 2020	
Assessment Not Done	False	
O2 Saturation	96 %	
O2 Saturation Units	%	
Temperature	97.3 F	
Chills	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Cough	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Shortness of Breath	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Difficulty Breathing	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
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Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (7)

Data signed: (b) (4) 22 Apr 2021 15:40:43

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	Not Done	<input type="radio"/>
Fatigue	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Muscle Aches (Myalgia)	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Body Aches	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Headache	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
New Loss of Taste	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
New Loss of Smell	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>

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Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (7)

Data signed: (b) (4) 22 Apr 2021 15:40:43

Generated On: 10 Jun 2021 09:13:35

Nasal Congestion	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Runny Nose (Rhinorrhea)	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Nausea	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Vomiting	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Diarrhea	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Sore Throat	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>



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Folder: Covid-19 Assessment 12 Nov 2020

Form: COVID Diagnostic Test

Data signed: (b) (4) 02 Apr 2021 20:59:29

Generated On: 10 Jun 2021 09:13:35

Date of Visit	12 NOV 2020
Was the Subject Tested For SARS-CoV-2 by RT-PCR?	Yes <input checked="" type="radio"/> No <input type="radio"/>
Did Subject Test Positive For SARS-CoV-2 by RT-PCR?	Yes <input type="radio"/> No <input checked="" type="radio"/>
Date of Test	12 NOV 2020
Type of Test Performed	Nasopharyngeal Swab <input checked="" type="radio"/> Nasal Swab <input type="radio"/> Saliva Test <input type="radio"/> Other <input type="radio"/>
Other, specify	
Was this diagnostic test performed at a lab other than the Study Central Lab?	Yes <input type="radio"/> No <input checked="" type="radio"/>
If yes, provide lab information below	
Lab/ Institution Test Performed	
CLIA Certified?	Yes <input type="radio"/> No <input type="radio"/>
COVID-19 Positive (CSA Programming Field Only)	0

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Folder: Covid-19 Assessment 12 Nov 2020

Form: Generate Next COVID-19 Assessment

Data signed: (b) (4) 02 Apr 2021 20:59:29

Generated On: 10 Jun 2021 09:13:35

---

[Generate Next COVID-19 Assessment](#)

Yes ☐

No ☒

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**US3632052**

**Folder: Illness Visit (1)**

**Form: Saliva Collection**

**Data signed: (b) (4) 02 Apr 2021 20:59:29**

**Generated On: 10 Jun 2021 09:13:35**

Visit	Was Saliva Collected?	Date of Collection
Day 3	Yes	14 NOV 2020
Day 5	Yes	16 NOV 2020
Day 7	NA (COVID-19 Negative)	
Day 9	NA (COVID-19 Negative)	
Day 14	NA (COVID-19 Negative)	
Day 21	NA (COVID-19 Negative)	
Day 28	NA (COVID-19 Negative)	

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Folder: Illness Visit Day 1 (1)

Form: Visit Date

Data signed: (b) (4) 02 Apr 2021 20:59:29

Generated On: 10 Jun 2021 09:13:35

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	12 NOV 2020
Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>
Folder OID	SICKD1

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Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Data signed: (b) (4) 02 Apr 2021 20:59:29

Generated On: 10 Jun 2021 09:13:35

Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (dd MMM yyyy)	12 NOV 2020
Time of assessment (00:00-23:59)	14:30 (24 HR)
Vital Signs Date and Time (derived)	12 NOV 2020 14:30
Height (xxx.x)	69 in
Weight (xxx.x)	96.5 kg
Temperature (xxx.x)	97.2 F
Route of measurement	Oral <input checked="" type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	69 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	14 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	138 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	89 mmHg
Diastolic Blood Pressure units	MMHG
Height (derived)	
Weight (derived)	

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Folder: Illness Visit Day 1 (1)

Form: Physical Examination

Data signed: (b) (4) 02 Apr 2021 20:59:29

Generated On: 10 Jun 2021 09:13:35

---

Was the physical examination performed?

Yes ☒

No ☐

---

Date of examination (dd MMM yyyy)

12 NOV 2020

---

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

---

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Folder: Illness Visit Day 1 (1)

Form: Blood Sample Collection for Immunologic Assessment of SARS-CoV-2 Infection

Data signed: (b) (4) 02 Apr 2021 20:59:29

Generated On: 10 Jun 2021 09:13:35

Was Blood Sample Taken for Immunologic Assessment of  
SARS\_COV-2 Infection?

Yes ☒

No ☐

NA (COVID-19 Negative) ☐

Date of Collection

12 NOV 2020

US3632052

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

Form: Visit Date

Data signed: (b) (4) 02 Apr 2021 20:59:29

Generated On: 10 Jun 2021 09:13:35

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>

Visit date (dd MMM yyyy)	04 JAN 2021
--------------------------	-------------

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

Form: Unblinding

Data signed: (b) (4) 12 Apr 2021 01:33:40

Generated On: 10 Jun 2021 09:13:35

Date of updated informed consent (dd MMM yyyy) 04 JAN 2021

N/A - Subject Unblinded under Amendment 5 and Discontinued from Study False

Was the participant unblinded? Yes ☒ No ☐

Under what version of the Protocol was the Participant unblinded? Amendment 5 ☐ Amendment 6 or later ☒

Date of unblinding (dd MMM yyyy) 04 JAN 2021

Participant randomization assignment mRNA-1273 ☒ Placebo ☐

Actual Dose 1 mRNA-1273 ☒ Placebo ☐ Not Administered ☐

Actual Dose 2 mRNA-1273 ☒ Placebo ☐ Not Administered ☐

Will participant receive mRNA-1273? Yes ☐ No ☒

Placebo Only Flag \_\_\_\_\_  
Continuing with mRNA-1273 \_\_\_\_\_

US3632052

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

Form: Immunogenicity Assessment

Data signed: (b) (4) 02 Apr 2021 20:59:29

Generated On: 10 Jun 2021 09:13:35

Was the sample collected?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Collection date (dd MMM yyyy)	04 JAN 2021
Collection time (00:00-23:59)	13:03 (24 HR)
Collection date and time (derived)	04 JAN 2021 13:03

US3632052

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

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Data signed: (b) (4) 02 Apr 2021 20:59:29

Generated On: 10 Jun 2021 09:13:35

Was the sample collected?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Collection date (dd MMM yyyy)	04 JAN 2021
Collection time (00:00 - 23:59)	13:11
Collection Date and Time (derived)	04 JAN 2021 13:11

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Folder: Adverse Events

Form: Adverse Events Summary

Data signed: (b) (4) 15 Mar 2021 12:25:04

Generated On: 10 Jun 2021 09:13:35

---

Did the participant experience any adverse events?

Yes ☒

No ☐

---

If Yes, enter details on the Adverse Events form.

---

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Folder: Adverse Events

Form: Adverse Events (3)

Data signed: (b) (4) 22 Apr 2021 15:40:43

Generated On: 10 Jun 2021 09:13:35

AEID

Adverse event

WORSENING HYPERTENSION

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)

8 SEP 2020

Start time (00:00-23:59)

AE start date and time (derived)

Ongoing?

Yes ☐

No ☒

If not Ongoing, end date (dd MMM yyyy)

6 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

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Folder: Adverse Events

Form: Adverse Events (3)

Data signed: (b) (4) 22 Apr 2021 15:40:43

Generated On: 10 Jun 2021 09:13:35

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 type="radio"/> Related <input type="radio"/> Not Applicable <input checked="" 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)	

US3632052

Folder: Adverse Events

Form: Adverse Events (4)

Data signed: (b) (4) 22 Apr 2021 15:40:43

Generated On: 10 Jun 2021 09:13:35

AEID	
Adverse event	ACUTE THUMB JOINT PAIN
Was this a medically-attended AE?	Yes <input type="radio"/> No <input checked="" 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)	13 OCT 2020
Start time (00:00-23:59)	
AE start date and time (derived)	
Ongoing?	Yes <input checked="" type="radio"/> No <input type="radio"/>
If not Ongoing, end date (dd MMM yyyy)	
End time (00:00-23:59)	
AE End Date and Time (derived)	
Severity	Grade 1/Mild <input type="radio"/> Grade 2/Moderate <input checked="" type="radio"/> Grade 3/Severe <input type="radio"/> Grade 4 <input type="radio"/>
Is the adverse event serious?	Yes <input type="radio"/> No <input checked="" type="radio"/>
AE is serious due To (check all that apply)	
Death	False
Life threatening	False
Requires inpatient or prolongation of existing Hospitalization	False
Hospital Admission Date (dd MMM yyyy)	
Hospital Discharge Date (dd MMM yyyy)	
Admitted to ICU?	Yes <input type="radio"/> No <input type="radio"/> Unknown <input type="radio"/>
Number of Days in ICU	

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Folder: Adverse Events

Form: Adverse Events (4)

Data signed: (b) (4) 22 Apr 2021 15:40:43

Generated On: 10 Jun 2021 09:13:35

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 checked="" type="radio"/> Recovered/Resolved <input 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)	_____



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Folder: Adverse Events

Form: Adverse Events (6)

Data signed: (b) (4) 22 Apr 2021 15:40:43

Generated On: 10 Jun 2021 09:13:35

AEID	USA-US120-2021-MRNA-1273-P30 1000005
Adverse event	PROSTATE CANCER
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)	22 MAR 2021
Start time (00:00-23:59)	
AE start date and time (derived)	
Ongoing?	Yes <input checked="" type="radio"/> No <input type="radio"/>
If not Ongoing, end date (dd MMM yyyy)	
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 checked="" type="radio"/> Unknown <input type="radio"/>

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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	True
Concomitant Medication	False
Concomitant Procedure	False
Outcome	Fatal <input type="radio"/> Not Recovered/Not Resolved <input type="radio"/> Recovered/Resolved <input type="radio"/> Recovered/Resolved with Sequelae <input type="radio"/> Recovering/Resolving <input checked="" type="radio"/> Unknown <input type="radio"/>
If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:	
Narrative	

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DURING VISIT 4, PARTICIPANT REPORTED NEWLY DIAGNOSED PROSTATE CANCER AS OF 3/22/2021. PARTICIPANT STATED THAT THIS WAS DISCOVERED AFTER AN OUTPATIENT PROSTATE BIOPSY WAS PERFORMED ON 3/4/2021. THE BIOPSY WAS PROMPTED AFTER DISCOVERING A PSA OF 4.5 DURING A ROUTINE PHYSICAL AT PRIMARY MD IN NOVEMBER OF 2020. PARTICIPANT STATES THAT AT THIS TIME HE HAS NOT UNDERGONE ANY INTERVENTION RELATED TO THE DIAGNOSIS, AS HE HAS AN UPCOMING VISIT WITH THE DOCTOR TO DISCUSS OPTIONS AND DEVELOP A TREATMENT PLAN. NO INPATIENT HOSPITALIZATIONS HAVE OCCURRED RELATED TO THIS NEW DIAGNOSIS. 13APR2021: PARTICIPANT REPORTS (b) (6) (b) (6) HAD PROSTATE CANCER. PARTICIPANT REPORTS PROSTATE CANCER WAS DIAGNOSED AND NEW PSA WAS DONE AND RESULTS WERE 7.25. PARTICIPANT AWAITING SCANS AND NEXT STEPS.

Serious Adverse Event Derived (CSA Programming Field Only)	1
Medically Attended AE Derived (CSA Programming Field Only)	1
Admitted to ICU Derived (CSA Programming Field Only)	0

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Folder: Adverse Events

Form: Adverse Events (7)

Data signed: (b) (4) 22 Apr 2021 15:40:43

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AEID	
Adverse event	ELEVATED PSA
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)	01 NOV 2020
Start time (00:00-23:59)	
AE start date and time (derived)	
Ongoing?	Yes <input checked="" type="radio"/> No <input type="radio"/>
If not Ongoing, end date (dd MMM yyyy)	
End time (00:00-23:59)	
AE End Date and Time (derived)	
Severity	Grade 1/Mild <input checked="" type="radio"/> Grade 2/Moderate <input type="radio"/> Grade 3/Severe <input type="radio"/> Grade 4 <input type="radio"/>
Is the adverse event serious?	Yes <input type="radio"/> No <input checked="" type="radio"/>
AE is serious due To (check all that apply)	
Death	False
Life threatening	False
Requires inpatient or prolongation of existing Hospitalization	False
Hospital Admission Date (dd MMM yyyy)	
Hospital Discharge Date (dd MMM yyyy)	
Admitted to ICU?	Yes <input type="radio"/> No <input type="radio"/> Unknown <input type="radio"/>
Number of Days in ICU	

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Folder: Adverse Events

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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 <input type="radio"/> Withdrawn <input type="radio"/> Not Applicable <input 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 type="radio"/> Recovering/Resolving <input checked="" 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)	

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Folder: Adverse Events

Form: Adverse Events (8)

Data signed: (b) (4) 22 Apr 2021 15:40:43

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AEID

Adverse event

GLOBUS PHARYNGEUS

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)

01 NOV 2020

Start time (00:00-23:59)

AE start date and time (derived)

Ongoing?

Yes ☐

No ☒

If not Ongoing, end date (dd MMM yyyy)

01 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

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Folder: Adverse Events

Form: Adverse Events (8)

Data signed: (b) (4) 22 Apr 2021 15:40:43

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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 <input type="radio"/> Withdrawn <input type="radio"/> Not Applicable <input type="radio"/>
Other action taken (check all that apply)	
None	False
Concomitant Medication	True
Concomitant Procedure	True
Outcome	Fatal <input type="radio"/> Not Recovered/Not Resolved <input type="radio"/> Recovered/Resolved <input checked="" type="radio"/> Recovered/Resolved with Sequelae <input type="radio"/> Recovering/Resolving <input type="radio"/> Unknown <input type="radio"/>
If outcome is Recovered/Resolved with Sequelae, please specify the sequelae: _____	
Narrative _____	
Serious Adverse Event Derived (CSA Programming Field Only)	0
Medically Attended AE Derived (CSA Programming Field Only)	1
Admitted to ICU Derived (CSA Programming Field Only)	_____

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination Summary

Data signed: (b) (4) 02 Apr 2021 20:59:28

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

Yes ☒

No ☐

---

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Data signed: (b) (4) 12 Apr 2021 01:33:39

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Name of Medication HYDROCHLOTHIAZIDE

Prophylaxis Yes ☐  
No ☒

Indication HYPERTENSION

Dose per administration 12.5

Dose unit mg ☒  
ug ☐  
mL ☐  
g ☐  
IU ☐  
tablet ☐  
capsule ☐  
puff ☐  
Other ☐

If dose unit is Other, specify

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

If frequency is Other, specify

Route of administration Oral ☒  
Topical ☐  
Subcutaneous ☐  
Transdermal ☐  
Intraocular ☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Data signed: (b) (4) 12 Apr 2021 01:33:39

Generated On: 10 Jun 2021 09:13:35

	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 2014	
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)	2	
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input checked="" type="radio"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Data signed: (b) (4) 12 Apr 2021 01:33:39

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Name of Medication ATORVASTATIN CALCIUM

Prophylaxis Yes ☐  
No ☒

Indication HYPERCHOLESTEROLEMIA

Dose per administration 40

Dose unit mg ☒  
ug ☐  
mL ☐  
g ☐  
IU ☐  
tablet ☐  
capsule ☐  
puff ☐  
Other ☐

If dose unit is Other, specify

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

If frequency is Other, specify

Route of administration Oral ☒  
Topical ☐  
Subcutaneous ☐  
Transdermal ☐  
Intraocular ☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Data signed: (b) (4) 12 Apr 2021 01:33:39

Generated On: 10 Jun 2021 09:13:35

	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	UN UNK 2016	
Start date completely unknown	False	
Ongoing?	Yes	<input checked="" type="radio"/>
	No	<input type="radio"/>
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived)	1	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input checked="" type="radio"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Data signed: (b) (4) 12 Apr 2021 01:33:39

Generated On: 10 Jun 2021 09:13:35

Name of Medication ASA

Prophylaxis Yes ☐  
No ☒

Indication HYPERCHOLESTEROLEMIA

Dose per administration 81

Dose unit mg ☒  
ug ☐  
mL ☐  
g ☐  
IU ☐  
tablet ☐  
capsule ☐  
puff ☐  
Other ☐

If dose unit is Other, specify

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

If frequency is Other, specify

Route of administration Oral ☒  
Topical ☐  
Subcutaneous ☐  
Transdermal ☐  
Intraocular ☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Data signed: (b) (4) 12 Apr 2021 01:33:39

Generated On: 10 Jun 2021 09:13:35

	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 2014	
Start date completely unknown	False	
Ongoing?	Yes	<input checked="" type="radio"/>
	No	<input type="radio"/>
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived)	1	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input checked="" type="radio"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Data signed: (b) (4) 12 Apr 2021 01:33:39

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Name of Medication FINASTERIDE

Prophylaxis Yes ☐  
No ☒

Indication BENIGN PROSTATIC  
HYPERTROPHY

Dose per administration 5

Dose unit mg ☒  
ug ☐  
mL ☐  
g ☐  
IU ☐  
tablet ☐  
capsule ☐  
puff ☐  
Other ☐

If dose unit is Other, specify

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

If frequency is Other, specify

Route of administration Oral ☒  
Topical ☐  
Subcutaneous ☐  
Transdermal ☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

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	Intraocular	<input type="checkbox"/>
	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify		
Start date (dd MMM yyyy)	UN	UNK 2019
Start date completely unknown	False	
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)		UN FEB 2021
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived)	1	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input checked="" type="checkbox"/>



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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Data signed: (b) (4) 12 Apr 2021 01:33:39

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Name of Medication LEVOCETIRIZINE

Prophylaxis Yes ☐  
No ☒

Indication SEASONAL ALLERGIES

Dose per administration 5

Dose unit mg ☒  
ug ☐  
mL ☐  
g ☐  
IU ☐  
tablet ☐  
capsule ☐  
puff ☐  
Other ☐

If dose unit is Other, specify

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

If frequency is Other, specify

Route of administration Oral ☒  
Topical ☐  
Subcutaneous ☐  
Transdermal ☐  
Intraocular ☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Data signed: (b) (4) 12 Apr 2021 01:33:39

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	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 2019	
Start date completely unknown	False	
Ongoing?	Yes	<input checked="" type="radio"/>
	No	<input type="radio"/>
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived) _____		
Interval Dosage Unit Number (derived) _____		
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input type="radio"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Data signed: (b) (4) 12 Apr 2021 01:33:39

Generated On: 10 Jun 2021 09:13:35

Name of Medication BECONASE

Prophylaxis Yes ☐  
No ☒

Indication SEASONAL ALLERGIES

Dose per administration 42

Dose unit mg ☐  
ug ☒  
mL ☐  
g ☐  
IU ☐  
tablet ☐  
capsule ☐  
puff ☐  
Other ☐

If dose unit is Other, specify

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

If frequency is Other, specify

Route of administration Oral ☐  
Topical ☐  
Subcutaneous ☐  
Transdermal ☐  
Intraocular ☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Data signed: (b) (4) 12 Apr 2021 01:33:39

Generated On: 10 Jun 2021 09:13:35

	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input checked="" type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	01 UNK 2018	
Start date completely unknown	False	
Ongoing?	Yes	<input checked="" type="checkbox"/>
	No	<input type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" 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"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Data signed: (b) (4) 12 Apr 2021 01:33:39

Generated On: 10 Jun 2021 09:13:35

Name of Medication ZOLPIDEM TARTRATE

Prophylaxis Yes ☐  
No ☒

Indication INSOMNIA

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 ☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Data signed: (b) (4) 12 Apr 2021 01:33:39

Generated On: 10 Jun 2021 09:13:35

	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	UN UNK 2016	
Start date completely unknown	False	
Ongoing?	Yes	<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"/>

US3632052

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Data signed: (b) (4) 12 Apr 2021 01:33:39

Generated On: 10 Jun 2021 09:13:35

Name of Medication ONE A DAY MEN'S VITAMIN

Prophylaxis Yes ☒  
No ☐

Indication GENERAL HEALTH

Dose per administration 1

Dose unit mg ☐  
ug ☐  
mL ☐  
g ☐  
IU ☐  
tablet ☒  
capsule ☐  
puff ☐  
Other ☐

If dose unit is Other, specify

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

If frequency is Other, specify

Route of administration Oral ☒  
Topical ☐  
Subcutaneous ☐  
Transdermal ☐  
Intraocular ☐

PRODUCTION RELEASE (v12.003

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EAB) (1725)

US3632052

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Data signed: (b) (4) 12 Apr 2021 01:33:39

Generated On: 10 Jun 2021 09:13:35

	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 2020
Start date completely unknown	False	
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)		UN FEB 2021
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived)	1	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input checked="" type="checkbox"/>



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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Data signed: (b) (4) 12 Apr 2021 01:33:39

Generated On: 10 Jun 2021 09:13:35

Name of Medication MASON ADVANCED EAR  
HEALTH FORMULA (VITAMIN  
C/VITAMIN B1/VITAMIN  
B2/NIACIN/VITAMIN  
B6/VITAMIN  
B12/PANTHOTHENIC  
ACID/CALCIUM/CHOLINE/BIOF  
LAVENOIDS/INOSITOL)

Prophylaxis Yes ☐  
No ☒

Indication TINNITUS BOTH EARS

Dose per administration 2

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

PRODUCTION RELEASE (v12.003  
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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Data signed: (b) (4) 12 Apr 2021 01:33:39

Generated On: 10 Jun 2021 09:13:35

Route of administration	Oral	<input checked="" type="radio"/>
	Topical	<input type="radio"/>
	Subcutaneous	<input type="radio"/>
	Transdermal	<input type="radio"/>
	Intraocular	<input type="radio"/>
	Intramuscular	<input type="radio"/>
	Respiratory (Inhalation)	<input type="radio"/>
	Intralesional	<input type="radio"/>
	Intraperitoneal	<input type="radio"/>
	Nasal	<input type="radio"/>
	Vaginal	<input type="radio"/>
	Rectal	<input type="radio"/>
	Intravenous	<input type="radio"/>
	Intravenous Bolus	<input type="radio"/>
	Intravenous Drip	<input type="radio"/>
	Other	<input type="radio"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	UN	UNK 2019
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"/>

US3632052

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Data signed: (b) (4) 12 Apr 2021 01:33:39

Generated On: 10 Jun 2021 09:13:35

Name of Medication DICLOFENAC 1%

Prophylaxis Yes ☐  
No ☒

Indication ACUTE THUMB JOINT PAIN

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  
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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Data signed: (b) (4) 12 Apr 2021 01:33:39

Generated On: 10 Jun 2021 09:13:35

	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)		13 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)		15 FEB 2021
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" 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"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Data signed: (b) (4) 12 Apr 2021 01:33:39

Generated On: 10 Jun 2021 09:13:35

Name of Medication EXTRA STRENGTH TYLENOL  
[ACETAMINOPHEN]

Prophylaxis Yes ☐  
No ☒

Indication MILD HEADACHE

Dose per administration 1000

Dose unit mg ☒  
ug ☐  
mL ☐  
g ☐  
IU ☐  
tablet ☐  
capsule ☐  
puff ☐  
Other ☐

If dose unit is Other, specify

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

If frequency is Other, specify

Route of administration Oral ☒  
Topical ☐  
Subcutaneous ☐  
Transdermal ☐

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EAB) (1725)

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Data signed: (b) (4) 12 Apr 2021 01:33:39

Generated On: 10 Jun 2021 09:13:35

	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)	14 SEP 2020	
Start date completely unknown	False	
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)		14 SEP 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"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Data signed: (b) (4) 12 Apr 2021 01:33:39

Generated On: 10 Jun 2021 09:13:35

Name of Medication TYLENOL

Prophylaxis Yes ☐  
No ☒

Indication PAIN AT INJECTION SITE

Dose per administration 650

Dose unit mg ☒  
ug ☐  
mL ☐  
g ☐  
IU ☐  
tablet ☐  
capsule ☐  
puff ☐  
Other ☐

If dose unit is Other, specify

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

If frequency is Other, specify

Route of administration Oral ☒  
Topical ☐  
Subcutaneous ☐  
Transdermal ☐  
Intraocular ☐

PRODUCTION RELEASE (v12.003  
EAB) (1725)

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Data signed: (b) (4) 12 Apr 2021 01:33:39

Generated On: 10 Jun 2021 09:13:35

	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)		6 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)		10 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"/>



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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Data signed: (b) (4) 12 Apr 2021 01:33:39

Generated On: 10 Jun 2021 09:13:35

Name of Medication ALEVE

Prophylaxis Yes ☐  
No ☒

Indication SORENESS FROM YARD WORK

Dose per administration 500

Dose unit mg ☒  
ug ☐  
mL ☐  
g ☐  
IU ☐  
tablet ☐  
capsule ☐  
puff ☐  
Other ☐

If dose unit is Other, specify

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

If frequency is Other, specify

Route of administration Oral ☒  
Topical ☐  
Subcutaneous ☐  
Transdermal ☐  
Intraocular ☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Data signed: (b) (4) 12 Apr 2021 01:33:39

Generated On: 10 Jun 2021 09:13:35

	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)	24 OCT 2020	
Start date completely unknown	False	
Ongoing?	Yes	<input checked="" type="radio"/>
	No	<input type="radio"/>
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived) _____		
Interval Dosage Unit Number (derived) _____		
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input type="radio"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Data signed: (b) (4) 12 Apr 2021 01:33:39

Generated On: 10 Jun 2021 09:13:35

Name of Medication FLU VACCINE

Prophylaxis Yes ☒  
No ☐

Indication GENERAL HEALTH

Dose per administration UNK

Dose unit mg ☐  
ug ☐  
mL ☐  
g ☐  
IU ☐  
tablet ☐  
capsule ☐  
puff ☐  
Other ☒

If dose unit is Other, specify UNKNOWN

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

If frequency is Other, specify

Route of administration Oral ☐  
Topical ☐  
Subcutaneous ☐  
Transdermal ☐  
Intraocular ☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Data signed: (b) (4) 12 Apr 2021 01:33:39

Generated On: 10 Jun 2021 09:13:35

	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)		28 OCT 2020
Start date completely unknown		False
Ongoing?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
If not Ongoing, End date (dd MMM yyyy)		28 OCT 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"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Data signed: (b) (4) 12 Apr 2021 01:33:39

Generated On: 10 Jun 2021 09:13:35

Name of Medication OMEPRAZOLE

Prophylaxis Yes ☐  
No ☒

Indication GLOBUS PHARYNGEUS

Dose per administration 20

Dose unit mg ☒  
ug ☐  
mL ☐  
g ☐  
IU ☐  
tablet ☐  
capsule ☐  
puff ☐  
Other ☐

If dose unit is Other, specify

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

If frequency is Other, specify

Route of administration Oral ☒  
Topical ☐  
Subcutaneous ☐  
Transdermal ☐  
Intraocular ☐

PRODUCTION RELEASE (v12.003  
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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Data signed: (b) (4) 12 Apr 2021 01:33:39

Generated On: 10 Jun 2021 09:13:35

	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)		12 FEB 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"/>

US3632052

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures Summary

Data signed: (b) (4) 02 Apr 2021 20:59:29

Generated On: 10 Jun 2021 09:13:35

---

Were any concomitant procedures performed?

Yes ☒

No ☐

---

If yes, please complete Concomitant Procedures form.

---

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Folder: Concomitant Procedures (1)

Form: Concomitant Procedures

Data signed: (b) (4) 02 Apr 2021 20:59:28

Generated On: 10 Jun 2021 09:13:35

Procedure/Surgery date (dd MMM yyyy)	Procedure/Surgery	Indication	If indication is Other, specify
05 FEB 2021	ENDOSCOPY	Adverse Event	
18 FEB 2021	COLONOSCOPY	Other	ROUTINE COLONOSCOPY FOR AGE
04 MAR 2021	PROSTATE BIOPSY	Diagnostic	



US3632052

Folder: End of Study (1)

Form: Dosing Discontinuation

Generated On: 10 Jun 2021 09:13:35

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

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Folder: End of Study (1)

Form: End of Study / Study Discontinuation

Generated On: 10 Jun 2021 09:13:35

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 ☐

US3632052

Folder: SAE USA-US120-2021-MRNA-1273-P301000005

Form: Safety Report Form

Data signed: (b) (4) 22 Apr 2021 15:40:43

Generated On: 10 Jun 2021 09:13:35

SAEID	USA-US120-2021-MRNA-1273-P301000005
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	COLLEEN
Investigator's Last Name	KELLEY
Site Address: Street	
Site Address: City	
Site Address: State	GA
Site Address: Postal Code	
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	2

US3632052

Folder: SAE USA-US120-2021-MRNA-1273-P301000005

Form: Safety Report Form (1)

Data signed: (b) (4) 22 Apr 2021 15:40:43

Generated On: 10 Jun 2021 09:13:35

SAEID	USA-US120-2021-MRNA-1273-P301000005
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	COLLEEN
Investigator's Last Name	KELLEY
Site Address: Street	
Site Address: City	
Site Address: State	GA
Site Address: Postal Code	
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	2
Date of submission (Pre-filled from custom function)	02/APR/2021 12:53
Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.	True

US3632052

Folder: SAE USA-US120-2021-MRNA-1273-P301000005

Form: Safety Report Form (2)

Data signed: (b) (4) 22 Apr 2021 15:40:43

Generated On: 10 Jun 2021 09:13:35

SAEID	USA-US120-2021-MRNA-1273-P301000005
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	COLLEEN
Investigator's Last Name	KELLEY
Site Address: Street	
Site Address: City	
Site Address: State	GA
Site Address: Postal Code	
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	2
Date of submission (Pre-filled from custom function)	14/APR/2021 06:17
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

Audit

US3632052 (Prod: Grady Health System)

**US3632052**

**Form: Participant Creation**

**Generated On: 10 Jun 2021 09:13:35**

[Participant ID](#)

Audit	User	Time (GMT)
User signature succeeded.	Colleen Kelley (b) (4)	02 Apr 2021 20:59:30
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	01 Mar 2021 21:58:06
User entered 'US3632052'	RWS_ENDPOINT	08 Sep 2020 12:29:38
	ENDPOINT (b) (4)	

US3632052

Folder: Screening

Form: Visit Date

Generated On: 10 Jun 2021 09:13:35

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:07:42
User signature succeeded.	Colleen Kelley (b) (4)	15 Mar 2021 12:20:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Nov 2020 16:09:54
User closed query 'Data is required. Please complete.' (Site from System).	System	08 Sep 2020 15:10:44
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	08 Sep 2020 15:10:44
User entered 'Yes (Y)' reason for change: Data Entry Error	Kelly Likos (b) (4) (b) (4)	08 Sep 2020 15:10:44
User opened query 'Data is required. Please complete.' (Site from System).	System	08 Sep 2020 15:10:38
User entered empty.	Kelly Likos (b) (4) (b) (4)	08 Sep 2020 15:10:38



**US3632052**

**Folder: Screening**

**Form: Visit Date**

**Generated On: 10 Jun 2021 09:13:35**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:07:42
User signature succeeded.	Colleen Kelley (b) (4)	15 Mar 2021 12:20:23
DataPoint Verified.	(b) (4)	19 Nov 2020 16:09:54
User entered '08 SEP 2020'	(b) (4), (b) (6)	
	RWS_ENDPOINT	08 Sep 2020 12:29:39
	ENDPOINT (b) (4)	

**US3632052**

**Folder: Screening**

**Form: Visit Date**

**Generated On: 10 Jun 2021 09:13:35**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:07:42
User signature succeeded.	Colleen Kelley (b) (4)	15 Mar 2021 12:20:23
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	19 Nov 2020 16:09:54
User entered 'Clinic (Clinic)'	Kelly Likos (b) (4)	08 Sep 2020 15:10:38
	(b) (4)	

**US3632052**

**Folder: Screening**

**Form: Visit Date**

**Generated On: 10 Jun 2021 09:13:35**

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:07:42
User entered 'SCRN'	System	08 Sep 2020 15:10:44
User entered empty.	System	08 Sep 2020 15:10:38

**US3632052**

**Folder: Screening**

**Form: Demographics**

**Generated On: 10 Jun 2021 09:13:35**

[Date of Birth \(MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:07:42
User signature succeeded.	Colleen Kelley (b) (4)	15 Mar 2021 12:20:23
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	19 Nov 2020 16:12:45
User entered (b) (6) 1959'	RWS_ENDPOINT ENDPOINT (b) (4)	08 Sep 2020 12:29:40

**US3632052**

**Folder: Screening**

**Form: Demographics**

**Generated On: 10 Jun 2021 09:13:35**

[Age](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:07:42
User signature succeeded.	Colleen Kelley (b) (4)	15 Mar 2021 12:20:23
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 16:12:50
User entered '61'	Kelly Likos (b) (4)	08 Sep 2020 15:11:35

**US3632052**

**Folder: Screening**

**Form: Demographics**

**Generated On: 10 Jun 2021 09:13:35**

[Age Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:07:42
User entered 'YEARS'	System	08 Sep 2020 15:11:35

**US3632052**

**Folder: Screening**

**Form: Demographics**

**Generated On: 10 Jun 2021 09:13:35**

[Age \(Derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:07:42
User entered '61'	System	08 Sep 2020 15:11:59

**US3632052**

**Folder: Screening**

**Form: Demographics**

**Generated On: 10 Jun 2021 09:13:35**

[Sex](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:07:42
User signature succeeded.	Colleen Kelley (b) (4)	15 Mar 2021 12:20:23
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	19 Nov 2020 16:13:05
User entered 'Male (M)'	Kelly Likos (b) (4)	08 Sep 2020 15:11:35
	(b) (4)	



US3632052

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 09:13:35

[Ethnicity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:07:42
User signature succeeded.	Colleen Kelley (b) (4)	15 Mar 2021 12:20:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Nov 2020 16:13:11
User entered 'Not Hispanic or Latino (NOT HISPANIC OR LATINO)'	Kelly Likos (b) (4) (b) (4)	08 Sep 2020 15:11:35

**US3632052**

**Folder: Screening**

**Form: Demographics**

**Generated On: 10 Jun 2021 09:13:35**

[White](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:07:42
User signature succeeded.	Colleen Kelley (b) (4)	15 Mar 2021 12:20:23
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	19 Nov 2020 16:13:17
User entered '0'	Kelly Likos (b) (4)	08 Sep 2020 15:11:35
	(b) (4)	

**US3632052**

**Folder: Screening**

**Form: Demographics**

**Generated On: 10 Jun 2021 09:13:35**

[Black](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:07:42
User signature succeeded.	Colleen Kelley (b) (4)	15 Mar 2021 12:20:23
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 16:13:17
User entered 'I'	Kelly Likos (b) (4)	08 Sep 2020 15:11:35

**US3632052**

**Folder: Screening**

**Form: Demographics**

**Generated On: 10 Jun 2021 09:13:35**

[Asian](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:07:42
User signature succeeded.	Colleen Kelley (b) (4)	15 Mar 2021 12:20:23
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	19 Nov 2020 16:13:17
User entered '0'	Kelly Likos (b) (4)	08 Sep 2020 15:11:35
	(b) (4)	

**US3632052**

**Folder: Screening**

**Form: Demographics**

**Generated On: 10 Jun 2021 09:13:35**

[American Indian or Alaska Native](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:07:42
User signature succeeded.	Colleen Kelley (b) (4)	15 Mar 2021 12:20:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Nov 2020 16:13:17
User entered '0'	Kelly Likos (b) (4) (b) (4)	08 Sep 2020 15:11:35

**US3632052**

**Folder: Screening**

**Form: Demographics**

**Generated On: 10 Jun 2021 09:13:35**

[Native Hawaiian or other Pacific Islander](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:07:42
User signature succeeded.	Colleen Kelley (b) (4)	15 Mar 2021 12:20:23
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	19 Nov 2020 16:13:17
User entered '0'	Kelly Likos (b) (4)	08 Sep 2020 15:11:35
	(b) (4)	

**US3632052**

**Folder: Screening**

**Form: Demographics**

**Generated On: 10 Jun 2021 09:13:35**

[Other](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:07:42
User signature succeeded.	Colleen Kelley (b) (4)	15 Mar 2021 12:20:23
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	19 Nov 2020 16:13:17
User entered '0'	Kelly Likos (b) (4)	08 Sep 2020 15:11:35
	(b) (4)	

**US3632052**

**Folder: Screening**

**Form: Demographics**

**Generated On: 10 Jun 2021 09:13:35**

[If race is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:07:42
User signature succeeded.	Colleen Kelley (b) (4)	15 Mar 2021 12:20:23
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	19 Nov 2020 16:13:17
User entered empty.	Kelly Likos (b) (4)	08 Sep 2020 15:11:35
	(b) (4)	



**US3632052**

**Folder: Screening**

**Form: Demographics**

**Generated On: 10 Jun 2021 09:13:35**

[Unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:07:42
User signature succeeded.	Colleen Kelley (b) (4)	15 Mar 2021 12:20:23
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 16:13:17
User entered '0'	Kelly Likos (b) (4)	08 Sep 2020 15:11:35

**US3632052**

**Folder: Screening**

**Form: Demographics**

**Generated On: 10 Jun 2021 09:13:35**

[Not reported](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:07:42
User signature succeeded.	Colleen Kelley (b) (4)	15 Mar 2021 12:20:23
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 16:13:17
User entered '0'	Kelly Likos (b) (4)	08 Sep 2020 15:11:35

**US3632052**

**Folder: Screening**

**Form: Enrollment**

**Generated On: 10 Jun 2021 09:13:35**

[Date of Informed Consent \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:07:42
User signature succeeded.	Colleen Kelley (b) (4)	15 Mar 2021 12:20:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Nov 2020 16:13:46
User entered '08 Sep 2020'	Kelly Likos (b) (4) (b) (4)	08 Sep 2020 15:11:59

**US3632052**

**Folder: Screening**

**Form: Enrollment**

**Generated On: 10 Jun 2021 09:13:35**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:07:42
User entered 'Sep 2020'	System	08 Sep 2020 15:11:59

**US3632052**

**Folder: Screening**

**Form: Enrollment**

**Generated On: 10 Jun 2021 09:13:35**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:07:42
User entered '2020'	System	08 Sep 2020 15:11:59

**US3632052**

**Folder: Screening**

**Form: Enrollment**

**Generated On: 10 Jun 2021 09:13:35**

[Protocol Version](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:07:42
User signature succeeded.	Colleen Kelley (b) (4)	15 Mar 2021 12:20:23
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 16:13:46
User entered 'Amendment 3 (3)'	Kelly Likos (b) (4)	08 Sep 2020 15:11:59

**US3632052**

**Folder: Screening**

**Form: Enrollment**

**Generated On: 10 Jun 2021 09:13:35**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:07:42
User signature succeeded.	Colleen Kelley (b) (4)	15 Mar 2021 12:20:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Nov 2020 16:13:46
User entered 'Yes (Y)'	Kelly Likos (b) (4) (b) (4)	08 Sep 2020 15:11:59

**US3632052**

**Folder: Screening**

**Form: Enrollment**

**Generated On: 10 Jun 2021 09:13:35**

[If No, indicate reason for screen fail](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:07:42
User signature succeeded.	Colleen Kelley (b) (4)	15 Mar 2021 12:20:23
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 16:13:46
User entered empty.	Kelly Likos (b) (4)	08 Sep 2020 15:11:59



**US3632052**

**Folder: Screening**

**Form: Enrollment**

**Generated On: 10 Jun 2021 09:13:35**

If reason for screen fail is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:07:42
User signature succeeded.	Colleen Kelley (b) (4)	15 Mar 2021 12:20:23
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 16:13:46
User entered empty.	Kelly Likos (b) (4)	08 Sep 2020 15:11:59

**US3632052**

**Folder: Screening**

**Form: Enrollment**

**Generated On: 10 Jun 2021 09:13:35**

[Was this participant screened previously?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:07:42
User signature succeeded.	Colleen Kelley (b) (4)	15 Mar 2021 12:20:23
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 16:13:46
User entered 'No (N)'	Kelly Likos (b) (4)	08 Sep 2020 15:11:59

**US3632052**

**Folder: Screening**

**Form: Enrollment**

**Generated On: 10 Jun 2021 09:13:35**

[If Yes, previous participant number](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:07:42
User signature succeeded.	Colleen Kelley (b) (4)	15 Mar 2021 12:20:23
DataPoint Verified.	(b) (4)	19 Nov 2020 16:13:46
User entered empty.	RWS_ENDPOINT ENDPOINT (b) (4)	08 Sep 2020 12:29:39

US3632052

Folder: Screening

Form: Enrollment

Generated On: 10 Jun 2021 09:13:35

[Enrollment Trigger](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:07:42
User entered 'I'	System	08 Sep 2020 15:11:59

**US3632052**

**Folder: Screening**

**Form: Inclusion/Exclusion Criteria Summary**

**Generated On: 10 Jun 2021 09:13:35**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:07:42
User signature succeeded.	Colleen Kelley (b) (4)	15 Mar 2021 12:20:23
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 16:14:33
User entered 'Yes (Y)'	Kelly Likos (b) (4)	08 Sep 2020 15:09:31

**US3632052**

**Folder: Screening**

**Form: Medical History Summary**

**Generated On: 10 Jun 2021 09:13:35**

[Were any significant conditions reported?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:07:42
User signature succeeded.	Colleen Kelley (b) (4)	15 Mar 2021 12:20:23
DataPoint Verified.	(b) (4)	19 Nov 2020 16:15:03
User entered 'Yes (Y)'	(b) (4), (b) (6)	08 Sep 2020 23:23:51

US3632052

Folder: Screening

Form: Medical History (1)

Generated On: 10 Jun 2021 09:13:35

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:07:42
User signature succeeded.	Colleen Kelley (b) (4)	15 Mar 2021 12:20:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Nov 2020 16:15:18
User coded data point as SOC: Vascular disorders, HLGT: Vascular hypertensive disorders, HLT: Vascular hypertensive disorders NEC, PT: Hypertension, LLT: Hypertension - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	08 Sep 2020 23:27:49
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	08 Sep 2020 23:27:49
Data point term sent to Coder	System	08 Sep 2020 23:27:13
User entered 'Hypertension'	(b) (4), (b) (6)	08 Sep 2020 23:26:46

US3632052

Folder: Screening

Form: Medical History (1)

Generated On: 10 Jun 2021 09:13:35

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:07:42
User signature succeeded.	Colleen Kelley (b) (4)	15 Mar 2021 12:20:23
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 20:08:59
Query 'Per source, the start date is just listed as 2014. Please update EDC to reflect an unknown start day so that it is UN-UNK-2014. ' canceled (Site from CRA).	(b) (4), (b) (6)	19 Nov 2020 20:08:57
User opened query 'Per source, the start date is just listed as 2014. Please update EDC to reflect an unknown start day so that it is UN-UNK-2014. ' (Site from CRA).	(b) (4), (b) (6)	19 Nov 2020 16:16:35
User entered '01 UNK 2014'	(b) (4), (b) (6)	08 Sep 2020 23:26:46



**US3632052**

**Folder: Screening**

**Form: Medical History (1)**

**Generated On: 10 Jun 2021 09:13:35**

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:07:42
User signature succeeded.	Colleen Kelley (b) (4)	15 Mar 2021 12:20:23
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 16:28:10
User entered '0'	(b) (4), (b) (6)	08 Sep 2020 23:26:46

**US3632052**

**Folder: Screening**

**Form: Medical History (1)**

**Generated On: 10 Jun 2021 09:13:35**

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:07:42
User signature succeeded.	Colleen Kelley (b) (4)	15 Mar 2021 12:20:23
DataPoint Verified.	(b) (4)	19 Nov 2020 16:28:22
User entered 'Yes (Y)'	(b) (4), (b) (6)	08 Sep 2020 23:26:46

**US3632052**

**Folder: Screening**

**Form: Medical History (1)**

**Generated On: 10 Jun 2021 09:13:35**

[If No, please specify the stop date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:07:42
User signature succeeded.	Colleen Kelley (b) (4)	15 Mar 2021 12:20:23
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 16:28:32
User entered empty.	(b) (4), (b) (6)	08 Sep 2020 23:26:46

**US3632052**

**Folder: Screening**

**Form: Medical History (1)**

**Generated On: 10 Jun 2021 09:13:35**

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:07:42
User signature succeeded.	Colleen Kelley (b) (4)	15 Mar 2021 12:20:23
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 16:28:35
User entered '0'	(b) (4), (b) (6)	08 Sep 2020 23:26:46

**US3632052**

**Folder: Screening**

**Form: Medical History (1)**

**Generated On: 10 Jun 2021 09:13:35**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:07:42
User entered 'Jan 2014'	System	08 Sep 2020 23:26:46

**US3632052**

**Folder: Screening**

**Form: Medical History (1)**

**Generated On: 10 Jun 2021 09:13:35**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:07:42
User entered '2014'	System	08 Sep 2020 23:26:46

**US3632052**

**Folder: Screening**

**Form: Medical History (1)**

**Generated On: 10 Jun 2021 09:13:35**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:07:42
User entered empty.	System	08 Sep 2020 23:26:46

**US3632052**

**Folder: Screening**

**Form: Medical History (1)**

**Generated On: 10 Jun 2021 09:13:35**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:07:42
User entered empty.	System	08 Sep 2020 23:26:46



US3632052

Folder: Screening

Form: Medical History (2)

Generated On: 10 Jun 2021 09:13:35

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:07:42
User signature succeeded.	Colleen Kelley (b) (4)	15 Mar 2021 12:20:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Nov 2020 16:28:45
User coded data point as SOC: Metabolism and nutrition disorders, HLGT: Lipid metabolism disorders, HLT: Elevated cholesterol, PT: Hypercholesterolaemia, LLT: Hypercholesterolemia - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	08 Sep 2020 23:28:51
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	08 Sep 2020 23:28:51
Data point term sent to Coder	System	08 Sep 2020 23:28:14
User entered 'Hypercholesterolemia'	(b) (4), (b) (6)	08 Sep 2020 23:27:15

US3632052

Folder: Screening

Form: Medical History (2)

Generated On: 10 Jun 2021 09:13:35

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:07:42
User signature succeeded.	Colleen Kelley (b) (4)	15 Mar 2021 12:20:23
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 20:09:04
Query 'Per source, the start date is just listed as 2016. Please update EDC to reflect an unknown start day so that it is UN-UNK-2016. ' canceled (Site from CRA).	(b) (4), (b) (6)	19 Nov 2020 20:09:02
User opened query 'Per source, the start date is just listed as 2016. Please update EDC to reflect an unknown start day so that it is UN-UNK-2016. ' (Site from CRA).	(b) (4), (b) (6)	19 Nov 2020 16:29:09
User entered '01 UNK 2016' reason for change:	Christina Bacher (b) (4)	20 Oct 2020 16:45:58
Data Entry Error	(b) (4)	
User entered '01 UNK 2017'	(b) (4), (b) (6)	08 Sep 2020 23:27:15

**US3632052**

**Folder: Screening**

**Form: Medical History (2)**

**Generated On: 10 Jun 2021 09:13:35**

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:07:42
User signature succeeded.	Colleen Kelley (b) (4)	15 Mar 2021 12:20:23
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 16:29:14
User entered '0'	(b) (4), (b) (6)	08 Sep 2020 23:27:15

**US3632052**

**Folder: Screening**

**Form: Medical History (2)**

**Generated On: 10 Jun 2021 09:13:35**

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:07:42
User signature succeeded.	Colleen Kelley (b) (4)	15 Mar 2021 12:20:23
DataPoint Verified.	(b) (4)	19 Nov 2020 16:29:17
User entered 'Yes (Y)'	(b) (4), (b) (6)	08 Sep 2020 23:27:15

**US3632052**

**Folder: Screening**

**Form: Medical History (2)**

**Generated On: 10 Jun 2021 09:13:35**

[If No, please specify the stop date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:07:42
User signature succeeded.	Colleen Kelley (b) (4)	15 Mar 2021 12:20:23
DataPoint Verified.	(b) (4)	19 Nov 2020 16:29:19
User entered empty.	(b) (4), (b) (6)	08 Sep 2020 23:27:15

**US3632052**

**Folder: Screening**

**Form: Medical History (2)**

**Generated On: 10 Jun 2021 09:13:35**

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:07:42
User signature succeeded.	Colleen Kelley (b) (4)	15 Mar 2021 12:20:23
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 16:29:25
User entered '0'	(b) (4), (b) (6)	08 Sep 2020 23:27:15

**US3632052**

**Folder: Screening**

**Form: Medical History (2)**

**Generated On: 10 Jun 2021 09:13:35**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:07:42
User entered 'Jan 2016'	System	20 Oct 2020 16:45:58
User entered 'Jan 2017'	System	08 Sep 2020 23:27:15

**US3632052**

**Folder: Screening**

**Form: Medical History (2)**

**Generated On: 10 Jun 2021 09:13:35**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:07:42
User entered '2016'	System	20 Oct 2020 16:45:58
User entered '2017'	System	08 Sep 2020 23:27:15



**US3632052**

**Folder: Screening**

**Form: Medical History (2)**

**Generated On: 10 Jun 2021 09:13:35**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:07:42
User entered empty.	System	08 Sep 2020 23:27:15

**US3632052**

**Folder: Screening**

**Form: Medical History (2)**

**Generated On: 10 Jun 2021 09:13:35**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:07:42
User entered empty.	System	08 Sep 2020 23:27:15

US3632052

Folder: Screening

Form: Medical History (3)

Generated On: 10 Jun 2021 09:13:35

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:07:42
User signature succeeded.	Colleen Kelley (b) (4)	15 Mar 2021 12:20:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Nov 2020 16:29:34
User coded data point as SOC: Reproductive system and breast disorders, HLGT: Prostatic disorders (excl infections and inflammations), HLT: Prostatic neoplasms and hypertrophy, PT: Benign prostatic hyperplasia, LLT: Benign prostatic hypertrophy - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	08 Sep 2020 23:28:50
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	08 Sep 2020 23:28:50
Data point term sent to Coder	System	08 Sep 2020 23:28:14
User entered 'Benign Prostatic Hypertrophy'	(b) (4), (b) (6)	08 Sep 2020 23:27:45

US3632052

Folder: Screening

Form: Medical History (3)

Generated On: 10 Jun 2021 09:13:35

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:07:42
User signature succeeded.	Colleen Kelley (b) (4)	15 Mar 2021 12:20:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Nov 2020 20:09:15
Query 'Per source, the start date is just listed as 2018. Please update EDC to reflect an unknown start day so that it is UN-UNK-2018. ' canceled (Site from CRA).	(b) (4), (b) (6)	19 Nov 2020 20:09:12
User opened query 'Per source, the start date is just listed as 2018. Please update EDC to reflect an unknown start day so that it is UN-UNK-2018. ' (Site from CRA).	(b) (4), (b) (6)	19 Nov 2020 16:30:09
User entered '01 UNK 2018'	(b) (4), (b) (6)	08 Sep 2020 23:27:45

**US3632052**

**Folder: Screening**

**Form: Medical History (3)**

**Generated On: 10 Jun 2021 09:13:35**

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:07:42
User signature succeeded.	Colleen Kelley (b) (4)	15 Mar 2021 12:20:23
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 16:30:17
User entered '0'	(b) (4), (b) (6)	08 Sep 2020 23:27:45

**US3632052**

**Folder: Screening**

**Form: Medical History (3)**

**Generated On: 10 Jun 2021 09:13:35**

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:07:42
User signature succeeded.	Colleen Kelley (b) (4)	15 Mar 2021 12:20:23
DataPoint Verified.	(b) (4)	19 Nov 2020 16:30:21
User entered 'Yes (Y)'	(b) (4), (b) (6)	08 Sep 2020 23:27:45

**US3632052**

**Folder: Screening**

**Form: Medical History (3)**

**Generated On: 10 Jun 2021 09:13:35**

[If No, please specify the stop date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:07:42
User signature succeeded.	Colleen Kelley (b) (4)	15 Mar 2021 12:20:23
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 16:30:33
User entered empty.	(b) (4), (b) (6)	08 Sep 2020 23:27:45

**US3632052**

**Folder: Screening**

**Form: Medical History (3)**

**Generated On: 10 Jun 2021 09:13:35**

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:07:42
User signature succeeded.	Colleen Kelley (b) (4)	15 Mar 2021 12:20:23
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	19 Nov 2020 16:30:37
User entered '0'	(b) (4), (b) (6)	08 Sep 2020 23:27:45



**US3632052**

**Folder: Screening**

**Form: Medical History (3)**

**Generated On: 10 Jun 2021 09:13:35**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:07:42
User entered 'Jan 2018'	System	08 Sep 2020 23:27:45

**US3632052**

**Folder: Screening**

**Form: Medical History (3)**

**Generated On: 10 Jun 2021 09:13:35**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:07:42
User entered '2018'	System	08 Sep 2020 23:27:45

**US3632052**

**Folder: Screening**

**Form: Medical History (3)**

**Generated On: 10 Jun 2021 09:13:35**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:07:42
User entered empty.	System	08 Sep 2020 23:27:45

**US3632052**

**Folder: Screening**

**Form: Medical History (3)**

**Generated On: 10 Jun 2021 09:13:35**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:07:42
User entered empty.	System	08 Sep 2020 23:27:45

US3632052

Folder: Screening

Form: Medical History (4)

Generated On: 10 Jun 2021 09:13:35

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:07:42
User signature succeeded.	Colleen Kelley (b) (4)	15 Mar 2021 12:20:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Nov 2020 16:30:45
User coded data point as SOC: Immune system disorders, HLGT: Allergic conditions, HLT: Atopic disorders, PT: Seasonal allergy, LLT: Seasonal allergy - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	08 Sep 2020 23:29:51
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	08 Sep 2020 23:29:51
Data point term sent to Coder	System	08 Sep 2020 23:29:16
User entered 'Seasonal Allergies'	(b) (4), (b) (6)	08 Sep 2020 23:28:16

US3632052

Folder: Screening

Form: Medical History (4)

Generated On: 10 Jun 2021 09:13:35

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:07:42
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 19:20:31
DataPoint Un-verified.	(b) (4), (b) (6)	24 Mar 2021 19:27:30
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 19:24:51
User signature succeeded.	Colleen Kelley (b) (4)	15 Mar 2021 12:20:23
DataPoint Un-verified.	Isaac Perez (b) (4)	15 Feb 2021 13:34:00
User entered '01 UNK 2018' reason for change: Per Query Resolution	Isaac Perez (b) (4)	15 Feb 2021 13:34:00
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 20:09:22
Query 'Per source, the start date is just listed as 2019. Please update EDC to reflect an unknown start day so that it is UN-UNK-2019. ' canceled (Site from CRA).	(b) (4), (b) (6)	19 Nov 2020 20:09:19
User opened query 'Per source, the start date is just listed as 2019. Please update EDC to reflect an unknown start day so that it is UN-UNK-2019. ' (Site from CRA).	(b) (4), (b) (6)	19 Nov 2020 16:31:07
User entered '01 UNK 2019'	(b) (4), (b) (6)	08 Sep 2020 23:28:16

**US3632052**

**Folder: Screening**

**Form: Medical History (4)**

**Generated On: 10 Jun 2021 09:13:35**

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:07:42
User signature succeeded.	Colleen Kelley (b) (4)	15 Mar 2021 12:20:23
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 16:31:14
User entered '0'	(b) (4), (b) (6)	08 Sep 2020 23:28:16

**US3632052**

**Folder: Screening**

**Form: Medical History (4)**

**Generated On: 10 Jun 2021 09:13:35**

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:07:42
User signature succeeded.	Colleen Kelley (b) (4)	15 Mar 2021 12:20:23
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 16:31:12
User entered 'Yes (Y)'	(b) (4), (b) (6)	08 Sep 2020 23:28:16



**US3632052**

**Folder: Screening**

**Form: Medical History (4)**

**Generated On: 10 Jun 2021 09:13:35**

[If No, please specify the stop date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:07:42
User signature succeeded.	Colleen Kelley (b) (4)	15 Mar 2021 12:20:23
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 16:31:19
User entered empty.	(b) (4), (b) (6)	08 Sep 2020 23:28:16

**US3632052**

**Folder: Screening**

**Form: Medical History (4)**

**Generated On: 10 Jun 2021 09:13:35**

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:07:42
User signature succeeded.	Colleen Kelley (b) (4)	15 Mar 2021 12:20:23
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 16:31:21
User entered '0'	(b) (4), (b) (6)	08 Sep 2020 23:28:16

**US3632052**

**Folder: Screening**

**Form: Medical History (4)**

**Generated On: 10 Jun 2021 09:13:35**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:07:42
User entered 'Jan 2018'	System	15 Feb 2021 13:34:00
User entered 'Jan 2019'	System	08 Sep 2020 23:28:16

**US3632052**

**Folder: Screening**

**Form: Medical History (4)**

**Generated On: 10 Jun 2021 09:13:35**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:07:42
User entered '2018'	System	15 Feb 2021 13:34:00
User entered '2019'	System	08 Sep 2020 23:28:16

**US3632052**

**Folder: Screening**

**Form: Medical History (4)**

**Generated On: 10 Jun 2021 09:13:35**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:07:42
User entered empty.	System	08 Sep 2020 23:28:16

**US3632052**

**Folder: Screening**

**Form: Medical History (4)**

**Generated On: 10 Jun 2021 09:13:35**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:07:42
User entered empty.	System	08 Sep 2020 23:28:16

US3632052

Folder: Screening

Form: Medical History (5)

Generated On: 10 Jun 2021 09:13:35

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:07:42
User signature succeeded.	Colleen Kelley (b) (4)	15 Mar 2021 12:20:23
DataPoint Verified.	(b) (4)	19 Nov 2020 16:31:51
DataPoint Un-verified.	(b) (4), (b) (6)	19 Nov 2020 16:31:29
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 16:31:26
User coded data point as SOC: Ear and labyrinth disorders, HLGT: Inner ear and VIIIth cranial nerve disorders, HLT: Inner ear signs and symptoms, PT: Tinnitus, LLT: Tinnitus - version MedDRA\\23.0.	Coder Import (b) (4)	15 Oct 2020 05:52:31
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4)	15 Oct 2020 05:52:31
Data point term sent to Coder	System	14 Oct 2020 18:30:17
Coding entries removed.	Isaac Perez (b) (4)	14 Oct 2020 18:30:05
User entered 'TINNITUS in both ears' reason for change: Data Entry Error	(b) (4)	14 Oct 2020 18:30:05
User coded data point as SOC: Ear and labyrinth disorders, HLGT: Inner ear and VIIIth cranial nerve disorders, HLT: Inner ear signs and symptoms, PT: Tinnitus, LLT: Tinnitus - version MedDRA\\23.0.	Isaac Perez (b) (4)	14 Oct 2020 18:30:05
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	08 Sep 2020 23:29:52
Data point term sent to Coder	(b) (4)	08 Sep 2020 23:29:52
User entered 'Tinnitus'	System	08 Sep 2020 23:29:17
	(b) (4), (b) (6)	08 Sep 2020 23:28:40

US3632052

Folder: Screening

Form: Medical History (5)

Generated On: 10 Jun 2021 09:13:35

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:07:42
User signature succeeded.	Colleen Kelley (b) (4)	15 Mar 2021 12:20:23
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 20:09:32
Query 'Per source, the start date is just listed as 2016. Please update EDC to reflect an unknown start day so that it is UN-UNK-2016. ' canceled (Site from CRA).	(b) (4), (b) (6)	19 Nov 2020 20:09:27
User opened query 'Per source, the start date is just listed as 2016. Please update EDC to reflect an unknown start day so that it is UN-UNK-2016. ' (Site from CRA).	(b) (4), (b) (6)	19 Nov 2020 16:31:47
User entered '01 UNK 2016' reason for change:	Christina Bacher (b) (4)	20 Oct 2020 16:47:42
Data Entry Error	(b) (4)	
User entered '01 UNK 2017'	(b) (4), (b) (6)	08 Sep 2020 23:28:40



**US3632052**

**Folder: Screening**

**Form: Medical History (5)**

**Generated On: 10 Jun 2021 09:13:35**

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:07:42
User signature succeeded.	Colleen Kelley (b) (4)	15 Mar 2021 12:20:23
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 16:32:01
User entered '0'	(b) (4), (b) (6)	08 Sep 2020 23:28:40

**US3632052**

**Folder: Screening**

**Form: Medical History (5)**

**Generated On: 10 Jun 2021 09:13:35**

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:07:42
User signature succeeded.	Colleen Kelley (b) (4)	15 Mar 2021 12:20:23
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 16:32:06
User entered 'Yes (Y)'	(b) (4), (b) (6)	08 Sep 2020 23:28:40

**US3632052**

**Folder: Screening**

**Form: Medical History (5)**

**Generated On: 10 Jun 2021 09:13:35**

[If No, please specify the stop date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:07:42
User signature succeeded.	Colleen Kelley (b) (4)	15 Mar 2021 12:20:23
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 16:32:09
User entered empty.	(b) (4), (b) (6)	08 Sep 2020 23:28:40

**US3632052**

**Folder: Screening**

**Form: Medical History (5)**

**Generated On: 10 Jun 2021 09:13:35**

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:07:42
User signature succeeded.	Colleen Kelley (b) (4)	15 Mar 2021 12:20:23
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 16:32:12
User entered '0'	(b) (4), (b) (6)	08 Sep 2020 23:28:40

**US3632052**

**Folder: Screening**

**Form: Medical History (5)**

**Generated On: 10 Jun 2021 09:13:35**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:07:42
User entered 'Jan 2016'	System	20 Oct 2020 16:47:42
User entered 'Jan 2017'	System	08 Sep 2020 23:28:40

**US3632052**

**Folder: Screening**

**Form: Medical History (5)**

**Generated On: 10 Jun 2021 09:13:35**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:07:42
User entered '2016'	System	20 Oct 2020 16:47:42
User entered '2017'	System	08 Sep 2020 23:28:40

**US3632052**

**Folder: Screening**

**Form: Medical History (5)**

**Generated On: 10 Jun 2021 09:13:35**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:07:42
User entered empty.	System	08 Sep 2020 23:28:40

**US3632052**

**Folder: Screening**

**Form: Medical History (5)**

**Generated On: 10 Jun 2021 09:13:35**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:07:42
User entered empty.	System	08 Sep 2020 23:28:40



US3632052

Folder: Screening

Form: Medical History (6)

Generated On: 10 Jun 2021 09:13:35

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:07:42
User signature succeeded.	Colleen Kelley (b) (4)	15 Mar 2021 12:20:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Nov 2020 16:32:28
User coded data point as SOC: Psychiatric disorders, HLTG: Sleep disorders and disturbances, HLT: Disturbances in initiating and maintaining sleep, PT: Insomnia, LLT: Insomnia - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	08 Sep 2020 23:31:52
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	08 Sep 2020 23:31:52
Data point term sent to Coder	System	08 Sep 2020 23:30:17
User entered 'Insomnia'	(b) (4), (b) (6)	08 Sep 2020 23:29:22

US3632052

Folder: Screening

Form: Medical History (6)

Generated On: 10 Jun 2021 09:13:35

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:07:42
User signature succeeded.	Colleen Kelley (b) (4)	15 Mar 2021 12:20:23
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 20:09:41
Query 'Per source, the start date is just listed as 2016. Please update EDC to reflect an unknown start day so that it is UN-UNK-2016. ' canceled (Site from CRA).	(b) (4), (b) (6)	19 Nov 2020 20:09:36
User opened query 'Per source, the start date is just listed as 2016. Please update EDC to reflect an unknown start day so that it is UN-UNK-2016. ' (Site from CRA).	(b) (4), (b) (6)	19 Nov 2020 16:32:43
User entered '01 UNK 2016'	(b) (4), (b) (6)	08 Sep 2020 23:29:22

**US3632052**

**Folder: Screening**

**Form: Medical History (6)**

**Generated On: 10 Jun 2021 09:13:35**

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:07:42
User signature succeeded.	Colleen Kelley (b) (4)	15 Mar 2021 12:20:23
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 16:32:49
User entered '0'	(b) (4), (b) (6)	08 Sep 2020 23:29:22

**US3632052**

**Folder: Screening**

**Form: Medical History (6)**

**Generated On: 10 Jun 2021 09:13:35**

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:07:42
User signature succeeded.	Colleen Kelley (b) (4)	15 Mar 2021 12:20:23
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 16:32:52
User entered 'Yes (Y)'	(b) (4), (b) (6)	08 Sep 2020 23:29:22

**US3632052**

**Folder: Screening**

**Form: Medical History (6)**

**Generated On: 10 Jun 2021 09:13:35**

[If No, please specify the stop date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:07:42
User signature succeeded.	Colleen Kelley (b) (4)	15 Mar 2021 12:20:23
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 16:32:56
User entered empty.	(b) (4), (b) (6)	08 Sep 2020 23:29:22

**US3632052**

**Folder: Screening**

**Form: Medical History (6)**

**Generated On: 10 Jun 2021 09:13:35**

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:07:42
User signature succeeded.	Colleen Kelley (b) (4)	15 Mar 2021 12:20:23
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 16:33:00
User entered '0'	(b) (4), (b) (6)	08 Sep 2020 23:29:22

**US3632052**

**Folder: Screening**

**Form: Medical History (6)**

**Generated On: 10 Jun 2021 09:13:35**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:07:42
User entered 'Jan 2016'	System	08 Sep 2020 23:29:22

**US3632052**

**Folder: Screening**

**Form: Medical History (6)**

**Generated On: 10 Jun 2021 09:13:35**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:07:42
User entered '2016'	System	08 Sep 2020 23:29:22



**US3632052**

**Folder: Screening**

**Form: Medical History (6)**

**Generated On: 10 Jun 2021 09:13:35**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:07:42
User entered empty.	System	08 Sep 2020 23:29:22

**US3632052**

**Folder: Screening**

**Form: Medical History (6)**

**Generated On: 10 Jun 2021 09:13:35**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:07:42
User entered empty.	System	08 Sep 2020 23:29:22

**US3632052**

**Folder: Screening**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 09:13:35**

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:07:42
User signature succeeded.	Colleen Kelley (b) (4)	15 Mar 2021 12:20:23
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	19 Nov 2020 16:35:30
User entered 'Yes (Y)'	(b) (4), (b) (6)	08 Sep 2020 23:31:20

**US3632052**

**Folder: Screening**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 09:13:35**

**Date of assessment** (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:07:42
User signature succeeded.	Colleen Kelley (b) (4)	15 Mar 2021 12:20:23
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 16:35:30
User entered '8 Sep 2020'	(b) (4), (b) (6)	08 Sep 2020 23:31:20

**US3632052**

**Folder: Screening**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 09:13:35**

[Time of assessment \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:07:42
User signature succeeded.	Colleen Kelley (b) (4)	15 Mar 2021 12:20:23
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 16:35:30
User entered '08:40' reason for change: Data Entry Error	(b) (4), (b) (6)	09 Sep 2020 13:35:09
User entered '08:00'	(b) (4), (b) (6)	08 Sep 2020 23:31:20

**US3632052**

**Folder: Screening**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 09:13:35**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:07:42
User entered '8 Sep 2020 08:40'	System	09 Sep 2020 13:35:09
User entered '8 Sep 2020 08:00'	System	08 Sep 2020 23:31:20

US3632052

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 09:13:35

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:07:42
User signature succeeded.	Colleen Kelley (b) (4)	15 Mar 2021 12:20:23
DataPoint Verified.	(b) (4)	19 Nov 2020 16:35:30
User entered '176' cm	(b) (4), (b) (6)	08 Sep 2020 23:31:20
DataPoint set to visible.	System	08 Sep 2020 15:11:59

US3632052

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 09:13:35

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:07:42
User signature succeeded.	Colleen Kelley (b) (4)	15 Mar 2021 12:20:23
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	19 Nov 2020 16:35:30
User entered '95' kg	(b) (4), (b) (6)	08 Sep 2020 23:31:20
DataPoint set to visible.	System	08 Sep 2020 15:11:59



**US3632052**

**Folder: Screening**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 09:13:35**

**BMI (xxx.x)**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:07:42
User entered '30.66890'	System	08 Sep 2020 23:31:20
DataPoint set to visible.	System	08 Sep 2020 15:11:59

**US3632052**

**Folder: Screening**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 09:13:35**

[BMI units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:07:42
User entered 'kg/m2'	System	08 Sep 2020 23:31:20
DataPoint set to visible.	System	08 Sep 2020 15:11:59

**US3632052**

**Folder: Screening**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 09:13:35**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:07:42
User signature succeeded.	Colleen Kelley (b) (4)	15 Mar 2021 12:20:23
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 16:35:30
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4), (b) (6)	11 Sep 2020 14:56:44
User entered '36.9' C	(b) (4), (b) (6)	08 Sep 2020 23:31:20

**US3632052**

**Folder: Screening**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 09:13:35**

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:07:42
User signature succeeded.	Colleen Kelley (b) (4)	15 Mar 2021 12:20:23
DataPoint Verified.	(b) (4)	19 Nov 2020 16:35:30
User entered empty; reason for change Data Entry Error	(b) (4), (b) (6)	11 Sep 2020 14:56:44
User entered 'Oral (Oral)'	(b) (4), (b) (6)	08 Sep 2020 23:31:20

**US3632052**

**Folder: Screening**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 09:13:35**

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:07:42
User signature succeeded.	Colleen Kelley (b) (4)	15 Mar 2021 12:20:23
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 16:35:30
User entered empty.	(b) (4), (b) (6)	08 Sep 2020 23:31:20

**US3632052**

**Folder: Screening**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 09:13:35**

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:07:42
User signature succeeded.	Colleen Kelley (b) (4)	15 Mar 2021 12:20:23
DataPoint Verified.	(b) (4)	19 Nov 2020 16:35:30
User entered missing code ND - Not Done; reason for	(b) (4), (b) (6)	11 Sep 2020 14:56:44
change Data Entry Error		
User entered '74'	(b) (4), (b) (6)	08 Sep 2020 23:31:20

**US3632052**

**Folder: Screening**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 09:13:35**

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:07:42
User entered 'bpm'	System	08 Sep 2020 23:31:20

US3632052

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 09:13:35

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:07:42
User signature succeeded.	Colleen Kelley (b) (4)	15 Mar 2021 12:20:23
DataPoint Verified.	(b) (4)	19 Nov 2020 16:35:30
User entered missing code ND - Not Done; reason for	(b) (4), (b) (6)	11 Sep 2020 14:56:44
change Data Entry Error		
User entered '16'	(b) (4), (b) (6)	08 Sep 2020 23:31:20



US3632052

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 09:13:35

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:07:42
User entered 'breaths/min'	System	08 Sep 2020 23:31:20

**US3632052**

**Folder: Screening**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 09:13:35**

[Systolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:07:42
User signature succeeded.	Colleen Kelley (b) (4)	15 Mar 2021 12:20:23
DataPoint Verified.	(b) (4)	19 Nov 2020 16:35:30
User entered missing code ND - Not Done; reason for	(b) (4), (b) (6)	11 Sep 2020 14:56:44
change Data Entry Error		
User entered '134'	(b) (4), (b) (6)	08 Sep 2020 23:31:20

**US3632052**

**Folder: Screening**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 09:13:35**

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:07:42
User entered 'mmHg'	System	08 Sep 2020 23:31:20

**US3632052**

**Folder: Screening**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 09:13:35**

[Diastolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:07:42
User signature succeeded.	Colleen Kelley (b) (4)	15 Mar 2021 12:20:23
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 16:35:30
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4), (b) (6)	11 Sep 2020 14:56:44
User entered '81'	(b) (4), (b) (6)	08 Sep 2020 23:31:20

**US3632052**

**Folder: Screening**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 09:13:35**

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:07:42
User entered 'mmHg'	System	08 Sep 2020 23:31:20

US3632052

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 09:13:35

Height (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:07:42

**US3632052**

**Folder: Screening**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 09:13:35**

[Weight \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:07:42

**US3632052**

**Folder: Screening**

**Form: Physical Examination**

**Generated On: 10 Jun 2021 09:13:35**

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:07:42
User signature succeeded.	Colleen Kelley (b) (4)	15 Mar 2021 12:20:23
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 16:37:13
User entered 'Yes (Y)'	(b) (4), (b) (6)	08 Sep 2020 23:31:28



**US3632052**

**Folder: Screening**

**Form: Physical Examination**

**Generated On: 10 Jun 2021 09:13:35**

**Date of examination (dd MMM yyyy)**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:07:42
User signature succeeded.	Colleen Kelley (b) (4)	15 Mar 2021 12:20:23
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 16:37:13
User entered '8 Sep 2020'	(b) (4), (b) (6)	08 Sep 2020 23:31:28

US3632052

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 09:13:35

[Healthcare workers](#) (e.g., doctors, nurses, dentists, hospital support staff, morgue/mortuary workers)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:07:42
User signature succeeded.	Colleen Kelley (b) (4)	15 Mar 2021 12:20:23
DataPoint Verified.	(b) (4)	19 Nov 2020 16:42:45
User entered 'No (N)'	(b) (4), (b) (6)	08 Sep 2020 23:32:47

US3632052

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 09:13:35

**Emergency Response** (e.g., Law enforcement officers, Firefighters, emergency medical service workers)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:07:42
User signature succeeded.	Colleen Kelley (b) (4)	15 Mar 2021 12:20:23
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 16:42:45
User entered 'No (N)'	(b) (4), (b) (6)	08 Sep 2020 23:32:47

US3632052

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 09:13:35

**Retail or Restaurant Operations**, particularly those in critical and/high-customer volume (e.g., grocery, convenience, hardware, big-box stores)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:07:42
User signature succeeded.	Colleen Kelley (b) (4)	15 Mar 2021 12:20:23
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 16:42:45
User entered 'No (N)'	(b) (4), (b) (6)	08 Sep 2020 23:32:47

US3632052

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 09:13:35

**Manufacturing & Production Operations** with inherent overcrowding (e.g., factory workers, meat/food processing plants)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:07:42
User signature succeeded.	Colleen Kelley (b) (4)	15 Mar 2021 12:20:23
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 16:37:39
User entered 'Yes (Y)'	(b) (4), (b) (6)	08 Sep 2020 23:32:47

US3632052

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 09:13:35

[Warehouse shipping and fulfillment centers and jobs \(e.g., Amazon facilities\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:07:42
User signature succeeded.	Colleen Kelley (b) (4)	15 Mar 2021 12:20:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Nov 2020 16:42:45
User entered 'No (N)'	(b) (4), (b) (6)	08 Sep 2020 23:32:47

US3632052

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 09:13:35

[Transportation and delivery services](#) (e.g., airlines, public transit, taxi/UBER, fed ex/UPS, postal workers)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:07:42
User signature succeeded.	Colleen Kelley (b) (4)	15 Mar 2021 12:20:23
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 16:42:45
User entered 'No (N)'	(b) (4), (b) (6)	08 Sep 2020 23:32:47

US3632052

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 09:13:35

**Border Protection and Military Personnel** (e.g., TSA, custom and border protection agents, military personnel not social distancing)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:07:42
User signature succeeded.	Colleen Kelley (b) (4)	15 Mar 2021 12:20:23
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 16:42:45
User entered 'No (N)'	(b) (4), (b) (6)	08 Sep 2020 23:32:47



US3632052

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 09:13:35

[Personal Care and in-home services](#) (e.g., barber/salon/spa, in-home repair services, electricians, plumbers, janitorial services)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:07:42
User signature succeeded.	Colleen Kelley (b) (4)	15 Mar 2021 12:20:23
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 16:42:45
User entered 'No (N)'	(b) (4), (b) (6)	08 Sep 2020 23:32:47

US3632052

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 09:13:35

[Hospitality and Tourism Workers](#) (e.g., hotel, casino, amusement/theme park, entertainment, ski resorts)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:07:42
User signature succeeded.	Colleen Kelley (b) (4)	15 Mar 2021 12:20:23
DataPoint Verified.	(b) (4)	19 Nov 2020 16:42:45
User entered 'No (N)'	(b) (4), (b) (6)	08 Sep 2020 23:32:47

US3632052

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 09:13:35

**Pastoral, Social or Public Health Workers** requiring frequent contact with community members (e.g., social workers, volunteers, religious clergy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:07:42
User signature succeeded.	Colleen Kelley (b) (4)	15 Mar 2021 12:20:23
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 16:42:45
User entered 'No (N)'	(b) (4), (b) (6)	08 Sep 2020 23:32:47

US3632052

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 09:13:35

**Educators and Students** (e.g., teachers, administrators, support staff, and students interacting in face-to-face school setting)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:07:42
User signature succeeded.	Colleen Kelley (b) (4)	15 Mar 2021 12:20:23
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 16:42:45
User entered 'No (N)'	(b) (4), (b) (6)	08 Sep 2020 23:32:47

US3632052

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 09:13:35

Other

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:07:42
User signature succeeded.	Colleen Kelley (b) (4)	15 Mar 2021 12:20:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Nov 2020 16:42:45
User closed query 'Data is required. Please complete.' (Site from System).	System	08 Sep 2020 23:33:01
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	08 Sep 2020 23:33:01
User entered 'No (N)' reason for change: New Information	(b) (4), (b) (6)	08 Sep 2020 23:33:01
User opened query 'Data is required. Please complete.' (Site from System).	System	08 Sep 2020 23:32:47
User entered empty.	(b) (4), (b) (6)	08 Sep 2020 23:32:47

US3632052

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 09:13:35

[Specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:07:42
User signature succeeded.	Colleen Kelley (b) (4)	15 Mar 2021 12:20:23
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 16:42:45
User entered empty.	(b) (4), (b) (6)	08 Sep 2020 23:32:47

**US3632052**

**Folder: Screening**

**Form: Risk of Exposure**

**Generated On: 10 Jun 2021 09:13:35**

**No Risk Identified**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:07:42
User signature succeeded.	Colleen Kelley (b) (4)	15 Mar 2021 12:20:23
User entered '0'	(b) (4), (b) (6)	08 Sep 2020 23:32:47

US3632052

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 09:13:35

[Resides in Nursing Home or Assisted Living Facility](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:07:42
User signature succeeded.	Colleen Kelley (b) (4)	15 Mar 2021 12:20:23
DataPoint Verified.	(b) (4)	19 Nov 2020 16:42:45
User entered '0'	(b) (4), (b) (6)	08 Sep 2020 23:32:47



US3632052

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 09:13:35

**Resides in Multi-family dwelling** (e.g., cohabitation in dwelling with > 5 people, includes grandparents living with children < 18yrs)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:07:42
User signature succeeded.	Colleen Kelley (b) (4)	15 Mar 2021 12:20:23
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 16:42:45
User entered '0'	(b) (4), (b) (6)	08 Sep 2020 23:32:47

US3632052

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 09:13:35

[Resides in high density housing](#) (e.g., high rise apartments with shared entrances or elevators)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:07:42
User signature succeeded.	Colleen Kelley (b) (4)	15 Mar 2021 12:20:23
DataPoint Verified.	(b) (4)	19 Nov 2020 16:42:45
User entered '0'	(b) (4), (b) (6)	08 Sep 2020 23:32:47

US3632052

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 09:13:35

**Resides in low density, multi-family setting without** (e.g., apartments complex without shared entrances or elevators, duplexes)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:07:42
User signature succeeded.	Colleen Kelley (b) (4)	15 Mar 2021 12:20:23
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 18:58:18
DataPoint Un-verified.	(b) (4), (b) (6)	19 Nov 2020 16:42:53
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 16:42:45
User entered '0'	(b) (4), (b) (6)	08 Sep 2020 23:32:47

US3632052

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 09:13:35

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:07:42
User signature succeeded.	Colleen Kelley (b) (4)	15 Mar 2021 12:20:23
Query 'This living circumstance risk is not listed in source. Please verify whether this risk is applicable and add note in source if it is.' canceled (Site from CRA).	(b) (4) (b) (4), (b) (6)	19 Nov 2020 19:00:32
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 19:00:30
User opened query 'This living circumstance risk is not listed in source. Please verify whether this risk is applicable and add note in source if it is.' (Site from CRA).	(b) (4), (b) (6)	19 Nov 2020 16:45:40
DataPoint Un-verified.	(b) (4), (b) (6)	19 Nov 2020 16:42:57
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 16:42:45
User entered 'I'	(b) (4), (b) (6)	08 Sep 2020 23:32:47

**US3632052**

**Folder: Screening**

**Form: Risk of Exposure**

**Generated On: 10 Jun 2021 09:13:35**

**Other**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:07:42
User signature succeeded.	Colleen Kelley (b) (4)	15 Mar 2021 12:20:23
User entered 'I'	(b) (4), (b) (6)	08 Sep 2020 23:32:47

US3632052

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 09:13:35

[Specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:07:42
User signature succeeded.	Colleen Kelley (b) (4)	15 Mar 2021 12:20:23
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 16:42:45
User entered 'Errands, groceries, restaurants'	(b) (4), (b) (6)	08 Sep 2020 23:32:47

US3632052

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 10 Jun 2021 09:13:35

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:19:13
User signature succeeded.	Colleen Kelley (b) (4)	08 Mar 2021 14:31:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Nov 2020 16:46:28
User closed query 'Data is required. Please complete.' (Site from System).	System	08 Sep 2020 15:10:05
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	08 Sep 2020 15:10:05
User entered 'Yes (Y)' reason for change: Data Entry Error	Kelly Likos (b) (4) (b) (4)	08 Sep 2020 15:10:05
User opened query 'Data is required. Please complete.' (Site from System).	System	08 Sep 2020 15:09:57
User entered empty.	Kelly Likos (b) (4) (b) (4)	08 Sep 2020 15:09:57

**US3632052**

**Folder: Visit 1 Day 1**

**Form: Visit Date**

**Generated On: 10 Jun 2021 09:13:35**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:19:13
User signature succeeded.	Colleen Kelley (b) (4)	08 Mar 2021 14:31:04
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	19 Nov 2020 16:46:28
User entered '08 Sep 2020'	Kelly Likos (b) (4)	08 Sep 2020 15:09:57
	(b) (4)	



**US3632052**

**Folder: Visit 1 Day 1**

**Form: Visit Date**

**Generated On: 10 Jun 2021 09:13:35**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:19:13
User signature succeeded.	Colleen Kelley (b) (4)	08 Mar 2021 14:31:04
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	19 Nov 2020 16:46:28
User entered 'Clinic (Clinic)'	Kelly Likos (b) (4)	08 Sep 2020 15:09:57
	(b) (4)	

US3632052

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 10 Jun 2021 09:13:35

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:19:13
User entered 'VISIT1'	System	08 Sep 2020 15:10:05
User entered empty.	System	08 Sep 2020 15:09:57

US3632052

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 10 Jun 2021 09:13:35

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:19:13
User signature succeeded.	Colleen Kelley (b) (4)	08 Mar 2021 14:31:04
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	19 Nov 2020 16:47:15
User entered '08 SEP 2020'	RWS_ENDPOINT ENDPOINT (b) (4)	08 Sep 2020 13:40:01

US3632052

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 10 Jun 2021 09:13:35

[What was the participant's randomization number?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:19:13
User signature succeeded.	Colleen Kelley (b) (4)	08 Mar 2021 14:31:04
DataPoint Verified.	(b) (4)	19 Nov 2020 16:47:15
User entered '111919'	RWS_ENDPOINT ENDPOINT (b) (4)	08 Sep 2020 13:40:01

US3632052

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 10 Jun 2021 09:13:35

[In what Cohort was the participant enrolled?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:19:13
User signature succeeded.	Colleen Kelley (b) (4)	08 Mar 2021 14:31:04
DataPoint Verified.	(b) (4)	19 Nov 2020 16:47:15
User entered '>=18 and <65 years and not at risk (1)'	RWS_ENDPOINT ENDPOINT (b) (4)	08 Sep 2020 13:40:01

US3632052

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 10 Jun 2021 09:13:35

Chronic lung disease (eg, emphysema and chronic bronchitis, idiopathic pulmonary fibrosis and cystic fibrosis, or moderate to severe asthma)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:19:13
User signature succeeded.	Colleen Kelley (b) (4)	08 Mar 2021 14:31:04
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 16:47:15
User entered 'No (N)'	Kelly Likos (b) (4)	08 Sep 2020 15:10:30

US3632052

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 10 Jun 2021 09:13:35

Significant cardiac disease (eg, heart failure, coronary artery disease, congenital heart disease, cardiomyopathies, and pulmonary hypertension)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:19:13
User signature succeeded.	Colleen Kelley (b) (4)	08 Mar 2021 14:31:04
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 16:47:15
User entered 'No (N)'	Kelly Likos (b) (4)	08 Sep 2020 15:10:30

US3632052

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 10 Jun 2021 09:13:35

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:19:13
User signature succeeded.	Colleen Kelley (b) (4)	08 Mar 2021 14:31:04
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	19 Nov 2020 16:47:15
User entered 'No (N)'	Kelly Likos (b) (4)	08 Sep 2020 15:10:30
	(b) (4)	



**US3632052**

**Folder: Visit 1 Day 1**

**Form: Randomization**

**Generated On: 10 Jun 2021 09:13:35**

[Diabetes \(Type I, Type 2, or gestational\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:19:13
User signature succeeded.	Colleen Kelley (b) (4)	08 Mar 2021 14:31:04
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	19 Nov 2020 16:47:15
User entered 'No (N)'	Kelly Likos (b) (4)	08 Sep 2020 15:10:30
	(b) (4)	

**US3632052**

**Folder: Visit 1 Day 1**

**Form: Randomization**

**Generated On: 10 Jun 2021 09:13:35**

[Liver Disease](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:19:13
User signature succeeded.	Colleen Kelley (b) (4)	08 Mar 2021 14:31:04
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 16:47:15
User entered 'No (N)'	Kelly Likos (b) (4)	08 Sep 2020 15:10:30

**US3632052**

**Folder: Visit 1 Day 1**

**Form: Randomization**

**Generated On: 10 Jun 2021 09:13:35**

[Human Immunodeficiency Virus \(HIV\) infection](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:19:13
User signature succeeded.	Colleen Kelley (b) (4)	08 Mar 2021 14:31:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Nov 2020 16:47:15
User entered 'No (N)'	Kelly Likos (b) (4)	08 Oct 2020 20:02:49
Amendment Manager: DataPoint set to visible.	(b) (4) System	19 Sep 2020 05:35:57
Amendment Manager inserted this DataPoint.	System	19 Sep 2020 05:35:55

**US3632052**

**Folder: Visit 1 Day 1**

**Form: Vital Signs - Dosing**

**Generated On: 10 Jun 2021 09:13:35**

[Height](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:19:13
User signature succeeded.	Colleen Kelley (b) (4)	08 Mar 2021 14:31:04
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 16:35:36
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4), (b) (6)	11 Sep 2020 14:56:20
User entered '176' cm	(b) (4), (b) (6)	08 Sep 2020 23:05:22

US3632052

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 10 Jun 2021 09:13:35

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:19:13
User signature succeeded.	Colleen Kelley (b) (4)	08 Mar 2021 14:31:04
DataPoint Verified.	(b) (4)	19 Nov 2020 16:35:42
User entered missing code ND - Not Done; reason for	(b) (4), (b) (6)	11 Sep 2020 14:56:20
change Data Entry Error		
User entered '95' kg	(b) (4), (b) (6)	08 Sep 2020 23:05:22

**US3632052**

**Folder: Visit 1 Day 1**

**Form: Vital Signs - Dosing**

**Generated On: 10 Jun 2021 09:13:35**

[Height](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:19:13
User signature succeeded.	Colleen Kelley (b) (4)	08 Mar 2021 14:31:04
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 16:35:36
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4), (b) (6)	11 Sep 2020 14:56:20
User entered '176' cm	(b) (4), (b) (6)	08 Sep 2020 23:05:22

**US3632052**

**Folder: Visit 1 Day 1**

**Form: Vital Signs - Dosing**

**Generated On: 10 Jun 2021 09:13:35**

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:19:13
User signature succeeded.	Colleen Kelley (b) (4)	08 Mar 2021 14:31:04
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	19 Nov 2020 16:35:42
User entered missing code ND - Not Done; reason for	(b) (4), (b) (6)	11 Sep 2020 14:56:20
change Data Entry Error		
User entered '95' kg	(b) (4), (b) (6)	08 Sep 2020 23:05:22

US3632052

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:13:35

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:19:13
User accepted default value 'Pre-Dose (PREDOSE)'	(b) (4), (b) (6)	08 Sep 2020 23:05:22



US3632052

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:13:35

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:19:13
User signature succeeded.	Colleen Kelley (b) (4)	08 Mar 2021 14:31:04
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 16:35:46
User entered 'Yes (Y)'	(b) (4), (b) (6)	08 Sep 2020 23:05:22

**US3632052**

**Folder: Visit 1 Day 1**

**Form: Vital Signs - Dosing (1)**

**Generated On: 10 Jun 2021 09:13:35**

**Date of assessment** (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:19:13
User signature succeeded.	Colleen Kelley (b) (4)	08 Mar 2021 14:31:04
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 16:35:53
User entered '8 Sep 2020'	(b) (4), (b) (6)	08 Sep 2020 23:05:22

**US3632052**

**Folder: Visit 1 Day 1**

**Form: Vital Signs - Dosing (1)**

**Generated On: 10 Jun 2021 09:13:35**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:19:13
User signature succeeded.	Colleen Kelley (b) (4)	08 Mar 2021 14:31:04
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 16:35:57
User entered '08:40'	(b) (4), (b) (6)	08 Sep 2020 23:05:22

US3632052

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:13:35

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:19:13
User entered '8 Sep 2020 08:40'	System	08 Sep 2020 23:05:22

US3632052

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:13:35

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:19:13
User signature succeeded.	Colleen Kelley (b) (4)	08 Mar 2021 14:31:04
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 16:36:00
User entered '36.9' C	(b) (4), (b) (6)	08 Sep 2020 23:05:22

**US3632052**

**Folder: Visit 1 Day 1**

**Form: Vital Signs - Dosing (1)**

**Generated On: 10 Jun 2021 09:13:35**

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:19:13
User signature succeeded.	Colleen Kelley (b) (4)	08 Mar 2021 14:31:04
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 16:36:04
User entered 'Oral (Oral)'	(b) (4), (b) (6)	08 Sep 2020 23:05:22

**US3632052**

**Folder: Visit 1 Day 1**

**Form: Vital Signs - Dosing (1)**

**Generated On: 10 Jun 2021 09:13:35**

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:19:13
User signature succeeded.	Colleen Kelley (b) (4)	08 Mar 2021 14:31:04
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 16:36:08
User entered empty.	(b) (4), (b) (6)	08 Sep 2020 23:05:22

US3632052

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:13:35

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:19:13
User signature succeeded.	Colleen Kelley (b) (4)	08 Mar 2021 14:31:04
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 16:36:11
User entered '74'	(b) (4), (b) (6)	08 Sep 2020 23:05:22



US3632052

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:13:35

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:19:13
User entered 'bpm'	System	08 Sep 2020 23:05:22

US3632052

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:13:35

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:19:13
User signature succeeded.	Colleen Kelley (b) (4)	08 Mar 2021 14:31:04
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 16:36:14
User entered '16'	(b) (4), (b) (6)	08 Sep 2020 23:05:22

US3632052

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:13:35

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:19:13
User entered 'breaths/min'	System	08 Sep 2020 23:05:22

US3632052

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:13:35

[Systolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:19:13
User signature succeeded.	Colleen Kelley (b) (4)	08 Mar 2021 14:31:04
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 16:36:17
User entered '134'	(b) (4), (b) (6)	08 Sep 2020 23:05:22

**US3632052**

**Folder: Visit 1 Day 1**

**Form: Vital Signs - Dosing (1)**

**Generated On: 10 Jun 2021 09:13:35**

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:19:13
User entered 'mmHg'	System	08 Sep 2020 23:05:22

US3632052

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:13:35

[Diastolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:19:13
User signature succeeded.	Colleen Kelley (b) (4)	08 Mar 2021 14:31:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Nov 2020 16:36:22
User entered '81'	(b) (4), (b) (6)	08 Sep 2020 23:05:22

US3632052

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:13:35

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:19:13
User entered 'mmHg'	System	08 Sep 2020 23:05:22

**US3632052**

**Folder: Visit 1 Day 1**

**Form: Vital Signs - Dosing**

**Generated On: 10 Jun 2021 09:13:35**

[Height](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:19:13
User signature succeeded.	Colleen Kelley (b) (4)	08 Mar 2021 14:31:04
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	19 Nov 2020 16:35:36
User entered missing code ND - Not Done; reason for	(b) (4), (b) (6)	11 Sep 2020 14:56:20
change Data Entry Error		
User entered '176' cm	(b) (4), (b) (6)	08 Sep 2020 23:05:22



US3632052

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 10 Jun 2021 09:13:35

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:19:13
User signature succeeded.	Colleen Kelley (b) (4)	08 Mar 2021 14:31:04
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	19 Nov 2020 16:35:42
User entered missing code ND - Not Done; reason for	(b) (4), (b) (6)	11 Sep 2020 14:56:20
change Data Entry Error		
User entered '95' kg	(b) (4), (b) (6)	08 Sep 2020 23:05:22

US3632052

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:13:35

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:19:13
User accepted default value 'Post-Dose (POSTDOSE)'	(b) (4), (b) (6)	08 Sep 2020 23:05:22

US3632052

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:13:35

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:19:13
User signature succeeded.	Colleen Kelley (b) (4)	08 Mar 2021 14:31:04
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	19 Nov 2020 16:49:39
User entered 'Yes (Y)'	(b) (4), (b) (6)	08 Sep 2020 23:05:22

**US3632052**

**Folder: Visit 1 Day 1**

**Form: Vital Signs - Dosing (2)**

**Generated On: 10 Jun 2021 09:13:35**

**Date of assessment** (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:19:13
User signature succeeded.	Colleen Kelley (b) (4)	08 Mar 2021 14:31:04
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 16:49:43
User entered '8 Sep 2020'	(b) (4), (b) (6)	08 Sep 2020 23:05:22

**US3632052**

**Folder: Visit 1 Day 1**

**Form: Vital Signs - Dosing (2)**

**Generated On: 10 Jun 2021 09:13:35**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:19:13
User signature succeeded.	Colleen Kelley (b) (4)	08 Mar 2021 14:31:04
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 16:49:55
User entered '11:38'	(b) (4), (b) (6)	08 Sep 2020 23:05:22

US3632052

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:13:35

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:19:13
User entered '8 Sep 2020 11:38'	System	08 Sep 2020 23:05:22

US3632052

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:13:35

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:19:13
User signature succeeded.	Colleen Kelley (b) (4)	08 Mar 2021 14:31:04
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 16:49:59
User closed query 'Temperature reported is out of range < 36C (96.8 F) per protocol considered grade 3. Please indicate if CS/NCS and report as AE, if appropriate.' (Site from System).	(b) (4), (b) (6)	22 Sep 2020 10:20:24
Query 'Temperature reported is out of range < 36C (96.8 F) per protocol considered grade 3. Please indicate if CS/NCS and report as AE, if appropriate.' answered with 'Temperature was assessed as NCS.' (Site from System).	Isaac Perez (b) (4)	21 Sep 2020 19:45:35
Amendment Manager: User opened query 'Temperature reported is out of range < 36C (96.8 F) per protocol considered grade 3. Please indicate if CS/NCS and report as AE, if appropriate.' (Site from System).	System	17 Sep 2020 00:29:52
User entered '35.6' C	(b) (4), (b) (6)	08 Sep 2020 23:05:22

**US3632052**

**Folder: Visit 1 Day 1**

**Form: Vital Signs - Dosing (2)**

**Generated On: 10 Jun 2021 09:13:35**

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:19:13
User signature succeeded.	Colleen Kelley (b) (4)	08 Mar 2021 14:31:04
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	19 Nov 2020 16:50:23
User entered 'Oral (Oral)'	(b) (4), (b) (6)	08 Sep 2020 23:05:22



**US3632052**

**Folder: Visit 1 Day 1**

**Form: Vital Signs - Dosing (2)**

**Generated On: 10 Jun 2021 09:13:35**

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:19:13
User signature succeeded.	Colleen Kelley (b) (4)	08 Mar 2021 14:31:04
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 16:50:25
User entered empty.	(b) (4), (b) (6)	08 Sep 2020 23:05:22

**US3632052**

**Folder: Visit 1 Day 1**

**Form: Vital Signs - Dosing (2)**

**Generated On: 10 Jun 2021 09:13:35**

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:19:13
User signature succeeded.	Colleen Kelley (b) (4)	08 Mar 2021 14:31:04
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 16:52:55
User entered '59'	(b) (4), (b) (6)	08 Sep 2020 23:05:22

**US3632052**

**Folder: Visit 1 Day 1**

**Form: Vital Signs - Dosing (2)**

**Generated On: 10 Jun 2021 09:13:35**

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:19:13
User entered 'bpm'	System	08 Sep 2020 23:05:22

US3632052

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:13:35

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:19:13
User signature succeeded.	Colleen Kelley (b) (4)	08 Mar 2021 14:31:04
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 16:53:02
User entered '20'	(b) (4), (b) (6)	08 Sep 2020 23:05:22

US3632052

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:13:35

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:19:13
User entered 'breaths/min'	System	08 Sep 2020 23:05:22

US3632052

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:13:35

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:19:13
User signature succeeded.	Colleen Kelley (b) (4)	08 Mar 2021 14:31:04
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 16:53:06
User closed query 'Systolic Blood Pressure reported is out of range < 80 or > 155 per protocol considered grade 3. Please indicate if CS/NCS and report as AE, if appropriate.' (Site from System).	(b) (4), (b) (6)	10 Sep 2020 14:14:55
Query 'Systolic Blood Pressure reported is out of range < 80 or > 155 per protocol considered grade 3. Please indicate if CS/NCS and report as AE, if appropriate.' answered with 'NCS- Will monitor, take daily medications. Follow-up with PCP ' (Site from System).	(b) (4), (b) (6)	09 Sep 2020 13:36:55
User opened query 'Systolic Blood Pressure reported is out of range < 80 or > 155 per protocol considered grade 3. Please indicate if CS/NCS and report as AE, if appropriate.' (Site from System).	System	08 Sep 2020 23:05:22
User entered '156'	(b) (4), (b) (6)	08 Sep 2020 23:05:22

US3632052

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:13:35

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:19:13
User entered 'mmHg'	System	08 Sep 2020 23:05:22

US3632052

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:13:35

[Diastolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:19:13
User signature succeeded.	Colleen Kelley (b) (4)	08 Mar 2021 14:31:04
DataPoint Verified.	(b) (4)	19 Nov 2020 16:53:11
User entered '87'	(b) (4), (b) (6)	08 Sep 2020 23:05:22



US3632052

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:13:35

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:19:13
User entered 'mmHg'	System	08 Sep 2020 23:05:22

US3632052

Folder: Visit 1 Day 1

Form: Physical Examination

Generated On: 10 Jun 2021 09:13:35

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:19:13
User signature succeeded.	Colleen Kelley (b) (4)	08 Mar 2021 14:31:04
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 16:53:29
User entered 'Yes (Y)'	(b) (4), (b) (6)	08 Sep 2020 23:05:37

US3632052

Folder: Visit 1 Day 1

Form: Physical Examination

Generated On: 10 Jun 2021 09:13:35

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:19:13
User signature succeeded.	Colleen Kelley (b) (4)	08 Mar 2021 14:31:04
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 16:53:29
User entered '8 Sep 2020'	(b) (4), (b) (6)	08 Sep 2020 23:05:37

US3632052

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 10 Jun 2021 09:13:35

[Was study treatment given?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:19:13
User signature succeeded.	Colleen Kelley (b) (4)	08 Mar 2021 14:31:04
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 16:53:44
User entered 'Yes (Y)'	Kelly Likos (b) (4)	08 Sep 2020 15:12:50

**US3632052**

**Folder: Visit 1 Day 1**

**Form: Exposure**

**Generated On: 10 Jun 2021 09:13:35**

[If No, reason not given](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:19:13
User signature succeeded.	Colleen Kelley (b) (4)	08 Mar 2021 14:31:04
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 16:53:51
User entered empty.	Kelly Likos (b) (4)	08 Sep 2020 15:12:50

US3632052

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 10 Jun 2021 09:13:35

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:19:13
User signature succeeded.	Colleen Kelley (b) (4)	08 Mar 2021 14:31:04
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 16:53:51
User entered empty.	Kelly Likos (b) (4)	08 Sep 2020 15:12:50

US3632052

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 10 Jun 2021 09:13:35

[What was the study treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:19:13
User entered 'MRNA-1273 OR PLACEBO'	System	08 Sep 2020 15:12:50

US3632052

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 10 Jun 2021 09:13:35

What was the treatment date? (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:19:13
User signature succeeded.	Colleen Kelley (b) (4)	08 Mar 2021 14:31:04
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 16:53:51
User entered '08 Sep 2020'	Kelly Likos (b) (4)	08 Sep 2020 15:12:50



US3632052

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 10 Jun 2021 09:13:35

[What was the treatment time? \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:19:13
User signature succeeded.	Colleen Kelley (b) (4)	08 Mar 2021 14:31:04
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 16:53:51
User entered '11:02'	Kelly Likos (b) (4)	08 Sep 2020 15:12:50

**US3632052**

**Folder: Visit 1 Day 1**

**Form: Exposure**

**Generated On: 10 Jun 2021 09:13:35**

[Treatment Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:19:13
User entered '08 Sep 2020 11:02'	System	08 Sep 2020 15:12:50

US3632052

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 10 Jun 2021 09:13:35

[Which arm was used to give treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:19:13
User signature succeeded.	Colleen Kelley (b) (4)	08 Mar 2021 14:31:04
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 16:53:51
User entered 'Left Arm (LEFT ARM)'	Kelly Likos (b) (4)	08 Sep 2020 15:12:50

US3632052

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 10 Jun 2021 09:13:35

[What was the frequency of the study treatment dosing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:19:13
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 16:53:51
User entered 'ONCE'	System	08 Sep 2020 15:12:50

US3632052

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 10 Jun 2021 09:13:35

What was the route of administration for the study treatment?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:19:13
User entered 'INTRAMUSCULAR'	System	08 Sep 2020 15:12:50

US3632052

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 09:13:35

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:19:13
User signature succeeded.	Colleen Kelley (b) (4)	08 Mar 2021 14:31:04
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 16:54:15
User entered 'Yes (Y)'	(b) (4), (b) (6)	08 Sep 2020 23:06:28

US3632052

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 09:13:35

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:19:13
User signature succeeded.	Colleen Kelley (b) (4)	08 Mar 2021 14:31:04
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 16:54:15
User entered '8 Sep 2020'	(b) (4), (b) (6)	08 Sep 2020 23:06:28

**US3632052**

**Folder: Visit 1 Day 1**

**Form: Immunogenicity Assessment**

**Generated On: 10 Jun 2021 09:13:35**

[Collection time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:19:13
User signature succeeded.	Colleen Kelley (b) (4)	08 Mar 2021 14:31:04
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 16:54:15
User entered '10:02'	(b) (4), (b) (6)	08 Sep 2020 23:06:28



**US3632052**

**Folder: Visit 1 Day 1**

**Form: Immunogenicity Assessment**

**Generated On: 10 Jun 2021 09:13:35**

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:19:13
User entered '8 Sep 2020 10:02'	System	08 Sep 2020 23:06:28

US3632052

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab

Generated On: 10 Jun 2021 09:13:35

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:19:13
User signature succeeded.	Colleen Kelley (b) (4)	08 Mar 2021 14:31:04
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 16:54:30
User entered '8 Sep 2020' reason for change: New Information	(b) (4), (b) (6)	09 Sep 2020 13:37:41
User entered empty.	(b) (4), (b) (6)	08 Sep 2020 23:07:23

**US3632052**

**Folder: Visit 1 Day 1**

**Form: Central Laboratory - Nasopharyngeal Swab (1)**

**Generated On: 10 Jun 2021 09:13:35**

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:19:13
User accepted default value 'Nasopharyngeal Swab 1 (NASAL1)'	(b) (4), (b) (6)	08 Sep 2020 23:07:23

US3632052

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 10 Jun 2021 09:13:35

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:19:13
User signature succeeded.	Colleen Kelley (b) (4)	08 Mar 2021 14:31:04
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 16:54:40
User entered 'Yes (Y)'	(b) (4), (b) (6)	08 Sep 2020 23:07:23

**US3632052**

**Folder: Visit 1 Day 1**

**Form: Central Laboratory - Nasopharyngeal Swab (1)**

**Generated On: 10 Jun 2021 09:13:35**

[Collection time \(00:00 - 23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:19:13
User signature succeeded.	Colleen Kelley (b) (4)	08 Mar 2021 14:31:04
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 16:54:43
User entered '09:50'	(b) (4), (b) (6)	08 Sep 2020 23:07:23

**US3632052**

**Folder: Visit 1 Day 1**

**Form: Central Laboratory - Nasopharyngeal Swab (1)**

**Generated On: 10 Jun 2021 09:13:35**

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:19:13
User entered '8 Sep 2020 09:50'	System	09 Sep 2020 13:37:41
User entered empty.	System	08 Sep 2020 23:07:23

**US3632052**

**Folder: Visit 1 Day 1**

**Form: Central Laboratory - Nasopharyngeal Swab (2)**

**Generated On: 10 Jun 2021 09:13:35**

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:19:13
User accepted default value 'Nasopharyngeal Swab 2 (NASAL2)'	(b) (4), (b) (6)	09 Sep 2020 13:37:41

**US3632052**

**Folder: Visit 1 Day 1**

**Form: Central Laboratory - Nasopharyngeal Swab (2)**

**Generated On: 10 Jun 2021 09:13:35**

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:19:13
User signature succeeded.	Colleen Kelley (b) (4)	08 Mar 2021 14:31:04
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 16:54:47
User entered 'No (N)'	(b) (4), (b) (6)	09 Sep 2020 13:37:41



**US3632052**

**Folder: Visit 1 Day 1**

**Form: Central Laboratory - Nasopharyngeal Swab (2)**

**Generated On: 10 Jun 2021 09:13:35**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:19:13
User signature succeeded.	Colleen Kelley (b) (4)	08 Mar 2021 14:31:04
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 16:54:50
User entered empty.	(b) (4), (b) (6)	09 Sep 2020 13:37:41

**US3632052**

**Folder: Visit 1 Day 1**

**Form: Central Laboratory - Nasopharyngeal Swab (2)**

**Generated On: 10 Jun 2021 09:13:35**

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:19:13
User entered empty.	System	09 Sep 2020 13:37:41

US3632052

Folder: Visit 1 Day 1

Form: Continuing

Generated On: 10 Jun 2021 09:13:35

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:19:13
User signature succeeded.	Colleen Kelley (b) (4)	08 Mar 2021 14:31:04
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 16:55:04
User entered 'Yes (Y)'	(b) (4), (b) (6)	09 Sep 2020 13:37:45

**US3632052**

**Folder: Visit 1 Day 1**

**Form: Continuing**

**Generated On: 10 Jun 2021 09:13:35**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:19:13
User entered 'I'	System	09 Sep 2020 13:37:45

US3632052

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/1)

Generated On: 10 Jun 2021 09:13:35

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:58:03
Data entry locked.	System	08 Sep 2020 15:12:50
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	08 Sep 2020 15:12:50

US3632052

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/1)

Generated On: 10 Jun 2021 09:13:35

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:58:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (aa5f64f6ca3050f6)', Time: '2020-09-08T11:41:01', User OID: 'PatientReportedOutcome (US3632052)', ODM File OID: '398edcac-7e67-4967-a14b-996de861001b'	System	08 Sep 2020 15:41:30
User entered 'Yes (Y)'	System	08 Sep 2020 15:41:30

US3632052

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/1)

Generated On: 10 Jun 2021 09:13:35

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:58:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (aa5f64f6ca3050f6)', Time: '2020-09-08T11:41:13', User OID: 'PatientReportedOutcome (US3632052)', ODM File OID: '398edcac-7e67-4967-a14b-996de861001b' User entered '96.2'	System	08 Sep 2020 15:41:30
	System	08 Sep 2020 15:41:30

US3632052

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/1)

Generated On: 10 Jun 2021 09:13:35

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:58:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (aa5f64f6ca3050f6)', Time: '2020-09-08T11:41:20', User OID: 'PatientReportedOutcome (US3632052)', ODM File OID: '398edcac-7e67-4967-a14b-996de861001b'	System	08 Sep 2020 15:41:30
User entered 'No (N)'	System	08 Sep 2020 15:41:30



**US3632052**

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(1/1)**

**Generated On: 10 Jun 2021 09:13:35**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:58:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (aa5f64f6ca3050f6)', Time: '2020-09-08T11:41:27', User OID: 'PatientReportedOutcome (US3632052)', ODM File OID: '398edcac-7e67-4967-a14b-996de861001b'	System	08 Sep 2020 15:41:30
User entered '08 Sep 2020 11:41'	System	08 Sep 2020 15:41:30

**US3632052**

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(1/1)**

**Generated On: 10 Jun 2021 09:13:35**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:58:03
User entered '08 Sep 2020 11:22'	System	08 Sep 2020 15:12:50

**US3632052**

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(1/1)**

**Generated On: 10 Jun 2021 09:13:35**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:58:03
User entered '08 Sep 2020 13:52'	System	08 Sep 2020 15:12:50

US3632052

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/2)

Generated On: 10 Jun 2021 09:13:35

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:58:03
Data entry locked.	System	08 Sep 2020 15:12:50
User entered 'Day 1, after vaccination (at home)'	System	08 Sep 2020 15:12:50

US3632052

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/2)

Generated On: 10 Jun 2021 09:13:35

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:58:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (aa5f64f6ca3050f6)', Time: '2020-09-08T15:35:35', User OID: 'PatientReportedOutcome (US3632052)', ODM File OID: 'a1234ea0-06a3-4020-9970-f07d694b243d'	System	08 Sep 2020 19:35:58
User entered 'Yes (Y)'	System	08 Sep 2020 19:35:58

US3632052

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/2)

Generated On: 10 Jun 2021 09:13:35

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:58:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (aa5f64f6ca3050f6)', Time: '2020-09-08T15:35:42', User OID: 'PatientReportedOutcome (US3632052)', ODM File OID: 'a1234ea0-06a3-4020-9970-f07d694b243d' User entered '96.9'	System	08 Sep 2020 19:35:58

US3632052

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/2)

Generated On: 10 Jun 2021 09:13:35

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:58:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (aa5f64f6ca3050f6)', Time: '2020-09-08T15:35:49', User OID: 'PatientReportedOutcome (US3632052)', ODM File OID: 'a1234ea0-06a3-4020-9970-f07d694b243d'	System	08 Sep 2020 19:35:58
User entered 'No (N)'	System	08 Sep 2020 19:35:58

**US3632052**

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(1/2)**

**Generated On: 10 Jun 2021 09:13:35**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:58:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (aa5f64f6ca3050f6)', Time: '2020-09-08T15:35:55', User OID: 'PatientReportedOutcome (US3632052)', ODM File OID: 'a1234ea0-06a3-4020-9970-f07d694b243d'	System	08 Sep 2020 19:35:58
User entered '08 Sep 2020 15:35'	System	08 Sep 2020 19:35:58



**US3632052**

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(1/2)**

**Generated On: 10 Jun 2021 09:13:35**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:58:03
User entered '08 Sep 2020 14:47'	System	08 Sep 2020 15:12:50

**US3632052**

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(1/2)**

**Generated On: 10 Jun 2021 09:13:35**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:58:03
User entered '09 Sep 2020 11:59'	System	08 Sep 2020 15:12:50

US3632052

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(2)

Generated On: 10 Jun 2021 09:13:35

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:58:03
Data entry locked.	System	08 Sep 2020 15:12:50
User entered 'Day 2'	System	08 Sep 2020 15:12:50

US3632052

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(2)

Generated On: 10 Jun 2021 09:13:35

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:58:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (aa5f64f6ca3050f6)', Time: '2020-09-09T21:50:47', User OID: 'PatientReportedOutcome (US3632052)', ODM File OID: '70195e85-855b-4a88-8e23-2bb19f8207db'	System	10 Sep 2020 01:51:16
User entered 'Yes (Y)'	System	10 Sep 2020 01:51:16

US3632052

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(2)

Generated On: 10 Jun 2021 09:13:35

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:58:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (aa5f64f6ca3050f6)', Time: '2020-09-09T21:50:57', User OID: 'PatientReportedOutcome (US3632052)', ODM File OID: '70195e85-855b-4a88-8e23-2bb19f8207db'	System	10 Sep 2020 01:51:16
User entered '96.8'	System	10 Sep 2020 01:51:16

US3632052

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(2)

Generated On: 10 Jun 2021 09:13:35

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:58:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (aa5f64f6ca3050f6)', Time: '2020-09-09T21:51:07', User OID: 'PatientReportedOutcome (US3632052)', ODM File OID: '70195e85-855b-4a88-8e23-2bb19f8207db'	System	10 Sep 2020 01:51:16
User entered 'No (N)'	System	10 Sep 2020 01:51:16

**US3632052**

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(2)**

**Generated On: 10 Jun 2021 09:13:35**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:58:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (aa5f64f6ca3050f6)', Time: '2020-09-09T21:51:13', User OID: 'PatientReportedOutcome (US3632052)', ODM File OID: '70195e85-855b-4a88-8e23-2bb19f8207db'	System	10 Sep 2020 01:51:16
User entered '09 Sep 2020 21:51'	System	10 Sep 2020 01:51:16

**US3632052**

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(2)**

**Generated On: 10 Jun 2021 09:13:35**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:58:03
User entered '09 Sep 2020 12:00'	System	08 Sep 2020 15:12:50



**US3632052**

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(2)**

**Generated On: 10 Jun 2021 09:13:35**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:58:03
User entered '10 Sep 2020 11:59'	System	08 Sep 2020 15:12:50

US3632052

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(3)

Generated On: 10 Jun 2021 09:13:35

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:58:03
Data entry locked.	System	08 Sep 2020 15:12:50
User entered 'Day 3'	System	08 Sep 2020 15:12:50

US3632052

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(3)

Generated On: 10 Jun 2021 09:13:35

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:58:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (aa5f64f6ca3050f6)', Time: '2020-09-10T23:32:05', User OID: 'PatientReportedOutcome (US3632052)', ODM File OID: '35462dab-3361-489a-a897-d5f77cf3a447'	System	11 Sep 2020 03:32:35
User entered 'Yes (Y)'	System	11 Sep 2020 03:32:35

US3632052

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(3)

Generated On: 10 Jun 2021 09:13:35

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:58:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (aa5f64f6ca3050f6)', Time: '2020-09-10T23:32:10', User OID: 'PatientReportedOutcome (US3632052)', ODM File OID: '35462dab-3361-489a-a897-d5f77cf3a447'	System	11 Sep 2020 03:32:35
User entered '96.8'	System	11 Sep 2020 03:32:35

US3632052

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(3)

Generated On: 10 Jun 2021 09:13:35

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:58:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (aa5f64f6ca3050f6)', Time: '2020-09-10T23:32:25', User OID: 'PatientReportedOutcome (US3632052)', ODM File OID: '35462dab-3361-489a-a897-d5f77cf3a447'	System	11 Sep 2020 03:32:35
User entered 'No (N)'	System	11 Sep 2020 03:32:35

**US3632052**

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(3)**

**Generated On: 10 Jun 2021 09:13:35**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:58:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (aa5f64f6ca3050f6)', Time: '2020-09-10T23:32:29', User OID: 'PatientReportedOutcome (US3632052)', ODM File OID: '35462dab-3361-489a-a897-d5f77cf3a447'	System	11 Sep 2020 03:32:35
User entered '10 Sep 2020 23:32'	System	11 Sep 2020 03:32:35

**US3632052**

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(3)**

**Generated On: 10 Jun 2021 09:13:35**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:58:03
User entered '10 Sep 2020 12:00'	System	08 Sep 2020 15:12:50

**US3632052**

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(3)**

**Generated On: 10 Jun 2021 09:13:35**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:58:03
User entered '11 Sep 2020 11:59'	System	08 Sep 2020 15:12:50



US3632052

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(4)

Generated On: 10 Jun 2021 09:13:35

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:58:03
Data entry locked.	System	08 Sep 2020 15:12:50
User entered 'Day 4'	System	08 Sep 2020 15:12:50

US3632052

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(4)

Generated On: 10 Jun 2021 09:13:35

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:58:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (44467b427832a52f)', Time: '2020-09-11T22:25:00', User OID: 'PatientReportedOutcome (US3632052)', ODM File OID: '3250762a-66e5-43f4-9a5c-2f94519f845e'	System	12 Sep 2020 02:30:18
User entered 'Yes (Y)'	System	12 Sep 2020 02:30:18

US3632052

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(4)

Generated On: 10 Jun 2021 09:13:35

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:58:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (44467b427832a52f)', Time: '2020-09-11T22:25:07', User OID: 'PatientReportedOutcome (US3632052)', ODM File OID: '3250762a-66e5-43f4-9a5c-2f94519f845e' User entered '97.0'	System	12 Sep 2020 02:30:18
	System	12 Sep 2020 02:30:18

US3632052

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(4)

Generated On: 10 Jun 2021 09:13:35

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:58:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (44467b427832a52f)', Time: '2020-09-11T22:25:13', User OID: 'PatientReportedOutcome (US3632052)', ODM File OID: '3250762a-66e5-43f4-9a5c-2f94519f845e'	System	12 Sep 2020 02:30:18
User entered 'No (N)'	System	12 Sep 2020 02:30:18

US3632052

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(4)

Generated On: 10 Jun 2021 09:13:35

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:58:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (44467b427832a52f)', Time: '2020-09-11T22:25:16', User OID: 'PatientReportedOutcome (US3632052)', ODM File OID: '3250762a-66e5-43f4-9a5c-2f94519f845e'	System	12 Sep 2020 02:30:18
User entered '11 Sep 2020 22:25'	System	12 Sep 2020 02:30:18

**US3632052**

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(4)**

**Generated On: 10 Jun 2021 09:13:35**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:58:03
User entered '11 Sep 2020 12:00'	System	08 Sep 2020 15:12:50

**US3632052**

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(4)**

**Generated On: 10 Jun 2021 09:13:35**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:58:03
User entered '12 Sep 2020 11:59'	System	08 Sep 2020 15:12:50

US3632052

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(5)

Generated On: 10 Jun 2021 09:13:35

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:58:03
Data entry locked.	System	08 Sep 2020 15:12:50
User entered 'Day 5'	System	08 Sep 2020 15:12:50



US3632052

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(5)

Generated On: 10 Jun 2021 09:13:35

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:58:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (44467b427832a52f)', Time: '2020-09-12T23:39:58', User OID: 'PatientReportedOutcome (US3632052)', ODM File OID: 'df2f20c5-dc92-4148-92a2-928c7ea6e90c'	System	13 Sep 2020 03:40:15
User entered 'Yes (Y)'	System	13 Sep 2020 03:40:15

US3632052

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(5)

Generated On: 10 Jun 2021 09:13:35

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:58:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (44467b427832a52f)', Time: '2020-09-12T23:40:05', User OID: 'PatientReportedOutcome (US3632052)', ODM File OID: 'df2f20c5-dc92-4148-92a2-928c7ea6e90c'	System	13 Sep 2020 03:40:15
User entered '97.0'	System	13 Sep 2020 03:40:15

US3632052

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(5)

Generated On: 10 Jun 2021 09:13:35

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:58:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (44467b427832a52f)', Time: '2020-09-12T23:40:10', User OID: 'PatientReportedOutcome (US3632052)', ODM File OID: 'df2f20c5-dc92-4148-92a2-928c7ea6e90c'	System	13 Sep 2020 03:40:15
User entered 'No (N)'	System	13 Sep 2020 03:40:15

**US3632052**

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(5)**

**Generated On: 10 Jun 2021 09:13:35**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:58:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (44467b427832a52f)', Time: '2020-09-12T23:40:13', User OID: 'PatientReportedOutcome (US3632052)', ODM File OID: 'df2f20c5-dc92-4148-92a2-928c7ea6e90c'	System	13 Sep 2020 03:40:15
User entered '12 Sep 2020 23:40'	System	13 Sep 2020 03:40:15

**US3632052**

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(5)**

**Generated On: 10 Jun 2021 09:13:35**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:58:03
User entered '12 Sep 2020 12:00'	System	08 Sep 2020 15:12:50

**US3632052**

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(5)**

**Generated On: 10 Jun 2021 09:13:35**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:58:03
User entered '13 Sep 2020 11:59'	System	08 Sep 2020 15:12:50

US3632052

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(6)

Generated On: 10 Jun 2021 09:13:35

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:58:03
Data entry locked.	System	08 Sep 2020 15:12:50
User entered 'Day 6'	System	08 Sep 2020 15:12:50

US3632052

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(6)

Generated On: 10 Jun 2021 09:13:35

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:58:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (44467b427832a52f)', Time: '2020-09-13T22:36:41', User OID: 'PatientReportedOutcome (US3632052)', ODM File OID: 'f931c270-22fe-4039-8859-4cde5a46ea3f'	System	14 Sep 2020 02:37:11
User entered 'Yes (Y)'	System	14 Sep 2020 02:37:11



US3632052

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(6)

Generated On: 10 Jun 2021 09:13:35

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:58:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (44467b427832a52f)', Time: '2020-09-13T22:36:56', User OID: 'PatientReportedOutcome (US3632052)', ODM File OID: 'f931c270-22fe-4039-8859-4cde5a46ea3f' User entered '96.7'	System	14 Sep 2020 02:37:11
	System	14 Sep 2020 02:37:11

US3632052

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(6)

Generated On: 10 Jun 2021 09:13:35

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:58:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (44467b427832a52f)', Time: '2020-09-13T22:37:05', User OID: 'PatientReportedOutcome (US3632052)', ODM File OID: 'f931c270-22fe-4039-8859-4cde5a46ea3f'	System	14 Sep 2020 02:37:11
User entered 'No (N)'	System	14 Sep 2020 02:37:11

US3632052

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(6)

Generated On: 10 Jun 2021 09:13:35

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:58:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (44467b427832a52f)', Time: '2020-09-13T22:37:07', User OID: 'PatientReportedOutcome (US3632052)', ODM File OID: 'f931c270-22fe-4039-8859-4cde5a46ea3f'	System	14 Sep 2020 02:37:11
User entered '13 Sep 2020 22:37'	System	14 Sep 2020 02:37:11

**US3632052**

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(6)**

**Generated On: 10 Jun 2021 09:13:35**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:58:03
User entered '13 Sep 2020 12:00'	System	08 Sep 2020 15:12:50

**US3632052**

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(6)**

**Generated On: 10 Jun 2021 09:13:35**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:58:03
User entered '14 Sep 2020 11:59'	System	08 Sep 2020 15:12:50

US3632052

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(7)

Generated On: 10 Jun 2021 09:13:35

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:58:03
Data entry locked.	System	08 Sep 2020 15:12:50
User entered 'Day 7'	System	08 Sep 2020 15:12:50

US3632052

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(7)

Generated On: 10 Jun 2021 09:13:35

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:58:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (44467b427832a52f)', Time: '2020-09-14T23:20:00', User OID: 'PatientReportedOutcome (US3632052)', ODM File OID: '415051c8-226e-4367-aad8-89dd791b7518'	System	15 Sep 2020 03:20:17
User entered 'Yes (Y)'	System	15 Sep 2020 03:20:17

US3632052

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(7)

Generated On: 10 Jun 2021 09:13:35

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:58:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (44467b427832a52f)', Time: '2020-09-14T23:20:07', User OID: 'PatientReportedOutcome (US3632052)', ODM File OID: '415051c8-226e-4367-aad8-89dd791b7518'	System	15 Sep 2020 03:20:17
User entered '97.5'	System	15 Sep 2020 03:20:17



US3632052

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(7)

Generated On: 10 Jun 2021 09:13:35

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:58:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (44467b427832a52f)', Time: '2020-09-14T23:20:13', User OID: 'PatientReportedOutcome (US3632052)', ODM File OID: '415051c8-226e-4367-aad8-89dd791b7518'	System	15 Sep 2020 03:20:17
User entered 'No (N)'	System	15 Sep 2020 03:20:17

**US3632052**

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(7)**

**Generated On: 10 Jun 2021 09:13:35**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:58:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (44467b427832a52f)', Time: '2020-09-14T23:20:15', User OID: 'PatientReportedOutcome (US3632052)', ODM File OID: '415051c8-226e-4367-aad8-89dd791b7518'	System	15 Sep 2020 03:20:17
User entered '14 Sep 2020 23:20'	System	15 Sep 2020 03:20:17

**US3632052**

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(7)**

**Generated On: 10 Jun 2021 09:13:35**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:58:03
User entered '14 Sep 2020 12:00'	System	08 Sep 2020 15:12:50

**US3632052**

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(7)**

**Generated On: 10 Jun 2021 09:13:35**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:58:03
User entered '15 Sep 2020 11:59'	System	08 Sep 2020 15:12:50

US3632052

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/1)

Generated On: 10 Jun 2021 09:13:35

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:58:03
Data entry locked.	System	08 Sep 2020 15:12:50
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	08 Sep 2020 15:12:50

US3632052

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/1)

Generated On: 10 Jun 2021 09:13:35

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 10:58:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (aa5f64f6ca3050f6)', Time: '2020-09-08T11:41:40', User OID: 'PatientReportedOutcome (US3632052)', ODM File OID: '14b8443c-b1c7-4538-9ebe-508aafea7675'	System	08 Sep 2020 15:42:42
User entered 'None (1)'	System	08 Sep 2020 15:42:42

US3632052

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/1)

Generated On: 10 Jun 2021 09:13:35

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:58:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (aa5f64f6ca3050f6)', Time: '2020-09-08T11:42:00', User OID: 'PatientReportedOutcome (US3632052)', ODM File OID: '14b8443c-b1c7-4538-9ebe-508aafea7675'	System	08 Sep 2020 15:42:42
User entered 'No (N)'	System	08 Sep 2020 15:42:42

US3632052

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/1)

Generated On: 10 Jun 2021 09:13:35

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:58:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (aa5f64f6ca3050f6)', Time: '2020-09-08T11:42:16', User OID: 'PatientReportedOutcome (US3632052)', ODM File OID: '14b8443c-b1c7-4538-9ebe-508aafea7675'	System	08 Sep 2020 15:42:42
User entered 'No (N)'	System	08 Sep 2020 15:42:42



US3632052

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/1)

Generated On: 10 Jun 2021 09:13:35

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 10:58:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (aa5f64f6ca3050f6)', Time: '2020-09-08T11:42:32', User OID: 'PatientReportedOutcome (US3632052)', ODM File OID: '14b8443c-b1c7-4538-9ebe-508aafea7675'	System	08 Sep 2020 15:42:42
User entered 'None (1)'	System	08 Sep 2020 15:42:42

**US3632052**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(1/1)**

**Generated On: 10 Jun 2021 09:13:35**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:58:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (aa5f64f6ca3050f6)', Time: '2020-09-08T11:42:39', User OID: 'PatientReportedOutcome (US3632052)', ODM File OID: '14b8443c-b1c7-4538-9ebe-508aafea7675'	System	08 Sep 2020 15:42:42
User entered '08 Sep 2020 11:42'	System	08 Sep 2020 15:42:42

**US3632052**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(1/1)**

**Generated On: 10 Jun 2021 09:13:35**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:58:03
User entered '08 Sep 2020 11:22'	System	08 Sep 2020 15:12:50

**US3632052**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(1/1)**

**Generated On: 10 Jun 2021 09:13:35**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:58:03
User entered '08 Sep 2020 13:52'	System	08 Sep 2020 15:12:50

US3632052

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/2)

Generated On: 10 Jun 2021 09:13:35

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:58:03
Data entry locked.	System	08 Sep 2020 15:12:50
User entered 'Day 1, after vaccination (at home)'	System	08 Sep 2020 15:12:50

US3632052

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/2)

Generated On: 10 Jun 2021 09:13:35

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 10:58:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (aa5f64f6ca3050f6)', Time: '2020-09-08T15:36:11', User OID: 'PatientReportedOutcome (US3632052)', ODM File OID: '1aa5e939-e97a-4143-b299-117e4dcb38d5'	System	08 Sep 2020 19:36:37
User entered 'None (1)'	System	08 Sep 2020 19:36:37

US3632052

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/2)

Generated On: 10 Jun 2021 09:13:35

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:58:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (aa5f64f6ca3050f6)', Time: '2020-09-08T15:36:15', User OID: 'PatientReportedOutcome (US3632052)', ODM File OID: '1aa5e939-e97a-4143-b299-117e4dcb38d5'	System	08 Sep 2020 19:36:37
User entered 'No (N)'	System	08 Sep 2020 19:36:37

US3632052

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/2)

Generated On: 10 Jun 2021 09:13:35

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:58:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (aa5f64f6ca3050f6)', Time: '2020-09-08T15:36:24', User OID: 'PatientReportedOutcome (US3632052)', ODM File OID: '1aa5e939-e97a-4143-b299-117e4dcb38d5'	System	08 Sep 2020 19:36:37
User entered 'No (N)'	System	08 Sep 2020 19:36:37



US3632052

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/2)

Generated On: 10 Jun 2021 09:13:35

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 10:58:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (aa5f64f6ca3050f6)', Time: '2020-09-08T15:36:30', User OID: 'PatientReportedOutcome (US3632052)', ODM File OID: '1aa5e939-e97a-4143-b299-117e4dcb38d5'	System	08 Sep 2020 19:36:37
User entered 'None (1)'	System	08 Sep 2020 19:36:37

**US3632052**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(1/2)**

**Generated On: 10 Jun 2021 09:13:35**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:58:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (aa5f64f6ca3050f6)', Time: '2020-09-08T15:36:34', User OID: 'PatientReportedOutcome (US3632052)', ODM File OID: '1aa5e939-e97a-4143-b299-117e4dcb38d5'	System	08 Sep 2020 19:36:37
User entered '08 Sep 2020 15:36'	System	08 Sep 2020 19:36:37

**US3632052**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(1/2)**

**Generated On: 10 Jun 2021 09:13:35**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:58:03
User entered '08 Sep 2020 14:47'	System	08 Sep 2020 15:12:50

**US3632052**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(1/2)**

**Generated On: 10 Jun 2021 09:13:35**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:58:03
User entered '09 Sep 2020 11:59'	System	08 Sep 2020 15:12:50

US3632052

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(2)

Generated On: 10 Jun 2021 09:13:35

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:58:03
Data entry locked.	System	08 Sep 2020 15:12:50
User entered 'Day 2'	System	08 Sep 2020 15:12:50

US3632052

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(2)

Generated On: 10 Jun 2021 09:13:35

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 10:58:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (aa5f64f6ca3050f6)', Time: '2020-09-09T21:51:46', User OID: 'PatientReportedOutcome (US3632052)', ODM File OID: 'ad1a4f14-4dd6-49a6-8583-c0740d37facd'	System	10 Sep 2020 01:52:10
User entered 'Does not interfere with activity (2)'	System	10 Sep 2020 01:52:10

US3632052

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(2)

Generated On: 10 Jun 2021 09:13:35

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:58:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (aa5f64f6ca3050f6)', Time: '2020-09-09T21:51:51', User OID: 'PatientReportedOutcome (US3632052)', ODM File OID: 'ad1a4f14-4dd6-49a6-8583-c0740d37facd'	System	10 Sep 2020 01:52:10
User entered 'No (N)'	System	10 Sep 2020 01:52:10

US3632052

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(2)

Generated On: 10 Jun 2021 09:13:35

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:58:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (aa5f64f6ca3050f6)', Time: '2020-09-09T21:51:58', User OID: 'PatientReportedOutcome (US3632052)', ODM File OID: 'ad1a4f14-4dd6-49a6-8583-c0740d37facd'	System	10 Sep 2020 01:52:10
User entered 'No (N)'	System	10 Sep 2020 01:52:10



US3632052

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(2)

Generated On: 10 Jun 2021 09:13:35

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 10:58:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (aa5f64f6ca3050f6)', Time: '2020-09-09T21:52:05', User OID: 'PatientReportedOutcome (US3632052)', ODM File OID: 'ad1a4f14-4dd6-49a6-8583-c0740d37facd'	System	10 Sep 2020 01:52:10
User entered 'None (1)'	System	10 Sep 2020 01:52:10

**US3632052**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(2)**

**Generated On: 10 Jun 2021 09:13:35**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:58:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (aa5f64f6ca3050f6)', Time: '2020-09-09T21:52:08', User OID: 'PatientReportedOutcome (US3632052)', ODM File OID: 'ad1a4f14-4dd6-49a6-8583-c0740d37facd'	System	10 Sep 2020 01:52:10
User entered '09 Sep 2020 21:52'	System	10 Sep 2020 01:52:10

**US3632052**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(2)**

**Generated On: 10 Jun 2021 09:13:35**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:58:03
User entered '09 Sep 2020 12:00'	System	08 Sep 2020 15:12:50

**US3632052**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(2)**

**Generated On: 10 Jun 2021 09:13:35**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:58:03
User entered '10 Sep 2020 11:59'	System	08 Sep 2020 15:12:50

US3632052

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(3)

Generated On: 10 Jun 2021 09:13:35

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:58:03
Data entry locked.	System	08 Sep 2020 15:12:50
User entered 'Day 3'	System	08 Sep 2020 15:12:50

US3632052

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(3)

Generated On: 10 Jun 2021 09:13:35

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 10:58:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (aa5f64f6ca3050f6)', Time: '2020-09-10T23:32:46', User OID: 'PatientReportedOutcome (US3632052)', ODM File OID: '4d3db4d8-9cce-4f8f-a26c-160741f8d8b2'	System	11 Sep 2020 03:33:05
User entered 'None (1)'	System	11 Sep 2020 03:33:05

US3632052

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(3)

Generated On: 10 Jun 2021 09:13:35

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:58:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (aa5f64f6ca3050f6)', Time: '2020-09-10T23:32:49', User OID: 'PatientReportedOutcome (US3632052)', ODM File OID: '4d3db4d8-9cce-4f8f-a26c-160741f8d8b2'	System	11 Sep 2020 03:33:05
User entered 'No (N)'	System	11 Sep 2020 03:33:05

US3632052

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(3)

Generated On: 10 Jun 2021 09:13:35

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:58:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (aa5f64f6ca3050f6)', Time: '2020-09-10T23:32:55', User OID: 'PatientReportedOutcome (US3632052)', ODM File OID: '4d3db4d8-9cce-4f8f-a26c-160741f8d8b2'	System	11 Sep 2020 03:33:05
User entered 'No (N)'	System	11 Sep 2020 03:33:05



US3632052

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(3)

Generated On: 10 Jun 2021 09:13:35

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 10:58:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (aa5f64f6ca3050f6)', Time: '2020-09-10T23:32:57', User OID: 'PatientReportedOutcome (US3632052)', ODM File OID: '4d3db4d8-9cce-4f8f-a26c-160741f8d8b2'	System	11 Sep 2020 03:33:05
User entered 'None (1)'	System	11 Sep 2020 03:33:05

US3632052

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(3)

Generated On: 10 Jun 2021 09:13:35

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:58:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (aa5f64f6ca3050f6)', Time: '2020-09-10T23:33:02', User OID: 'PatientReportedOutcome (US3632052)', ODM File OID: '4d3db4d8-9cce-4f8f-a26c-160741f8d8b2'	System	11 Sep 2020 03:33:05
User entered '10 Sep 2020 23:33'	System	11 Sep 2020 03:33:05

**US3632052**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(3)**

**Generated On: 10 Jun 2021 09:13:35**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:58:03
User entered '10 Sep 2020 12:00'	System	08 Sep 2020 15:12:50

**US3632052**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(3)**

**Generated On: 10 Jun 2021 09:13:35**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:58:03
User entered '11 Sep 2020 11:59'	System	08 Sep 2020 15:12:50

US3632052

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(4)

Generated On: 10 Jun 2021 09:13:35

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:58:03
Data entry locked.	System	08 Sep 2020 15:12:50
User entered 'Day 4'	System	08 Sep 2020 15:12:50

US3632052

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(4)

Generated On: 10 Jun 2021 09:13:35

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 10:58:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (44467b427832a52f)', Time: '2020-09-11T22:25:27', User OID: 'PatientReportedOutcome (US3632052)', ODM File OID: '3b0241db-058b-4233-aef5-e24efe03afd8'	System	12 Sep 2020 02:28:41
User entered 'None (1)'	System	12 Sep 2020 02:28:41

US3632052

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(4)

Generated On: 10 Jun 2021 09:13:35

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:58:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (44467b427832a52f)', Time: '2020-09-11T22:25:31', User OID: 'PatientReportedOutcome (US3632052)', ODM File OID: '3b0241db-058b-4233-aef5-e24efe03afd8'	System	12 Sep 2020 02:28:41
User entered 'No (N)'	System	12 Sep 2020 02:28:41

US3632052

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(4)

Generated On: 10 Jun 2021 09:13:35

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:58:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (44467b427832a52f)', Time: '2020-09-11T22:25:35', User OID: 'PatientReportedOutcome (US3632052)', ODM File OID: '3b0241db-058b-4233-aef5-e24efe03afd8'	System	12 Sep 2020 02:28:41
User entered 'No (N)'	System	12 Sep 2020 02:28:41



US3632052

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(4)

Generated On: 10 Jun 2021 09:13:35

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 10:58:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (44467b427832a52f)', Time: '2020-09-11T22:25:39', User OID: 'PatientReportedOutcome (US3632052)', ODM File OID: '3b0241db-058b-4233-aef5-e24efe03afd8'	System	12 Sep 2020 02:28:41
User entered 'None (1)'	System	12 Sep 2020 02:28:41

US3632052

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(4)

Generated On: 10 Jun 2021 09:13:35

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:58:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (44467b427832a52f)', Time: '2020-09-11T22:25:42', User OID: 'PatientReportedOutcome (US3632052)', ODM File OID: '3b0241db-058b-4233-aef5-e24efe03afd8'	System	12 Sep 2020 02:28:41
User entered '11 Sep 2020 22:25'	System	12 Sep 2020 02:28:41

**US3632052**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(4)**

**Generated On: 10 Jun 2021 09:13:35**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:58:03
User entered '11 Sep 2020 12:00'	System	08 Sep 2020 15:12:50

**US3632052**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(4)**

**Generated On: 10 Jun 2021 09:13:35**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:58:03
User entered '12 Sep 2020 11:59'	System	08 Sep 2020 15:12:50

US3632052

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(5)

Generated On: 10 Jun 2021 09:13:35

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:58:03
Data entry locked.	System	08 Sep 2020 15:12:50
User entered 'Day 5'	System	08 Sep 2020 15:12:50

US3632052

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(5)

Generated On: 10 Jun 2021 09:13:35

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 10:58:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (44467b427832a52f)', Time: '2020-09-12T23:40:27', User OID: 'PatientReportedOutcome (US3632052)', ODM File OID: '0dae9746-fa25-4da6-b157-d8f1554655ec'	System	13 Sep 2020 03:40:44
User entered 'None (1)'	System	13 Sep 2020 03:40:44

US3632052

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(5)

Generated On: 10 Jun 2021 09:13:35

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:58:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (44467b427832a52f)', Time: '2020-09-12T23:40:31', User OID: 'PatientReportedOutcome (US3632052)', ODM File OID: '0dae9746-fa25-4da6-b157-d8f1554655ec'	System	13 Sep 2020 03:40:44
User entered 'No (N)'	System	13 Sep 2020 03:40:44

US3632052

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(5)

Generated On: 10 Jun 2021 09:13:35

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:58:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (44467b427832a52f)', Time: '2020-09-12T23:40:34', User OID: 'PatientReportedOutcome (US3632052)', ODM File OID: '0dae9746-fa25-4da6-b157-d8f1554655ec'	System	13 Sep 2020 03:40:44
User entered 'No (N)'	System	13 Sep 2020 03:40:44



US3632052

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(5)

Generated On: 10 Jun 2021 09:13:35

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 10:58:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (44467b427832a52f)', Time: '2020-09-12T23:40:37', User OID: 'PatientReportedOutcome (US3632052)', ODM File OID: '0dae9746-fa25-4da6-b157-d8f1554655ec'	System	13 Sep 2020 03:40:44
User entered 'None (1)'	System	13 Sep 2020 03:40:44

**US3632052**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(5)**

**Generated On: 10 Jun 2021 09:13:35**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:58:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (44467b427832a52f)', Time: '2020-09-12T23:40:40', User OID: 'PatientReportedOutcome (US3632052)', ODM File OID: '0dae9746-fa25-4da6-b157-d8f1554655ec'	System	13 Sep 2020 03:40:44
User entered '12 Sep 2020 23:40'	System	13 Sep 2020 03:40:44

**US3632052**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(5)**

**Generated On: 10 Jun 2021 09:13:35**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:58:03
User entered '12 Sep 2020 12:00'	System	08 Sep 2020 15:12:50

**US3632052**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(5)**

**Generated On: 10 Jun 2021 09:13:35**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:58:03
User entered '13 Sep 2020 11:59'	System	08 Sep 2020 15:12:50

US3632052

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(6)

Generated On: 10 Jun 2021 09:13:35

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:58:03
Data entry locked.	System	08 Sep 2020 15:12:50
User entered 'Day 6'	System	08 Sep 2020 15:12:50

US3632052

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(6)

Generated On: 10 Jun 2021 09:13:35

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 10:58:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (44467b427832a52f)', Time: '2020-09-13T22:37:14', User OID: 'PatientReportedOutcome (US3632052)', ODM File OID: '29f3b0a8-7ab3-42c1-9b8e-691177604386'	System	14 Sep 2020 02:37:35
User entered 'None (1)'	System	14 Sep 2020 02:37:35

US3632052

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(6)

Generated On: 10 Jun 2021 09:13:35

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:58:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (44467b427832a52f)', Time: '2020-09-13T22:37:18', User OID: 'PatientReportedOutcome (US3632052)', ODM File OID: '29f3b0a8-7ab3-42c1-9b8e-691177604386'	System	14 Sep 2020 02:37:35
User entered 'No (N)'	System	14 Sep 2020 02:37:35

US3632052

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(6)

Generated On: 10 Jun 2021 09:13:35

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:58:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (44467b427832a52f)', Time: '2020-09-13T22:37:23', User OID: 'PatientReportedOutcome (US3632052)', ODM File OID: '29f3b0a8-7ab3-42c1-9b8e-691177604386'	System	14 Sep 2020 02:37:35
User entered 'No (N)'	System	14 Sep 2020 02:37:35



US3632052

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(6)

Generated On: 10 Jun 2021 09:13:35

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 10:58:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (44467b427832a52f)', Time: '2020-09-13T22:37:26', User OID: 'PatientReportedOutcome (US3632052)', ODM File OID: '29f3b0a8-7ab3-42c1-9b8e-691177604386'	System	14 Sep 2020 02:37:35
User entered 'None (1)'	System	14 Sep 2020 02:37:35

**US3632052**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(6)**

**Generated On: 10 Jun 2021 09:13:35**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:58:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (44467b427832a52f)', Time: '2020-09-13T22:37:30', User OID: 'PatientReportedOutcome (US3632052)', ODM File OID: '29f3b0a8-7ab3-42c1-9b8e-691177604386'	System	14 Sep 2020 02:37:35
User entered '13 Sep 2020 22:37'	System	14 Sep 2020 02:37:35

**US3632052**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(6)**

**Generated On: 10 Jun 2021 09:13:35**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:58:03
User entered '13 Sep 2020 12:00'	System	08 Sep 2020 15:12:50

**US3632052**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(6)**

**Generated On: 10 Jun 2021 09:13:35**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:58:03
User entered '14 Sep 2020 11:59'	System	08 Sep 2020 15:12:50

US3632052

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(7)

Generated On: 10 Jun 2021 09:13:35

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:58:03
Data entry locked.	System	08 Sep 2020 15:12:50
User entered 'Day 7'	System	08 Sep 2020 15:12:50

US3632052

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(7)

Generated On: 10 Jun 2021 09:13:35

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 10:58:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (44467b427832a52f)', Time: '2020-09-14T23:20:22', User OID: 'PatientReportedOutcome (US3632052)', ODM File OID: 'ad24bea8-4684-4599-b640-226cb8f17c59'	System	15 Sep 2020 03:20:36
User entered 'None (1)'	System	15 Sep 2020 03:20:36

US3632052

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(7)

Generated On: 10 Jun 2021 09:13:35

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:58:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (44467b427832a52f)', Time: '2020-09-14T23:20:26', User OID: 'PatientReportedOutcome (US3632052)', ODM File OID: 'ad24bea8-4684-4599-b640-226cb8f17c59'	System	15 Sep 2020 03:20:36
User entered 'No (N)'	System	15 Sep 2020 03:20:36

US3632052

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(7)

Generated On: 10 Jun 2021 09:13:35

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:58:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (44467b427832a52f)', Time: '2020-09-14T23:20:28', User OID: 'PatientReportedOutcome (US3632052)', ODM File OID: 'ad24bea8-4684-4599-b640-226cb8f17c59'	System	15 Sep 2020 03:20:36
User entered 'No (N)'	System	15 Sep 2020 03:20:36



US3632052

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(7)

Generated On: 10 Jun 2021 09:13:35

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 10:58:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (44467b427832a52f)', Time: '2020-09-14T23:20:31', User OID: 'PatientReportedOutcome (US3632052)', ODM File OID: 'ad24bea8-4684-4599-b640-226cb8f17c59'	System	15 Sep 2020 03:20:36
User entered 'None (1)'	System	15 Sep 2020 03:20:36

US3632052

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(7)

Generated On: 10 Jun 2021 09:13:35

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:58:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (44467b427832a52f)', Time: '2020-09-14T23:20:33', User OID: 'PatientReportedOutcome (US3632052)', ODM File OID: 'ad24bea8-4684-4599-b640-226cb8f17c59'	System	15 Sep 2020 03:20:36
User entered '14 Sep 2020 23:20'	System	15 Sep 2020 03:20:36

**US3632052**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(7)**

**Generated On: 10 Jun 2021 09:13:35**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:58:03
User entered '14 Sep 2020 12:00'	System	08 Sep 2020 15:12:50

**US3632052**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(7)**

**Generated On: 10 Jun 2021 09:13:35**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:58:03
User entered '15 Sep 2020 11:59'	System	08 Sep 2020 15:12:50

US3632052

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 10 Jun 2021 09:13:35

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:58:03
Data entry locked.	System	08 Sep 2020 15:12:50
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	08 Sep 2020 15:12:50

US3632052

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 10 Jun 2021 09:13:35

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:58:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (aa5f64f6ca3050f6)', Time: '2020-09-08T11:42:51', User OID: 'PatientReportedOutcome (US3632052)', ODM File OID: 'b6c11fdf-06a5-4136-8e63-511768c10567'	System	08 Sep 2020 15:43:55
User entered 'None (0)'	System	08 Sep 2020 15:43:55

US3632052

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 10 Jun 2021 09:13:35

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:58:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (aa5f64f6ca3050f6)', Time: '2020-09-08T11:42:56', User OID: 'PatientReportedOutcome (US3632052)', ODM File OID: 'b6c11fdf-06a5-4136-8e63-511768c10567'	System	08 Sep 2020 15:43:55
User entered 'None (0)'	System	08 Sep 2020 15:43:55

US3632052

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 10 Jun 2021 09:13:35

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:58:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (aa5f64f6ca3050f6)', Time: '2020-09-08T11:43:27', User OID: 'PatientReportedOutcome (US3632052)', ODM File OID: 'b6c11fdf-06a5-4136-8e63-511768c10567'	System	08 Sep 2020 15:43:55
User entered 'None (0)'	System	08 Sep 2020 15:43:55



US3632052

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 10 Jun 2021 09:13:35

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:58:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (aa5f64f6ca3050f6)', Time: '2020-09-08T11:43:32', User OID: 'PatientReportedOutcome (US3632052)', ODM File OID: 'b6c11fdf-06a5-4136-8e63-511768c10567'	System	08 Sep 2020 15:43:55
User entered 'None (0)'	System	08 Sep 2020 15:43:55

US3632052

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 10 Jun 2021 09:13:35

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:58:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (aa5f64f6ca3050f6)', Time: '2020-09-08T11:43:36', User OID: 'PatientReportedOutcome (US3632052)', ODM File OID: 'b6c11fdf-06a5-4136-8e63-511768c10567'	System	08 Sep 2020 15:43:55
User entered 'None (0)'	System	08 Sep 2020 15:43:55

US3632052

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 10 Jun 2021 09:13:35

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:58:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (aa5f64f6ca3050f6)', Time: '2020-09-08T11:43:41', User OID: 'PatientReportedOutcome (US3632052)', ODM File OID: 'b6c11fdf-06a5-4136-8e63-511768c10567'	System	08 Sep 2020 15:43:55
User entered 'None (0)'	System	08 Sep 2020 15:43:55

US3632052

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 10 Jun 2021 09:13:35

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:58:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (aa5f64f6ca3050f6)', Time: '2020-09-08T11:43:49', User OID: 'PatientReportedOutcome (US3632052)', ODM File OID: 'b6c11fdf-06a5-4136-8e63-511768c10567'	System	08 Sep 2020 15:43:55
User entered 'No (N)'	System	08 Sep 2020 15:43:55

US3632052

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 10 Jun 2021 09:13:35

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:58:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (aa5f64f6ca3050f6)', Time: '2020-09-08T11:43:53', User OID: 'PatientReportedOutcome (US3632052)', ODM File OID: 'b6c11fdf-06a5-4136-8e63-511768c10567'	System	08 Sep 2020 15:43:55
User entered '08 Sep 2020 11:43'	System	08 Sep 2020 15:43:55

**US3632052**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(1/1)**

**Generated On: 10 Jun 2021 09:13:35**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:58:03
User entered '08 Sep 2020 11:22'	System	08 Sep 2020 15:12:50

**US3632052**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(1/1)**

**Generated On: 10 Jun 2021 09:13:35**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:58:03
User entered '08 Sep 2020 13:52'	System	08 Sep 2020 15:12:50

US3632052

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 10 Jun 2021 09:13:35

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:58:03
Data entry locked.	System	08 Sep 2020 15:12:50
User entered 'Day 1, after vaccination (at home)'	System	08 Sep 2020 15:12:50



US3632052

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 10 Jun 2021 09:13:35

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:58:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (aa5f64f6ca3050f6)', Time: '2020-09-08T15:36:41', User OID: 'PatientReportedOutcome (US3632052)', ODM File OID: '241e5fd0-138e-4c59-a8c1-5a760cd9616d'	System	08 Sep 2020 19:37:07
User entered 'None (0)'	System	08 Sep 2020 19:37:07

US3632052

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 10 Jun 2021 09:13:35

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:58:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (aa5f64f6ca3050f6)', Time: '2020-09-08T15:36:44', User OID: 'PatientReportedOutcome (US3632052)', ODM File OID: '241e5fd0-138e-4c59-a8c1-5a760cd9616d'	System	08 Sep 2020 19:37:07
User entered 'None (0)'	System	08 Sep 2020 19:37:07

US3632052

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 10 Jun 2021 09:13:35

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:58:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (aa5f64f6ca3050f6)', Time: '2020-09-08T15:36:47', User OID: 'PatientReportedOutcome (US3632052)', ODM File OID: '241e5fd0-138e-4c59-a8c1-5a760cd9616d'	System	08 Sep 2020 19:37:07
User entered 'None (0)'	System	08 Sep 2020 19:37:07

US3632052

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 10 Jun 2021 09:13:35

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:58:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (aa5f64f6ca3050f6)', Time: '2020-09-08T15:36:50', User OID: 'PatientReportedOutcome (US3632052)', ODM File OID: '241e5fd0-138e-4c59-a8c1-5a760cd9616d' User entered 'None (0)'	System	08 Sep 2020 19:37:07
	System	08 Sep 2020 19:37:07

US3632052

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 10 Jun 2021 09:13:35

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:58:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (aa5f64f6ca3050f6)', Time: '2020-09-08T15:36:53', User OID: 'PatientReportedOutcome (US3632052)', ODM File OID: '241e5fd0-138e-4c59-a8c1-5a760cd9616d'	System	08 Sep 2020 19:37:07
User entered 'None (0)'	System	08 Sep 2020 19:37:07

**US3632052**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(1/2)**

**Generated On: 10 Jun 2021 09:13:35**

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:58:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (aa5f64f6ca3050f6)', Time: '2020-09-08T15:36:55', User OID: 'PatientReportedOutcome (US3632052)', ODM File OID: '241e5fd0-138e-4c59-a8c1-5a760cd9616d'	System	08 Sep 2020 19:37:07
User entered 'None (0)'	System	08 Sep 2020 19:37:07

US3632052

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 10 Jun 2021 09:13:35

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:58:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (aa5f64f6ca3050f6)', Time: '2020-09-08T15:36:59', User OID: 'PatientReportedOutcome (US3632052)', ODM File OID: '241e5fd0-138e-4c59-a8c1-5a760cd9616d'	System	08 Sep 2020 19:37:07
User entered 'No (N)'	System	08 Sep 2020 19:37:07

**US3632052**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(1/2)**

**Generated On: 10 Jun 2021 09:13:35**

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:58:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (aa5f64f6ca3050f6)', Time: '2020-09-08T15:37:02', User OID: 'PatientReportedOutcome (US3632052)', ODM File OID: '241e5fd0-138e-4c59-a8c1-5a760cd9616d'	System	08 Sep 2020 19:37:07
User entered '08 Sep 2020 15:37'	System	08 Sep 2020 19:37:07



**US3632052**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(1/2)**

**Generated On: 10 Jun 2021 09:13:35**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:58:03
User entered '08 Sep 2020 14:47'	System	08 Sep 2020 15:12:50

**US3632052**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(1/2)**

**Generated On: 10 Jun 2021 09:13:35**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:58:03
User entered '09 Sep 2020 11:59'	System	08 Sep 2020 15:12:50

US3632052

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 10 Jun 2021 09:13:35

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:58:03
Data entry locked.	System	08 Sep 2020 15:12:50
User entered 'Day 2'	System	08 Sep 2020 15:12:50

US3632052

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 10 Jun 2021 09:13:35

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:58:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (aa5f64f6ca3050f6)', Time: '2020-09-09T21:52:21', User OID: 'PatientReportedOutcome (US3632052)', ODM File OID: 'abbcb7e8-43c4-49b5-930e-5eecda69d2a9'	System	10 Sep 2020 01:52:54
User entered 'None (0)'	System	10 Sep 2020 01:52:54

**US3632052**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(2)**

**Generated On: 10 Jun 2021 09:13:35**

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:58:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (aa5f64f6ca3050f6)', Time: '2020-09-09T21:52:27', User OID: 'PatientReportedOutcome (US3632052)', ODM File OID: 'abbcb7e8-43c4-49b5-930e-5eecda69d2a9'	System	10 Sep 2020 01:52:54
User entered 'None (0)'	System	10 Sep 2020 01:52:54

US3632052

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 10 Jun 2021 09:13:35

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:58:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (aa5f64f6ca3050f6)', Time: '2020-09-09T21:52:32', User OID: 'PatientReportedOutcome (US3632052)', ODM File OID: 'abbcb7e8-43c4-49b5-930e-5eecda69d2a9'	System	10 Sep 2020 01:52:54
User entered 'No interference with activity (1)'	System	10 Sep 2020 01:52:54

US3632052

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 10 Jun 2021 09:13:35

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:58:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (aa5f64f6ca3050f6)', Time: '2020-09-09T21:52:36', User OID: 'PatientReportedOutcome (US3632052)', ODM File OID: 'abbcb7e8-43c4-49b5-930e-5eecda69d2a9'	System	10 Sep 2020 01:52:54
User entered 'None (0)'	System	10 Sep 2020 01:52:54

US3632052

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 10 Jun 2021 09:13:35

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:58:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (aa5f64f6ca3050f6)', Time: '2020-09-09T21:52:38', User OID: 'PatientReportedOutcome (US3632052)', ODM File OID: 'abbcb7e8-43c4-49b5-930e-5eecda69d2a9'	System	10 Sep 2020 01:52:54
User entered 'None (0)'	System	10 Sep 2020 01:52:54



US3632052

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 10 Jun 2021 09:13:35

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:58:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (aa5f64f6ca3050f6)', Time: '2020-09-09T21:52:41', User OID: 'PatientReportedOutcome (US3632052)', ODM File OID: 'abbcb7e8-43c4-49b5-930e-5eecda69d2a9'	System	10 Sep 2020 01:52:54
User entered 'None (0)'	System	10 Sep 2020 01:52:54

US3632052

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 10 Jun 2021 09:13:35

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:58:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (aa5f64f6ca3050f6)', Time: '2020-09-09T21:52:46', User OID: 'PatientReportedOutcome (US3632052)', ODM File OID: 'abbcb7e8-43c4-49b5-930e-5eecda69d2a9'	System	10 Sep 2020 01:52:54
User entered 'No (N)'	System	10 Sep 2020 01:52:54

**US3632052**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(2)**

**Generated On: 10 Jun 2021 09:13:35**

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:58:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (aa5f64f6ca3050f6)', Time: '2020-09-09T21:52:50', User OID: 'PatientReportedOutcome (US3632052)', ODM File OID: 'abbcb7e8-43c4-49b5-930e-5eecda69d2a9'	System	10 Sep 2020 01:52:54
User entered '09 Sep 2020 21:52'	System	10 Sep 2020 01:52:54

**US3632052**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(2)**

**Generated On: 10 Jun 2021 09:13:35**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:58:03
User entered '09 Sep 2020 12:00'	System	08 Sep 2020 15:12:50

**US3632052**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(2)**

**Generated On: 10 Jun 2021 09:13:35**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:58:03
User entered '10 Sep 2020 11:59'	System	08 Sep 2020 15:12:50

**US3632052**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(3)**

**Generated On: 10 Jun 2021 09:13:35**

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:58:03
Data entry locked.	System	08 Sep 2020 15:12:50
User entered 'Day 3'	System	08 Sep 2020 15:12:50

US3632052

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 10 Jun 2021 09:13:35

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:58:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (aa5f64f6ca3050f6)', Time: '2020-09-10T23:33:07', User OID: 'PatientReportedOutcome (US3632052)', ODM File OID: 'bd124eff-d06d-428b-9174-b8b7bf1a13f5'	System	11 Sep 2020 03:33:35
User entered 'None (0)'	System	11 Sep 2020 03:33:35

US3632052

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 10 Jun 2021 09:13:35

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:58:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (aa5f64f6ca3050f6)', Time: '2020-09-10T23:33:10', User OID: 'PatientReportedOutcome (US3632052)', ODM File OID: 'bd124eff-d06d-428b-9174-b8b7bf1a13f5'	System	11 Sep 2020 03:33:35
User entered 'None (0)'	System	11 Sep 2020 03:33:35



US3632052

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 10 Jun 2021 09:13:35

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:58:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (aa5f64f6ca3050f6)', Time: '2020-09-10T23:33:13', User OID: 'PatientReportedOutcome (US3632052)', ODM File OID: 'bd124eff-d06d-428b-9174-b8b7bf1a13f5'	System	11 Sep 2020 03:33:35
User entered 'None (0)'	System	11 Sep 2020 03:33:35

US3632052

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 10 Jun 2021 09:13:35

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:58:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (aa5f64f6ca3050f6)', Time: '2020-09-10T23:33:16', User OID: 'PatientReportedOutcome (US3632052)', ODM File OID: 'bd124eff-d06d-428b-9174-b8b7bf1a13f5'	System	11 Sep 2020 03:33:35
User entered 'None (0)'	System	11 Sep 2020 03:33:35

US3632052

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 10 Jun 2021 09:13:35

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:58:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (aa5f64f6ca3050f6)', Time: '2020-09-10T23:33:18', User OID: 'PatientReportedOutcome (US3632052)', ODM File OID: 'bd124eff-d06d-428b-9174-b8b7bf1a13f5'	System	11 Sep 2020 03:33:35
User entered 'None (0)'	System	11 Sep 2020 03:33:35

US3632052

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 10 Jun 2021 09:13:35

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:58:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (aa5f64f6ca3050f6)', Time: '2020-09-10T23:33:21', User OID: 'PatientReportedOutcome (US3632052)', ODM File OID: 'bd124eff-d06d-428b-9174-b8b7bf1a13f5'	System	11 Sep 2020 03:33:35
User entered 'None (0)'	System	11 Sep 2020 03:33:35

US3632052

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 10 Jun 2021 09:13:35

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:58:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (aa5f64f6ca3050f6)', Time: '2020-09-10T23:33:27', User OID: 'PatientReportedOutcome (US3632052)', ODM File OID: 'bd124eff-d06d-428b-9174-b8b7bf1a13f5'	System	11 Sep 2020 03:33:35
User entered 'No (N)'	System	11 Sep 2020 03:33:35

**US3632052**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(3)**

**Generated On: 10 Jun 2021 09:13:35**

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:58:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (aa5f64f6ca3050f6)', Time: '2020-09-10T23:33:30', User OID: 'PatientReportedOutcome (US3632052)', ODM File OID: 'bd124eff-d06d-428b-9174-b8b7bf1a13f5'	System	11 Sep 2020 03:33:35
User entered '10 Sep 2020 23:33'	System	11 Sep 2020 03:33:35

**US3632052**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(3)**

**Generated On: 10 Jun 2021 09:13:35**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:58:03
User entered '10 Sep 2020 12:00'	System	08 Sep 2020 15:12:50

**US3632052**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(3)**

**Generated On: 10 Jun 2021 09:13:35**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:58:03
User entered '11 Sep 2020 11:59'	System	08 Sep 2020 15:12:50



US3632052

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 10 Jun 2021 09:13:35

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:58:03
Data entry locked.	System	08 Sep 2020 15:12:50
User entered 'Day 4'	System	08 Sep 2020 15:12:50

US3632052

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 10 Jun 2021 09:13:35

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:58:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (44467b427832a52f)', Time: '2020-09-11T22:25:48', User OID: 'PatientReportedOutcome (US3632052)', ODM File OID: 'b028e41d-d3c8-4af3-9c99-3ca5caa9db15'	System	12 Sep 2020 02:27:30
User entered 'None (0)'	System	12 Sep 2020 02:27:30

US3632052

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 10 Jun 2021 09:13:35

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:58:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (44467b427832a52f)', Time: '2020-09-11T22:25:52', User OID: 'PatientReportedOutcome (US3632052)', ODM File OID: 'b028e41d-d3c8-4af3-9c99-3ca5caa9db15'	System	12 Sep 2020 02:27:30
User entered 'None (0)'	System	12 Sep 2020 02:27:30

US3632052

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 10 Jun 2021 09:13:35

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:58:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (44467b427832a52f)', Time: '2020-09-11T22:25:55', User OID: 'PatientReportedOutcome (US3632052)', ODM File OID: 'b028e41d-d3c8-4af3-9c99-3ca5caa9db15'	System	12 Sep 2020 02:27:30
User entered 'None (0)'	System	12 Sep 2020 02:27:30

US3632052

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 10 Jun 2021 09:13:35

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:58:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (44467b427832a52f)', Time: '2020-09-11T22:25:58', User OID: 'PatientReportedOutcome (US3632052)', ODM File OID: 'b028e41d-d3c8-4af3-9c99-3ca5caa9db15'	System	12 Sep 2020 02:27:30
User entered 'None (0)'	System	12 Sep 2020 02:27:30

US3632052

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 10 Jun 2021 09:13:35

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:58:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (44467b427832a52f)', Time: '2020-09-11T22:26:01', User OID: 'PatientReportedOutcome (US3632052)', ODM File OID: 'b028e41d-d3c8-4af3-9c99-3ca5caa9db15'	System	12 Sep 2020 02:27:30
User entered 'None (0)'	System	12 Sep 2020 02:27:30

US3632052

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 10 Jun 2021 09:13:35

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:58:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (44467b427832a52f)', Time: '2020-09-11T22:26:03', User OID: 'PatientReportedOutcome (US3632052)', ODM File OID: 'b028e41d-d3c8-4af3-9c99-3ca5caa9db15'	System	12 Sep 2020 02:27:30
User entered 'None (0)'	System	12 Sep 2020 02:27:30

US3632052

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 10 Jun 2021 09:13:35

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:58:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (44467b427832a52f)', Time: '2020-09-11T22:26:09', User OID: 'PatientReportedOutcome (US3632052)', ODM File OID: 'b028e41d-d3c8-4af3-9c99-3ca5caa9db15'	System	12 Sep 2020 02:27:30
User entered 'No (N)'	System	12 Sep 2020 02:27:30



**US3632052**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(4)**

**Generated On: 10 Jun 2021 09:13:35**

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:58:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (44467b427832a52f)', Time: '2020-09-11T22:26:11', User OID: 'PatientReportedOutcome (US3632052)', ODM File OID: 'b028e41d-d3c8-4af3-9c99-3ca5caa9db15'	System	12 Sep 2020 02:27:30
User entered '11 Sep 2020 22:26'	System	12 Sep 2020 02:27:30

**US3632052**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(4)**

**Generated On: 10 Jun 2021 09:13:35**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:58:03
User entered '11 Sep 2020 12:00'	System	08 Sep 2020 15:12:50

**US3632052**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(4)**

**Generated On: 10 Jun 2021 09:13:35**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:58:03
User entered '12 Sep 2020 11:59'	System	08 Sep 2020 15:12:50

US3632052

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 10 Jun 2021 09:13:35

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:58:03
Data entry locked.	System	08 Sep 2020 15:12:50
User entered 'Day 5'	System	08 Sep 2020 15:12:50

US3632052

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 10 Jun 2021 09:13:35

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:58:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (44467b427832a52f)', Time: '2020-09-12T23:40:44', User OID: 'PatientReportedOutcome (US3632052)', ODM File OID: '606c95e3-2271-4768-887a-b5f78014bdc6'	System	13 Sep 2020 03:41:08
User entered 'None (0)'	System	13 Sep 2020 03:41:08

US3632052

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 10 Jun 2021 09:13:35

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:58:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (44467b427832a52f)', Time: '2020-09-12T23:40:48', User OID: 'PatientReportedOutcome (US3632052)', ODM File OID: '606c95e3-2271-4768-887a-b5f78014bdc6'	System	13 Sep 2020 03:41:08
User entered 'None (0)'	System	13 Sep 2020 03:41:08

US3632052

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 10 Jun 2021 09:13:35

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:58:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (44467b427832a52f)', Time: '2020-09-12T23:40:50', User OID: 'PatientReportedOutcome (US3632052)', ODM File OID: '606c95e3-2271-4768-887a-b5f78014bdc6'	System	13 Sep 2020 03:41:08
User entered 'None (0)'	System	13 Sep 2020 03:41:08

US3632052

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 10 Jun 2021 09:13:35

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:58:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (44467b427832a52f)', Time: '2020-09-12T23:40:52', User OID: 'PatientReportedOutcome (US3632052)', ODM File OID: '606c95e3-2271-4768-887a-b5f78014bdc6'	System	13 Sep 2020 03:41:08
User entered 'None (0)'	System	13 Sep 2020 03:41:08



**US3632052**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(5)**

**Generated On: 10 Jun 2021 09:13:35**

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:58:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (44467b427832a52f)', Time: '2020-09-12T23:40:55', User OID: 'PatientReportedOutcome (US3632052)', ODM File OID: '606c95e3-2271-4768-887a-b5f78014bdc6'	System	13 Sep 2020 03:41:08
User entered 'None (0)'	System	13 Sep 2020 03:41:08

**US3632052**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(5)**

**Generated On: 10 Jun 2021 09:13:35**

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:58:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (44467b427832a52f)', Time: '2020-09-12T23:40:58', User OID: 'PatientReportedOutcome (US3632052)', ODM File OID: '606c95e3-2271-4768-887a-b5f78014bdc6'	System	13 Sep 2020 03:41:08
User entered 'None (0)'	System	13 Sep 2020 03:41:08

US3632052

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 10 Jun 2021 09:13:35

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:58:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (44467b427832a52f)', Time: '2020-09-12T23:41:03', User OID: 'PatientReportedOutcome (US3632052)', ODM File OID: '606c95e3-2271-4768-887a-b5f78014bdc6'	System	13 Sep 2020 03:41:08
User entered 'No (N)'	System	13 Sep 2020 03:41:08

**US3632052**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(5)**

**Generated On: 10 Jun 2021 09:13:35**

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:58:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (44467b427832a52f)', Time: '2020-09-12T23:41:06', User OID: 'PatientReportedOutcome (US3632052)', ODM File OID: '606c95e3-2271-4768-887a-b5f78014bdc6'	System	13 Sep 2020 03:41:08
User entered '12 Sep 2020 23:41'	System	13 Sep 2020 03:41:08

**US3632052**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(5)**

**Generated On: 10 Jun 2021 09:13:35**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:58:03
User entered '12 Sep 2020 12:00'	System	08 Sep 2020 15:12:50

**US3632052**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(5)**

**Generated On: 10 Jun 2021 09:13:35**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:58:03
User entered '13 Sep 2020 11:59'	System	08 Sep 2020 15:12:50

US3632052

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 10 Jun 2021 09:13:35

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:58:03
Data entry locked.	System	08 Sep 2020 15:12:50
User entered 'Day 6'	System	08 Sep 2020 15:12:50

US3632052

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 10 Jun 2021 09:13:35

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:58:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (44467b427832a52f)', Time: '2020-09-13T22:37:51', User OID: 'PatientReportedOutcome (US3632052)', ODM File OID: 'e67efb83-82eb-447c-b9c1-1570161f1e42'	System	14 Sep 2020 02:38:25
User entered 'No interference with activity (1)'	System	14 Sep 2020 02:38:25



US3632052

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 10 Jun 2021 09:13:35

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:58:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (44467b427832a52f)', Time: '2020-09-13T22:37:59', User OID: 'PatientReportedOutcome (US3632052)', ODM File OID: 'e67efb83-82eb-447c-b9c1-1570161f1e42'	System	14 Sep 2020 02:38:25
User entered 'No interference with activity (1)'	System	14 Sep 2020 02:38:25

US3632052

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 10 Jun 2021 09:13:35

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:58:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (44467b427832a52f)', Time: '2020-09-13T22:38:03', User OID: 'PatientReportedOutcome (US3632052)', ODM File OID: 'e67efb83-82eb-447c-b9c1-1570161f1e42'	System	14 Sep 2020 02:38:25
User entered 'None (0)'	System	14 Sep 2020 02:38:25

US3632052

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 10 Jun 2021 09:13:35

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:58:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (44467b427832a52f)', Time: '2020-09-13T22:38:06', User OID: 'PatientReportedOutcome (US3632052)', ODM File OID: 'e67efb83-82eb-447c-b9c1-1570161f1e42'	System	14 Sep 2020 02:38:25
User entered 'None (0)'	System	14 Sep 2020 02:38:25

US3632052

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 10 Jun 2021 09:13:35

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:58:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (44467b427832a52f)', Time: '2020-09-13T22:38:09', User OID: 'PatientReportedOutcome (US3632052)', ODM File OID: 'e67efb83-82eb-447c-b9c1-1570161f1e42'	System	14 Sep 2020 02:38:25
User entered 'None (0)'	System	14 Sep 2020 02:38:25

US3632052

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 10 Jun 2021 09:13:35

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:58:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (44467b427832a52f)', Time: '2020-09-13T22:38:12', User OID: 'PatientReportedOutcome (US3632052)', ODM File OID: 'e67efb83-82eb-447c-b9c1-1570161f1e42'	System	14 Sep 2020 02:38:25
User entered 'None (0)'	System	14 Sep 2020 02:38:25

US3632052

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 10 Jun 2021 09:13:35

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:58:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (44467b427832a52f)', Time: '2020-09-13T22:38:18', User OID: 'PatientReportedOutcome (US3632052)', ODM File OID: 'e67efb83-82eb-447c-b9c1-1570161f1e42'	System	14 Sep 2020 02:38:25
User entered 'No (N)'	System	14 Sep 2020 02:38:25

**US3632052**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(6)**

**Generated On: 10 Jun 2021 09:13:35**

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:58:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (44467b427832a52f)', Time: '2020-09-13T22:38:20', User OID: 'PatientReportedOutcome (US3632052)', ODM File OID: 'e67efb83-82eb-447c-b9c1-1570161f1e42'	System	14 Sep 2020 02:38:25
User entered '13 Sep 2020 22:38'	System	14 Sep 2020 02:38:25

**US3632052**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(6)**

**Generated On: 10 Jun 2021 09:13:35**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:58:03
User entered '13 Sep 2020 12:00'	System	08 Sep 2020 15:12:50



**US3632052**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(6)**

**Generated On: 10 Jun 2021 09:13:35**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:58:03
User entered '14 Sep 2020 11:59'	System	08 Sep 2020 15:12:50

**US3632052**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(7)**

**Generated On: 10 Jun 2021 09:13:35**

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:58:03
Data entry locked.	System	08 Sep 2020 15:12:50
User entered 'Day 7'	System	08 Sep 2020 15:12:50

US3632052

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 10 Jun 2021 09:13:35

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:58:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (44467b427832a52f)', Time: '2020-09-14T23:20:42', User OID: 'PatientReportedOutcome (US3632052)', ODM File OID: '54e8904b-6cb8-409c-960a-b3dea3600109'	System	15 Sep 2020 03:21:08
User entered 'No interference with activity (1)'	System	15 Sep 2020 03:21:08

**US3632052**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(7)**

**Generated On: 10 Jun 2021 09:13:35**

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:58:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (44467b427832a52f)', Time: '2020-09-14T23:20:45', User OID: 'PatientReportedOutcome (US3632052)', ODM File OID: '54e8904b-6cb8-409c-960a-b3dea3600109'	System	15 Sep 2020 03:21:08
User entered 'None (0)'	System	15 Sep 2020 03:21:08

US3632052

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 10 Jun 2021 09:13:35

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:58:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (44467b427832a52f)', Time: '2020-09-14T23:20:47', User OID: 'PatientReportedOutcome (US3632052)', ODM File OID: '54e8904b-6cb8-409c-960a-b3dea3600109'	System	15 Sep 2020 03:21:08
User entered 'None (0)'	System	15 Sep 2020 03:21:08

US3632052

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 10 Jun 2021 09:13:35

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:58:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (44467b427832a52f)', Time: '2020-09-14T23:20:49', User OID: 'PatientReportedOutcome (US3632052)', ODM File OID: '54e8904b-6cb8-409c-960a-b3dea3600109'	System	15 Sep 2020 03:21:08
User entered 'None (0)'	System	15 Sep 2020 03:21:08

US3632052

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 10 Jun 2021 09:13:35

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:58:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (44467b427832a52f)', Time: '2020-09-14T23:20:51', User OID: 'PatientReportedOutcome (US3632052)', ODM File OID: '54e8904b-6cb8-409c-960a-b3dea3600109'	System	15 Sep 2020 03:21:08
User entered 'None (0)'	System	15 Sep 2020 03:21:08

US3632052

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 10 Jun 2021 09:13:35

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:58:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (44467b427832a52f)', Time: '2020-09-14T23:20:53', User OID: 'PatientReportedOutcome (US3632052)', ODM File OID: '54e8904b-6cb8-409c-960a-b3dea3600109'	System	15 Sep 2020 03:21:08
User entered 'None (0)'	System	15 Sep 2020 03:21:08



US3632052

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 10 Jun 2021 09:13:35

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:58:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (44467b427832a52f)', Time: '2020-09-14T23:21:01', User OID: 'PatientReportedOutcome (US3632052)', ODM File OID: '54e8904b-6cb8-409c-960a-b3dea3600109'	System	15 Sep 2020 03:21:08
User entered 'No (N)'	System	15 Sep 2020 03:21:08

**US3632052**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(7)**

**Generated On: 10 Jun 2021 09:13:35**

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:58:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (44467b427832a52f)', Time: '2020-09-14T23:21:04', User OID: 'PatientReportedOutcome (US3632052)', ODM File OID: '54e8904b-6cb8-409c-960a-b3dea3600109'	System	15 Sep 2020 03:21:08
User entered '14 Sep 2020 23:21'	System	15 Sep 2020 03:21:08

**US3632052**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(7)**

**Generated On: 10 Jun 2021 09:13:35**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:58:03
User entered '14 Sep 2020 12:00'	System	08 Sep 2020 15:12:50

**US3632052**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(7)**

**Generated On: 10 Jun 2021 09:13:35**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:58:03
User entered '15 Sep 2020 11:59'	System	08 Sep 2020 15:12:50

US3632052

Folder: Diary Dose 1 (1)

Form: Headache\_Day(8)

Generated On: 10 Jun 2021 09:13:35

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:58:03
Data entry locked.	System	14 Sep 2020 02:38:25
User entered 'Day 8'	System	14 Sep 2020 02:38:25

**US3632052**

**Folder: Diary Dose 1 (1)**

**Form: Headache\_Day(8)**

**Generated On: 10 Jun 2021 09:13:35**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:58:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (44467b427832a52f)', Time: '2020-09-15T23:54:08', User OID: 'PatientReportedOutcome (US3632052)', ODM File OID: '669efb30-1165-43c7-adc3-e9be80000009'	System	16 Sep 2020 03:54:15
User entered 'None (0)'	System	16 Sep 2020 03:54:15

**US3632052**

**Folder: Diary Dose 1 (1)**

**Form: Headache\_Day(8)**

**Generated On: 10 Jun 2021 09:13:35**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:58:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (44467b427832a52f)', Time: '2020-09-15T23:54:12', User OID: 'PatientReportedOutcome (US3632052)', ODM File OID: '669efb30-1165-43c7-adc3-e9be80000009'	System	16 Sep 2020 03:54:15
User entered '15 Sep 2020 23:54'	System	16 Sep 2020 03:54:15

**US3632052**

**Folder: Diary Dose 1 (1)**

**Form: Headache\_Day(8)**

**Generated On: 10 Jun 2021 09:13:35**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:58:03
User entered '15 Sep 2020 12:00'	System	14 Sep 2020 02:38:25



**US3632052**

**Folder: Diary Dose 1 (1)**

**Form: Headache\_Day(8)**

**Generated On: 10 Jun 2021 09:13:35**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:58:03
User entered '16 Sep 2020 11:59'	System	14 Sep 2020 02:38:25

**US3632052**

**Folder: Diary Dose 1 (1)**

**Form: Medical Attention\_Day(8)**

**Generated On: 10 Jun 2021 09:13:35**

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:58:03
Data entry locked.	System	14 Sep 2020 02:38:25
User entered 'Day 8'	System	14 Sep 2020 02:38:25

US3632052

Folder: Diary Dose 1 (1)

Form: Medical Attention\_Day(8)

Generated On: 10 Jun 2021 09:13:35

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:58:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (44467b427832a52f)', Time: '2020-09-15T23:54:17', User OID: 'PatientReportedOutcome (US3632052)', ODM File OID: 'b28c95d2-1e16-4702-80e7-c08c2b95e765'	System	16 Sep 2020 03:54:26
User entered 'No (N)'	System	16 Sep 2020 03:54:26

**US3632052**

**Folder: Diary Dose 1 (1)**

**Form: Medical Attention\_Day(8)**

**Generated On: 10 Jun 2021 09:13:35**

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:58:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (44467b427832a52f)', Time: '2020-09-15T23:54:23', User OID: 'PatientReportedOutcome (US3632052)', ODM File OID: 'b28c95d2-1e16-4702-80e7-c08c2b95e765'	System	16 Sep 2020 03:54:26
User entered '15 Sep 2020 23:54'	System	16 Sep 2020 03:54:26

**US3632052**

**Folder: Diary Dose 1 (1)**

**Form: Medical Attention\_Day(8)**

**Generated On: 10 Jun 2021 09:13:35**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:58:03
User entered '15 Sep 2020 12:00'	System	14 Sep 2020 02:38:25

**US3632052**

**Folder: Diary Dose 1 (1)**

**Form: Medical Attention\_Day(8)**

**Generated On: 10 Jun 2021 09:13:35**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:58:03
User entered '16 Sep 2020 11:59'	System	14 Sep 2020 02:38:25

**US3632052**

**Folder: Safety Call Day 8 (1)**

**Form: Safety Call**

**Generated On: 10 Jun 2021 09:13:35**

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:19:13
User signature succeeded.	Colleen Kelley (b) (4)	08 Mar 2021 14:31:04
DataPoint Verified.	(b) (4)	19 Nov 2020 16:57:08
User entered 'Yes (Y)'	(b) (4), (b) (6)	15 Sep 2020 17:39:48
	Bezuayehu Mandefro	
	(b) (4)	

**US3632052**

**Folder: Safety Call Day 8 (1)**

**Form: Safety Call**

**Generated On: 10 Jun 2021 09:13:35**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:19:13
User signature succeeded.	Colleen Kelley (b) (4)	08 Mar 2021 14:31:04
DataPoint Verified.	(b) (4)	19 Nov 2020 16:57:08
User entered '15 Sep 2020'	(b) (4), (b) (6)	15 Sep 2020 17:39:48
	Bezuayehu Mandefro	
	(b) (4)	



US3632052

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:13:35

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:19:13
User signature succeeded.	Colleen Kelley (b) (4)	08 Mar 2021 14:31:04
DataPoint Verified.	(b) (4)	19 Nov 2020 16:57:08
User entered 'Contact Made (CONTACT MADE)'	(b) (4), (b) (6)	15 Sep 2020 17:39:48
	Bezuayehu Mandefro	
	(b) (4)	

US3632052

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:13:35

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:19:13
User signature succeeded.	Colleen Kelley (b) (4)	08 Mar 2021 14:31:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Nov 2020 16:57:08
User entered empty.	Bezuayehu Mandefro (b) (4)	15 Sep 2020 17:39:48

US3632052

Folder: Safety Call Day 8 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:13:35

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:19:13
User signature succeeded.	Colleen Kelley (b) (4)	08 Mar 2021 14:31:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Nov 2020 16:57:34
User entered 'Yes (Y)'	Bezuayehu Mandefro (b) (4)	15 Sep 2020 17:42:39

**US3632052**

**Folder: Safety Call Day 8 (1)**

**Form: Continuing**

**Generated On: 10 Jun 2021 09:13:35**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:19:13
User entered 'I'	System	15 Sep 2020 17:42:39

**US3632052**

**Folder: Safety Call Day 15 (1)**

**Form: Safety Call**

**Generated On: 10 Jun 2021 09:13:35**

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:19:13
User signature succeeded.	Colleen Kelley (b) (4)	08 Mar 2021 14:31:04
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 16:57:53
User entered 'Yes (Y)'	Sarah Wiatrek (b) (4)	22 Sep 2020 17:57:56

**US3632052**

**Folder: Safety Call Day 15 (1)**

**Form: Safety Call**

**Generated On: 10 Jun 2021 09:13:35**

[Date of Contact or Contact Attempt \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:19:13
User signature succeeded.	Colleen Kelley (b) (4)	08 Mar 2021 14:31:04
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 16:57:53
User entered '22 Sep 2020'	Sarah Wiatrek (b) (4)	22 Sep 2020 17:57:56

**US3632052**

**Folder: Safety Call Day 15 (1)**

**Form: Safety Call**

**Generated On: 10 Jun 2021 09:13:35**

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:19:13
User signature succeeded.	Colleen Kelley (b) (4)	08 Mar 2021 14:31:04
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 16:57:53
User entered 'Contact Made (CONTACT MADE)'	Sarah Wiatrek (b) (4)	22 Sep 2020 17:57:56

**US3632052**

**Folder: Safety Call Day 15 (1)**

**Form: Safety Call**

**Generated On: 10 Jun 2021 09:13:35**

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:19:13
User signature succeeded.	Colleen Kelley (b) (4)	08 Mar 2021 14:31:04
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 16:57:53
User entered empty.	Sarah Wiatrek (b) (4)	22 Sep 2020 17:57:56



**US3632052**

**Folder: Safety Call Day 15 (1)**

**Form: Continuing**

**Generated On: 10 Jun 2021 09:13:35**

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:19:13
User signature succeeded.	Colleen Kelley (b) (4)	08 Mar 2021 14:31:04
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 16:58:13
User entered 'Yes (Y)'	Sarah Wiatrek (b) (4)	22 Sep 2020 17:58:00

**US3632052**

**Folder: Safety Call Day 15 (1)**

**Form: Continuing**

**Generated On: 10 Jun 2021 09:13:35**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:19:13
User entered 'I'	System	22 Sep 2020 17:58:00

**US3632052**

**Folder: Safety Call Day 22 (1)**

**Form: Safety Call**

**Generated On: 10 Jun 2021 09:13:35**

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:19:13
User signature succeeded.	Colleen Kelley (b) (4)	08 Mar 2021 14:31:04
DataPoint Verified.	(b) (4)	19 Nov 2020 16:58:42
User entered 'Yes (Y)'	(b) (4), (b) (6)	29 Sep 2020 16:48:39
	Bezuayehu Mandefro	
	(b) (4)	

US3632052

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:13:35

Date of Contact or Contact Attempt (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:19:13
User signature succeeded.	Colleen Kelley (b) (4)	08 Mar 2021 14:31:04
DataPoint Verified.	(b) (4)	19 Nov 2020 16:58:42
User entered '29 Sep 2020'	(b) (4), (b) (6)	19 Nov 2020 16:58:42
	Bezuayehu Mandefro	29 Sep 2020 16:48:39
	(b) (4)	

US3632052

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:13:35

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:19:13
User signature succeeded.	Colleen Kelley (b) (4)	08 Mar 2021 14:31:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Nov 2020 16:58:42
User entered 'Contact Made (CONTACT MADE)'	Bezuayehu Mandefro (b) (4)	29 Sep 2020 16:48:39

US3632052

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:13:35

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:19:13
User signature succeeded.	Colleen Kelley (b) (4)	08 Mar 2021 14:31:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Nov 2020 16:58:42
User entered empty.	Bezuayehu Mandefro (b) (4)	29 Sep 2020 16:48:39

US3632052

Folder: Safety Call Day 22 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:13:35

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:19:13
User signature succeeded.	Colleen Kelley (b) (4)	08 Mar 2021 14:31:04
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	19 Nov 2020 16:59:00
User entered 'Yes (Y)'	Bezuayehu Mandefro	29 Sep 2020 16:48:43
	(b) (4)	

**US3632052**

**Folder: Safety Call Day 22 (1)**

**Form: Continuing**

**Generated On: 10 Jun 2021 09:13:35**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:19:13
User entered 'I'	System	29 Sep 2020 16:48:43



US3632052

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 10 Jun 2021 09:13:35

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:19:13
User signature succeeded.	Colleen Kelley (b) (4)	08 Mar 2021 14:31:04
DataPoint Verified.	(b) (4), (b) (6)	16 Dec 2020 17:15:34
User entered 'Yes (Y)'	(b) (4), (b) (6)	06 Oct 2020 14:23:06

**US3632052**

**Folder: Visit 2 Day 29 (1)**

**Form: Visit Date**

**Generated On: 10 Jun 2021 09:13:35**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:19:13
User signature succeeded.	Colleen Kelley (b) (4)	08 Mar 2021 14:31:04
DataPoint Verified.	(b) (4), (b) (6)	16 Dec 2020 17:15:34
User entered '6 Oct 2020'	(b) (4), (b) (6)	06 Oct 2020 14:23:06

US3632052

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 10 Jun 2021 09:13:35

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:19:13
User signature succeeded.	Colleen Kelley (b) (4)	08 Mar 2021 14:31:04
DataPoint Verified.	(b) (4), (b) (6)	16 Dec 2020 17:15:34
User entered 'Clinic (Clinic)'	(b) (4), (b) (6)	06 Oct 2020 14:23:06

**US3632052**

**Folder: Visit 2 Day 29 (1)**

**Form: Visit Date**

**Generated On: 10 Jun 2021 09:13:35**

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:19:13
User entered 'VISIT2'	System	06 Oct 2020 14:23:06

US3632052

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:13:35

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:19:13
User accepted default value 'Pre-Dose (PREDOSE)'	(b) (4), (b) (6)	06 Oct 2020 16:52:50

US3632052

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:13:35

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:19:13
User signature succeeded.	Colleen Kelley (b) (4)	08 Mar 2021 14:31:04
DataPoint Verified.	(b) (4), (b) (6)	16 Dec 2020 17:16:13
User entered 'Yes (Y)'	(b) (4), (b) (6)	06 Oct 2020 16:52:50

**US3632052**

**Folder: Visit 2 Day 29 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 10 Jun 2021 09:13:35**

**Date of assessment** (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:19:13
User signature succeeded.	Colleen Kelley (b) (4)	08 Mar 2021 14:31:04
DataPoint Verified.	(b) (4), (b) (6)	16 Dec 2020 17:16:13
User entered '6 Oct 2020'	(b) (4), (b) (6)	06 Oct 2020 16:52:50

**US3632052**

**Folder: Visit 2 Day 29 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 10 Jun 2021 09:13:35**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:19:13
User signature succeeded.	Colleen Kelley (b) (4)	08 Mar 2021 14:31:04
DataPoint Verified.	(b) (4), (b) (6)	16 Dec 2020 17:16:13
User entered '10:14'	(b) (4), (b) (6)	06 Oct 2020 16:52:50



US3632052

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:13:35

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:19:13
User entered '6 Oct 2020 10:14'	System	06 Oct 2020 16:52:50

US3632052

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:13:35

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:19:13
User signature succeeded.	Colleen Kelley (b) (4)	08 Mar 2021 14:31:04
DataPoint Verified.	(b) (4), (b) (6)	16 Dec 2020 17:16:13
User entered '97.6' F	(b) (4), (b) (6)	06 Oct 2020 16:52:50

US3632052

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:13:35

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:19:13
User signature succeeded.	Colleen Kelley (b) (4)	08 Mar 2021 14:31:04
DataPoint Verified.	(b) (4), (b) (6)	16 Dec 2020 17:16:13
User entered 'Oral (Oral)'	(b) (4), (b) (6)	06 Oct 2020 16:52:50

**US3632052**

**Folder: Visit 2 Day 29 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 10 Jun 2021 09:13:35**

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:19:13
User signature succeeded.	Colleen Kelley (b) (4)	08 Mar 2021 14:31:04
DataPoint Verified.	(b) (4), (b) (6)	16 Dec 2020 17:16:13
User entered empty.	(b) (4), (b) (6)	06 Oct 2020 16:52:50

**US3632052**

**Folder: Visit 2 Day 29 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 10 Jun 2021 09:13:35**

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:19:13
User signature succeeded.	Colleen Kelley (b) (4)	08 Mar 2021 14:31:04
DataPoint Verified.	(b) (4), (b) (6)	16 Dec 2020 17:16:13
User entered '78'	(b) (4), (b) (6)	06 Oct 2020 16:52:50

**US3632052**

**Folder: Visit 2 Day 29 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 10 Jun 2021 09:13:35**

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:19:13
User entered 'bpm'	System	06 Oct 2020 16:52:50

US3632052

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:13:35

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:19:13
User signature succeeded.	Colleen Kelley (b) (4)	08 Mar 2021 14:31:04
DataPoint Verified.	(b) (4), (b) (6)	16 Dec 2020 17:16:13
User entered '16'	(b) (4), (b) (6)	06 Oct 2020 16:52:50

US3632052

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:13:35

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:19:13
User entered 'breaths/min'	System	06 Oct 2020 16:52:50



US3632052

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:13:35

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:19:13
User signature succeeded.	Colleen Kelley (b) (4)	08 Mar 2021 14:31:04
DataPoint Verified.	(b) (4), (b) (6)	16 Dec 2020 17:16:13
User entered '130'	(b) (4), (b) (6)	06 Oct 2020 16:52:50

US3632052

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:13:35

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:19:13
User entered 'mmHg'	System	06 Oct 2020 16:52:50

US3632052

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:13:35

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:19:13
User signature succeeded.	Colleen Kelley (b) (4)	08 Mar 2021 14:31:04
DataPoint Verified.	(b) (4), (b) (6)	16 Dec 2020 17:16:13
User entered '78'	(b) (4), (b) (6)	06 Oct 2020 16:52:50

US3632052

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:13:35

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:19:13
User entered 'mmHg'	System	06 Oct 2020 16:52:50

US3632052

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:13:35

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:19:13
User accepted default value 'Post-Dose (POSTDOSE)'	(b) (4), (b) (6)	06 Oct 2020 16:52:50

US3632052

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:13:35

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:19:13
User signature succeeded.	Colleen Kelley (b) (4)	08 Mar 2021 14:31:04
DataPoint Verified.	(b) (4), (b) (6)	16 Dec 2020 17:16:13
User entered 'Yes (Y)'	(b) (4), (b) (6)	06 Oct 2020 16:52:50

**US3632052**

**Folder: Visit 2 Day 29 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 10 Jun 2021 09:13:35**

**Date of assessment** (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:19:13
User signature succeeded.	Colleen Kelley (b) (4)	08 Mar 2021 14:31:04
DataPoint Verified.	(b) (4), (b) (6)	16 Dec 2020 17:16:13
User entered '6 Oct 2020'	(b) (4), (b) (6)	06 Oct 2020 16:52:50

**US3632052**

**Folder: Visit 2 Day 29 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 10 Jun 2021 09:13:35**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:19:13
User signature succeeded.	Colleen Kelley (b) (4)	08 Mar 2021 14:31:04
DataPoint Verified.	(b) (4), (b) (6)	16 Dec 2020 17:16:13
User entered '12:05'	(b) (4), (b) (6)	06 Oct 2020 16:52:50



**US3632052**

**Folder: Visit 2 Day 29 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 10 Jun 2021 09:13:35**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:19:13
User entered '6 Oct 2020 12:05'	System	06 Oct 2020 16:52:50

US3632052

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:13:35

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:19:13
User signature succeeded.	Colleen Kelley (b) (4)	08 Mar 2021 14:31:04
DataPoint Verified.	(b) (4), (b) (6)	16 Dec 2020 17:16:13
User entered '97.4' F	(b) (4), (b) (6)	06 Oct 2020 16:52:50

US3632052

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:13:35

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:19:13
User signature succeeded.	Colleen Kelley (b) (4)	08 Mar 2021 14:31:04
DataPoint Verified.	(b) (4), (b) (6)	16 Dec 2020 17:16:13
User entered 'Oral (Oral)'	(b) (4), (b) (6)	06 Oct 2020 16:52:50

**US3632052**

**Folder: Visit 2 Day 29 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 10 Jun 2021 09:13:35**

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:19:13
User signature succeeded.	Colleen Kelley (b) (4)	08 Mar 2021 14:31:04
DataPoint Verified.	(b) (4), (b) (6)	16 Dec 2020 17:16:13
User entered empty.	(b) (4), (b) (6)	06 Oct 2020 16:52:50

**US3632052**

**Folder: Visit 2 Day 29 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 10 Jun 2021 09:13:35**

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:19:13
User signature succeeded.	Colleen Kelley (b) (4)	08 Mar 2021 14:31:04
DataPoint Verified.	(b) (4), (b) (6)	16 Dec 2020 17:16:13
User entered '72'	(b) (4), (b) (6)	06 Oct 2020 16:52:50

**US3632052**

**Folder: Visit 2 Day 29 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 10 Jun 2021 09:13:35**

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:19:13
User entered 'bpm'	System	06 Oct 2020 16:52:50

US3632052

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:13:35

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:19:13
User signature succeeded.	Colleen Kelley (b) (4)	08 Mar 2021 14:31:04
DataPoint Verified.	(b) (4), (b) (6)	16 Dec 2020 17:16:13
User entered '20'	(b) (4), (b) (6)	06 Oct 2020 16:52:50

US3632052

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:13:35

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:19:13
User entered 'breaths/min'	System	06 Oct 2020 16:52:50



US3632052

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:13:35

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:19:13
User signature succeeded.	Colleen Kelley (b) (4)	08 Mar 2021 14:31:04
DataPoint Verified.	(b) (4), (b) (6)	16 Dec 2020 17:16:13
User entered '143'	(b) (4), (b) (6)	06 Oct 2020 16:52:50

US3632052

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:13:35

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:19:13
User entered 'mmHg'	System	06 Oct 2020 16:52:50

US3632052

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:13:35

[Diastolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:19:13
User signature succeeded.	Colleen Kelley (b) (4)	08 Mar 2021 14:31:04
DataPoint Verified.	(b) (4), (b) (6)	16 Dec 2020 17:16:13
User entered '81'	(b) (4), (b) (6)	06 Oct 2020 16:52:50

US3632052

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:13:35

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:19:13
User entered 'mmHg'	System	06 Oct 2020 16:52:50

US3632052

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Generated On: 10 Jun 2021 09:13:35

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:19:13
User signature succeeded.	Colleen Kelley (b) (4)	08 Mar 2021 14:31:04
DataPoint Verified.	(b) (4), (b) (6)	16 Dec 2020 17:17:22
User entered 'Yes (Y)'	(b) (4), (b) (6)	06 Oct 2020 14:23:15

US3632052

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Generated On: 10 Jun 2021 09:13:35

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:19:13
User signature succeeded.	Colleen Kelley (b) (4)	08 Mar 2021 14:31:04
DataPoint Verified.	(b) (4), (b) (6)	16 Dec 2020 17:17:22
User entered '6 Oct 2020'	(b) (4), (b) (6)	06 Oct 2020 14:23:15

US3632052

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 10 Jun 2021 09:13:35

[Was study treatment given?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:19:13
User signature succeeded.	Colleen Kelley (b) (4)	08 Mar 2021 14:31:04
DataPoint Verified.	(b) (4), (b) (6)	16 Dec 2020 17:18:01
User entered 'Yes (Y)'	(b) (4), (b) (6)	06 Oct 2020 15:39:56

**US3632052**

**Folder: Visit 2 Day 29 (1)**

**Form: Exposure**

**Generated On: 10 Jun 2021 09:13:35**

[If No, reason not given](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:19:13
User signature succeeded.	Colleen Kelley (b) (4)	08 Mar 2021 14:31:04
DataPoint Verified.	(b) (4), (b) (6)	16 Dec 2020 17:18:01
User entered empty.	(b) (4), (b) (6)	06 Oct 2020 15:39:56



US3632052

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 10 Jun 2021 09:13:35

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:19:13
User signature succeeded.	Colleen Kelley (b) (4)	08 Mar 2021 14:31:04
DataPoint Verified.	(b) (4), (b) (6)	16 Dec 2020 17:18:01
User entered empty.	(b) (4), (b) (6)	06 Oct 2020 15:39:56

US3632052

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 10 Jun 2021 09:13:35

[What was the study treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:19:13
User entered 'MRNA-1273 OR PLACEBO'	System	06 Oct 2020 15:39:56

US3632052

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 10 Jun 2021 09:13:35

What was the treatment date? (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:19:13
User signature succeeded.	Colleen Kelley (b) (4)	08 Mar 2021 14:31:04
DataPoint Verified.	(b) (4), (b) (6)	16 Dec 2020 17:18:01
User entered '6 Oct 2020'	(b) (4), (b) (6)	06 Oct 2020 15:39:56

US3632052

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 10 Jun 2021 09:13:35

[What was the treatment time? \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:19:13
User signature succeeded.	Colleen Kelley (b) (4)	08 Mar 2021 14:31:04
DataPoint Verified.	(b) (4), (b) (6)	16 Dec 2020 17:18:01
User entered '11:33'	(b) (4), (b) (6)	06 Oct 2020 15:39:56

**US3632052**

**Folder: Visit 2 Day 29 (1)**

**Form: Exposure**

**Generated On: 10 Jun 2021 09:13:35**

[Treatment Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:19:13
User entered '6 Oct 2020 11:33'	System	06 Oct 2020 15:39:56

US3632052

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 10 Jun 2021 09:13:35

[Which arm was used to give treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:19:13
User signature succeeded.	Colleen Kelley (b) (4)	08 Mar 2021 14:31:04
DataPoint Verified.	(b) (4), (b) (6)	16 Dec 2020 17:18:01
User entered 'Left Arm (LEFT ARM)'	(b) (4), (b) (6)	06 Oct 2020 15:39:56

US3632052

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 10 Jun 2021 09:13:35

[What was the frequency of the study treatment dosing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:19:13
DataPoint Verified.	(b) (4), (b) (6)	16 Dec 2020 17:18:01
User entered 'ONCE'	System	06 Oct 2020 15:39:56

US3632052

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 10 Jun 2021 09:13:35

What was the route of administration for the study treatment?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:19:13
User entered 'INTRAMUSCULAR'	System	06 Oct 2020 15:39:56



US3632052

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 09:13:35

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:19:13
User signature succeeded.	Colleen Kelley (b) (4)	08 Mar 2021 14:31:04
DataPoint Verified.	(b) (4), (b) (6)	16 Dec 2020 17:18:34
User entered 'Yes (Y)'	(b) (4), (b) (6)	06 Oct 2020 15:20:36

US3632052

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 09:13:35

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:19:13
User signature succeeded.	Colleen Kelley (b) (4)	08 Mar 2021 14:31:04
DataPoint Verified.	(b) (4), (b) (6)	16 Dec 2020 17:18:34
User entered '6 Oct 2020'	(b) (4), (b) (6)	06 Oct 2020 15:20:36

**US3632052**

**Folder: Visit 2 Day 29 (1)**

**Form: Immunogenicity Assessment**

**Generated On: 10 Jun 2021 09:13:35**

[Collection time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:19:13
User signature succeeded.	Colleen Kelley (b) (4)	08 Mar 2021 14:31:04
DataPoint Verified.	(b) (4), (b) (6)	16 Dec 2020 17:18:34
User entered '10:46'	(b) (4), (b) (6)	06 Oct 2020 15:20:36

**US3632052**

**Folder: Visit 2 Day 29 (1)**

**Form: Immunogenicity Assessment**

**Generated On: 10 Jun 2021 09:13:35**

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:19:13
User entered '6 Oct 2020 10:46'	System	06 Oct 2020 15:20:36

US3632052

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab

Generated On: 10 Jun 2021 09:13:35

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:19:13
User signature succeeded.	Colleen Kelley (b) (4)	08 Mar 2021 14:31:04
DataPoint Verified.	(b) (4), (b) (6)	16 Dec 2020 17:18:42
User entered '6 Oct 2020'	(b) (4), (b) (6)	06 Oct 2020 15:20:09

**US3632052**

**Folder: Visit 2 Day 29 (1)**

**Form: Central Laboratory - Nasopharyngeal Swab (1)**

**Generated On: 10 Jun 2021 09:13:35**

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:19:13
User accepted default value 'Nasopharyngeal Swab 1 (NASAL1)'	(b) (4), (b) (6)	06 Oct 2020 15:20:09

**US3632052**

**Folder: Visit 2 Day 29 (1)**

**Form: Central Laboratory - Nasopharyngeal Swab (1)**

**Generated On: 10 Jun 2021 09:13:35**

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:19:13
User signature succeeded.	Colleen Kelley (b) (4)	08 Mar 2021 14:31:04
DataPoint Verified.	(b) (4), (b) (6)	16 Dec 2020 17:18:42
User entered 'Yes (Y)'	(b) (4), (b) (6)	06 Oct 2020 15:20:09

**US3632052**

**Folder: Visit 2 Day 29 (1)**

**Form: Central Laboratory - Nasopharyngeal Swab (1)**

**Generated On: 10 Jun 2021 09:13:35**

[Collection time \(00:00 - 23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:19:13
User signature succeeded.	Colleen Kelley (b) (4)	08 Mar 2021 14:31:04
DataPoint Verified.	(b) (4), (b) (6)	16 Dec 2020 17:18:42
User entered '10:48'	(b) (4), (b) (6)	06 Oct 2020 15:20:09



**US3632052**

**Folder: Visit 2 Day 29 (1)**

**Form: Central Laboratory - Nasopharyngeal Swab (1)**

**Generated On: 10 Jun 2021 09:13:35**

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:19:13
User entered '6 Oct 2020 10:48'	System	06 Oct 2020 15:20:09

**US3632052**

**Folder: Visit 2 Day 29 (1)**

**Form: Central Laboratory - Nasopharyngeal Swab (2)**

**Generated On: 10 Jun 2021 09:13:35**

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:19:13
User accepted default value 'Nasopharyngeal Swab 2 (NASAL2)'	(b) (4), (b) (6)	06 Oct 2020 15:20:09

**US3632052**

**Folder: Visit 2 Day 29 (1)**

**Form: Central Laboratory - Nasopharyngeal Swab (2)**

**Generated On: 10 Jun 2021 09:13:35**

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:19:13
User signature succeeded.	Colleen Kelley (b) (4)	08 Mar 2021 14:31:04
DataPoint Verified.	(b) (4), (b) (6)	16 Dec 2020 17:18:42
User entered 'No (N)'	(b) (4), (b) (6)	06 Oct 2020 15:20:09

**US3632052**

**Folder: Visit 2 Day 29 (1)**

**Form: Central Laboratory - Nasopharyngeal Swab (2)**

**Generated On: 10 Jun 2021 09:13:35**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:19:13
User signature succeeded.	Colleen Kelley (b) (4)	08 Mar 2021 14:31:04
DataPoint Verified.	(b) (4), (b) (6)	16 Dec 2020 17:18:42
User entered empty.	(b) (4), (b) (6)	06 Oct 2020 15:20:09

**US3632052**

**Folder: Visit 2 Day 29 (1)**

**Form: Central Laboratory - Nasopharyngeal Swab (2)**

**Generated On: 10 Jun 2021 09:13:35**

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:19:13
User entered empty.	System	06 Oct 2020 15:20:09

US3632052

Folder: Visit 2 Day 29 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:13:35

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:19:13
User signature succeeded.	Colleen Kelley (b) (4)	08 Mar 2021 14:31:04
DataPoint Verified.	(b) (4), (b) (6)	16 Dec 2020 17:18:50
User entered 'Yes (Y)'	(b) (4), (b) (6)	06 Oct 2020 16:50:39

**US3632052**

**Folder: Visit 2 Day 29 (1)**

**Form: Continuing**

**Generated On: 10 Jun 2021 09:13:35**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:19:13
User entered 'I'	System	06 Oct 2020 16:50:39

US3632052

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/1)

Generated On: 10 Jun 2021 09:13:35

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:58:03
Data entry locked.	System	06 Oct 2020 15:39:56
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	06 Oct 2020 15:39:56



US3632052

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/1)

Generated On: 10 Jun 2021 09:13:35

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:58:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (44467b427832a52f)', Time: '2020-10-06T12:08:42', User OID: 'PatientReportedOutcome (US3632052)', ODM File OID: 'c1bf8b8e-3867-42a4-8856-2c6e32a24387'	System	06 Oct 2020 16:09:04
User entered 'Yes (Y)'	System	06 Oct 2020 16:09:04

US3632052

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/1)

Generated On: 10 Jun 2021 09:13:35

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:58:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (44467b427832a52f)', Time: '2020-10-06T12:08:52', User OID: 'PatientReportedOutcome (US3632052)', ODM File OID: 'c1bf8b8e-3867-42a4-8856-2c6e32a24387'	System	06 Oct 2020 16:09:04
User entered '97.4'	System	06 Oct 2020 16:09:04

US3632052

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/1)

Generated On: 10 Jun 2021 09:13:35

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:58:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (44467b427832a52f)', Time: '2020-10-06T12:08:56', User OID: 'PatientReportedOutcome (US3632052)', ODM File OID: 'c1bf8b8e-3867-42a4-8856-2c6e32a24387'	System	06 Oct 2020 16:09:04
User entered 'No (N)'	System	06 Oct 2020 16:09:04

**US3632052**

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(1/1)**

**Generated On: 10 Jun 2021 09:13:35**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:58:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (44467b427832a52f)', Time: '2020-10-06T12:09:01', User OID: 'PatientReportedOutcome (US3632052)', ODM File OID: 'c1bf8b8e-3867-42a4-8856-2c6e32a24387'	System	06 Oct 2020 16:09:04
User entered '06 Oct 2020 12:09'	System	06 Oct 2020 16:09:04

**US3632052**

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(1/1)**

**Generated On: 10 Jun 2021 09:13:35**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:58:03
User entered '06 Oct 2020 11:53'	System	06 Oct 2020 15:39:56

**US3632052**

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(1/1)**

**Generated On: 10 Jun 2021 09:13:35**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:58:03
User entered '06 Oct 2020 14:23'	System	06 Oct 2020 15:39:56

US3632052

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/2)

Generated On: 10 Jun 2021 09:13:35

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:58:03
Data entry locked.	System	06 Oct 2020 15:39:56
User entered 'Day 1, after vaccination (at home)'	System	06 Oct 2020 15:39:56

US3632052

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/2)

Generated On: 10 Jun 2021 09:13:35

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:58:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (44467b427832a52f)', Time: '2020-10-06T21:56:44', User OID: 'PatientReportedOutcome (US3632052)', ODM File OID: '788c4090-e462-461b-a08c-1b52935bbb5e'	System	07 Oct 2020 01:57:29
User entered 'Yes (Y)'	System	07 Oct 2020 01:57:29



US3632052

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/2)

Generated On: 10 Jun 2021 09:13:35

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:58:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (44467b427832a52f)', Time: '2020-10-06T21:56:53', User OID: 'PatientReportedOutcome (US3632052)', ODM File OID: '788c4090-e462-461b-a08c-1b52935bbb5e'	System	07 Oct 2020 01:57:29
User entered '96.9'	System	07 Oct 2020 01:57:29

US3632052

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/2)

Generated On: 10 Jun 2021 09:13:35

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:58:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (44467b427832a52f)', Time: '2020-10-06T21:57:04', User OID: 'PatientReportedOutcome (US3632052)', ODM File OID: '788c4090-e462-461b-a08c-1b52935bbb5e'	System	07 Oct 2020 01:57:29
User entered 'Yes (Y)'	System	07 Oct 2020 01:57:29

US3632052

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/2)

Generated On: 10 Jun 2021 09:13:35

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:58:03
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 added to concomitant medication.' (Site from System).	(b) (4), (b) (6)	14 Oct 2020 09:25:19
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).	Isaac Perez (b) (4)	13 Oct 2020 19:51:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (44467b427832a52f)', Time: '2020-10-06T21:57:19', User OID: 'PatientReportedOutcome (US3632052)', ODM File OID: '788c4090-e462-461b-a08c-1b52935bbb5e'	(b) (4)	
User entered '1'	System	07 Oct 2020 01:57:29
	System	07 Oct 2020 01:57:29
	System	07 Oct 2020 01:57:29

US3632052

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/2)

Generated On: 10 Jun 2021 09:13:35

To **PREVENT** pain or fever from occurring

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:58:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (44467b427832a52f)', Time: '2020-10-06T21:57:19', User OID: 'PatientReportedOutcome (US3632052)', ODM File OID: '788c4090-e462-461b-a08c-1b52935bbb5e'	System	07 Oct 2020 01:57:29
User entered '0'	System	07 Oct 2020 01:57:29

US3632052

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/2)

Generated On: 10 Jun 2021 09:13:35

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:58:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (44467b427832a52f)', Time: '2020-10-06T21:57:25', User OID: 'PatientReportedOutcome (US3632052)', ODM File OID: '788c4090-e462-461b-a08c-1b52935bbb5e'	System	07 Oct 2020 01:57:29
User entered '06 Oct 2020 21:57'	System	07 Oct 2020 01:57:29

**US3632052**

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(1/2)**

**Generated On: 10 Jun 2021 09:13:35**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:58:03
User entered '06 Oct 2020 15:18'	System	06 Oct 2020 15:39:56

**US3632052**

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(1/2)**

**Generated On: 10 Jun 2021 09:13:35**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:58:03
User entered '07 Oct 2020 11:59'	System	06 Oct 2020 15:39:56

US3632052

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(2)

Generated On: 10 Jun 2021 09:13:35

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:58:03
Data entry locked.	System	06 Oct 2020 15:39:56
User entered 'Day 2'	System	06 Oct 2020 15:39:56



US3632052

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(2)

Generated On: 10 Jun 2021 09:13:35

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:58:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (44467b427832a52f)', Time: '2020-10-07T22:39:39', User OID: 'PatientReportedOutcome (US3632052)', ODM File OID: '980ab819-9fde-4e77-a5a9-5e0a9c116594'	System	08 Oct 2020 02:40:06
User entered 'Yes (Y)'	System	08 Oct 2020 02:40:06

US3632052

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(2)

Generated On: 10 Jun 2021 09:13:35

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:58:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (44467b427832a52f)', Time: '2020-10-07T22:39:46', User OID: 'PatientReportedOutcome (US3632052)', ODM File OID: '980ab819-9fde-4e77-a5a9-5e0a9c116594'	System	08 Oct 2020 02:40:06
User entered '97.8'	System	08 Oct 2020 02:40:06

US3632052

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(2)

Generated On: 10 Jun 2021 09:13:35

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:58:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (44467b427832a52f)', Time: '2020-10-07T22:39:55', User OID: 'PatientReportedOutcome (US3632052)', ODM File OID: '980ab819-9fde-4e77-a5a9-5e0a9c116594'	System	08 Oct 2020 02:40:06
User entered 'No (N)'	System	08 Oct 2020 02:40:06

**US3632052**

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(2)**

**Generated On: 10 Jun 2021 09:13:35**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:58:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (44467b427832a52f)', Time: '2020-10-07T22:39:58', User OID: 'PatientReportedOutcome (US3632052)', ODM File OID: '980ab819-9fde-4e77-a5a9-5e0a9c116594'	System	08 Oct 2020 02:40:06
User entered '07 Oct 2020 22:39'	System	08 Oct 2020 02:40:06

**US3632052**

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(2)**

**Generated On: 10 Jun 2021 09:13:35**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:58:03
User entered '07 Oct 2020 12:00'	System	06 Oct 2020 15:39:56

**US3632052**

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(2)**

**Generated On: 10 Jun 2021 09:13:35**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:58:03
User entered '08 Oct 2020 11:59'	System	06 Oct 2020 15:39:56

US3632052

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(3)

Generated On: 10 Jun 2021 09:13:35

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:58:03
Data entry locked.	System	06 Oct 2020 15:39:56
User entered 'Day 3'	System	06 Oct 2020 15:39:56

US3632052

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(3)

Generated On: 10 Jun 2021 09:13:35

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:58:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (44467b427832a52f)', Time: '2020-10-08T23:03:09', User OID: 'PatientReportedOutcome (US3632052)', ODM File OID: '69759b0a-c7ff-4e79-a0e5-f335d7e569e3'	System	09 Oct 2020 03:03:29
User entered 'Yes (Y)'	System	09 Oct 2020 03:03:29



US3632052

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(3)

Generated On: 10 Jun 2021 09:13:35

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:58:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (44467b427832a52f)', Time: '2020-10-08T23:03:18', User OID: 'PatientReportedOutcome (US3632052)', ODM File OID: '69759b0a-c7ff-4e79-a0e5-f335d7e569e3'	System	09 Oct 2020 03:03:29
User entered '96.9'	System	09 Oct 2020 03:03:29

US3632052

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(3)

Generated On: 10 Jun 2021 09:13:35

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:58:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (44467b427832a52f)', Time: '2020-10-08T23:03:22', User OID: 'PatientReportedOutcome (US3632052)', ODM File OID: '69759b0a-c7ff-4e79-a0e5-f335d7e569e3'	System	09 Oct 2020 03:03:29
User entered 'No (N)'	System	09 Oct 2020 03:03:29

US3632052

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(3)

Generated On: 10 Jun 2021 09:13:35

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:58:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (44467b427832a52f)', Time: '2020-10-08T23:03:26', User OID: 'PatientReportedOutcome (US3632052)', ODM File OID: '69759b0a-c7ff-4e79-a0e5-f335d7e569e3'	System	09 Oct 2020 03:03:29
User entered '08 Oct 2020 23:03'	System	09 Oct 2020 03:03:29

**US3632052**

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(3)**

**Generated On: 10 Jun 2021 09:13:35**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:58:03
User entered '08 Oct 2020 12:00'	System	06 Oct 2020 15:39:56

**US3632052**

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(3)**

**Generated On: 10 Jun 2021 09:13:35**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:58:03
User entered '09 Oct 2020 11:59'	System	06 Oct 2020 15:39:56

US3632052

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(4)

Generated On: 10 Jun 2021 09:13:35

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:58:03
Data entry locked.	System	06 Oct 2020 15:39:56
User entered 'Day 4'	System	06 Oct 2020 15:39:56

US3632052

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(4)

Generated On: 10 Jun 2021 09:13:35

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:58:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (44467b427832a52f)', Time: '2020-10-09T22:59:39', User OID: 'PatientReportedOutcome (US3632052)', ODM File OID: '731e5951-b973-49c4-9a8a-6aac789ef807'	System	10 Oct 2020 02:59:58
User entered 'Yes (Y)'	System	10 Oct 2020 02:59:58

US3632052

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(4)

Generated On: 10 Jun 2021 09:13:35

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:58:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (44467b427832a52f)', Time: '2020-10-09T22:59:47', User OID: 'PatientReportedOutcome (US3632052)', ODM File OID: '731e5951-b973-49c4-9a8a-6aac789ef807'	System	10 Oct 2020 02:59:58
User entered '96.6'	System	10 Oct 2020 02:59:58



US3632052

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(4)

Generated On: 10 Jun 2021 09:13:35

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:58:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (44467b427832a52f)', Time: '2020-10-09T22:59:51', User OID: 'PatientReportedOutcome (US3632052)', ODM File OID: '731e5951-b973-49c4-9a8a-6aac789ef807'	System	10 Oct 2020 02:59:58
User entered 'No (N)'	System	10 Oct 2020 02:59:58

**US3632052**

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(4)**

**Generated On: 10 Jun 2021 09:13:35**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:58:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (44467b427832a52f)', Time: '2020-10-09T22:59:55', User OID: 'PatientReportedOutcome (US3632052)', ODM File OID: '731e5951-b973-49c4-9a8a-6aac789ef807'	System	10 Oct 2020 02:59:58
User entered '09 Oct 2020 22:59'	System	10 Oct 2020 02:59:58

US3632052

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(4)

Generated On: 10 Jun 2021 09:13:35

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:58:03
User entered '09 Oct 2020 12:00'	System	06 Oct 2020 15:39:56

**US3632052**

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(4)**

**Generated On: 10 Jun 2021 09:13:35**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:58:03
User entered '10 Oct 2020 11:59'	System	06 Oct 2020 15:39:56

US3632052

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(5)

Generated On: 10 Jun 2021 09:13:35

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:58:03
Data entry locked.	System	06 Oct 2020 15:39:56
User entered 'Day 5'	System	06 Oct 2020 15:39:56

US3632052

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(5)

Generated On: 10 Jun 2021 09:13:35

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:58:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (44467b427832a52f)', Time: '2020-10-10T22:36:01', User OID: 'PatientReportedOutcome (US3632052)', ODM File OID: 'f1c0b6cc-3b96-42b5-b5cf-4eb8763c77b1'	System	11 Oct 2020 02:36:38
User entered 'Yes (Y)'	System	11 Oct 2020 02:36:38

US3632052

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(5)

Generated On: 10 Jun 2021 09:13:35

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:58:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (44467b427832a52f)', Time: '2020-10-10T22:36:06', User OID: 'PatientReportedOutcome (US3632052)', ODM File OID: 'f1c0b6cc-3b96-42b5-b5cf-4eb8763c77b1'	System	11 Oct 2020 02:36:38
User entered '97.7'	System	11 Oct 2020 02:36:38

US3632052

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(5)

Generated On: 10 Jun 2021 09:13:35

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:58:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (44467b427832a52f)', Time: '2020-10-10T22:36:16', User OID: 'PatientReportedOutcome (US3632052)', ODM File OID: 'f1c0b6cc-3b96-42b5-b5cf-4eb8763c77b1'	System	11 Oct 2020 02:36:38
User entered 'Yes (Y)'	System	11 Oct 2020 02:36:38



US3632052

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(5)

Generated On: 10 Jun 2021 09:13:35

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:58:03
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 added to concomitant medication.' (Site from System).	(b) (4), (b) (6)	14 Oct 2020 09:19:37
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).	Isaac Perez (b) (4)	13 Oct 2020 19:51:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (44467b427832a52f)', Time: '2020-10-10T22:36:31', User OID: 'PatientReportedOutcome (US3632052)', ODM File OID: 'f1c0b6cc-3b96-42b5-b5cf-4eb8763c77b1'	(b) (4)	
User entered '1'	System	11 Oct 2020 02:36:38
	System	11 Oct 2020 02:36:38
	System	11 Oct 2020 02:36:38

US3632052

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(5)

Generated On: 10 Jun 2021 09:13:35

To **PREVENT** pain or fever from occurring

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:58:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (44467b427832a52f)', Time: '2020-10-10T22:36:31', User OID: 'PatientReportedOutcome (US3632052)', ODM File OID: 'f1c0b6cc-3b96-42b5-b5cf-4eb8763c77b1'	System	11 Oct 2020 02:36:38
User entered '0'	System	11 Oct 2020 02:36:38

**US3632052**

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(5)**

**Generated On: 10 Jun 2021 09:13:35**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:58:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (44467b427832a52f)', Time: '2020-10-10T22:36:35', User OID: 'PatientReportedOutcome (US3632052)', ODM File OID: 'f1c0b6cc-3b96-42b5-b5cf-4eb8763c77b1'	System	11 Oct 2020 02:36:38
User entered '10 Oct 2020 22:36'	System	11 Oct 2020 02:36:38

**US3632052**

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(5)**

**Generated On: 10 Jun 2021 09:13:35**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:58:03
User entered '10 Oct 2020 12:00'	System	06 Oct 2020 15:39:56

**US3632052**

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(5)**

**Generated On: 10 Jun 2021 09:13:35**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:58:03
User entered '11 Oct 2020 11:59'	System	06 Oct 2020 15:39:56

US3632052

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(6)

Generated On: 10 Jun 2021 09:13:35

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:58:03
Data entry locked.	System	06 Oct 2020 15:39:56
User entered 'Day 6'	System	06 Oct 2020 15:39:56

US3632052

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(6)

Generated On: 10 Jun 2021 09:13:35

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:58:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (44467b427832a52f)', Time: '2020-10-11T23:31:34', User OID: 'PatientReportedOutcome (US3632052)', ODM File OID: 'd5bf4f1b-62c4-4577-b26b-9a95d431e37a'	System	12 Oct 2020 03:32:14
User entered 'Yes (Y)'	System	12 Oct 2020 03:32:14

US3632052

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(6)

Generated On: 10 Jun 2021 09:13:35

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:58:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (44467b427832a52f)', Time: '2020-10-11T23:32:03', User OID: 'PatientReportedOutcome (US3632052)', ODM File OID: 'd5bf4f1b-62c4-4577-b26b-9a95d431e37a'	System	12 Oct 2020 03:32:14
User entered '97.7'	System	12 Oct 2020 03:32:14



US3632052

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(6)

Generated On: 10 Jun 2021 09:13:35

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:58:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (44467b427832a52f)', Time: '2020-10-11T23:32:08', User OID: 'PatientReportedOutcome (US3632052)', ODM File OID: 'd5bf4f1b-62c4-4577-b26b-9a95d431e37a'	System	12 Oct 2020 03:32:14
User entered 'No (N)'	System	12 Oct 2020 03:32:14

**US3632052**

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(6)**

**Generated On: 10 Jun 2021 09:13:35**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:58:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (44467b427832a52f)', Time: '2020-10-11T23:32:12', User OID: 'PatientReportedOutcome (US3632052)', ODM File OID: 'd5bf4f1b-62c4-4577-b26b-9a95d431e37a'	System	12 Oct 2020 03:32:14
User entered '11 Oct 2020 23:32'	System	12 Oct 2020 03:32:14

**US3632052**

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(6)**

**Generated On: 10 Jun 2021 09:13:35**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:58:03
User entered '11 Oct 2020 12:00'	System	06 Oct 2020 15:39:56

**US3632052**

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(6)**

**Generated On: 10 Jun 2021 09:13:35**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:58:03
User entered '12 Oct 2020 11:59'	System	06 Oct 2020 15:39:56

US3632052

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(7)

Generated On: 10 Jun 2021 09:13:35

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:58:03
Data entry locked.	System	06 Oct 2020 15:39:56
User entered 'Day 7'	System	06 Oct 2020 15:39:56

US3632052

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(7)

Generated On: 10 Jun 2021 09:13:35

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:58:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (44467b427832a52f)', Time: '2020-10-12T23:17:29', User OID: 'PatientReportedOutcome (US3632052)', ODM File OID: '117d3007-ee42-4533-8695-fb4f51da401b'	System	13 Oct 2020 03:17:43
User entered 'Yes (Y)'	System	13 Oct 2020 03:17:43

US3632052

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(7)

Generated On: 10 Jun 2021 09:13:35

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:58:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (44467b427832a52f)', Time: '2020-10-12T23:17:34', User OID: 'PatientReportedOutcome (US3632052)', ODM File OID: '117d3007-ee42-4533-8695-fb4f51da401b'	System	13 Oct 2020 03:17:43
User entered '97.5'	System	13 Oct 2020 03:17:43

US3632052

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(7)

Generated On: 10 Jun 2021 09:13:35

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:58:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (44467b427832a52f)', Time: '2020-10-12T23:17:38', User OID: 'PatientReportedOutcome (US3632052)', ODM File OID: '117d3007-ee42-4533-8695-fb4f51da401b'	System	13 Oct 2020 03:17:43
User entered 'No (N)'	System	13 Oct 2020 03:17:43



**US3632052**

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(7)**

**Generated On: 10 Jun 2021 09:13:35**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:58:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (44467b427832a52f)', Time: '2020-10-12T23:17:41', User OID: 'PatientReportedOutcome (US3632052)', ODM File OID: '117d3007-ee42-4533-8695-fb4f51da401b'	System	13 Oct 2020 03:17:43
User entered '12 Oct 2020 23:17'	System	13 Oct 2020 03:17:43

**US3632052**

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(7)**

**Generated On: 10 Jun 2021 09:13:35**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:58:03
User entered '12 Oct 2020 12:00'	System	06 Oct 2020 15:39:56

**US3632052**

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(7)**

**Generated On: 10 Jun 2021 09:13:35**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:58:03
User entered '13 Oct 2020 11:59'	System	06 Oct 2020 15:39:56

US3632052

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/1)

Generated On: 10 Jun 2021 09:13:35

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:58:03
Data entry locked.	System	06 Oct 2020 15:39:56
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	06 Oct 2020 15:39:56

US3632052

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/1)

Generated On: 10 Jun 2021 09:13:35

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 10:58:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (44467b427832a52f)', Time: '2020-10-06T12:09:08', User OID: 'PatientReportedOutcome (US3632052)', ODM File OID: '90a877aa-b16c-4432-a5cf-92e5419992f0'	System	06 Oct 2020 16:09:50
User entered 'None (1)'	System	06 Oct 2020 16:09:50

US3632052

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/1)

Generated On: 10 Jun 2021 09:13:35

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:58:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (44467b427832a52f)', Time: '2020-10-06T12:09:25', User OID: 'PatientReportedOutcome (US3632052)', ODM File OID: '90a877aa-b16c-4432-a5cf-92e5419992f0'	System	06 Oct 2020 16:09:50
User entered 'No (N)'	System	06 Oct 2020 16:09:50

US3632052

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/1)

Generated On: 10 Jun 2021 09:13:35

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:58:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (44467b427832a52f)', Time: '2020-10-06T12:09:34', User OID: 'PatientReportedOutcome (US3632052)', ODM File OID: '90a877aa-b16c-4432-a5cf-92e5419992f0'	System	06 Oct 2020 16:09:50
User entered 'No (N)'	System	06 Oct 2020 16:09:50

US3632052

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/1)

Generated On: 10 Jun 2021 09:13:35

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 10:58:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (44467b427832a52f)', Time: '2020-10-06T12:09:42', User OID: 'PatientReportedOutcome (US3632052)', ODM File OID: '90a877aa-b16c-4432-a5cf-92e5419992f0'	System	06 Oct 2020 16:09:50
User entered 'None (1)'	System	06 Oct 2020 16:09:50



**US3632052**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(1/1)**

**Generated On: 10 Jun 2021 09:13:35**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:58:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (44467b427832a52f)', Time: '2020-10-06T12:09:46', User OID: 'PatientReportedOutcome (US3632052)', ODM File OID: '90a877aa-b16c-4432-a5cf-92e5419992f0'	System	06 Oct 2020 16:09:50
User entered '06 Oct 2020 12:09'	System	06 Oct 2020 16:09:50

**US3632052**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(1/1)**

**Generated On: 10 Jun 2021 09:13:35**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:58:03
User entered '06 Oct 2020 11:53'	System	06 Oct 2020 15:39:56

**US3632052**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(1/1)**

**Generated On: 10 Jun 2021 09:13:35**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:58:03
User entered '06 Oct 2020 14:23'	System	06 Oct 2020 15:39:56

US3632052

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/2)

Generated On: 10 Jun 2021 09:13:35

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:58:03
Data entry locked.	System	06 Oct 2020 15:39:56
User entered 'Day 1, after vaccination (at home)'	System	06 Oct 2020 15:39:56

US3632052

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/2)

Generated On: 10 Jun 2021 09:13:35

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 10:58:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (44467b427832a52f)', Time: '2020-10-06T21:57:44', User OID: 'PatientReportedOutcome (US3632052)', ODM File OID: '0b7d2f2a-5660-4a01-a09a-c6e1e6ba6990'	System	07 Oct 2020 01:58:46
User entered 'Does not interfere with activity (2)'	System	07 Oct 2020 01:58:46

US3632052

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/2)

Generated On: 10 Jun 2021 09:13:35

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:58:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (44467b427832a52f)', Time: '2020-10-06T21:57:48', User OID: 'PatientReportedOutcome (US3632052)', ODM File OID: '0b7d2f2a-5660-4a01-a09a-c6e1e6ba6990'	System	07 Oct 2020 01:58:46
User entered 'No (N)'	System	07 Oct 2020 01:58:46

US3632052

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/2)

Generated On: 10 Jun 2021 09:13:35

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:58:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (44467b427832a52f)', Time: '2020-10-06T21:58:39', User OID: 'PatientReportedOutcome (US3632052)', ODM File OID: '0b7d2f2a-5660-4a01-a09a-c6e1e6ba6990'	System	07 Oct 2020 01:58:46
User entered 'No (N)'	System	07 Oct 2020 01:58:46

US3632052

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/2)

Generated On: 10 Jun 2021 09:13:35

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 10:58:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (44467b427832a52f)', Time: '2020-10-06T21:58:26', User OID: 'PatientReportedOutcome (US3632052)', ODM File OID: '0b7d2f2a-5660-4a01-a09a-c6e1e6ba6990'	System	07 Oct 2020 01:58:46
User entered 'None (1)'	System	07 Oct 2020 01:58:46



**US3632052**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(1/2)**

**Generated On: 10 Jun 2021 09:13:35**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:58:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (44467b427832a52f)', Time: '2020-10-06T21:58:42', User OID: 'PatientReportedOutcome (US3632052)', ODM File OID: '0b7d2f2a-5660-4a01-a09a-c6e1e6ba6990'	System	07 Oct 2020 01:58:46
User entered '06 Oct 2020 21:58'	System	07 Oct 2020 01:58:46

**US3632052**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(1/2)**

**Generated On: 10 Jun 2021 09:13:35**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:58:03
User entered '06 Oct 2020 15:18'	System	06 Oct 2020 15:39:56

**US3632052**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(1/2)**

**Generated On: 10 Jun 2021 09:13:35**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:58:03
User entered '07 Oct 2020 11:59'	System	06 Oct 2020 15:39:56

US3632052

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(2)

Generated On: 10 Jun 2021 09:13:35

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:58:03
Data entry locked.	System	06 Oct 2020 15:39:56
User entered 'Day 2'	System	06 Oct 2020 15:39:56

US3632052

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(2)

Generated On: 10 Jun 2021 09:13:35

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 10:58:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (44467b427832a52f)', Time: '2020-10-07T22:40:06', User OID: 'PatientReportedOutcome (US3632052)', ODM File OID: '1561cb4a-4a40-4668-a182-feddd68eefa2d'	System	08 Oct 2020 02:40:50
User entered 'Does not interfere with activity (2)'	System	08 Oct 2020 02:40:50

US3632052

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(2)

Generated On: 10 Jun 2021 09:13:35

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:58:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (44467b427832a52f)', Time: '2020-10-07T22:40:09', User OID: 'PatientReportedOutcome (US3632052)', ODM File OID: '1561cb4a-4a40-4668-a182-fed68eefa2d'	System	08 Oct 2020 02:40:50
User entered 'No (N)'	System	08 Oct 2020 02:40:50

US3632052

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(2)

Generated On: 10 Jun 2021 09:13:35

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:58:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (44467b427832a52f)', Time: '2020-10-07T22:40:30', User OID: 'PatientReportedOutcome (US3632052)', ODM File OID: '1561cb4a-4a40-4668-a182-fed68eefa2d'	System	08 Oct 2020 02:40:50
User entered 'No (N)'	System	08 Oct 2020 02:40:50

US3632052

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(2)

Generated On: 10 Jun 2021 09:13:35

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 10:58:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (44467b427832a52f)', Time: '2020-10-07T22:40:36', User OID: 'PatientReportedOutcome (US3632052)', ODM File OID: '1561cb4a-4a40-4668-a182-fed68eefa2d'	System	08 Oct 2020 02:40:50
User entered 'None (1)'	System	08 Oct 2020 02:40:50



**US3632052**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(2)**

**Generated On: 10 Jun 2021 09:13:35**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:58:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (44467b427832a52f)', Time: '2020-10-07T22:40:47', User OID: 'PatientReportedOutcome (US3632052)', ODM File OID: '1561cb4a-4a40-4668-a182-fedd68eefa2d'	System	08 Oct 2020 02:40:50
User entered '07 Oct 2020 22:40'	System	08 Oct 2020 02:40:50

**US3632052**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(2)**

**Generated On: 10 Jun 2021 09:13:35**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:58:03
User entered '07 Oct 2020 12:00'	System	06 Oct 2020 15:39:56

**US3632052**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(2)**

**Generated On: 10 Jun 2021 09:13:35**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:58:03
User entered '08 Oct 2020 11:59'	System	06 Oct 2020 15:39:56

US3632052

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(3)

Generated On: 10 Jun 2021 09:13:35

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:58:03
Data entry locked.	System	06 Oct 2020 15:39:56
User entered 'Day 3'	System	06 Oct 2020 15:39:56

US3632052

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(3)

Generated On: 10 Jun 2021 09:13:35

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 10:58:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (44467b427832a52f)', Time: '2020-10-08T23:03:39', User OID: 'PatientReportedOutcome (US3632052)', ODM File OID: 'ef5e00ca-2587-4b5c-a94c-e57827bc417b'	System	09 Oct 2020 03:03:58
User entered 'None (1)'	System	09 Oct 2020 03:03:58

US3632052

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(3)

Generated On: 10 Jun 2021 09:13:35

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:58:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (44467b427832a52f)', Time: '2020-10-08T23:03:44', User OID: 'PatientReportedOutcome (US3632052)', ODM File OID: 'ef5e00ca-2587-4b5c-a94c-e57827bc417b'	System	09 Oct 2020 03:03:58
User entered 'No (N)'	System	09 Oct 2020 03:03:58

US3632052

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(3)

Generated On: 10 Jun 2021 09:13:35

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:58:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (44467b427832a52f)', Time: '2020-10-08T23:03:49', User OID: 'PatientReportedOutcome (US3632052)', ODM File OID: 'ef5e00ca-2587-4b5c-a94c-e57827bc417b'	System	09 Oct 2020 03:03:58
User entered 'No (N)'	System	09 Oct 2020 03:03:58

US3632052

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(3)

Generated On: 10 Jun 2021 09:13:35

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 10:58:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (44467b427832a52f)', Time: '2020-10-08T23:03:52', User OID: 'PatientReportedOutcome (US3632052)', ODM File OID: 'ef5e00ca-2587-4b5c-a94c-e57827bc417b'	System	09 Oct 2020 03:03:58
User entered 'None (1)'	System	09 Oct 2020 03:03:58



US3632052

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(3)

Generated On: 10 Jun 2021 09:13:35

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:58:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (44467b427832a52f)', Time: '2020-10-08T23:03:54', User OID: 'PatientReportedOutcome (US3632052)', ODM File OID: 'ef5e00ca-2587-4b5c-a94c-e57827bc417b'	System	09 Oct 2020 03:03:58
User entered '08 Oct 2020 23:03'	System	09 Oct 2020 03:03:58

**US3632052**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(3)**

**Generated On: 10 Jun 2021 09:13:35**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:58:03
User entered '08 Oct 2020 12:00'	System	06 Oct 2020 15:39:56

**US3632052**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(3)**

**Generated On: 10 Jun 2021 09:13:35**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:58:03
User entered '09 Oct 2020 11:59'	System	06 Oct 2020 15:39:56

US3632052

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(4)

Generated On: 10 Jun 2021 09:13:35

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:58:03
Data entry locked.	System	06 Oct 2020 15:39:56
User entered 'Day 4'	System	06 Oct 2020 15:39:56

US3632052

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(4)

Generated On: 10 Jun 2021 09:13:35

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 10:58:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (44467b427832a52f)', Time: '2020-10-09T22:59:59', User OID: 'PatientReportedOutcome (US3632052)', ODM File OID: '827017a7-5d1d-43ae-ba90-744e985166ba'	System	10 Oct 2020 03:00:18
User entered 'None (1)'	System	10 Oct 2020 03:00:18

US3632052

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(4)

Generated On: 10 Jun 2021 09:13:35

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:58:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (44467b427832a52f)', Time: '2020-10-09T23:00:04', User OID: 'PatientReportedOutcome (US3632052)', ODM File OID: '827017a7-5d1d-43ae-ba90-744e985166ba'	System	10 Oct 2020 03:00:18
User entered 'No (N)'	System	10 Oct 2020 03:00:18

US3632052

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(4)

Generated On: 10 Jun 2021 09:13:35

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:58:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (44467b427832a52f)', Time: '2020-10-09T23:00:07', User OID: 'PatientReportedOutcome (US3632052)', ODM File OID: '827017a7-5d1d-43ae-ba90-744e985166ba'	System	10 Oct 2020 03:00:18
User entered 'No (N)'	System	10 Oct 2020 03:00:18

US3632052

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(4)

Generated On: 10 Jun 2021 09:13:35

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 10:58:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (44467b427832a52f)', Time: '2020-10-09T23:00:09', User OID: 'PatientReportedOutcome (US3632052)', ODM File OID: '827017a7-5d1d-43ae-ba90-744e985166ba'	System	10 Oct 2020 03:00:18
User entered 'None (1)'	System	10 Oct 2020 03:00:18



**US3632052**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(4)**

**Generated On: 10 Jun 2021 09:13:35**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:58:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (44467b427832a52f)', Time: '2020-10-09T23:00:12', User OID: 'PatientReportedOutcome (US3632052)', ODM File OID: '827017a7-5d1d-43ae-ba90-744e985166ba'	System	10 Oct 2020 03:00:18
User entered '09 Oct 2020 23:00'	System	10 Oct 2020 03:00:18

**US3632052**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(4)**

**Generated On: 10 Jun 2021 09:13:35**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:58:03
User entered '09 Oct 2020 12:00'	System	06 Oct 2020 15:39:56

**US3632052**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(4)**

**Generated On: 10 Jun 2021 09:13:35**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:58:03
User entered '10 Oct 2020 11:59'	System	06 Oct 2020 15:39:56

US3632052

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(5)

Generated On: 10 Jun 2021 09:13:35

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:58:03
Data entry locked.	System	06 Oct 2020 15:39:56
User entered 'Day 5'	System	06 Oct 2020 15:39:56

US3632052

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(5)

Generated On: 10 Jun 2021 09:13:35

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 10:58:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (44467b427832a52f)', Time: '2020-10-10T22:36:43', User OID: 'PatientReportedOutcome (US3632052)', ODM File OID: '6bbb0e40-582e-41d5-9a43-80e17887dbc8'	System	11 Oct 2020 02:36:59
User entered 'Does not interfere with activity (2)'	System	11 Oct 2020 02:36:59

US3632052

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(5)

Generated On: 10 Jun 2021 09:13:35

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:58:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (44467b427832a52f)', Time: '2020-10-10T22:36:46', User OID: 'PatientReportedOutcome (US3632052)', ODM File OID: '6bbb0e40-582e-41d5-9a43-80e17887dbc8'	System	11 Oct 2020 02:36:59
User entered 'No (N)'	System	11 Oct 2020 02:36:59

US3632052

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(5)

Generated On: 10 Jun 2021 09:13:35

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:58:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (44467b427832a52f)', Time: '2020-10-10T22:36:48', User OID: 'PatientReportedOutcome (US3632052)', ODM File OID: '6bbb0e40-582e-41d5-9a43-80e17887dbc8'	System	11 Oct 2020 02:36:59
User entered 'No (N)'	System	11 Oct 2020 02:36:59

US3632052

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(5)

Generated On: 10 Jun 2021 09:13:35

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 10:58:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (44467b427832a52f)', Time: '2020-10-10T22:36:51', User OID: 'PatientReportedOutcome (US3632052)', ODM File OID: '6bbb0e40-582e-41d5-9a43-80e17887dbc8'	System	11 Oct 2020 02:36:59
User entered 'None (1)'	System	11 Oct 2020 02:36:59



**US3632052**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(5)**

**Generated On: 10 Jun 2021 09:13:35**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:58:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (44467b427832a52f)', Time: '2020-10-10T22:36:54', User OID: 'PatientReportedOutcome (US3632052)', ODM File OID: '6bbb0e40-582e-41d5-9a43-80e17887dbc8'	System	11 Oct 2020 02:36:59
User entered '10 Oct 2020 22:36'	System	11 Oct 2020 02:36:59

**US3632052**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(5)**

**Generated On: 10 Jun 2021 09:13:35**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:58:03
User entered '10 Oct 2020 12:00'	System	06 Oct 2020 15:39:56

**US3632052**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(5)**

**Generated On: 10 Jun 2021 09:13:35**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:58:03
User entered '11 Oct 2020 11:59'	System	06 Oct 2020 15:39:56

US3632052

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(6)

Generated On: 10 Jun 2021 09:13:35

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:58:03
Data entry locked.	System	06 Oct 2020 15:39:56
User entered 'Day 6'	System	06 Oct 2020 15:39:56

US3632052

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(6)

Generated On: 10 Jun 2021 09:13:35

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 10:58:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (44467b427832a52f)', Time: '2020-10-11T23:32:18', User OID: 'PatientReportedOutcome (US3632052)', ODM File OID: '226f028e-4f85-4b5e-8eeb-4ef9947f84a0'	System	12 Oct 2020 03:32:34
User entered 'None (1)'	System	12 Oct 2020 03:32:34

US3632052

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(6)

Generated On: 10 Jun 2021 09:13:35

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:58:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (44467b427832a52f)', Time: '2020-10-11T23:32:22', User OID: 'PatientReportedOutcome (US3632052)', ODM File OID: '226f028e-4f85-4b5e-8eeb-4ef9947f84a0'	System	12 Oct 2020 03:32:34
User entered 'No (N)'	System	12 Oct 2020 03:32:34

US3632052

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(6)

Generated On: 10 Jun 2021 09:13:35

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:58:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (44467b427832a52f)', Time: '2020-10-11T23:32:23', User OID: 'PatientReportedOutcome (US3632052)', ODM File OID: '226f028e-4f85-4b5e-8eeb-4ef9947f84a0'	System	12 Oct 2020 03:32:34
User entered 'No (N)'	System	12 Oct 2020 03:32:34

US3632052

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(6)

Generated On: 10 Jun 2021 09:13:35

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 10:58:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (44467b427832a52f)', Time: '2020-10-11T23:32:26', User OID: 'PatientReportedOutcome (US3632052)', ODM File OID: '226f028e-4f85-4b5e-8eeb-4ef9947f84a0'	System	12 Oct 2020 03:32:34
User entered 'None (1)'	System	12 Oct 2020 03:32:34



**US3632052**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(6)**

**Generated On: 10 Jun 2021 09:13:35**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:58:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (44467b427832a52f)', Time: '2020-10-11T23:32:30', User OID: 'PatientReportedOutcome (US3632052)', ODM File OID: '226f028e-4f85-4b5e-8eeb-4ef9947f84a0'	System	12 Oct 2020 03:32:34
User entered '11 Oct 2020 23:32'	System	12 Oct 2020 03:32:34

**US3632052**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(6)**

**Generated On: 10 Jun 2021 09:13:35**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:58:03
User entered '11 Oct 2020 12:00'	System	06 Oct 2020 15:39:56

**US3632052**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(6)**

**Generated On: 10 Jun 2021 09:13:35**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:58:03
User entered '12 Oct 2020 11:59'	System	06 Oct 2020 15:39:56

US3632052

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(7)

Generated On: 10 Jun 2021 09:13:35

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:58:03
Data entry locked.	System	06 Oct 2020 15:39:56
User entered 'Day 7'	System	06 Oct 2020 15:39:56

US3632052

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(7)

Generated On: 10 Jun 2021 09:13:35

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 10:58:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (44467b427832a52f)', Time: '2020-10-12T23:17:45', User OID: 'PatientReportedOutcome (US3632052)', ODM File OID: 'b1e456d6-0f2c-40d6-9c60-fcdc23d85639'	System	13 Oct 2020 03:18:01
User entered 'None (1)'	System	13 Oct 2020 03:18:01

US3632052

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(7)

Generated On: 10 Jun 2021 09:13:35

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:58:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (44467b427832a52f)', Time: '2020-10-12T23:17:48', User OID: 'PatientReportedOutcome (US3632052)', ODM File OID: 'b1e456d6-0f2c-40d6-9c60-fcdc23d85639'	System	13 Oct 2020 03:18:01
User entered 'No (N)'	System	13 Oct 2020 03:18:01

US3632052

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(7)

Generated On: 10 Jun 2021 09:13:35

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:58:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (44467b427832a52f)', Time: '2020-10-12T23:17:52', User OID: 'PatientReportedOutcome (US3632052)', ODM File OID: 'b1e456d6-0f2c-40d6-9c60-fcdc23d85639'	System	13 Oct 2020 03:18:01
User entered 'No (N)'	System	13 Oct 2020 03:18:01

US3632052

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(7)

Generated On: 10 Jun 2021 09:13:35

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 10:58:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (44467b427832a52f)', Time: '2020-10-12T23:17:54', User OID: 'PatientReportedOutcome (US3632052)', ODM File OID: 'b1e456d6-0f2c-40d6-9c60-fcdc23d85639'	System	13 Oct 2020 03:18:01
User entered 'None (1)'	System	13 Oct 2020 03:18:01



**US3632052**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(7)**

**Generated On: 10 Jun 2021 09:13:35**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:58:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (44467b427832a52f)', Time: '2020-10-12T23:17:57', User OID: 'PatientReportedOutcome (US3632052)', ODM File OID: 'b1e456d6-0f2c-40d6-9c60-fcdc23d85639'	System	13 Oct 2020 03:18:01
User entered '12 Oct 2020 23:17'	System	13 Oct 2020 03:18:01

**US3632052**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(7)**

**Generated On: 10 Jun 2021 09:13:35**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:58:03
User entered '12 Oct 2020 12:00'	System	06 Oct 2020 15:39:56

**US3632052**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(7)**

**Generated On: 10 Jun 2021 09:13:35**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:58:03
User entered '13 Oct 2020 11:59'	System	06 Oct 2020 15:39:56

US3632052

Folder: Diary Dose 2 (1)

Form: General\_Day(1/1)

Generated On: 10 Jun 2021 09:13:35

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:58:03
Data entry locked.	System	06 Oct 2020 15:39:56
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	06 Oct 2020 15:39:56

US3632052

Folder: Diary Dose 2 (1)

Form: General\_Day(1/1)

Generated On: 10 Jun 2021 09:13:35

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:58:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (44467b427832a52f)', Time: '2020-10-06T12:09:59', User OID: 'PatientReportedOutcome (US3632052)', ODM File OID: '5a4f0985-d9cf-4ac2-b1f0-ba958f16d4c7'	System	06 Oct 2020 16:10:33
User entered 'None (0)'	System	06 Oct 2020 16:10:33

US3632052

Folder: Diary Dose 2 (1)

Form: General\_Day(1/1)

Generated On: 10 Jun 2021 09:13:35

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:58:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (44467b427832a52f)', Time: '2020-10-06T12:10:03', User OID: 'PatientReportedOutcome (US3632052)', ODM File OID: '5a4f0985-d9cf-4ac2-b1f0-ba958f16d4c7'	System	06 Oct 2020 16:10:33
User entered 'None (0)'	System	06 Oct 2020 16:10:33

US3632052

Folder: Diary Dose 2 (1)

Form: General\_Day(1/1)

Generated On: 10 Jun 2021 09:13:35

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:58:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (44467b427832a52f)', Time: '2020-10-06T12:10:09', User OID: 'PatientReportedOutcome (US3632052)', ODM File OID: '5a4f0985-d9cf-4ac2-b1f0-ba958f16d4c7'	System	06 Oct 2020 16:10:33
User entered 'None (0)'	System	06 Oct 2020 16:10:33

US3632052

Folder: Diary Dose 2 (1)

Form: General\_Day(1/1)

Generated On: 10 Jun 2021 09:13:35

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:58:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (44467b427832a52f)', Time: '2020-10-06T12:10:13', User OID: 'PatientReportedOutcome (US3632052)', ODM File OID: '5a4f0985-d9cf-4ac2-b1f0-ba958f16d4c7'	System	06 Oct 2020 16:10:33
User entered 'None (0)'	System	06 Oct 2020 16:10:33



US3632052

Folder: Diary Dose 2 (1)

Form: General\_Day(1/1)

Generated On: 10 Jun 2021 09:13:35

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:58:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (44467b427832a52f)', Time: '2020-10-06T12:10:18', User OID: 'PatientReportedOutcome (US3632052)', ODM File OID: '5a4f0985-d9cf-4ac2-b1f0-ba958f16d4c7'	System	06 Oct 2020 16:10:33
User entered 'None (0)'	System	06 Oct 2020 16:10:33

US3632052

Folder: Diary Dose 2 (1)

Form: General\_Day(1/1)

Generated On: 10 Jun 2021 09:13:35

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:58:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (44467b427832a52f)', Time: '2020-10-06T12:10:21', User OID: 'PatientReportedOutcome (US3632052)', ODM File OID: '5a4f0985-d9cf-4ac2-b1f0-ba958f16d4c7'	System	06 Oct 2020 16:10:33
User entered 'None (0)'	System	06 Oct 2020 16:10:33

US3632052

Folder: Diary Dose 2 (1)

Form: General\_Day(1/1)

Generated On: 10 Jun 2021 09:13:35

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:58:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (44467b427832a52f)', Time: '2020-10-06T12:10:26', User OID: 'PatientReportedOutcome (US3632052)', ODM File OID: '5a4f0985-d9cf-4ac2-b1f0-ba958f16d4c7'	System	06 Oct 2020 16:10:33
User entered 'No (N)'	System	06 Oct 2020 16:10:33

**US3632052**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(1/1)**

**Generated On: 10 Jun 2021 09:13:35**

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:58:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (44467b427832a52f)', Time: '2020-10-06T12:10:29', User OID: 'PatientReportedOutcome (US3632052)', ODM File OID: '5a4f0985-d9cf-4ac2-b1f0-ba958f16d4c7'	System	06 Oct 2020 16:10:33
User entered '06 Oct 2020 12:10'	System	06 Oct 2020 16:10:33

**US3632052**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(1/1)**

**Generated On: 10 Jun 2021 09:13:35**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:58:03
User entered '06 Oct 2020 11:53'	System	06 Oct 2020 15:39:56

**US3632052**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(1/1)**

**Generated On: 10 Jun 2021 09:13:35**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:58:03
User entered '06 Oct 2020 14:23'	System	06 Oct 2020 15:39:56

US3632052

Folder: Diary Dose 2 (1)

Form: General\_Day(1/2)

Generated On: 10 Jun 2021 09:13:35

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:58:03
Data entry locked.	System	06 Oct 2020 15:39:56
User entered 'Day 1, after vaccination (at home)'	System	06 Oct 2020 15:39:56

US3632052

Folder: Diary Dose 2 (1)

Form: General\_Day(1/2)

Generated On: 10 Jun 2021 09:13:35

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:58:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (44467b427832a52f)', Time: '2020-10-06T21:58:55', User OID: 'PatientReportedOutcome (US3632052)', ODM File OID: 'a337a8c7-c146-476a-81b5-27f313827ee2'	System	07 Oct 2020 01:59:25
User entered 'None (0)'	System	07 Oct 2020 01:59:25



US3632052

Folder: Diary Dose 2 (1)

Form: General\_Day(1/2)

Generated On: 10 Jun 2021 09:13:35

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:58:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (44467b427832a52f)', Time: '2020-10-06T21:58:58', User OID: 'PatientReportedOutcome (US3632052)', ODM File OID: 'a337a8c7-c146-476a-81b5-27f313827ee2'	System	07 Oct 2020 01:59:25
User entered 'None (0)'	System	07 Oct 2020 01:59:25

US3632052

Folder: Diary Dose 2 (1)

Form: General\_Day(1/2)

Generated On: 10 Jun 2021 09:13:35

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:58:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (44467b427832a52f)', Time: '2020-10-06T21:59:04', User OID: 'PatientReportedOutcome (US3632052)', ODM File OID: 'a337a8c7-c146-476a-81b5-27f313827ee2'	System	07 Oct 2020 01:59:25
User entered 'None (0)'	System	07 Oct 2020 01:59:25

US3632052

Folder: Diary Dose 2 (1)

Form: General\_Day(1/2)

Generated On: 10 Jun 2021 09:13:35

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:58:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (44467b427832a52f)', Time: '2020-10-06T21:59:07', User OID: 'PatientReportedOutcome (US3632052)', ODM File OID: 'a337a8c7-c146-476a-81b5-27f313827ee2'	System	07 Oct 2020 01:59:25
User entered 'None (0)'	System	07 Oct 2020 01:59:25

US3632052

Folder: Diary Dose 2 (1)

Form: General\_Day(1/2)

Generated On: 10 Jun 2021 09:13:35

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:58:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (44467b427832a52f)', Time: '2020-10-06T21:59:09', User OID: 'PatientReportedOutcome (US3632052)', ODM File OID: 'a337a8c7-c146-476a-81b5-27f313827ee2'	System	07 Oct 2020 01:59:25
User entered 'None (0)'	System	07 Oct 2020 01:59:25

US3632052

Folder: Diary Dose 2 (1)

Form: General\_Day(1/2)

Generated On: 10 Jun 2021 09:13:35

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:58:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (44467b427832a52f)', Time: '2020-10-06T21:59:12', User OID: 'PatientReportedOutcome (US3632052)', ODM File OID: 'a337a8c7-c146-476a-81b5-27f313827ee2'	System	07 Oct 2020 01:59:25
User entered 'None (0)'	System	07 Oct 2020 01:59:25

US3632052

Folder: Diary Dose 2 (1)

Form: General\_Day(1/2)

Generated On: 10 Jun 2021 09:13:35

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:58:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (44467b427832a52f)', Time: '2020-10-06T21:59:20', User OID: 'PatientReportedOutcome (US3632052)', ODM File OID: 'a337a8c7-c146-476a-81b5-27f313827ee2'	System	07 Oct 2020 01:59:25
User entered 'No (N)'	System	07 Oct 2020 01:59:25

**US3632052**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(1/2)**

**Generated On: 10 Jun 2021 09:13:35**

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:58:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (44467b427832a52f)', Time: '2020-10-06T21:59:24', User OID: 'PatientReportedOutcome (US3632052)', ODM File OID: 'a337a8c7-c146-476a-81b5-27f313827ee2'	System	07 Oct 2020 01:59:25
User entered '06 Oct 2020 21:59'	System	07 Oct 2020 01:59:25

**US3632052**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(1/2)**

**Generated On: 10 Jun 2021 09:13:35**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:58:03
User entered '06 Oct 2020 15:18'	System	06 Oct 2020 15:39:56



**US3632052**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(1/2)**

**Generated On: 10 Jun 2021 09:13:35**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:58:03
User entered '07 Oct 2020 11:59'	System	06 Oct 2020 15:39:56

US3632052

Folder: Diary Dose 2 (1)

Form: General\_Day(2)

Generated On: 10 Jun 2021 09:13:35

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:58:03
Data entry locked.	System	06 Oct 2020 15:39:56
User entered 'Day 2'	System	06 Oct 2020 15:39:56

US3632052

Folder: Diary Dose 2 (1)

Form: General\_Day(2)

Generated On: 10 Jun 2021 09:13:35

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:58:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (44467b427832a52f)', Time: '2020-10-07T22:40:51', User OID: 'PatientReportedOutcome (US3632052)', ODM File OID: 'f8948283-57b3-4d2a-aeac-df364a00f06c'	System	08 Oct 2020 02:41:20
User entered 'None (0)'	System	08 Oct 2020 02:41:20

US3632052

Folder: Diary Dose 2 (1)

Form: General\_Day(2)

Generated On: 10 Jun 2021 09:13:35

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:58:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (44467b427832a52f)', Time: '2020-10-07T22:40:53', User OID: 'PatientReportedOutcome (US3632052)', ODM File OID: 'f8948283-57b3-4d2a-aeac-df364a00f06c'	System	08 Oct 2020 02:41:20
User entered 'None (0)'	System	08 Oct 2020 02:41:20

US3632052

Folder: Diary Dose 2 (1)

Form: General\_Day(2)

Generated On: 10 Jun 2021 09:13:35

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:58:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (44467b427832a52f)', Time: '2020-10-07T22:40:56', User OID: 'PatientReportedOutcome (US3632052)', ODM File OID: 'f8948283-57b3-4d2a-aeac-df364a00f06c'	System	08 Oct 2020 02:41:20
User entered 'None (0)'	System	08 Oct 2020 02:41:20

US3632052

Folder: Diary Dose 2 (1)

Form: General\_Day(2)

Generated On: 10 Jun 2021 09:13:35

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:58:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (44467b427832a52f)', Time: '2020-10-07T22:41:04', User OID: 'PatientReportedOutcome (US3632052)', ODM File OID: 'f8948283-57b3-4d2a-aeac-df364a00f06c'	System	08 Oct 2020 02:41:20
User entered 'None (0)'	System	08 Oct 2020 02:41:20

US3632052

Folder: Diary Dose 2 (1)

Form: General\_Day(2)

Generated On: 10 Jun 2021 09:13:35

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:58:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (44467b427832a52f)', Time: '2020-10-07T22:41:06', User OID: 'PatientReportedOutcome (US3632052)', ODM File OID: 'f8948283-57b3-4d2a-aeac-df364a00f06c'	System	08 Oct 2020 02:41:20
User entered 'None (0)'	System	08 Oct 2020 02:41:20

US3632052

Folder: Diary Dose 2 (1)

Form: General\_Day(2)

Generated On: 10 Jun 2021 09:13:35

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:58:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (44467b427832a52f)', Time: '2020-10-07T22:41:08', User OID: 'PatientReportedOutcome (US3632052)', ODM File OID: 'f8948283-57b3-4d2a-aeac-df364a00f06c'	System	08 Oct 2020 02:41:20
User entered 'None (0)'	System	08 Oct 2020 02:41:20



US3632052

Folder: Diary Dose 2 (1)

Form: General\_Day(2)

Generated On: 10 Jun 2021 09:13:35

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:58:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (44467b427832a52f)', Time: '2020-10-07T22:41:14', User OID: 'PatientReportedOutcome (US3632052)', ODM File OID: 'f8948283-57b3-4d2a-aeac-df364a00f06c'	System	08 Oct 2020 02:41:20
User entered 'No (N)'	System	08 Oct 2020 02:41:20

**US3632052**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(2)**

**Generated On: 10 Jun 2021 09:13:35**

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:58:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (44467b427832a52f)', Time: '2020-10-07T22:41:17', User OID: 'PatientReportedOutcome (US3632052)', ODM File OID: 'f8948283-57b3-4d2a-aeac-df364a00f06c'	System	08 Oct 2020 02:41:20
User entered '07 Oct 2020 22:41'	System	08 Oct 2020 02:41:20

**US3632052**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(2)**

**Generated On: 10 Jun 2021 09:13:35**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:58:03
User entered '07 Oct 2020 12:00'	System	06 Oct 2020 15:39:56

**US3632052**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(2)**

**Generated On: 10 Jun 2021 09:13:35**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:58:03
User entered '08 Oct 2020 11:59'	System	06 Oct 2020 15:39:56

US3632052

Folder: Diary Dose 2 (1)

Form: General\_Day(3)

Generated On: 10 Jun 2021 09:13:35

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:58:03
Data entry locked.	System	06 Oct 2020 15:39:56
User entered 'Day 3'	System	06 Oct 2020 15:39:56

US3632052

Folder: Diary Dose 2 (1)

Form: General\_Day(3)

Generated On: 10 Jun 2021 09:13:35

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:58:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (44467b427832a52f)', Time: '2020-10-08T23:03:59', User OID: 'PatientReportedOutcome (US3632052)', ODM File OID: '8e571851-dde3-4160-bfab-a23bb25bd519'	System	09 Oct 2020 03:04:20
User entered 'None (0)'	System	09 Oct 2020 03:04:20

US3632052

Folder: Diary Dose 2 (1)

Form: General\_Day(3)

Generated On: 10 Jun 2021 09:13:35

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:58:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (44467b427832a52f)', Time: '2020-10-08T23:04:01', User OID: 'PatientReportedOutcome (US3632052)', ODM File OID: '8e571851-dde3-4160-bfab-a23bb25bd519'	System	09 Oct 2020 03:04:20
User entered 'None (0)'	System	09 Oct 2020 03:04:20

US3632052

Folder: Diary Dose 2 (1)

Form: General\_Day(3)

Generated On: 10 Jun 2021 09:13:35

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:58:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (44467b427832a52f)', Time: '2020-10-08T23:04:03', User OID: 'PatientReportedOutcome (US3632052)', ODM File OID: '8e571851-dde3-4160-bfab-a23bb25bd519'	System	09 Oct 2020 03:04:20
User entered 'None (0)'	System	09 Oct 2020 03:04:20



US3632052

Folder: Diary Dose 2 (1)

Form: General\_Day(3)

Generated On: 10 Jun 2021 09:13:35

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:58:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (44467b427832a52f)', Time: '2020-10-08T23:04:05', User OID: 'PatientReportedOutcome (US3632052)', ODM File OID: '8e571851-dde3-4160-bfab-a23bb25bd519' User entered 'None (0)'	System	09 Oct 2020 03:04:20
	System	09 Oct 2020 03:04:20

**US3632052**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(3)**

**Generated On: 10 Jun 2021 09:13:35**

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:58:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (44467b427832a52f)', Time: '2020-10-08T23:04:07', User OID: 'PatientReportedOutcome (US3632052)', ODM File OID: '8e571851-dde3-4160-bfab-a23bb25bd519'	System	09 Oct 2020 03:04:20
User entered 'None (0)'	System	09 Oct 2020 03:04:20

US3632052

Folder: Diary Dose 2 (1)

Form: General\_Day(3)

Generated On: 10 Jun 2021 09:13:35

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:58:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (44467b427832a52f)', Time: '2020-10-08T23:04:09', User OID: 'PatientReportedOutcome (US3632052)', ODM File OID: '8e571851-dde3-4160-bfab-a23bb25bd519'	System	09 Oct 2020 03:04:20
User entered 'None (0)'	System	09 Oct 2020 03:04:20

US3632052

Folder: Diary Dose 2 (1)

Form: General\_Day(3)

Generated On: 10 Jun 2021 09:13:35

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:58:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (44467b427832a52f)', Time: '2020-10-08T23:04:13', User OID: 'PatientReportedOutcome (US3632052)', ODM File OID: '8e571851-dde3-4160-bfab-a23bb25bd519'	System	09 Oct 2020 03:04:20
User entered 'No (N)'	System	09 Oct 2020 03:04:20

**US3632052**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(3)**

**Generated On: 10 Jun 2021 09:13:35**

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:58:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (44467b427832a52f)', Time: '2020-10-08T23:04:16', User OID: 'PatientReportedOutcome (US3632052)', ODM File OID: '8e571851-dde3-4160-bfab-a23bb25bd519'	System	09 Oct 2020 03:04:20
User entered '08 Oct 2020 23:04'	System	09 Oct 2020 03:04:20

**US3632052**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(3)**

**Generated On: 10 Jun 2021 09:13:35**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:58:03
User entered '08 Oct 2020 12:00'	System	06 Oct 2020 15:39:56

**US3632052**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(3)**

**Generated On: 10 Jun 2021 09:13:35**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:58:03
User entered '09 Oct 2020 11:59'	System	06 Oct 2020 15:39:56

US3632052

Folder: Diary Dose 2 (1)

Form: General\_Day(4)

Generated On: 10 Jun 2021 09:13:35

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:58:03
Data entry locked.	System	06 Oct 2020 15:39:56
User entered 'Day 4'	System	06 Oct 2020 15:39:56



US3632052

Folder: Diary Dose 2 (1)

Form: General\_Day(4)

Generated On: 10 Jun 2021 09:13:35

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:58:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (44467b427832a52f)', Time: '2020-10-09T23:00:16', User OID: 'PatientReportedOutcome (US3632052)', ODM File OID: 'a3757544-6431-44e6-8e9d-b38322b61b93'	System	10 Oct 2020 03:01:02
User entered 'None (0)'	System	10 Oct 2020 03:01:02

US3632052

Folder: Diary Dose 2 (1)

Form: General\_Day(4)

Generated On: 10 Jun 2021 09:13:35

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:58:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (44467b427832a52f)', Time: '2020-10-09T23:00:19', User OID: 'PatientReportedOutcome (US3632052)', ODM File OID: 'a3757544-6431-44e6-8e9d-b38322b61b93'	System	10 Oct 2020 03:01:02
User entered 'None (0)'	System	10 Oct 2020 03:01:02

US3632052

Folder: Diary Dose 2 (1)

Form: General\_Day(4)

Generated On: 10 Jun 2021 09:13:35

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:58:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (44467b427832a52f)', Time: '2020-10-09T23:00:21', User OID: 'PatientReportedOutcome (US3632052)', ODM File OID: 'a3757544-6431-44e6-8e9d-b38322b61b93'	System	10 Oct 2020 03:01:02
User entered 'None (0)'	System	10 Oct 2020 03:01:02

US3632052

Folder: Diary Dose 2 (1)

Form: General\_Day(4)

Generated On: 10 Jun 2021 09:13:35

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:58:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (44467b427832a52f)', Time: '2020-10-09T23:00:23', User OID: 'PatientReportedOutcome (US3632052)', ODM File OID: 'a3757544-6431-44e6-8e9d-b38322b61b93'	System	10 Oct 2020 03:01:02
User entered 'None (0)'	System	10 Oct 2020 03:01:02

**US3632052**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(4)**

**Generated On: 10 Jun 2021 09:13:35**

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:58:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (44467b427832a52f)', Time: '2020-10-09T23:00:25', User OID: 'PatientReportedOutcome (US3632052)', ODM File OID: 'a3757544-6431-44e6-8e9d-b38322b61b93'	System	10 Oct 2020 03:01:02
User entered 'None (0)'	System	10 Oct 2020 03:01:02

US3632052

Folder: Diary Dose 2 (1)

Form: General\_Day(4)

Generated On: 10 Jun 2021 09:13:35

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:58:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (44467b427832a52f)', Time: '2020-10-09T23:00:50', User OID: 'PatientReportedOutcome (US3632052)', ODM File OID: 'a3757544-6431-44e6-8e9d-b38322b61b93'	System	10 Oct 2020 03:01:02
User entered 'None (0)'	System	10 Oct 2020 03:01:02

US3632052

Folder: Diary Dose 2 (1)

Form: General\_Day(4)

Generated On: 10 Jun 2021 09:13:35

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:58:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (44467b427832a52f)', Time: '2020-10-09T23:00:54', User OID: 'PatientReportedOutcome (US3632052)', ODM File OID: 'a3757544-6431-44e6-8e9d-b38322b61b93'	System	10 Oct 2020 03:01:02
User entered 'No (N)'	System	10 Oct 2020 03:01:02

**US3632052**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(4)**

**Generated On: 10 Jun 2021 09:13:35**

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:58:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (44467b427832a52f)', Time: '2020-10-09T23:00:57', User OID: 'PatientReportedOutcome (US3632052)', ODM File OID: 'a3757544-6431-44e6-8e9d-b38322b61b93'	System	10 Oct 2020 03:01:02
User entered '09 Oct 2020 23:00'	System	10 Oct 2020 03:01:02



**US3632052**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(4)**

**Generated On: 10 Jun 2021 09:13:35**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:58:03
User entered '09 Oct 2020 12:00'	System	06 Oct 2020 15:39:56

**US3632052**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(4)**

**Generated On: 10 Jun 2021 09:13:35**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:58:03
User entered '10 Oct 2020 11:59'	System	06 Oct 2020 15:39:56

**US3632052**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(5)**

**Generated On: 10 Jun 2021 09:13:35**

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:58:03
Data entry locked.	System	06 Oct 2020 15:39:56
User entered 'Day 5'	System	06 Oct 2020 15:39:56

US3632052

Folder: Diary Dose 2 (1)

Form: General\_Day(5)

Generated On: 10 Jun 2021 09:13:35

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:58:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (44467b427832a52f)', Time: '2020-10-10T22:36:58', User OID: 'PatientReportedOutcome (US3632052)', ODM File OID: 'eeef39f3-a609-40d9-8765-c9e22a1c3202'	System	11 Oct 2020 02:37:15
User entered 'None (0)'	System	11 Oct 2020 02:37:15

US3632052

Folder: Diary Dose 2 (1)

Form: General\_Day(5)

Generated On: 10 Jun 2021 09:13:35

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:58:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (44467b427832a52f)', Time: '2020-10-10T22:36:59', User OID: 'PatientReportedOutcome (US3632052)', ODM File OID: 'eeef39f3-a609-40d9-8765-c9e22a1c3202'	System	11 Oct 2020 02:37:15
User entered 'None (0)'	System	11 Oct 2020 02:37:15

US3632052

Folder: Diary Dose 2 (1)

Form: General\_Day(5)

Generated On: 10 Jun 2021 09:13:35

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:58:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (44467b427832a52f)', Time: '2020-10-10T22:37:00', User OID: 'PatientReportedOutcome (US3632052)', ODM File OID: 'eeef39f3-a609-40d9-8765-c9e22a1c3202'	System	11 Oct 2020 02:37:15
User entered 'None (0)'	System	11 Oct 2020 02:37:15

US3632052

Folder: Diary Dose 2 (1)

Form: General\_Day(5)

Generated On: 10 Jun 2021 09:13:35

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:58:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (44467b427832a52f)', Time: '2020-10-10T22:37:02', User OID: 'PatientReportedOutcome (US3632052)', ODM File OID: 'eeef39f3-a609-40d9-8765-c9e22a1c3202'	System	11 Oct 2020 02:37:15
User entered 'None (0)'	System	11 Oct 2020 02:37:15

**US3632052**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(5)**

**Generated On: 10 Jun 2021 09:13:35**

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:58:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (44467b427832a52f)', Time: '2020-10-10T22:37:04', User OID: 'PatientReportedOutcome (US3632052)', ODM File OID: 'eeef39f3-a609-40d9-8765-c9e22a1c3202'	System	11 Oct 2020 02:37:15
User entered 'None (0)'	System	11 Oct 2020 02:37:15



**US3632052**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(5)**

**Generated On: 10 Jun 2021 09:13:35**

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:58:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (44467b427832a52f)', Time: '2020-10-10T22:37:06', User OID: 'PatientReportedOutcome (US3632052)', ODM File OID: 'eeef39f3-a609-40d9-8765-c9e22a1c3202'	System	11 Oct 2020 02:37:15
User entered 'None (0)'	System	11 Oct 2020 02:37:15

US3632052

Folder: Diary Dose 2 (1)

Form: General\_Day(5)

Generated On: 10 Jun 2021 09:13:35

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:58:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (44467b427832a52f)', Time: '2020-10-10T22:37:09', User OID: 'PatientReportedOutcome (US3632052)', ODM File OID: 'eeef39f3-a609-40d9-8765-c9e22a1c3202'	System	11 Oct 2020 02:37:15
User entered 'No (N)'	System	11 Oct 2020 02:37:15

**US3632052**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(5)**

**Generated On: 10 Jun 2021 09:13:35**

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:58:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (44467b427832a52f)', Time: '2020-10-10T22:37:12', User OID: 'PatientReportedOutcome (US3632052)', ODM File OID: 'eeef39f3-a609-40d9-8765-c9e22a1c3202'	System	11 Oct 2020 02:37:15
User entered '10 Oct 2020 22:37'	System	11 Oct 2020 02:37:15

**US3632052**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(5)**

**Generated On: 10 Jun 2021 09:13:35**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:58:03
User entered '10 Oct 2020 12:00'	System	06 Oct 2020 15:39:56

**US3632052**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(5)**

**Generated On: 10 Jun 2021 09:13:35**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:58:03
User entered '11 Oct 2020 11:59'	System	06 Oct 2020 15:39:56

**US3632052**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(6)**

**Generated On: 10 Jun 2021 09:13:35**

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:58:03
Data entry locked.	System	06 Oct 2020 15:39:56
User entered 'Day 6'	System	06 Oct 2020 15:39:56

US3632052

Folder: Diary Dose 2 (1)

Form: General\_Day(6)

Generated On: 10 Jun 2021 09:13:35

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:58:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (44467b427832a52f)', Time: '2020-10-11T23:32:35', User OID: 'PatientReportedOutcome (US3632052)', ODM File OID: '7acedfee-b01f-45f4-b78a-261998098c2b' User entered 'None (0)'	System	12 Oct 2020 03:32:57
	System	12 Oct 2020 03:32:57

US3632052

Folder: Diary Dose 2 (1)

Form: General\_Day(6)

Generated On: 10 Jun 2021 09:13:35

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:58:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (44467b427832a52f)', Time: '2020-10-11T23:32:37', User OID: 'PatientReportedOutcome (US3632052)', ODM File OID: '7acedfee-b01f-45f4-b78a-261998098c2b'	System	12 Oct 2020 03:32:57
User entered 'None (0)'	System	12 Oct 2020 03:32:57



US3632052

Folder: Diary Dose 2 (1)

Form: General\_Day(6)

Generated On: 10 Jun 2021 09:13:35

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:58:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (44467b427832a52f)', Time: '2020-10-11T23:32:39', User OID: 'PatientReportedOutcome (US3632052)', ODM File OID: '7acedfee-b01f-45f4-b78a-261998098c2b'	System	12 Oct 2020 03:32:57
User entered 'None (0)'	System	12 Oct 2020 03:32:57

US3632052

Folder: Diary Dose 2 (1)

Form: General\_Day(6)

Generated On: 10 Jun 2021 09:13:35

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:58:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (44467b427832a52f)', Time: '2020-10-11T23:32:42', User OID: 'PatientReportedOutcome (US3632052)', ODM File OID: '7acedfee-b01f-45f4-b78a-261998098c2b'	System	12 Oct 2020 03:32:57
User entered 'None (0)'	System	12 Oct 2020 03:32:57

US3632052

Folder: Diary Dose 2 (1)

Form: General\_Day(6)

Generated On: 10 Jun 2021 09:13:35

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:58:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (44467b427832a52f)', Time: '2020-10-11T23:32:44', User OID: 'PatientReportedOutcome (US3632052)', ODM File OID: '7acedfee-b01f-45f4-b78a-261998098c2b'	System	12 Oct 2020 03:32:57
User entered 'None (0)'	System	12 Oct 2020 03:32:57

US3632052

Folder: Diary Dose 2 (1)

Form: General\_Day(6)

Generated On: 10 Jun 2021 09:13:35

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:58:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (44467b427832a52f)', Time: '2020-10-11T23:32:46', User OID: 'PatientReportedOutcome (US3632052)', ODM File OID: '7acedfee-b01f-45f4-b78a-261998098c2b'	System	12 Oct 2020 03:32:57
User entered 'None (0)'	System	12 Oct 2020 03:32:57

US3632052

Folder: Diary Dose 2 (1)

Form: General\_Day(6)

Generated On: 10 Jun 2021 09:13:35

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:58:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (44467b427832a52f)', Time: '2020-10-11T23:32:51', User OID: 'PatientReportedOutcome (US3632052)', ODM File OID: '7acedfee-b01f-45f4-b78a-261998098c2b'	System	12 Oct 2020 03:32:57
User entered 'No (N)'	System	12 Oct 2020 03:32:57

**US3632052**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(6)**

**Generated On: 10 Jun 2021 09:13:35**

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:58:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (44467b427832a52f)', Time: '2020-10-11T23:32:53', User OID: 'PatientReportedOutcome (US3632052)', ODM File OID: '7acedfee-b01f-45f4-b78a-261998098c2b'	System	12 Oct 2020 03:32:57
User entered '11 Oct 2020 23:32'	System	12 Oct 2020 03:32:57

**US3632052**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(6)**

**Generated On: 10 Jun 2021 09:13:35**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:58:03
User entered '11 Oct 2020 12:00'	System	06 Oct 2020 15:39:56

**US3632052**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(6)**

**Generated On: 10 Jun 2021 09:13:35**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:58:03
User entered '12 Oct 2020 11:59'	System	06 Oct 2020 15:39:56



**US3632052**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(7)**

**Generated On: 10 Jun 2021 09:13:35**

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:58:03
Data entry locked.	System	06 Oct 2020 15:39:56
User entered 'Day 7'	System	06 Oct 2020 15:39:56

US3632052

Folder: Diary Dose 2 (1)

Form: General\_Day(7)

Generated On: 10 Jun 2021 09:13:35

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:58:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (44467b427832a52f)', Time: '2020-10-12T23:18:12', User OID: 'PatientReportedOutcome (US3632052)', ODM File OID: 'd613fa7a-d629-43e4-976b-596d8de88449'	System	13 Oct 2020 03:18:36
User entered 'None (0)'	System	13 Oct 2020 03:18:36

US3632052

Folder: Diary Dose 2 (1)

Form: General\_Day(7)

Generated On: 10 Jun 2021 09:13:35

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:58:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (44467b427832a52f)', Time: '2020-10-12T23:18:14', User OID: 'PatientReportedOutcome (US3632052)', ODM File OID: 'd613fa7a-d629-43e4-976b-596d8de88449'	System	13 Oct 2020 03:18:36
User entered 'None (0)'	System	13 Oct 2020 03:18:36

US3632052

Folder: Diary Dose 2 (1)

Form: General\_Day(7)

Generated On: 10 Jun 2021 09:13:35

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:58:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (44467b427832a52f)', Time: '2020-10-12T23:18:16', User OID: 'PatientReportedOutcome (US3632052)', ODM File OID: 'd613fa7a-d629-43e4-976b-596d8de88449'	System	13 Oct 2020 03:18:36
User entered 'None (0)'	System	13 Oct 2020 03:18:36

US3632052

Folder: Diary Dose 2 (1)

Form: General\_Day(7)

Generated On: 10 Jun 2021 09:13:35

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:58:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (44467b427832a52f)', Time: '2020-10-12T23:18:18', User OID: 'PatientReportedOutcome (US3632052)', ODM File OID: 'd613fa7a-d629-43e4-976b-596d8de88449'	System	13 Oct 2020 03:18:36
User entered 'None (0)'	System	13 Oct 2020 03:18:36

**US3632052**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(7)**

**Generated On: 10 Jun 2021 09:13:35**

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:58:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (44467b427832a52f)', Time: '2020-10-12T23:18:20', User OID: 'PatientReportedOutcome (US3632052)', ODM File OID: 'd613fa7a-d629-43e4-976b-596d8de88449'	System	13 Oct 2020 03:18:36
User entered 'None (0)'	System	13 Oct 2020 03:18:36

US3632052

Folder: Diary Dose 2 (1)

Form: General\_Day(7)

Generated On: 10 Jun 2021 09:13:35

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:58:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (44467b427832a52f)', Time: '2020-10-12T23:18:25', User OID: 'PatientReportedOutcome (US3632052)', ODM File OID: 'd613fa7a-d629-43e4-976b-596d8de88449'	System	13 Oct 2020 03:18:36
User entered 'None (0)'	System	13 Oct 2020 03:18:36

US3632052

Folder: Diary Dose 2 (1)

Form: General\_Day(7)

Generated On: 10 Jun 2021 09:13:35

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:58:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (44467b427832a52f)', Time: '2020-10-12T23:18:28', User OID: 'PatientReportedOutcome (US3632052)', ODM File OID: 'd613fa7a-d629-43e4-976b-596d8de88449'	System	13 Oct 2020 03:18:36
User entered 'No (N)'	System	13 Oct 2020 03:18:36



**US3632052**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(7)**

**Generated On: 10 Jun 2021 09:13:35**

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:58:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (44467b427832a52f)', Time: '2020-10-12T23:18:33', User OID: 'PatientReportedOutcome (US3632052)', ODM File OID: 'd613fa7a-d629-43e4-976b-596d8de88449'	System	13 Oct 2020 03:18:36
User entered '12 Oct 2020 23:18'	System	13 Oct 2020 03:18:36

**US3632052**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(7)**

**Generated On: 10 Jun 2021 09:13:35**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:58:03
User entered '12 Oct 2020 12:00'	System	06 Oct 2020 15:39:56

**US3632052**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(7)**

**Generated On: 10 Jun 2021 09:13:35**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:58:03
User entered '13 Oct 2020 11:59'	System	06 Oct 2020 15:39:56

**US3632052**

**Folder: Safety Call Day 36 (1)**

**Form: Safety Call**

**Generated On: 10 Jun 2021 09:13:35**

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:19:13
User signature succeeded.	Colleen Kelley (b) (4)	08 Mar 2021 14:31:04
DataPoint Verified.	(b) (4), (b) (6)	16 Dec 2020 17:20:39
User entered 'Yes (Y)'	Isaac Perez (b) (4)	13 Oct 2020 18:09:09

**US3632052**

**Folder: Safety Call Day 36 (1)**

**Form: Safety Call**

**Generated On: 10 Jun 2021 09:13:35**

[Date of Contact or Contact Attempt \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:19:13
User signature succeeded.	Colleen Kelley (b) (4)	08 Mar 2021 14:31:04
DataPoint Verified.	(b) (4), (b) (6)	16 Dec 2020 17:20:39
User entered '13 Oct 2020'	Isaac Perez (b) (4)	13 Oct 2020 18:09:09

US3632052

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:13:35

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:19:13
User signature succeeded.	Colleen Kelley (b) (4)	08 Mar 2021 14:31:04
DataPoint Verified.	(b) (4), (b) (6)	16 Dec 2020 17:20:39
User entered 'Contact Made (CONTACT MADE)'	Isaac Perez (b) (4)	13 Oct 2020 18:09:09

US3632052

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:13:35

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:19:13
User signature succeeded.	Colleen Kelley (b) (4)	08 Mar 2021 14:31:04
DataPoint Verified.	(b) (4), (b) (6)	16 Dec 2020 17:20:39
User entered empty.	Isaac Perez (b) (4)	13 Oct 2020 18:09:09

**US3632052**

**Folder: Safety Call Day 36 (1)**

**Form: Continuing**

**Generated On: 10 Jun 2021 09:13:35**

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:19:13
User signature succeeded.	Colleen Kelley (b) (4)	08 Mar 2021 14:31:04
DataPoint Verified.	(b) (4), (b) (6)	16 Dec 2020 17:21:18
User entered 'Yes (Y)'	Isaac Perez (b) (4)	13 Oct 2020 18:09:14



**US3632052**

**Folder: Safety Call Day 36 (1)**

**Form: Continuing**

**Generated On: 10 Jun 2021 09:13:35**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:19:13
User entered 'I'	System	13 Oct 2020 18:09:14

**US3632052**

**Folder: Safety Call Day 43 (1)**

**Form: Safety Call**

**Generated On: 10 Jun 2021 09:13:35**

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:19:13
User signature succeeded.	Colleen Kelley (b) (4)	08 Mar 2021 14:31:04
DataPoint Verified.	(b) (4), (b) (6)	16 Dec 2020 17:21:44
User entered 'Yes (Y)'	Christina Bacher (b) (4)	20 Oct 2020 16:44:28

**US3632052**

**Folder: Safety Call Day 43 (1)**

**Form: Safety Call**

**Generated On: 10 Jun 2021 09:13:35**

[Date of Contact or Contact Attempt \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:19:13
User signature succeeded.	Colleen Kelley (b) (4)	08 Mar 2021 14:31:04
DataPoint Verified.	(b) (4), (b) (6)	16 Dec 2020 17:21:44
User entered '20 Oct 2020'	Christina Bacher (b) (4)	20 Oct 2020 16:44:28

**US3632052**

**Folder: Safety Call Day 43 (1)**

**Form: Safety Call**

**Generated On: 10 Jun 2021 09:13:35**

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:19:13
User signature succeeded.	Colleen Kelley (b) (4)	08 Mar 2021 14:31:04
DataPoint Verified.	(b) (4), (b) (6)	16 Dec 2020 17:21:44
User entered 'Contact Made (CONTACT MADE)'	Christina Bacher (b) (4)	20 Oct 2020 16:44:28

US3632052

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:13:35

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:19:13
User signature succeeded.	Colleen Kelley (b) (4)	08 Mar 2021 14:31:04
DataPoint Verified.	(b) (4), (b) (6)	16 Dec 2020 17:21:44
User entered empty.	Christina Bacher (b) (4)	20 Oct 2020 16:44:28

US3632052

Folder: Safety Call Day 43 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:13:35

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:19:13
User signature succeeded.	Colleen Kelley (b) (4)	08 Mar 2021 14:31:04
DataPoint Verified.	(b) (4), (b) (6)	16 Dec 2020 17:21:51
User entered 'Yes (Y)'	Christina Bacher (b) (4)	20 Oct 2020 16:44:32

**US3632052**

**Folder: Safety Call Day 43 (1)**

**Form: Continuing**

**Generated On: 10 Jun 2021 09:13:35**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:19:13
User entered 'I'	System	20 Oct 2020 16:44:32

**US3632052**

**Folder: Safety Call Day 50 (1)**

**Form: Safety Call**

**Generated On: 10 Jun 2021 09:13:35**

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:19:13
User signature succeeded.	Colleen Kelley (b) (4)	08 Mar 2021 14:31:04
DataPoint Verified.	(b) (4), (b) (6)	16 Dec 2020 17:21:59
User entered 'Yes (Y)'	Sarah Wiatrek (b) (4)	27 Oct 2020 20:06:16



**US3632052**

**Folder: Safety Call Day 50 (1)**

**Form: Safety Call**

**Generated On: 10 Jun 2021 09:13:35**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:19:13
User signature succeeded.	Colleen Kelley (b) (4)	08 Mar 2021 14:31:04
DataPoint Verified.	(b) (4), (b) (6)	16 Dec 2020 17:21:59
User entered '27 Oct 2020'	Sarah Wiatrek (b) (4)	27 Oct 2020 20:06:16

**US3632052**

**Folder: Safety Call Day 50 (1)**

**Form: Safety Call**

**Generated On: 10 Jun 2021 09:13:35**

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:19:13
User signature succeeded.	Colleen Kelley (b) (4)	08 Mar 2021 14:31:04
DataPoint Verified.	(b) (4), (b) (6)	16 Dec 2020 17:21:59
User entered 'Contact Made (CONTACT MADE)'	Sarah Wiatrek (b) (4)	27 Oct 2020 20:06:16

US3632052

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:13:35

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:19:13
User signature succeeded.	Colleen Kelley (b) (4)	08 Mar 2021 14:31:04
DataPoint Verified.	(b) (4), (b) (6)	16 Dec 2020 17:21:59
User entered empty.	Sarah Wiatrek (b) (4)	27 Oct 2020 20:06:16

**US3632052**

**Folder: Safety Call Day 50 (1)**

**Form: Continuing**

**Generated On: 10 Jun 2021 09:13:35**

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:19:13
User signature succeeded.	Colleen Kelley (b) (4)	08 Mar 2021 14:31:04
DataPoint Verified.	(b) (4), (b) (6)	16 Dec 2020 17:22:06
User entered 'Yes (Y)'	Sarah Wiatrek (b) (4)	27 Oct 2020 20:06:20

**US3632052**

**Folder: Safety Call Day 50 (1)**

**Form: Continuing**

**Generated On: 10 Jun 2021 09:13:35**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:19:13
User entered 'I'	System	27 Oct 2020 20:06:20

**US3632052**

**Folder: Visit 3 Day 57 (1)**

**Form: Visit Date**

**Generated On: 10 Jun 2021 09:13:35**

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:19:13
User signature succeeded.	Colleen Kelley (b) (4)	08 Mar 2021 14:31:04
DataPoint Verified.	(b) (4), (b) (6)	16 Dec 2020 17:24:48
User entered 'Yes (Y)'	Aastha KC (b) (4)	02 Nov 2020 20:10:25

**US3632052**

**Folder: Visit 3 Day 57 (1)**

**Form: Visit Date**

**Generated On: 10 Jun 2021 09:13:35**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:19:13
User signature succeeded.	Colleen Kelley (b) (4)	08 Mar 2021 14:31:04
DataPoint Verified.	(b) (4), (b) (6)	16 Dec 2020 17:24:48
User entered '2 Nov 2020'	Aastha KC (b) (4)	02 Nov 2020 20:10:25

**US3632052**

**Folder: Visit 3 Day 57 (1)**

**Form: Visit Date**

**Generated On: 10 Jun 2021 09:13:35**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:19:13
User signature succeeded.	Colleen Kelley (b) (4)	08 Mar 2021 14:31:04
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	16 Dec 2020 17:24:48
User entered 'Clinic (Clinic)'	Aastha KC (b) (4)	02 Nov 2020 20:10:25
	(b) (4)	



**US3632052**

**Folder: Visit 3 Day 57 (1)**

**Form: Visit Date**

**Generated On: 10 Jun 2021 09:13:35**

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:19:13
User entered 'VISIT3'	System	02 Nov 2020 20:10:25

US3632052

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:13:35

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:19:13
User signature succeeded.	Colleen Kelley (b) (4)	08 Mar 2021 14:31:04
DataPoint Verified.	(b) (4), (b) (6)	16 Dec 2020 17:27:23
User entered 'Yes (Y)'	Aastha KC (b) (4)	02 Nov 2020 20:11:17

**US3632052**

**Folder: Visit 3 Day 57 (1)**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 09:13:35**

**Date of assessment** (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:19:13
User signature succeeded.	Colleen Kelley (b) (4)	08 Mar 2021 14:31:04
DataPoint Verified.	(b) (4), (b) (6)	16 Dec 2020 17:27:23
User entered '2 Nov 2020'	Aastha KC (b) (4)	02 Nov 2020 20:11:17

**US3632052**

**Folder: Visit 3 Day 57 (1)**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 09:13:35**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:19:13
User signature succeeded.	Colleen Kelley (b) (4)	08 Mar 2021 14:31:04
DataPoint Verified.	(b) (4), (b) (6)	16 Dec 2020 17:27:23
User entered '14:08'	Aastha KC (b) (4)	02 Nov 2020 20:11:17

**US3632052**

**Folder: Visit 3 Day 57 (1)**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 09:13:35**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:19:13
User entered '2 Nov 2020 14:08'	System	02 Nov 2020 20:11:17

US3632052

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:13:35

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:19:13
User signature succeeded.	Colleen Kelley (b) (4)	08 Mar 2021 14:31:04
DataPoint Verified.	(b) (4), (b) (6)	16 Dec 2020 17:27:23
User entered '97.2' F	Aastha KC (b) (4)	02 Nov 2020 20:11:17

**US3632052**

**Folder: Visit 3 Day 57 (1)**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 09:13:35**

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:19:13
User signature succeeded.	Colleen Kelley (b) (4)	08 Mar 2021 14:31:04
DataPoint Verified.	(b) (4), (b) (6)	16 Dec 2020 17:27:23
User entered 'Oral (Oral)'	Aastha KC (b) (4)	02 Nov 2020 20:11:17

**US3632052**

**Folder: Visit 3 Day 57 (1)**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 09:13:35**

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:19:13
User signature succeeded.	Colleen Kelley (b) (4)	08 Mar 2021 14:31:04
DataPoint Verified.	(b) (4), (b) (6)	16 Dec 2020 17:27:23
User entered empty.	Aastha KC (b) (4)	02 Nov 2020 20:11:17



**US3632052**

**Folder: Visit 3 Day 57 (1)**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 09:13:35**

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:19:13
User signature succeeded.	Colleen Kelley (b) (4)	08 Mar 2021 14:31:04
DataPoint Verified.	(b) (4), (b) (6)	16 Dec 2020 17:27:23
User entered '77'	Aastha KC (b) (4)	02 Nov 2020 20:11:17

**US3632052**

**Folder: Visit 3 Day 57 (1)**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 09:13:35**

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:19:13
User entered 'bpm'	System	02 Nov 2020 20:11:17

US3632052

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:13:35

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:19:13
User signature succeeded.	Colleen Kelley (b) (4)	08 Mar 2021 14:31:04
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	16 Dec 2020 17:27:23
User entered '16'	Aastha KC (b) (4)	02 Nov 2020 20:11:17
	(b) (4)	

US3632052

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:13:35

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:19:13
User entered 'breaths/min'	System	02 Nov 2020 20:11:17

US3632052

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:13:35

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:19:13
User signature succeeded.	Colleen Kelley (b) (4)	08 Mar 2021 14:31:04
DataPoint Verified.	(b) (4), (b) (6)	16 Dec 2020 17:27:23
User entered '125'	Aastha KC (b) (4)	02 Nov 2020 20:11:17

**US3632052**

**Folder: Visit 3 Day 57 (1)**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 09:13:35**

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:19:13
User entered 'mmHg'	System	02 Nov 2020 20:11:17

**US3632052**

**Folder: Visit 3 Day 57 (1)**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 09:13:35**

[Diastolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:19:13
User signature succeeded.	Colleen Kelley (b) (4)	08 Mar 2021 14:31:04
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	16 Dec 2020 17:27:23
User entered '79'	Aastha KC (b) (4)	02 Nov 2020 20:11:17
	(b) (4)	

**US3632052**

**Folder: Visit 3 Day 57 (1)**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 09:13:35**

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:19:13
User entered 'mmHg'	System	02 Nov 2020 20:11:17



**US3632052**

**Folder: Visit 3 Day 57 (1)**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 09:13:35**

[Height \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:19:13

**US3632052**

**Folder: Visit 3 Day 57 (1)**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 09:13:35**

[Weight \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:19:13

US3632052

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Generated On: 10 Jun 2021 09:13:35

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:19:13
User signature succeeded.	Colleen Kelley (b) (4)	08 Mar 2021 14:31:04
DataPoint Verified.	(b) (4), (b) (6)	16 Dec 2020 17:27:50
User entered 'No (N)'	Aastha KC (b) (4)	02 Nov 2020 20:11:26

US3632052

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Generated On: 10 Jun 2021 09:13:35

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:19:13
User signature succeeded.	Colleen Kelley (b) (4)	08 Mar 2021 14:31:04
DataPoint Verified.	(b) (4), (b) (6)	16 Dec 2020 17:27:50
User entered empty.	Aastha KC (b) (4)	02 Nov 2020 20:11:26

US3632052

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 09:13:35

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:19:13
User signature succeeded.	Colleen Kelley (b) (4)	08 Mar 2021 14:31:04
DataPoint Verified.	(b) (4), (b) (6)	16 Dec 2020 17:29:35
User entered 'Yes (Y)'	Aastha KC (b) (4)	02 Nov 2020 20:11:42

**US3632052**

**Folder: Visit 3 Day 57 (1)**

**Form: Immunogenicity Assessment**

**Generated On: 10 Jun 2021 09:13:35**

**Collection date** (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:19:13
User signature succeeded.	Colleen Kelley (b) (4)	08 Mar 2021 14:31:04
DataPoint Verified.	(b) (4), (b) (6)	16 Dec 2020 17:29:35
User entered '2 Nov 2020'	Aastha KC (b) (4)	02 Nov 2020 20:11:42

**US3632052**

**Folder: Visit 3 Day 57 (1)**

**Form: Immunogenicity Assessment**

**Generated On: 10 Jun 2021 09:13:35**

[Collection time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:19:13
User signature succeeded.	Colleen Kelley (b) (4)	08 Mar 2021 14:31:04
DataPoint Verified.	(b) (4), (b) (6)	16 Dec 2020 17:29:35
User entered '14:38' reason for change: Data Entry Error	Aastha KC (b) (4)	02 Nov 2020 20:12:08
User entered '14:28'	Aastha KC (b) (4)	02 Nov 2020 20:11:42

**US3632052**

**Folder: Visit 3 Day 57 (1)**

**Form: Immunogenicity Assessment**

**Generated On: 10 Jun 2021 09:13:35**

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:19:13
User entered '2 Nov 2020 14:38'	System	02 Nov 2020 20:12:08
User entered '2 Nov 2020 14:28'	System	02 Nov 2020 20:11:42



US3632052

Folder: Visit 3 Day 57 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:13:35

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:19:13
User signature succeeded.	Colleen Kelley (b) (4)	08 Mar 2021 14:31:04
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	16 Dec 2020 17:29:51
User entered 'Yes (Y)'	Aastha KC (b) (4)	02 Nov 2020 20:12:13
	(b) (4)	

**US3632052**

**Folder: Visit 3 Day 57 (1)**

**Form: Continuing**

**Generated On: 10 Jun 2021 09:13:35**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:19:13
User entered 'I'	System	02 Nov 2020 20:12:13

**US3632052**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:13:35**

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:58:03
Data entry locked.	System	08 Sep 2020 15:12:50
User entered 'Day 64'	System	08 Sep 2020 15:12:50

US3632052

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:13:35

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:58:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (44467b427832a52f)', Time: '2020-11-08T16:19:55', User OID: 'PatientReportedOutcome (US3632052)', ODM File OID: '643b5392-0ea0-4dad-9108-3798686dbc66'	System	08 Nov 2020 21:22:52
User entered 'No (N)'	System	08 Nov 2020 21:22:52

US3632052

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:13:35

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:58:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (44467b427832a52f)', Time: '2020-11-08T16:22:05', User OID: 'PatientReportedOutcome (US3632052)', ODM File OID: '643b5392-0ea0-4dad-9108-3798686dbc66'	System	08 Nov 2020 21:22:52
User entered 'No (N)'	System	08 Nov 2020 21:22:52

**US3632052**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:13:35**

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:58:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (44467b427832a52f)', Time: '2020-11-08T16:22:48', User OID: 'PatientReportedOutcome (US3632052)', ODM File OID: '643b5392-0ea0-4dad-9108-3798686dbc66'	System	08 Nov 2020 21:22:52
User entered '08 Nov 2020 16:22:48'	System	08 Nov 2020 21:22:52

**US3632052**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:13:35**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:58:03
Data entry locked.	System	08 Sep 2020 15:12:50
User entered '08 Nov 2020 00:01'	System	08 Sep 2020 15:12:50

**US3632052**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:13:35**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:58:03
Data entry locked.	System	08 Sep 2020 15:12:50
User entered '12 Nov 2020 23:59'	System	08 Sep 2020 15:12:50



**US3632052**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:13:35**

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:58:03
Data entry locked.	System	08 Sep 2020 15:12:50
User entered 'Day 71'	System	08 Sep 2020 15:12:50

**US3632052**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:13:35**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:58:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (44467b427832a52f)', Time: '2020-11-15T11:01:38', User OID: 'PatientReportedOutcome (US3632052)', ODM File OID: 'f7d6f4ae-4f2c-44bf-8bc8-9259d86d6a1b'	System	15 Nov 2020 16:01:48
User entered 'No (N)'	System	15 Nov 2020 16:01:48

US3632052

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:13:35

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:58:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (44467b427832a52f)', Time: '2020-11-15T11:01:44', User OID: 'PatientReportedOutcome (US3632052)', ODM File OID: 'f7d6f4ae-4f2c-44bf-8bc8-9259d86d6a1b'	System	15 Nov 2020 16:01:48
User entered 'No (N)'	System	15 Nov 2020 16:01:48

**US3632052**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:13:35**

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:58:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (44467b427832a52f)', Time: '2020-11-15T11:01:47', User OID: 'PatientReportedOutcome (US3632052)', ODM File OID: 'f7d6f4ae-4f2c-44bf-8bc8-9259d86d6a1b' User entered '15 Nov 2020 11:01:47'	System	15 Nov 2020 16:01:48
	System	15 Nov 2020 16:01:48

**US3632052**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:13:35**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:58:03
Data entry locked.	System	08 Sep 2020 15:12:50
User entered '15 Nov 2020 00:01'	System	08 Sep 2020 15:12:50

**US3632052**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:13:35**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:58:03
Data entry locked.	System	08 Sep 2020 15:12:50
User entered '19 Nov 2020 23:59'	System	08 Sep 2020 15:12:50

**US3632052**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:13:35**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:56:41
Amendment Manager: User entered 'Day 75'	System	20 Nov 2020 05:56:41

**US3632052**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:13:35**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:56:41
Amendment Manager: User entered '19 Nov 2020 00:01'	System	20 Nov 2020 05:56:41



**US3632052**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:13:35**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:56:41
Amendment Manager: User entered '23 Nov 2020 23:59'	System	20 Nov 2020 05:56:41

**US3632052**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:13:35**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:56:41
Amendment Manager: User entered 'Day 82'	System	20 Nov 2020 05:56:41

**US3632052**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:13:35**

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (44467b427832a52f)', Time: '2020-11-27T18:36:56', User OID: 'PatientReportedOutcome (US3632052)', ODM File OID: 'f1d00fab-d6d1-4708-9cee-195a43beed7'	System	27 Nov 2020 23:37:12
User entered 'No (N)'	System	27 Nov 2020 23:37:12

**US3632052**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:13:35**

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (44467b427832a52f)', Time: '2020-11-27T18:37:04', User OID: 'PatientReportedOutcome (US3632052)', ODM File OID: 'f1d00fab-d6d1-4708-9cee-195a43beed7'	System	27 Nov 2020 23:37:12
User entered 'No (N)'	System	27 Nov 2020 23:37:12

**US3632052**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:13:35**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (44467b427832a52f)', Time: '2020-11-27T18:37:08', User OID: 'PatientReportedOutcome (US3632052)', ODM File OID: 'f1d00fab-d6d1-4708-9cee-195a43beed7'	System	27 Nov 2020 23:37:12
User entered '27 Nov 2020 18:37:08'	System	27 Nov 2020 23:37:12

**US3632052**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:13:35**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:56:41
Amendment Manager: User entered '26 Nov 2020 00:01'	System	20 Nov 2020 05:56:41

**US3632052**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:13:35**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:56:41
Amendment Manager: User entered '30 Nov 2020 23:59'	System	20 Nov 2020 05:56:41

**US3632052**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:13:35**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:56:41
Amendment Manager: User entered 'Day 89'	System	20 Nov 2020 05:56:41



**US3632052**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:13:35**

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (44467b427832a52f)', Time: '2020-12-03T12:46:17', User OID: 'PatientReportedOutcome (US3632052)', ODM File OID: '5e126789-8e15-4662-8927-01e63c9d0682'	System	03 Dec 2020 17:51:34
User entered 'No (N)'	System	03 Dec 2020 17:51:34

**US3632052**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:13:35**

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (44467b427832a52f)', Time: '2020-12-03T12:46:24', User OID: 'PatientReportedOutcome (US3632052)', ODM File OID: '5e126789-8e15-4662-8927-01e63c9d0682'	System	03 Dec 2020 17:51:34
User entered 'No (N)'	System	03 Dec 2020 17:51:34

**US3632052**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:13:35**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (44467b427832a52f)', Time: '2020-12-03T12:46:27', User OID: 'PatientReportedOutcome (US3632052)', ODM File OID: '5e126789-8e15-4662-8927-01e63c9d0682'	System	03 Dec 2020 17:51:34
User entered '03 Dec 2020 12:46:27'	System	03 Dec 2020 17:51:34

**US3632052**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:13:35**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:56:41
Amendment Manager: User entered '03 Dec 2020 00:01'	System	20 Nov 2020 05:56:41

**US3632052**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:13:35**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:56:41
Amendment Manager: User entered '07 Dec 2020 23:59'	System	20 Nov 2020 05:56:41

**US3632052**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:13:35**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:56:41
Amendment Manager: User entered 'Day 96'	System	20 Nov 2020 05:56:41

**US3632052**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:13:35**

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (44467b427832a52f)', Time: '2020-12-10T10:57:53', User OID: 'PatientReportedOutcome (US3632052)', ODM File OID: 'e21b115f-d551-4878-9d9b-79550ca26333'	System	10 Dec 2020 15:58:13
User entered 'No (N)'	System	10 Dec 2020 15:58:13

**US3632052**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:13:35**

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (44467b427832a52f)', Time: '2020-12-10T10:58:05', User OID: 'PatientReportedOutcome (US3632052)', ODM File OID: 'e21b115f-d551-4878-9d9b-79550ca26333'	System	10 Dec 2020 15:58:13
User entered 'No (N)'	System	10 Dec 2020 15:58:13



**US3632052**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:13:35**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (44467b427832a52f)', Time: '2020-12-10T10:58:08', User OID: 'PatientReportedOutcome (US3632052)', ODM File OID: 'e21b115f-d551-4878-9d9b-79550ca26333'	System	10 Dec 2020 15:58:13
User entered '10 Dec 2020 10:58:08'	System	10 Dec 2020 15:58:13

**US3632052**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:13:35**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:56:41
Amendment Manager: User entered '10 Dec 2020 00:01'	System	20 Nov 2020 05:56:41

**US3632052**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:13:35**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:56:41
Amendment Manager: User entered '14 Dec 2020 23:59'	System	20 Nov 2020 05:56:41

**US3632052**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:13:35**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:56:41
Amendment Manager: User entered 'Day 103'	System	20 Nov 2020 05:56:41

**US3632052**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:13:35**

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (44467b427832a52f)', Time: '2020-12-17T09:11:17', User OID: 'PatientReportedOutcome (US3632052)', ODM File OID: 'e51235e6-1510-45cd-9e2b-576efb4db875'	System	17 Dec 2020 14:11:41
User entered 'No (N)'	System	17 Dec 2020 14:11:41

**US3632052**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:13:35**

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (44467b427832a52f)', Time: '2020-12-17T09:11:36', User OID: 'PatientReportedOutcome (US3632052)', ODM File OID: 'e51235e6-1510-45cd-9e2b-576efb4db875'	System	17 Dec 2020 14:11:41
User entered 'No (N)'	System	17 Dec 2020 14:11:41

**US3632052**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:13:35**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (44467b427832a52f)', Time: '2020-12-17T09:11:38', User OID: 'PatientReportedOutcome (US3632052)', ODM File OID: 'e51235e6-1510-45cd-9e2b-576efb4db875'	System	17 Dec 2020 14:11:41
User entered '17 Dec 2020 09:11:38'	System	17 Dec 2020 14:11:41

**US3632052**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:13:35**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:56:41
Amendment Manager: User entered '17 Dec 2020 00:01'	System	20 Nov 2020 05:56:41



**US3632052**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:13:35**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:56:41
Amendment Manager: User entered '21 Dec 2020 23:59'	System	20 Nov 2020 05:56:41

**US3632052**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:13:35**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:56:41
Amendment Manager: User entered 'Day 110'	System	20 Nov 2020 05:56:41

**US3632052**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:13:35**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:56:41
Amendment Manager: User entered '24 Dec 2020 00:01'	System	20 Nov 2020 05:56:41

**US3632052**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:13:35**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:56:41
Amendment Manager: User entered '28 Dec 2020 23:59'	System	20 Nov 2020 05:56:41

**US3632052**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:13:35**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:56:41
Amendment Manager: User entered 'Day 117'	System	20 Nov 2020 05:56:41

**US3632052**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:13:35**

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (44467b427832a52f)', Time: '2021-01-02T08:54:43', User OID: 'PatientReportedOutcome (US3632052)', ODM File OID: 'eadc4dad-a21a-49a9-81ea-13018e5d8158'	System	02 Jan 2021 13:54:55
User entered 'No (N)'	System	02 Jan 2021 13:54:55

**US3632052**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:13:35**

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (44467b427832a52f)', Time: '2021-01-02T08:54:49', User OID: 'PatientReportedOutcome (US3632052)', ODM File OID: 'eadc4dad-a21a-49a9-81ea-13018e5d8158'	System	02 Jan 2021 13:54:55
User entered 'No (N)'	System	02 Jan 2021 13:54:55

**US3632052**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:13:35**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (44467b427832a52f)', Time: '2021-01-02T08:54:52', User OID: 'PatientReportedOutcome (US3632052)', ODM File OID: 'eadc4dad-a21a-49a9-81ea-13018e5d8158'	System	02 Jan 2021 13:54:55
User entered '02 Jan 2021 08:54:52'	System	02 Jan 2021 13:54:55



**US3632052**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:13:35**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:56:41
Amendment Manager: User entered '31 Dec 2020 00:01'	System	20 Nov 2020 05:56:41

**US3632052**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:13:35**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:56:41
Amendment Manager: User entered '04 Jan 2021 23:59'	System	20 Nov 2020 05:56:41

**US3632052**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:13:35**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:56:41
Amendment Manager: User entered 'Day 124'	System	20 Nov 2020 05:56:41

**US3632052**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:13:35**

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (44467b427832a52f)', Time: '2021-01-09T07:33:51', User OID: 'PatientReportedOutcome (US3632052)', ODM File OID: '42537d2e-2266-4dd3-8a45-3522fcd39782'	System	09 Jan 2021 12:34:05
User entered 'No (N)'	System	09 Jan 2021 12:34:05

**US3632052**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:13:35**

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (44467b427832a52f)', Time: '2021-01-09T07:33:56', User OID: 'PatientReportedOutcome (US3632052)', ODM File OID: '42537d2e-2266-4dd3-8a45-3522fcd39782'	System	09 Jan 2021 12:34:05
User entered 'No (N)'	System	09 Jan 2021 12:34:05

**US3632052**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:13:35**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (44467b427832a52f)', Time: '2021-01-09T07:34:01', User OID: 'PatientReportedOutcome (US3632052)', ODM File OID: '42537d2e-2266-4dd3-8a45-3522fcd39782'	System	09 Jan 2021 12:34:05
User entered '09 Jan 2021 07:34:01'	System	09 Jan 2021 12:34:05

**US3632052**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:13:35**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:56:41
Amendment Manager: User entered '07 Jan 2021 00:01'	System	20 Nov 2020 05:56:41

**US3632052**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:13:35**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:56:41
Amendment Manager: User entered '11 Jan 2021 23:59'	System	20 Nov 2020 05:56:41



**US3632052**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:13:35**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:56:41
Amendment Manager: User entered 'Day 131'	System	20 Nov 2020 05:56:41

**US3632052**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:13:35**

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (44467b427832a52f)', Time: '2021-01-14T12:16:13', User OID: 'PatientReportedOutcome (US3632052)', ODM File OID: '088863f3-193c-48cf-9176-d961b8743837'	System	14 Jan 2021 17:16:31
User entered 'No (N)'	System	14 Jan 2021 17:16:31

**US3632052**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:13:35**

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (44467b427832a52f)', Time: '2021-01-14T12:16:19', User OID: 'PatientReportedOutcome (US3632052)', ODM File OID: '088863f3-193c-48cf-9176-d961b8743837'	System	14 Jan 2021 17:16:31
User entered 'No (N)'	System	14 Jan 2021 17:16:31

**US3632052**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:13:35**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (44467b427832a52f)', Time: '2021-01-14T12:16:28', User OID: 'PatientReportedOutcome (US3632052)', ODM File OID: '088863f3-193c-48cf-9176-d961b8743837'	System	14 Jan 2021 17:16:31
User entered '14 Jan 2021 12:16:28'	System	14 Jan 2021 17:16:31

**US3632052**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:13:35**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:56:41
Amendment Manager: User entered '14 Jan 2021 00:01'	System	20 Nov 2020 05:56:41

**US3632052**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:13:35**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:56:41
Amendment Manager: User entered '18 Jan 2021 23:59'	System	20 Nov 2020 05:56:41

**US3632052**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:13:35**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:56:41
Amendment Manager: User entered 'Day 138'	System	20 Nov 2020 05:56:41

**US3632052**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:13:35**

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (44467b427832a52f)', Time: '2021-01-21T15:54:41', User OID: 'PatientReportedOutcome (US3632052)', ODM File OID: '07ffd056-38f8-4156-b827-055a527f58b6'	System	21 Jan 2021 20:54:56
User entered 'No (N)'	System	21 Jan 2021 20:54:56



**US3632052**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:13:35**

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (44467b427832a52f)', Time: '2021-01-21T15:54:49', User OID: 'PatientReportedOutcome (US3632052)', ODM File OID: '07ffd056-38f8-4156-b827-055a527f58b6'	System	21 Jan 2021 20:54:56
User entered 'No (N)'	System	21 Jan 2021 20:54:56

**US3632052**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:13:35**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (44467b427832a52f)', Time: '2021-01-21T15:54:52', User OID: 'PatientReportedOutcome (US3632052)', ODM File OID: '07ffd056-38f8-4156-b827-055a527f58b6'	System	21 Jan 2021 20:54:56
User entered '21 Jan 2021 15:54:52'	System	21 Jan 2021 20:54:56

**US3632052**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:13:35**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:56:41
Amendment Manager: User entered '21 Jan 2021 00:01'	System	20 Nov 2020 05:56:41

**US3632052**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:13:35**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:56:41
Amendment Manager: User entered '25 Jan 2021 23:59'	System	20 Nov 2020 05:56:41

**US3632052**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:13:35**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:56:41
Amendment Manager: User entered 'Day 145'	System	20 Nov 2020 05:56:41

**US3632052**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:13:35**

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (44467b427832a52f)', Time: '2021-01-28T15:52:41', User OID: 'PatientReportedOutcome (US3632052)', ODM File OID: '8d82a0d6-a874-4d5b-92d2-048caff4221e'	System	28 Jan 2021 20:52:51
User entered 'No (N)'	System	28 Jan 2021 20:52:51

**US3632052**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:13:35**

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (44467b427832a52f)', Time: '2021-01-28T15:52:45', User OID: 'PatientReportedOutcome (US3632052)', ODM File OID: '8d82a0d6-a874-4d5b-92d2-048caff4221e'	System	28 Jan 2021 20:52:51
User entered 'No (N)'	System	28 Jan 2021 20:52:51

**US3632052**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:13:35**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (44467b427832a52f)', Time: '2021-01-28T15:52:48', User OID: 'PatientReportedOutcome (US3632052)', ODM File OID: '8d82a0d6-a874-4d5b-92d2-048caff4221e'	System	28 Jan 2021 20:52:51
User entered '28 Jan 2021 15:52:48'	System	28 Jan 2021 20:52:51



**US3632052**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:13:35**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:56:41
Amendment Manager: User entered '28 Jan 2021 00:01'	System	20 Nov 2020 05:56:41

**US3632052**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:13:35**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:56:41
Amendment Manager: User entered '01 Feb 2021 23:59'	System	20 Nov 2020 05:56:41

**US3632052**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:13:35**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:56:41
Amendment Manager: User entered 'Day 152'	System	20 Nov 2020 05:56:41

**US3632052**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:13:35**

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (44467b427832a52f)', Time: '2021-02-05T19:42:05', User OID: 'PatientReportedOutcome (US3632052)', ODM File OID: '5c3c7b42-2a4c-4f99-9ad8-c158ccb7c69c'	System	06 Feb 2021 00:42:21
User entered 'No (N)'	System	06 Feb 2021 00:42:21

**US3632052**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:13:35**

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (44467b427832a52f)', Time: '2021-02-05T19:42:13', User OID: 'PatientReportedOutcome (US3632052)', ODM File OID: '5c3c7b42-2a4c-4f99-9ad8-c158ccb7c69c'	System	06 Feb 2021 00:42:21
User entered 'No (N)'	System	06 Feb 2021 00:42:21

**US3632052**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:13:35**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (44467b427832a52f)', Time: '2021-02-05T19:42:17', User OID: 'PatientReportedOutcome (US3632052)', ODM File OID: '5c3c7b42-2a4c-4f99-9ad8-c158ccb7c69c'	System	06 Feb 2021 00:42:21
User entered '05 Feb 2021 19:42:17'	System	06 Feb 2021 00:42:21

**US3632052**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:13:35**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:56:41
Amendment Manager: User entered '04 Feb 2021 00:01'	System	20 Nov 2020 05:56:41

**US3632052**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:13:35**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:56:41
Amendment Manager: User entered '08 Feb 2021 23:59'	System	20 Nov 2020 05:56:41



**US3632052**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:13:35**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:56:41
Amendment Manager: User entered 'Day 159'	System	20 Nov 2020 05:56:41

**US3632052**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:13:35**

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (44467b427832a52f)', Time: '2021-02-11T10:14:03', User OID: 'PatientReportedOutcome (US3632052)', ODM File OID: '819b0bcf-5ebd-465b-a65a-ccd48c65c874'	System	11 Feb 2021 15:14:16
User entered 'No (N)'	System	11 Feb 2021 15:14:16

**US3632052**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:13:35**

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (44467b427832a52f)', Time: '2021-02-11T10:14:07', User OID: 'PatientReportedOutcome (US3632052)', ODM File OID: '819b0bcf-5ebd-465b-a65a-ccd48c65c874'	System	11 Feb 2021 15:14:16
User entered 'No (N)'	System	11 Feb 2021 15:14:16

**US3632052**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:13:35**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (44467b427832a52f)', Time: '2021-02-11T10:14:10', User OID: 'PatientReportedOutcome (US3632052)', ODM File OID: '819b0bcf-5ebd-465b-a65a-ccd48c65c874'	System	11 Feb 2021 15:14:16
User entered '11 Feb 2021 10:14:10'	System	11 Feb 2021 15:14:16

**US3632052**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:13:35**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:56:41
Amendment Manager: User entered '11 Feb 2021 00:01'	System	20 Nov 2020 05:56:41

**US3632052**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:13:35**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:56:41
Amendment Manager: User entered '15 Feb 2021 23:59'	System	20 Nov 2020 05:56:41

**US3632052**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:13:35**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:56:41
Amendment Manager: User entered 'Day 166'	System	20 Nov 2020 05:56:41

**US3632052**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:13:35**

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (44467b427832a52f)', Time: '2021-02-18T10:56:19', User OID: 'PatientReportedOutcome (US3632052)', ODM File OID: 'b0492397-8e8a-4288-87b4-40f195f23252'	System	18 Feb 2021 15:57:11
User entered 'No (N)'	System	18 Feb 2021 15:57:11



**US3632052**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:13:35**

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (44467b427832a52f)', Time: '2021-02-18T10:56:42', User OID: 'PatientReportedOutcome (US3632052)', ODM File OID: 'b0492397-8e8a-4288-87b4-40f195f23252'	System	18 Feb 2021 15:57:11
User entered 'Yes (Y)'	System	18 Feb 2021 15:57:11

**US3632052**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:13:35**

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (44467b427832a52f)', Time: '2021-02-18T10:56:54', User OID: 'PatientReportedOutcome (US3632052)', ODM File OID: 'b0492397-8e8a-4288-87b4-40f195f23252'	System	18 Feb 2021 15:57:11
User entered 'I confirm I have read this message and will call the study clinic immediately (9)'	System	18 Feb 2021 15:57:11

**US3632052**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:13:35**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (44467b427832a52f)', Time: '2021-02-18T10:56:56', User OID: 'PatientReportedOutcome (US3632052)', ODM File OID: 'b0492397-8e8a-4288-87b4-40f195f23252'	System	18 Feb 2021 15:57:11
User entered '18 Feb 2021 10:56:56'	System	18 Feb 2021 15:57:11

**US3632052**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:13:35**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:56:41
Amendment Manager: User entered '18 Feb 2021 00:01'	System	20 Nov 2020 05:56:41

**US3632052**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:13:35**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:56:41
Amendment Manager: User entered '22 Feb 2021 23:59'	System	20 Nov 2020 05:56:41

**US3632052**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:13:35**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:56:41
Amendment Manager: User entered 'Day 173'	System	20 Nov 2020 05:56:41

**US3632052**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:13:35**

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (44467b427832a52f)', Time: '2021-02-27T10:26:42-05:00', User OID: 'PatientReportedOutcome (US3632052)', ODM File OID: 'c8ab2600-2cac-4f9a-ae25-23856db6e8f7'	System	27 Feb 2021 15:26:52
User entered 'No (N)'	System	27 Feb 2021 15:26:52

**US3632052**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:13:35**

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (44467b427832a52f)', Time: '2021-02-27T10:26:47-05:00', User OID: 'PatientReportedOutcome (US3632052)', ODM File OID: 'c8ab2600-2cac-4f9a-ae25-23856db6e8f7'	System	27 Feb 2021 15:26:52
User entered 'No (N)'	System	27 Feb 2021 15:26:52



**US3632052**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:13:35**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (44467b427832a52f)', Time: '2021-02-27T10:26:51-05:00', User OID: 'PatientReportedOutcome (US3632052)', ODM File OID: 'c8ab2600-2cac-4f9a-ae25-23856db6e8f7'	System	27 Feb 2021 15:26:52
User entered '27 Feb 2021 10:26:51'	System	27 Feb 2021 15:26:52

**US3632052**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:13:35**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:56:41
Amendment Manager: User entered '25 Feb 2021 00:01'	System	20 Nov 2020 05:56:41

**US3632052**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:13:35**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:56:41
Amendment Manager: User entered '01 Mar 2021 23:59'	System	20 Nov 2020 05:56:41

**US3632052**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:13:35**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:56:41
Amendment Manager: User entered 'Day 180'	System	20 Nov 2020 05:56:41

**US3632052**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:13:35**

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (44467b427832a52f)', Time: '2021-03-04T11:18:08-05:00', User OID: 'PatientReportedOutcome (US3632052)', ODM File OID: '61b65d65-cccd-47cf-b28c-2b3fd753f658'	System	04 Mar 2021 16:18:28
User entered 'No (N)'	System	04 Mar 2021 16:18:28

**US3632052**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:13:35**

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (44467b427832a52f)', Time: '2021-03-04T11:18:13-05:00', User OID: 'PatientReportedOutcome (US3632052)', ODM File OID: '61b65d65-cccd-47cf-b28c-2b3fd753f658'	System	04 Mar 2021 16:18:28
User entered 'No (N)'	System	04 Mar 2021 16:18:28

**US3632052**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:13:35**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (44467b427832a52f)', Time: '2021-03-04T11:18:16-05:00', User OID: 'PatientReportedOutcome (US3632052)', ODM File OID: '61b65d65-cccd-47cf-b28c-2b3fd753f658'	System	04 Mar 2021 16:18:28
User entered '04 Mar 2021 11:18:16'	System	04 Mar 2021 16:18:28

**US3632052**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:13:35**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:56:41
Amendment Manager: User entered '04 Mar 2021 00:01'	System	20 Nov 2020 05:56:41



**US3632052**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:13:35**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:56:41
Amendment Manager: User entered '08 Mar 2021 23:59'	System	20 Nov 2020 05:56:41

**US3632052**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:13:35**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:56:41
Amendment Manager: User entered 'Day 187'	System	20 Nov 2020 05:56:41

**US3632052**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:13:35**

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (44467b427832a52f)', Time: '2021-03-15T14:08:28-04:00', User OID: 'PatientReportedOutcome (US3632052)', ODM File OID: 'bb5b62c2-1fc4-44e6-8b0d-0b5eb703d408'	System	15 Mar 2021 18:08:37
User entered 'No (N)'	System	15 Mar 2021 18:08:37

**US3632052**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:13:35**

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (44467b427832a52f)', Time: '2021-03-15T14:08:32-04:00', User OID: 'PatientReportedOutcome (US3632052)', ODM File OID: 'bb5b62c2-1fc4-44e6-8b0d-0b5eb703d408'	System	15 Mar 2021 18:08:37
User entered 'No (N)'	System	15 Mar 2021 18:08:37

**US3632052**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:13:35**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (44467b427832a52f)', Time: '2021-03-15T14:08:34-04:00', User OID: 'PatientReportedOutcome (US3632052)', ODM File OID: 'bb5b62c2-1fc4-44e6-8b0d-0b5eb703d408'	System	15 Mar 2021 18:08:37
User entered '15 Mar 2021 14:08:34'	System	15 Mar 2021 18:08:37

**US3632052**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:13:35**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:56:41
Amendment Manager: User entered '11 Mar 2021 00:01'	System	20 Nov 2020 05:56:41

**US3632052**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:13:35**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:56:41
Amendment Manager: User entered '15 Mar 2021 23:59'	System	20 Nov 2020 05:56:41

**US3632052**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:13:35**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:56:41
Amendment Manager: User entered 'Day 194'	System	20 Nov 2020 05:56:41



**US3632052**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:13:35**

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (44467b427832a52f)', Time: '2021-03-18T10:05:05-04:00', User OID: 'PatientReportedOutcome (US3632052)', ODM File OID: '59e47675-113c-4939-9465-f25aa8033f42'	System	18 Mar 2021 14:05:15
User entered 'No (N)'	System	18 Mar 2021 14:05:15

**US3632052**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:13:35**

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (44467b427832a52f)', Time: '2021-03-18T10:05:09-04:00', User OID: 'PatientReportedOutcome (US3632052)', ODM File OID: '59e47675-113c-4939-9465-f25aa8033f42'	System	18 Mar 2021 14:05:15
User entered 'No (N)'	System	18 Mar 2021 14:05:15

**US3632052**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:13:35**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (44467b427832a52f)', Time: '2021-03-18T10:05:11-04:00', User OID: 'PatientReportedOutcome (US3632052)', ODM File OID: '59e47675-113c-4939-9465-f25aa8033f42'	System	18 Mar 2021 14:05:15
User entered '18 Mar 2021 10:05:11'	System	18 Mar 2021 14:05:15

**US3632052**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:13:35**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:56:41
Amendment Manager: User entered '18 Mar 2021 00:01'	System	20 Nov 2020 05:56:41

**US3632052**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:13:35**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:56:41
Amendment Manager: User entered '22 Mar 2021 23:59'	System	20 Nov 2020 05:56:41

**US3632052**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:13:35**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:56:41
Amendment Manager: User entered 'Day 201'	System	20 Nov 2020 05:56:41

**US3632052**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:13:35**

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (44467b427832a52f)', Time: '2021-03-25T09:38:20-04:00', User OID: 'PatientReportedOutcome (US3632052)', ODM File OID: 'dbd80034-e1b0-4033-b9eb-15badf6c85de'	System	25 Mar 2021 13:38:35
User entered 'No (N)'	System	25 Mar 2021 13:38:35

**US3632052**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:13:35**

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (44467b427832a52f)', Time: '2021-03-25T09:38:24-04:00', User OID: 'PatientReportedOutcome (US3632052)', ODM File OID: 'dbd80034-e1b0-4033-b9eb-15badf6c85de'	System	25 Mar 2021 13:38:35
User entered 'No (N)'	System	25 Mar 2021 13:38:35



**US3632052**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:13:35**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (44467b427832a52f)', Time: '2021-03-25T09:38:28-04:00', User OID: 'PatientReportedOutcome (US3632052)', ODM File OID: 'dbd80034-e1b0-4033-b9eb-15badf6c85de' User entered '25 Mar 2021 09:38:28'	System	25 Mar 2021 13:38:35
	System	25 Mar 2021 13:38:35

**US3632052**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:13:35**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:56:41
Amendment Manager: User entered '25 Mar 2021 00:01'	System	20 Nov 2020 05:56:41

**US3632052**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:13:35**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:56:41
Amendment Manager: User entered '29 Mar 2021 23:59'	System	20 Nov 2020 05:56:41

**US3632052**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:13:35**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:56:41
Amendment Manager: User entered 'Day 208'	System	20 Nov 2020 05:56:41

**US3632052**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:13:35**

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (44467b427832a52f)', Time: '2021-04-01T11:34:30-04:00', User OID: 'PatientReportedOutcome (US3632052)', ODM File OID: '1134cdaf-1ba4-405d-94e0-c3d3a858bb4c'	System	01 Apr 2021 15:34:46
User entered 'No (N)'	System	01 Apr 2021 15:34:46

**US3632052**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:13:35**

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (44467b427832a52f)', Time: '2021-04-01T11:34:39-04:00', User OID: 'PatientReportedOutcome (US3632052)', ODM File OID: '1134cdaf-1ba4-405d-94e0-c3d3a858bb4c'	System	01 Apr 2021 15:34:46
User entered 'No (N)'	System	01 Apr 2021 15:34:46

**US3632052**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:13:35**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (44467b427832a52f)', Time: '2021-04-01T11:34:43-04:00', User OID: 'PatientReportedOutcome (US3632052)', ODM File OID: '1134cdaf-1ba4-405d-94e0-c3d3a858bb4c' User entered '01 Apr 2021 11:34:43'	System	01 Apr 2021 15:34:46
	System	01 Apr 2021 15:34:46

**US3632052**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:13:35**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:56:41
Amendment Manager: User entered '01 Apr 2021 00:01'	System	20 Nov 2020 05:56:41



**US3632052**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:13:35**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:56:41
Amendment Manager: User entered '05 Apr 2021 23:59'	System	20 Nov 2020 05:56:41

**US3632052**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:13:35**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:56:41
Amendment Manager: User entered 'Day 215'	System	20 Nov 2020 05:56:41

**US3632052**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:13:35**

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (44467b427832a52f)', Time: '2021-04-10T12:00:59-04:00', User OID: 'PatientReportedOutcome (US3632052)', ODM File OID: 'c026fab4-4f31-41a6-ae7f-198b0218af50'	System	10 Apr 2021 16:02:28
User entered 'No (N)'	System	10 Apr 2021 16:02:28

**US3632052**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:13:35**

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (44467b427832a52f)', Time: '2021-04-10T12:01:04-04:00', User OID: 'PatientReportedOutcome (US3632052)', ODM File OID: 'c026fab4-4f31-41a6-ae7f-198b0218af50'	System	10 Apr 2021 16:02:28
User entered 'No (N)'	System	10 Apr 2021 16:02:28

**US3632052**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:13:35**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (44467b427832a52f)', Time: '2021-04-10T12:01:07-04:00', User OID: 'PatientReportedOutcome (US3632052)', ODM File OID: 'c026fab4-4f31-41a6-ae7f-198b0218af50' User entered '10 Apr 2021 12:01:07'	System	10 Apr 2021 16:02:28
	System	10 Apr 2021 16:02:28

**US3632052**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:13:35**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:56:41
Amendment Manager: User entered '08 Apr 2021 00:01'	System	20 Nov 2020 05:56:41

**US3632052**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:13:35**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:56:41
Amendment Manager: User entered '12 Apr 2021 23:59'	System	20 Nov 2020 05:56:41

**US3632052**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:13:35**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:56:41
Amendment Manager: User entered 'Day 222'	System	20 Nov 2020 05:56:41



**US3632052**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:13:35**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:56:41
Amendment Manager: User entered '15 Apr 2021 00:01'	System	20 Nov 2020 05:56:41

**US3632052**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:13:35**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:56:41
Amendment Manager: User entered '19 Apr 2021 23:59'	System	20 Nov 2020 05:56:41

**US3632052**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:13:35**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:56:41
Amendment Manager: User entered 'Day 229'	System	20 Nov 2020 05:56:41

**US3632052**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:13:35**

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (44467b427832a52f)', Time: '2021-04-22T10:50:08-04:00', User OID: 'PatientReportedOutcome (US3632052)', ODM File OID: '99831b43-8c81-4302-bf95-cad542d7af7e' User entered 'No (N)'	System	22 Apr 2021 14:50:19
	System	22 Apr 2021 14:50:19

**US3632052**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:13:35**

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (44467b427832a52f)', Time: '2021-04-22T10:50:12-04:00', User OID: 'PatientReportedOutcome (US3632052)', ODM File OID: '99831b43-8c81-4302-bf95-cad542d7af7e'	System	22 Apr 2021 14:50:19
User entered 'No (N)'	System	22 Apr 2021 14:50:19

**US3632052**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:13:35**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (44467b427832a52f)', Time: '2021-04-22T10:50:14-04:00', User OID: 'PatientReportedOutcome (US3632052)', ODM File OID: '99831b43-8c81-4302-bf95-cad542d7af7e' User entered '22 Apr 2021 10:50:14'	System	22 Apr 2021 14:50:19
	System	22 Apr 2021 14:50:19

**US3632052**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:13:35**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:56:41
Amendment Manager: User entered '22 Apr 2021 00:01'	System	20 Nov 2020 05:56:41

**US3632052**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:13:35**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:56:41
Amendment Manager: User entered '26 Apr 2021 23:59'	System	20 Nov 2020 05:56:41



**US3632052**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:13:35**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:56:41
Amendment Manager: User entered 'Day 236'	System	20 Nov 2020 05:56:41

**US3632052**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:13:35**

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (44467b427832a52f)', Time: '2021-04-30T18:32:28-04:00', User OID: 'PatientReportedOutcome (US3632052)', ODM File OID: '3d421571-e01e-4700-9059-b847ef6118e1' User entered 'No (N)'	System	30 Apr 2021 22:32:46
	System	30 Apr 2021 22:32:46

**US3632052**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:13:35**

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (44467b427832a52f)', Time: '2021-04-30T18:32:40-04:00', User OID: 'PatientReportedOutcome (US3632052)', ODM File OID: '3d421571-e01e-4700-9059-b847ef6118e1' User entered 'No (N)'	System	30 Apr 2021 22:32:46
	System	30 Apr 2021 22:32:46

**US3632052**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:13:35**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (44467b427832a52f)', Time: '2021-04-30T18:32:43-04:00', User OID: 'PatientReportedOutcome (US3632052)', ODM File OID: '3d421571-e01e-4700-9059-b847ef6118e1' User entered '30 Apr 2021 18:32:43'	System	30 Apr 2021 22:32:46
	System	30 Apr 2021 22:32:46

**US3632052**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:13:35**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:56:41
Amendment Manager: User entered '29 Apr 2021 00:01'	System	20 Nov 2020 05:56:41

**US3632052**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:13:35**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:56:41
Amendment Manager: User entered '03 May 2021 23:59'	System	20 Nov 2020 05:56:41

**US3632052**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:13:35**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:56:41
Amendment Manager: User entered 'Day 243'	System	20 Nov 2020 05:56:41

**US3632052**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:13:35**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:56:41
Amendment Manager: User entered '06 May 2021 00:01'	System	20 Nov 2020 05:56:41



**US3632052**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:13:35**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:56:41
Amendment Manager: User entered '10 May 2021 23:59'	System	20 Nov 2020 05:56:41

**US3632052**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:13:35**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:56:41
Amendment Manager: User entered 'Day 250'	System	20 Nov 2020 05:56:41

**US3632052**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:13:35**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:56:41
Amendment Manager: User entered '13 May 2021 00:01'	System	20 Nov 2020 05:56:41

**US3632052**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:13:35**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:56:41
Amendment Manager: User entered '17 May 2021 23:59'	System	20 Nov 2020 05:56:41

**US3632052**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:13:35**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:56:41
Amendment Manager: User entered 'Day 257'	System	20 Nov 2020 05:56:41

**US3632052**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:13:35**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:56:41
Amendment Manager: User entered '20 May 2021 00:01'	System	20 Nov 2020 05:56:41

**US3632052**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:13:35**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:56:41
Amendment Manager: User entered '24 May 2021 23:59'	System	20 Nov 2020 05:56:41

**US3632052**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:13:35**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:56:41
Amendment Manager: User entered 'Day 264'	System	20 Nov 2020 05:56:41



**US3632052**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:13:35**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:56:41
Amendment Manager: User entered '27 May 2021 00:01'	System	20 Nov 2020 05:56:41

**US3632052**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:13:35**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:56:41
Amendment Manager: User entered '31 May 2021 23:59'	System	20 Nov 2020 05:56:41

**US3632052**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:13:35**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:56:41
Amendment Manager: User entered 'Day 271'	System	20 Nov 2020 05:56:41

**US3632052**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:13:35**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:56:41
Amendment Manager: User entered '03 Jun 2021 00:01'	System	20 Nov 2020 05:56:41

**US3632052**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:13:35**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:56:41
Amendment Manager: User entered '07 Jun 2021 23:59'	System	20 Nov 2020 05:56:41

**US3632052**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:13:35**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:56:41
Amendment Manager: User entered 'Day 278'	System	20 Nov 2020 05:56:41

**US3632052**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:13:35**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:56:41
Amendment Manager: User entered '10 Jun 2021 00:01'	System	20 Nov 2020 05:56:41

**US3632052**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:13:35**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:56:41
Amendment Manager: User entered '14 Jun 2021 23:59'	System	20 Nov 2020 05:56:41



**US3632052**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:13:35**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:56:41
Amendment Manager: User entered 'Day 285'	System	20 Nov 2020 05:56:41

**US3632052**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:13:35**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:56:41
Amendment Manager: User entered '17 Jun 2021 00:01'	System	20 Nov 2020 05:56:41

**US3632052**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:13:35**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:56:41
Amendment Manager: User entered '21 Jun 2021 23:59'	System	20 Nov 2020 05:56:41

**US3632052**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:13:35**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:56:41
Amendment Manager: User entered 'Day 292'	System	20 Nov 2020 05:56:41

**US3632052**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:13:35**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:56:41
Amendment Manager: User entered '24 Jun 2021 00:01'	System	20 Nov 2020 05:56:41

**US3632052**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:13:35**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:56:41
Amendment Manager: User entered '28 Jun 2021 23:59'	System	20 Nov 2020 05:56:41

**US3632052**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:13:35**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:56:41
Amendment Manager: User entered 'Day 299'	System	20 Nov 2020 05:56:41

**US3632052**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:13:35**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:56:41
Amendment Manager: User entered '01 Jul 2021 00:01'	System	20 Nov 2020 05:56:41



**US3632052**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:13:35**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:56:41
Amendment Manager: User entered '05 Jul 2021 23:59'	System	20 Nov 2020 05:56:41

**US3632052**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:13:35**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:56:41
Amendment Manager: User entered 'Day 306'	System	20 Nov 2020 05:56:41

**US3632052**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:13:35**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:56:41
Amendment Manager: User entered '08 Jul 2021 00:01'	System	20 Nov 2020 05:56:41

**US3632052**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:13:35**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:56:41
Amendment Manager: User entered '12 Jul 2021 23:59'	System	20 Nov 2020 05:56:41

**US3632052**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:13:35**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:56:41
Amendment Manager: User entered 'Day 313'	System	20 Nov 2020 05:56:41

**US3632052**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:13:35**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:56:41
Amendment Manager: User entered '15 Jul 2021 00:01'	System	20 Nov 2020 05:56:41

**US3632052**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:13:35**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:56:41
Amendment Manager: User entered '19 Jul 2021 23:59'	System	20 Nov 2020 05:56:41

**US3632052**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:13:35**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:56:41
Amendment Manager: User entered 'Day 320'	System	20 Nov 2020 05:56:41



**US3632052**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:13:35**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:56:41
Amendment Manager: User entered '22 Jul 2021 00:01'	System	20 Nov 2020 05:56:41

**US3632052**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:13:35**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:56:41
Amendment Manager: User entered '26 Jul 2021 23:59'	System	20 Nov 2020 05:56:41

**US3632052**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:13:35**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:56:41
Amendment Manager: User entered 'Day 327'	System	20 Nov 2020 05:56:41

**US3632052**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:13:35**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:56:41
Amendment Manager: User entered '29 Jul 2021 00:01'	System	20 Nov 2020 05:56:41

**US3632052**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:13:35**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:56:41
Amendment Manager: User entered '02 Aug 2021 23:59'	System	20 Nov 2020 05:56:41

**US3632052**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:13:35**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:56:41
Amendment Manager: User entered 'Day 334'	System	20 Nov 2020 05:56:41

**US3632052**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:13:35**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:56:41
Amendment Manager: User entered '05 Aug 2021 00:01'	System	20 Nov 2020 05:56:41

**US3632052**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:13:35**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:56:41
Amendment Manager: User entered '09 Aug 2021 23:59'	System	20 Nov 2020 05:56:41



**US3632052**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:13:35**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:56:41
Amendment Manager: User entered 'Day 341'	System	20 Nov 2020 05:56:41

**US3632052**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:13:35**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:56:41
Amendment Manager: User entered '12 Aug 2021 00:01'	System	20 Nov 2020 05:56:41

**US3632052**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:13:35**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:56:41
Amendment Manager: User entered '16 Aug 2021 23:59'	System	20 Nov 2020 05:56:41

**US3632052**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:13:35**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:56:41
Amendment Manager: User entered 'Day 348'	System	20 Nov 2020 05:56:41

**US3632052**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:13:35**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:56:41
Amendment Manager: User entered '19 Aug 2021 00:01'	System	20 Nov 2020 05:56:41

**US3632052**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:13:35**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:56:41
Amendment Manager: User entered '23 Aug 2021 23:59'	System	20 Nov 2020 05:56:41

**US3632052**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:13:35**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:56:41
Amendment Manager: User entered 'Day 355'	System	20 Nov 2020 05:56:41

**US3632052**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:13:35**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:56:41
Amendment Manager: User entered '26 Aug 2021 00:01'	System	20 Nov 2020 05:56:41



**US3632052**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:13:35**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:56:41
Amendment Manager: User entered '30 Aug 2021 23:59'	System	20 Nov 2020 05:56:41

**US3632052**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:13:35**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:56:41
Amendment Manager: User entered 'Day 362'	System	20 Nov 2020 05:56:41

**US3632052**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:13:35**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:56:41
Amendment Manager: User entered '02 Sep 2021 00:01'	System	20 Nov 2020 05:56:41

**US3632052**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:13:35**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:56:41
Amendment Manager: User entered '06 Sep 2021 23:59'	System	20 Nov 2020 05:56:41

**US3632052**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:13:35**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:56:41
Amendment Manager: User entered 'Day 369'	System	20 Nov 2020 05:56:41

**US3632052**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:13:35**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:56:41
Amendment Manager: User entered '09 Sep 2021 00:01'	System	20 Nov 2020 05:56:41

**US3632052**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:13:35**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:56:41
Amendment Manager: User entered '13 Sep 2021 23:59'	System	20 Nov 2020 05:56:41

**US3632052**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:13:35**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:56:41
Amendment Manager: User entered 'Day 376'	System	20 Nov 2020 05:56:41



**US3632052**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:13:35**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:56:41
Amendment Manager: User entered '16 Sep 2021 00:01'	System	20 Nov 2020 05:56:41

**US3632052**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:13:35**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:56:41
Amendment Manager: User entered '20 Sep 2021 23:59'	System	20 Nov 2020 05:56:41

**US3632052**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:13:35**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:56:41
Amendment Manager: User entered 'Day 383'	System	20 Nov 2020 05:56:41

**US3632052**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:13:35**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:56:41
Amendment Manager: User entered '23 Sep 2021 00:01'	System	20 Nov 2020 05:56:41

**US3632052**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:13:35**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:56:41
Amendment Manager: User entered '27 Sep 2021 23:59'	System	20 Nov 2020 05:56:41

**US3632052**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:13:35**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:56:41
Amendment Manager: User entered 'Day 390'	System	20 Nov 2020 05:56:41

**US3632052**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:13:35**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:56:41
Amendment Manager: User entered '30 Sep 2021 00:01'	System	20 Nov 2020 05:56:41

**US3632052**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:13:35**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:56:41
Amendment Manager: User entered '04 Oct 2021 23:59'	System	20 Nov 2020 05:56:41



**US3632052**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:13:35**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:56:41
Amendment Manager: User entered 'Day 397'	System	20 Nov 2020 05:56:41

**US3632052**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:13:35**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:56:41
Amendment Manager: User entered '07 Oct 2021 00:01'	System	20 Nov 2020 05:56:41

**US3632052**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:13:35**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:56:41
Amendment Manager: User entered '11 Oct 2021 23:59'	System	20 Nov 2020 05:56:41

**US3632052**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:13:35**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:56:41
Amendment Manager: User entered 'Day 404'	System	20 Nov 2020 05:56:41

**US3632052**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:13:35**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:56:41
Amendment Manager: User entered '14 Oct 2021 00:01'	System	20 Nov 2020 05:56:41

**US3632052**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:13:35**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:56:41
Amendment Manager: User entered '18 Oct 2021 23:59'	System	20 Nov 2020 05:56:41

**US3632052**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:13:35**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:56:41
Amendment Manager: User entered 'Day 411'	System	20 Nov 2020 05:56:41

**US3632052**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:13:35**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:56:41
Amendment Manager: User entered '21 Oct 2021 00:01'	System	20 Nov 2020 05:56:41



**US3632052**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:13:35**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:56:41
Amendment Manager: User entered '25 Oct 2021 23:59'	System	20 Nov 2020 05:56:41

**US3632052**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:13:35**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:56:41
Amendment Manager: User entered 'Day 418'	System	20 Nov 2020 05:56:41

**US3632052**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:13:35**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:56:41
Amendment Manager: User entered '28 Oct 2021 00:01'	System	20 Nov 2020 05:56:41

**US3632052**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:13:35**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:56:41
Amendment Manager: User entered '01 Nov 2021 23:59'	System	20 Nov 2020 05:56:41

**US3632052**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:13:35**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:56:41
Amendment Manager: User entered 'Day 425'	System	20 Nov 2020 05:56:41

**US3632052**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:13:35**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:56:41
Amendment Manager: User entered '04 Nov 2021 00:01'	System	20 Nov 2020 05:56:41

**US3632052**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:13:35**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:56:41
Amendment Manager: User entered '08 Nov 2021 23:59'	System	20 Nov 2020 05:56:41

**US3632052**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:13:35**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:56:41
Amendment Manager: User entered 'Day 432'	System	20 Nov 2020 05:56:41



**US3632052**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:13:35**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:56:41
Amendment Manager: User entered '11 Nov 2021 00:01'	System	20 Nov 2020 05:56:41

**US3632052**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:13:35**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:56:41
Amendment Manager: User entered '15 Nov 2021 23:59'	System	20 Nov 2020 05:56:41

**US3632052**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:13:35**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:56:41
Amendment Manager: User entered 'Day 439'	System	20 Nov 2020 05:56:41

**US3632052**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:13:35**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:56:41
Amendment Manager: User entered '18 Nov 2021 00:01'	System	20 Nov 2020 05:56:41

**US3632052**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:13:35**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:56:41
Amendment Manager: User entered '22 Nov 2021 23:59'	System	20 Nov 2020 05:56:41

**US3632052**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:13:35**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:56:41
Amendment Manager: User entered 'Day 446'	System	20 Nov 2020 05:56:41

**US3632052**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:13:35**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:56:41
Amendment Manager: User entered '25 Nov 2021 00:01'	System	20 Nov 2020 05:56:41

**US3632052**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:13:35**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:56:41
Amendment Manager: User entered '29 Nov 2021 23:59'	System	20 Nov 2020 05:56:41



**US3632052**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:13:35**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:56:41
Amendment Manager: User entered 'Day 453'	System	20 Nov 2020 05:56:41

**US3632052**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:13:35**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:56:41
Amendment Manager: User entered '02 Dec 2021 00:01'	System	20 Nov 2020 05:56:41

**US3632052**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:13:35**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:56:41
Amendment Manager: User entered '06 Dec 2021 23:59'	System	20 Nov 2020 05:56:41

**US3632052**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:13:35**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:56:41
Amendment Manager: User entered 'Day 460'	System	20 Nov 2020 05:56:41

**US3632052**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:13:35**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:56:41
Amendment Manager: User entered '09 Dec 2021 00:01'	System	20 Nov 2020 05:56:41

**US3632052**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:13:35**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:56:41
Amendment Manager: User entered '13 Dec 2021 23:59'	System	20 Nov 2020 05:56:41

**US3632052**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:13:35**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:56:41
Amendment Manager: User entered 'Day 467'	System	20 Nov 2020 05:56:41

**US3632052**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:13:35**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:56:41
Amendment Manager: User entered '16 Dec 2021 00:01'	System	20 Nov 2020 05:56:41



**US3632052**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:13:35**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:56:41
Amendment Manager: User entered '20 Dec 2021 23:59'	System	20 Nov 2020 05:56:41

**US3632052**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:13:35**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:56:41
Amendment Manager: User entered 'Day 474'	System	20 Nov 2020 05:56:41

**US3632052**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:13:35**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:56:41
Amendment Manager: User entered '23 Dec 2021 00:01'	System	20 Nov 2020 05:56:41

**US3632052**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:13:35**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:56:41
Amendment Manager: User entered '27 Dec 2021 23:59'	System	20 Nov 2020 05:56:41

**US3632052**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:13:35**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:56:41
Amendment Manager: User entered 'Day 481'	System	20 Nov 2020 05:56:41

**US3632052**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:13:35**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:56:41
Amendment Manager: User entered '30 Dec 2021 00:01'	System	20 Nov 2020 05:56:41

**US3632052**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:13:35**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:56:41
Amendment Manager: User entered '03 Jan 2022 23:59'	System	20 Nov 2020 05:56:41

**US3632052**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:13:35**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:56:41
Amendment Manager: User entered 'Day 488'	System	20 Nov 2020 05:56:41



**US3632052**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:13:35**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:56:41
Amendment Manager: User entered '06 Jan 2022 00:01'	System	20 Nov 2020 05:56:41

**US3632052**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:13:35**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:56:41
Amendment Manager: User entered '10 Jan 2022 23:59'	System	20 Nov 2020 05:56:41

**US3632052**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:13:35**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:56:41
Amendment Manager: User entered 'Day 495'	System	20 Nov 2020 05:56:41

**US3632052**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:13:35**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:56:41
Amendment Manager: User entered '13 Jan 2022 00:01'	System	20 Nov 2020 05:56:41

**US3632052**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:13:35**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:56:41
Amendment Manager: User entered '17 Jan 2022 23:59'	System	20 Nov 2020 05:56:41

**US3632052**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:13:35**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:56:41
Amendment Manager: User entered 'Day 502'	System	20 Nov 2020 05:56:41

**US3632052**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:13:35**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:56:41
Amendment Manager: User entered '20 Jan 2022 00:01'	System	20 Nov 2020 05:56:41

**US3632052**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:13:35**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:56:41
Amendment Manager: User entered '24 Jan 2022 23:59'	System	20 Nov 2020 05:56:41



**US3632052**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:13:35**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:56:41
Amendment Manager: User entered 'Day 509'	System	20 Nov 2020 05:56:41

**US3632052**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:13:35**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:56:41
Amendment Manager: User entered '27 Jan 2022 00:01'	System	20 Nov 2020 05:56:41

**US3632052**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:13:35**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:56:41
Amendment Manager: User entered '31 Jan 2022 23:59'	System	20 Nov 2020 05:56:41

**US3632052**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:13:35**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:56:41
Amendment Manager: User entered 'Day 516'	System	20 Nov 2020 05:56:41

**US3632052**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:13:35**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:56:41
Amendment Manager: User entered '03 Feb 2022 00:01'	System	20 Nov 2020 05:56:41

**US3632052**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:13:35**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:56:41
Amendment Manager: User entered '07 Feb 2022 23:59'	System	20 Nov 2020 05:56:41

**US3632052**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:13:35**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:56:41
Amendment Manager: User entered 'Day 523'	System	20 Nov 2020 05:56:41

**US3632052**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:13:35**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:56:41
Amendment Manager: User entered '10 Feb 2022 00:01'	System	20 Nov 2020 05:56:41



**US3632052**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:13:35**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:56:41
Amendment Manager: User entered '14 Feb 2022 23:59'	System	20 Nov 2020 05:56:41

**US3632052**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:13:35**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:56:41
Amendment Manager: User entered 'Day 530'	System	20 Nov 2020 05:56:41

**US3632052**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:13:35**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:56:41
Amendment Manager: User entered '17 Feb 2022 00:01'	System	20 Nov 2020 05:56:41

**US3632052**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:13:35**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:56:41
Amendment Manager: User entered '21 Feb 2022 23:59'	System	20 Nov 2020 05:56:41

**US3632052**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:13:35**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:56:41
Amendment Manager: User entered 'Day 537'	System	20 Nov 2020 05:56:41

**US3632052**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:13:35**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:56:41
Amendment Manager: User entered '24 Feb 2022 00:01'	System	20 Nov 2020 05:56:41

**US3632052**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:13:35**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:56:41
Amendment Manager: User entered '28 Feb 2022 23:59'	System	20 Nov 2020 05:56:41

**US3632052**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:13:35**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:56:41
Amendment Manager: User entered 'Day 544'	System	20 Nov 2020 05:56:41



**US3632052**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:13:35**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:56:41
Amendment Manager: User entered '03 Mar 2022 00:01'	System	20 Nov 2020 05:56:41

**US3632052**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:13:35**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:56:41
Amendment Manager: User entered '07 Mar 2022 23:59'	System	20 Nov 2020 05:56:41

**US3632052**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:13:35**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:56:41
Amendment Manager: User entered 'Day 551'	System	20 Nov 2020 05:56:41

**US3632052**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:13:35**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:56:41
Amendment Manager: User entered '10 Mar 2022 00:01'	System	20 Nov 2020 05:56:41

**US3632052**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:13:35**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:56:41
Amendment Manager: User entered '14 Mar 2022 23:59'	System	20 Nov 2020 05:56:41

**US3632052**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:13:35**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:56:41
Amendment Manager: User entered 'Day 558'	System	20 Nov 2020 05:56:41

**US3632052**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:13:35**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:56:41
Amendment Manager: User entered '17 Mar 2022 00:01'	System	20 Nov 2020 05:56:41

**US3632052**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:13:35**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:56:41
Amendment Manager: User entered '21 Mar 2022 23:59'	System	20 Nov 2020 05:56:41



**US3632052**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:13:35**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:56:41
Amendment Manager: User entered 'Day 565'	System	20 Nov 2020 05:56:41

**US3632052**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:13:35**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:56:41
Amendment Manager: User entered '24 Mar 2022 00:01'	System	20 Nov 2020 05:56:41

**US3632052**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:13:35**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:56:41
Amendment Manager: User entered '28 Mar 2022 23:59'	System	20 Nov 2020 05:56:41

**US3632052**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:13:35**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:56:41
Amendment Manager: User entered 'Day 572'	System	20 Nov 2020 05:56:41

**US3632052**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:13:35**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:56:41
Amendment Manager: User entered '31 Mar 2022 00:01'	System	20 Nov 2020 05:56:41

**US3632052**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:13:35**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:56:41
Amendment Manager: User entered '04 Apr 2022 23:59'	System	20 Nov 2020 05:56:41

**US3632052**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:13:35**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:56:41
Amendment Manager: User entered 'Day 579'	System	20 Nov 2020 05:56:41

**US3632052**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:13:35**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:56:41
Amendment Manager: User entered '07 Apr 2022 00:01'	System	20 Nov 2020 05:56:41



**US3632052**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:13:35**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:56:41
Amendment Manager: User entered '11 Apr 2022 23:59'	System	20 Nov 2020 05:56:41

**US3632052**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:13:35**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:56:41
Amendment Manager: User entered 'Day 586'	System	20 Nov 2020 05:56:41

**US3632052**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:13:35**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:56:41
Amendment Manager: User entered '14 Apr 2022 00:01'	System	20 Nov 2020 05:56:41

**US3632052**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:13:35**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:56:41
Amendment Manager: User entered '18 Apr 2022 23:59'	System	20 Nov 2020 05:56:41

**US3632052**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:13:35**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:56:41
Amendment Manager: User entered 'Day 593'	System	20 Nov 2020 05:56:41

**US3632052**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:13:35**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:56:41
Amendment Manager: User entered '21 Apr 2022 00:01'	System	20 Nov 2020 05:56:41

**US3632052**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:13:35**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:56:41
Amendment Manager: User entered '25 Apr 2022 23:59'	System	20 Nov 2020 05:56:41

**US3632052**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:13:35**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:56:41
Amendment Manager: User entered 'Day 600'	System	20 Nov 2020 05:56:41



**US3632052**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:13:35**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:56:41
Amendment Manager: User entered '28 Apr 2022 00:01'	System	20 Nov 2020 05:56:41

**US3632052**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:13:35**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:56:41
Amendment Manager: User entered '02 May 2022 23:59'	System	20 Nov 2020 05:56:41

**US3632052**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:13:35**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:56:41
Amendment Manager: User entered 'Day 607'	System	20 Nov 2020 05:56:41

**US3632052**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:13:35**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:56:41
Amendment Manager: User entered '05 May 2022 00:01'	System	20 Nov 2020 05:56:41

**US3632052**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:13:35**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:56:41
Amendment Manager: User entered '09 May 2022 23:59'	System	20 Nov 2020 05:56:41

**US3632052**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:13:35**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:56:41
Amendment Manager: User entered 'Day 614'	System	20 Nov 2020 05:56:41

**US3632052**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:13:35**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:56:41
Amendment Manager: User entered '12 May 2022 00:01'	System	20 Nov 2020 05:56:41

**US3632052**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:13:35**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:56:41
Amendment Manager: User entered '16 May 2022 23:59'	System	20 Nov 2020 05:56:41



**US3632052**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:13:35**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:56:41
Amendment Manager: User entered 'Day 621'	System	20 Nov 2020 05:56:41

**US3632052**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:13:35**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:56:41
Amendment Manager: User entered '19 May 2022 00:01'	System	20 Nov 2020 05:56:41

**US3632052**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:13:35**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:56:41
Amendment Manager: User entered '23 May 2022 23:59'	System	20 Nov 2020 05:56:41

**US3632052**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:13:35**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:56:41
Amendment Manager: User entered 'Day 628'	System	20 Nov 2020 05:56:41

**US3632052**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:13:35**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:56:41
Amendment Manager: User entered '26 May 2022 00:01'	System	20 Nov 2020 05:56:41

**US3632052**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:13:35**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:56:41
Amendment Manager: User entered '30 May 2022 23:59'	System	20 Nov 2020 05:56:41

**US3632052**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:13:35**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:56:41
Amendment Manager: User entered 'Day 635'	System	20 Nov 2020 05:56:41

**US3632052**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:13:35**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:56:41
Amendment Manager: User entered '02 Jun 2022 00:01'	System	20 Nov 2020 05:56:41



**US3632052**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:13:35**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:56:41
Amendment Manager: User entered '06 Jun 2022 23:59'	System	20 Nov 2020 05:56:41

**US3632052**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:13:35**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:56:41
Amendment Manager: User entered 'Day 642'	System	20 Nov 2020 05:56:41

**US3632052**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:13:35**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:56:41
Amendment Manager: User entered '09 Jun 2022 00:01'	System	20 Nov 2020 05:56:41

**US3632052**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:13:35**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:56:41
Amendment Manager: User entered '13 Jun 2022 23:59'	System	20 Nov 2020 05:56:41

**US3632052**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:13:35**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:56:41
Amendment Manager: User entered 'Day 649'	System	20 Nov 2020 05:56:41

**US3632052**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:13:35**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:56:41
Amendment Manager: User entered '16 Jun 2022 00:01'	System	20 Nov 2020 05:56:41

**US3632052**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:13:35**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:56:41
Amendment Manager: User entered '20 Jun 2022 23:59'	System	20 Nov 2020 05:56:41

**US3632052**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:13:35**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:56:41
Amendment Manager: User entered 'Day 656'	System	20 Nov 2020 05:56:41



**US3632052**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:13:35**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:56:41
Amendment Manager: User entered '23 Jun 2022 00:01'	System	20 Nov 2020 05:56:41

**US3632052**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:13:35**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:56:41
Amendment Manager: User entered '27 Jun 2022 23:59'	System	20 Nov 2020 05:56:41

**US3632052**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:13:35**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:56:41
Amendment Manager: User entered 'Day 663'	System	20 Nov 2020 05:56:41

**US3632052**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:13:35**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:56:41
Amendment Manager: User entered '30 Jun 2022 00:01'	System	20 Nov 2020 05:56:41

**US3632052**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:13:35**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:56:41
Amendment Manager: User entered '04 Jul 2022 23:59'	System	20 Nov 2020 05:56:41

**US3632052**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:13:35**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:56:41
Amendment Manager: User entered 'Day 670'	System	20 Nov 2020 05:56:41

**US3632052**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:13:35**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:56:41
Amendment Manager: User entered '07 Jul 2022 00:01'	System	20 Nov 2020 05:56:41

**US3632052**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:13:35**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:56:41
Amendment Manager: User entered '11 Jul 2022 23:59'	System	20 Nov 2020 05:56:41



**US3632052**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:13:35**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:56:41
Amendment Manager: User entered 'Day 677'	System	20 Nov 2020 05:56:41

**US3632052**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:13:35**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:56:41
Amendment Manager: User entered '14 Jul 2022 00:01'	System	20 Nov 2020 05:56:41

**US3632052**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:13:35**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:56:41
Amendment Manager: User entered '18 Jul 2022 23:59'	System	20 Nov 2020 05:56:41

**US3632052**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:13:35**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:56:41
Amendment Manager: User entered 'Day 684'	System	20 Nov 2020 05:56:41

**US3632052**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:13:35**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:56:41
Amendment Manager: User entered '21 Jul 2022 00:01'	System	20 Nov 2020 05:56:41

**US3632052**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:13:35**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:56:41
Amendment Manager: User entered '25 Jul 2022 23:59'	System	20 Nov 2020 05:56:41

**US3632052**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:13:35**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:56:41
Amendment Manager: User entered 'Day 691'	System	20 Nov 2020 05:56:41

**US3632052**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:13:35**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:56:41
Amendment Manager: User entered '28 Jul 2022 00:01'	System	20 Nov 2020 05:56:41



**US3632052**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:13:35**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:56:41
Amendment Manager: User entered '01 Aug 2022 23:59'	System	20 Nov 2020 05:56:41

**US3632052**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:13:35**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:56:41
Amendment Manager: User entered 'Day 698'	System	20 Nov 2020 05:56:41

**US3632052**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:13:35**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:56:41
Amendment Manager: User entered '04 Aug 2022 00:01'	System	20 Nov 2020 05:56:41

**US3632052**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:13:35**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:56:41
Amendment Manager: User entered '08 Aug 2022 23:59'	System	20 Nov 2020 05:56:41

**US3632052**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:13:35**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:56:41
Amendment Manager: User entered 'Day 705'	System	20 Nov 2020 05:56:41

**US3632052**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:13:35**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:56:41
Amendment Manager: User entered '11 Aug 2022 00:01'	System	20 Nov 2020 05:56:41

**US3632052**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:13:35**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:56:41
Amendment Manager: User entered '15 Aug 2022 23:59'	System	20 Nov 2020 05:56:41

**US3632052**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:13:35**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:56:41
Amendment Manager: User entered 'Day 712'	System	20 Nov 2020 05:56:41



**US3632052**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:13:35**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:56:41
Amendment Manager: User entered '18 Aug 2022 00:01'	System	20 Nov 2020 05:56:41

**US3632052**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:13:35**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:56:41
Amendment Manager: User entered '22 Aug 2022 23:59'	System	20 Nov 2020 05:56:41

**US3632052**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:13:35**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:56:41
Amendment Manager: User entered 'Day 719'	System	20 Nov 2020 05:56:41

**US3632052**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:13:35**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:56:41
Amendment Manager: User entered '25 Aug 2022 00:01'	System	20 Nov 2020 05:56:41

**US3632052**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:13:35**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:56:41
Amendment Manager: User entered '29 Aug 2022 23:59'	System	20 Nov 2020 05:56:41

**US3632052**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:13:35**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:56:41
Amendment Manager: User entered 'Day 726'	System	20 Nov 2020 05:56:41

**US3632052**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:13:35**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:56:41
Amendment Manager: User entered '01 Sep 2022 00:01'	System	20 Nov 2020 05:56:41

**US3632052**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:13:35**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:56:41
Amendment Manager: User entered '05 Sep 2022 23:59'	System	20 Nov 2020 05:56:41



**US3632052**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:13:35**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:56:41
Amendment Manager: User entered 'Day 733'	System	20 Nov 2020 05:56:41

**US3632052**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:13:35**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:56:41
Amendment Manager: User entered '08 Sep 2022 00:01'	System	20 Nov 2020 05:56:41

**US3632052**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:13:35**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:56:41
Amendment Manager: User entered '12 Sep 2022 23:59'	System	20 Nov 2020 05:56:41

**US3632052**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:13:35**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:56:41
Amendment Manager: User entered 'Day 740'	System	20 Nov 2020 05:56:41

**US3632052**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:13:35**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:56:41
Amendment Manager: User entered '15 Sep 2022 00:01'	System	20 Nov 2020 05:56:41

**US3632052**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:13:35**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:56:41
Amendment Manager: User entered '19 Sep 2022 23:59'	System	20 Nov 2020 05:56:41

**US3632052**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:13:35**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:56:41
Amendment Manager: User entered 'Day 747'	System	20 Nov 2020 05:56:41

**US3632052**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:13:35**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:56:41
Amendment Manager: User entered '22 Sep 2022 00:01'	System	20 Nov 2020 05:56:41



**US3632052**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:13:35**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:56:41
Amendment Manager: User entered '26 Sep 2022 23:59'	System	20 Nov 2020 05:56:41

**US3632052**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:13:35**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:56:41
Amendment Manager: User entered 'Day 754'	System	20 Nov 2020 05:56:41

**US3632052**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:13:35**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:56:41
Amendment Manager: User entered '29 Sep 2022 00:01'	System	20 Nov 2020 05:56:41

**US3632052**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:13:35**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:56:41
Amendment Manager: User entered '03 Oct 2022 23:59'	System	20 Nov 2020 05:56:41

**US3632052**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:13:35**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:56:41
Amendment Manager: User entered 'Day 761'	System	20 Nov 2020 05:56:41

**US3632052**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:13:35**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:56:41
Amendment Manager: User entered '06 Oct 2022 00:01'	System	20 Nov 2020 05:56:41

**US3632052**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:13:35**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:56:41
Amendment Manager: User entered '10 Oct 2022 23:59'	System	20 Nov 2020 05:56:41

**US3632052**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:13:35**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:56:41
Amendment Manager: User entered 'Day 768'	System	20 Nov 2020 05:56:41



**US3632052**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:13:35**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:56:41
Amendment Manager: User entered '13 Oct 2022 00:01'	System	20 Nov 2020 05:56:41

**US3632052**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:13:35**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:56:41
Amendment Manager: User entered '17 Oct 2022 23:59'	System	20 Nov 2020 05:56:41

**US3632052**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:13:35**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:56:41
Amendment Manager: User entered 'Day 775'	System	20 Nov 2020 05:56:41

**US3632052**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:13:35**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:56:41
Amendment Manager: User entered '20 Oct 2022 00:01'	System	20 Nov 2020 05:56:41

**US3632052**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:13:35**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:56:41
Amendment Manager: User entered '24 Oct 2022 23:59'	System	20 Nov 2020 05:56:41

**US3632052**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:13:35**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:56:41
Amendment Manager: User entered 'Day 782'	System	20 Nov 2020 05:56:41

**US3632052**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:13:35**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:56:41
Amendment Manager: User entered '27 Oct 2022 00:01'	System	20 Nov 2020 05:56:41

**US3632052**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:13:35**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:56:41
Amendment Manager: User entered '31 Oct 2022 23:59'	System	20 Nov 2020 05:56:41



**US3632052**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:13:35**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:56:41
Amendment Manager: User entered 'Day 789'	System	20 Nov 2020 05:56:41

**US3632052**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:13:35**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:56:41
Amendment Manager: User entered '03 Nov 2022 00:01'	System	20 Nov 2020 05:56:41

**US3632052**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:13:35**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:56:41
Amendment Manager: User entered '07 Nov 2022 23:59'	System	20 Nov 2020 05:56:41

**US3632052**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:13:35**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:56:41
Amendment Manager: User entered 'Day 796'	System	20 Nov 2020 05:56:41

**US3632052**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:13:35**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:56:41
Amendment Manager: User entered '10 Nov 2022 00:01'	System	20 Nov 2020 05:56:41

**US3632052**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:13:35**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:56:41
Amendment Manager: User entered '14 Nov 2022 23:59'	System	20 Nov 2020 05:56:41

US3632052

**Folder: Cosmetic Injections and Dermal Fillers**

**Form: Cosmetic Injection\_ Dermal Filler eDiary (1)**

**Generated On: 10 Jun 2021 09:13:35**

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 19:39:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (44467b427832a52f)', Time: '2021-02-27T10:27:04-05:00', User OID: 'PatientReportedOutcome (US3632052)', ODM File OID: '2f103b56-5c6d-4ce7-8423-6cd164888fcf'	System	27 Feb 2021 15:27:11
User entered 'No (N)'	System	27 Feb 2021 15:27:11

**US3632052**

**Folder: Cosmetic Injections and Dermal Fillers**

**Form: Cosmetic Injection\_ Dermal Filler eDiary (1)**

**Generated On: 10 Jun 2021 09:13:35**

[Date & Time of Submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 19:39:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (44467b427832a52f)', Time: '2021-02-27T10:27:09-05:00', User OID: 'PatientReportedOutcome (US3632052)', ODM File OID: '2f103b56-5c6d-4ce7-8423-6cd164888fcf' User entered '27 Feb 2021 10:27:09'	System	27 Feb 2021 15:27:11
	System	27 Feb 2021 15:27:11



**US3632052**

**Folder: Safety Call Day 85 (1)**

**Form: Safety Call**

**Generated On: 10 Jun 2021 09:13:35**

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:19:13
DataPoint Verified.	(b) (4), (b) (6)	11 Mar 2021 19:53:13
User signature succeeded.	Colleen Kelley (b) (4)	08 Mar 2021 14:31:04
User entered 'Yes (Y)'	Isaac Perez (b) (4)	01 Dec 2020 14:46:49

**US3632052**

**Folder: Safety Call Day 85 (1)**

**Form: Safety Call**

**Generated On: 10 Jun 2021 09:13:35**

[Date of Contact or Contact Attempt \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:19:13
DataPoint Verified.	(b) (4), (b) (6)	11 Mar 2021 19:53:13
User signature succeeded.	Colleen Kelley (b) (4)	08 Mar 2021 14:31:04
User entered '1 Dec 2020'	(b) (4) Isaac Perez (b) (4) (b) (4)	01 Dec 2020 14:46:49

**US3632052**

**Folder: Safety Call Day 85 (1)**

**Form: Safety Call**

**Generated On: 10 Jun 2021 09:13:35**

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:19:13
DataPoint Verified.	(b) (4), (b) (6)	11 Mar 2021 19:53:13
User signature succeeded.	Colleen Kelley (b) (4)	08 Mar 2021 14:31:04
User entered 'Contact Made (CONTACT MADE)'	Isaac Perez (b) (4)	01 Dec 2020 14:46:49

**US3632052**

**Folder: Safety Call Day 85 (1)**

**Form: Safety Call**

**Generated On: 10 Jun 2021 09:13:35**

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:19:13
DataPoint Verified.	(b) (4), (b) (6)	11 Mar 2021 19:53:13
User signature succeeded.	Colleen Kelley (b) (4)	08 Mar 2021 14:31:04
User entered empty.	(b) (4) Isaac Perez (b) (4) (b) (4)	01 Dec 2020 14:46:49

**US3632052**

**Folder: Safety Call Day 85 (1)**

**Form: Continuing**

**Generated On: 10 Jun 2021 09:13:35**

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:19:13
DataPoint Verified.	(b) (4), (b) (6)	11 Mar 2021 19:54:00
User signature succeeded.	Colleen Kelley (b) (4)	08 Mar 2021 14:31:04
User entered 'Yes (Y)'	Isaac Perez (b) (4)	01 Dec 2020 14:46:53

**US3632052**

**Folder: Safety Call Day 85 (1)**

**Form: Continuing**

**Generated On: 10 Jun 2021 09:13:35**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:19:13
User entered 'I'	System	01 Dec 2020 14:46:53

US3632052

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:13:35

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 11:33:39
User signature succeeded.	Colleen Kelley (b) (4)	02 Apr 2021 20:59:30
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Mar 2021 19:54:52
User closed query 'Was Contact Attempted? = No and 'Date of Contact or Contact Attempt' or ' Please select one status for the follow-up contact' is provided. Please review and reconcile.' (Site from System).	System	08 Feb 2021 17:26:14
User opened query 'Was Contact Attempted? = No and 'Date of Contact or Contact Attempt' or ' Please select one status for the follow-up contact' is provided. Please review and reconcile.' (Site from System).	System	03 Feb 2021 17:22:33
User closed query 'Was Contact Attempted? = Yes and 'Date of Contact or Contact Attempt' or ' Please select one status for the follow-up contact' is missing. Please review and reconcile.' (Site from System).	System	03 Feb 2021 17:22:33
User entered 'No (N)' reason for change: Data Entry Error	Isaac Perez (b) (4) (b) (4)	03 Feb 2021 17:22:33
User opened query 'Was Contact Attempted? = Yes and 'Date of Contact or Contact Attempt' or ' Please select one status for the follow-up contact' is missing. Please review and reconcile.' (Site from System).	System	03 Feb 2021 17:22:23
User closed query 'Was Contact Attempted? = No and 'Date of Contact or Contact Attempt' or ' Please select one status for the follow-up contact' is provided. Please review and reconcile.' (Site from System).	System	03 Feb 2021 17:22:23
User entered 'Yes (Y)' reason for change: Data Entry Error	Isaac Perez (b) (4) (b) (4)	03 Feb 2021 17:22:23
User opened query 'Was Contact Attempted? = No and 'Date of Contact or Contact Attempt' or ' Please select one status for the follow-up contact' is provided. Please review and reconcile.' (Site from System).	System	14 Jan 2021 15:23:21
User entered 'No (N)'	(b) (4), (b) (6)	14 Jan 2021 15:23:21

**US3632052**

**Folder: Safety Call Day 119 (1)**

**Form: Safety Call**

**Generated On: 10 Jun 2021 09:13:35**

[Date of Contact or Contact Attempt \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 11:33:39
User signature succeeded.	Colleen Kelley (b) (4)	02 Apr 2021 20:59:30
DataPoint Verified.	(b) (4), (b) (6)	11 Mar 2021 19:54:52
User entered empty.	(b) (4), (b) (6)	14 Jan 2021 15:23:21



**US3632052**

**Folder: Safety Call Day 119 (1)**

**Form: Safety Call**

**Generated On: 10 Jun 2021 09:13:35**

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 11:33:39
User signature succeeded.	Colleen Kelley (b) (4)	02 Apr 2021 20:59:30
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Mar 2021 19:54:52
User entered empty; reason for change Data Entry Error	Bezuayehu Mandefro (b) (4)	08 Feb 2021 17:26:14
User entered 'Contact Not Made (CONTACT NOT MADE)'	(b) (4), (b) (6)	14 Jan 2021 15:23:21

US3632052

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:13:35

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 11:33:39
User signature succeeded.	Colleen Kelley (b) (4)	02 Apr 2021 20:59:30
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Mar 2021 19:54:52
User closed query 'The Contact Status is 'CONTACT NOT MADE'; however, Comments have not been provided. Please review and reconcile.' (Site from System).	System	03 Feb 2021 17:21:59
User entered 'Participant was in Illness protocol during SC window.' reason for change: Data Entry Error	Isaac Perez (b) (4) (b) (4)	03 Feb 2021 17:21:59
User opened query 'The Contact Status is 'CONTACT NOT MADE'; however, Comments have not been provided. Please review and reconcile.' (Site from System).	System	14 Jan 2021 15:26:02
User entered empty; reason for change Data Entry Error	(b) (4), (b) (6)	14 Jan 2021 15:26:02
User entered 'Participants unblinding visit was 1/4.'	(b) (4), (b) (6)	14 Jan 2021 15:23:21

**US3632052**

**Folder: Safety Call Day 119 (1)**

**Form: Continuing**

**Generated On: 10 Jun 2021 09:13:35**

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 11:33:39
User signature succeeded.	Colleen Kelley (b) (4)	02 Apr 2021 20:59:30
DataPoint Verified.	(b) (4), (b) (6)	11 Mar 2021 19:55:00
User entered 'Yes (Y)'	Isaac Perez (b) (4)	03 Feb 2021 17:22:39

**US3632052**

**Folder: Safety Call Day 119 (1)**

**Form: Continuing**

**Generated On: 10 Jun 2021 09:13:35**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 11:33:39
User entered 'I'	System	03 Feb 2021 17:22:39

**US3632052**

**Folder: Safety Call Day 149 (1)**

**Form: Safety Call**

**Generated On: 10 Jun 2021 09:13:35**

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 11:33:39
User signature succeeded.	Colleen Kelley (b) (4)	02 Apr 2021 20:59:30
DataPoint Verified.	(b) (4), (b) (6)	11 Mar 2021 19:55:08
User entered 'Yes (Y)'	Isaac Perez (b) (4)	03 Feb 2021 17:36:21

**US3632052**

**Folder: Safety Call Day 149 (1)**

**Form: Safety Call**

**Generated On: 10 Jun 2021 09:13:35**

[Date of Contact or Contact Attempt \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 11:33:39
User signature succeeded.	Colleen Kelley (b) (4)	02 Apr 2021 20:59:30
DataPoint Verified.	(b) (4), (b) (6)	11 Mar 2021 19:55:08
User entered '3 Feb 2021'	Isaac Perez (b) (4)	03 Feb 2021 17:36:21

**US3632052**

**Folder: Safety Call Day 149 (1)**

**Form: Safety Call**

**Generated On: 10 Jun 2021 09:13:35**

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 11:33:39
User signature succeeded.	Colleen Kelley (b) (4)	02 Apr 2021 20:59:30
DataPoint Verified.	(b) (4), (b) (6)	11 Mar 2021 19:55:08
User entered 'Contact Made (CONTACT MADE)'	Isaac Perez (b) (4)	03 Feb 2021 17:36:21

**US3632052**

**Folder: Safety Call Day 149 (1)**

**Form: Safety Call**

**Generated On: 10 Jun 2021 09:13:35**

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 11:33:39
User signature succeeded.	Colleen Kelley (b) (4)	02 Apr 2021 20:59:30
DataPoint Verified.	(b) (4), (b) (6)	11 Mar 2021 19:55:08
User entered empty.	Isaac Perez (b) (4)	03 Feb 2021 17:36:21



**US3632052**

**Folder: Safety Call Day 149 (1)**

**Form: Continuing**

**Generated On: 10 Jun 2021 09:13:35**

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 11:33:39
User signature succeeded.	Colleen Kelley (b) (4)	02 Apr 2021 20:59:30
DataPoint Verified.	(b) (4), (b) (6)	11 Mar 2021 19:55:14
User entered 'Yes (Y)'	Isaac Perez (b) (4)	03 Feb 2021 17:36:26

**US3632052**

**Folder: Safety Call Day 149 (1)**

**Form: Continuing**

**Generated On: 10 Jun 2021 09:13:35**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 11:33:39
User entered 'I'	System	03 Feb 2021 17:36:26

**US3632052**

**Folder: Safety Call Day 179 (1)**

**Form: Safety Call**

**Generated On: 10 Jun 2021 09:13:35**

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 11:33:39
User signature succeeded.	Colleen Kelley (b) (4)	02 Apr 2021 20:59:30
DataPoint Verified.	(b) (4), (b) (6)	11 Mar 2021 19:55:31
User entered 'Yes (Y)'	Sarah Wiatrek (b) (4)	05 Mar 2021 16:37:04

**US3632052**

**Folder: Safety Call Day 179 (1)**

**Form: Safety Call**

**Generated On: 10 Jun 2021 09:13:35**

[Date of Contact or Contact Attempt \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 11:33:39
User signature succeeded.	Colleen Kelley (b) (4)	02 Apr 2021 20:59:30
DataPoint Verified.	(b) (4), (b) (6)	11 Mar 2021 19:55:31
User entered '5 Mar 2021'	Sarah Wiatrek (b) (4)	05 Mar 2021 16:37:04

**US3632052**

**Folder: Safety Call Day 179 (1)**

**Form: Safety Call**

**Generated On: 10 Jun 2021 09:13:35**

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 11:33:39
User signature succeeded.	Colleen Kelley (b) (4)	02 Apr 2021 20:59:30
DataPoint Verified.	(b) (4), (b) (6)	11 Mar 2021 19:55:31
User entered 'Contact Made (CONTACT MADE)'	Sarah Wiatrek (b) (4)	05 Mar 2021 16:37:04

**US3632052**

**Folder: Safety Call Day 179 (1)**

**Form: Safety Call**

**Generated On: 10 Jun 2021 09:13:35**

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 11:33:39
User signature succeeded.	Colleen Kelley (b) (4)	02 Apr 2021 20:59:30
DataPoint Verified.	(b) (4), (b) (6)	11 Mar 2021 19:55:31
User entered empty.	Sarah Wiatrek (b) (4)	05 Mar 2021 16:37:04

**US3632052**

**Folder: Safety Call Day 179 (1)**

**Form: Continuing**

**Generated On: 10 Jun 2021 09:13:35**

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 11:33:39
User signature succeeded.	Colleen Kelley (b) (4)	02 Apr 2021 20:59:30
DataPoint Verified.	(b) (4), (b) (6)	11 Mar 2021 19:55:58
User entered 'Yes (Y)'	Sarah Wiatrek (b) (4)	05 Mar 2021 16:37:10

**US3632052**

**Folder: Safety Call Day 179 (1)**

**Form: Continuing**

**Generated On: 10 Jun 2021 09:13:35**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 11:33:39
User entered 'I'	System	05 Mar 2021 16:37:10



**US3632052**

**Folder: Visit 4 Day 209 (1)**

**Form: Visit Date**

**Generated On: 10 Jun 2021 09:13:35**

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:56:00
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 19:21:45
User signature succeeded.	Colleen Kelley (b) (4)	02 Apr 2021 20:59:30
	(b) (4)	
User entered 'Yes (Y)'	(b) (4), (b) (6)	01 Apr 2021 19:26:38

**US3632052**

**Folder: Visit 4 Day 209 (1)**

**Form: Visit Date**

**Generated On: 10 Jun 2021 09:13:35**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:56:00
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 19:21:45
User signature succeeded.	Colleen Kelley (b) (4)	02 Apr 2021 20:59:30
	(b) (4)	
User entered '01 Apr 2021'	(b) (4), (b) (6)	01 Apr 2021 19:26:38

US3632052

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Generated On: 10 Jun 2021 09:13:35

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:56:00
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 19:21:45
User signature succeeded.	Colleen Kelley (b) (4)	02 Apr 2021 20:59:30
	(b) (4)	
User entered 'Clinic (Clinic)'	(b) (4), (b) (6)	01 Apr 2021 19:26:38

**US3632052**

**Folder: Visit 4 Day 209 (1)**

**Form: Visit Date**

**Generated On: 10 Jun 2021 09:13:35**

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:56:00
User entered 'VISIT4'	System	01 Apr 2021 19:26:38

US3632052

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:13:35

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:56:00
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 19:21:55
User signature succeeded.	Colleen Kelley (b) (4)	02 Apr 2021 20:59:30
User entered 'No (N)'	(b) (4), (b) (6)	01 Apr 2021 19:26:49

US3632052

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:13:35

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:56:00
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 19:21:55
User signature succeeded.	Colleen Kelley (b) (4)	02 Apr 2021 20:59:30
	(b) (4)	
User entered empty.	(b) (4), (b) (6)	01 Apr 2021 19:26:49

**US3632052**

**Folder: Visit 4 Day 209 (1)**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 09:13:35**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:56:00
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 19:21:55
User signature succeeded.	Colleen Kelley (b) (4)	02 Apr 2021 20:59:30
	(b) (4)	
User entered empty.	(b) (4), (b) (6)	01 Apr 2021 19:26:49

**US3632052**

**Folder: Visit 4 Day 209 (1)**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 09:13:35**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:56:00
User entered empty.	System	01 Apr 2021 19:26:49



US3632052

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:13:35

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:56:00
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 19:21:55
User signature succeeded.	Colleen Kelley (b) (4)	02 Apr 2021 20:59:30
	(b) (4)	
User entered empty.	(b) (4), (b) (6)	01 Apr 2021 19:26:49

US3632052

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:13:35

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:56:00
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 19:21:55
User signature succeeded.	Colleen Kelley (b) (4)	02 Apr 2021 20:59:30
	(b) (4)	
User entered empty.	(b) (4), (b) (6)	01 Apr 2021 19:26:49

US3632052

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:13:35

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:56:00
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 19:21:55
User signature succeeded.	Colleen Kelley (b) (4)	02 Apr 2021 20:59:30
	(b) (4)	
User entered empty.	(b) (4), (b) (6)	01 Apr 2021 19:26:49

US3632052

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:13:35

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:56:00
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 19:21:55
User signature succeeded.	Colleen Kelley (b) (4)	02 Apr 2021 20:59:30
	(b) (4)	
User entered empty.	(b) (4), (b) (6)	01 Apr 2021 19:26:49

**US3632052**

**Folder: Visit 4 Day 209 (1)**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 09:13:35**

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:56:00
User entered empty.	System	01 Apr 2021 19:26:49

US3632052

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:13:35

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:56:00
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 19:21:55
User signature succeeded.	Colleen Kelley (b) (4)	02 Apr 2021 20:59:30
	(b) (4)	
User entered empty.	(b) (4), (b) (6)	01 Apr 2021 19:26:49

US3632052

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:13:35

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:56:00
User entered empty.	System	01 Apr 2021 19:26:49

US3632052

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:13:35

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:56:00
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 19:21:55
User signature succeeded.	Colleen Kelley (b) (4)	02 Apr 2021 20:59:30
	(b) (4)	
User entered empty.	(b) (4), (b) (6)	01 Apr 2021 19:26:49



**US3632052**

**Folder: Visit 4 Day 209 (1)**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 09:13:35**

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:56:00
User entered empty.	System	01 Apr 2021 19:26:49

US3632052

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:13:35

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:56:00
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 19:21:55
User signature succeeded.	Colleen Kelley (b) (4)	02 Apr 2021 20:59:30
	(b) (4)	
User entered empty.	(b) (4), (b) (6)	01 Apr 2021 19:26:49

US3632052

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:13:35

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:56:00
User entered empty.	System	01 Apr 2021 19:26:49

**US3632052**

**Folder: Visit 4 Day 209 (1)**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 09:13:35**

[Height \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:56:00

**US3632052**

**Folder: Visit 4 Day 209 (1)**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 09:13:35**

[Weight \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:56:00

US3632052

Folder: Visit 4 Day 209 (1)

Form: Physical Examination

Generated On: 10 Jun 2021 09:13:35

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:56:00
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 19:22:04
User signature succeeded.	Colleen Kelley (b) (4)	02 Apr 2021 20:59:30
	(b) (4)	
User entered 'No (N)'	(b) (4), (b) (6)	01 Apr 2021 19:26:57

US3632052

Folder: Visit 4 Day 209 (1)

Form: Physical Examination

Generated On: 10 Jun 2021 09:13:35

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:56:00
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 19:22:04
User signature succeeded.	Colleen Kelley (b) (4)	02 Apr 2021 20:59:30
	(b) (4)	
User entered empty.	(b) (4), (b) (6)	01 Apr 2021 19:26:57

**US3632052**

**Folder: Visit 4 Day 209 (1)**

**Form: Immunogenicity Assessment**

**Generated On: 10 Jun 2021 09:13:35**

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:56:00
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 19:22:13
User signature succeeded.	Colleen Kelley (b) (4)	02 Apr 2021 20:59:30
	(b) (4)	
User entered 'Yes (Y)'	(b) (4), (b) (6)	01 Apr 2021 19:27:09



US3632052

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 09:13:35

Collection date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:56:00
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 19:22:13
User signature succeeded.	Colleen Kelley (b) (4)	02 Apr 2021 20:59:30
	(b) (4)	
User entered '01 Apr 2021'	(b) (4), (b) (6)	01 Apr 2021 19:27:09

**US3632052**

**Folder: Visit 4 Day 209 (1)**

**Form: Immunogenicity Assessment**

**Generated On: 10 Jun 2021 09:13:35**

[Collection time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:56:00
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 19:22:13
User signature succeeded.	Colleen Kelley (b) (4)	02 Apr 2021 20:59:30
	(b) (4)	
User entered '13:58'	(b) (4), (b) (6)	01 Apr 2021 19:27:09

**US3632052**

**Folder: Visit 4 Day 209 (1)**

**Form: Immunogenicity Assessment**

**Generated On: 10 Jun 2021 09:13:35**

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:56:00
User entered '01 Apr 2021 13:58'	System	01 Apr 2021 19:27:09

US3632052

Folder: Visit 4 Day 209 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:13:35

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:56:00
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 19:22:58
User signature succeeded.	Colleen Kelley (b) (4)	02 Apr 2021 20:59:30
	(b) (4)	
User entered 'Yes (Y)'	(b) (4), (b) (6)	01 Apr 2021 19:27:17

**US3632052**

**Folder: Visit 4 Day 209 (1)**

**Form: Continuing**

**Generated On: 10 Jun 2021 09:13:35**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:56:00
User entered 'I'	System	01 Apr 2021 19:27:17

**US3632052**

**Folder: Covid-19 Assessment 12 Nov 2020**

**Form: COVID-19 Contact**

**Generated On: 10 Jun 2021 09:13:35**

[Date of Contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:16:57
User signature succeeded.	Colleen Kelley (b) (4)	02 Apr 2021 20:59:30
DataPoint Verified.	(b) (4), (b) (6)	16 Dec 2020 17:35:59
User entered '12 Nov 2020'	(b) (4), (b) (6)	12 Nov 2020 21:51:17

**US3632052**

**Folder: Covid-19 Assessment 12 Nov 2020**

**Form: COVID-19 Contact**

**Generated On: 10 Jun 2021 09:13:35**

[Time of Contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:16:57
User signature succeeded.	Colleen Kelley (b) (4)	02 Apr 2021 20:59:30
DataPoint Verified.	(b) (4), (b) (6)	16 Dec 2020 17:35:59
User entered '14:00'	(b) (4), (b) (6)	12 Nov 2020 21:51:17

**US3632052**

**Folder: Covid-19 Assessment 12 Nov 2020**

**Form: COVID-19 Contact**

**Generated On: 10 Jun 2021 09:13:35**

[Date and Time of Contact \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:16:57
User entered '12 Nov 2020 14:00'	System	12 Nov 2020 21:51:17



**US3632052**

**Folder: Covid-19 Assessment 12 Nov 2020**

**Form: COVID-19 Contact**

**Generated On: 10 Jun 2021 09:13:35**

[Type of Contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:16:57
User signature succeeded.	Colleen Kelley (b) (4)	02 Apr 2021 20:59:30
DataPoint Verified.	(b) (4), (b) (6)	16 Dec 2020 17:35:59
User entered 'Clinical Visit - Unscheduled (Clinical Visit - Unscheduled)'	(b) (4), (b) (6)	12 Nov 2020 21:51:17

**US3632052**

**Folder: Covid-19 Assessment 12 Nov 2020**

**Form: COVID-19 Contact**

**Generated On: 10 Jun 2021 09:13:35**

[Has the subject reported symptoms of SARS-COV-2?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:16:57
User signature succeeded.	Colleen Kelley (b) (4)	02 Apr 2021 20:59:30
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	16 Dec 2020 17:35:59
User entered 'Yes (Y)'	(b) (4), (b) (6)	12 Nov 2020 21:51:17

**US3632052**

**Folder: Covid-19 Assessment 12 Nov 2020**

**Form: Symptom Log (1)**

**Generated On: 10 Jun 2021 09:13:35**

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:17:03
User signature succeeded.	Colleen Kelley (b) (4)	02 Apr 2021 20:59:30
User entered 'Day 1 (Day 1)'	(b) (4) (b) (4), (b) (6)	12 Nov 2020 21:53:56

**US3632052**

**Folder: Covid-19 Assessment 12 Nov 2020**

**Form: Symptom Log (1)**

**Generated On: 10 Jun 2021 09:13:35**

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:17:03
User signature succeeded.	Colleen Kelley (b) (4)	02 Apr 2021 20:59:30
DataPoint Verified.	(b) (4), (b) (6)	16 Dec 2020 17:53:03
User entered '10 Nov 2020'	(b) (4), (b) (6)	12 Nov 2020 21:53:56

**US3632052**

**Folder: Covid-19 Assessment 12 Nov 2020**

**Form: Symptom Log (1)**

**Generated On: 10 Jun 2021 09:13:35**

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:17:03
User signature succeeded.	Colleen Kelley (b) (4)	02 Apr 2021 20:59:30
DataPoint Verified.	(b) (4), (b) (6)	16 Dec 2020 17:53:03
User entered '0'	(b) (4), (b) (6)	12 Nov 2020 21:53:56

**US3632052**

**Folder: Covid-19 Assessment 12 Nov 2020**

**Form: Symptom Log (1)**

**Generated On: 10 Jun 2021 09:13:35**

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:17:03
User signature succeeded.	Colleen Kelley (b) (4)	02 Apr 2021 20:59:30
DataPoint Verified.	(b) (4), (b) (6)	16 Dec 2020 17:53:03
User entered missing code ND - Not Done.	(b) (4), (b) (6)	12 Nov 2020 21:53:56

**US3632052**

**Folder: Covid-19 Assessment 12 Nov 2020**

**Form: Symptom Log (1)**

**Generated On: 10 Jun 2021 09:13:35**

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:17:03
User entered '%'	System	12 Nov 2020 21:53:56

**US3632052**

**Folder: Covid-19 Assessment 12 Nov 2020**

**Form: Symptom Log (1)**

**Generated On: 10 Jun 2021 09:13:35**

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:17:03
User signature succeeded.	Colleen Kelley (b) (4)	02 Apr 2021 20:59:30
DataPoint Verified.	(b) (4), (b) (6)	16 Dec 2020 17:53:03
User entered missing code ND - Not Done.	(b) (4), (b) (6)	12 Nov 2020 21:53:56



**US3632052**

**Folder: Covid-19 Assessment 12 Nov 2020**

**Form: Symptom Log (1)**

**Generated On: 10 Jun 2021 09:13:35**

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:17:03
User signature succeeded.	Colleen Kelley (b) (4)	02 Apr 2021 20:59:30
DataPoint Verified.	(b) (4), (b) (6)	16 Dec 2020 17:53:03
User entered 'None (None)'	(b) (4), (b) (6)	12 Nov 2020 21:53:56

**US3632052**

**Folder: Covid-19 Assessment 12 Nov 2020**

**Form: Symptom Log (1)**

**Generated On: 10 Jun 2021 09:13:35**

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:17:03
User signature succeeded.	Colleen Kelley (b) (4)	02 Apr 2021 20:59:30
DataPoint Verified.	(b) (4), (b) (6)	16 Dec 2020 17:53:03
User entered 'None (None)'	(b) (4), (b) (6)	12 Nov 2020 21:53:56

US3632052

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (1)

Generated On: 10 Jun 2021 09:13:35

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:17:03
User signature succeeded.	Colleen Kelley (b) (4)	02 Apr 2021 20:59:30
DataPoint Verified.	(b) (4), (b) (6)	16 Dec 2020 17:53:03
User entered 'None (None)'	(b) (4), (b) (6)	12 Nov 2020 21:53:56

US3632052

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (1)

Generated On: 10 Jun 2021 09:13:35

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:17:03
User signature succeeded.	Colleen Kelley (b) (4)	02 Apr 2021 20:59:30
DataPoint Verified.	(b) (4), (b) (6)	16 Dec 2020 17:53:03
User entered 'None (None)'	(b) (4), (b) (6)	12 Nov 2020 21:53:56

US3632052

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (1)

Generated On: 10 Jun 2021 09:13:35

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:17:03
User signature succeeded.	Colleen Kelley (b) (4)	02 Apr 2021 20:59:30
DataPoint Verified.	(b) (4), (b) (6)	16 Dec 2020 17:53:03
User entered 'Moderate (Moderate)'	(b) (4), (b) (6)	12 Nov 2020 21:53:56

US3632052

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (1)

Generated On: 10 Jun 2021 09:13:35

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:17:03
User signature succeeded.	Colleen Kelley (b) (4)	02 Apr 2021 20:59:30
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	16 Dec 2020 17:53:03
User entered 'None (None)'	(b) (4), (b) (6)	12 Nov 2020 21:53:56

**US3632052**

**Folder: Covid-19 Assessment 12 Nov 2020**

**Form: Symptom Log (1)**

**Generated On: 10 Jun 2021 09:13:35**

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:17:03
User signature succeeded.	Colleen Kelley (b) (4)	02 Apr 2021 20:59:30
DataPoint Verified.	(b) (4), (b) (6)	16 Dec 2020 17:53:03
User entered 'Mild (Mild)'	(b) (4), (b) (6)	12 Nov 2020 21:53:56

**US3632052**

**Folder: Covid-19 Assessment 12 Nov 2020**

**Form: Symptom Log (1)**

**Generated On: 10 Jun 2021 09:13:35**

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:17:03
User signature succeeded.	Colleen Kelley (b) (4)	02 Apr 2021 20:59:30
DataPoint Verified.	(b) (4), (b) (6)	16 Dec 2020 17:53:03
User entered 'Mild (Mild)'	(b) (4), (b) (6)	12 Nov 2020 21:53:56



US3632052

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (1)

Generated On: 10 Jun 2021 09:13:35

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:17:03
User signature succeeded.	Colleen Kelley (b) (4)	02 Apr 2021 20:59:30
DataPoint Verified.	(b) (4), (b) (6)	16 Dec 2020 17:53:03
User entered 'None (None)'	(b) (4), (b) (6)	12 Nov 2020 21:53:56

**US3632052**

**Folder: Covid-19 Assessment 12 Nov 2020**

**Form: Symptom Log (1)**

**Generated On: 10 Jun 2021 09:13:35**

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:17:03
User signature succeeded.	Colleen Kelley (b) (4)	02 Apr 2021 20:59:30
DataPoint Verified.	(b) (4), (b) (6)	16 Dec 2020 17:53:03
User entered 'None (None)'	(b) (4), (b) (6)	12 Nov 2020 21:53:56

**US3632052**

**Folder: Covid-19 Assessment 12 Nov 2020**

**Form: Symptom Log (1)**

**Generated On: 10 Jun 2021 09:13:35**

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:17:03
User signature succeeded.	Colleen Kelley (b) (4)	02 Apr 2021 20:59:30
DataPoint Verified.	(b) (4), (b) (6)	16 Dec 2020 17:53:03
User entered 'None (None)'	(b) (4), (b) (6)	12 Nov 2020 21:53:56

US3632052

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (1)

Generated On: 10 Jun 2021 09:13:35

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:17:03
User signature succeeded.	Colleen Kelley (b) (4)	02 Apr 2021 20:59:30
DataPoint Verified.	(b) (4), (b) (6)	16 Dec 2020 17:53:03
User entered 'None (None)'	(b) (4), (b) (6)	12 Nov 2020 21:53:56

**US3632052**

**Folder: Covid-19 Assessment 12 Nov 2020**

**Form: Symptom Log (1)**

**Generated On: 10 Jun 2021 09:13:35**

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:17:03
User signature succeeded.	Colleen Kelley (b) (4)	02 Apr 2021 20:59:30
DataPoint Verified.	(b) (4), (b) (6)	16 Dec 2020 17:53:03
User entered 'None (None)'	(b) (4), (b) (6)	12 Nov 2020 21:53:56

US3632052

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (1)

Generated On: 10 Jun 2021 09:13:35

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:17:03
User signature succeeded.	Colleen Kelley (b) (4)	02 Apr 2021 20:59:30
DataPoint Verified.	(b) (4), (b) (6)	16 Dec 2020 17:53:03
User entered 'None (None)'	(b) (4), (b) (6)	12 Nov 2020 21:53:56

**US3632052**

**Folder: Covid-19 Assessment 12 Nov 2020**

**Form: Symptom Log (1)**

**Generated On: 10 Jun 2021 09:13:35**

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:17:03
User signature succeeded.	Colleen Kelley (b) (4)	02 Apr 2021 20:59:30
DataPoint Verified.	(b) (4), (b) (6)	16 Dec 2020 17:53:03
User entered 'None (None)'	(b) (4), (b) (6)	12 Nov 2020 21:53:56

**US3632052**

**Folder: Covid-19 Assessment 12 Nov 2020**

**Form: Symptom Log (1)**

**Generated On: 10 Jun 2021 09:13:35**

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:17:03
User signature succeeded.	Colleen Kelley (b) (4)	02 Apr 2021 20:59:30
DataPoint Verified.	(b) (4), (b) (6)	16 Dec 2020 17:53:03
User entered 'None (None)'	(b) (4), (b) (6)	12 Nov 2020 21:53:56



US3632052

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (2)

Generated On: 10 Jun 2021 09:13:35

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:17:03
User signature succeeded.	Colleen Kelley (b) (4)	02 Apr 2021 20:59:30
User entered 'Day 2 (Day 2)'	(b) (4) (b) (4), (b) (6)	12 Nov 2020 21:55:04

**US3632052**

**Folder: Covid-19 Assessment 12 Nov 2020**

**Form: Symptom Log (2)**

**Generated On: 10 Jun 2021 09:13:35**

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:17:03
User signature succeeded.	Colleen Kelley (b) (4)	02 Apr 2021 20:59:30
DataPoint Verified.	(b) (4), (b) (6)	16 Dec 2020 17:53:03
User entered '11 Nov 2020'	(b) (4), (b) (6)	12 Nov 2020 21:55:04

**US3632052**

**Folder: Covid-19 Assessment 12 Nov 2020**

**Form: Symptom Log (2)**

**Generated On: 10 Jun 2021 09:13:35**

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:17:03
User signature succeeded.	Colleen Kelley (b) (4)	02 Apr 2021 20:59:30
DataPoint Verified.	(b) (4), (b) (6)	16 Dec 2020 17:53:03
User entered '0'	(b) (4), (b) (6)	12 Nov 2020 21:55:04

**US3632052**

**Folder: Covid-19 Assessment 12 Nov 2020**

**Form: Symptom Log (2)**

**Generated On: 10 Jun 2021 09:13:35**

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:17:03
User signature succeeded.	Colleen Kelley (b) (4)	02 Apr 2021 20:59:30
DataPoint Verified.	(b) (4), (b) (6)	16 Dec 2020 17:53:03
User entered missing code ND - Not Done.	(b) (4), (b) (6)	12 Nov 2020 21:55:04

**US3632052**

**Folder: Covid-19 Assessment 12 Nov 2020**

**Form: Symptom Log (2)**

**Generated On: 10 Jun 2021 09:13:35**

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:17:03
User entered '%'	System	12 Nov 2020 21:55:04

US3632052

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (2)

Generated On: 10 Jun 2021 09:13:35

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:17:03
User signature succeeded.	Colleen Kelley (b) (4)	02 Apr 2021 20:59:30
DataPoint Verified.	(b) (4), (b) (6)	16 Dec 2020 17:53:03
User entered missing code ND - Not Done.	(b) (4), (b) (6)	12 Nov 2020 21:55:04

**US3632052**

**Folder: Covid-19 Assessment 12 Nov 2020**

**Form: Symptom Log (2)**

**Generated On: 10 Jun 2021 09:13:35**

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:17:03
User signature succeeded.	Colleen Kelley (b) (4)	02 Apr 2021 20:59:30
DataPoint Verified.	(b) (4), (b) (6)	16 Dec 2020 17:53:03
User entered 'None (None)'	(b) (4), (b) (6)	12 Nov 2020 21:55:04

**US3632052**

**Folder: Covid-19 Assessment 12 Nov 2020**

**Form: Symptom Log (2)**

**Generated On: 10 Jun 2021 09:13:35**

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:17:03
User signature succeeded.	Colleen Kelley (b) (4)	02 Apr 2021 20:59:30
DataPoint Verified.	(b) (4), (b) (6)	16 Dec 2020 17:53:03
User entered 'None (None)'	(b) (4), (b) (6)	12 Nov 2020 21:55:04



US3632052

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (2)

Generated On: 10 Jun 2021 09:13:35

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:17:03
User signature succeeded.	Colleen Kelley (b) (4)	02 Apr 2021 20:59:30
DataPoint Verified.	(b) (4), (b) (6)	16 Dec 2020 17:53:03
User entered 'None (None)'	(b) (4), (b) (6)	12 Nov 2020 21:55:04

**US3632052**

**Folder: Covid-19 Assessment 12 Nov 2020**

**Form: Symptom Log (2)**

**Generated On: 10 Jun 2021 09:13:35**

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:17:03
User signature succeeded.	Colleen Kelley (b) (4)	02 Apr 2021 20:59:30
DataPoint Verified.	(b) (4), (b) (6)	16 Dec 2020 17:53:03
User entered 'None (None)'	(b) (4), (b) (6)	12 Nov 2020 21:55:04

US3632052

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (2)

Generated On: 10 Jun 2021 09:13:35

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:17:03
User signature succeeded.	Colleen Kelley (b) (4)	02 Apr 2021 20:59:30
DataPoint Verified.	(b) (4), (b) (6)	16 Dec 2020 17:53:03
User entered 'Moderate (Moderate)'	(b) (4), (b) (6)	12 Nov 2020 21:55:04

**US3632052**

**Folder: Covid-19 Assessment 12 Nov 2020**

**Form: Symptom Log (2)**

**Generated On: 10 Jun 2021 09:13:35**

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:17:03
User signature succeeded.	Colleen Kelley (b) (4)	02 Apr 2021 20:59:30
DataPoint Verified.	(b) (4), (b) (6)	16 Dec 2020 17:53:03
User entered 'None (None)'	(b) (4), (b) (6)	12 Nov 2020 21:55:04

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Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (2)

Generated On: 10 Jun 2021 09:13:35

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:17:03
User signature succeeded.	Colleen Kelley (b) (4)	02 Apr 2021 20:59:30
DataPoint Verified.	(b) (4), (b) (6)	16 Dec 2020 17:53:03
User entered 'Mild (Mild)'	(b) (4), (b) (6)	12 Nov 2020 21:55:04

US3632052

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (2)

Generated On: 10 Jun 2021 09:13:35

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:17:03
User signature succeeded.	Colleen Kelley (b) (4)	02 Apr 2021 20:59:30
DataPoint Verified.	(b) (4), (b) (6)	16 Dec 2020 17:53:03
User entered 'Mild (Mild)'	(b) (4), (b) (6)	12 Nov 2020 21:55:04

**US3632052**

**Folder: Covid-19 Assessment 12 Nov 2020**

**Form: Symptom Log (2)**

**Generated On: 10 Jun 2021 09:13:35**

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:17:03
User signature succeeded.	Colleen Kelley (b) (4)	02 Apr 2021 20:59:30
DataPoint Verified.	(b) (4), (b) (6)	16 Dec 2020 17:53:03
User entered 'None (None)'	(b) (4), (b) (6)	12 Nov 2020 21:55:04

**US3632052**

**Folder: Covid-19 Assessment 12 Nov 2020**

**Form: Symptom Log (2)**

**Generated On: 10 Jun 2021 09:13:35**

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:17:03
User signature succeeded.	Colleen Kelley (b) (4)	02 Apr 2021 20:59:30
DataPoint Verified.	(b) (4), (b) (6)	16 Dec 2020 17:53:03
User entered 'None (None)'	(b) (4), (b) (6)	12 Nov 2020 21:55:04



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**Folder: Covid-19 Assessment 12 Nov 2020**

**Form: Symptom Log (2)**

**Generated On: 10 Jun 2021 09:13:35**

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:17:03
User signature succeeded.	Colleen Kelley (b) (4)	02 Apr 2021 20:59:30
DataPoint Verified.	(b) (4), (b) (6)	16 Dec 2020 17:53:03
User entered 'None (None)'	(b) (4), (b) (6)	12 Nov 2020 21:55:04

**US3632052**

**Folder: Covid-19 Assessment 12 Nov 2020**

**Form: Symptom Log (2)**

**Generated On: 10 Jun 2021 09:13:35**

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:17:03
User signature succeeded.	Colleen Kelley (b) (4)	02 Apr 2021 20:59:30
DataPoint Verified.	(b) (4), (b) (6)	16 Dec 2020 17:53:03
User entered 'None (None)'	(b) (4), (b) (6)	12 Nov 2020 21:55:04

**US3632052**

**Folder: Covid-19 Assessment 12 Nov 2020**

**Form: Symptom Log (2)**

**Generated On: 10 Jun 2021 09:13:35**

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:17:03
User signature succeeded.	Colleen Kelley (b) (4)	02 Apr 2021 20:59:30
DataPoint Verified.	(b) (4), (b) (6)	16 Dec 2020 17:53:03
User entered 'None (None)'	(b) (4), (b) (6)	12 Nov 2020 21:55:04

**US3632052**

**Folder: Covid-19 Assessment 12 Nov 2020**

**Form: Symptom Log (2)**

**Generated On: 10 Jun 2021 09:13:35**

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:17:03
User signature succeeded.	Colleen Kelley (b) (4)	02 Apr 2021 20:59:30
DataPoint Verified.	(b) (4), (b) (6)	16 Dec 2020 17:53:03
User entered 'None (None)'	(b) (4), (b) (6)	12 Nov 2020 21:55:04

**US3632052**

**Folder: Covid-19 Assessment 12 Nov 2020**

**Form: Symptom Log (2)**

**Generated On: 10 Jun 2021 09:13:35**

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:17:03
User signature succeeded.	Colleen Kelley (b) (4)	02 Apr 2021 20:59:30
DataPoint Verified.	(b) (4), (b) (6)	16 Dec 2020 17:53:03
User entered 'None (None)'	(b) (4), (b) (6)	12 Nov 2020 21:55:04

**US3632052**

**Folder: Covid-19 Assessment 12 Nov 2020**

**Form: Symptom Log (2)**

**Generated On: 10 Jun 2021 09:13:35**

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:17:03
User signature succeeded.	Colleen Kelley (b) (4)	02 Apr 2021 20:59:30
DataPoint Verified.	(b) (4), (b) (6)	16 Dec 2020 17:53:03
User entered 'None (None)'	(b) (4), (b) (6)	12 Nov 2020 21:55:04

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Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (3)

Generated On: 10 Jun 2021 09:13:35

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:17:03
User signature succeeded.	Colleen Kelley (b) (4)	02 Apr 2021 20:59:30
User entered 'Day 3 (Day 3)'	(b) (4) (b) (4), (b) (6)	12 Nov 2020 21:56:24

**US3632052**

**Folder: Covid-19 Assessment 12 Nov 2020**

**Form: Symptom Log (3)**

**Generated On: 10 Jun 2021 09:13:35**

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:17:03
User signature succeeded.	Colleen Kelley (b) (4)	02 Apr 2021 20:59:30
DataPoint Verified.	(b) (4), (b) (6)	16 Dec 2020 17:53:03
User entered '12 Nov 2020'	(b) (4), (b) (6)	12 Nov 2020 21:56:24



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**Folder: Covid-19 Assessment 12 Nov 2020**

**Form: Symptom Log (3)**

**Generated On: 10 Jun 2021 09:13:35**

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:17:03
User signature succeeded.	Colleen Kelley (b) (4)	02 Apr 2021 20:59:30
DataPoint Verified.	(b) (4), (b) (6)	16 Dec 2020 17:53:03
User entered '0'	(b) (4), (b) (6)	12 Nov 2020 21:56:24

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**Folder: Covid-19 Assessment 12 Nov 2020**

**Form: Symptom Log (3)**

**Generated On: 10 Jun 2021 09:13:35**

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:17:03
User signature succeeded.	Colleen Kelley (b) (4)	02 Apr 2021 20:59:30
DataPoint Verified.	(b) (4), (b) (6)	16 Dec 2020 17:53:03
User entered '99'	(b) (4), (b) (6)	12 Nov 2020 21:56:24

**US3632052**

**Folder: Covid-19 Assessment 12 Nov 2020**

**Form: Symptom Log (3)**

**Generated On: 10 Jun 2021 09:13:35**

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:17:03
User entered '%'	System	12 Nov 2020 21:56:24

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Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (3)

Generated On: 10 Jun 2021 09:13:35

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:17:03
User signature succeeded.	Colleen Kelley (b) (4)	02 Apr 2021 20:59:30
DataPoint Verified.	(b) (4), (b) (6)	16 Dec 2020 17:53:03
User entered '97.2' F	(b) (4), (b) (6)	12 Nov 2020 21:56:24

US3632052

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (3)

Generated On: 10 Jun 2021 09:13:35

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:17:03
User signature succeeded.	Colleen Kelley (b) (4)	02 Apr 2021 20:59:30
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	16 Dec 2020 17:53:03
User entered 'None (None)'	(b) (4), (b) (6)	12 Nov 2020 21:56:24

**US3632052**

**Folder: Covid-19 Assessment 12 Nov 2020**

**Form: Symptom Log (3)**

**Generated On: 10 Jun 2021 09:13:35**

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:17:03
User signature succeeded.	Colleen Kelley (b) (4)	02 Apr 2021 20:59:30
DataPoint Verified.	(b) (4), (b) (6)	16 Dec 2020 17:53:03
User entered 'None (None)'	(b) (4), (b) (6)	12 Nov 2020 21:56:24

**US3632052**

**Folder: Covid-19 Assessment 12 Nov 2020**

**Form: Symptom Log (3)**

**Generated On: 10 Jun 2021 09:13:35**

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:17:03
User signature succeeded.	Colleen Kelley (b) (4)	02 Apr 2021 20:59:30
DataPoint Verified.	(b) (4), (b) (6)	16 Dec 2020 17:53:03
User entered 'None (None)'	(b) (4), (b) (6)	12 Nov 2020 21:56:24

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Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (3)

Generated On: 10 Jun 2021 09:13:35

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:17:03
User signature succeeded.	Colleen Kelley (b) (4)	02 Apr 2021 20:59:30
DataPoint Verified.	(b) (4), (b) (6)	16 Dec 2020 17:53:03
User entered 'None (None)'	(b) (4), (b) (6)	12 Nov 2020 21:56:24



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Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (3)

Generated On: 10 Jun 2021 09:13:35

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:17:03
User signature succeeded.	Colleen Kelley (b) (4)	02 Apr 2021 20:59:30
DataPoint Verified.	(b) (4), (b) (6)	16 Dec 2020 17:53:03
User entered 'Moderate (Moderate)'	(b) (4), (b) (6)	12 Nov 2020 21:56:24

US3632052

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (3)

Generated On: 10 Jun 2021 09:13:35

Muscle Aches (Myalgia)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:17:03
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 16:10:57
User signature succeeded.	Colleen Kelley (b) (4)	12 Apr 2021 01:33:40
DataPoint Un-verified.	(b) (4), (b) (6)	09 Apr 2021 17:56:32
Signature has been broken.	(b) (4), (b) (6)	09 Apr 2021 17:56:32
User entered 'Mild (Mild)' reason for change: Data Entry Error	(b) (4), (b) (6)	09 Apr 2021 17:56:32
User signature succeeded.	Colleen Kelley (b) (4)	02 Apr 2021 20:59:30
DataPoint Verified.	(b) (4), (b) (6)	16 Dec 2020 17:53:03
User entered 'None (None)'	(b) (4), (b) (6)	12 Nov 2020 21:56:24

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Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (3)

Generated On: 10 Jun 2021 09:13:35

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:17:03
User signature succeeded.	Colleen Kelley (b) (4)	22 Apr 2021 15:40:44
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 15:46:30
User closed query 'Chart notes this as mild; please verify and update.' (Site from CRA).	(b) (4), (b) (6)	16 Apr 2021 15:46:14
Query 'Chart notes this as mild; please verify and update.' answered with 'corrected' (Site from CRA).	(b) (4), (b) (6)	16 Apr 2021 14:52:55
Signature has been broken.	(b) (4), (b) (6)	16 Apr 2021 14:52:35
User entered 'Mild (Mild)' reason for change: Data Entry Error	(b) (4), (b) (6)	16 Apr 2021 14:52:35
User opened query 'Chart notes this as mild; please verify and update.' (Site from CRA).	(b) (4), (b) (6)	15 Apr 2021 16:12:31
User signature succeeded.	Colleen Kelley (b) (4)	12 Apr 2021 01:33:40
DataPoint Un-verified.	(b) (4), (b) (6)	09 Apr 2021 17:56:32
Signature has been broken.	(b) (4), (b) (6)	09 Apr 2021 17:56:32
User entered 'None (None)' reason for change: Data Entry Error	(b) (4), (b) (6)	09 Apr 2021 17:56:32
User signature succeeded.	Colleen Kelley (b) (4)	02 Apr 2021 20:59:30
DataPoint Verified.	(b) (4), (b) (6)	16 Dec 2020 17:53:03
User entered 'Mild (Mild)'	(b) (4), (b) (6)	12 Nov 2020 21:56:24

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Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (3)

Generated On: 10 Jun 2021 09:13:35

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:17:03
User signature succeeded.	Colleen Kelley (b) (4)	22 Apr 2021 15:40:44
User closed query 'Chart notes this as mild; please verify and update.' (Site from CRA).	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 15:47:01
	(b) (4), (b) (6)	16 Apr 2021 15:46:48
Query 'Chart notes this as mild; please verify and update.' answered with 'corrected' (Site from CRA).	(b) (4), (b) (6)	16 Apr 2021 14:53:24
Signature has been broken.	(b) (4), (b) (6)	16 Apr 2021 14:52:35
User entered 'Mild (Mild)' reason for change: Data Entry Error	(b) (4), (b) (6)	16 Apr 2021 14:52:35
User opened query 'Chart notes this as mild; please verify and update.' (Site from CRA).	(b) (4), (b) (6)	15 Apr 2021 16:12:49
User signature succeeded.	Colleen Kelley (b) (4)	12 Apr 2021 01:33:40
DataPoint Un-verified.	(b) (4)	
	(b) (4), (b) (6)	09 Apr 2021 17:56:32
Signature has been broken.	(b) (4), (b) (6)	09 Apr 2021 17:56:32
User entered 'Moderate (Moderate)' reason for change: Data Entry Error	(b) (4), (b) (6)	09 Apr 2021 17:56:32
User signature succeeded.	Colleen Kelley (b) (4)	02 Apr 2021 20:59:30
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	16 Dec 2020 17:53:03
User entered 'Mild (Mild)'	(b) (4), (b) (6)	12 Nov 2020 21:56:24

**US3632052**

**Folder: Covid-19 Assessment 12 Nov 2020**

**Form: Symptom Log (3)**

**Generated On: 10 Jun 2021 09:13:35**

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:17:03
User signature succeeded.	Colleen Kelley (b) (4)	02 Apr 2021 20:59:30
DataPoint Verified.	(b) (4), (b) (6)	16 Dec 2020 17:53:03
User entered 'None (None)'	(b) (4), (b) (6)	12 Nov 2020 21:56:24

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Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (3)

Generated On: 10 Jun 2021 09:13:35

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:17:03
User signature succeeded.	Colleen Kelley (b) (4)	02 Apr 2021 20:59:30
DataPoint Verified.	(b) (4), (b) (6)	16 Dec 2020 17:53:03
User entered 'None (None)'	(b) (4), (b) (6)	12 Nov 2020 21:56:24

**US3632052**

**Folder: Covid-19 Assessment 12 Nov 2020**

**Form: Symptom Log (3)**

**Generated On: 10 Jun 2021 09:13:35**

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:17:03
User signature succeeded.	Colleen Kelley (b) (4)	02 Apr 2021 20:59:30
DataPoint Verified.	(b) (4), (b) (6)	16 Dec 2020 17:53:03
User entered 'None (None)'	(b) (4), (b) (6)	12 Nov 2020 21:56:24

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Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (3)

Generated On: 10 Jun 2021 09:13:35

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:17:03
User signature succeeded.	Colleen Kelley (b) (4)	02 Apr 2021 20:59:30
DataPoint Verified.	(b) (4), (b) (6)	16 Dec 2020 17:53:03
User entered 'None (None)'	(b) (4), (b) (6)	12 Nov 2020 21:56:24



**US3632052**

**Folder: Covid-19 Assessment 12 Nov 2020**

**Form: Symptom Log (3)**

**Generated On: 10 Jun 2021 09:13:35**

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:17:03
User signature succeeded.	Colleen Kelley (b) (4)	02 Apr 2021 20:59:30
DataPoint Verified.	(b) (4), (b) (6)	16 Dec 2020 17:53:03
User entered 'Mild (Mild)'	(b) (4), (b) (6)	12 Nov 2020 21:56:24

US3632052

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (3)

Generated On: 10 Jun 2021 09:13:35

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:17:03
User signature succeeded.	Colleen Kelley (b) (4)	02 Apr 2021 20:59:30
DataPoint Verified.	(b) (4), (b) (6)	16 Dec 2020 17:53:03
User entered 'Mild (Mild)'	(b) (4), (b) (6)	12 Nov 2020 21:56:24

**US3632052**

**Folder: Covid-19 Assessment 12 Nov 2020**

**Form: Symptom Log (3)**

**Generated On: 10 Jun 2021 09:13:35**

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:17:03
User signature succeeded.	Colleen Kelley (b) (4)	02 Apr 2021 20:59:30
DataPoint Verified.	(b) (4), (b) (6)	16 Dec 2020 17:53:03
User entered 'None (None)'	(b) (4), (b) (6)	12 Nov 2020 21:56:24

**US3632052**

**Folder: Covid-19 Assessment 12 Nov 2020**

**Form: Symptom Log (3)**

**Generated On: 10 Jun 2021 09:13:35**

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:17:03
User signature succeeded.	Colleen Kelley (b) (4)	02 Apr 2021 20:59:30
DataPoint Verified.	(b) (4), (b) (6)	16 Dec 2020 17:53:03
User entered 'None (None)'	(b) (4), (b) (6)	12 Nov 2020 21:56:24

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Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (4)

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[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:17:03
User signature succeeded.	Colleen Kelley (b) (4)	02 Apr 2021 20:59:30
User entered 'Day 4 (Day 4)'	Christina Bacher (b) (4)	13 Nov 2020 19:14:49

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Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (4)

Generated On: 10 Jun 2021 09:13:35

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:17:03
User signature succeeded.	Colleen Kelley (b) (4)	02 Apr 2021 20:59:30
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	16 Dec 2020 17:53:03
User entered '13 Nov 2020'	Christina Bacher (b) (4)	13 Nov 2020 19:14:49
	(b) (4)	

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[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:17:03
User signature succeeded.	Colleen Kelley (b) (4)	02 Apr 2021 20:59:30
DataPoint Verified.	(b) (4), (b) (6)	16 Dec 2020 17:53:03
User entered '0'	Christina Bacher (b) (4)	13 Nov 2020 19:14:49

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Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (4)

Generated On: 10 Jun 2021 09:13:35

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:17:03
User signature succeeded.	Colleen Kelley (b) (4)	02 Apr 2021 20:59:30
DataPoint Verified.	(b) (4), (b) (6)	16 Dec 2020 17:53:03
User entered '98'	Christina Bacher (b) (4)	13 Nov 2020 19:14:49



**US3632052**

**Folder: Covid-19 Assessment 12 Nov 2020**

**Form: Symptom Log (4)**

**Generated On: 10 Jun 2021 09:13:35**

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:17:03
User entered '%'	System	13 Nov 2020 19:14:49

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Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (4)

Generated On: 10 Jun 2021 09:13:35

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:17:03
User signature succeeded.	Colleen Kelley (b) (4)	02 Apr 2021 20:59:30
DataPoint Verified.	(b) (4), (b) (6)	16 Dec 2020 17:53:03
User entered '96.4' F	Christina Bacher (b) (4)	13 Nov 2020 19:14:49

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Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (4)

Generated On: 10 Jun 2021 09:13:35

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:17:03
User signature succeeded.	Colleen Kelley (b) (4)	02 Apr 2021 20:59:30
DataPoint Verified.	(b) (4), (b) (6)	16 Dec 2020 17:53:03
User entered 'None (None)'	Christina Bacher (b) (4)	13 Nov 2020 19:14:49

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Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (4)

Generated On: 10 Jun 2021 09:13:35

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:17:03
User signature succeeded.	Colleen Kelley (b) (4)	02 Apr 2021 20:59:30
DataPoint Verified.	(b) (4), (b) (6)	16 Dec 2020 17:53:03
User entered 'None (None)'	Christina Bacher (b) (4)	13 Nov 2020 19:14:49

US3632052

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (4)

Generated On: 10 Jun 2021 09:13:35

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:17:03
User signature succeeded.	Colleen Kelley (b) (4)	02 Apr 2021 20:59:30
DataPoint Verified.	(b) (4), (b) (6)	16 Dec 2020 17:53:03
User entered 'None (None)'	Christina Bacher (b) (4)	13 Nov 2020 19:14:49

US3632052

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (4)

Generated On: 10 Jun 2021 09:13:35

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:17:03
User signature succeeded.	Colleen Kelley (b) (4)	02 Apr 2021 20:59:30
DataPoint Verified.	(b) (4), (b) (6)	16 Dec 2020 17:53:03
User entered 'None (None)'	Christina Bacher (b) (4)	13 Nov 2020 19:14:49

US3632052

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (4)

Generated On: 10 Jun 2021 09:13:35

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:17:03
User signature succeeded.	Colleen Kelley (b) (4)	02 Apr 2021 20:59:30
DataPoint Verified.	(b) (4), (b) (6)	16 Dec 2020 17:53:03
User entered 'None (None)'	Christina Bacher (b) (4)	13 Nov 2020 19:14:49

US3632052

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (4)

Generated On: 10 Jun 2021 09:13:35

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:17:03
User signature succeeded.	Colleen Kelley (b) (4)	02 Apr 2021 20:59:30
DataPoint Verified.	(b) (4), (b) (6)	16 Dec 2020 17:53:03
User entered 'None (None)'	Christina Bacher (b) (4)	13 Nov 2020 19:14:49



US3632052

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (4)

Generated On: 10 Jun 2021 09:13:35

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:17:03
User signature succeeded.	Colleen Kelley (b) (4)	02 Apr 2021 20:59:30
DataPoint Verified.	(b) (4), (b) (6)	16 Dec 2020 17:53:03
User entered 'None (None)'	Christina Bacher (b) (4)	13 Nov 2020 19:14:49

US3632052

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (4)

Generated On: 10 Jun 2021 09:13:35

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:17:03
User signature succeeded.	Colleen Kelley (b) (4)	02 Apr 2021 20:59:30
DataPoint Verified.	(b) (4), (b) (6)	16 Dec 2020 17:53:03
User entered 'None (None)'	Christina Bacher (b) (4)	13 Nov 2020 19:14:49

US3632052

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (4)

Generated On: 10 Jun 2021 09:13:35

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:17:03
User signature succeeded.	Colleen Kelley (b) (4)	02 Apr 2021 20:59:30
DataPoint Verified.	(b) (4), (b) (6)	16 Dec 2020 17:53:03
User entered 'None (None)'	Christina Bacher (b) (4)	13 Nov 2020 19:14:49

US3632052

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (4)

Generated On: 10 Jun 2021 09:13:35

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:17:03
User signature succeeded.	Colleen Kelley (b) (4)	02 Apr 2021 20:59:30
DataPoint Verified.	(b) (4), (b) (6)	16 Dec 2020 17:53:03
User entered 'None (None)'	Christina Bacher (b) (4)	13 Nov 2020 19:14:49

US3632052

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (4)

Generated On: 10 Jun 2021 09:13:35

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:17:03
User signature succeeded.	Colleen Kelley (b) (4)	02 Apr 2021 20:59:30
DataPoint Verified.	(b) (4), (b) (6)	16 Dec 2020 17:53:03
User entered 'None (None)'	Christina Bacher (b) (4)	13 Nov 2020 19:14:49

US3632052

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (4)

Generated On: 10 Jun 2021 09:13:35

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:17:03
User signature succeeded.	Colleen Kelley (b) (4)	02 Apr 2021 20:59:30
DataPoint Verified.	(b) (4), (b) (6)	16 Dec 2020 17:53:03
User entered 'None (None)'	Christina Bacher (b) (4)	13 Nov 2020 19:14:49

**US3632052**

**Folder: Covid-19 Assessment 12 Nov 2020**

**Form: Symptom Log (4)**

**Generated On: 10 Jun 2021 09:13:35**

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:17:03
User signature succeeded.	Colleen Kelley (b) (4)	02 Apr 2021 20:59:30
DataPoint Verified.	(b) (4), (b) (6)	16 Dec 2020 17:53:03
User entered 'Mild (Mild)'	Christina Bacher (b) (4)	13 Nov 2020 19:14:49

US3632052

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (4)

Generated On: 10 Jun 2021 09:13:35

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:17:03
User signature succeeded.	Colleen Kelley (b) (4)	02 Apr 2021 20:59:30
DataPoint Verified.	(b) (4), (b) (6)	16 Dec 2020 17:53:03
User entered 'None (None)'	Christina Bacher (b) (4)	13 Nov 2020 19:14:49



US3632052

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (4)

Generated On: 10 Jun 2021 09:13:35

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:17:03
User signature succeeded.	Colleen Kelley (b) (4)	02 Apr 2021 20:59:30
DataPoint Verified.	(b) (4), (b) (6)	16 Dec 2020 17:53:03
User entered 'None (None)'	Christina Bacher (b) (4)	13 Nov 2020 19:14:49

US3632052

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (4)

Generated On: 10 Jun 2021 09:13:35

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:17:03
User signature succeeded.	Colleen Kelley (b) (4)	02 Apr 2021 20:59:30
DataPoint Verified.	(b) (4), (b) (6)	16 Dec 2020 17:53:03
User entered 'None (None)'	Christina Bacher (b) (4)	13 Nov 2020 19:14:49

US3632052

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (5)

Generated On: 10 Jun 2021 09:13:35

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:17:03
User signature succeeded.	Colleen Kelley (b) (4)	02 Apr 2021 20:59:30
User entered 'Day 5 (Day 5)'	(b) (4) (b) (4), (b) (6)	16 Nov 2020 14:32:09

**US3632052**

**Folder: Covid-19 Assessment 12 Nov 2020**

**Form: Symptom Log (5)**

**Generated On: 10 Jun 2021 09:13:35**

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:17:03
User signature succeeded.	Colleen Kelley (b) (4)	02 Apr 2021 20:59:30
DataPoint Verified.	(b) (4), (b) (6)	16 Dec 2020 17:53:03
User entered '14 Nov 2020'	(b) (4), (b) (6)	16 Nov 2020 14:32:09

**US3632052**

**Folder: Covid-19 Assessment 12 Nov 2020**

**Form: Symptom Log (5)**

**Generated On: 10 Jun 2021 09:13:35**

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:17:03
User signature succeeded.	Colleen Kelley (b) (4)	02 Apr 2021 20:59:30
DataPoint Verified.	(b) (4), (b) (6)	16 Dec 2020 17:53:03
User entered '0'	(b) (4), (b) (6)	16 Nov 2020 14:32:09

US3632052

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (5)

Generated On: 10 Jun 2021 09:13:35

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:17:03
User signature succeeded.	Colleen Kelley (b) (4)	02 Apr 2021 20:59:30
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	16 Dec 2020 17:53:03
User entered '98' reason for change: Data Entry Error	(b) (4), (b) (6)	17 Nov 2020 14:01:51
User entered empty.	(b) (4), (b) (6)	16 Nov 2020 14:32:09

**US3632052**

**Folder: Covid-19 Assessment 12 Nov 2020**

**Form: Symptom Log (5)**

**Generated On: 10 Jun 2021 09:13:35**

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:17:03
User entered '%'	System	17 Nov 2020 14:01:51
User entered empty.	System	16 Nov 2020 14:32:09

**US3632052**

**Folder: Covid-19 Assessment 12 Nov 2020**

**Form: Symptom Log (5)**

**Generated On: 10 Jun 2021 09:13:35**

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:17:03
User signature succeeded.	Colleen Kelley (b) (4)	02 Apr 2021 20:59:30
DataPoint Verified.	(b) (4), (b) (6)	16 Dec 2020 17:53:03
User entered '97.4' F reason for change: Data Entry Error	(b) (4), (b) (6)	17 Nov 2020 14:01:51
User entered empty.	(b) (4), (b) (6)	16 Nov 2020 14:32:09



**US3632052**

**Folder: Covid-19 Assessment 12 Nov 2020**

**Form: Symptom Log (5)**

**Generated On: 10 Jun 2021 09:13:35**

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:17:03
User signature succeeded.	Colleen Kelley (b) (4)	02 Apr 2021 20:59:30
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	16 Dec 2020 17:53:03
User entered 'None (None)' reason for change: Data Entry Error	(b) (4), (b) (6)	17 Nov 2020 14:01:51
User entered empty.	(b) (4), (b) (6)	16 Nov 2020 14:32:09

US3632052

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (5)

Generated On: 10 Jun 2021 09:13:35

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:17:03
User signature succeeded.	Colleen Kelley (b) (4)	02 Apr 2021 20:59:30
DataPoint Verified.	(b) (4), (b) (6)	16 Dec 2020 17:53:03
User entered 'None (None)' reason for change: Data Entry Error	(b) (4), (b) (6)	17 Nov 2020 14:01:51
User entered empty.	(b) (4), (b) (6)	16 Nov 2020 14:32:09

US3632052

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (5)

Generated On: 10 Jun 2021 09:13:35

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:17:03
User signature succeeded.	Colleen Kelley (b) (4)	02 Apr 2021 20:59:30
DataPoint Verified.	(b) (4), (b) (6)	16 Dec 2020 17:53:03
User entered 'None (None)' reason for change: Data Entry Error	(b) (4), (b) (6)	17 Nov 2020 14:01:51
User entered empty.	(b) (4), (b) (6)	16 Nov 2020 14:32:09

US3632052

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (5)

Generated On: 10 Jun 2021 09:13:35

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:17:03
User signature succeeded.	Colleen Kelley (b) (4)	02 Apr 2021 20:59:30
DataPoint Verified.	(b) (4), (b) (6)	16 Dec 2020 17:53:03
User entered 'None (None)' reason for change: Data Entry Error	(b) (4), (b) (6)	17 Nov 2020 14:01:51
User entered empty.	(b) (4), (b) (6)	16 Nov 2020 14:32:09

US3632052

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (5)

Generated On: 10 Jun 2021 09:13:35

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:17:03
User signature succeeded.	Colleen Kelley (b) (4)	02 Apr 2021 20:59:30
DataPoint Verified.	(b) (4), (b) (6)	16 Dec 2020 17:53:03
User entered 'Moderate (Moderate)' reason for change: Data Entry Error	(b) (4), (b) (6)	17 Nov 2020 14:01:51
User entered empty.	(b) (4), (b) (6)	16 Nov 2020 14:32:09

US3632052

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (5)

Generated On: 10 Jun 2021 09:13:35

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:17:03
User signature succeeded.	Colleen Kelley (b) (4)	02 Apr 2021 20:59:30
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	16 Dec 2020 17:53:03
User entered 'None (None)' reason for change: Data Entry Error	(b) (4), (b) (6)	17 Nov 2020 14:01:51
User entered empty.	(b) (4), (b) (6)	16 Nov 2020 14:32:09

US3632052

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (5)

Generated On: 10 Jun 2021 09:13:35

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:17:03
User signature succeeded.	Colleen Kelley (b) (4)	02 Apr 2021 20:59:30
DataPoint Verified.	(b) (4), (b) (6)	16 Dec 2020 17:53:03
User entered 'None (None)' reason for change: Data Entry Error	(b) (4), (b) (6)	17 Nov 2020 14:01:51
User entered empty.	(b) (4), (b) (6)	16 Nov 2020 14:32:09

US3632052

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (5)

Generated On: 10 Jun 2021 09:13:35

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:17:03
User signature succeeded.	Colleen Kelley (b) (4)	02 Apr 2021 20:59:30
DataPoint Verified.	(b) (4), (b) (6)	16 Dec 2020 17:53:03
User entered 'None (None)' reason for change: Data Entry Error	(b) (4), (b) (6)	17 Nov 2020 14:01:51
User entered empty.	(b) (4), (b) (6)	16 Nov 2020 14:32:09



US3632052

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (5)

Generated On: 10 Jun 2021 09:13:35

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:17:03
User signature succeeded.	Colleen Kelley (b) (4)	02 Apr 2021 20:59:30
DataPoint Verified.	(b) (4), (b) (6)	16 Dec 2020 17:53:03
User entered 'None (None)' reason for change: Data Entry Error	(b) (4), (b) (6)	17 Nov 2020 14:01:51
User entered empty.	(b) (4), (b) (6)	16 Nov 2020 14:32:09

US3632052

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (5)

Generated On: 10 Jun 2021 09:13:35

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:17:03
User signature succeeded.	Colleen Kelley (b) (4)	02 Apr 2021 20:59:30
DataPoint Verified.	(b) (4), (b) (6)	16 Dec 2020 17:53:03
User entered 'None (None)' reason for change: Data Entry Error	(b) (4), (b) (6)	17 Nov 2020 14:01:51
User entered empty.	(b) (4), (b) (6)	16 Nov 2020 14:32:09

**US3632052**

**Folder: Covid-19 Assessment 12 Nov 2020**

**Form: Symptom Log (5)**

**Generated On: 10 Jun 2021 09:13:35**

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:17:03
User signature succeeded.	Colleen Kelley (b) (4)	02 Apr 2021 20:59:30
DataPoint Verified.	(b) (4), (b) (6)	16 Dec 2020 17:53:03
User entered 'None (None)' reason for change: Data Entry Error	(b) (4), (b) (6)	17 Nov 2020 14:01:51
User entered empty.	(b) (4), (b) (6)	16 Nov 2020 14:32:09

US3632052

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (5)

Generated On: 10 Jun 2021 09:13:35

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:17:03
User signature succeeded.	Colleen Kelley (b) (4)	02 Apr 2021 20:59:30
DataPoint Verified.	(b) (4), (b) (6)	16 Dec 2020 17:53:03
User entered 'None (None)' reason for change: Data Entry Error	(b) (4), (b) (6)	17 Nov 2020 14:01:51
User entered empty.	(b) (4), (b) (6)	16 Nov 2020 14:32:09

**US3632052**

**Folder: Covid-19 Assessment 12 Nov 2020**

**Form: Symptom Log (5)**

**Generated On: 10 Jun 2021 09:13:35**

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:17:03
User signature succeeded.	Colleen Kelley (b) (4)	02 Apr 2021 20:59:30
DataPoint Verified.	(b) (4), (b) (6)	16 Dec 2020 17:53:03
User entered 'None (None)' reason for change: Data Entry Error	(b) (4), (b) (6)	17 Nov 2020 14:01:51
User entered empty.	(b) (4), (b) (6)	16 Nov 2020 14:32:09

US3632052

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (5)

Generated On: 10 Jun 2021 09:13:35

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:17:03
User signature succeeded.	Colleen Kelley (b) (4)	02 Apr 2021 20:59:30
DataPoint Verified.	(b) (4), (b) (6)	16 Dec 2020 17:53:03
User entered 'None (None)' reason for change: Data Entry Error	(b) (4), (b) (6)	17 Nov 2020 14:01:51
User entered empty.	(b) (4), (b) (6)	16 Nov 2020 14:32:09

**US3632052**

**Folder: Covid-19 Assessment 12 Nov 2020**

**Form: Symptom Log (5)**

**Generated On: 10 Jun 2021 09:13:35**

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:17:03
User signature succeeded.	Colleen Kelley (b) (4)	02 Apr 2021 20:59:30
DataPoint Verified.	(b) (4), (b) (6)	16 Dec 2020 17:53:03
User entered 'None (None)' reason for change: Data Entry Error	(b) (4), (b) (6)	17 Nov 2020 14:01:51
User entered empty.	(b) (4), (b) (6)	16 Nov 2020 14:32:09

US3632052

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (5)

Generated On: 10 Jun 2021 09:13:35

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:17:03
User signature succeeded.	Colleen Kelley (b) (4)	02 Apr 2021 20:59:30
DataPoint Verified.	(b) (4), (b) (6)	16 Dec 2020 17:53:03
User entered 'None (None)' reason for change: Data Entry Error	(b) (4), (b) (6)	17 Nov 2020 14:01:51
User entered empty.	(b) (4), (b) (6)	16 Nov 2020 14:32:09



US3632052

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (6)

Generated On: 10 Jun 2021 09:13:35

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:17:03
User signature succeeded.	Colleen Kelley (b) (4)	02 Apr 2021 20:59:30
User entered 'Day 6 (Day 6)'	(b) (4) (b) (4), (b) (6)	16 Nov 2020 14:33:38

**US3632052**

**Folder: Covid-19 Assessment 12 Nov 2020**

**Form: Symptom Log (6)**

**Generated On: 10 Jun 2021 09:13:35**

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:17:03
User signature succeeded.	Colleen Kelley (b) (4)	02 Apr 2021 20:59:30
DataPoint Verified.	(b) (4), (b) (6)	16 Dec 2020 17:53:03
User entered '15 Nov 2020'	(b) (4), (b) (6)	16 Nov 2020 14:33:38

**US3632052**

**Folder: Covid-19 Assessment 12 Nov 2020**

**Form: Symptom Log (6)**

**Generated On: 10 Jun 2021 09:13:35**

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:17:03
User signature succeeded.	Colleen Kelley (b) (4)	02 Apr 2021 20:59:30
DataPoint Verified.	(b) (4), (b) (6)	16 Dec 2020 17:53:03
User entered '0'	(b) (4), (b) (6)	16 Nov 2020 14:33:38

**US3632052**

**Folder: Covid-19 Assessment 12 Nov 2020**

**Form: Symptom Log (6)**

**Generated On: 10 Jun 2021 09:13:35**

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:17:03
User signature succeeded.	Colleen Kelley (b) (4)	02 Apr 2021 20:59:30
DataPoint Verified.	(b) (4), (b) (6)	16 Dec 2020 17:53:03
User entered '98'	(b) (4), (b) (6)	16 Nov 2020 14:33:38

US3632052

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (6)

Generated On: 10 Jun 2021 09:13:35

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:17:03
User entered '%'	System	16 Nov 2020 14:33:38

US3632052

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (6)

Generated On: 10 Jun 2021 09:13:35

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:17:03
User signature succeeded.	Colleen Kelley (b) (4)	02 Apr 2021 20:59:30
DataPoint Verified.	(b) (4), (b) (6)	16 Dec 2020 17:53:03
User entered '96.7' F	(b) (4), (b) (6)	16 Nov 2020 14:33:38

**US3632052**

**Folder: Covid-19 Assessment 12 Nov 2020**

**Form: Symptom Log (6)**

**Generated On: 10 Jun 2021 09:13:35**

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:17:03
User signature succeeded.	Colleen Kelley (b) (4)	02 Apr 2021 20:59:30
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	16 Dec 2020 17:53:03
User entered 'None (None)'	(b) (4), (b) (6)	16 Nov 2020 14:33:38

**US3632052**

**Folder: Covid-19 Assessment 12 Nov 2020**

**Form: Symptom Log (6)**

**Generated On: 10 Jun 2021 09:13:35**

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:17:03
User signature succeeded.	Colleen Kelley (b) (4)	02 Apr 2021 20:59:30
DataPoint Verified.	(b) (4), (b) (6)	16 Dec 2020 17:53:03
User entered 'None (None)'	(b) (4), (b) (6)	16 Nov 2020 14:33:38



US3632052

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (6)

Generated On: 10 Jun 2021 09:13:35

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:17:03
User signature succeeded.	Colleen Kelley (b) (4)	02 Apr 2021 20:59:30
DataPoint Verified.	(b) (4), (b) (6)	16 Dec 2020 17:53:03
User entered 'None (None)'	(b) (4), (b) (6)	16 Nov 2020 14:33:38

US3632052

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (6)

Generated On: 10 Jun 2021 09:13:35

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:17:03
User signature succeeded.	Colleen Kelley (b) (4)	02 Apr 2021 20:59:30
DataPoint Verified.	(b) (4), (b) (6)	16 Dec 2020 17:53:03
User entered 'None (None)'	(b) (4), (b) (6)	16 Nov 2020 14:33:38

US3632052

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (6)

Generated On: 10 Jun 2021 09:13:35

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:17:03
User signature succeeded.	Colleen Kelley (b) (4)	02 Apr 2021 20:59:30
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	16 Dec 2020 17:53:03
User entered 'None (None)'	(b) (4), (b) (6)	16 Nov 2020 14:33:38

US3632052

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (6)

Generated On: 10 Jun 2021 09:13:35

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:17:03
User signature succeeded.	Colleen Kelley (b) (4)	02 Apr 2021 20:59:30
DataPoint Verified.	(b) (4), (b) (6)	16 Dec 2020 17:53:03
User entered 'None (None)'	(b) (4), (b) (6)	16 Nov 2020 14:33:38

US3632052

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (6)

Generated On: 10 Jun 2021 09:13:35

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:17:03
User signature succeeded.	Colleen Kelley (b) (4)	02 Apr 2021 20:59:30
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	16 Dec 2020 17:53:03
User entered 'None (None)'	(b) (4), (b) (6)	16 Nov 2020 14:33:38

US3632052

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (6)

Generated On: 10 Jun 2021 09:13:35

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:17:03
User signature succeeded.	Colleen Kelley (b) (4)	02 Apr 2021 20:59:30
DataPoint Verified.	(b) (4), (b) (6)	16 Dec 2020 17:53:03
User entered 'None (None)'	(b) (4), (b) (6)	16 Nov 2020 14:33:38

**US3632052**

**Folder: Covid-19 Assessment 12 Nov 2020**

**Form: Symptom Log (6)**

**Generated On: 10 Jun 2021 09:13:35**

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:17:03
User signature succeeded.	Colleen Kelley (b) (4)	02 Apr 2021 20:59:30
DataPoint Verified.	(b) (4), (b) (6)	16 Dec 2020 17:53:03
User entered 'None (None)'	(b) (4), (b) (6)	16 Nov 2020 14:33:38

**US3632052**

**Folder: Covid-19 Assessment 12 Nov 2020**

**Form: Symptom Log (6)**

**Generated On: 10 Jun 2021 09:13:35**

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:17:03
User signature succeeded.	Colleen Kelley (b) (4)	02 Apr 2021 20:59:30
DataPoint Verified.	(b) (4), (b) (6)	16 Dec 2020 17:53:03
User entered 'None (None)'	(b) (4), (b) (6)	16 Nov 2020 14:33:38



**US3632052**

**Folder: Covid-19 Assessment 12 Nov 2020**

**Form: Symptom Log (6)**

**Generated On: 10 Jun 2021 09:13:35**

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:17:03
User signature succeeded.	Colleen Kelley (b) (4)	02 Apr 2021 20:59:30
DataPoint Verified.	(b) (4), (b) (6)	16 Dec 2020 17:53:03
User entered 'None (None)'	(b) (4), (b) (6)	16 Nov 2020 14:33:38

**US3632052**

**Folder: Covid-19 Assessment 12 Nov 2020**

**Form: Symptom Log (6)**

**Generated On: 10 Jun 2021 09:13:35**

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:17:03
User signature succeeded.	Colleen Kelley (b) (4)	02 Apr 2021 20:59:30
DataPoint Verified.	(b) (4), (b) (6)	16 Dec 2020 17:53:03
User entered 'None (None)'	(b) (4), (b) (6)	16 Nov 2020 14:33:38

**US3632052**

**Folder: Covid-19 Assessment 12 Nov 2020**

**Form: Symptom Log (6)**

**Generated On: 10 Jun 2021 09:13:35**

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:17:03
User signature succeeded.	Colleen Kelley (b) (4)	02 Apr 2021 20:59:30
DataPoint Verified.	(b) (4), (b) (6)	16 Dec 2020 17:53:03
User entered 'None (None)'	(b) (4), (b) (6)	16 Nov 2020 14:33:38

**US3632052**

**Folder: Covid-19 Assessment 12 Nov 2020**

**Form: Symptom Log (6)**

**Generated On: 10 Jun 2021 09:13:35**

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:17:03
User signature succeeded.	Colleen Kelley (b) (4)	02 Apr 2021 20:59:30
DataPoint Verified.	(b) (4), (b) (6)	16 Dec 2020 17:53:03
User entered 'None (None)'	(b) (4), (b) (6)	16 Nov 2020 14:33:38

**US3632052**

**Folder: Covid-19 Assessment 12 Nov 2020**

**Form: Symptom Log (6)**

**Generated On: 10 Jun 2021 09:13:35**

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:17:03
User signature succeeded.	Colleen Kelley (b) (4)	02 Apr 2021 20:59:30
DataPoint Verified.	(b) (4), (b) (6)	16 Dec 2020 17:53:03
User entered 'None (None)'	(b) (4), (b) (6)	16 Nov 2020 14:33:38

US3632052

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (6)

Generated On: 10 Jun 2021 09:13:35

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:17:03
User signature succeeded.	Colleen Kelley (b) (4)	02 Apr 2021 20:59:30
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	16 Dec 2020 17:53:03
User entered 'None (None)'	(b) (4), (b) (6)	16 Nov 2020 14:33:38

US3632052

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (7)

Generated On: 10 Jun 2021 09:13:35

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:17:03
User signature succeeded.	Colleen Kelley (b) (4)	02 Apr 2021 20:59:30
User entered 'Day 7 (Day 7)'	Christina Bacher (b) (4)	16 Nov 2020 21:08:03

US3632052

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (7)

Generated On: 10 Jun 2021 09:13:35

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:17:03
User signature succeeded.	Colleen Kelley (b) (4)	02 Apr 2021 20:59:30
DataPoint Verified.	(b) (4), (b) (6)	16 Dec 2020 17:53:03
User entered '16 Nov 2020'	Christina Bacher (b) (4)	16 Nov 2020 21:08:03



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Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (7)

Generated On: 10 Jun 2021 09:13:35

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:17:03
User signature succeeded.	Colleen Kelley (b) (4)	02 Apr 2021 20:59:30
DataPoint Verified.	(b) (4), (b) (6)	16 Dec 2020 17:53:03
User entered '0'	Christina Bacher (b) (4)	16 Nov 2020 21:08:03

US3632052

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (7)

Generated On: 10 Jun 2021 09:13:35

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:17:03
User signature succeeded.	Colleen Kelley (b) (4)	02 Apr 2021 20:59:30
DataPoint Verified.	(b) (4), (b) (6)	16 Dec 2020 17:53:03
User entered '96'	Christina Bacher (b) (4)	16 Nov 2020 21:08:03

**US3632052**

**Folder: Covid-19 Assessment 12 Nov 2020**

**Form: Symptom Log (7)**

**Generated On: 10 Jun 2021 09:13:35**

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:17:03
User entered '%'	System	16 Nov 2020 21:08:03

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Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (7)

Generated On: 10 Jun 2021 09:13:35

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:17:03
User signature succeeded.	Colleen Kelley (b) (4)	02 Apr 2021 20:59:30
DataPoint Verified.	(b) (4), (b) (6)	16 Dec 2020 17:53:03
User entered '97.3' F	Christina Bacher (b) (4)	16 Nov 2020 21:08:03

US3632052

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (7)

Generated On: 10 Jun 2021 09:13:35

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:17:03
User signature succeeded.	Colleen Kelley (b) (4)	02 Apr 2021 20:59:30
DataPoint Verified.	(b) (4), (b) (6)	16 Dec 2020 17:53:03
User entered 'None (None)'	Christina Bacher (b) (4)	16 Nov 2020 21:08:03

US3632052

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (7)

Generated On: 10 Jun 2021 09:13:35

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:17:03
User signature succeeded.	Colleen Kelley (b) (4)	02 Apr 2021 20:59:30
DataPoint Verified.	(b) (4), (b) (6)	16 Dec 2020 17:53:03
User entered 'None (None)'	Christina Bacher (b) (4)	16 Nov 2020 21:08:03

US3632052

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (7)

Generated On: 10 Jun 2021 09:13:35

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:17:03
User signature succeeded.	Colleen Kelley (b) (4)	02 Apr 2021 20:59:30
DataPoint Verified.	(b) (4), (b) (6)	16 Dec 2020 17:53:03
User entered 'None (None)'	Christina Bacher (b) (4)	16 Nov 2020 21:08:03

US3632052

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (7)

Generated On: 10 Jun 2021 09:13:35

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:17:03
User signature succeeded.	Colleen Kelley (b) (4)	02 Apr 2021 20:59:30
DataPoint Verified.	(b) (4), (b) (6)	16 Dec 2020 17:53:03
User entered 'None (None)'	Christina Bacher (b) (4)	16 Nov 2020 21:08:03



US3632052

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (7)

Generated On: 10 Jun 2021 09:13:35

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:17:03
User signature succeeded.	Colleen Kelley (b) (4)	02 Apr 2021 20:59:30
DataPoint Verified.	(b) (4), (b) (6)	16 Dec 2020 17:53:03
User entered 'None (None)'	Christina Bacher (b) (4)	16 Nov 2020 21:08:03

US3632052

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (7)

Generated On: 10 Jun 2021 09:13:35

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:17:03
User signature succeeded.	Colleen Kelley (b) (4)	02 Apr 2021 20:59:30
DataPoint Verified.	(b) (4), (b) (6)	16 Dec 2020 17:53:03
User entered 'None (None)'	Christina Bacher (b) (4)	16 Nov 2020 21:08:03

US3632052

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (7)

Generated On: 10 Jun 2021 09:13:35

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:17:03
User signature succeeded.	Colleen Kelley (b) (4)	02 Apr 2021 20:59:30
DataPoint Verified.	(b) (4), (b) (6)	16 Dec 2020 17:53:03
User entered 'None (None)'	Christina Bacher (b) (4)	16 Nov 2020 21:08:03

US3632052

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (7)

Generated On: 10 Jun 2021 09:13:35

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:17:03
User signature succeeded.	Colleen Kelley (b) (4)	02 Apr 2021 20:59:30
DataPoint Verified.	(b) (4), (b) (6)	16 Dec 2020 17:53:03
User entered 'None (None)'	Christina Bacher (b) (4)	16 Nov 2020 21:08:03

US3632052

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (7)

Generated On: 10 Jun 2021 09:13:35

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:17:03
User signature succeeded.	Colleen Kelley (b) (4)	02 Apr 2021 20:59:30
DataPoint Verified.	(b) (4), (b) (6)	16 Dec 2020 17:53:03
User entered 'None (None)'	Christina Bacher (b) (4)	16 Nov 2020 21:08:03

US3632052

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (7)

Generated On: 10 Jun 2021 09:13:35

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:17:03
User signature succeeded.	Colleen Kelley (b) (4)	02 Apr 2021 20:59:30
DataPoint Verified.	(b) (4), (b) (6)	16 Dec 2020 17:53:03
User entered 'None (None)'	Christina Bacher (b) (4)	16 Nov 2020 21:08:03

**US3632052**

**Folder: Covid-19 Assessment 12 Nov 2020**

**Form: Symptom Log (7)**

**Generated On: 10 Jun 2021 09:13:35**

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:17:03
User signature succeeded.	Colleen Kelley (b) (4)	02 Apr 2021 20:59:30
DataPoint Verified.	(b) (4), (b) (6)	16 Dec 2020 17:53:03
User entered 'None (None)'	Christina Bacher (b) (4)	16 Nov 2020 21:08:03

US3632052

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (7)

Generated On: 10 Jun 2021 09:13:35

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:17:03
User signature succeeded.	Colleen Kelley (b) (4)	02 Apr 2021 20:59:30
DataPoint Verified.	(b) (4), (b) (6)	16 Dec 2020 17:53:03
User entered 'None (None)'	Christina Bacher (b) (4)	16 Nov 2020 21:08:03



**US3632052**

**Folder: Covid-19 Assessment 12 Nov 2020**

**Form: Symptom Log (7)**

**Generated On: 10 Jun 2021 09:13:35**

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:17:03
User signature succeeded.	Colleen Kelley (b) (4)	02 Apr 2021 20:59:30
DataPoint Verified.	(b) (4), (b) (6)	16 Dec 2020 17:53:03
User entered 'None (None)'	Christina Bacher (b) (4)	16 Nov 2020 21:08:03

US3632052

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (7)

Generated On: 10 Jun 2021 09:13:35

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:17:03
User signature succeeded.	Colleen Kelley (b) (4)	02 Apr 2021 20:59:30
DataPoint Verified.	(b) (4), (b) (6)	16 Dec 2020 17:53:03
User entered 'None (None)'	Christina Bacher (b) (4)	16 Nov 2020 21:08:03

US3632052

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (7)

Generated On: 10 Jun 2021 09:13:35

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:17:03
User signature succeeded.	Colleen Kelley (b) (4)	02 Apr 2021 20:59:30
DataPoint Verified.	(b) (4), (b) (6)	16 Dec 2020 17:53:03
User entered 'None (None)'	Christina Bacher (b) (4)	16 Nov 2020 21:08:03

US3632052

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (7)

Generated On: 10 Jun 2021 09:13:35

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:17:03
User signature succeeded.	Colleen Kelley (b) (4)	02 Apr 2021 20:59:30
DataPoint Verified.	(b) (4), (b) (6)	16 Dec 2020 17:53:03
User entered 'None (None)'	Christina Bacher (b) (4)	16 Nov 2020 21:08:03

**US3632052**

**Folder: Covid-19 Assessment 12 Nov 2020**

**Form: COVID Diagnostic Test**

**Generated On: 10 Jun 2021 09:13:35**

[Date of Visit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:17:11
User signature succeeded.	Colleen Kelley (b) (4)	02 Apr 2021 20:59:30
DataPoint Verified.	(b) (4), (b) (6)	16 Dec 2020 17:53:29
User entered '12 Nov 2020'	(b) (4), (b) (6)	17 Nov 2020 20:52:24

**US3632052**

**Folder: Covid-19 Assessment 12 Nov 2020**

**Form: COVID Diagnostic Test**

**Generated On: 10 Jun 2021 09:13:35**

[Was the Subject Tested For SARS-CoV-2 by RT-PCR?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:17:11
User signature succeeded.	Colleen Kelley (b) (4)	02 Apr 2021 20:59:30
DataPoint Verified.	(b) (4), (b) (6)	16 Dec 2020 17:53:29
User entered 'Yes (Y)'	(b) (4), (b) (6)	17 Nov 2020 20:52:24

US3632052

Folder: Covid-19 Assessment 12 Nov 2020

Form: COVID Diagnostic Test

Generated On: 10 Jun 2021 09:13:35

[Did Subject Test Positive For SARS-CoV-2 by RT-PCR?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:17:11
User signature succeeded.	Colleen Kelley (b) (4)	02 Apr 2021 20:59:30
DataPoint Verified.	(b) (4), (b) (6)	16 Dec 2020 17:53:29
User entered 'No (N)'	(b) (4), (b) (6)	17 Nov 2020 20:52:24

**US3632052**

**Folder: Covid-19 Assessment 12 Nov 2020**

**Form: COVID Diagnostic Test**

**Generated On: 10 Jun 2021 09:13:35**

[Date of Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:17:11
User signature succeeded.	Colleen Kelley (b) (4)	02 Apr 2021 20:59:30
DataPoint Verified.	(b) (4), (b) (6)	16 Dec 2020 17:53:29
User entered '12 Nov 2020'	(b) (4), (b) (6)	17 Nov 2020 20:52:24



**US3632052**

**Folder: Covid-19 Assessment 12 Nov 2020**

**Form: COVID Diagnostic Test**

**Generated On: 10 Jun 2021 09:13:35**

[Type of Test Performed](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:17:11
User signature succeeded.	Colleen Kelley (b) (4)	02 Apr 2021 20:59:30
DataPoint Verified.	(b) (4), (b) (6)	16 Dec 2020 17:53:29
User entered 'Nasopharyngeal Swab (Nasopharyngeal Swab)'	(b) (4), (b) (6)	17 Nov 2020 20:52:24

US3632052

Folder: Covid-19 Assessment 12 Nov 2020

Form: COVID Diagnostic Test

Generated On: 10 Jun 2021 09:13:35

[Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:17:11
User signature succeeded.	Colleen Kelley (b) (4)	02 Apr 2021 20:59:30
DataPoint Verified.	(b) (4), (b) (6)	16 Dec 2020 17:53:29
User entered empty.	(b) (4), (b) (6)	17 Nov 2020 20:52:24

**US3632052**

**Folder: Covid-19 Assessment 12 Nov 2020**

**Form: COVID Diagnostic Test**

**Generated On: 10 Jun 2021 09:13:35**

[Was this diagnostic test performed at a lab other than the Study Central Lab?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:17:11
User signature succeeded.	Colleen Kelley (b) (4)	02 Apr 2021 20:59:30
DataPoint Verified.	(b) (4), (b) (6)	16 Dec 2020 17:53:29
User entered 'No (N)'	(b) (4), (b) (6)	17 Nov 2020 20:52:24

US3632052

Folder: Covid-19 Assessment 12 Nov 2020

Form: COVID Diagnostic Test

Generated On: 10 Jun 2021 09:13:35

[Lab/ Institution Test Performed](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:17:11
User signature succeeded.	Colleen Kelley (b) (4)	02 Apr 2021 20:59:30
DataPoint Verified.	(b) (4), (b) (6)	16 Dec 2020 17:53:29
User entered empty.	(b) (4), (b) (6)	17 Nov 2020 20:52:24

US3632052

Folder: Covid-19 Assessment 12 Nov 2020

Form: COVID Diagnostic Test

Generated On: 10 Jun 2021 09:13:35

[CLIA Certified?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:17:11
User signature succeeded.	Colleen Kelley (b) (4)	02 Apr 2021 20:59:30
DataPoint Verified.	(b) (4), (b) (6)	16 Dec 2020 17:53:29
User entered empty.	(b) (4), (b) (6)	17 Nov 2020 20:52:24

**US3632052**

**Folder: Covid-19 Assessment 12 Nov 2020**

**Form: COVID Diagnostic Test**

**Generated On: 10 Jun 2021 09:13:35**

**COVID-19 Positive (CSA Programming Field Only)**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:17:11
User entered '0'	System	17 Nov 2020 20:52:24

US3632052

Folder: Covid-19 Assessment 12 Nov 2020

Form: Generate Next COVID-19 Assessment

Generated On: 10 Jun 2021 09:13:35

[Generate Next COVID-19 Assessment](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:17:17
User signature succeeded.	Colleen Kelley (b) (4)	02 Apr 2021 20:59:30
DataPoint Verified.	(b) (4), (b) (6)	11 Mar 2021 19:56:59
User entered 'No (N)'	(b) (4), (b) (6)	13 Jan 2021 14:40:58

**US3632052**

**Folder: Illness Visit (1)**

**Form: Saliva Collection (1)**

**Generated On: 10 Jun 2021 09:13:35**

[Visit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 19:53:56
User accepted default value 'Day 3 (Day 3)'	(b) (4), (b) (6)	16 Nov 2020 14:34:01



**US3632052**

**Folder: Illness Visit (1)**

**Form: Saliva Collection (1)**

**Generated On: 10 Jun 2021 09:13:35**

[Was Saliva Collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 19:53:56
User signature succeeded.	Colleen Kelley (b) (4)	02 Apr 2021 20:59:30
DataPoint Verified.	(b) (4), (b) (6)	16 Dec 2020 17:42:42
User entered 'Yes (Y)'	(b) (4), (b) (6)	16 Nov 2020 14:34:01

**US3632052**

**Folder: Illness Visit (1)**

**Form: Saliva Collection (1)**

**Generated On: 10 Jun 2021 09:13:35**

[Date of Collection](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 19:53:56
User signature succeeded.	Colleen Kelley (b) (4)	02 Apr 2021 20:59:30
DataPoint Verified.	(b) (4), (b) (6)	16 Dec 2020 17:42:42
User entered '14 Nov 2020'	(b) (4), (b) (6)	16 Nov 2020 14:34:01

**US3632052**

**Folder: Illness Visit (1)**

**Form: Saliva Collection (2)**

**Generated On: 10 Jun 2021 09:13:35**

[Visit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 19:53:56
User accepted default value 'Day 5 (Day 5)'	(b) (4), (b) (6)	16 Nov 2020 14:34:01

US3632052

Folder: Illness Visit (1)

Form: Saliva Collection (2)

Generated On: 10 Jun 2021 09:13:35

[Was Saliva Collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 19:53:56
User signature succeeded.	Colleen Kelley (b) (4)	02 Apr 2021 20:59:30
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	16 Dec 2020 17:42:42
User closed query 'Data is required. Please complete.' (Site from System).	System	16 Nov 2020 17:42:52
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	16 Nov 2020 17:42:52
User entered 'Yes (Y)' reason for change: Data Entry Error	(b) (4), (b) (6)	16 Nov 2020 17:42:52
User opened query 'Data is required. Please complete.' (Site from System).	System	16 Nov 2020 14:34:01
User entered empty.	(b) (4), (b) (6)	16 Nov 2020 14:34:01

**US3632052**

**Folder: Illness Visit (1)**

**Form: Saliva Collection (2)**

**Generated On: 10 Jun 2021 09:13:35**

[Date of Collection](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 19:53:56
User signature succeeded.	Colleen Kelley (b) (4)	02 Apr 2021 20:59:30
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	16 Dec 2020 17:42:42
User entered '16 Nov 2020' reason for change: Data Entry Error	(b) (4), (b) (6)	16 Nov 2020 17:42:52
User entered empty.	(b) (4), (b) (6)	16 Nov 2020 14:34:01

**US3632052**

**Folder: Illness Visit (1)**

**Form: Saliva Collection (3)**

**Generated On: 10 Jun 2021 09:13:35**

[Visit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 19:53:56
User accepted default value 'Day 7 (Day 7)'	(b) (4), (b) (6)	16 Nov 2020 14:34:01

US3632052

Folder: Illness Visit (1)

Form: Saliva Collection (3)

Generated On: 10 Jun 2021 09:13:35

[Was Saliva Collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 19:53:56
User signature succeeded.	Colleen Kelley (b) (4)	02 Apr 2021 20:59:30
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	16 Dec 2020 17:42:42
User closed query 'Data is required. Please complete.' (Site from System).	System	17 Nov 2020 20:53:00
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	17 Nov 2020 20:53:00
User entered 'NA (COVID-19 Negative) (NA)' reason for change: Data Entry Error	(b) (4), (b) (6)	17 Nov 2020 20:53:00
User opened query 'Data is required. Please complete.' (Site from System).	System	16 Nov 2020 14:34:01
User entered empty.	(b) (4), (b) (6)	16 Nov 2020 14:34:01

**US3632052**

**Folder: Illness Visit (1)**

**Form: Saliva Collection (3)**

**Generated On: 10 Jun 2021 09:13:35**

[Date of Collection](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 19:53:56
User signature succeeded.	Colleen Kelley (b) (4)	02 Apr 2021 20:59:30
DataPoint Verified.	(b) (4), (b) (6)	16 Dec 2020 17:42:42
User entered empty.	(b) (4), (b) (6)	16 Nov 2020 14:34:01



**US3632052**

**Folder: Illness Visit (1)**

**Form: Saliva Collection (4)**

**Generated On: 10 Jun 2021 09:13:35**

[Visit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 19:53:56
User accepted default value 'Day 9 (Day 9)'	(b) (4), (b) (6)	16 Nov 2020 14:34:01

US3632052

Folder: Illness Visit (1)

Form: Saliva Collection (4)

Generated On: 10 Jun 2021 09:13:35

[Was Saliva Collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 19:53:56
User signature succeeded.	Colleen Kelley (b) (4)	02 Apr 2021 20:59:30
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	16 Dec 2020 17:42:42
User closed query 'Data is required. Please complete.' (Site from System).	System	17 Nov 2020 20:53:00
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	17 Nov 2020 20:53:00
User entered 'NA (COVID-19 Negative) (NA)' reason for change: Data Entry Error	(b) (4), (b) (6)	17 Nov 2020 20:53:00
User opened query 'Data is required. Please complete.' (Site from System).	System	16 Nov 2020 14:34:01
User entered empty.	(b) (4), (b) (6)	16 Nov 2020 14:34:01

**US3632052**

**Folder: Illness Visit (1)**

**Form: Saliva Collection (4)**

**Generated On: 10 Jun 2021 09:13:35**

[Date of Collection](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 19:53:56
User signature succeeded.	Colleen Kelley (b) (4)	02 Apr 2021 20:59:30
DataPoint Verified.	(b) (4), (b) (6)	16 Dec 2020 17:42:42
User entered empty.	(b) (4), (b) (6)	16 Nov 2020 14:34:01

**US3632052**

**Folder: Illness Visit (1)**

**Form: Saliva Collection (5)**

**Generated On: 10 Jun 2021 09:13:35**

[Visit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 19:53:56
User accepted default value 'Day 14 (Day 14)'	(b) (4), (b) (6)	16 Nov 2020 14:34:01

US3632052

Folder: Illness Visit (1)

Form: Saliva Collection (5)

Generated On: 10 Jun 2021 09:13:35

[Was Saliva Collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 19:53:56
User signature succeeded.	Colleen Kelley (b) (4)	02 Apr 2021 20:59:30
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	16 Dec 2020 17:42:42
User closed query 'Data is required. Please complete.' (Site from System).	System	17 Nov 2020 20:53:00
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	17 Nov 2020 20:53:00
User entered 'NA (COVID-19 Negative) (NA)' reason for change: Data Entry Error	(b) (4), (b) (6)	17 Nov 2020 20:53:00
User opened query 'Data is required. Please complete.' (Site from System).	System	16 Nov 2020 14:34:01
User entered empty.	(b) (4), (b) (6)	16 Nov 2020 14:34:01

**US3632052**

**Folder: Illness Visit (1)**

**Form: Saliva Collection (5)**

**Generated On: 10 Jun 2021 09:13:35**

[Date of Collection](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 19:53:56
User signature succeeded.	Colleen Kelley (b) (4)	02 Apr 2021 20:59:30
DataPoint Verified.	(b) (4), (b) (6)	16 Dec 2020 17:42:42
User entered empty.	(b) (4), (b) (6)	16 Nov 2020 14:34:01

**US3632052**

**Folder: Illness Visit (1)**

**Form: Saliva Collection (6)**

**Generated On: 10 Jun 2021 09:13:35**

[Visit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 19:53:56
User accepted default value 'Day 21 (Day 21)'	(b) (4), (b) (6)	16 Nov 2020 14:34:01

US3632052

Folder: Illness Visit (1)

Form: Saliva Collection (6)

Generated On: 10 Jun 2021 09:13:35

[Was Saliva Collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 19:53:56
User signature succeeded.	Colleen Kelley (b) (4)	02 Apr 2021 20:59:30
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	16 Dec 2020 17:42:42
User closed query 'Data is required. Please complete.' (Site from System).	System	17 Nov 2020 20:53:00
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	17 Nov 2020 20:53:00
User entered 'NA (COVID-19 Negative) (NA)' reason for change: Data Entry Error	(b) (4), (b) (6)	17 Nov 2020 20:53:00
User opened query 'Data is required. Please complete.' (Site from System).	System	16 Nov 2020 14:34:01
User entered empty.	(b) (4), (b) (6)	16 Nov 2020 14:34:01



**US3632052**

**Folder: Illness Visit (1)**

**Form: Saliva Collection (6)**

**Generated On: 10 Jun 2021 09:13:35**

[Date of Collection](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 19:53:56
User signature succeeded.	Colleen Kelley (b) (4)	02 Apr 2021 20:59:30
DataPoint Verified.	(b) (4), (b) (6)	16 Dec 2020 17:42:42
User entered empty.	(b) (4), (b) (6)	16 Nov 2020 14:34:01

**US3632052**

**Folder: Illness Visit (1)**

**Form: Saliva Collection (7)**

**Generated On: 10 Jun 2021 09:13:35**

[Visit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 19:53:56
User accepted default value 'Day 28 (Day 28)'	(b) (4), (b) (6)	16 Nov 2020 14:34:01

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Folder: Illness Visit (1)

Form: Saliva Collection (7)

Generated On: 10 Jun 2021 09:13:35

[Was Saliva Collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 19:53:56
User signature succeeded.	Colleen Kelley (b) (4)	02 Apr 2021 20:59:30
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	16 Dec 2020 17:42:42
User closed query 'Data is required. Please complete.' (Site from System).	System	17 Nov 2020 20:53:00
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	17 Nov 2020 20:53:00
User entered 'NA (COVID-19 Negative) (NA)' reason for change: Data Entry Error	(b) (4), (b) (6)	17 Nov 2020 20:53:00
User opened query 'Data is required. Please complete.' (Site from System).	System	16 Nov 2020 14:34:01
User entered empty.	(b) (4), (b) (6)	16 Nov 2020 14:34:01

**US3632052**

**Folder: Illness Visit (1)**

**Form: Saliva Collection (7)**

**Generated On: 10 Jun 2021 09:13:35**

[Date of Collection](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 19:53:56
User signature succeeded.	Colleen Kelley (b) (4)	02 Apr 2021 20:59:30
DataPoint Verified.	(b) (4), (b) (6)	16 Dec 2020 17:42:42
User entered empty.	(b) (4), (b) (6)	16 Nov 2020 14:34:01

**US3632052**

**Folder: Illness Visit Day 1 (1)**

**Form: Visit Date**

**Generated On: 10 Jun 2021 09:13:35**

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 19:53:36
User signature succeeded.	Colleen Kelley (b) (4)	02 Apr 2021 20:59:30
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	16 Dec 2020 17:40:11
User entered 'Yes (Y)'	(b) (4), (b) (6)	12 Nov 2020 21:57:51

**US3632052**

**Folder: Illness Visit Day 1 (1)**

**Form: Visit Date**

**Generated On: 10 Jun 2021 09:13:35**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 19:53:36
User signature succeeded.	Colleen Kelley (b) (4)	02 Apr 2021 20:59:30
DataPoint Verified.	(b) (4), (b) (6)	16 Dec 2020 17:40:11
User entered '12 Nov 2020'	(b) (4), (b) (6)	12 Nov 2020 21:57:51

**US3632052**

**Folder: Illness Visit Day 1 (1)**

**Form: Visit Date**

**Generated On: 10 Jun 2021 09:13:35**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 19:53:36
User signature succeeded.	Colleen Kelley (b) (4)	02 Apr 2021 20:59:30
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	16 Dec 2020 17:40:11
User entered 'Clinic (Clinic)'	(b) (4), (b) (6)	12 Nov 2020 21:57:51

**US3632052**

**Folder: Illness Visit Day 1 (1)**

**Form: Visit Date**

**Generated On: 10 Jun 2021 09:13:35**

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 19:53:36
User entered 'SICKD1'	System	12 Nov 2020 21:57:51



**US3632052**

**Folder: Illness Visit Day 1 (1)**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 09:13:35**

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 19:53:39
User signature succeeded.	Colleen Kelley (b) (4)	02 Apr 2021 20:59:30
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	16 Dec 2020 17:40:46
User entered 'Yes (Y)'	(b) (4), (b) (6)	12 Nov 2020 21:58:55

**US3632052**

**Folder: Illness Visit Day 1 (1)**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 09:13:35**

**Date of assessment** (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 19:53:39
User signature succeeded.	Colleen Kelley (b) (4)	02 Apr 2021 20:59:30
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	16 Dec 2020 17:40:46
User entered '12 Nov 2020'	(b) (4), (b) (6)	12 Nov 2020 21:58:55

**US3632052**

**Folder: Illness Visit Day 1 (1)**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 09:13:35**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 19:53:39
User signature succeeded.	Colleen Kelley (b) (4)	02 Apr 2021 20:59:30
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	16 Dec 2020 17:40:46
User entered '14:30'	(b) (4), (b) (6)	12 Nov 2020 21:58:55

**US3632052**

**Folder: Illness Visit Day 1 (1)**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 09:13:35**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 19:53:39
User entered '12 Nov 2020 14:30'	System	12 Nov 2020 21:58:55

US3632052

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:13:35

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 19:53:39
User signature succeeded.	Colleen Kelley (b) (4)	02 Apr 2021 20:59:30
DataPoint Verified.	(b) (4), (b) (6)	16 Dec 2020 17:40:46
User entered '69' in	(b) (4), (b) (6)	12 Nov 2020 21:58:55
DataPoint set to visible.	System	12 Nov 2020 21:57:51

**US3632052**

**Folder: Illness Visit Day 1 (1)**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 09:13:35**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 19:53:39
User signature succeeded.	Colleen Kelley (b) (4)	02 Apr 2021 20:59:30
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	16 Dec 2020 17:40:46
User entered '96.5' kg	(b) (4), (b) (6)	12 Nov 2020 21:58:55
DataPoint set to visible.	System	12 Nov 2020 21:57:51

**US3632052**

**Folder: Illness Visit Day 1 (1)**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 09:13:35**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 19:53:39
User signature succeeded.	Colleen Kelley (b) (4)	02 Apr 2021 20:59:30
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	16 Dec 2020 17:40:46
User entered '97.2' F	(b) (4), (b) (6)	12 Nov 2020 21:58:55

**US3632052**

**Folder: Illness Visit Day 1 (1)**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 09:13:35**

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 19:53:39
User signature succeeded.	Colleen Kelley (b) (4)	02 Apr 2021 20:59:30
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	16 Dec 2020 17:40:46
User entered 'Oral (Oral)'	(b) (4), (b) (6)	12 Nov 2020 21:58:55



**US3632052**

**Folder: Illness Visit Day 1 (1)**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 09:13:35**

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 19:53:39
User signature succeeded.	Colleen Kelley (b) (4)	02 Apr 2021 20:59:30
DataPoint Verified.	(b) (4), (b) (6)	16 Dec 2020 17:40:46
User entered empty.	(b) (4), (b) (6)	12 Nov 2020 21:58:55

**US3632052**

**Folder: Illness Visit Day 1 (1)**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 09:13:35**

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 19:53:39
User signature succeeded.	Colleen Kelley (b) (4)	02 Apr 2021 20:59:30
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	16 Dec 2020 17:40:46
User entered '69'	(b) (4), (b) (6)	12 Nov 2020 21:58:55

**US3632052**

**Folder: Illness Visit Day 1 (1)**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 09:13:35**

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 19:53:39
User entered 'bpm'	System	12 Nov 2020 21:58:55

US3632052

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:13:35

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 19:53:39
User signature succeeded.	Colleen Kelley (b) (4)	02 Apr 2021 20:59:30
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	16 Dec 2020 17:40:46
User entered '14'	(b) (4), (b) (6)	12 Nov 2020 21:58:55

US3632052

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:13:35

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 19:53:39
User entered 'breaths/min'	System	12 Nov 2020 21:58:55

US3632052

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:13:35

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 19:53:39
User signature succeeded.	Colleen Kelley (b) (4)	02 Apr 2021 20:59:30
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	16 Dec 2020 17:40:46
User entered '138'	(b) (4), (b) (6)	12 Nov 2020 21:58:55

**US3632052**

**Folder: Illness Visit Day 1 (1)**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 09:13:35**

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 19:53:39
User entered 'mmHg'	System	12 Nov 2020 21:58:55

**US3632052**

**Folder: Illness Visit Day 1 (1)**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 09:13:35**

[Diastolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 19:53:39
User signature succeeded.	Colleen Kelley (b) (4)	02 Apr 2021 20:59:30
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	16 Dec 2020 17:40:46
User entered '89'	(b) (4), (b) (6)	12 Nov 2020 21:58:55



**US3632052**

**Folder: Illness Visit Day 1 (1)**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 09:13:35**

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 19:53:39
User entered 'mmHg'	System	12 Nov 2020 21:58:55

**US3632052**

**Folder: Illness Visit Day 1 (1)**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 09:13:35**

[Height \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 19:53:39

**US3632052**

**Folder: Illness Visit Day 1 (1)**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 09:13:35**

[Weight \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 19:53:39

**US3632052**

**Folder: Illness Visit Day 1 (1)**

**Form: Physical Examination**

**Generated On: 10 Jun 2021 09:13:35**

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 19:53:43
User signature succeeded.	Colleen Kelley (b) (4)	02 Apr 2021 20:59:30
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	16 Dec 2020 17:41:01
User entered 'Yes (Y)'	(b) (4), (b) (6)	12 Nov 2020 21:59:02

**US3632052**

**Folder: Illness Visit Day 1 (1)**

**Form: Physical Examination**

**Generated On: 10 Jun 2021 09:13:35**

**Date of examination (dd MMM yyyy)**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 19:53:43
User signature succeeded.	Colleen Kelley (b) (4)	02 Apr 2021 20:59:30
DataPoint Verified.	(b) (4), (b) (6)	16 Dec 2020 17:41:01
User entered '12 Nov 2020'	(b) (4), (b) (6)	12 Nov 2020 21:59:02

US3632052

Folder: Illness Visit Day 1 (1)

Form: Blood Sample Collection for Immunologic Assessment of SARS-CoV-2 Infection

Generated On: 10 Jun 2021 09:13:35

[Was Blood Sample Taken for Immunologic Assessment of SARS\\_COV-2 Infection?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 19:53:47
User signature succeeded.	Colleen Kelley (b) (4)	02 Apr 2021 20:59:30
DataPoint Verified.	(b) (4), (b) (6)	16 Dec 2020 17:41:16
User entered 'Yes (Y)'	(b) (4), (b) (6)	12 Nov 2020 21:59:13

**US3632052**

**Folder: Illness Visit Day 1 (1)**

**Form: Blood Sample Collection for Immunologic Assessment of SARS-CoV-2 Infection**

**Generated On: 10 Jun 2021 09:13:35**

[Date of Collection](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 19:53:47
User signature succeeded.	Colleen Kelley (b) (4)	02 Apr 2021 20:59:30
DataPoint Verified.	(b) (4), (b) (6)	16 Dec 2020 17:41:16
User entered '12 Nov 2020'	(b) (4), (b) (6)	12 Nov 2020 21:59:13

**US3632052**

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

**Form: Visit Date**

**Generated On: 10 Jun 2021 09:13:35**

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:07:42
User signature succeeded.	Colleen Kelley (b) (4)	02 Apr 2021 20:59:30
DataPoint Verified.	(b) (4), (b) (6)	11 Mar 2021 19:57:31
User entered 'Yes (Y)'	Bezuayehu Mandefro (b) (4)	04 Jan 2021 18:25:03



US3632052

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

Form: Visit Date

Generated On: 10 Jun 2021 09:13:35

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:07:42
User signature succeeded.	Colleen Kelley (b) (4)	02 Apr 2021 20:59:30
DataPoint Verified.	(b) (4), (b) (6)	11 Mar 2021 19:57:31
User entered '04 Jan 2021'	Bezuayehu Mandefro (b) (4)	04 Jan 2021 18:25:03

**US3632052**

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

**Form: Visit Date**

**Generated On: 10 Jun 2021 09:13:35**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:07:42
User signature succeeded.	Colleen Kelley (b) (4)	02 Apr 2021 20:59:30
DataPoint Verified.	(b) (4), (b) (6)	11 Mar 2021 19:57:31
User entered 'Clinic (Clinic)'	Bezuayehu Mandefro (b) (4)	04 Jan 2021 18:25:03

**US3632052**

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

**Form: Visit Date**

**Generated On: 10 Jun 2021 09:13:35**

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:07:42
User entered 'UNBLND_DECIDE'	System	04 Jan 2021 18:25:03

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

Form: Unblinding

Generated On: 10 Jun 2021 09:13:35

Date of updated informed consent (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:07:42
User signature succeeded.	Colleen Kelley (b) (4)	02 Apr 2021 20:59:30
DataPoint Verified.	(b) (4), (b) (6)	11 Mar 2021 19:57:39
User entered '04 Jan 2021'	Bezuayehu Mandefro (b) (4)	04 Jan 2021 18:25:47

**US3632052**

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

**Form: Unblinding**

**Generated On: 10 Jun 2021 09:13:35**

[N/A - Subject Unblinded under Amendment 5 and Discontinued from Study](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:07:42
User signature succeeded.	Colleen Kelley (b) (4)	12 Apr 2021 01:33:40
DataPoint Verified.	(b) (4), (b) (6)	09 Apr 2021 14:58:22
User entered '0'	(b) (4), (b) (6)	09 Apr 2021 12:17:20
Amendment Manager inserted this DataPoint.	System	06 Mar 2021 08:31:40

US3632052

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

Form: Unblinding

Generated On: 10 Jun 2021 09:13:35

[Was the participant unblinded?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:07:42
User signature succeeded.	Colleen Kelley (b) (4)	02 Apr 2021 20:59:30
DataPoint Verified.	(b) (4), (b) (6)	11 Mar 2021 19:57:39
User entered 'Yes (Y)'	Bezuayehu Mandefro (b) (4)	04 Jan 2021 18:25:47

US3632052

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

Form: Unblinding

Generated On: 10 Jun 2021 09:13:35

[Under what version of the Protocol was the Participant unblinded?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:07:42
User closed query 'Per CDA, per sponsor review: Per IRT system use and date, this subject was unblinded when the site was approved for A6. Subject was unblinded under A6, please review and update blank field.' (Site from DM).	(b) (4), (b) (6)	12 Apr 2021 15:45:20
User signature succeeded.	Colleen Kelley (b) (4)	12 Apr 2021 01:33:40
DataPoint Verified.	(b) (4), (b) (6)	09 Apr 2021 14:58:22
Query 'Per CDA, per sponsor review: Per IRT system use and date, this subject was unblinded when the site was approved for A6. Subject was unblinded under A6, please review and update blank field.' answered with 'updated' (Site from DM).	(b) (4), (b) (6)	09 Apr 2021 12:17:27
User entered 'Amendment 6 or later (Amendment 6 or later)'	(b) (4), (b) (6)	09 Apr 2021 12:17:20
User opened query 'Per CDA, per sponsor review: Per IRT system use and date, this subject was unblinded when the site was approved for A6. Subject was unblinded under A6, please review and update blank field.' (Site from DM).	(b) (4), (b) (6)	08 Apr 2021 20:07:15
Amendment Manager inserted this DataPoint.	System	06 Mar 2021 08:31:40

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

Form: Unblinding

Generated On: 10 Jun 2021 09:13:35

Date of unblinding (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:07:42
User signature succeeded.	Colleen Kelley (b) (4)	02 Apr 2021 20:59:30
DataPoint Verified.	(b) (4), (b) (6)	11 Mar 2021 19:57:39
User entered '04 Jan 2021'	Bezuayehu Mandefro (b) (4)	04 Jan 2021 18:25:47



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

Form: Unblinding

Generated On: 10 Jun 2021 09:13:35

[Participant randomization assignment](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:07:42
User signature succeeded.	Colleen Kelley (b) (4)	02 Apr 2021 20:59:30
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Mar 2021 19:57:39
User entered 'mRNA-1273 (mRNA-1273)'	Bezuayehu Mandefro (b) (4)	04 Jan 2021 18:25:47

US3632052

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

Form: Unblinding

Generated On: 10 Jun 2021 09:13:35

[Actual Dose 1](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:07:42
User signature succeeded.	Colleen Kelley (b) (4)	02 Apr 2021 20:59:30
DataPoint Verified.	(b) (4), (b) (6)	11 Mar 2021 19:57:39
Amendment Manager: User entered 'mRNA-1273 (mRNA-1273)'	System	20 Jan 2021 09:09:11
User entered 'mRNA-1273 (mRNA-1273)'	Bezuayehu Mandefro (b) (4)	04 Jan 2021 18:25:47

**US3632052**

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

**Form: Unblinding**

**Generated On: 10 Jun 2021 09:13:35**

[Actual Dose 2](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:07:42
User signature succeeded.	Colleen Kelley (b) (4)	02 Apr 2021 20:59:30
DataPoint Verified.	(b) (4), (b) (6)	11 Mar 2021 19:57:39
Amendment Manager: User entered 'mRNA-1273 (mRNA-1273)'	System	20 Jan 2021 09:09:11
User entered 'mRNA-1273 (mRNA-1273)'	Bezuayehu Mandefro (b) (4)	04 Jan 2021 18:25:47

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

Form: Unblinding

Generated On: 10 Jun 2021 09:13:35

[Will participant receive mRNA-1273?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:07:42
User signature succeeded.	Colleen Kelley (b) (4)	02 Apr 2021 20:59:30
DataPoint Verified.	(b) (4), (b) (6)	11 Mar 2021 19:57:39
User entered 'No (N)'	Bezuayehu Mandefro (b) (4)	04 Jan 2021 18:25:47

**US3632052**

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

**Form: Unblinding**

**Generated On: 10 Jun 2021 09:13:35**

[Placebo Only Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:07:42
User entered empty.	System	04 Jan 2021 18:25:47

**US3632052**

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

**Form: Unblinding**

**Generated On: 10 Jun 2021 09:13:35**

[Continuing with mRNA-1273](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:07:42
User entered empty.	System	04 Jan 2021 18:25:47

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

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 09:13:35

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:07:42
User signature succeeded.	Colleen Kelley (b) (4)	02 Apr 2021 20:59:30
DataPoint Verified.	(b) (4), (b) (6)	11 Mar 2021 19:57:51
User entered 'Yes (Y)'	Bezuayehu Mandefro (b) (4)	04 Jan 2021 18:26:44

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

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 09:13:35

Collection date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:07:42
User signature succeeded.	Colleen Kelley (b) (4)	02 Apr 2021 20:59:30
DataPoint Verified.	(b) (4), (b) (6)	11 Mar 2021 19:57:51
User closed query 'Per GCL Lab Reconciliation: Immunogenicity Assessment: Per GCL, there is an Immunogenicity Assessment sample collected on 04JAN2020 for the Participant Decision Visit, however, the Collection Date recorded here is 04JAN2021. Please confirm the correct Collection Date in the query response and update if appropriate. ' (Site from DM).	(b) (4), (b) (6)	13 Jan 2021 22:53:02
Query 'Per GCL Lab Reconciliation: Immunogenicity Assessment: Per GCL, there is an Immunogenicity Assessment sample collected on 04JAN2020 for the Participant Decision Visit, however, the Collection Date recorded here is 04JAN2021. Please confirm the correct Collection Date in the query response and update if appropriate. ' answered with 'The date is 04JAN2021' (Site from DM).	(b) (4), (b) (6)	13 Jan 2021 16:09:42
User opened query 'Per GCL Lab Reconciliation: Immunogenicity Assessment: Per GCL, there is an Immunogenicity Assessment sample collected on 04JAN2020 for the Participant Decision Visit, however, the Collection Date recorded here is 04JAN2021. Please confirm the correct Collection Date in the query response and update if appropriate. ' (Site from DM).	(b) (4), (b) (6)	12 Jan 2021 22:05:28
User entered '04 Jan 2021'	Bezuayehu Mandefro (b) (4)	04 Jan 2021 18:26:44



**US3632052**

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

**Form: Immunogenicity Assessment**

**Generated On: 10 Jun 2021 09:13:35**

[Collection time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:07:42
User signature succeeded.	Colleen Kelley (b) (4)	02 Apr 2021 20:59:30
DataPoint Verified.	(b) (4), (b) (6)	11 Mar 2021 19:57:51
User entered '13:03'	Bezuayehu Mandefro (b) (4)	04 Jan 2021 18:26:44

**US3632052**

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

**Form: Immunogenicity Assessment**

**Generated On: 10 Jun 2021 09:13:35**

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:07:42
User entered '04 Jan 2021 13:03'	System	04 Jan 2021 18:26:44

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

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 10 Jun 2021 09:13:35

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:07:42
User signature succeeded.	Colleen Kelley (b) (4)	02 Apr 2021 20:59:30
DataPoint Verified.	(b) (4), (b) (6)	11 Mar 2021 19:58:02
User entered 'Yes (Y)'	Bezuayehu Mandefro (b) (4)	04 Jan 2021 18:27:15

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

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 10 Jun 2021 09:13:35

Collection date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:07:42
User signature succeeded.	Colleen Kelley (b) (4)	02 Apr 2021 20:59:30
DataPoint Verified.	(b) (4), (b) (6)	11 Mar 2021 19:58:02
User entered '04 Jan 2021'	Bezuayehu Mandefro (b) (4)	04 Jan 2021 18:27:15

**US3632052**

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

**Form: Central Laboratory - Nasopharyngeal Swab (Single)**

**Generated On: 10 Jun 2021 09:13:35**

[Collection time \(00:00 - 23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:07:42
User signature succeeded.	Colleen Kelley (b) (4)	02 Apr 2021 20:59:30
DataPoint Verified.	(b) (4), (b) (6)	11 Mar 2021 19:58:02
User entered '13:11'	Bezuayehu Mandefro (b) (4)	04 Jan 2021 18:27:15

**US3632052**

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

**Form: Central Laboratory - Nasopharyngeal Swab (Single)**

**Generated On: 10 Jun 2021 09:13:35**

[Collection Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:07:42
User entered '04 Jan 2021 13:11'	System	04 Jan 2021 18:27:15

US3632052

Folder: Adverse Events

Form: Adverse Events Summary

Generated On: 10 Jun 2021 09:13:35

[Did the participant experience any adverse events?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 09:04:15
User signature succeeded.	Colleen Kelley (b) (4)	15 Mar 2021 12:25:04
DataPoint Verified.	(b) (4), (b) (6)	11 Mar 2021 19:59:09
User entered 'Yes (Y)' reason for change: Data Entry Error	Sarah Wiatrek (b) (4)	08 Feb 2021 20:26:55
DataPoint Un-verified.	Bezuayehu Mandefro (b) (4)	08 Feb 2021 17:27:01
User entered 'No (N)' reason for change: Data Entry Error	Bezuayehu Mandefro (b) (4)	08 Feb 2021 17:27:01
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 16:59:41
User entered 'Yes (Y)'	Bezuayehu Mandefro (b) (4)	15 Sep 2020 17:42:56

**US3632052**

**Folder: Adverse Events**

**Form: Adverse Events (3)**

**Generated On: 10 Jun 2021 09:13:35**

[AEID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:28:37



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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 09:13:35

[Adverse event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:28:37
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 16:14:31
User signature succeeded.	Colleen Kelley (b) (4)	02 Apr 2021 20:59:30
User closed query 'Per MM, Please confirm if this meets criteria for discontinuation of study treatment per protocol section 7.2 (Site from DM).	(b) (4), (b) (6)	31 Mar 2021 08:15:04
Query 'Per MM, Please confirm if this meets criteria for discontinuation of study treatment per protocol section 7.2	(b) (4), (b) (6)	30 Mar 2021 14:13:34
' answered with 'Does not meet criteria for discontinuation of study treatment' (Site from DM).		
User opened query 'Per MM, Please confirm if this meets criteria for discontinuation of study treatment per protocol section 7.2	(b) (4), (b) (6)	30 Mar 2021 07:42:20
' (Site from DM).		
User coded data point as SOC: Vascular disorders, HLGT: Vascular hypertensive disorders, HLT: Vascular hypertensive disorders NEC, PT: Hypertension, LLT: Hypertension worsened - version MedDRA\\23.0.	Coder Import (b) (4)	25 Mar 2021 16:40:30
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	(b) (4)	25 Mar 2021 16:40:30
Data point term sent to Coder	System	25 Mar 2021 16:39:53
Coding entries removed.	Kelly Likos (b) (4)	25 Mar 2021 16:39:15
Signature has been broken.	(b) (4)	
	Kelly Likos (b) (4)	25 Mar 2021 16:39:15
User entered 'WORSENING HYPERTENSION' reason for change: Data Entry Error	(b) (4)	
DataPoint Un-verified.	Kelly Likos (b) (4)	25 Mar 2021 16:39:15
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 19:34:42
	(b) (4), (b) (6)	
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 19:34:31
	(b) (4), (b) (6)	
User signature succeeded.	Colleen Kelley (b) (4)	15 Mar 2021 12:25:04
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 09:13:35

[Adverse event](#)

Audit	User	Time (GMT)
User closed query 'Per DM CLR: Please confirm if this AE is a worsening of HYPERTENSION noted in the MH eCRF. If yes, please update the AE term to reflect the term 'worsening or exacerbation' and ensure any Con Med indications are updated if required. Otherwise, If this is a duplicate please confirm if it meets the AE reporting criteria. ' (Site from DM).	(b) (4), (b) (6)	12 Mar 2021 16:24:24
User coded data point as SOC: Investigations, HLGT: Cardiac and vascular investigations (excl enzyme tests), HLT: Vascular tests NEC (incl blood pressure), PT: Blood pressure increased, LLT: Increased blood pressure - version MedDRA\\23.0.	Coder Import (b) (4)	11 Mar 2021 14:51:49
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	(b) (4)	11 Mar 2021 14:51:49
Data point term sent to Coder	System	11 Mar 2021 14:50:54
Query 'Per DM CLR: Please confirm if this AE is a worsening of HYPERTENSION noted in the MH eCRF. If yes, please update the AE term to reflect the term 'worsening or exacerbation' and ensure any Con Med indications are updated if required. Otherwise, If this is a duplicate please confirm if it meets the AE reporting criteria.	(b) (4), (b) (6)	11 Mar 2021 14:50:42
' answered with 'Updated' (Site from DM).		
Coding entries removed.	(b) (4), (b) (6)	11 Mar 2021 14:50:27
User entered 'Worsening BLOOD PRESSURE' reason for change: Data Entry Error	(b) (4), (b) (6)	11 Mar 2021 14:50:27
User opened query 'Per DM CLR: Please confirm if this AE is a worsening of HYPERTENSION noted in the MH eCRF. If yes, please update the AE term to reflect the term 'worsening or exacerbation' and ensure any Con Med indications are updated if required. Otherwise, If this is a duplicate please confirm if it meets the AE reporting criteria.	(b) (4), (b) (6)	08 Mar 2021 07:11:33
' (Site from DM).		

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 09:13:35

[Adverse event](#)

Audit	User	Time (GMT)
User coded data point as SOC: Investigations, HLT: Cardiac and vascular investigations (excl enzyme tests), HLT: Vascular tests NEC (incl blood pressure), PT: Blood pressure increased, LLT: Increased blood pressure - version MedDRA\\23.0.	Coder Import (b) (4)	08 Feb 2021 20:30:43
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	08 Feb 2021 20:30:43
Data point term sent to Coder	System	08 Feb 2021 20:30:12
User entered 'ELEVATED BLOOD PRESSURE'	Sarah Wiatrek (b) (4)	08 Feb 2021 20:29:15

**US3632052**

**Folder: Adverse Events**

**Form: Adverse Events (3)**

**Generated On: 10 Jun 2021 09:13:35**

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:28:37
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 19:34:31
User signature succeeded.	Colleen Kelley (b) (4)	15 Mar 2021 12:25:04
User entered 'No (N)'	(b) (4) Sarah Wiatrek (b) (4) (b) (4)	08 Feb 2021 20:29:15

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**Folder: Adverse Events**

**Form: Adverse Events (3)**

**Generated On: 10 Jun 2021 09:13:35**

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:28:37
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 19:34:31
User signature succeeded.	Colleen Kelley (b) (4)	15 Mar 2021 12:25:04
User entered 'No (N)'	(b) (4) Sarah Wiatrek (b) (4) (b) (4)	08 Feb 2021 20:29:15

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**Folder: Adverse Events**

**Form: Adverse Events (3)**

**Generated On: 10 Jun 2021 09:13:35**

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:28:37
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 19:34:31
User signature succeeded.	Colleen Kelley (b) (4)	15 Mar 2021 12:25:04
User entered 'No (N)'	(b) (4) Sarah Wiatrek (b) (4) (b) (4)	08 Feb 2021 20:29:15

**US3632052**

**Folder: Adverse Events**

**Form: Adverse Events (3)**

**Generated On: 10 Jun 2021 09:13:35**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:28:37
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 19:34:31
User signature succeeded.	Colleen Kelley (b) (4)	15 Mar 2021 12:25:04
User entered '8 Sep 2020'	(b) (4) Sarah Wiatrek (b) (4) (b) (4)	08 Feb 2021 20:29:15

US3632052

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 09:13:35

Start time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:28:37
User signature succeeded.	Colleen Kelley (b) (4)	22 Apr 2021 15:40:44
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 19:51:13
User closed query 'Per CDM: Start time is 00:00 which is prior to Exposure (11:02) on Visit 1 Day 1 and relationship to investigational product is related. Please review if the AE started after the first dose and update as appropriate per CCGs. If start time is unknown, then please leave this field empty. Thank you. ' (Site from DM).	(b) (4), (b) (6)	06 Apr 2021 09:50:46
User closed query 'Data is required. Please provide.' (Site from System).	(b) (4), (b) (6)	06 Apr 2021 09:49:59
Query 'Data is required. Please provide.' answered with 'Time of unset unknown' (Site from System).	(b) (4), (b) (6)	05 Apr 2021 14:26:55
Query 'Per CDM: Start time is 00:00 which is prior to Exposure (11:02) on Visit 1 Day 1 and relationship to investigational product is related. Please review if the AE started after the first dose and update as appropriate per CCGs. If start time is unknown, then please leave this field empty. Thank you. ' answered with 'Time of onset unknown' (Site from DM).	(b) (4), (b) (6)	05 Apr 2021 14:26:15
User opened query 'Data is required. Please provide.' (Site from System).	System	05 Apr 2021 14:25:44
DataPoint Un-verified.	(b) (4), (b) (6)	05 Apr 2021 14:25:44
Signature has been broken.	(b) (4), (b) (6)	05 Apr 2021 14:25:44
User entered empty; reason for change Data Entry Error	(b) (4), (b) (6)	05 Apr 2021 14:25:44
User opened query 'Per CDM: Start time is 00:00 which is prior to Exposure (11:02) on Visit 1 Day 1 and relationship to investigational product is related. Please review if the AE started after the first dose and update as appropriate per CCGs. If start time is unknown, then please leave this field empty. Thank you. ' (Site from DM).	(b) (4), (b) (6)	05 Apr 2021 11:40:15

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EAB) (1725)

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**US3632052**

**Folder: Adverse Events**

**Form: Adverse Events (3)**

**Generated On: 10 Jun 2021 09:13:35**

[Start time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 19:34:31
User signature succeeded.	Colleen Kelley (b) (4)	15 Mar 2021 12:25:04
User closed query 'Data is required. Please provide.' (Site from System).	System	08 Feb 2021 20:29:35
User entered '00:00' reason for change: Data Entry Error	Sarah Wiatrek (b) (4)	08 Feb 2021 20:29:35
User opened query 'Data is required. Please provide.' (Site from System).	System	08 Feb 2021 20:29:15
User entered empty.	Sarah Wiatrek (b) (4)	08 Feb 2021 20:29:15

**US3632052**

**Folder: Adverse Events**

**Form: Adverse Events (3)**

**Generated On: 10 Jun 2021 09:13:35**

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:28:37
User entered empty.	System	05 Apr 2021 14:25:44
User entered '8 Sep 2020 00:00'	System	08 Feb 2021 20:29:35
User entered empty.	System	08 Feb 2021 20:29:15

**US3632052**

**Folder: Adverse Events**

**Form: Adverse Events (3)**

**Generated On: 10 Jun 2021 09:13:35**

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:28:37
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 19:34:31
User signature succeeded.	Colleen Kelley (b) (4)	15 Mar 2021 12:25:04
User entered 'No (N)'	(b) (4) Sarah Wiatrek (b) (4) (b) (4)	08 Feb 2021 20:29:15

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**Folder: Adverse Events**

**Form: Adverse Events (3)**

**Generated On: 10 Jun 2021 09:13:35**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:28:37
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 19:34:31
User signature succeeded.	Colleen Kelley (b) (4)	15 Mar 2021 12:25:04
User entered '6 Oct 2020'	Sarah Wiatrek (b) (4)	08 Feb 2021 20:29:15

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 09:13:35

End time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:28:37
User signature succeeded.	Colleen Kelley (b) (4)	22 Apr 2021 15:40:44
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 19:51:18
User closed query 'Data is required. Please provide.' (Site from System).	(b) (4), (b) (6)	06 Apr 2021 09:50:03
Query 'Data is required. Please provide.' answered with 'Time of unset unknown ' (Site from System).	(b) (4), (b) (6)	05 Apr 2021 14:27:25
User opened query 'Data is required. Please provide.' (Site from System).	System	05 Apr 2021 14:25:44
DataPoint Un-verified.	(b) (4), (b) (6)	05 Apr 2021 14:25:44
Signature has been broken.	(b) (4), (b) (6)	05 Apr 2021 14:25:44
User entered empty; reason for change Data Entry Error	(b) (4), (b) (6)	05 Apr 2021 14:25:44
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 19:34:31
User signature succeeded.	Colleen Kelley (b) (4)	15 Mar 2021 12:25:04
User closed query 'Data is required. Please provide.' (Site from System).	System	08 Feb 2021 20:29:35
User entered '00:00' reason for change: Data Entry Error	Sarah Wiatrek (b) (4)	08 Feb 2021 20:29:35
User opened query 'Data is required. Please provide.' (Site from System).	System	08 Feb 2021 20:29:15
User entered empty.	Sarah Wiatrek (b) (4)	08 Feb 2021 20:29:15

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**Folder: Adverse Events**

**Form: Adverse Events (3)**

**Generated On: 10 Jun 2021 09:13:35**

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:28:37
User entered empty.	System	05 Apr 2021 14:25:44
User entered '6 Oct 2020 00:00'	System	08 Feb 2021 20:29:35
User entered empty.	System	08 Feb 2021 20:29:15

**US3632052**

**Folder: Adverse Events**

**Form: Adverse Events (3)**

**Generated On: 10 Jun 2021 09:13:35**

[Severity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:28:37
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 19:34:31
User signature succeeded.	Colleen Kelley (b) (4)	15 Mar 2021 12:25:04
User entered 'Grade 3/Severe (Grade 3/Severe)'	Sarah Wiatrek (b) (4)	08 Feb 2021 20:29:15

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 09:13:35

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:28:37
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 19:34:31
User signature succeeded.	Colleen Kelley (b) (4)	15 Mar 2021 12:25:04
User entered 'No (N)'	(b) (4) Sarah Wiatrek (b) (4) (b) (4)	08 Feb 2021 20:29:15



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**Folder: Adverse Events**

**Form: Adverse Events (3)**

**Generated On: 10 Jun 2021 09:13:35**

[Death](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:28:37
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 19:34:31
User signature succeeded.	Colleen Kelley (b) (4)	15 Mar 2021 12:25:04
User entered '0'	(b) (4) Sarah Wiatrek (b) (4) (b) (4)	08 Feb 2021 20:29:15

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**Folder: Adverse Events**

**Form: Adverse Events (3)**

**Generated On: 10 Jun 2021 09:13:35**

[Life threatening](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:28:37
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 19:34:31
User signature succeeded.	Colleen Kelley (b) (4)	15 Mar 2021 12:25:04
User entered '0'	(b) (4) Sarah Wiatrek (b) (4) (b) (4)	08 Feb 2021 20:29:15

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**Folder: Adverse Events**

**Form: Adverse Events (3)**

**Generated On: 10 Jun 2021 09:13:35**

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:28:37
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 19:34:31
User signature succeeded.	Colleen Kelley (b) (4)	15 Mar 2021 12:25:04
User entered '0'	Sarah Wiatrek (b) (4)	08 Feb 2021 20:29:15

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**Folder: Adverse Events**

**Form: Adverse Events (3)**

**Generated On: 10 Jun 2021 09:13:35**

**Hospital Admission Date (dd MMM yyyy)**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:28:37
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 19:34:31
User signature succeeded.	Colleen Kelley (b) (4)	15 Mar 2021 12:25:04
User entered empty.	Sarah Wiatrek (b) (4)	08 Feb 2021 20:29:15

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**Folder: Adverse Events**

**Form: Adverse Events (3)**

**Generated On: 10 Jun 2021 09:13:35**

[Hospital Discharge Date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:28:37
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 19:34:31
User signature succeeded.	Colleen Kelley (b) (4)	15 Mar 2021 12:25:04
User entered empty.	Sarah Wiatrek (b) (4)	08 Feb 2021 20:29:15

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**Folder: Adverse Events**

**Form: Adverse Events (3)**

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[Admitted to ICU?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:28:37
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 19:34:31
User signature succeeded.	Colleen Kelley (b) (4)	15 Mar 2021 12:25:04
User entered empty.	Sarah Wiatrek (b) (4)	08 Feb 2021 20:29:15

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**Folder: Adverse Events**

**Form: Adverse Events (3)**

**Generated On: 10 Jun 2021 09:13:35**

[Number of Days in ICU](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:28:37
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 19:34:31
User signature succeeded.	Colleen Kelley (b) (4)	15 Mar 2021 12:25:04
User entered empty.	Sarah Wiatrek (b) (4)	08 Feb 2021 20:29:15

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**Folder: Adverse Events**

**Form: Adverse Events (3)**

**Generated On: 10 Jun 2021 09:13:35**

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:28:37
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 19:34:31
User signature succeeded.	Colleen Kelley (b) (4)	15 Mar 2021 12:25:04
User entered '0'	Sarah Wiatrek (b) (4)	08 Feb 2021 20:29:15



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**Folder: Adverse Events**

**Form: Adverse Events (3)**

**Generated On: 10 Jun 2021 09:13:35**

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:28:37
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 19:34:31
User signature succeeded.	Colleen Kelley (b) (4)	15 Mar 2021 12:25:04
User entered '0'	Sarah Wiatrek (b) (4)	08 Feb 2021 20:29:15

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**Folder: Adverse Events**

**Form: Adverse Events (3)**

**Generated On: 10 Jun 2021 09:13:35**

[Other medically important event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:28:37
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 19:34:31
User signature succeeded.	Colleen Kelley (b) (4)	15 Mar 2021 12:25:04
User entered '0'	(b) (4) Sarah Wiatrek (b) (4) (b) (4)	08 Feb 2021 20:29:15

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**Folder: Adverse Events**

**Form: Adverse Events (3)**

**Generated On: 10 Jun 2021 09:13:35**

[Relationship to investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:28:37
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 19:34:31
User signature succeeded.	Colleen Kelley (b) (4)	15 Mar 2021 12:25:04
User entered 'Related (RELATED)'	(b) (4) Sarah Wiatrek (b) (4) (b) (4)	08 Feb 2021 20:29:15

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**Folder: Adverse Events**

**Form: Adverse Events (3)**

**Generated On: 10 Jun 2021 09:13:35**

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:28:37
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 19:34:31
User signature succeeded.	Colleen Kelley (b) (4)	15 Mar 2021 12:25:04
User entered 'Not Applicable (NOT APPLICABLE)'	Sarah Wiatrek (b) (4)	08 Feb 2021 20:29:15

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**Folder: Adverse Events**

**Form: Adverse Events (3)**

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[Action taken with investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:28:37
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 19:34:31
User signature succeeded.	Colleen Kelley (b) (4)	15 Mar 2021 12:25:04
User entered 'None (NONE)'	Sarah Wiatrek (b) (4)	08 Feb 2021 20:29:15

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**Folder: Adverse Events**

**Form: Adverse Events (3)**

**Generated On: 10 Jun 2021 09:13:35**

[None](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:28:37
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 19:34:31
User signature succeeded.	Colleen Kelley (b) (4)	15 Mar 2021 12:25:04
User entered 'I'	(b) (4) Sarah Wiatrek (b) (4) (b) (4)	08 Feb 2021 20:29:15

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**Folder: Adverse Events**

**Form: Adverse Events (3)**

**Generated On: 10 Jun 2021 09:13:35**

[Concomitant Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:28:37
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 19:34:31
User signature succeeded.	Colleen Kelley (b) (4)	15 Mar 2021 12:25:04
User entered '0'	(b) (4) Sarah Wiatrek (b) (4) (b) (4)	08 Feb 2021 20:29:15

**US3632052**

**Folder: Adverse Events**

**Form: Adverse Events (3)**

**Generated On: 10 Jun 2021 09:13:35**

[Concomitant Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:28:37
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 19:34:31
User signature succeeded.	Colleen Kelley (b) (4)	15 Mar 2021 12:25:04
User entered '0'	(b) (4) Sarah Wiatrek (b) (4) (b) (4)	08 Feb 2021 20:29:15



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**Folder: Adverse Events**

**Form: Adverse Events (3)**

**Generated On: 10 Jun 2021 09:13:35**

[Outcome](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:28:37
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 19:34:31
User signature succeeded.	Colleen Kelley (b) (4)	15 Mar 2021 12:25:04
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)'	(b) (4) Sarah Wiatrek (b) (4) (b) (4)	08 Feb 2021 20:29:15

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**Folder: Adverse Events**

**Form: Adverse Events (3)**

**Generated On: 10 Jun 2021 09:13:35**

[If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:28:37
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 19:34:31
User signature succeeded.	Colleen Kelley (b) (4)	15 Mar 2021 12:25:04
User entered empty.	Sarah Wiatrek (b) (4)	08 Feb 2021 20:29:15

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**Folder: Adverse Events**

**Form: Adverse Events (3)**

**Generated On: 10 Jun 2021 09:13:35**

[Narrative](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:28:37
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 19:34:31
User signature succeeded.	Colleen Kelley (b) (4)	15 Mar 2021 12:25:04
User entered empty.	Sarah Wiatrek (b) (4)	08 Feb 2021 20:29:15

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**Folder: Adverse Events**

**Form: Adverse Events (3)**

**Generated On: 10 Jun 2021 09:13:35**

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:28:37
User entered '0'	System	08 Feb 2021 20:29:15

**US3632052**

**Folder: Adverse Events**

**Form: Adverse Events (3)**

**Generated On: 10 Jun 2021 09:13:35**

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:28:37
User entered '0'	System	08 Feb 2021 20:29:15

**US3632052**

**Folder: Adverse Events**

**Form: Adverse Events (3)**

**Generated On: 10 Jun 2021 09:13:35**

[Admitted to ICU Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:28:37

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 09:13:35

[Adverse event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 19:34:33
User signature succeeded.	Colleen Kelley (b) (4)	15 Mar 2021 12:25:04
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 hand - version MedDRA\\23.0.	Coder Import (b) (4)	17 Feb 2021 10:37:57
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4)	17 Feb 2021 10:37:57
Data point term sent to Coder	System	15 Feb 2021 17:33:15
User entered 'Acute Thumb Joint Pain'	Sarah Wiatrek (b) (4)	15 Feb 2021 17:32:24
	(b) (4)	

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**Folder: Adverse Events**

**Form: Adverse Events (4)**

**Generated On: 10 Jun 2021 09:13:35**

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 19:34:33
User signature succeeded.	Colleen Kelley (b) (4)	15 Mar 2021 12:25:04
User entered 'No (N)'	Sarah Wiatrek (b) (4)	15 Feb 2021 17:32:24



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**Folder: Adverse Events**

**Form: Adverse Events (4)**

**Generated On: 10 Jun 2021 09:13:35**

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 19:34:33
User signature succeeded.	Colleen Kelley (b) (4)	15 Mar 2021 12:25:04
User entered 'No (N)'	Sarah Wiatrek (b) (4)	15 Feb 2021 17:32:24

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**Folder: Adverse Events**

**Form: Adverse Events (4)**

**Generated On: 10 Jun 2021 09:13:35**

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 19:34:33
User signature succeeded.	Colleen Kelley (b) (4)	15 Mar 2021 12:25:04
User entered 'No (N)'	Sarah Wiatrek (b) (4)	15 Feb 2021 17:32:24

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**Folder: Adverse Events**

**Form: Adverse Events (4)**

**Generated On: 10 Jun 2021 09:13:35**

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 19:34:33
User signature succeeded.	Colleen Kelley (b) (4)	15 Mar 2021 12:25:04
User entered '13 Oct 2020'	Sarah Wiatrek (b) (4)	15 Feb 2021 17:32:24

**US3632052**

**Folder: Adverse Events**

**Form: Adverse Events (4)**

**Generated On: 10 Jun 2021 09:13:35**

[Start time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 19:34:33
User signature succeeded.	Colleen Kelley (b) (4)	15 Mar 2021 12:25:04
User entered empty.	Sarah Wiatrek (b) (4)	15 Feb 2021 17:32:24

**US3632052**

**Folder: Adverse Events**

**Form: Adverse Events (4)**

**Generated On: 10 Jun 2021 09:13:35**

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	15 Feb 2021 17:32:24

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 09:13:35

[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 19:34:33
User signature succeeded.	Colleen Kelley (b) (4)	15 Mar 2021 12:25:04
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)	12 Mar 2021 16:24:40
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 'Participant reported joint pain is still ongoing. ' (Site from DM).	(b) (4), (b) (6)	11 Mar 2021 14:55:41
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)	08 Mar 2021 07:11:47
User entered 'Yes (Y)'	Sarah Wiatrek (b) (4)	15 Feb 2021 17:32:24

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**Folder: Adverse Events**

**Form: Adverse Events (4)**

**Generated On: 10 Jun 2021 09:13:35**

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 19:34:33
User signature succeeded.	Colleen Kelley (b) (4)	15 Mar 2021 12:25:04
User entered empty.	Sarah Wiatrek (b) (4)	15 Feb 2021 17:32:24

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**Folder: Adverse Events**

**Form: Adverse Events (4)**

**Generated On: 10 Jun 2021 09:13:35**

[End time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 19:34:33
User signature succeeded.	Colleen Kelley (b) (4)	15 Mar 2021 12:25:04
User entered empty.	Sarah Wiatrek (b) (4)	15 Feb 2021 17:32:24



**US3632052**

**Folder: Adverse Events**

**Form: Adverse Events (4)**

**Generated On: 10 Jun 2021 09:13:35**

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	15 Feb 2021 17:32:24

**US3632052**

**Folder: Adverse Events**

**Form: Adverse Events (4)**

**Generated On: 10 Jun 2021 09:13:35**

[Severity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 19:34:33
User signature succeeded.	Colleen Kelley (b) (4)	15 Mar 2021 12:25:04
User entered 'Grade 2/Moderate (Grade 2/Moderate)'	Sarah Wiatrek (b) (4)	15 Feb 2021 17:32:24

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 09:13:35

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 19:34:33
User signature succeeded.	Colleen Kelley (b) (4)	15 Mar 2021 12:25:04
User entered 'No (N)'	Sarah Wiatrek (b) (4)	15 Feb 2021 17:32:24

**US3632052**

**Folder: Adverse Events**

**Form: Adverse Events (4)**

**Generated On: 10 Jun 2021 09:13:35**

[Death](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 19:34:33
User signature succeeded.	Colleen Kelley (b) (4)	15 Mar 2021 12:25:04
User entered '0'	Sarah Wiatrek (b) (4)	15 Feb 2021 17:32:24

**US3632052**

**Folder: Adverse Events**

**Form: Adverse Events (4)**

**Generated On: 10 Jun 2021 09:13:35**

[Life threatening](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 19:34:33
User signature succeeded.	Colleen Kelley (b) (4)	15 Mar 2021 12:25:04
User entered '0'	Sarah Wiatrek (b) (4)	15 Feb 2021 17:32:24

**US3632052**

**Folder: Adverse Events**

**Form: Adverse Events (4)**

**Generated On: 10 Jun 2021 09:13:35**

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 19:34:33
User signature succeeded.	Colleen Kelley (b) (4)	15 Mar 2021 12:25:04
User entered '0'	Sarah Wiatrek (b) (4)	15 Feb 2021 17:32:24

**US3632052**

**Folder: Adverse Events**

**Form: Adverse Events (4)**

**Generated On: 10 Jun 2021 09:13:35**

**Hospital Admission Date** (*dd MMM yyyy*)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 19:34:33
User signature succeeded.	Colleen Kelley (b) (4)	15 Mar 2021 12:25:04
User entered empty.	Sarah Wiatrek (b) (4)	15 Feb 2021 17:32:24

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 09:13:35

Hospital Discharge Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 19:34:33
User signature succeeded.	Colleen Kelley (b) (4)	15 Mar 2021 12:25:04
User entered empty.	Sarah Wiatrek (b) (4)	15 Feb 2021 17:32:24



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**Folder: Adverse Events**

**Form: Adverse Events (4)**

**Generated On: 10 Jun 2021 09:13:35**

[Admitted to ICU?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 19:34:33
User signature succeeded.	Colleen Kelley (b) (4)	15 Mar 2021 12:25:04
User entered empty.	Sarah Wiatrek (b) (4)	15 Feb 2021 17:32:24

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**Folder: Adverse Events**

**Form: Adverse Events (4)**

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[Number of Days in ICU](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 19:34:33
User signature succeeded.	Colleen Kelley (b) (4)	15 Mar 2021 12:25:04
User entered empty.	Sarah Wiatrek (b) (4)	15 Feb 2021 17:32:24

**US3632052**

**Folder: Adverse Events**

**Form: Adverse Events (4)**

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[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 19:34:33
User signature succeeded.	Colleen Kelley (b) (4)	15 Mar 2021 12:25:04
User entered '0'	Sarah Wiatrek (b) (4)	15 Feb 2021 17:32:24

**US3632052**

**Folder: Adverse Events**

**Form: Adverse Events (4)**

**Generated On: 10 Jun 2021 09:13:35**

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 19:34:33
User signature succeeded.	Colleen Kelley (b) (4)	15 Mar 2021 12:25:04
User entered '0'	Sarah Wiatrek (b) (4)	15 Feb 2021 17:32:24

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Folder: Adverse Events

Form: Adverse Events (4)

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[Other medically important event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 19:34:33
User signature succeeded.	Colleen Kelley (b) (4)	15 Mar 2021 12:25:04
User entered '0'	Sarah Wiatrek (b) (4)	15 Feb 2021 17:32:24

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**Folder: Adverse Events**

**Form: Adverse Events (4)**

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[Relationship to investigational product](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 19:34:33
User signature succeeded.	Colleen Kelley (b) (4)	15 Mar 2021 12:25:04
User entered 'Not Related (NOT RELATED)'	Sarah Wiatrek (b) (4)	15 Feb 2021 17:32:24

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**Folder: Adverse Events**

**Form: Adverse Events (4)**

**Generated On: 10 Jun 2021 09:13:35**

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 19:34:33
User signature succeeded.	Colleen Kelley (b) (4)	15 Mar 2021 12:25:04
User entered 'Not Related (NOT RELATED)'	Sarah Wiatrek (b) (4)	15 Feb 2021 17:32:24

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**Folder: Adverse Events**

**Form: Adverse Events (4)**

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[Action taken with investigational product](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 19:34:33
User signature succeeded.	Colleen Kelley (b) (4)	15 Mar 2021 12:25:04
User entered 'Not Applicable (NOT APPLICABLE)'	Sarah Wiatrek (b) (4)	15 Feb 2021 17:32:24



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**Folder: Adverse Events**

**Form: Adverse Events (4)**

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[None](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 19:34:33
User signature succeeded.	Colleen Kelley (b) (4)	15 Mar 2021 12:25:04
User entered '0'	Sarah Wiatrek (b) (4)	15 Feb 2021 17:32:24

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**Folder: Adverse Events**

**Form: Adverse Events (4)**

**Generated On: 10 Jun 2021 09:13:35**

[Concomitant Medication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 19:34:33
User signature succeeded.	Colleen Kelley (b) (4)	15 Mar 2021 12:25:04
User entered 'I'	Sarah Wiatrek (b) (4)	15 Feb 2021 17:32:24

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**Folder: Adverse Events**

**Form: Adverse Events (4)**

**Generated On: 10 Jun 2021 09:13:35**

[Concomitant Procedure](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 19:34:33
User signature succeeded.	Colleen Kelley (b) (4)	15 Mar 2021 12:25:04
User entered '0'	Sarah Wiatrek (b) (4)	15 Feb 2021 17:32:24

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**Folder: Adverse Events**

**Form: Adverse Events (4)**

**Generated On: 10 Jun 2021 09:13:35**

[Outcome](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 19:34:33
User signature succeeded.	Colleen Kelley (b) (4)	15 Mar 2021 12:25:04
User entered 'Not Recovered/Not Resolved (NOT RECOVERED/NOT RESOLVED)'	Sarah Wiatrek (b) (4)	15 Feb 2021 17:32:24

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**Folder: Adverse Events**

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[If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 19:34:33
User signature succeeded.	Colleen Kelley (b) (4)	15 Mar 2021 12:25:04
User entered empty.	Sarah Wiatrek (b) (4)	15 Feb 2021 17:32:24

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**Folder: Adverse Events**

**Form: Adverse Events (4)**

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[Narrative](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 19:34:33
User signature succeeded.	Colleen Kelley (b) (4)	15 Mar 2021 12:25:04
User entered empty.	Sarah Wiatrek (b) (4)	15 Feb 2021 17:32:24

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**Folder: Adverse Events**

**Form: Adverse Events (4)**

**Generated On: 10 Jun 2021 09:13:35**

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '0'	System	15 Feb 2021 17:32:24

**US3632052**

**Folder: Adverse Events**

**Form: Adverse Events (4)**

**Generated On: 10 Jun 2021 09:13:35**

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '0'	System	15 Feb 2021 17:32:24



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**Folder: Adverse Events**

**Form: Adverse Events (6)**

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[AEID](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 19:54:33
User signature succeeded.	Colleen Kelley (b) (4)	02 Apr 2021 20:59:30
Reviewed for Safety.	(b) (4)	
	(b) (4), (b) (6)	02 Apr 2021 16:52:18
User entered		
'USA-US120-2021-mRNA-1273-P301000005'	System	02 Apr 2021 16:51:27
User entered 'New'	(b) (4), (b) (6)	02 Apr 2021 16:51:27

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Folder: Adverse Events

Form: Adverse Events (6)

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[Adverse event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 19:54:33
User signature succeeded.	Colleen Kelley (b) (4)	02 Apr 2021 20:59:30
User coded data point as SOC: Neoplasms benign, malignant and unspecified (incl cysts and polyps), HLGT: Reproductive neoplasms male malignant and unspecified, HLT: Prostatic neoplasms malignant, PT: Prostate cancer, LLT: Prostate cancer - version MedDRA\\23.0.	Coder Import (b) (4)	01 Apr 2021 19:39:24
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	01 Apr 2021 19:39:24
Data point term sent to Coder	System	01 Apr 2021 19:38:30
User entered 'prostate cancer'	(b) (4), (b) (6)	01 Apr 2021 19:38:03

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**Folder: Adverse Events**

**Form: Adverse Events (6)**

**Generated On: 10 Jun 2021 09:13:35**

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 19:54:33
User signature succeeded.	Colleen Kelley (b) (4)	02 Apr 2021 20:59:30
User entered 'Yes (Y)'	(b) (4), (b) (6)	01 Apr 2021 19:38:03

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**Folder: Adverse Events**

**Form: Adverse Events (6)**

**Generated On: 10 Jun 2021 09:13:35**

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 19:54:33
User signature succeeded.	Colleen Kelley (b) (4)	02 Apr 2021 20:59:30
User entered 'No (N)'	(b) (4), (b) (6)	01 Apr 2021 19:38:03

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**Folder: Adverse Events**

**Form: Adverse Events (6)**

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[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 19:54:33
User signature succeeded.	Colleen Kelley (b) (4)	02 Apr 2021 20:59:30
User entered 'No (N)'	(b) (4), (b) (6)	01 Apr 2021 19:38:03

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Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 09:13:35

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User closed query 'PV Query: Since the event onset date should be the date when first signs/symptoms appeared or in this case when the event was first found (PSA 4.5 in Nov 2020). Therefore, kindly consider updating the event onset date to the date, when the first sign of the event was found. ' (Site from Safety). DataPoint Verified.	(b) (4), (b) (6)	09 Apr 2021 13:24:31
	(b) (4), (b) (6)	08 Apr 2021 19:54:33
Query 'PV Query: Since the event onset date should be the date when first signs/symptoms appeared or in this case when the event was first found (PSA 4.5 in Nov 2020). Therefore, kindly consider updating the event onset date to the date, when the first sign of the event was found. ' answered with 'The participant was not diagnosed with prostate cancer until March 22. It was simply elevated PSA until official diagnosis.' (Site from Safety).	(b) (4), (b) (6)	08 Apr 2021 17:50:46
User opened query 'PV Query: Since the event onset date should be the date when first signs/symptoms appeared or in this case when the event was first found (PSA 4.5 in Nov 2020). Therefore, kindly consider updating the event onset date to the date, when the first sign of the event was found. ' (Site from Safety).	(b) (4), (b) (6)	08 Apr 2021 15:55:33
User signature succeeded.	Colleen Kelley (b) (4)	02 Apr 2021 20:59:30
	(b) (4)	
User entered '22 Mar 2021'	(b) (4), (b) (6)	01 Apr 2021 19:38:03

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**Folder: Adverse Events**

**Form: Adverse Events (6)**

**Generated On: 10 Jun 2021 09:13:35**

[Start time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 19:54:33
User signature succeeded.	Colleen Kelley (b) (4)	02 Apr 2021 20:59:30
User entered empty.	(b) (4) (b) (4), (b) (6)	01 Apr 2021 19:38:03

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**Folder: Adverse Events**

**Form: Adverse Events (6)**

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[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	01 Apr 2021 19:38:03



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[Ongoing?](#)

Audit	User	Time (GMT)
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)	20 Apr 2021 21:44:51
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 'Not expected to resolve, planning for surveillance only at this time. No active treatment planned' (Site from Safety).	(b) (4), (b) (6)	19 Apr 2021 13:55:19
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)	16 Apr 2021 21:22:39
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.	(b) (4), (b) (6)	16 Apr 2021 21:22:30
2. Re-Query: PV Query: Please provide any relevant laboratory and diagnostic test results (biopsy report). Please include units and reference ranges if applicable.		
' canceled (Site from Safety).		
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.	(b) (4), (b) (6)	16 Apr 2021 21:22:26
2. Re-Query: PV Query: Please provide any relevant laboratory and diagnostic test results (biopsy report). Please include units and reference ranges if applicable.		
' (Site from Safety).		
User closed 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)	09 Apr 2021 13:24:35
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 19:54:33

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[Ongoing?](#)

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. ' answered with 'The AE is still ongoing. No end date is available' (Site from Safety).	(b) (4), (b) (6)	08 Apr 2021 18:01:59
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)	08 Apr 2021 15:56:12
User signature succeeded.	Colleen Kelley (b) (4)	02 Apr 2021 20:59:30
User entered 'Yes (Y)'	(b) (4), (b) (6)	01 Apr 2021 19:38:03

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Folder: Adverse Events

Form: Adverse Events (6)

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If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
User closed 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 DM).	(b) (4), (b) (6)	29 Apr 2021 04:07:15
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. ' answered with 'AE is still ongoing' (Site from DM).	(b) (4), (b) (6)	27 Apr 2021 13:56:46
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 DM).	(b) (4), (b) (6)	23 Apr 2021 18:03:05
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 19:54:33
User signature succeeded.	Colleen Kelley (b) (4)	02 Apr 2021 20:59:30
User entered empty.	(b) (4), (b) (6)	01 Apr 2021 19:38:03

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**Folder: Adverse Events**

**Form: Adverse Events (6)**

**Generated On: 10 Jun 2021 09:13:35**

[End time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 19:54:33
User signature succeeded.	Colleen Kelley (b) (4)	02 Apr 2021 20:59:30
User entered empty.	(b) (4), (b) (6)	01 Apr 2021 19:38:03

**US3632052**

**Folder: Adverse Events**

**Form: Adverse Events (6)**

**Generated On: 10 Jun 2021 09:13:35**

[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.	(b) (4), (b) (6)	27 Apr 2021 22:01:51
' canceled (Site from Safety).		
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.	(b) (4), (b) (6)	16 Apr 2021 21:22:56
' (Site from Safety).		
User entered empty.	System	01 Apr 2021 19:38:03

**US3632052**

**Folder: Adverse Events**

**Form: Adverse Events (6)**

**Generated On: 10 Jun 2021 09:13:35**

[Severity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 19:54:33
User signature succeeded.	Colleen Kelley (b) (4)	02 Apr 2021 20:59:30
User entered 'Grade 3/Severe (Grade 3/Severe)'	(b) (4) (b) (4), (b) (6)	01 Apr 2021 19:38:03

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**Folder: Adverse Events**

**Form: Adverse Events (6)**

**Generated On: 10 Jun 2021 09:13:35**

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 19:54:33
User signature succeeded.	Colleen Kelley (b) (4)	02 Apr 2021 20:59:30
User entered 'Yes (Y)'	(b) (4), (b) (6)	01 Apr 2021 19:38:03

**US3632052**

**Folder: Adverse Events**

**Form: Adverse Events (6)**

**Generated On: 10 Jun 2021 09:13:35**

[Death](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 19:54:33
User signature succeeded.	Colleen Kelley (b) (4)	02 Apr 2021 20:59:30
User entered '0'	(b) (4), (b) (6)	01 Apr 2021 19:38:03



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[Life threatening](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 19:54:33
User signature succeeded.	Colleen Kelley (b) (4)	02 Apr 2021 20:59:30
User entered '0'	(b) (4), (b) (6)	01 Apr 2021 19:38:03

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Form: Adverse Events (6)

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[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 19:54:33
User closed query 'Requires inpatient or prolongation of existing Hospitalization is not checked, but hospitalization data has been provided. Please correct.' (Site from System).	(b) (4), (b) (6)	04 Apr 2021 06:10:41
User signature succeeded.	Colleen Kelley (b) (4)	02 Apr 2021 20:59:30
Query 'Requires inpatient or prolongation of existing Hospitalization is not checked, but hospitalization data has been provided. Please correct.' answered with 'As stated in narrative, there has been no inpatient hospitalization as a result of new diagnosis. ' (Site from System).	(b) (4), (b) (6)	01 Apr 2021 19:40:03
User opened query 'Requires inpatient or prolongation of existing Hospitalization is not checked, but hospitalization data has been provided. Please correct.' (Site from System).	System	01 Apr 2021 19:38:03
User entered '0'	(b) (4), (b) (6)	01 Apr 2021 19:38:03

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**Form: Adverse Events (6)**

**Generated On: 10 Jun 2021 09:13:35**

**Hospital Admission Date** (*dd MMM yyyy*)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 19:54:33
User signature succeeded.	Colleen Kelley (b) (4)	02 Apr 2021 20:59:30
User entered empty.	(b) (4), (b) (6)	01 Apr 2021 19:38:03

**US3632052**

**Folder: Adverse Events**

**Form: Adverse Events (6)**

**Generated On: 10 Jun 2021 09:13:35**

[Hospital Discharge Date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 19:54:33
User signature succeeded.	Colleen Kelley (b) (4)	02 Apr 2021 20:59:30
User entered empty.	(b) (4), (b) (6)	01 Apr 2021 19:38:03

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**Folder: Adverse Events**

**Form: Adverse Events (6)**

**Generated On: 10 Jun 2021 09:13:35**

[Admitted to ICU?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 19:54:33
User signature succeeded.	Colleen Kelley (b) (4)	02 Apr 2021 20:59:30
User entered 'No (N)'	(b) (4), (b) (6)	01 Apr 2021 19:38:03

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**Folder: Adverse Events**

**Form: Adverse Events (6)**

**Generated On: 10 Jun 2021 09:13:35**

[Number of Days in ICU](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 19:54:33
User signature succeeded.	Colleen Kelley (b) (4)	02 Apr 2021 20:59:30
User entered empty.	(b) (4), (b) (6)	01 Apr 2021 19:38:03

**US3632052**

**Folder: Adverse Events**

**Form: Adverse Events (6)**

**Generated On: 10 Jun 2021 09:13:35**

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 19:54:33
User signature succeeded.	Colleen Kelley (b) (4)	02 Apr 2021 20:59:30
User entered '0'	(b) (4), (b) (6)	01 Apr 2021 19:38:03

**US3632052**

**Folder: Adverse Events**

**Form: Adverse Events (6)**

**Generated On: 10 Jun 2021 09:13:35**

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 19:54:33
User signature succeeded.	Colleen Kelley (b) (4)	02 Apr 2021 20:59:30
User entered '0'	(b) (4), (b) (6)	01 Apr 2021 19:38:03



**US3632052**

**Folder: Adverse Events**

**Form: Adverse Events (6)**

**Generated On: 10 Jun 2021 09:13:35**

[Other medically important event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 19:54:33
User signature succeeded.	Colleen Kelley (b) (4)	02 Apr 2021 20:59:30
User entered 'I'	(b) (4), (b) (6)	01 Apr 2021 19:38:03

**US3632052**

**Folder: Adverse Events**

**Form: Adverse Events (6)**

**Generated On: 10 Jun 2021 09:13:35**

[Relationship to investigational product](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 19:54:33
User signature succeeded.	Colleen Kelley (b) (4)	02 Apr 2021 20:59:30
User entered 'Not Related (NOT RELATED)'	(b) (4) (b) (4), (b) (6)	01 Apr 2021 19:38:03

**US3632052**

**Folder: Adverse Events**

**Form: Adverse Events (6)**

**Generated On: 10 Jun 2021 09:13:35**

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 19:54:33
User signature succeeded.	Colleen Kelley (b) (4)	02 Apr 2021 20:59:30
User entered 'Not Related (NOT RELATED)'	(b) (4), (b) (6)	01 Apr 2021 19:38:03

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**Folder: Adverse Events**

**Form: Adverse Events (6)**

**Generated On: 10 Jun 2021 09:13:35**

[Action taken with investigational product](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 19:54:33
User signature succeeded.	Colleen Kelley (b) (4)	02 Apr 2021 20:59:30
User entered 'Not Applicable (NOT APPLICABLE)'	(b) (4), (b) (6)	01 Apr 2021 19:38:03

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**Folder: Adverse Events**

**Form: Adverse Events (6)**

**Generated On: 10 Jun 2021 09:13:35**

[None](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 19:54:33
User signature succeeded.	Colleen Kelley (b) (4)	02 Apr 2021 20:59:30
User entered 'I'	(b) (4), (b) (6)	01 Apr 2021 19:38:03

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**Folder: Adverse Events**

**Form: Adverse Events (6)**

**Generated On: 10 Jun 2021 09:13:35**

[Concomitant Medication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 19:54:33
User signature succeeded.	Colleen Kelley (b) (4)	02 Apr 2021 20:59:30
User entered '0'	(b) (4), (b) (6)	01 Apr 2021 19:38:03

**US3632052**

**Folder: Adverse Events**

**Form: Adverse Events (6)**

**Generated On: 10 Jun 2021 09:13:35**

[Concomitant Procedure](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 19:54:33
User signature succeeded.	Colleen Kelley (b) (4)	02 Apr 2021 20:59:30
User entered '0'	(b) (4), (b) (6)	01 Apr 2021 19:38:03

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Folder: Adverse Events

Form: Adverse Events (6)

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[Outcome](#)

Audit	User	Time (GMT)
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). DataPoint Verified.	(b) (4), (b) (6)	09 Apr 2021 13:25:23
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 'NO final outcome available. AE still ongoing' (Site from Safety).	(b) (4), (b) (6)	08 Apr 2021 18:02:25
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)	08 Apr 2021 15:55:52
User signature succeeded.	Colleen Kelley (b) (4)	02 Apr 2021 20:59:30
User entered 'Recovering/Resolving (RECOVERING/RESOLVING)'	(b) (4), (b) (6)	01 Apr 2021 19:38:03



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**Folder: Adverse Events**

**Form: Adverse Events (6)**

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[If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 19:54:33
User signature succeeded.	Colleen Kelley (b) (4)	02 Apr 2021 20:59:30
User entered empty.	(b) (4), (b) (6)	01 Apr 2021 19:38:03

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Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 09:13:35

[Narrative](#)

Audit	User	Time (GMT)
User signature succeeded.	Colleen Kelley (b) (4)	22 Apr 2021 15:40:44
User closed query 'Re-Query: PV Query: Please provide any relevant laboratory and diagnostic test results (biopsy report). Please include units and reference ranges if applicable. ' (Site from Safety). Query 'Re-Query: PV Query: Please provide any relevant laboratory and diagnostic test results (biopsy report). Please include units and reference ranges if applicable. ' answered with 'No relevant laboratory or diagnostic test results available at this time.' (Site from Safety).	(b) (4) (b) (4), (b) (6)	20 Apr 2021 21:44:56
User opened query 'Re-Query: PV Query: Please provide any relevant laboratory and diagnostic test results (biopsy report). Please include units and reference ranges if applicable. ' (Site from Safety). DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 17:31:10
User closed query 'PV Query: Please provide any relevant laboratory and diagnostic test results (biopsy report). Please include units and reference ranges if applicable. ' (Site from Safety).	(b) (4), (b) (6)	16 Apr 2021 21:23:03
User closed query 'PV Query: Did the subject have any family history of cancers? ' (Site from Safety). Query 'PV Query: Please provide any relevant laboratory and diagnostic test results (biopsy report). Please include units and reference ranges if applicable. ' answered with 'Diagnosis updates added' (Site from Safety).	(b) (4), (b) (6)	15 Apr 2021 16:16:20
Query 'PV Query: Did the subject have any family history of cancers? ' answered with 'Familial history updated' (Site from Safety). DataPoint Un-verified.	(b) (4), (b) (6)	14 Apr 2021 14:17:12
Signature has been broken.	(b) (4), (b) (6)	14 Apr 2021 14:17:09
	(b) (4), (b) (6)	13 Apr 2021 14:03:40
	(b) (4), (b) (6)	13 Apr 2021 14:03:16
	(b) (4), (b) (6)	13 Apr 2021 14:02:40
	(b) (4), (b) (6)	13 Apr 2021 14:02:40

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Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 09:13:35

[Narrative](#)

Audit	User	Time (GMT)
User entered 'DURING VISIT 4, PARTICIPANT REPORTED NEWLY DIAGNOSED PROSTATE CANCER AS OF 3/22/2021. PARTICIPANT STATED THAT THIS WAS DISCOVERED AFTER AN OUTPATIENT PROSTATE BIOPSY WAS PERFORMED ON 3/4/2021. THE BIOPSY WAS PROMPTED AFTER DISCOVERING A PSA OF 4.5 DURING A ROUTINE PHYSICAL AT PRIMARY MD IN NOVEMBER OF 2020. PARTICIPANT STATES THAT AT THIS TIME HE HAS NOT UNDERGONE ANY INTERVENTION RELATED TO THE DIAGNOSIS, AS HE HAS AN UPCOMING VISIT WITH THE DOCTOR TO DISCUSS OPTIONS AND DEVELOP A TREATMENT PLAN. NO INPATIENT HOSPITALIZATIONS HAVE OCCURRED RELATED TO THIS NEW DIAGNOSIS.  13APR2021: Participant reports (b) (4), (b) (6) had prostate cancer. Participant reports prostate cancer was diagnosed and new PSA was done and results were 7.25. Participant awaiting scans and next steps.' reason for change: Data Entry Error	(b) (4), (b) (6)	13 Apr 2021 14:02:40
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)	09 Apr 2021 13:24:59
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 19:54:33
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 'No treatment has been reported for the AE.' (Site from Safety).	(b) (4), (b) (6)	08 Apr 2021 18:04:51

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EAB) (1725)

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Folder: Adverse Events

Form: Adverse Events (6)

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[Narrative](#)

Audit	User	Time (GMT)
User opened query 'PV Query: Please provide any relevant laboratory and diagnostic test results (biopsy report). Please include units and reference ranges if applicable. ' (Site from Safety).	(b) (4), (b) (6)	08 Apr 2021 15:56:00
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)	08 Apr 2021 15:55:42
User opened query 'PV Query: Did the subject have any family history of cancers? ' (Site from Safety).	(b) (4), (b) (6)	08 Apr 2021 15:55:24
User signature succeeded.	Colleen Kelley (b) (4)	02 Apr 2021 20:59:30
User entered 'during visit 4, participant reported newly diagnosed prostate cancer as of 3/22/2021. participant stated that this was discovered after an outpatient prostate biopsy was performed on 3/4/2021. The biopsy was prompted after discovering a PSA of 4.5 during a routine physical at primary MD in November of 2020. participant states that at this time he has not undergone any intervention related to the diagnosis, as he has an upcoming visit with the doctor to discuss options and develop a treatment plan. No inpatient hospitalizations have occurred related to this new diagnosis.'	(b) (4) (b) (4), (b) (6)	01 Apr 2021 19:38:03

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**Folder: Adverse Events**

**Form: Adverse Events (6)**

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[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered 'I'	System	01 Apr 2021 19:38:03

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**Folder: Adverse Events**

**Form: Adverse Events (6)**

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[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered 'I'	System	01 Apr 2021 19:38:03

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**Folder: Adverse Events**

**Form: Adverse Events (6)**

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[Admitted to ICU Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '0'	System	01 Apr 2021 19:38:03

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Folder: Adverse Events

Form: Adverse Events (7)

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[Adverse event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 19:54:36
User signature succeeded.	Colleen Kelley (b) (4)	02 Apr 2021 20:59:30
User coded data point as SOC: Investigations, HLG: Cytogenetic investigations, HLT: Cell marker analyses, PT: Prostatic specific antigen increased, LLT: PSA increased - version MedDRA\\23.0.	Coder Import (b) (4)	01 Apr 2021 19:43:11
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	01 Apr 2021 19:43:11
Data point term sent to Coder	System	01 Apr 2021 19:42:40
User entered 'elevated PSA'	(b) (4), (b) (6)	01 Apr 2021 19:42:37



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**Folder: Adverse Events**

**Form: Adverse Events (7)**

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[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 19:54:36
User signature succeeded.	Colleen Kelley (b) (4)	02 Apr 2021 20:59:30
User entered 'Yes (Y)'	(b) (4), (b) (6)	01 Apr 2021 19:42:37

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**Folder: Adverse Events**

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[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 19:54:36
User signature succeeded.	Colleen Kelley (b) (4)	02 Apr 2021 20:59:30
User entered 'No (N)'	(b) (4), (b) (6)	01 Apr 2021 19:42:37

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**Folder: Adverse Events**

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[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 19:54:36
User signature succeeded.	Colleen Kelley (b) (4)	02 Apr 2021 20:59:30
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	01 Apr 2021 19:42:37

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**Folder: Adverse Events**

**Form: Adverse Events (7)**

**Generated On: 10 Jun 2021 09:13:35**

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 19:54:36
User signature succeeded.	Colleen Kelley (b) (4)	02 Apr 2021 20:59:30
User entered '01 Nov 2020'	(b) (4), (b) (6)	01 Apr 2021 19:42:37

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**Folder: Adverse Events**

**Form: Adverse Events (7)**

**Generated On: 10 Jun 2021 09:13:35**

[Start time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 19:54:36
User signature succeeded.	Colleen Kelley (b) (4)	02 Apr 2021 20:59:30
User entered empty.	(b) (4) (b) (4), (b) (6)	01 Apr 2021 19:42:37

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**Folder: Adverse Events**

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[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	01 Apr 2021 19:42:37

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[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 19:54:36
User signature succeeded.	Colleen Kelley (b) (4)	02 Apr 2021 20:59:30
User entered 'Yes (Y)'	(b) (4), (b) (6)	01 Apr 2021 19:42:37

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 19:54:36
User signature succeeded.	Colleen Kelley (b) (4)	02 Apr 2021 20:59:30
User entered empty.	(b) (4), (b) (6)	01 Apr 2021 19:42:37



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[End time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 19:54:36
User signature succeeded.	Colleen Kelley (b) (4)	02 Apr 2021 20:59:30
User entered empty.	(b) (4), (b) (6)	01 Apr 2021 19:42:37

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**Folder: Adverse Events**

**Form: Adverse Events (7)**

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[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	01 Apr 2021 19:42:37

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**Folder: Adverse Events**

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[Severity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 19:54:36
User signature succeeded.	Colleen Kelley (b) (4)	02 Apr 2021 20:59:30
User entered 'Grade 1/Mild (Grade 1/Mild)'	(b) (4) (b) (4), (b) (6)	01 Apr 2021 19:42:37

**US3632052**

**Folder: Adverse Events**

**Form: Adverse Events (7)**

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[Is the adverse event serious?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 19:54:36
User signature succeeded.	Colleen Kelley (b) (4)	02 Apr 2021 20:59:30
User entered 'No (N)'	(b) (4), (b) (6)	01 Apr 2021 19:42:37

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**Folder: Adverse Events**

**Form: Adverse Events (7)**

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[Death](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 19:54:36
User signature succeeded.	Colleen Kelley (b) (4)	02 Apr 2021 20:59:30
User entered '0'	(b) (4), (b) (6)	01 Apr 2021 19:42:37

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**Folder: Adverse Events**

**Form: Adverse Events (7)**

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[Life threatening](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 19:54:36
User signature succeeded.	Colleen Kelley (b) (4)	02 Apr 2021 20:59:30
User entered '0'	(b) (4), (b) (6)	01 Apr 2021 19:42:37

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**Folder: Adverse Events**

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[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 19:54:36
User signature succeeded.	Colleen Kelley (b) (4)	02 Apr 2021 20:59:30
User entered '0'	(b) (4), (b) (6)	01 Apr 2021 19:42:37

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**Folder: Adverse Events**

**Form: Adverse Events (7)**

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**Hospital Admission Date** (*dd MMM yyyy*)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 19:54:36
User signature succeeded.	Colleen Kelley (b) (4)	02 Apr 2021 20:59:30
User entered empty.	(b) (4) (b) (4), (b) (6)	01 Apr 2021 19:42:37



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**Folder: Adverse Events**

**Form: Adverse Events (7)**

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[Hospital Discharge Date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 19:54:36
User signature succeeded.	Colleen Kelley (b) (4)	02 Apr 2021 20:59:30
User entered empty.	(b) (4) (b) (4), (b) (6)	01 Apr 2021 19:42:37

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**Folder: Adverse Events**

**Form: Adverse Events (7)**

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[Admitted to ICU?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 19:54:36
User signature succeeded.	Colleen Kelley (b) (4)	02 Apr 2021 20:59:30
User entered empty.	(b) (4), (b) (6)	01 Apr 2021 19:42:37

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[Number of Days in ICU](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 19:54:36
User signature succeeded.	Colleen Kelley (b) (4)	02 Apr 2021 20:59:30
User entered empty.	(b) (4) (b) (4), (b) (6)	01 Apr 2021 19:42:37

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**Folder: Adverse Events**

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[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 19:54:36
User signature succeeded.	Colleen Kelley (b) (4)	02 Apr 2021 20:59:30
User entered '0'	(b) (4), (b) (6)	01 Apr 2021 19:42:37

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**Folder: Adverse Events**

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[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 19:54:36
User signature succeeded.	Colleen Kelley (b) (4)	02 Apr 2021 20:59:30
User entered '0'	(b) (4), (b) (6)	01 Apr 2021 19:42:37

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**Folder: Adverse Events**

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[Other medically important event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 19:54:36
User signature succeeded.	Colleen Kelley (b) (4)	02 Apr 2021 20:59:30
User entered '0'	(b) (4), (b) (6)	01 Apr 2021 19:42:37

**US3632052**

**Folder: Adverse Events**

**Form: Adverse Events (7)**

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[Relationship to investigational product](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 19:54:36
User signature succeeded.	Colleen Kelley (b) (4)	02 Apr 2021 20:59:30
User entered 'Not Related (NOT RELATED)'	(b) (4) (b) (4), (b) (6)	01 Apr 2021 19:42:37

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**Folder: Adverse Events**

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[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 19:54:36
User signature succeeded.	Colleen Kelley (b) (4)	02 Apr 2021 20:59:30
User entered 'Not Related (NOT RELATED)'	(b) (4) (b) (4), (b) (6)	01 Apr 2021 19:42:37



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**Folder: Adverse Events**

**Form: Adverse Events (7)**

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[Action taken with investigational product](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 19:54:36
User signature succeeded.	Colleen Kelley (b) (4)	02 Apr 2021 20:59:30
User entered 'None (NONE)'	(b) (4), (b) (6)	01 Apr 2021 19:42:37

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**Folder: Adverse Events**

**Form: Adverse Events (7)**

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[None](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 19:54:36
User signature succeeded.	Colleen Kelley (b) (4)	02 Apr 2021 20:59:30
User entered '0'	(b) (4), (b) (6)	01 Apr 2021 19:42:37

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**Folder: Adverse Events**

**Form: Adverse Events (7)**

**Generated On: 10 Jun 2021 09:13:35**

[Concomitant Medication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 19:54:36
User signature succeeded.	Colleen Kelley (b) (4)	02 Apr 2021 20:59:30
User entered '0'	(b) (4), (b) (6)	01 Apr 2021 19:42:37

**US3632052**

**Folder: Adverse Events**

**Form: Adverse Events (7)**

**Generated On: 10 Jun 2021 09:13:35**

[Concomitant Procedure](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 19:54:36
User signature succeeded.	Colleen Kelley (b) (4)	02 Apr 2021 20:59:30
User entered 'I'	(b) (4), (b) (6)	01 Apr 2021 19:42:37

**US3632052**

**Folder: Adverse Events**

**Form: Adverse Events (7)**

**Generated On: 10 Jun 2021 09:13:35**

[Outcome](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 19:54:36
User signature succeeded.	Colleen Kelley (b) (4)	02 Apr 2021 20:59:30
User entered 'Recovering/Resolving (RECOVERING/RESOLVING)'	(b) (4), (b) (6)	01 Apr 2021 19:42:37

**US3632052**

**Folder: Adverse Events**

**Form: Adverse Events (7)**

**Generated On: 10 Jun 2021 09:13:35**

[If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 19:54:36
User signature succeeded.	Colleen Kelley (b) (4)	02 Apr 2021 20:59:30
User entered empty.	(b) (4), (b) (6)	01 Apr 2021 19:42:37

**US3632052**

**Folder: Adverse Events**

**Form: Adverse Events (7)**

**Generated On: 10 Jun 2021 09:13:35**

[Narrative](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 19:54:36
User signature succeeded.	Colleen Kelley (b) (4)	02 Apr 2021 20:59:30
User entered empty.	(b) (4), (b) (6)	01 Apr 2021 19:42:37

**US3632052**

**Folder: Adverse Events**

**Form: Adverse Events (7)**

**Generated On: 10 Jun 2021 09:13:35**

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '0'	System	01 Apr 2021 19:42:37



**US3632052**

**Folder: Adverse Events**

**Form: Adverse Events (7)**

**Generated On: 10 Jun 2021 09:13:35**

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered 'I'	System	01 Apr 2021 19:42:37

**US3632052**

**Folder: Adverse Events**

**Form: Adverse Events (8)**

**Generated On: 10 Jun 2021 09:13:35**

[AEID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:28:51

US3632052

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 10 Jun 2021 09:13:35

[Adverse event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:28:51
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 19:54:44
User coded data point as SOC: General disorders and administration site conditions, HLGT: General system disorders NEC, HLT: Feelings and sensations NEC, PT: Sensation of foreign body, LLT: Globus feeling in pharynx - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	05 Apr 2021 10:32:37
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	05 Apr 2021 10:32:37
User signature succeeded.	Colleen Kelley (b) (4) (b) (4)	02 Apr 2021 20:59:30
Data point term sent to Coder	System	01 Apr 2021 19:47:44
User entered 'globus pharyngeus'	(b) (4), (b) (6)	01 Apr 2021 19:47:13

**US3632052**

**Folder: Adverse Events**

**Form: Adverse Events (8)**

**Generated On: 10 Jun 2021 09:13:35**

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:28:51
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 19:54:44
User signature succeeded.	Colleen Kelley (b) (4)	02 Apr 2021 20:59:30
User entered 'Yes (Y)'	(b) (4), (b) (6)	01 Apr 2021 19:47:13

**US3632052**

**Folder: Adverse Events**

**Form: Adverse Events (8)**

**Generated On: 10 Jun 2021 09:13:35**

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:28:51
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 19:54:44
User signature succeeded.	Colleen Kelley (b) (4)	02 Apr 2021 20:59:30
User entered 'No (N)'	(b) (4), (b) (6)	01 Apr 2021 19:47:13

**US3632052**

**Folder: Adverse Events**

**Form: Adverse Events (8)**

**Generated On: 10 Jun 2021 09:13:35**

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:28:51
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 19:54:44
User signature succeeded.	Colleen Kelley (b) (4)	02 Apr 2021 20:59:30
User entered 'No (N)'	(b) (4), (b) (6)	01 Apr 2021 19:47:13

**US3632052**

**Folder: Adverse Events**

**Form: Adverse Events (8)**

**Generated On: 10 Jun 2021 09:13:35**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:28:51
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 19:54:44
User signature succeeded.	Colleen Kelley (b) (4)	02 Apr 2021 20:59:30
User entered '01 Nov 2020'	(b) (4), (b) (6)	01 Apr 2021 19:47:13

**US3632052**

**Folder: Adverse Events**

**Form: Adverse Events (8)**

**Generated On: 10 Jun 2021 09:13:35**

[Start time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:28:51
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 19:54:44
User signature succeeded.	Colleen Kelley (b) (4)	02 Apr 2021 20:59:30
User entered empty.	(b) (4), (b) (6)	01 Apr 2021 19:47:13



**US3632052**

**Folder: Adverse Events**

**Form: Adverse Events (8)**

**Generated On: 10 Jun 2021 09:13:35**

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:28:51
User entered empty.	System	01 Apr 2021 19:47:13

**US3632052**

**Folder: Adverse Events**

**Form: Adverse Events (8)**

**Generated On: 10 Jun 2021 09:13:35**

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:28:51
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 19:54:44
User signature succeeded.	Colleen Kelley (b) (4)	02 Apr 2021 20:59:30
User entered 'No (N)'	(b) (4), (b) (6)	01 Apr 2021 19:47:13

US3632052

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 10 Jun 2021 09:13:35

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:28:51
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 19:54:44
User signature succeeded.	Colleen Kelley (b) (4)	02 Apr 2021 20:59:30
User closed query 'Outcome is not Recovered/Resolved, Recovered/Resolved with sequelae or Fatal, but End Date is provided. Please correct.' (Site from System).	(b) (4) System	01 Apr 2021 19:47:37
Query 'Outcome is not Recovered/Resolved, Recovered/Resolved with sequelae or Fatal, but End Date is provided. Please correct.' answered by data change (Site from System).	System	01 Apr 2021 19:47:37
User opened query 'Outcome is not Recovered/Resolved, Recovered/Resolved with sequelae or Fatal, but End Date is provided. Please correct.' (Site from System).	System	01 Apr 2021 19:47:13
User entered '01 Feb 2021'	(b) (4), (b) (6)	01 Apr 2021 19:47:13

**US3632052**

**Folder: Adverse Events**

**Form: Adverse Events (8)**

**Generated On: 10 Jun 2021 09:13:35**

[End time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:28:51
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 19:54:44
User signature succeeded.	Colleen Kelley (b) (4)	02 Apr 2021 20:59:30
User entered empty.	(b) (4), (b) (6)	01 Apr 2021 19:47:13

**US3632052**

**Folder: Adverse Events**

**Form: Adverse Events (8)**

**Generated On: 10 Jun 2021 09:13:35**

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:28:51
User entered empty.	System	01 Apr 2021 19:47:13

**US3632052**

**Folder: Adverse Events**

**Form: Adverse Events (8)**

**Generated On: 10 Jun 2021 09:13:35**

[Severity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:28:51
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 19:54:44
User signature succeeded.	Colleen Kelley (b) (4)	02 Apr 2021 20:59:30
User entered 'Grade 1/Mild (Grade 1/Mild)'	(b) (4), (b) (6)	01 Apr 2021 19:47:13

**US3632052**

**Folder: Adverse Events**

**Form: Adverse Events (8)**

**Generated On: 10 Jun 2021 09:13:35**

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:28:51
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 19:54:44
User signature succeeded.	Colleen Kelley (b) (4)	02 Apr 2021 20:59:30
User entered 'No (N)'	(b) (4), (b) (6)	01 Apr 2021 19:47:13

**US3632052**

**Folder: Adverse Events**

**Form: Adverse Events (8)**

**Generated On: 10 Jun 2021 09:13:35**

[Death](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:28:51
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 19:54:44
User signature succeeded.	Colleen Kelley (b) (4)	02 Apr 2021 20:59:30
User entered '0'	(b) (4), (b) (6)	01 Apr 2021 19:47:13



**US3632052**

**Folder: Adverse Events**

**Form: Adverse Events (8)**

**Generated On: 10 Jun 2021 09:13:35**

[Life threatening](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:28:51
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 19:54:44
User signature succeeded.	Colleen Kelley (b) (4)	02 Apr 2021 20:59:30
User entered '0'	(b) (4), (b) (6)	01 Apr 2021 19:47:13

**US3632052**

**Folder: Adverse Events**

**Form: Adverse Events (8)**

**Generated On: 10 Jun 2021 09:13:35**

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:28:51
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 19:54:44
User signature succeeded.	Colleen Kelley (b) (4)	02 Apr 2021 20:59:30
User entered '0'	(b) (4), (b) (6)	01 Apr 2021 19:47:13

**US3632052**

**Folder: Adverse Events**

**Form: Adverse Events (8)**

**Generated On: 10 Jun 2021 09:13:35**

**Hospital Admission Date** (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:28:51
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 19:54:44
User signature succeeded.	Colleen Kelley (b) (4)	02 Apr 2021 20:59:30
User entered empty.	(b) (4), (b) (6)	01 Apr 2021 19:47:13

**US3632052**

**Folder: Adverse Events**

**Form: Adverse Events (8)**

**Generated On: 10 Jun 2021 09:13:35**

**Hospital Discharge Date (dd MMM yyyy)**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:28:51
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 19:54:44
User signature succeeded.	Colleen Kelley (b) (4)	02 Apr 2021 20:59:30
User entered empty.	(b) (4), (b) (6)	01 Apr 2021 19:47:13

**US3632052**

**Folder: Adverse Events**

**Form: Adverse Events (8)**

**Generated On: 10 Jun 2021 09:13:35**

[Admitted to ICU?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:28:51
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 19:54:44
User signature succeeded.	Colleen Kelley (b) (4)	02 Apr 2021 20:59:30
User entered empty.	(b) (4), (b) (6)	01 Apr 2021 19:47:13

**US3632052**

**Folder: Adverse Events**

**Form: Adverse Events (8)**

**Generated On: 10 Jun 2021 09:13:35**

[Number of Days in ICU](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:28:51
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 19:54:44
User signature succeeded.	Colleen Kelley (b) (4)	02 Apr 2021 20:59:30
User entered empty.	(b) (4), (b) (6)	01 Apr 2021 19:47:13

**US3632052**

**Folder: Adverse Events**

**Form: Adverse Events (8)**

**Generated On: 10 Jun 2021 09:13:35**

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:28:51
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 19:54:44
User signature succeeded.	Colleen Kelley (b) (4)	02 Apr 2021 20:59:30
User entered '0'	(b) (4), (b) (6)	01 Apr 2021 19:47:13

**US3632052**

**Folder: Adverse Events**

**Form: Adverse Events (8)**

**Generated On: 10 Jun 2021 09:13:35**

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:28:51
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 19:54:44
User signature succeeded.	Colleen Kelley (b) (4)	02 Apr 2021 20:59:30
User entered '0'	(b) (4), (b) (6)	01 Apr 2021 19:47:13



**US3632052**

**Folder: Adverse Events**

**Form: Adverse Events (8)**

**Generated On: 10 Jun 2021 09:13:35**

[Other medically important event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:28:51
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 19:54:44
User signature succeeded.	Colleen Kelley (b) (4)	02 Apr 2021 20:59:30
User entered '0'	(b) (4), (b) (6)	01 Apr 2021 19:47:13

**US3632052**

**Folder: Adverse Events**

**Form: Adverse Events (8)**

**Generated On: 10 Jun 2021 09:13:35**

[Relationship to investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:28:51
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 19:54:44
User signature succeeded.	Colleen Kelley (b) (4)	02 Apr 2021 20:59:30
User entered 'Not Related (NOT RELATED)'	(b) (4), (b) (6)	01 Apr 2021 19:47:13

**US3632052**

**Folder: Adverse Events**

**Form: Adverse Events (8)**

**Generated On: 10 Jun 2021 09:13:35**

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:28:51
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 19:54:44
User signature succeeded.	Colleen Kelley (b) (4)	02 Apr 2021 20:59:30
User entered 'Not Related (NOT RELATED)'	(b) (4), (b) (6)	01 Apr 2021 19:47:13

**US3632052**

**Folder: Adverse Events**

**Form: Adverse Events (8)**

**Generated On: 10 Jun 2021 09:13:35**

[Action taken with investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:28:51
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 19:54:44
User signature succeeded.	Colleen Kelley (b) (4)	02 Apr 2021 20:59:30
User entered 'None (NONE)'	(b) (4), (b) (6)	01 Apr 2021 19:47:13

**US3632052**

**Folder: Adverse Events**

**Form: Adverse Events (8)**

**Generated On: 10 Jun 2021 09:13:35**

[None](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:28:51
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 19:54:44
User signature succeeded.	Colleen Kelley (b) (4)	02 Apr 2021 20:59:30
User entered '0'	(b) (4), (b) (6)	01 Apr 2021 19:47:13

**US3632052**

**Folder: Adverse Events**

**Form: Adverse Events (8)**

**Generated On: 10 Jun 2021 09:13:35**

[Concomitant Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:28:51
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 19:54:44
User signature succeeded.	Colleen Kelley (b) (4)	02 Apr 2021 20:59:30
User entered 'l'	(b) (4), (b) (6)	01 Apr 2021 19:47:13

**US3632052**

**Folder: Adverse Events**

**Form: Adverse Events (8)**

**Generated On: 10 Jun 2021 09:13:35**

[Concomitant Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:28:51
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 19:54:44
User signature succeeded.	Colleen Kelley (b) (4)	02 Apr 2021 20:59:30
User entered 'l'	(b) (4), (b) (6)	01 Apr 2021 19:47:13

**US3632052**

**Folder: Adverse Events**

**Form: Adverse Events (8)**

**Generated On: 10 Jun 2021 09:13:35**

[Outcome](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:28:51
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 19:54:44
User signature succeeded.	Colleen Kelley (b) (4)	02 Apr 2021 20:59:30
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)' reason for change:	(b) (4) (b) (4), (b) (6)	01 Apr 2021 19:47:37
Data Entry Error		
User entered 'Recovering/Resolving (RECOVERING/RESOLVING)'	(b) (4), (b) (6)	01 Apr 2021 19:47:13



**US3632052**

**Folder: Adverse Events**

**Form: Adverse Events (8)**

**Generated On: 10 Jun 2021 09:13:35**

[If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:28:51
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 19:54:44
User signature succeeded.	Colleen Kelley (b) (4)	02 Apr 2021 20:59:30
User entered empty.	(b) (4), (b) (6)	01 Apr 2021 19:47:13

**US3632052**

**Folder: Adverse Events**

**Form: Adverse Events (8)**

**Generated On: 10 Jun 2021 09:13:35**

[Narrative](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:28:51
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 19:54:44
User signature succeeded.	Colleen Kelley (b) (4)	02 Apr 2021 20:59:30
User entered empty.	(b) (4), (b) (6)	01 Apr 2021 19:47:13

**US3632052**

**Folder: Adverse Events**

**Form: Adverse Events (8)**

**Generated On: 10 Jun 2021 09:13:35**

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:28:51
User entered '0'	System	01 Apr 2021 19:47:13

**US3632052**

**Folder: Adverse Events**

**Form: Adverse Events (8)**

**Generated On: 10 Jun 2021 09:13:35**

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:28:51
User entered 'I'	System	01 Apr 2021 19:47:13

**US3632052**

**Folder: Adverse Events**

**Form: Adverse Events (8)**

**Generated On: 10 Jun 2021 09:13:35**

[Admitted to ICU Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:28:51

US3632052

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination Summary

Generated On: 10 Jun 2021 09:13:35

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 09:04:15
User signature succeeded.	Colleen Kelley (b) (4)	02 Apr 2021 20:59:30
User closed query 'Per source, Tylenol for headache on 12Nov2020 is listed on ConMeds list in source. Please add this entry to the ConMeds list in EDC.' (Site from CRA).	(b) (4), (b) (6)	10 Dec 2020 16:30:19
Query 'Per source, Tylenol for headache on 12Nov2020 is listed on ConMeds list in source. Please add this entry to the ConMeds list in EDC.' answered with 'Tylenol taken for headache on 12NOV2020 added to EDC.' (Site from CRA).	Catherine Abrams (b) (4)	23 Nov 2020 20:35:30
User opened query 'Per source, Tylenol for headache on 12Nov2020 is listed on ConMeds list in source. Please add this entry to the ConMeds list in EDC.' (Site from CRA).	(b) (4), (b) (6)	19 Nov 2020 18:01:02
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 17:03:34
User closed query 'Per CDM: On Diary Dose 2 ,Temperature_Day 1,Response noted. However, please consider to confirm the logline number of medication taken to treat pain or fever. Thank you.' (Site from DM).	(b) (4), (b) (6)	16 Oct 2020 08:47:03
Query 'Per CDM: On Diary Dose 2 ,Temperature_Day 1,Response noted. However, please consider to confirm the logline number of medication taken to treat pain or fever. Thank you.' answered with 'Log line 12' (Site from DM).	Kelly Likos (b) (4)	15 Oct 2020 17:56:15
User opened query 'Per CDM: On Diary Dose 2 ,Temperature_Day 1,Response noted. However, please consider to confirm the logline number of medication taken to treat pain or fever. Thank you.' (Site from DM).	(b) (4), (b) (6)	14 Oct 2020 09:30:47
User entered 'Yes (Y)'	(b) (4), (b) (6)	08 Sep 2020 23:07:57

US3632052

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 09:13:35

Name of Medication

Audit	User	Time (GMT)
User signature succeeded.	Colleen Kelley (b) (4)	12 Apr 2021 01:33:40
User coded data point as ATC: CARDIOVASCULAR SYSTEM, ATC: DIURETICS, ATC: LOW-CEILING DIURETICS, THIAZIDES, ATC: THIAZIDES, PLAIN, PRODUCT: HYDROCHLOROTHIAZIDE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	08 Apr 2021 19:43:48
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	08 Apr 2021 19:43:48
Data point term sent to Coder DataPoint activated with code reason code Data required.	System (b) (4), (b) (6)	08 Apr 2021 19:42:52 08 Apr 2021 19:42:29
Data point term sent to Coder DataPoint inactivated with code reason code Data not required.	System (b) (4), (b) (6)	08 Apr 2021 19:41:42 08 Apr 2021 19:41:29
Signature has been broken.	(b) (4), (b) (6)	08 Apr 2021 19:41:29
User signature succeeded.	Colleen Kelley (b) (4)	02 Apr 2021 20:59:30
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 17:04:01
User coded data point as ATC: CARDIOVASCULAR SYSTEM, ATC: DIURETICS, ATC: LOW-CEILING DIURETICS, THIAZIDES, ATC: THIAZIDES, PLAIN, PRODUCT: HYDROCHLOROTHIAZIDE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	09 Sep 2020 01:00:53
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	09 Sep 2020 01:00:53
Data point term sent to Coder User entered 'Hydrochlothiazide'	System (b) (4), (b) (6)	08 Sep 2020 23:09:43 08 Sep 2020 23:09:30

US3632052

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 09:13:35

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Colleen Kelley (b) (4)	12 Apr 2021 01:33:40
	(b) (4)	
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	08 Apr 2021 19:42:29
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	08 Apr 2021 19:41:29
Signature has been broken.	(b) (4), (b) (6)	08 Apr 2021 19:41:29
User signature succeeded.	Colleen Kelley (b) (4)	02 Apr 2021 20:59:30
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 17:04:04
User entered 'No (N)'	(b) (4), (b) (6)	08 Sep 2020 23:09:30



US3632052

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 09:13:35

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Colleen Kelley (b) (4)	12 Apr 2021 01:33:40
DataPoint activated with code reason code Data required.	(b) (4)	
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	08 Apr 2021 19:42:29
Signature has been broken.	(b) (4), (b) (6)	08 Apr 2021 19:41:29
User signature succeeded.	Colleen Kelley (b) (4)	02 Apr 2021 20:59:30
DataPoint Verified.	(b) (4)	
User entered 'hypertension'	(b) (4), (b) (6)	19 Nov 2020 17:04:07
		08 Sep 2020 23:09:30

US3632052

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 09:13:35

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Colleen Kelley (b) (4)	12 Apr 2021 01:33:40
	(b) (4)	
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	08 Apr 2021 19:42:29
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	08 Apr 2021 19:41:29
Signature has been broken.	(b) (4), (b) (6)	08 Apr 2021 19:41:29
User signature succeeded.	Colleen Kelley (b) (4)	02 Apr 2021 20:59:30
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 17:04:12
User entered '12.5'	(b) (4), (b) (6)	08 Sep 2020 23:09:30

US3632052

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 09:13:35

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Colleen Kelley (b) (4)	12 Apr 2021 01:33:40
DataPoint activated with code reason code Data required.	(b) (4)	
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	08 Apr 2021 19:42:29
Signature has been broken.	(b) (4), (b) (6)	08 Apr 2021 19:41:29
User signature succeeded.	Colleen Kelley (b) (4)	02 Apr 2021 20:59:30
DataPoint Verified.	(b) (4)	
User entered 'mg (mg)'	(b) (4), (b) (6)	19 Nov 2020 17:04:15
	(b) (4), (b) (6)	08 Sep 2020 23:09:30

US3632052

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 09:13:35

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Colleen Kelley (b) (4)	12 Apr 2021 01:33:40
DataPoint activated with code reason code Data required.	(b) (4)	
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	08 Apr 2021 19:42:29
Signature has been broken.	(b) (4), (b) (6)	08 Apr 2021 19:41:29
User signature succeeded.	Colleen Kelley (b) (4)	02 Apr 2021 20:59:30
DataPoint Verified.	(b) (4)	
User entered empty.	(b) (4), (b) (6)	19 Nov 2020 17:04:17
	(b) (4), (b) (6)	08 Sep 2020 23:09:30

US3632052

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 09:13:35

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Colleen Kelley (b) (4)	12 Apr 2021 01:33:40
DataPoint activated with code reason code Data required.	(b) (4)	
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	08 Apr 2021 19:42:29
Signature has been broken.	(b) (4), (b) (6)	08 Apr 2021 19:41:29
User signature succeeded.	Colleen Kelley (b) (4)	02 Apr 2021 20:59:30
DataPoint Verified.	(b) (4)	
User entered 'every other day (QOD)'	(b) (4), (b) (6)	19 Nov 2020 17:04:22
	(b) (4), (b) (6)	08 Sep 2020 23:09:30

US3632052

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 09:13:35

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Colleen Kelley (b) (4)	12 Apr 2021 01:33:40
DataPoint activated with code reason code Data required.	(b) (4)	
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	08 Apr 2021 19:42:29
Signature has been broken.	(b) (4), (b) (6)	08 Apr 2021 19:41:29
User signature succeeded.	Colleen Kelley (b) (4)	02 Apr 2021 20:59:30
DataPoint Verified.	(b) (4)	
User entered empty.	(b) (4), (b) (6)	19 Nov 2020 17:04:25
		08 Sep 2020 23:09:30

US3632052

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 09:13:35

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Colleen Kelley (b) (4)	12 Apr 2021 01:33:40
DataPoint activated with code reason code Data required.	(b) (4)	
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	08 Apr 2021 19:42:29
Signature has been broken.	(b) (4), (b) (6)	08 Apr 2021 19:41:29
User signature succeeded.	Colleen Kelley (b) (4)	02 Apr 2021 20:59:30
DataPoint Verified.	(b) (4)	
User entered 'Oral (ORAL)'	(b) (4), (b) (6)	19 Nov 2020 17:04:28
	(b) (4), (b) (6)	08 Sep 2020 23:09:30

US3632052

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 09:13:35

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Colleen Kelley (b) (4)	12 Apr 2021 01:33:40
DataPoint activated with code reason code Data required.	(b) (4)	
	(b) (4), (b) (6)	08 Apr 2021 19:42:29
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	08 Apr 2021 19:41:29
Signature has been broken.	(b) (4), (b) (6)	08 Apr 2021 19:41:29
User signature succeeded.	Colleen Kelley (b) (4)	02 Apr 2021 20:59:30
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	19 Nov 2020 17:04:32
User entered empty.	(b) (4), (b) (6)	08 Sep 2020 23:09:30



US3632052

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 09:13:35

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Colleen Kelley (b) (4)	12 Apr 2021 01:33:40
DataPoint activated with code reason code Data required.	(b) (4)	
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	08 Apr 2021 19:42:29
Signature has been broken.	(b) (4), (b) (6)	08 Apr 2021 19:41:29
User signature succeeded.	Colleen Kelley (b) (4)	02 Apr 2021 20:59:30
DataPoint Verified.	(b) (4)	
User closed query 'Per source, start date is recorded as 2014. Please update date in EDC to include an unknown day such as, UN-UNK-2014.' (Site from CRA).	(b) (4), (b) (6)	10 Dec 2020 16:36:42
Query 'Per source, start date is recorded as 2014. Please update date in EDC to include an unknown day such as, UN-UNK-2014.' answered with 'UPDATED' (Site from CRA).	(b) (4), (b) (6)	10 Dec 2020 16:26:40
User entered 'UN UNK 2014' reason for change: Data Entry Error	Kelly Likos (b) (4)	20 Nov 2020 14:44:35
User opened query 'Per source, start date is recorded as 2014. Please update date in EDC to include an unknown day such as, UN-UNK-2014.' (Site from CRA).	(b) (4)	
User entered '01 UNK 2014'	(b) (4), (b) (6)	20 Nov 2020 14:44:29
	(b) (4), (b) (6)	19 Nov 2020 17:05:53
	(b) (4), (b) (6)	08 Sep 2020 23:09:30

US3632052

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 09:13:35

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Colleen Kelley (b) (4)	12 Apr 2021 01:33:40
DataPoint activated with code reason code Data required.	(b) (4)	
	(b) (4), (b) (6)	08 Apr 2021 19:42:29
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	08 Apr 2021 19:41:29
Signature has been broken.	(b) (4), (b) (6)	08 Apr 2021 19:41:29
User signature succeeded.	Colleen Kelley (b) (4)	02 Apr 2021 20:59:30
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	19 Nov 2020 17:05:55
User entered '0'	(b) (4), (b) (6)	08 Sep 2020 23:09:30

US3632052

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 09:13:35

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Colleen Kelley (b) (4)	12 Apr 2021 01:33:40
	(b) (4)	
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	08 Apr 2021 19:42:29
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	08 Apr 2021 19:41:29
Signature has been broken.	(b) (4), (b) (6)	08 Apr 2021 19:41:29
User signature succeeded.	Colleen Kelley (b) (4)	02 Apr 2021 20:59:30
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 17:05:57
User entered 'Yes (Y)'	(b) (4), (b) (6)	08 Sep 2020 23:09:30

US3632052

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 09:13:35

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Colleen Kelley (b) (4)	12 Apr 2021 01:33:40
	(b) (4)	
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	08 Apr 2021 19:42:29
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	08 Apr 2021 19:41:29
Signature has been broken.	(b) (4), (b) (6)	08 Apr 2021 19:41:29
User signature succeeded.	Colleen Kelley (b) (4)	02 Apr 2021 20:59:30
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 17:05:59
User entered empty.	(b) (4), (b) (6)	08 Sep 2020 23:09:30

US3632052

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 09:13:35

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Colleen Kelley (b) (4)	12 Apr 2021 01:33:40
DataPoint activated with code reason code Data required.	(b) (4)	
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	08 Apr 2021 19:42:29
Signature has been broken.	(b) (4), (b) (6)	08 Apr 2021 19:41:29
User signature succeeded.	Colleen Kelley (b) (4)	02 Apr 2021 20:59:30
DataPoint Verified.	(b) (4)	
User entered 'No (N)'	(b) (4), (b) (6)	19 Nov 2020 17:06:00
	(b) (4), (b) (6)	08 Sep 2020 23:09:30

US3632052

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 10 Jun 2021 09:13:35**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	08 Apr 2021 19:42:29
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	08 Apr 2021 19:41:29
User entered 'I'	System	08 Sep 2020 23:09:30

US3632052

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 10 Jun 2021 09:13:35**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	08 Apr 2021 19:42:29
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	08 Apr 2021 19:41:29
User entered '2'	System	08 Sep 2020 23:09:30

**US3632052**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 10 Jun 2021 09:13:35**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	08 Apr 2021 19:42:29
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	08 Apr 2021 19:41:29
User entered '804 (804)'	System	08 Sep 2020 23:09:30



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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 09:13:35

Name of Medication

Audit	User	Time (GMT)
User signature succeeded.	Colleen Kelley (b) (4)	12 Apr 2021 01:33:40
User coded data point as ATC: CARDIOVASCULAR SYSTEM, ATC: LIPID MODIFYING AGENTS, ATC: LIPID MODIFYING AGENTS, PLAIN, ATC: HMG COA REDUCTASE INHIBITORS, PRODUCT: ATORVASTATIN CALCIUM - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	08 Apr 2021 19:44:34
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	08 Apr 2021 19:44:34
Data point term sent to Coder	System	08 Apr 2021 19:42:52
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	08 Apr 2021 19:42:29
Data point term sent to Coder	System	08 Apr 2021 19:41:43
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	08 Apr 2021 19:41:29
Signature has been broken.	(b) (4), (b) (6)	08 Apr 2021 19:41:29
User signature succeeded.	Colleen Kelley (b) (4)	02 Apr 2021 20:59:30
DataPoint Verified.	(b) (4), (b) (6)	10 Dec 2020 16:36:42
User closed query 'Per source, medication is listed as "Atorvastatin Calcium". Please verify with source and update EDC accordingly.' (Site from CRA).	(b) (4), (b) (6)	10 Dec 2020 16:31:00
User coded data point as ATC: CARDIOVASCULAR SYSTEM, ATC: LIPID MODIFYING AGENTS, ATC: LIPID MODIFYING AGENTS, PLAIN, ATC: HMG COA REDUCTASE INHIBITORS, PRODUCT: ATORVASTATIN CALCIUM - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	20 Nov 2020 16:26:35
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	20 Nov 2020 16:26:35
Data point term sent to Coder	System	20 Nov 2020 14:47:17
Query 'Per source, medication is listed as "Atorvastatin Calcium". Please verify with source and update EDC accordingly.' answered with 'UPDATED' (Site from CRA).	Kelly Likos (b) (4)	20 Nov 2020 14:46:59

US3632052

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 09:13:35

[Name of Medication](#)

Audit	User	Time (GMT)
Coding entries removed.	Kelly Likos (b) (4)	20 Nov 2020 14:46:52
	(b) (4)	
User entered 'ATORVASTATIN CALCIUM'	Kelly Likos (b) (4)	20 Nov 2020 14:46:52
reason for change: Data Entry Error	(b) (4)	
User opened query 'Per source, medication is listed as	(b) (4), (b) (6)	19 Nov 2020 17:07:17
"Atorvastatin Calcium". Please verify with source		
and update EDC accordingly.' (Site from CRA).		
DataPoint Un-verified.	(b) (4), (b) (6)	19 Nov 2020 17:06:08
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 17:06:07
User coded data point as ATC:	Coder Import (b) (4)	08 Sep 2020 23:13:00
CARDIOVASCULAR SYSTEM, ATC: LIPID	(b) (4)	
MODIFYING AGENTS, ATC: LIPID MODIFYING		
AGENTS, PLAIN, ATC: HMG COA REDUCTASE		
INHIBITORS, PRODUCT: ATORVASTATIN -		
version WHODrug-Global-B3\202003.		
User coded data point as Term Coded data point by	Coder Import (b) (4)	08 Sep 2020 23:13:00
User: Coder System - version	(b) (4)	
WHODrug-Global-B3\202003.		
Data point term sent to Coder	System	08 Sep 2020 23:11:46
User entered 'Atorvastatin'	(b) (4), (b) (6)	08 Sep 2020 23:11:29

US3632052

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 09:13:35

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Colleen Kelley (b) (4)	12 Apr 2021 01:33:40
DataPoint activated with code reason code Data required.	(b) (4)	
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	08 Apr 2021 19:42:29
Signature has been broken.	(b) (4), (b) (6)	08 Apr 2021 19:41:29
User signature succeeded.	Colleen Kelley (b) (4)	02 Apr 2021 20:59:30
DataPoint Verified.	(b) (4)	
User entered 'No (N)'	(b) (4), (b) (6)	19 Nov 2020 17:08:08
	(b) (4), (b) (6)	08 Sep 2020 23:11:29

US3632052

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 09:13:35

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Colleen Kelley (b) (4)	12 Apr 2021 01:33:40
DataPoint activated with code reason code Data required.	(b) (4)	
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	08 Apr 2021 19:42:29
Signature has been broken.	(b) (4), (b) (6)	08 Apr 2021 19:41:29
User signature succeeded.	Colleen Kelley (b) (4)	02 Apr 2021 20:59:30
DataPoint Verified.	(b) (4)	
User entered 'hypercholesterolemia'	(b) (4), (b) (6)	19 Nov 2020 17:08:12
		08 Sep 2020 23:11:29

US3632052

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 09:13:35

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Colleen Kelley (b) (4)	12 Apr 2021 01:33:40
	(b) (4)	
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	08 Apr 2021 19:42:29
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	08 Apr 2021 19:41:29
Signature has been broken.	(b) (4), (b) (6)	08 Apr 2021 19:41:29
User signature succeeded.	Colleen Kelley (b) (4)	02 Apr 2021 20:59:30
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 17:08:14
User entered '40'	(b) (4), (b) (6)	08 Sep 2020 23:11:29

US3632052

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 09:13:35

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Colleen Kelley (b) (4)	12 Apr 2021 01:33:40
DataPoint activated with code reason code Data required.	(b) (4)	
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	08 Apr 2021 19:42:29
Signature has been broken.	(b) (4), (b) (6)	08 Apr 2021 19:41:29
User signature succeeded.	Colleen Kelley (b) (4)	02 Apr 2021 20:59:30
DataPoint Verified.	(b) (4)	
User entered 'mg (mg)'	(b) (4), (b) (6)	19 Nov 2020 17:08:16
	(b) (4), (b) (6)	08 Sep 2020 23:11:29

US3632052

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 09:13:35

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Colleen Kelley (b) (4)	12 Apr 2021 01:33:40
DataPoint activated with code reason code Data required.	(b) (4)	
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	08 Apr 2021 19:42:29
Signature has been broken.	(b) (4), (b) (6)	08 Apr 2021 19:41:29
User signature succeeded.	Colleen Kelley (b) (4)	02 Apr 2021 20:59:30
DataPoint Verified.	(b) (4)	
User entered empty.	(b) (4), (b) (6)	19 Nov 2020 17:08:18
	(b) (4), (b) (6)	08 Sep 2020 23:11:29

US3632052

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 09:13:35

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Colleen Kelley (b) (4)	12 Apr 2021 01:33:40
DataPoint activated with code reason code Data required.	(b) (4)	
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	08 Apr 2021 19:42:29
Signature has been broken.	(b) (4), (b) (6)	08 Apr 2021 19:41:29
User signature succeeded.	Colleen Kelley (b) (4)	02 Apr 2021 20:59:30
DataPoint Verified.	(b) (4)	
User entered 'once daily (QD)'	(b) (4), (b) (6)	19 Nov 2020 17:08:20
	(b) (4), (b) (6)	08 Sep 2020 23:11:29



US3632052

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 09:13:35

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Colleen Kelley (b) (4)	12 Apr 2021 01:33:40
DataPoint activated with code reason code Data required.	(b) (4)	
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	08 Apr 2021 19:42:29
Signature has been broken.	(b) (4), (b) (6)	08 Apr 2021 19:41:29
User signature succeeded.	Colleen Kelley (b) (4)	02 Apr 2021 20:59:30
DataPoint Verified.	(b) (4)	
User entered empty.	(b) (4), (b) (6)	19 Nov 2020 17:08:22
		08 Sep 2020 23:11:29

US3632052

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 09:13:35

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Colleen Kelley (b) (4)	12 Apr 2021 01:33:40
DataPoint activated with code reason code Data required.	(b) (4)	
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	08 Apr 2021 19:42:29
Signature has been broken.	(b) (4), (b) (6)	08 Apr 2021 19:41:29
User signature succeeded.	Colleen Kelley (b) (4)	02 Apr 2021 20:59:30
DataPoint Verified.	(b) (4)	
User entered 'Oral (ORAL)'	(b) (4), (b) (6)	19 Nov 2020 17:08:24
		08 Sep 2020 23:11:29

US3632052

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 09:13:35

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Colleen Kelley (b) (4)	12 Apr 2021 01:33:40
DataPoint activated with code reason code Data required.	(b) (4)	
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	08 Apr 2021 19:42:29
Signature has been broken.	(b) (4), (b) (6)	08 Apr 2021 19:41:29
User signature succeeded.	Colleen Kelley (b) (4)	02 Apr 2021 20:59:30
DataPoint Verified.	(b) (4)	
User entered empty.	(b) (4), (b) (6)	19 Nov 2020 17:08:26
		08 Sep 2020 23:11:29

US3632052

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 09:13:35

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Colleen Kelley (b) (4)	12 Apr 2021 01:33:40
DataPoint activated with code reason code Data required.	(b) (4)	
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	08 Apr 2021 19:42:29
Signature has been broken.	(b) (4), (b) (6)	08 Apr 2021 19:41:29
User signature succeeded.	Colleen Kelley (b) (4)	02 Apr 2021 20:59:30
DataPoint Verified.	(b) (4)	
User closed query 'Per source, start date is recorded as 2016. Please update date in EDC to include an unknown day such as, UN-UNK-2016.' (Site from CRA).	(b) (4), (b) (6)	10 Dec 2020 16:36:42
Query 'Per source, start date is recorded as 2016. Please update date in EDC to include an unknown day such as, UN-UNK-2016.' answered with 'UPDATED' (Site from CRA).	(b) (4), (b) (6)	10 Dec 2020 16:31:10
User entered 'UN UNK 2016' reason for change: Data Entry Error	Kelly Likos (b) (4)	20 Nov 2020 14:47:04
User opened query 'Per source, start date is recorded as 2016. Please update date in EDC to include an unknown day such as, UN-UNK-2016.' (Site from CRA).	(b) (4)	
Query 'Per source, start date is recorded as 2016. Please update date in EDC to include an unknown day such as, UN-UNK-2014.' canceled (Site from CRA).	(b) (4), (b) (6)	20 Nov 2020 14:46:52
User opened query 'Per source, start date is recorded as 2016. Please update date in EDC to include an unknown day such as, UN-UNK-2014.' (Site from CRA).	(b) (4), (b) (6)	19 Nov 2020 17:09:41
User closed query 'Per DM CLR: Con Med start date is prior to the start date of the Med History condition of HYPERCHOLESTEROLEMIA. Please review and reconcile Con Med and Med History start dates as appropriate.	(b) (4), (b) (6)	19 Nov 2020 17:09:08
' (Site from DM).	(b) (4), (b) (6)	19 Nov 2020 17:09:05
	(b) (4), (b) (6)	23 Oct 2020 18:18:25

US3632052

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 09:13:35

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Query 'Per DM CLR: Con Med start date is prior to the start date of the Med History condition of HYPERCHOLESTEROLEMIA. Please review and reconcile Con Med and Med History start dates as appropriate. ' answered with 'updated' (Site from DM).	Christina Bacher (b) (4) (b) (4)	20 Oct 2020 16:46:24
User opened query 'Per DM CLR: Con Med start date is prior to the start date of the Med History condition of HYPERCHOLESTEROLEMIA. Please review and reconcile Con Med and Med History start dates as appropriate. ' (Site from DM).	(b) (4), (b) (6) (b) (4) (b) (4)	05 Oct 2020 19:29:54
User entered '01 UNK 2016'	(b) (4), (b) (6) (b) (4)	08 Sep 2020 23:11:29

US3632052

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 09:13:35

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Colleen Kelley (b) (4)	12 Apr 2021 01:33:40
DataPoint activated with code reason code Data required.	(b) (4)	
	(b) (4), (b) (6)	08 Apr 2021 19:42:29
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	08 Apr 2021 19:41:29
Signature has been broken.	(b) (4), (b) (6)	08 Apr 2021 19:41:29
User signature succeeded.	Colleen Kelley (b) (4)	02 Apr 2021 20:59:30
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	19 Nov 2020 17:10:09
User entered '0'	(b) (4), (b) (6)	08 Sep 2020 23:11:29

US3632052

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 09:13:35

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Colleen Kelley (b) (4)	12 Apr 2021 01:33:40
DataPoint activated with code reason code Data required.	(b) (4)	
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	08 Apr 2021 19:42:29
Signature has been broken.	(b) (4), (b) (6)	08 Apr 2021 19:41:29
User signature succeeded.	Colleen Kelley (b) (4)	02 Apr 2021 20:59:30
DataPoint Verified.	(b) (4)	
User entered 'Yes (Y)'	(b) (4), (b) (6)	19 Nov 2020 17:10:13
	(b) (4), (b) (6)	08 Sep 2020 23:11:29

US3632052

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 09:13:35

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

Audit	User	Time (GMT)
User signature succeeded.	Colleen Kelley (b) (4)	12 Apr 2021 01:33:40
DataPoint activated with code reason code Data required.	(b) (4)	
	(b) (4), (b) (6)	08 Apr 2021 19:42:29
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	08 Apr 2021 19:41:29
Signature has been broken.	(b) (4), (b) (6)	08 Apr 2021 19:41:29
User signature succeeded.	Colleen Kelley (b) (4)	02 Apr 2021 20:59:30
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	19 Nov 2020 17:10:18
User entered empty.	(b) (4), (b) (6)	08 Sep 2020 23:11:29



US3632052

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 09:13:35

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Colleen Kelley (b) (4)	12 Apr 2021 01:33:40
DataPoint activated with code reason code Data required.	(b) (4)	
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	08 Apr 2021 19:42:29
Signature has been broken.	(b) (4), (b) (6)	08 Apr 2021 19:41:29
User signature succeeded.	Colleen Kelley (b) (4)	02 Apr 2021 20:59:30
DataPoint Verified.	(b) (4)	
User entered 'No (N)'	(b) (4), (b) (6)	19 Nov 2020 17:10:21
	(b) (4), (b) (6)	08 Sep 2020 23:11:29

US3632052

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 10 Jun 2021 09:13:35**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	08 Apr 2021 19:42:29
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	08 Apr 2021 19:41:29
User entered 'I'	System	08 Sep 2020 23:11:29

**US3632052**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 10 Jun 2021 09:13:35**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	08 Apr 2021 19:42:29
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	08 Apr 2021 19:41:29
User entered 'I'	System	08 Sep 2020 23:11:29

**US3632052**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 10 Jun 2021 09:13:35**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	08 Apr 2021 19:42:29
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	08 Apr 2021 19:41:29
User entered '804 (804)'	System	08 Sep 2020 23:11:29

US3632052

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 09:13:35

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Colleen Kelley (b) (4)	12 Apr 2021 01:33:40
User coded data point as ATC: MUSCULO-SKELETAL SYSTEM, ATC: TOPICAL PRODUCTS FOR JOINT AND MUSCULAR PAIN, ATC: TOPICAL PRODUCTS FOR JOINT AND MUSCULAR PAIN, ATC: PREPARATIONS WITH SALICYLIC ACID DERIVATIVES, PRODUCT: ACETYLSALICYLIC ACID, PRODUCTSYNONYM: ASA - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	08 Apr 2021 19:43:49
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	08 Apr 2021 19:43:49
Data point term sent to Coder DataPoint activated with code reason code Data required.	System (b) (4), (b) (6)	08 Apr 2021 19:42:50 08 Apr 2021 19:42:29
Data point term sent to Coder DataPoint inactivated with code reason code Data not required.	System (b) (4), (b) (6)	08 Apr 2021 19:41:43 08 Apr 2021 19:41:29
Signature has been broken.	(b) (4), (b) (6)	08 Apr 2021 19:41:29
User signature succeeded.	Colleen Kelley (b) (4)	02 Apr 2021 20:59:30
User coded data point as ATC: MUSCULO-SKELETAL SYSTEM, ATC: TOPICAL PRODUCTS FOR JOINT AND MUSCULAR PAIN, ATC: TOPICAL PRODUCTS FOR JOINT AND MUSCULAR PAIN, ATC: PREPARATIONS WITH SALICYLIC ACID DERIVATIVES, PRODUCT: ACETYLSALICYLIC ACID, PRODUCTSYNONYM: ASA - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	23 Nov 2020 20:53:02
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	23 Nov 2020 20:53:02
Data point term sent to Coder Coding entries removed.	System Catherine Abrams (b) (4)	23 Nov 2020 20:52:05 23 Nov 2020 20:51:28
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 17:13:08

US3632052

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 09:13:35

Name of Medication

Audit	User	Time (GMT)
User coded data point as ATC: BLOOD AND BLOOD FORMING ORGANS, ATC: ANTITHROMBOTIC AGENTS, ATC: ANTITHROMBOTIC AGENTS, ATC: PLATELET AGGREGATION INHIBITORS EXCL. HEPARIN, PRODUCT: ACETYLSALICYLIC ACID, PRODUCTSYNONYM: ASA - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	08 Oct 2020 23:59:45
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	08 Oct 2020 23:59:45
Data point term sent to Coder Coding entries removed.	System Isaac Perez (b) (4) (b) (4)	08 Oct 2020 19:08:33 08 Oct 2020 19:07:37
User coded data point as ATC: MUSCULO-SKELETAL SYSTEM, ATC: TOPICAL PRODUCTS FOR JOINT AND MUSCULAR PAIN, ATC: TOPICAL PRODUCTS FOR JOINT AND MUSCULAR PAIN, ATC: PREPARATIONS WITH SALICYLIC ACID DERIVATIVES, PRODUCT: ACETYLSALICYLIC ACID, PRODUCTSYNONYM: ASA - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	08 Sep 2020 23:59:03
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	08 Sep 2020 23:59:03
Data point term sent to Coder User entered 'ASA'	System (b) (4), (b) (6) (b) (4)	08 Sep 2020 23:12:50 08 Sep 2020 23:12:27

US3632052

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 09:13:35

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Colleen Kelley (b) (4)	12 Apr 2021 01:33:40
DataPoint activated with code reason code Data required.	(b) (4)	
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	08 Apr 2021 19:42:29
Signature has been broken.	(b) (4), (b) (6)	08 Apr 2021 19:41:29
User signature succeeded.	Colleen Kelley (b) (4)	02 Apr 2021 20:59:30
DataPoint Verified.	(b) (4)	
User closed query ' Per DM CLR: Prophylaxis=YES. HYPERCHOLESTEROLEMIA is recorded as an actual medical condition in the Med Hx eCRF. Please review and update the response to NO. Otherwise, clarify.' (Site from DM).	(b) (4), (b) (6)	24 Mar 2021 19:37:06
Query ' Per DM CLR: Prophylaxis=YES. HYPERCHOLESTEROLEMIA is recorded as an actual medical condition in the Med Hx eCRF. Please review and update the response to NO. Otherwise, clarify.' answered with 'Updated response.' (Site from DM).	Isaac Perez (b) (4)	07 Jan 2021 04:31:07
DataPoint Un-verified.	(b) (4)	
User entered 'No (N)' reason for change: Data Entry Error	Isaac Perez (b) (4)	06 Jan 2021 17:25:10
User opened query ' Per DM CLR: Prophylaxis=YES. HYPERCHOLESTEROLEMIA is recorded as an actual medical condition in the Med Hx eCRF. Please review and update the response to NO. Otherwise, clarify.' (Site from DM).	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	06 Jan 2021 17:25:03
User entered 'Yes (Y)'	(b) (4), (b) (6)	06 Jan 2021 17:25:03
	(b) (4), (b) (6)	23 Dec 2020 07:49:32
	(b) (4), (b) (6)	
	(b) (4), (b) (6)	19 Nov 2020 17:13:20
	(b) (4), (b) (6)	08 Sep 2020 23:12:27

US3632052

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 09:13:35

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Colleen Kelley (b) (4)	12 Apr 2021 01:33:40
DataPoint activated with code reason code Data required.	(b) (4)	
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	08 Apr 2021 19:42:29
Signature has been broken.	(b) (4), (b) (6)	08 Apr 2021 19:41:29
User signature succeeded.	Colleen Kelley (b) (4)	02 Apr 2021 20:59:30
DataPoint Verified.	(b) (4)	
User closed query 'Per source, indication is medical history of hypercholesterolemia. Please verify with source and update EDC accordingly.' (Site from CRA).	(b) (4), (b) (6)	10 Dec 2020 16:34:19
Query 'Per source, indication is medical history of hypercholesterolemia. Please verify with source and update EDC accordingly.' answered with 'updated with indication as hypercholesterolemia' (Site from CRA).	(b) (4), (b) (6)	10 Dec 2020 16:33:57
User entered 'hypercholesterolemia' reason for change: Per Query Resolution	Catherine Abrams (b) (4)	23 Nov 2020 20:52:13
User opened query 'Per source, indication is medical history of hypercholesterolemia. Please verify with source and update EDC accordingly.' (Site from CRA).	(b) (4)	
User entered 'CARDIAC PREVENTION' reason for change: Data Entry Error	Catherine Abrams (b) (4)	23 Nov 2020 20:51:28
User entered 'Hypercholesterolemia'	(b) (4), (b) (6)	19 Nov 2020 17:14:05
	(b) (4)	
	(b) (4), (b) (6)	08 Oct 2020 19:07:37
	(b) (4)	
	(b) (4), (b) (6)	08 Sep 2020 23:12:27



US3632052

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 09:13:35

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Colleen Kelley (b) (4)	12 Apr 2021 01:33:40
	(b) (4)	
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	08 Apr 2021 19:42:29
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	08 Apr 2021 19:41:29
Signature has been broken.	(b) (4), (b) (6)	08 Apr 2021 19:41:29
User signature succeeded.	Colleen Kelley (b) (4)	02 Apr 2021 20:59:30
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 17:14:09
User entered '81'	(b) (4), (b) (6)	08 Sep 2020 23:12:27

US3632052

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 09:13:35

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Colleen Kelley (b) (4)	12 Apr 2021 01:33:40
	(b) (4)	
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	08 Apr 2021 19:42:29
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	08 Apr 2021 19:41:29
Signature has been broken.	(b) (4), (b) (6)	08 Apr 2021 19:41:29
User signature succeeded.	Colleen Kelley (b) (4)	02 Apr 2021 20:59:30
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 17:14:12
User entered 'mg (mg)'	(b) (4), (b) (6)	08 Sep 2020 23:12:27

US3632052

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 09:13:35

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Colleen Kelley (b) (4)	12 Apr 2021 01:33:40
DataPoint activated with code reason code Data required.	(b) (4)	
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	08 Apr 2021 19:42:29
Signature has been broken.	(b) (4), (b) (6)	08 Apr 2021 19:41:29
User signature succeeded.	Colleen Kelley (b) (4)	02 Apr 2021 20:59:30
DataPoint Verified.	(b) (4)	
User entered empty.	(b) (4), (b) (6)	10 Dec 2020 16:34:25
	(b) (4), (b) (6)	08 Sep 2020 23:12:27

US3632052

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 09:13:35

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Colleen Kelley (b) (4)	12 Apr 2021 01:33:40
DataPoint activated with code reason code Data required.	(b) (4)	
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	08 Apr 2021 19:42:29
Signature has been broken.	(b) (4), (b) (6)	08 Apr 2021 19:41:29
User signature succeeded.	Colleen Kelley (b) (4)	02 Apr 2021 20:59:30
DataPoint Verified.	(b) (4)	
User entered 'once daily (QD)'	(b) (4), (b) (6)	19 Nov 2020 17:14:17
	(b) (4), (b) (6)	08 Sep 2020 23:12:27

US3632052

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 09:13:35

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Colleen Kelley (b) (4)	12 Apr 2021 01:33:40
	(b) (4)	
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	08 Apr 2021 19:42:29
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	08 Apr 2021 19:41:29
Signature has been broken.	(b) (4), (b) (6)	08 Apr 2021 19:41:29
User signature succeeded.	Colleen Kelley (b) (4)	02 Apr 2021 20:59:30
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 17:14:21
User entered empty.	(b) (4), (b) (6)	08 Sep 2020 23:12:27

US3632052

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 09:13:35

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Colleen Kelley (b) (4)	12 Apr 2021 01:33:40
	(b) (4)	
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	08 Apr 2021 19:42:29
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	08 Apr 2021 19:41:29
Signature has been broken.	(b) (4), (b) (6)	08 Apr 2021 19:41:29
User signature succeeded.	Colleen Kelley (b) (4)	02 Apr 2021 20:59:30
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 17:14:24
User entered 'Oral (ORAL)'	(b) (4), (b) (6)	08 Sep 2020 23:12:27

US3632052

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 09:13:35

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Colleen Kelley (b) (4)	12 Apr 2021 01:33:40
	(b) (4)	
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	08 Apr 2021 19:42:29
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	08 Apr 2021 19:41:29
Signature has been broken.	(b) (4), (b) (6)	08 Apr 2021 19:41:29
User signature succeeded.	Colleen Kelley (b) (4)	02 Apr 2021 20:59:30
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 17:14:26
User entered empty.	(b) (4), (b) (6)	08 Sep 2020 23:12:27

US3632052

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 09:13:35

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Colleen Kelley (b) (4)	12 Apr 2021 01:33:40
DataPoint activated with code reason code Data required.	(b) (4)	
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	08 Apr 2021 19:42:29
Signature has been broken.	(b) (4), (b) (6)	08 Apr 2021 19:41:29
User signature succeeded.	Colleen Kelley (b) (4)	02 Apr 2021 20:59:30
DataPoint Verified.	(b) (4)	
User closed query 'Per source, start date is recorded as 2014. Please update date in EDC to include an unknown day such as, UN-UNK-2014.' (Site from CRA).	(b) (4), (b) (6)	10 Dec 2020 16:33:40
Query 'Per source, start date is recorded as 2014. Please update date in EDC to include an unknown day such as, UN-UNK-2014.' answered with 'UPDATED' (Site from CRA).	(b) (4), (b) (6)	10 Dec 2020 16:33:34
User entered 'UN UNK 2014' reason for change: Data Entry Error	Kelly Likos (b) (4)	20 Nov 2020 14:52:07
User opened query 'Per source, start date is recorded as 2014. Please update date in EDC to include an unknown day such as, UN-UNK-2014.' (Site from CRA).	(b) (4)	
User closed query 'Per DM CLR: Con Med start date is prior to the start date of the Med History condition of HYPERCHOLESTEROLEMIA. Please review and reconcile Con Med and Med History start dates as appropriate.	(b) (4), (b) (6)	20 Nov 2020 14:52:00
' (Site from DM).	(b) (4)	
Query 'Per DM CLR: Con Med start date is prior to the start date of the Med History condition of HYPERCHOLESTEROLEMIA. Please review and reconcile Con Med and Med History start dates as appropriate.	(b) (4), (b) (6)	19 Nov 2020 17:14:41
' answered with 'UPdated indication.' (Site from DM).	(b) (4), (b) (6)	
	(b) (4), (b) (6)	12 Oct 2020 15:55:26
	(b) (4), (b) (6)	
	Isaac Perez (b) (4)	08 Oct 2020 19:07:44
	(b) (4)	



US3632052

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 09:13:35

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User opened query 'Per DM CLR: Con Med start date is prior to the start date of the Med History condition of HYPERCHOLESTEROLEMIA. Please review and reconcile Con Med and Med History start dates as appropriate. ' (Site from DM).	(b) (4), (b) (6)	05 Oct 2020 19:30:18
User entered '01 UNK 2014'	(b) (4), (b) (6)	08 Sep 2020 23:12:27

US3632052

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 09:13:35

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Colleen Kelley (b) (4)	12 Apr 2021 01:33:40
	(b) (4)	
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	08 Apr 2021 19:42:29
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	08 Apr 2021 19:41:29
Signature has been broken.	(b) (4), (b) (6)	08 Apr 2021 19:41:29
User signature succeeded.	Colleen Kelley (b) (4)	02 Apr 2021 20:59:30
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 17:14:46
User entered '0'	(b) (4), (b) (6)	08 Sep 2020 23:12:27

US3632052

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 09:13:35

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Colleen Kelley (b) (4)	12 Apr 2021 01:33:40
DataPoint activated with code reason code Data required.	(b) (4)	
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	08 Apr 2021 19:42:29
Signature has been broken.	(b) (4), (b) (6)	08 Apr 2021 19:41:29
User signature succeeded.	Colleen Kelley (b) (4)	02 Apr 2021 20:59:30
DataPoint Verified.	(b) (4)	
User entered 'Yes (Y)'	(b) (4), (b) (6)	10 Dec 2020 16:34:30
	(b) (4), (b) (6)	08 Sep 2020 23:12:27

US3632052

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 09:13:35

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

Audit	User	Time (GMT)
User signature succeeded.	Colleen Kelley (b) (4)	12 Apr 2021 01:33:40
DataPoint activated with code reason code Data required.	(b) (4)	
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	08 Apr 2021 19:42:29
Signature has been broken.	(b) (4), (b) (6)	08 Apr 2021 19:41:29
User signature succeeded.	Colleen Kelley (b) (4)	02 Apr 2021 20:59:30
DataPoint Verified.	(b) (4)	
User entered empty.	(b) (4), (b) (6)	10 Dec 2020 16:34:34
		08 Sep 2020 23:12:27

US3632052

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 09:13:35

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Colleen Kelley (b) (4)	12 Apr 2021 01:33:40
DataPoint activated with code reason code Data required.	(b) (4)	
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	08 Apr 2021 19:42:29
Signature has been broken.	(b) (4), (b) (6)	08 Apr 2021 19:41:29
User signature succeeded.	Colleen Kelley (b) (4)	02 Apr 2021 20:59:30
DataPoint Verified.	(b) (4)	
User entered 'No (N)'	(b) (4), (b) (6)	19 Nov 2020 17:14:54
	(b) (4), (b) (6)	08 Sep 2020 23:12:27

**US3632052**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 10 Jun 2021 09:13:35**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	08 Apr 2021 19:42:29
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	08 Apr 2021 19:41:29
User entered 'I'	System	08 Sep 2020 23:12:27

US3632052

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 10 Jun 2021 09:13:35**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	08 Apr 2021 19:42:29
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	08 Apr 2021 19:41:29
User entered 'I'	System	08 Sep 2020 23:12:27

**US3632052**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 10 Jun 2021 09:13:35**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	08 Apr 2021 19:42:29
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	08 Apr 2021 19:41:29
User entered '804 (804)'	System	08 Sep 2020 23:12:27



US3632052

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 09:13:35

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 06:09:57
User signature succeeded.	Colleen Kelley (b) (4)	12 Apr 2021 01:33:40
User coded data point as ATC: GENITO URINARY SYSTEM AND SEX HORMONES, ATC: UROLOGICALS, ATC: DRUGS USED IN BENIGN PROSTATIC HYPERTROPHY, ATC: TESTOSTERONE-5-ALPHA REDUCTASE INHIBITORS, PRODUCT: FINASTERIDE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	08 Apr 2021 19:43:48
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	08 Apr 2021 19:43:48
Data point term sent to Coder	System	08 Apr 2021 19:42:50
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	08 Apr 2021 19:42:29
Data point term sent to Coder	System	08 Apr 2021 19:41:45
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	08 Apr 2021 19:41:29
Signature has been broken.	(b) (4), (b) (6)	08 Apr 2021 19:41:29
User signature succeeded.	Colleen Kelley (b) (4)	02 Apr 2021 20:59:30
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 17:15:10
User coded data point as ATC: GENITO URINARY SYSTEM AND SEX HORMONES, ATC: UROLOGICALS, ATC: DRUGS USED IN BENIGN PROSTATIC HYPERTROPHY, ATC: TESTOSTERONE-5-ALPHA REDUCTASE INHIBITORS, PRODUCT: FINASTERIDE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	08 Sep 2020 23:14:57
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	08 Sep 2020 23:14:57
Data point term sent to Coder	System	08 Sep 2020 23:13:54
User entered 'Finasteride'	(b) (4), (b) (6)	08 Sep 2020 23:13:21

US3632052

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 09:13:35

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 06:09:57
User signature succeeded.	Colleen Kelley (b) (4)	12 Apr 2021 01:33:40
DataPoint activated with code reason code Data required.	(b) (4)	08 Apr 2021 19:42:29
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	08 Apr 2021 19:41:29
Signature has been broken.	(b) (4), (b) (6)	08 Apr 2021 19:41:29
User signature succeeded.	Colleen Kelley (b) (4)	02 Apr 2021 20:59:30
DataPoint Verified.	(b) (4)	19 Nov 2020 17:15:15
User entered 'No (N)'	(b) (4), (b) (6)	08 Sep 2020 23:13:21

US3632052

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 09:13:35

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 06:09:57
User signature succeeded.	Colleen Kelley (b) (4)	12 Apr 2021 01:33:40
DataPoint activated with code reason code Data required.	(b) (4)	08 Apr 2021 19:42:29
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	08 Apr 2021 19:41:29
Signature has been broken.	(b) (4), (b) (6)	08 Apr 2021 19:41:29
User signature succeeded.	Colleen Kelley (b) (4)	02 Apr 2021 20:59:30
DataPoint Verified.	(b) (4)	19 Nov 2020 17:15:18
User entered 'benign prostatic hypertrophy'	(b) (4), (b) (6)	08 Sep 2020 23:13:21

US3632052

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 09:13:35

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 06:09:57
User signature succeeded.	Colleen Kelley (b) (4)	12 Apr 2021 01:33:40
DataPoint activated with code reason code Data required.	(b) (4)	08 Apr 2021 19:42:29
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	08 Apr 2021 19:41:29
Signature has been broken.	(b) (4), (b) (6)	08 Apr 2021 19:41:29
User signature succeeded.	Colleen Kelley (b) (4)	02 Apr 2021 20:59:30
DataPoint Verified.	(b) (4)	19 Nov 2020 17:15:24
User entered '5'	(b) (4), (b) (6)	08 Sep 2020 23:13:21

US3632052

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 09:13:35

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 06:09:57
User signature succeeded.	Colleen Kelley (b) (4)	12 Apr 2021 01:33:40
DataPoint activated with code reason code Data required.	(b) (4)	08 Apr 2021 19:42:29
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	08 Apr 2021 19:41:29
Signature has been broken.	(b) (4), (b) (6)	08 Apr 2021 19:41:29
User signature succeeded.	Colleen Kelley (b) (4)	02 Apr 2021 20:59:30
DataPoint Verified.	(b) (4)	19 Nov 2020 17:15:26
User entered 'mg (mg)'	(b) (4), (b) (6)	08 Sep 2020 23:13:21

US3632052

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 09:13:35

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 06:09:57
User signature succeeded.	Colleen Kelley (b) (4)	12 Apr 2021 01:33:40
DataPoint activated with code reason code Data required.	(b) (4)	08 Apr 2021 19:42:29
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	08 Apr 2021 19:41:29
Signature has been broken.	(b) (4), (b) (6)	08 Apr 2021 19:41:29
User signature succeeded.	Colleen Kelley (b) (4)	02 Apr 2021 20:59:30
DataPoint Verified.	(b) (4)	19 Nov 2020 17:15:31
User entered empty.	(b) (4), (b) (6)	08 Sep 2020 23:13:21

US3632052

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 09:13:35

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 06:09:57
User signature succeeded.	Colleen Kelley (b) (4)	12 Apr 2021 01:33:40
DataPoint activated with code reason code Data required.	(b) (4)	08 Apr 2021 19:42:29
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	08 Apr 2021 19:41:29
Signature has been broken.	(b) (4), (b) (6)	08 Apr 2021 19:41:29
User signature succeeded.	Colleen Kelley (b) (4)	02 Apr 2021 20:59:30
DataPoint Verified.	(b) (4)	19 Nov 2020 17:15:50
User entered 'once daily (QD)'	(b) (4), (b) (6)	08 Sep 2020 23:13:21

US3632052

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 09:13:35

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 06:09:57
User signature succeeded.	Colleen Kelley (b) (4)	12 Apr 2021 01:33:40
DataPoint activated with code reason code Data required.	(b) (4)	08 Apr 2021 19:42:29
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	08 Apr 2021 19:41:29
Signature has been broken.	(b) (4), (b) (6)	08 Apr 2021 19:41:29
User signature succeeded.	Colleen Kelley (b) (4)	02 Apr 2021 20:59:30
DataPoint Verified.	(b) (4)	19 Nov 2020 17:15:52
User entered empty.	(b) (4), (b) (6)	08 Sep 2020 23:13:21



US3632052

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 09:13:35

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 06:09:57
User signature succeeded.	Colleen Kelley (b) (4)	12 Apr 2021 01:33:40
DataPoint activated with code reason code Data required.	(b) (4)	08 Apr 2021 19:42:29
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	08 Apr 2021 19:41:29
Signature has been broken.	(b) (4), (b) (6)	08 Apr 2021 19:41:29
User signature succeeded.	Colleen Kelley (b) (4)	02 Apr 2021 20:59:30
DataPoint Verified.	(b) (4)	19 Nov 2020 17:15:54
User entered 'Oral (ORAL)'	(b) (4), (b) (6)	08 Sep 2020 23:13:21

US3632052

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 09:13:35

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 06:09:57
User signature succeeded.	Colleen Kelley (b) (4)	12 Apr 2021 01:33:40
DataPoint activated with code reason code Data required.	(b) (4)	08 Apr 2021 19:42:29
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	08 Apr 2021 19:41:29
Signature has been broken.	(b) (4), (b) (6)	08 Apr 2021 19:41:29
User signature succeeded.	Colleen Kelley (b) (4)	02 Apr 2021 20:59:30
DataPoint Verified.	(b) (4)	19 Nov 2020 17:15:57
User entered empty.	(b) (4), (b) (6)	08 Sep 2020 23:13:21

US3632052

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 09:13:35

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 06:09:57
User signature succeeded.	Colleen Kelley (b) (4)	12 Apr 2021 01:33:40
DataPoint activated with code reason code Data required.	(b) (4)	08 Apr 2021 19:42:29
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	08 Apr 2021 19:41:29
Signature has been broken.	(b) (4), (b) (6)	08 Apr 2021 19:41:29
User signature succeeded.	Colleen Kelley (b) (4)	02 Apr 2021 20:59:30
DataPoint Verified.	(b) (4)	10 Dec 2020 16:36:42
User closed query 'Per source, start date is recorded as 2019. Please update date in EDC to include an unknown day such as, UN-UNK-2019.' (Site from CRA).	(b) (4), (b) (6)	10 Dec 2020 16:35:56
Query 'Per source, start date is recorded as 2019. Please update date in EDC to include an unknown day such as, UN-UNK-2019.' answered with 'UPDATED' (Site from CRA).	Kelly Likos (b) (4)	20 Nov 2020 16:05:52
User entered 'UN UNK 2019' reason for change: Data Entry Error	(b) (4)	20 Nov 2020 16:05:43
User opened query 'Per source, start date is recorded as 2019. Please update date in EDC to include an unknown day such as, UN-UNK-2019.' (Site from CRA).	(b) (4), (b) (6)	19 Nov 2020 17:16:14
User entered '01 UNK 2019'	(b) (4), (b) (6)	08 Sep 2020 23:13:21

US3632052

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 09:13:35

Start date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 06:09:57
User signature succeeded.	Colleen Kelley (b) (4)	12 Apr 2021 01:33:40
DataPoint activated with code reason code Data required.	(b) (4)	08 Apr 2021 19:42:29
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	08 Apr 2021 19:41:29
Signature has been broken.	(b) (4), (b) (6)	08 Apr 2021 19:41:29
User signature succeeded.	Colleen Kelley (b) (4)	02 Apr 2021 20:59:30
DataPoint Verified.	(b) (4)	19 Nov 2020 17:16:16
User entered '0'	(b) (4), (b) (6)	08 Sep 2020 23:13:21

US3632052

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 09:13:35

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 06:09:57
User signature succeeded.	Colleen Kelley (b) (4)	12 Apr 2021 01:33:40
DataPoint Verified.	(b) (4)	08 Apr 2021 19:45:49
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	08 Apr 2021 19:42:29
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	08 Apr 2021 19:41:29
Signature has been broken.	(b) (4), (b) (6)	08 Apr 2021 19:41:29
User signature succeeded.	Colleen Kelley (b) (4)	02 Apr 2021 20:59:30
DataPoint Un-verified.	(b) (4)	01 Apr 2021 19:51:14
User entered 'No (N)' reason for change: New Information	(b) (4), (b) (6)	01 Apr 2021 19:51:14
DataPoint Verified.	(b) (4), (b) (6)	10 Dec 2020 16:36:42
User entered 'Yes (Y)'	(b) (4), (b) (6)	08 Sep 2020 23:13:21

US3632052

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 09:13:35

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 06:09:57
User signature succeeded.	Colleen Kelley (b) (4)	12 Apr 2021 01:33:40
DataPoint Verified.	(b) (4)	08 Apr 2021 19:45:53
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	08 Apr 2021 19:42:29
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	08 Apr 2021 19:41:29
Signature has been broken.	(b) (4), (b) (6)	08 Apr 2021 19:41:29
User signature succeeded.	Colleen Kelley (b) (4)	02 Apr 2021 20:59:30
DataPoint Un-verified.	(b) (4)	01 Apr 2021 19:51:14
User entered 'un Feb 2021' reason for change: Data Entry Error	(b) (4), (b) (6)	01 Apr 2021 19:51:14
DataPoint Verified.	(b) (4), (b) (6)	10 Dec 2020 16:36:42
User entered empty.	(b) (4), (b) (6)	08 Sep 2020 23:13:21

US3632052

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 09:13:35

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 06:09:57
User signature succeeded.	Colleen Kelley (b) (4)	12 Apr 2021 01:33:40
DataPoint activated with code reason code Data required.	(b) (4)	08 Apr 2021 19:42:29
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	08 Apr 2021 19:41:29
Signature has been broken.	(b) (4), (b) (6)	08 Apr 2021 19:41:29
User signature succeeded.	Colleen Kelley (b) (4)	02 Apr 2021 20:59:30
DataPoint Verified.	(b) (4)	19 Nov 2020 17:16:20
User entered 'No (N)'	(b) (4), (b) (6)	08 Sep 2020 23:13:21

US3632052

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 09:13:35

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 06:09:57
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	08 Apr 2021 19:42:29
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	08 Apr 2021 19:41:29
User entered 'I'	System	08 Sep 2020 23:13:21



US3632052

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 09:13:35

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 06:09:57
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	08 Apr 2021 19:42:29
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	08 Apr 2021 19:41:29
User entered '1'	System	08 Sep 2020 23:13:21

US3632052

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 09:13:35

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 06:09:57
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	08 Apr 2021 19:42:29
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	08 Apr 2021 19:41:29
User entered '804 (804)'	System	08 Sep 2020 23:13:21

US3632052

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 09:13:35

Name of Medication

Audit	User	Time (GMT)
User signature succeeded.	Colleen Kelley (b) (4)	12 Apr 2021 01:33:40
User coded data point as ATC: RESPIRATORY SYSTEM, ATC: ANTIHISTAMINES FOR SYSTEMIC USE, ATC: ANTIHISTAMINES FOR SYSTEMIC USE, ATC: PIPERAZINE DERIVATIVES, PRODUCT: LEVOCETIRIZINE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	08 Apr 2021 19:43:49
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	08 Apr 2021 19:43:49
Data point term sent to Coder	System	08 Apr 2021 19:42:53
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	08 Apr 2021 19:42:29
Data point term sent to Coder	System	08 Apr 2021 19:41:43
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	08 Apr 2021 19:41:29
Signature has been broken.	(b) (4), (b) (6)	08 Apr 2021 19:41:29
User signature succeeded.	Colleen Kelley (b) (4)	02 Apr 2021 20:59:30
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 17:16:32
User coded data point as ATC: RESPIRATORY SYSTEM, ATC: ANTIHISTAMINES FOR SYSTEMIC USE, ATC: ANTIHISTAMINES FOR SYSTEMIC USE, ATC: PIPERAZINE DERIVATIVES, PRODUCT: LEVOCETIRIZINE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	08 Sep 2020 23:15:54
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	08 Sep 2020 23:15:54
Data point term sent to Coder	System	08 Sep 2020 23:14:56
User entered 'levocetirizine'	(b) (4), (b) (6)	08 Sep 2020 23:14:53

US3632052

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 09:13:35

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Colleen Kelley (b) (4)	12 Apr 2021 01:33:40
	(b) (4)	
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	08 Apr 2021 19:42:29
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	08 Apr 2021 19:41:29
Signature has been broken.	(b) (4), (b) (6)	08 Apr 2021 19:41:29
User signature succeeded.	Colleen Kelley (b) (4)	02 Apr 2021 20:59:30
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 17:16:40
User entered 'No (N)'	(b) (4), (b) (6)	08 Sep 2020 23:14:53

US3632052

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 09:13:35

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Colleen Kelley (b) (4)	12 Apr 2021 01:33:40
DataPoint activated with code reason code Data required.	(b) (4)	
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	08 Apr 2021 19:42:29
Signature has been broken.	(b) (4), (b) (6)	08 Apr 2021 19:41:29
User signature succeeded.	Colleen Kelley (b) (4)	02 Apr 2021 20:59:30
DataPoint Verified.	(b) (4)	
User entered 'seasonal allergies'	(b) (4), (b) (6)	19 Nov 2020 17:16:43
		08 Sep 2020 23:14:53

US3632052

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 09:13:35

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Colleen Kelley (b) (4)	12 Apr 2021 01:33:40
	(b) (4)	
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	08 Apr 2021 19:42:29
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	08 Apr 2021 19:41:29
Signature has been broken.	(b) (4), (b) (6)	08 Apr 2021 19:41:29
User signature succeeded.	Colleen Kelley (b) (4)	02 Apr 2021 20:59:30
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 17:16:46
User entered '5'	(b) (4), (b) (6)	08 Sep 2020 23:14:53

US3632052

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 09:13:35

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Colleen Kelley (b) (4)	12 Apr 2021 01:33:40
DataPoint activated with code reason code Data required.	(b) (4)	
	(b) (4), (b) (6)	08 Apr 2021 19:42:29
DataPoint inactivated with code reason code Data not required.		
	(b) (4), (b) (6)	08 Apr 2021 19:41:29
Signature has been broken.		
	(b) (4), (b) (6)	08 Apr 2021 19:41:29
User signature succeeded.	Colleen Kelley (b) (4)	02 Apr 2021 20:59:30
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 17:16:49
User entered 'mg (mg)'	(b) (4), (b) (6)	08 Sep 2020 23:14:53

US3632052

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 09:13:35

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Colleen Kelley (b) (4)	12 Apr 2021 01:33:40
DataPoint activated with code reason code Data required.	(b) (4)	
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	08 Apr 2021 19:42:29
Signature has been broken.	(b) (4), (b) (6)	08 Apr 2021 19:41:29
User signature succeeded.	Colleen Kelley (b) (4)	02 Apr 2021 20:59:30
DataPoint Verified.	(b) (4)	
User entered empty.	(b) (4), (b) (6)	19 Nov 2020 17:16:51
	(b) (4), (b) (6)	08 Sep 2020 23:14:53



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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 09:13:35

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Colleen Kelley (b) (4)	12 Apr 2021 01:33:40
DataPoint activated with code reason code Data required.	(b) (4)	
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	08 Apr 2021 19:42:29
Signature has been broken.	(b) (4), (b) (6)	08 Apr 2021 19:41:29
User signature succeeded.	Colleen Kelley (b) (4)	02 Apr 2021 20:59:30
DataPoint Verified.	(b) (4)	
User entered 'as needed (PRN)'	(b) (4), (b) (6)	19 Nov 2020 17:16:54
	(b) (4), (b) (6)	08 Sep 2020 23:14:53

US3632052

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 09:13:35

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Colleen Kelley (b) (4)	12 Apr 2021 01:33:40
	(b) (4)	
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	08 Apr 2021 19:42:29
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	08 Apr 2021 19:41:29
Signature has been broken.	(b) (4), (b) (6)	08 Apr 2021 19:41:29
User signature succeeded.	Colleen Kelley (b) (4)	02 Apr 2021 20:59:30
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 17:16:56
User entered empty.	(b) (4), (b) (6)	08 Sep 2020 23:14:53

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 09:13:35

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Colleen Kelley (b) (4)	12 Apr 2021 01:33:40
	(b) (4)	
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	08 Apr 2021 19:42:29
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	08 Apr 2021 19:41:29
Signature has been broken.	(b) (4), (b) (6)	08 Apr 2021 19:41:29
	(b) (4)	
User signature succeeded.	Colleen Kelley (b) (4)	02 Apr 2021 20:59:30
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 17:16:58
	(b) (4)	
User entered 'Oral (ORAL)'	(b) (4), (b) (6)	08 Sep 2020 23:14:53
	(b) (4)	

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 09:13:35

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Colleen Kelley (b) (4)	12 Apr 2021 01:33:40
	(b) (4)	
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	08 Apr 2021 19:42:29
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	08 Apr 2021 19:41:29
Signature has been broken.	(b) (4), (b) (6)	08 Apr 2021 19:41:29
User signature succeeded.	Colleen Kelley (b) (4)	02 Apr 2021 20:59:30
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 17:17:00
User entered empty.	(b) (4), (b) (6)	08 Sep 2020 23:14:53

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 09:13:35

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Colleen Kelley (b) (4)	12 Apr 2021 01:33:40
DataPoint activated with code reason code Data required.	(b) (4)	
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	08 Apr 2021 19:42:29
Signature has been broken.	(b) (4), (b) (6)	08 Apr 2021 19:41:29
User signature succeeded.	Colleen Kelley (b) (4)	02 Apr 2021 20:59:30
DataPoint Verified.	(b) (4)	
User closed query 'Per source, start date is recorded as 2019. Please update date in EDC to include an unknown day such as, UN-UNK-2019.' (Site from CRA).	(b) (4), (b) (6)	10 Dec 2020 16:36:42
Query 'Per source, start date is recorded as 2019. Please update date in EDC to include an unknown day such as, UN-UNK-2019.' answered with 'UPDATED' (Site from CRA).	(b) (4), (b) (6)	10 Dec 2020 16:36:19
User entered 'UN UNK 2019' reason for change: Data Entry Error	Kelly Likos (b) (4)	20 Nov 2020 16:06:31
User opened query 'Per source, start date is recorded as 2019. Please update date in EDC to include an unknown day such as, UN-UNK-2019.' (Site from CRA).	(b) (4)	
User entered '01 UNK 2019'	(b) (4), (b) (6)	20 Nov 2020 16:06:15
	(b) (4), (b) (6)	19 Nov 2020 17:17:13
	(b) (4), (b) (6)	08 Sep 2020 23:14:53

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 09:13:35

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Colleen Kelley (b) (4)	12 Apr 2021 01:33:40
DataPoint activated with code reason code Data required.	(b) (4)	
	(b) (4), (b) (6)	08 Apr 2021 19:42:29
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	08 Apr 2021 19:41:29
Signature has been broken.	(b) (4), (b) (6)	08 Apr 2021 19:41:29
User signature succeeded.	Colleen Kelley (b) (4)	02 Apr 2021 20:59:30
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	19 Nov 2020 17:17:23
User entered '0'	(b) (4), (b) (6)	08 Sep 2020 23:14:53

US3632052

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 09:13:35

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Colleen Kelley (b) (4)	12 Apr 2021 01:33:40
DataPoint activated with code reason code Data required.	(b) (4)	
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	08 Apr 2021 19:42:29
Signature has been broken.	(b) (4), (b) (6)	08 Apr 2021 19:41:29
User signature succeeded.	Colleen Kelley (b) (4)	02 Apr 2021 20:59:30
DataPoint Verified.	(b) (4)	
User closed query 'Data is required. Please complete.' (Site from System).	(b) (4), (b) (6)	19 Nov 2020 17:17:32
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	
User entered 'Yes (Y)' reason for change: Data Entry Error	System	09 Sep 2020 13:38:16
User opened query 'Data is required. Please complete.' (Site from System).	(b) (4), (b) (6)	09 Sep 2020 13:38:16
User entered empty.	System	09 Sep 2020 13:38:16
	System	08 Sep 2020 23:14:53
	(b) (4), (b) (6)	08 Sep 2020 23:14:53

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 09:13:35

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

Audit	User	Time (GMT)
User signature succeeded.	Colleen Kelley (b) (4)	12 Apr 2021 01:33:40
	(b) (4)	
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	08 Apr 2021 19:42:29
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	08 Apr 2021 19:41:29
Signature has been broken.	(b) (4), (b) (6)	08 Apr 2021 19:41:29
User signature succeeded.	Colleen Kelley (b) (4)	02 Apr 2021 20:59:30
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 17:17:37
User entered empty.	(b) (4), (b) (6)	08 Sep 2020 23:14:53



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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 09:13:35

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Colleen Kelley (b) (4)	12 Apr 2021 01:33:40
DataPoint activated with code reason code Data required.	(b) (4)	
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	08 Apr 2021 19:42:29
Signature has been broken.	(b) (4), (b) (6)	08 Apr 2021 19:41:29
User signature succeeded.	Colleen Kelley (b) (4)	02 Apr 2021 20:59:30
DataPoint Verified.	(b) (4)	
User entered 'No (N)'	(b) (4), (b) (6)	19 Nov 2020 17:17:41
	(b) (4), (b) (6)	08 Sep 2020 23:14:53

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 09:13:35

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	08 Apr 2021 19:42:29
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	08 Apr 2021 19:41:29
User entered empty.	System	08 Sep 2020 23:14:53

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 09:13:35

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	08 Apr 2021 19:42:29
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	08 Apr 2021 19:41:29
User entered empty.	System	08 Sep 2020 23:14:53

US3632052

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (5)**

**Generated On: 10 Jun 2021 09:13:35**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	08 Apr 2021 19:42:29
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	08 Apr 2021 19:41:29
User entered empty.	System	08 Sep 2020 23:14:53

US3632052

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 09:13:35

Name of Medication

Audit	User	Time (GMT)
User signature succeeded.	Colleen Kelley (b) (4)	12 Apr 2021 01:33:40
User coded data point as ATC: RESPIRATORY SYSTEM, ATC: NASAL PREPARATIONS, ATC: DECONGESTANTS AND OTHER NASAL PREPARATIONS FOR TOPICAL USE, ATC: CORTICOSTEROIDS, PRODUCT: BECLOMETASONE DIPROPIONATE, PRODUCTSYNONYM: BECONASE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	08 Apr 2021 19:43:50
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	08 Apr 2021 19:43:50
Data point term sent to Coder	System	08 Apr 2021 19:42:53
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	08 Apr 2021 19:42:29
Data point term sent to Coder	System	08 Apr 2021 19:41:46
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	08 Apr 2021 19:41:29
Signature has been broken.	(b) (4), (b) (6)	08 Apr 2021 19:41:29
User signature succeeded.	Colleen Kelley (b) (4)	02 Apr 2021 20:59:30
DataPoint Verified.	(b) (4), (b) (6)	10 Dec 2020 16:36:42
User closed query 'Per source, medication is written as Beconase. Please verify with source and update EDC accordingly.' (Site from CRA).	(b) (4), (b) (6)	10 Dec 2020 16:36:28
User coded data point as ATC: RESPIRATORY SYSTEM, ATC: NASAL PREPARATIONS, ATC: DECONGESTANTS AND OTHER NASAL PREPARATIONS FOR TOPICAL USE, ATC: CORTICOSTEROIDS, PRODUCT: BECLOMETASONE DIPROPIONATE, PRODUCTSYNONYM: BECONASE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	20 Nov 2020 16:39:01
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	20 Nov 2020 16:39:01

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 09:13:35

Name of Medication

Audit	User	Time (GMT)
Query 'Per source, medication is written as Beconase. Please verify with source and update EDC accordingly.' answered with 'UPDATED' (Site from CRA).	Kelly Likos (b) (4)	20 Nov 2020 16:07:52
Data point term sent to Coder	System	20 Nov 2020 16:07:04
Coding entries removed.	Kelly Likos (b) (4)	20 Nov 2020 16:06:58
User entered 'BECONASE' reason for change: Data Entry Error	Kelly Likos (b) (4)	20 Nov 2020 16:06:58
User opened query 'Per source, medication is written as Beconase. Please verify with source and update EDC accordingly.' (Site from CRA).	(b) (4), (b) (6)	19 Nov 2020 17:18:28
User coded data point as ATC: RESPIRATORY SYSTEM, ATC: NASAL PREPARATIONS, ATC: DECONGESTANTS AND OTHER NASAL PREPARATIONS FOR TOPICAL USE, ATC: CORTICOSTEROIDS, PRODUCT: BECLOMETASONE DIPROPIONATE, PRODUCTSYNONYM: BECONASE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	10 Sep 2020 06:52:37
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	10 Sep 2020 06:52:37
Data point term sent to Coder	System	08 Sep 2020 23:17:00
User entered 'Beconase Nasal spray'	(b) (4), (b) (6)	08 Sep 2020 23:16:31

US3632052

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 09:13:35

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Colleen Kelley (b) (4)	12 Apr 2021 01:33:40
DataPoint activated with code reason code Data required.	(b) (4)	
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	08 Apr 2021 19:42:29
Signature has been broken.	(b) (4), (b) (6)	08 Apr 2021 19:41:29
User signature succeeded.	Colleen Kelley (b) (4)	02 Apr 2021 20:59:30
DataPoint Verified.	(b) (4)	
User entered 'No (N)'	(b) (4), (b) (6)	19 Nov 2020 17:18:48
	(b) (4), (b) (6)	08 Sep 2020 23:16:31

US3632052

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 09:13:35

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Colleen Kelley (b) (4)	12 Apr 2021 01:33:40
DataPoint activated with code reason code Data required.	(b) (4)	
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	08 Apr 2021 19:42:29
Signature has been broken.	(b) (4), (b) (6)	08 Apr 2021 19:41:29
User signature succeeded.	Colleen Kelley (b) (4)	02 Apr 2021 20:59:30
DataPoint Verified.	(b) (4)	
Query 'Per DM CLR: Con Med start date is prior to the start date of the Med History condition of SEASONAL ALLERGIES. Please review and reconcile Con Med and Med History start dates as appropriate.	(b) (4), (b) (6)	19 Nov 2020 17:18:54
' canceled (Site from DM).		
User opened query 'Per DM CLR: Con Med start date is prior to the start date of the Med History condition of SEASONAL ALLERGIES. Please review and reconcile Con Med and Med History start dates as appropriate.	(b) (4), (b) (6)	05 Oct 2020 19:30:54
' (Site from DM).		
User entered 'seasonal allergies'	(b) (4), (b) (6)	08 Sep 2020 23:16:31



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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 09:13:35

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Colleen Kelley (b) (4)	12 Apr 2021 01:33:40
	(b) (4)	
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	08 Apr 2021 19:42:29
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	08 Apr 2021 19:41:29
Signature has been broken.	(b) (4), (b) (6)	08 Apr 2021 19:41:29
User signature succeeded.	Colleen Kelley (b) (4)	02 Apr 2021 20:59:30
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 17:22:24
User entered '42'	(b) (4), (b) (6)	08 Sep 2020 23:16:31

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 09:13:35

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Colleen Kelley (b) (4)	12 Apr 2021 01:33:40
DataPoint activated with code reason code Data required.	(b) (4)	
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	08 Apr 2021 19:42:29
Signature has been broken.	(b) (4), (b) (6)	08 Apr 2021 19:41:29
User signature succeeded.	Colleen Kelley (b) (4)	02 Apr 2021 20:59:30
DataPoint Verified.	(b) (4)	
User entered 'ug (ug)'	(b) (4), (b) (6)	19 Nov 2020 17:22:26
	(b) (4), (b) (6)	08 Sep 2020 23:16:31

US3632052

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 09:13:35

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Colleen Kelley (b) (4)	12 Apr 2021 01:33:40
DataPoint activated with code reason code Data required.	(b) (4)	
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	08 Apr 2021 19:42:29
Signature has been broken.	(b) (4), (b) (6)	08 Apr 2021 19:41:29
User signature succeeded.	Colleen Kelley (b) (4)	02 Apr 2021 20:59:30
DataPoint Verified.	(b) (4)	
User entered empty.	(b) (4), (b) (6)	19 Nov 2020 17:22:28
	(b) (4), (b) (6)	08 Sep 2020 23:16:31

US3632052

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 09:13:35

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Colleen Kelley (b) (4)	12 Apr 2021 01:33:40
DataPoint activated with code reason code Data required.	(b) (4)	
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	08 Apr 2021 19:42:29
Signature has been broken.	(b) (4), (b) (6)	08 Apr 2021 19:41:29
User signature succeeded.	Colleen Kelley (b) (4)	02 Apr 2021 20:59:30
DataPoint Verified.	(b) (4)	
User entered 'as needed (PRN)'	(b) (4), (b) (6)	19 Nov 2020 17:22:32
	(b) (4), (b) (6)	08 Sep 2020 23:16:31

US3632052

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 09:13:35

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Colleen Kelley (b) (4)	12 Apr 2021 01:33:40
DataPoint activated with code reason code Data required.	(b) (4)	
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	08 Apr 2021 19:42:29
Signature has been broken.	(b) (4), (b) (6)	08 Apr 2021 19:41:29
User signature succeeded.	Colleen Kelley (b) (4)	02 Apr 2021 20:59:30
DataPoint Verified.	(b) (4)	
User entered empty.	(b) (4), (b) (6)	19 Nov 2020 17:22:34
		08 Sep 2020 23:16:31

US3632052

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 09:13:35

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Colleen Kelley (b) (4)	12 Apr 2021 01:33:40
	(b) (4)	
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	08 Apr 2021 19:42:29
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	08 Apr 2021 19:41:29
Signature has been broken.	(b) (4), (b) (6)	08 Apr 2021 19:41:29
User signature succeeded.	Colleen Kelley (b) (4)	02 Apr 2021 20:59:30
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 17:22:42
User entered 'Nasal (NASAL)'	(b) (4), (b) (6)	08 Sep 2020 23:16:31

US3632052

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 09:13:35

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Colleen Kelley (b) (4)	12 Apr 2021 01:33:40
DataPoint activated with code reason code Data required.	(b) (4)	
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	08 Apr 2021 19:42:29
Signature has been broken.	(b) (4), (b) (6)	08 Apr 2021 19:41:29
User signature succeeded.	Colleen Kelley (b) (4)	02 Apr 2021 20:59:30
DataPoint Verified.	(b) (4)	
User entered empty.	(b) (4), (b) (6)	19 Nov 2020 17:23:01
		08 Sep 2020 23:16:31

US3632052

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 09:13:35

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Colleen Kelley (b) (4)	12 Apr 2021 01:33:40
DataPoint activated with code reason code Data required.	(b) (4)	
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	08 Apr 2021 19:42:29
Signature has been broken.	(b) (4), (b) (6)	08 Apr 2021 19:41:29
User signature succeeded.	Colleen Kelley (b) (4)	02 Apr 2021 20:59:30
DataPoint Verified.	(b) (4)	
User closed query 'Per DM CLR: Response noted. However, Conmed start date is prior to the start date of the corresponding MH condition start date (01UNK2019). Please review and reconcile Medical History start date for the appropriate match.' (Site from DM).	(b) (4), (b) (6)	24 Mar 2021 19:38:55
Query 'Per DM CLR: Response noted. However, Conmed start date is prior to the start date of the corresponding MH condition start date (01UNK2019). Please review and reconcile Medical History start date for the appropriate match.' answered with 'fixed' (Site from DM).	(b) (4), (b) (6)	16 Feb 2021 03:07:57
DataPoint Un-verified.	Sarah Wiatrek (b) (4)	15 Feb 2021 17:49:36
User entered '01 UNK 2018' reason for change: Per Query Resolution	(b) (4)	
User opened query 'Per DM CLR: Response noted. However, Conmed start date is prior to the start date of the corresponding MH condition start date (01UNK2019). Please review and reconcile Medical History start date for the appropriate match.' (Site from DM).	Sarah Wiatrek (b) (4)	15 Feb 2021 17:49:29
User closed query 'Per DM CLR: Con Med start date is prior to the start date of the corresponding MH condition. Please review and reconcile Con Med and MH start dates as appropriate.' (Site from DM).	(b) (4), (b) (6)	12 Jan 2021 04:55:12



US3632052

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 09:13:35

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Query 'Per DM CLR: Con Med start date is prior to the start date of the corresponding MH condition. Please review and reconcile Con Med and MH start dates as appropriate.' answered with 'The exact start date is unknown and reported per the participant.' (Site from DM).	(b) (4), (b) (6)	11 Jan 2021 17:26:41
User opened query 'Per DM CLR: Con Med start date is prior to the start date of the corresponding MH condition. Please review and reconcile Con Med and MH start dates as appropriate.' (Site from DM).	(b) (4), (b) (6)	23 Dec 2020 07:50:13
DataPoint Verified.	(b) (4), (b) (6)	10 Dec 2020 16:36:42
User closed query 'Per source, start date is recorded as 2018. Please update date in EDC to include an unknown day such as, UN-UNK-2018.' (Site from CRA).	(b) (4), (b) (6)	10 Dec 2020 16:36:37
Query 'Per source, start date is recorded as 2018. Please update date in EDC to include an unknown day such as, UN-UNK-2018.' answered with 'UPDATED' (Site from CRA).	Kelly Likos (b) (4)	20 Nov 2020 16:08:07
User entered 'UN UNK 2018' reason for change: Data Entry Error	Kelly Likos (b) (4)	20 Nov 2020 16:08:02
User opened query 'Per source, start date is recorded as 2018. Please update date in EDC to include an unknown day such as, UN-UNK-2018.' (Site from CRA).	(b) (4), (b) (6)	19 Nov 2020 17:23:14
User closed query 'Per DM CLR: Con Med start date is prior to the start date of the Med History condition of SEASONAL ALLERGIES. Please review and reconcile Con Med and Med History start dates as appropriate.' (Site from DM).	(b) (4), (b) (6)	15 Oct 2020 05:55:33
Query 'Per DM CLR: Con Med start date is prior to the start date of the Med History condition of SEASONAL ALLERGIES. Please review and reconcile Con Med and Med History start dates as appropriate.' answered with 'Participant used spray before being formally diagnosed with seasonal allergies.' (Site from DM).	Isaac Perez (b) (4)	14 Oct 2020 18:30:42

US3632052

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 09:13:35

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User opened query 'Per DM CLR: Con Med start date is prior to the start date of the Med History condition of SEASONAL ALLERGIES. Please review and reconcile Con Med and Med History start dates as appropriate. ' (Site from DM).	(b) (4), (b) (6)	05 Oct 2020 19:31:00
User entered '01 UNK 2018'	(b) (4), (b) (6)	08 Sep 2020 23:16:31

US3632052

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 09:13:35

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Colleen Kelley (b) (4)	12 Apr 2021 01:33:40
DataPoint activated with code reason code Data required.	(b) (4)	
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	08 Apr 2021 19:42:29
Signature has been broken.	(b) (4), (b) (6)	08 Apr 2021 19:41:29
User signature succeeded.	Colleen Kelley (b) (4)	02 Apr 2021 20:59:30
DataPoint Verified.	(b) (4)	
User entered '0'	(b) (4), (b) (6)	19 Nov 2020 17:23:20
		08 Sep 2020 23:16:31

US3632052

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 09:13:35

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Colleen Kelley (b) (4)	12 Apr 2021 01:33:40
	(b) (4)	
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	08 Apr 2021 19:42:29
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	08 Apr 2021 19:41:29
Signature has been broken.	(b) (4), (b) (6)	08 Apr 2021 19:41:29
User signature succeeded.	Colleen Kelley (b) (4)	02 Apr 2021 20:59:30
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 17:23:22
User entered 'Yes (Y)'	(b) (4), (b) (6)	08 Sep 2020 23:16:31

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 09:13:35

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

Audit	User	Time (GMT)
User signature succeeded.	Colleen Kelley (b) (4)	12 Apr 2021 01:33:40
	(b) (4)	
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	08 Apr 2021 19:42:29
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	08 Apr 2021 19:41:29
Signature has been broken.	(b) (4), (b) (6)	08 Apr 2021 19:41:29
User signature succeeded.	Colleen Kelley (b) (4)	02 Apr 2021 20:59:30
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 17:23:24
User entered empty.	(b) (4), (b) (6)	08 Sep 2020 23:16:31

**Folder: Concomitant Medication and Vaccination (1)**  
**Form: Prior/Concomitant Medication and Vaccination (6)**  
**Generated On: 10 Jun 2021 09:13:35**  
[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Colleen Kelley (b) (4)	12 Apr 2021 01:33:40
DataPoint activated with code reason code Data required.	(b) (4) (b) (4), (b) (6)	08 Apr 2021 19:42:29
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	08 Apr 2021 19:41:29
Signature has been broken.	(b) (4), (b) (6)	08 Apr 2021 19:41:29
User signature succeeded.	Colleen Kelley (b) (4)	02 Apr 2021 20:59:30
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Nov 2020 17:23:26
User closed query 'Data is required. Please complete.' (Site from System).	System	09 Sep 2020 13:38:38
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	09 Sep 2020 13:38:38
User entered 'No (N)' reason for change: Data Entry Error	(b) (4), (b) (6)	09 Sep 2020 13:38:38
User opened query 'Data is required. Please complete.' (Site from System).	System	08 Sep 2020 23:16:31
User entered empty.	(b) (4), (b) (6)	08 Sep 2020 23:16:31

**US3632052**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (6)**

**Generated On: 10 Jun 2021 09:13:35**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	08 Apr 2021 19:42:29
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	08 Apr 2021 19:41:29
User entered empty.	System	08 Sep 2020 23:16:31

**US3632052**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (6)**

**Generated On: 10 Jun 2021 09:13:35**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	08 Apr 2021 19:42:29
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	08 Apr 2021 19:41:29
User entered empty.	System	08 Sep 2020 23:16:31



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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 09:13:35

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	08 Apr 2021 19:42:29
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	08 Apr 2021 19:41:29
User entered empty.	System	08 Sep 2020 23:16:31

US3632052

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 09:13:35

Name of Medication

Audit	User	Time (GMT)
User signature succeeded.	Colleen Kelley (b) (4)	12 Apr 2021 01:33:40
User coded data point as ATC: NERVOUS SYSTEM, ATC: PSYCHOLEPTICS, ATC: HYPNOTICS AND SEDATIVES, ATC: BENZODIAZEPINE RELATED DRUGS, PRODUCT: ZOLPIDEM TARTRATE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	08 Apr 2021 19:43:50
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	08 Apr 2021 19:43:50
Data point term sent to Coder	System	08 Apr 2021 19:42:53
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	08 Apr 2021 19:42:29
Data point term sent to Coder	System	08 Apr 2021 19:41:46
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	08 Apr 2021 19:41:29
Signature has been broken.	(b) (4), (b) (6)	08 Apr 2021 19:41:29
User signature succeeded.	Colleen Kelley (b) (4)	02 Apr 2021 20:59:30
User closed query 'Per source, this medication is written as, "Zolpidem Tartrate". Please verify with source and update EDC accordingly.' (Site from CRA).	(b) (4), (b) (6)	10 Dec 2020 16:37:00
DataPoint Verified.	(b) (4), (b) (6)	10 Dec 2020 16:36:42
User coded data point as ATC: NERVOUS SYSTEM, ATC: PSYCHOLEPTICS, ATC: HYPNOTICS AND SEDATIVES, ATC: BENZODIAZEPINE RELATED DRUGS, PRODUCT: ZOLPIDEM TARTRATE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	01 Dec 2020 15:53:59
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	01 Dec 2020 15:53:59
Data point term sent to Coder	System	01 Dec 2020 15:52:14
Coding entries removed.	Isaac Perez (b) (4)	01 Dec 2020 15:51:16

US3632052

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 09:13:35

Name of Medication

Audit	User	Time (GMT)
User coded data point as ATC: NERVOUS SYSTEM, ATC: PSYCHOLEPTICS, ATC: HYPNOTICS AND SEDATIVES, ATC: BENZODIAZEPINE RELATED DRUGS, PRODUCT: ZOLPIDEM TARTRATE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	22 Nov 2020 05:23:10
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	22 Nov 2020 05:23:10
Data point term sent to Coder	System	20 Nov 2020 16:09:08
Query 'Per source, this medication is written as, "Zolpidem Tartrate". Please verify with source and update EDC accordingly.' answered with 'UPATED' (Site from CRA).	Kelly Likos (b) (4) (b) (4)	20 Nov 2020 16:09:02
Coding entries removed.	Kelly Likos (b) (4) (b) (4)	20 Nov 2020 16:08:53
User entered 'ZOLPIDEM TARTRATE' reason for change: Data Entry Error	Kelly Likos (b) (4) (b) (4)	20 Nov 2020 16:08:53
User opened query 'Per source, this medication is written as, "Zolpidem Tartrate". Please verify with source and update EDC accordingly.' (Site from CRA).	(b) (4), (b) (6) (b) (4)	19 Nov 2020 17:26:07
User coded data point as ATC: NERVOUS SYSTEM, ATC: PSYCHOLEPTICS, ATC: HYPNOTICS AND SEDATIVES, ATC: BENZODIAZEPINE RELATED DRUGS, PRODUCT: ZOLPIDEM - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	14 Oct 2020 04:56:24
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	14 Oct 2020 04:56:24
Data point term sent to Coder	System	13 Oct 2020 19:14:23
Coding entries removed.	Isaac Perez (b) (4) (b) (4)	13 Oct 2020 19:14:22
User coded data point as ATC: NERVOUS SYSTEM, ATC: PSYCHOLEPTICS, ATC: HYPNOTICS AND SEDATIVES, ATC: BENZODIAZEPINE RELATED DRUGS, PRODUCT: ZOLPIDEM - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	09 Sep 2020 01:16:30

US3632052

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 09:13:35

[Name of Medication](#)

Audit	User	Time (GMT)
User coded data point as Term Coded data point by	Coder Import (b) (4)	09 Sep 2020 01:16:30
User: (b) (6) - version	(b) (4)	
WHODrug-Global-B3\\202003.		
Data point term sent to Coder	System	08 Sep 2020 23:22:04
User entered 'Zolpidem'	(b) (4), (b) (6)	08 Sep 2020 23:21:30

US3632052

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 09:13:35

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Colleen Kelley (b) (4)	12 Apr 2021 01:33:40
	(b) (4)	
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	08 Apr 2021 19:42:29
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	08 Apr 2021 19:41:29
Signature has been broken.	(b) (4), (b) (6)	08 Apr 2021 19:41:29
User signature succeeded.	Colleen Kelley (b) (4)	02 Apr 2021 20:59:30
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 17:27:54
User entered 'No (N)'	(b) (4), (b) (6)	08 Sep 2020 23:21:30

US3632052

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 09:13:35

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Colleen Kelley (b) (4)	12 Apr 2021 01:33:40
DataPoint activated with code reason code Data required.	(b) (4)	
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	08 Apr 2021 19:42:29
Signature has been broken.	(b) (4), (b) (6)	08 Apr 2021 19:41:29
User signature succeeded.	Colleen Kelley (b) (4)	02 Apr 2021 20:59:30
DataPoint Verified.	(b) (4)	
User closed query 'Per DM CLR: Please review the indication of this medication as this is not the expected use for this medication. Either change the indication or provide explanation for alternate/different use. Update eCRF as appropriate.' (Site from DM).	(b) (4), (b) (6)	10 Dec 2020 16:36:42
Query 'Per DM CLR: Please review the indication of this medication as this is not the expected use for this medication. Either change the indication or provide explanation for alternate/different use. Update eCRF as appropriate.' answered with 'Updated indication' (Site from DM).	(b) (4), (b) (6)	02 Dec 2020 06:07:44
DataPoint Un-verified.	Isaac Perez (b) (4)	
User entered 'Insomnia' reason for change: Data Entry Error	(b) (4)	01 Dec 2020 15:51:23
User opened query 'Per DM CLR: Please review the indication of this medication as this is not the expected use for this medication. Either change the indication or provide explanation for alternate/different use. Update eCRF as appropriate.' (Site from DM).	Isaac Perez (b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	01 Dec 2020 15:51:16
User closed query 'Per DM CLR: Re query: Please reconcile updated indication with Med History eCRF as appropriate.' (Site from DM).	(b) (4)	01 Dec 2020 15:51:16
Query 'Per DM CLR: Re query: Please reconcile updated indication with Med History eCRF as appropriate.' answered with 'Updated MH' (Site from DM).	(b) (4), (b) (6)	25 Nov 2020 14:34:31
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 17:27:58
User closed query 'Per DM CLR: Re query: Please reconcile updated indication with Med History eCRF as appropriate.' (Site from DM).	(b) (4), (b) (6)	15 Oct 2020 06:00:48
Query 'Per DM CLR: Re query: Please reconcile updated indication with Med History eCRF as appropriate.' answered with 'Updated MH' (Site from DM).	Isaac Perez (b) (4)	
	(b) (4)	14 Oct 2020 18:31:34

PRODUCTION RELEASE (v12.003  
EAB) (1725)

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 09:13:35

[Indication](#)

Audit	User	Time (GMT)
User opened query 'Per DM CLR: Re query: Please reconcile updated indication with Med History eCRF as appropriate.' (Site from DM).	(b) (4), (b) (6)	14 Oct 2020 06:08:32
User closed query 'Per DM CLR: Please update the indication to reflect the location of TINNITUS ( in one or both ears). Please reconcile with the AE and Med History eCRFs as appropriate' (Site from DM).	(b) (4), (b) (6)	14 Oct 2020 05:55:14
Query 'Per DM CLR: Please update the indication to reflect the location of TINNITUS ( in one or both ears). Please reconcile with the AE and Med History eCRFs as appropriate' answered with 'Updated indication.' (Site from DM).	Isaac Perez (b) (4)	13 Oct 2020 19:14:32
User entered 'TINNITUS in both ears' reason for change: Data Entry Error	Isaac Perez (b) (4)	13 Oct 2020 19:14:22
User opened query 'Per DM CLR: Please update the indication to reflect the location of TINNITUS ( in one or both ears). Please reconcile with the AE and Med History eCRFs as appropriate' (Site from DM).	(b) (4), (b) (6)	05 Oct 2020 19:31:24
User entered 'Tinnitus'	(b) (4), (b) (6)	08 Sep 2020 23:21:30

US3632052

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 09:13:35

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Colleen Kelley (b) (4)	12 Apr 2021 01:33:40
DataPoint activated with code reason code Data required.	(b) (4)	
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	08 Apr 2021 19:42:29
Signature has been broken.	(b) (4), (b) (6)	08 Apr 2021 19:41:29
User signature succeeded.	Colleen Kelley (b) (4)	02 Apr 2021 20:59:30
DataPoint Verified.	(b) (4)	
User entered '10'	(b) (4), (b) (6)	19 Nov 2020 17:31:07
		08 Sep 2020 23:21:30



US3632052

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 09:13:35

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Colleen Kelley (b) (4)	12 Apr 2021 01:33:40
DataPoint activated with code reason code Data required.	(b) (4)	
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	08 Apr 2021 19:42:29
Signature has been broken.	(b) (4), (b) (6)	08 Apr 2021 19:41:29
User signature succeeded.	Colleen Kelley (b) (4)	02 Apr 2021 20:59:30
DataPoint Verified.	(b) (4)	
User entered 'mg (mg)'	(b) (4), (b) (6)	19 Nov 2020 17:32:01
	(b) (4), (b) (6)	08 Sep 2020 23:21:30

US3632052

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 09:13:35

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Colleen Kelley (b) (4)	12 Apr 2021 01:33:40
DataPoint activated with code reason code Data required.	(b) (4)	
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	08 Apr 2021 19:42:29
Signature has been broken.	(b) (4), (b) (6)	08 Apr 2021 19:41:29
User signature succeeded.	Colleen Kelley (b) (4)	02 Apr 2021 20:59:30
DataPoint Verified.	(b) (4)	
User entered empty.	(b) (4), (b) (6)	19 Nov 2020 17:32:04
		08 Sep 2020 23:21:30

US3632052

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 09:13:35

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Colleen Kelley (b) (4)	12 Apr 2021 01:33:40
DataPoint activated with code reason code Data required.	(b) (4)	
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	08 Apr 2021 19:42:29
Signature has been broken.	(b) (4), (b) (6)	08 Apr 2021 19:41:29
User signature succeeded.	Colleen Kelley (b) (4)	02 Apr 2021 20:59:30
DataPoint Verified.	(b) (4)	
User entered 'as needed (PRN)'	(b) (4), (b) (6)	19 Nov 2020 17:32:08
	(b) (4), (b) (6)	08 Sep 2020 23:21:30

US3632052

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 09:13:35

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Colleen Kelley (b) (4)	12 Apr 2021 01:33:40
DataPoint activated with code reason code Data required.	(b) (4)	
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	08 Apr 2021 19:42:29
Signature has been broken.	(b) (4), (b) (6)	08 Apr 2021 19:41:29
User signature succeeded.	Colleen Kelley (b) (4)	02 Apr 2021 20:59:30
DataPoint Verified.	(b) (4)	
User entered empty.	(b) (4), (b) (6)	19 Nov 2020 17:32:10
	(b) (4), (b) (6)	08 Sep 2020 23:21:30

US3632052

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 09:13:35

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Colleen Kelley (b) (4)	12 Apr 2021 01:33:40
DataPoint activated with code reason code Data required.	(b) (4)	
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	08 Apr 2021 19:42:29
Signature has been broken.	(b) (4), (b) (6)	08 Apr 2021 19:41:29
User signature succeeded.	Colleen Kelley (b) (4)	02 Apr 2021 20:59:30
DataPoint Verified.	(b) (4)	
User entered 'Oral (ORAL)'	(b) (4), (b) (6)	19 Nov 2020 17:32:13
	(b) (4), (b) (6)	08 Sep 2020 23:21:30

US3632052

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 09:13:35

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Colleen Kelley (b) (4)	12 Apr 2021 01:33:40
DataPoint activated with code reason code Data required.	(b) (4)	
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	08 Apr 2021 19:42:29
Signature has been broken.	(b) (4), (b) (6)	08 Apr 2021 19:41:29
User signature succeeded.	Colleen Kelley (b) (4)	02 Apr 2021 20:59:30
DataPoint Verified.	(b) (4)	
User entered empty.	(b) (4), (b) (6)	19 Nov 2020 17:32:18
	(b) (4), (b) (6)	08 Sep 2020 23:21:30

US3632052

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 09:13:35

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Colleen Kelley (b) (4)	12 Apr 2021 01:33:40
DataPoint activated with code reason code Data required.	(b) (4)	
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	08 Apr 2021 19:42:29
Signature has been broken.	(b) (4), (b) (6)	08 Apr 2021 19:41:29
User signature succeeded.	Colleen Kelley (b) (4)	02 Apr 2021 20:59:30
User closed query 'Per source, start date is recorded as 2016. Please update date in EDC to include an unknown day such as, UN-UNK-2016.' (Site from CRA).	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	10 Dec 2020 16:37:09
Query 'Per source, start date is recorded as 2016. Please update date in EDC to include an unknown day such as, UN-UNK-2016.' answered with 'UPDATED' (Site from CRA).	(b) (4), (b) (6)	10 Dec 2020 16:36:42
User entered 'UN UNK 2016' reason for change: Data Entry Error	Kelly Likos (b) (4)	20 Nov 2020 16:09:09
User opened query 'Per source, start date is recorded as 2016. Please update date in EDC to include an unknown day such as, UN-UNK-2016.' (Site from CRA).	(b) (4)	
User closed query 'Per DM CLR: Con Med start date is prior to the start date of the Med History condition of TINNITUS. Please review and reconcile Con Med and Med History start dates as appropriate.' (Site from DM).	(b) (4), (b) (6)	20 Nov 2020 16:08:53
Query 'Per DM CLR: Con Med start date is prior to the start date of the Med History condition of TINNITUS. Please review and reconcile Con Med and Med History start dates as appropriate.' answered with 'updated' (Site from DM).	(b) (4), (b) (6)	19 Nov 2020 17:33:47
User opened query 'Per DM CLR: Con Med start date is prior to the start date of the Med History condition of TINNITUS. Please review and reconcile Con Med and Med History start dates as appropriate.' (Site from DM).	(b) (4), (b) (6)	23 Oct 2020 18:19:32
Query 'Per DM CLR: Con Med start date is prior to the start date of the Med History condition of TINNITUS. Please review and reconcile Con Med and Med History start dates as appropriate.' answered with 'updated' (Site from DM).	Christina Bacher (b) (4)	20 Oct 2020 16:48:00
User opened query 'Per DM CLR: Con Med start date is prior to the start date of the Med History condition of TINNITUS. Please review and reconcile Con Med and Med History start dates as appropriate.' (Site from DM).	(b) (4)	
User opened query 'Per DM CLR: Con Med start date is prior to the start date of the Med History condition of TINNITUS. Please review and reconcile Con Med and Med History start dates as appropriate.' (Site from DM).	(b) (4), (b) (6)	05 Oct 2020 19:31:39

US3632052

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 09:13:35

Start date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User entered '01 UNK 2016'	(b) (4), (b) (6)	08 Sep 2020 23:21:30



US3632052

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 09:13:35

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Colleen Kelley (b) (4)	12 Apr 2021 01:33:40
DataPoint activated with code reason code Data required.	(b) (4)	
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	08 Apr 2021 19:42:29
Signature has been broken.	(b) (4), (b) (6)	08 Apr 2021 19:41:29
User signature succeeded.	Colleen Kelley (b) (4)	02 Apr 2021 20:59:30
DataPoint Verified.	(b) (4)	
User entered '0'	(b) (4), (b) (6)	19 Nov 2020 17:33:51
		08 Sep 2020 23:21:30

US3632052

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 09:13:35

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Colleen Kelley (b) (4)	12 Apr 2021 01:33:40
	(b) (4)	
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	08 Apr 2021 19:42:29
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	08 Apr 2021 19:41:29
Signature has been broken.	(b) (4), (b) (6)	08 Apr 2021 19:41:29
User signature succeeded.	Colleen Kelley (b) (4)	02 Apr 2021 20:59:30
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 17:33:54
User entered 'Yes (Y)'	(b) (4), (b) (6)	08 Sep 2020 23:21:30

US3632052

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 09:13:35

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

Audit	User	Time (GMT)
User signature succeeded.	Colleen Kelley (b) (4)	12 Apr 2021 01:33:40
DataPoint activated with code reason code Data required.	(b) (4)	
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	08 Apr 2021 19:42:29
Signature has been broken.	(b) (4), (b) (6)	08 Apr 2021 19:41:29
User signature succeeded.	Colleen Kelley (b) (4)	02 Apr 2021 20:59:30
DataPoint Verified.	(b) (4)	
User entered empty.	(b) (4), (b) (6)	19 Nov 2020 17:34:08
		08 Sep 2020 23:21:30

US3632052

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 09:13:35

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Colleen Kelley (b) (4)	12 Apr 2021 01:33:40
DataPoint activated with code reason code Data required.	(b) (4)	
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	08 Apr 2021 19:42:29
Signature has been broken.	(b) (4), (b) (6)	08 Apr 2021 19:41:29
User signature succeeded.	Colleen Kelley (b) (4)	02 Apr 2021 20:59:30
DataPoint Verified.	(b) (4)	
User entered 'No (N)'	(b) (4), (b) (6)	19 Nov 2020 17:34:10
	(b) (4), (b) (6)	08 Sep 2020 23:21:30

**US3632052**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (7)**

**Generated On: 10 Jun 2021 09:13:35**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	08 Apr 2021 19:42:29
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	08 Apr 2021 19:41:29
User entered empty.	System	08 Sep 2020 23:21:30

US3632052

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 09:13:35

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	08 Apr 2021 19:42:29
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	08 Apr 2021 19:41:29
User entered empty.	System	08 Sep 2020 23:21:30

US3632052

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 09:13:35

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	08 Apr 2021 19:42:29
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	08 Apr 2021 19:41:29
User entered empty.	System	08 Sep 2020 23:21:30

US3632052

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 09:13:35

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 06:10:03
User signature succeeded.	Colleen Kelley (b) (4)	12 Apr 2021 01:33:40
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: VITAMINS, ATC: MULTIVITAMINS, PLAIN, ATC: MULTIVITAMINS, PLAIN, PRODUCT: VITAMINS NOS, PRODUCTSYNONYM: MULTIVITAMIN [VITAMINS NOS] - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	08 Apr 2021 19:44:20
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	08 Apr 2021 19:44:20
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: VITAMINS, ATC: MULTIVITAMINS, PLAIN, ATC: MULTIVITAMINS, PLAIN, PRODUCT: VITAMINS NOS, PRODUCTSYNONYM: MULTIVITAMIN [VITAMINS NOS] - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	08 Apr 2021 19:43:49
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	08 Apr 2021 19:43:49
Data point term sent to Coder	System	08 Apr 2021 19:42:53
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	08 Apr 2021 19:42:29
Data point term sent to Coder	System	08 Apr 2021 19:41:46
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	08 Apr 2021 19:41:29
Signature has been broken.	(b) (4), (b) (6)	08 Apr 2021 19:41:29
User signature succeeded.	Colleen Kelley (b) (4)	02 Apr 2021 20:59:30
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 17:34:30



US3632052

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 09:13:35

[Name of Medication](#)

Audit	User	Time (GMT)
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: VITAMINS, ATC: MULTIVITAMINS, PLAIN, ATC: MULTIVITAMINS, PLAIN, PRODUCT: VITAMINS NOS, PRODUCTSYNONYM: MULTIVITAMIN [VITAMINS NOS] - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	09 Sep 2020 06:37:39
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	09 Sep 2020 06:37:39
Data point term sent to Coder	System	08 Sep 2020 23:23:05
User entered 'one a day men's vitamin'	(b) (4), (b) (6) (b) (4)	08 Sep 2020 23:22:32

US3632052

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 09:13:35

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 06:10:03
User signature succeeded.	Colleen Kelley (b) (4)	12 Apr 2021 01:33:40
DataPoint activated with code reason code Data required.	(b) (4)	08 Apr 2021 19:42:29
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	08 Apr 2021 19:41:29
Signature has been broken.	(b) (4), (b) (6)	08 Apr 2021 19:41:29
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 19:39:01
User signature succeeded.	Colleen Kelley (b) (4)	02 Apr 2021 20:59:30
DataPoint Un-verified.	(b) (4)	24 Mar 2021 19:40:40
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 17:34:35
User entered 'Yes (Y)'	(b) (4), (b) (6)	08 Sep 2020 23:22:32

US3632052

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 09:13:35

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 06:10:03
User signature succeeded.	Colleen Kelley (b) (4)	12 Apr 2021 01:33:40
DataPoint activated with code reason code Data required.	(b) (4)	08 Apr 2021 19:42:29
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	08 Apr 2021 19:41:29
Signature has been broken.	(b) (4), (b) (6)	08 Apr 2021 19:41:29
User signature succeeded.	Colleen Kelley (b) (4)	02 Apr 2021 20:59:30
DataPoint Verified.	(b) (4)	19 Nov 2020 17:34:39
User entered 'general health'	(b) (4), (b) (6)	08 Sep 2020 23:22:32

US3632052

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 09:13:35

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 06:10:03
User signature succeeded.	Colleen Kelley (b) (4)	12 Apr 2021 01:33:40
DataPoint activated with code reason code Data required.	(b) (4)	08 Apr 2021 19:42:29
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	08 Apr 2021 19:41:29
Signature has been broken.	(b) (4), (b) (6)	08 Apr 2021 19:41:29
User signature succeeded.	Colleen Kelley (b) (4)	02 Apr 2021 20:59:30
DataPoint Verified.	(b) (4)	10 Dec 2020 16:36:42
User entered 'I'	(b) (4), (b) (6)	08 Sep 2020 23:22:32

US3632052

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 09:13:35

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 06:10:03
User signature succeeded.	Colleen Kelley (b) (4)	12 Apr 2021 01:33:40
DataPoint activated with code reason code Data required.	(b) (4)	08 Apr 2021 19:42:29
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	08 Apr 2021 19:41:29
Signature has been broken.	(b) (4), (b) (6)	08 Apr 2021 19:41:29
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 19:39:07
User signature succeeded.	Colleen Kelley (b) (4)	02 Apr 2021 20:59:30
DataPoint Un-verified.	Isaac Perez (b) (4)	29 Mar 2021 18:26:13
User entered 'tablet (TABLET)' reason for change: Data Entry Error	Isaac Perez (b) (4)	29 Mar 2021 18:26:13
DataPoint Verified.	(b) (4), (b) (6)	10 Dec 2020 16:36:42
User entered 'Other (OTHER)'	(b) (4), (b) (6)	08 Sep 2020 23:22:32

US3632052

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 09:13:35

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 06:10:03
User signature succeeded.	Colleen Kelley (b) (4)	12 Apr 2021 01:33:40
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	08 Apr 2021 19:42:29
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	08 Apr 2021 19:41:29
Signature has been broken.	(b) (4), (b) (6)	08 Apr 2021 19:41:29
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 19:39:09
User signature succeeded.	Colleen Kelley (b) (4)	02 Apr 2021 20:59:30
User entered empty; reason for change Data Entry Error	Isaac Perez (b) (4)	29 Mar 2021 18:26:13
DataPoint Un-verified.	Isaac Perez (b) (4)	29 Mar 2021 18:25:50
User entered 'Tab' reason for change: Data Entry Error	Isaac Perez (b) (4)	29 Mar 2021 18:25:50
DataPoint Verified.	(b) (4), (b) (6)	10 Dec 2020 16:36:42
User closed query 'Dose unit is Other, however Other, specify is missing. Please provide.' (Site from System).	System	09 Sep 2020 13:39:04
User entered 'unknown' reason for change: Data Entry Error	(b) (4), (b) (6)	09 Sep 2020 13:39:04
User opened query 'Dose unit is Other, however Other, specify is missing. Please provide.' (Site from System).	System	08 Sep 2020 23:22:32
User entered empty.	(b) (4), (b) (6)	08 Sep 2020 23:22:32

US3632052

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 09:13:35

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 06:10:03
User signature succeeded.	Colleen Kelley (b) (4)	12 Apr 2021 01:33:40
DataPoint activated with code reason code Data required.	(b) (4)	08 Apr 2021 19:42:29
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	08 Apr 2021 19:41:29
Signature has been broken.	(b) (4), (b) (6)	08 Apr 2021 19:41:29
User signature succeeded.	Colleen Kelley (b) (4)	02 Apr 2021 20:59:30
DataPoint Verified.	(b) (4)	19 Nov 2020 17:34:47
User entered 'once daily (QD)'	(b) (4), (b) (6)	08 Sep 2020 23:22:32

US3632052

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 09:13:35

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 06:10:03
User signature succeeded.	Colleen Kelley (b) (4)	12 Apr 2021 01:33:40
DataPoint activated with code reason code Data required.	(b) (4)	08 Apr 2021 19:42:29
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	08 Apr 2021 19:41:29
Signature has been broken.	(b) (4), (b) (6)	08 Apr 2021 19:41:29
User signature succeeded.	Colleen Kelley (b) (4)	02 Apr 2021 20:59:30
DataPoint Verified.	(b) (4)	19 Nov 2020 17:34:50
User entered empty.	(b) (4), (b) (6)	08 Sep 2020 23:22:32



US3632052

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 09:13:35

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 06:10:03
User signature succeeded.	Colleen Kelley (b) (4)	12 Apr 2021 01:33:40
DataPoint activated with code reason code Data required.	(b) (4)	08 Apr 2021 19:42:29
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	08 Apr 2021 19:41:29
Signature has been broken.	(b) (4), (b) (6)	08 Apr 2021 19:41:29
User signature succeeded.	Colleen Kelley (b) (4)	02 Apr 2021 20:59:30
DataPoint Verified.	(b) (4)	19 Nov 2020 17:36:16
User entered 'Oral (ORAL)'	(b) (4), (b) (6)	08 Sep 2020 23:22:32

US3632052

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 09:13:35

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 06:10:03
User signature succeeded.	Colleen Kelley (b) (4)	12 Apr 2021 01:33:40
DataPoint activated with code reason code Data required.	(b) (4)	08 Apr 2021 19:42:29
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	08 Apr 2021 19:41:29
Signature has been broken.	(b) (4), (b) (6)	08 Apr 2021 19:41:29
User signature succeeded.	Colleen Kelley (b) (4)	02 Apr 2021 20:59:30
DataPoint Verified.	(b) (4)	19 Nov 2020 17:36:20
User entered empty.	(b) (4), (b) (6)	08 Sep 2020 23:22:32

US3632052

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 09:13:35

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 06:10:03
User signature succeeded.	Colleen Kelley (b) (4)	12 Apr 2021 01:33:40
DataPoint activated with code reason code Data required.	(b) (4)	
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	08 Apr 2021 19:42:29
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	08 Apr 2021 19:41:29
Signature has been broken.	(b) (4), (b) (6)	08 Apr 2021 19:41:29
User signature succeeded.	Colleen Kelley (b) (4)	02 Apr 2021 20:59:30
User closed query 'Per source, start date is recorded as 2020. Please update date in EDC to include an unknown day such as, UN-UNK-2020.' (Site from CRA).	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	10 Dec 2020 16:37:20
Query 'Per source, start date is recorded as 2020. Please update date in EDC to include an unknown day such as, UN-UNK-2020.' answered with 'UPDATED' (Site from CRA).	(b) (4), (b) (6)	10 Dec 2020 16:36:42
User entered 'UN UNK 2020' reason for change: Data Entry Error	Kelly Likos (b) (4)	20 Nov 2020 16:09:43
User opened query 'Per source, start date is recorded as 2020. Please update date in EDC to include an unknown day such as, UN-UNK-2020.' (Site from CRA).	(b) (4)	
User entered '01 UNK 2020'	(b) (4), (b) (6)	20 Nov 2020 16:09:35
	(b) (4)	
	(b) (4), (b) (6)	19 Nov 2020 17:36:39
	(b) (4), (b) (6)	
	(b) (4), (b) (6)	08 Sep 2020 23:22:32

US3632052

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 09:13:35

Start date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 06:10:03
User signature succeeded.	Colleen Kelley (b) (4)	12 Apr 2021 01:33:40
DataPoint activated with code reason code Data required.	(b) (4)	08 Apr 2021 19:42:29
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	08 Apr 2021 19:41:29
Signature has been broken.	(b) (4), (b) (6)	08 Apr 2021 19:41:29
User signature succeeded.	Colleen Kelley (b) (4)	02 Apr 2021 20:59:30
DataPoint Verified.	(b) (4)	19 Nov 2020 17:36:50
User entered '0'	(b) (4), (b) (6)	08 Sep 2020 23:22:32

US3632052

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 09:13:35

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 06:10:03
User signature succeeded.	Colleen Kelley (b) (4)	12 Apr 2021 01:33:40
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	08 Apr 2021 19:42:29
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	08 Apr 2021 19:41:29
Signature has been broken.	(b) (4), (b) (6)	08 Apr 2021 19:41:29
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 19:39:30
User signature succeeded.	Colleen Kelley (b) (4)	02 Apr 2021 20:59:30
DataPoint Un-verified.	(b) (4), (b) (6)	01 Apr 2021 19:51:46
User entered 'No (N)' reason for change: Data Entry Error	(b) (4), (b) (6)	01 Apr 2021 19:51:46
DataPoint Verified.	(b) (4), (b) (6)	10 Dec 2020 16:36:42
User entered 'Yes (Y)'	(b) (4), (b) (6)	08 Sep 2020 23:22:32

US3632052

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 09:13:35

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 06:10:03
User signature succeeded.	Colleen Kelley (b) (4)	12 Apr 2021 01:33:40
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	08 Apr 2021 19:42:29
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	08 Apr 2021 19:41:29
Signature has been broken.	(b) (4), (b) (6)	08 Apr 2021 19:41:29
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 19:39:34
User signature succeeded.	Colleen Kelley (b) (4)	02 Apr 2021 20:59:30
DataPoint Un-verified.	(b) (4), (b) (6)	01 Apr 2021 19:51:46
User entered 'un Feb 2021' reason for change: Data Entry Error	(b) (4), (b) (6)	01 Apr 2021 19:51:46
DataPoint Verified.	(b) (4), (b) (6)	10 Dec 2020 16:36:42
User entered empty.	(b) (4), (b) (6)	08 Sep 2020 23:22:32

US3632052

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 09:13:35

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 06:10:03
User signature succeeded.	Colleen Kelley (b) (4)	12 Apr 2021 01:33:40
DataPoint activated with code reason code Data required.	(b) (4)	08 Apr 2021 19:42:29
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	08 Apr 2021 19:41:29
Signature has been broken.	(b) (4), (b) (6)	08 Apr 2021 19:41:29
User signature succeeded.	Colleen Kelley (b) (4)	02 Apr 2021 20:59:30
DataPoint Verified.	(b) (4)	19 Nov 2020 17:36:52
User entered 'No (N)'	(b) (4), (b) (6)	08 Sep 2020 23:22:32

US3632052

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 09:13:35

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 06:10:03
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	08 Apr 2021 19:42:29
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	08 Apr 2021 19:41:29
User entered '1'	System	08 Sep 2020 23:22:32



US3632052

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 09:13:35

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 06:10:03
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	08 Apr 2021 19:42:29
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	08 Apr 2021 19:41:29
User entered '1'	System	08 Sep 2020 23:22:32

US3632052

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 09:13:35

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 06:10:03
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	08 Apr 2021 19:42:29
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	08 Apr 2021 19:41:29
User entered '804 (804)'	System	08 Sep 2020 23:22:32

US3632052

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 09:13:35

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Colleen Kelley (b) (4)	12 Apr 2021 01:33:40
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: VITAMINS, ATC: MULTIVITAMINS, COMBINATIONS, ATC: MULTIVITAMINS, OTHER COMBINATIONS, PRODUCT: MULTIVITAMINS, OTHER COMBINATIONS - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	08 Apr 2021 19:43:49
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	08 Apr 2021 19:43:49
Data point term sent to Coder	System	08 Apr 2021 19:42:53
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	08 Apr 2021 19:42:29
Data point term sent to Coder	System	08 Apr 2021 19:41:46
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	08 Apr 2021 19:41:29
Signature has been broken.	(b) (4), (b) (6)	08 Apr 2021 19:41:29
User signature succeeded.	Colleen Kelley (b) (4)	02 Apr 2021 20:59:30
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: VITAMINS, ATC: MULTIVITAMINS, COMBINATIONS, ATC: MULTIVITAMINS, OTHER COMBINATIONS, PRODUCT: MULTIVITAMINS, OTHER COMBINATIONS - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	24 Nov 2020 07:40:09
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	24 Nov 2020 07:40:09
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 17:39:05
Data point term sent to Coder	System	13 Oct 2020 19:20:39
Coding entries removed.	Isaac Perez (b) (4)	13 Oct 2020 19:19:54

US3632052

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 09:13:35

Name of Medication

Audit	User	Time (GMT)
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: VITAMINS, ATC: MULTIVITAMINS, PLAIN, ATC: MULTIVITAMINS, PLAIN, PRODUCT: VITAMINS NOS, PRODUCTSYNONYM: MULTIVITAMIN [VITAMINS NOS] - version WHODrug-Global-B3\202003.	Coder Import (b) (4) (b) (4)	29 Sep 2020 15:44:07
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\202003.	Coder Import (b) (4) (b) (4)	29 Sep 2020 15:44:07
Data point term sent to Coder	System	28 Sep 2020 17:47:01
User closed query 'CDM Coding: This medication can be referred as multiple ingredients in the standard coding dictionary. Please enter all the active ingredient(s) with drug name in drug name field and please make your changes to the reported term. Thank you.' (Site from System).	System	28 Sep 2020 17:46:37
Query 'CDM Coding: This medication can be referred as multiple ingredients in the standard coding dictionary. Please enter all the active ingredient(s) with drug name in drug name field and please make your changes to the reported term. Thank you.' answered with 'Active ingredients added' (Site from System).	Isaac Perez (b) (4) (b) (4)	28 Sep 2020 17:46:37
User entered 'MASON ADVANCED EAR HEALTH FORMULA (VITAMIN C/VITAMIN B1/VITAMIN B2/NIACIN/VITAMIN B6/VITAMIN B12/PANTHOTHENIC ACID/CALCIUM/CHOLINE/BIOFLAVENOIDS/I NOSITOL)' reason for change: Data Entry Error	Isaac Perez (b) (4) (b) (4)	28 Sep 2020 17:46:34
User opened query 'CDM Coding: This medication can be referred as multiple ingredients in the standard coding dictionary. Please enter all the active ingredient(s) with drug name in drug name field and please make your changes to the reported term. Thank you.' (Site from System).	Coder Import (b) (4) (b) (4)	14 Sep 2020 12:20:38
Data point term sent to Coder	System	08 Sep 2020 23:24:06
User entered 'Mason Advanced Ear Health Formula'	(b) (4), (b) (6)	08 Sep 2020 23:23:39

US3632052

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 09:13:35

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Colleen Kelley (b) (4)	12 Apr 2021 01:33:40
	(b) (4)	
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	08 Apr 2021 19:42:29
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	08 Apr 2021 19:41:29
Signature has been broken.	(b) (4), (b) (6)	08 Apr 2021 19:41:29
User signature succeeded.	Colleen Kelley (b) (4)	02 Apr 2021 20:59:30
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 17:39:09
User entered 'No (N)'	(b) (4), (b) (6)	08 Sep 2020 23:23:39

US3632052

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 09:13:35

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Colleen Kelley (b) (4)	12 Apr 2021 01:33:40
DataPoint activated with code reason code Data required.	(b) (4)	
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	08 Apr 2021 19:42:29
Signature has been broken.	(b) (4), (b) (6)	08 Apr 2021 19:41:29
User signature succeeded.	Colleen Kelley (b) (4)	02 Apr 2021 20:59:30
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	19 Nov 2020 17:39:16
User closed query 'Per DM CLR: Re query: Please reconcile updated indication with Med History eCRF as appropriate.' (Site from DM).	(b) (4), (b) (6)	15 Oct 2020 06:01:07
Query 'Per DM CLR: Re query: Please reconcile updated indication with Med History eCRF as appropriate.' answered with 'Updated MH' (Site from DM).	Isaac Perez (b) (4)	14 Oct 2020 18:30:56
	(b) (4)	
User opened query 'Per DM CLR: Re query: Please reconcile updated indication with Med History eCRF as appropriate.' (Site from DM).	(b) (4), (b) (6)	14 Oct 2020 06:08:07
User closed query 'Per DM CLR: Please update the indication to reflect the location of TINNITUS ( in one or both ears). Please reconcile with the AE and Med History eCRFs as appropriate.	(b) (4), (b) (6)	14 Oct 2020 06:08:07
' (Site from DM).		
Query 'Per DM CLR: Please update the indication to reflect the location of TINNITUS ( in one or both ears). Please reconcile with the AE and Med History eCRFs as appropriate.	Isaac Perez (b) (4)	13 Oct 2020 19:20:03
' answered with 'Indication updated.' (Site from DM).	(b) (4)	
User entered 'TINNITUS Both ears' reason for change: Data Entry Error	Isaac Perez (b) (4)	13 Oct 2020 19:19:54
	(b) (4)	
User opened query 'Per DM CLR: Please update the indication to reflect the location of TINNITUS ( in one or both ears). Please reconcile with the AE and Med History eCRFs as appropriate.	(b) (4), (b) (6)	05 Oct 2020 19:32:02
' (Site from DM).		
User entered 'Tinnitus'	(b) (4), (b) (6)	08 Sep 2020 23:23:39

US3632052

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 09:13:35

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Colleen Kelley (b) (4)	12 Apr 2021 01:33:40
	(b) (4)	
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	08 Apr 2021 19:42:29
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	08 Apr 2021 19:41:29
Signature has been broken.	(b) (4), (b) (6)	08 Apr 2021 19:41:29
User signature succeeded.	Colleen Kelley (b) (4)	02 Apr 2021 20:59:30
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 17:39:22
User entered '2' reason for change: Data Entry Error	(b) (4), (b) (6)	09 Sep 2020 13:39:37
User entered '1'	(b) (4), (b) (6)	08 Sep 2020 23:23:39

US3632052

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 09:13:35

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Colleen Kelley (b) (4)	12 Apr 2021 01:33:40
DataPoint activated with code reason code Data required.	(b) (4)	
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	08 Apr 2021 19:42:29
Signature has been broken.	(b) (4), (b) (6)	08 Apr 2021 19:41:29
User signature succeeded.	Colleen Kelley (b) (4)	02 Apr 2021 20:59:30
DataPoint Verified.	(b) (4)	
User entered 'tablet (TABLET)' reason for change: Data Entry Error	(b) (4), (b) (6)	19 Nov 2020 17:39:24
User entered 'Other (OTHER)'	(b) (4), (b) (6)	09 Sep 2020 13:39:37
		08 Sep 2020 23:23:39



US3632052

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 09:13:35

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Colleen Kelley (b) (4)	12 Apr 2021 01:33:40
DataPoint activated with code reason code Data required.	(b) (4)	
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	08 Apr 2021 19:42:29
Signature has been broken.	(b) (4), (b) (6)	08 Apr 2021 19:41:29
User signature succeeded.	Colleen Kelley (b) (4)	02 Apr 2021 20:59:30
DataPoint Verified.	(b) (4)	
User closed query 'Dose unit is Other, however Other, specify is missing. Please provide.' (Site from System).	(b) (4), (b) (6)	19 Nov 2020 17:39:32
User opened query 'Dose unit is Other, however Other, specify is missing. Please provide.' (Site from System).	System	09 Sep 2020 13:39:37
User entered empty.	System	08 Sep 2020 23:23:39
	(b) (4), (b) (6)	08 Sep 2020 23:23:39

US3632052

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 09:13:35

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Colleen Kelley (b) (4)	12 Apr 2021 01:33:40
DataPoint activated with code reason code Data required.	(b) (4)	
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	08 Apr 2021 19:42:29
Signature has been broken.	(b) (4), (b) (6)	08 Apr 2021 19:41:29
User signature succeeded.	Colleen Kelley (b) (4)	02 Apr 2021 20:59:30
DataPoint Verified.	(b) (4)	
User entered 'once daily (QD)'	(b) (4), (b) (6)	19 Nov 2020 17:42:44
	(b) (4), (b) (6)	08 Sep 2020 23:23:39

US3632052

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 09:13:35

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Colleen Kelley (b) (4)	12 Apr 2021 01:33:40
DataPoint activated with code reason code Data required.	(b) (4)	
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	08 Apr 2021 19:42:29
Signature has been broken.	(b) (4), (b) (6)	08 Apr 2021 19:41:29
User signature succeeded.	Colleen Kelley (b) (4)	02 Apr 2021 20:59:30
DataPoint Verified.	(b) (4)	
User entered empty.	(b) (4), (b) (6)	19 Nov 2020 17:42:46
	(b) (4), (b) (6)	08 Sep 2020 23:23:39

US3632052

Folder: Concomitant Medication and Vaccination (1)

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[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Colleen Kelley (b) (4)	12 Apr 2021 01:33:40
DataPoint activated with code reason code Data required.	(b) (4)	
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	08 Apr 2021 19:42:29
Signature has been broken.	(b) (4), (b) (6)	08 Apr 2021 19:41:29
User signature succeeded.	Colleen Kelley (b) (4)	02 Apr 2021 20:59:30
DataPoint Verified.	(b) (4)	
User entered 'Oral (ORAL)'	(b) (4), (b) (6)	19 Nov 2020 17:42:50
		08 Sep 2020 23:23:39

US3632052

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 09:13:35

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Colleen Kelley (b) (4)	12 Apr 2021 01:33:40
DataPoint activated with code reason code Data required.	(b) (4)	
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	08 Apr 2021 19:42:29
Signature has been broken.	(b) (4), (b) (6)	08 Apr 2021 19:41:29
User signature succeeded.	Colleen Kelley (b) (4)	02 Apr 2021 20:59:30
DataPoint Verified.	(b) (4)	
User entered empty.	(b) (4), (b) (6)	19 Nov 2020 17:43:10
	(b) (4), (b) (6)	08 Sep 2020 23:23:39

US3632052

Folder: Concomitant Medication and Vaccination (1)

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Generated On: 10 Jun 2021 09:13:35

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Colleen Kelley (b) (4)	12 Apr 2021 01:33:40
DataPoint activated with code reason code Data required.	(b) (4)	
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	08 Apr 2021 19:42:29
Signature has been broken.	(b) (4), (b) (6)	08 Apr 2021 19:41:29
User signature succeeded.	Colleen Kelley (b) (4)	02 Apr 2021 20:59:30
User closed query 'Per source, start date is recorded as 2019. Please update date in EDC to include an unknown day such as, UN-UNK-2019. ' (Site from CRA).	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	10 Dec 2020 16:37:35
Query 'Per source, start date is recorded as 2019. Please update date in EDC to include an unknown day such as, UN-UNK-2019. ' answered with 'UPDATED' (Site from CRA).	(b) (4)	
User entered 'UN UNK 2019' reason for change: Data Entry Error	Kelly Likos (b) (4)	20 Nov 2020 16:10:09
User opened query 'Per source, start date is recorded as 2019. Please update date in EDC to include an unknown day such as, UN-UNK-2019. ' (Site from CRA).	(b) (4)	
User entered '01 UNK 2019'	(b) (4), (b) (6)	20 Nov 2020 16:10:02
	(b) (4), (b) (6)	19 Nov 2020 17:52:27
	(b) (4), (b) (6)	08 Sep 2020 23:23:39

US3632052

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 09:13:35

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Colleen Kelley (b) (4)	12 Apr 2021 01:33:40
	(b) (4)	
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	08 Apr 2021 19:42:29
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	08 Apr 2021 19:41:29
Signature has been broken.	(b) (4), (b) (6)	08 Apr 2021 19:41:29
User signature succeeded.	Colleen Kelley (b) (4)	02 Apr 2021 20:59:30
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 17:52:29
User entered '0'	(b) (4), (b) (6)	08 Sep 2020 23:23:39

US3632052

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 09:13:35

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Colleen Kelley (b) (4)	12 Apr 2021 01:33:40
DataPoint activated with code reason code Data required.	(b) (4)	
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	08 Apr 2021 19:42:29
Signature has been broken.	(b) (4), (b) (6)	08 Apr 2021 19:41:29
User signature succeeded.	Colleen Kelley (b) (4)	02 Apr 2021 20:59:30
DataPoint Verified.	(b) (4)	
User entered 'Yes (Y)'	(b) (4), (b) (6)	19 Nov 2020 17:52:44
	(b) (4), (b) (6)	08 Sep 2020 23:23:39



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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 09:13:35

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

Audit	User	Time (GMT)
User signature succeeded.	Colleen Kelley (b) (4)	12 Apr 2021 01:33:40
DataPoint activated with code reason code Data required.	(b) (4)	
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	08 Apr 2021 19:42:29
Signature has been broken.	(b) (4), (b) (6)	08 Apr 2021 19:41:29
User signature succeeded.	Colleen Kelley (b) (4)	02 Apr 2021 20:59:30
DataPoint Verified.	(b) (4)	
User entered empty.	(b) (4), (b) (6)	19 Nov 2020 17:52:47
		08 Sep 2020 23:23:39

US3632052

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 09:13:35

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Colleen Kelley (b) (4)	12 Apr 2021 01:33:40
DataPoint activated with code reason code Data required.	(b) (4)	
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	08 Apr 2021 19:42:29
Signature has been broken.	(b) (4), (b) (6)	08 Apr 2021 19:41:29
User signature succeeded.	Colleen Kelley (b) (4)	02 Apr 2021 20:59:30
DataPoint Verified.	(b) (4)	
User entered 'No (N)'	(b) (4), (b) (6)	19 Nov 2020 17:52:49
	(b) (4), (b) (6)	08 Sep 2020 23:23:39

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 09:13:35

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	08 Apr 2021 19:42:29
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	08 Apr 2021 19:41:29
User entered 'I'	System	08 Sep 2020 23:23:39

**US3632052**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (9)**

**Generated On: 10 Jun 2021 09:13:35**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	08 Apr 2021 19:42:29
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	08 Apr 2021 19:41:29
User entered 'I'	System	08 Sep 2020 23:23:39

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 09:13:35

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	08 Apr 2021 19:42:29
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	08 Apr 2021 19:41:29
User entered '804 (804)'	System	08 Sep 2020 23:23:39

US3632052

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 09:13:35

Name of Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 06:51:30
User signature succeeded.	Colleen Kelley (b) (4)	12 Apr 2021 01:33:40
User coded data point as ATC: MUSCULO-SKELETAL SYSTEM, ATC: TOPICAL PRODUCTS FOR JOINT AND MUSCULAR PAIN, ATC: TOPICAL PRODUCTS FOR JOINT AND MUSCULAR PAIN, ATC: ANTIINFLAMMATORY PREPARATIONS, NON-STEROIDS FOR TOPICAL USE, PRODUCT: DICLOFENAC - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	08 Apr 2021 19:43:49
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	(b) (4)	08 Apr 2021 19:43:49
Data point term sent to Coder DataPoint activated with code reason code Data required.	System	08 Apr 2021 19:42:54
Data point term sent to Coder DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	08 Apr 2021 19:42:29
Signature has been broken.	(b) (4), (b) (6)	08 Apr 2021 19:41:29
User signature succeeded.	Colleen Kelley (b) (4)	02 Apr 2021 20:59:30
User coded data point as ATC: MUSCULO-SKELETAL SYSTEM, ATC: TOPICAL PRODUCTS FOR JOINT AND MUSCULAR PAIN, ATC: TOPICAL PRODUCTS FOR JOINT AND MUSCULAR PAIN, ATC: ANTIINFLAMMATORY PREPARATIONS, NON-STEROIDS FOR TOPICAL USE, PRODUCT: DICLOFENAC - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	01 Dec 2020 07:12:04
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	(b) (4)	01 Dec 2020 07:12:04
Data point term sent to Coder Coding entries removed.	System	30 Nov 2020 22:15:25
	(b) (4), (b) (6)	30 Nov 2020 22:14:47
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 17:53:03

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EAB) (1725)

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 09:13:35

[Name of Medication](#)

Audit	User	Time (GMT)
User coded data point as ATC: MUSCULO-SKELETAL SYSTEM, ATC: TOPICAL PRODUCTS FOR JOINT AND MUSCULAR PAIN, ATC: TOPICAL PRODUCTS FOR JOINT AND MUSCULAR PAIN, ATC: ANTIINFLAMMATORY PREPARATIONS, NON-STEROIDS FOR TOPICAL USE, PRODUCT: DICLOFENAC - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	13 Oct 2020 23:58:16
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	13 Oct 2020 23:58:16
Data point term sent to Coder	System	13 Oct 2020 19:19:38
User entered 'Diclofenac 1%'	Isaac Perez (b) (4) (b) (4)	13 Oct 2020 19:19:34
DataPoint activated with code reason code Data required.	Isaac Perez (b) (4) (b) (4)	13 Oct 2020 19:17:34
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	24 Sep 2020 15:13:11

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 09:13:35

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 06:51:30
User signature succeeded.	Colleen Kelley (b) (4)	12 Apr 2021 01:33:40
DataPoint activated with code reason code Data required.	(b) (4)	
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	08 Apr 2021 19:42:29
Signature has been broken.	(b) (4), (b) (6)	08 Apr 2021 19:41:29
User signature succeeded.	Colleen Kelley (b) (4)	02 Apr 2021 20:59:30
DataPoint Verified.	(b) (4)	
User entered 'No (N)'	(b) (4), (b) (6)	19 Nov 2020 17:53:09
DataPoint activated with code reason code Data required.	Isaac Perez (b) (4)	13 Oct 2020 19:19:34
DataPoint inactivated with code reason code Data not required.	(b) (4)	
	Isaac Perez (b) (4)	13 Oct 2020 19:17:34
	(b) (4)	
	(b) (4), (b) (6)	24 Sep 2020 15:13:11



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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 09:13:35

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 06:51:30
User signature succeeded.	Colleen Kelley (b) (4)	12 Apr 2021 01:33:40
DataPoint activated with code reason code Data required.	(b) (4)	
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	08 Apr 2021 19:42:29
Signature has been broken.	(b) (4), (b) (6)	08 Apr 2021 19:41:29
User signature succeeded.	Colleen Kelley (b) (4)	02 Apr 2021 20:59:30
User closed query 'Per DM CLR: Please note that there is no AE that matches this Con Med indication. Please review Con Med use and add a medical condition and all applicable details to the appropriate AE eCRF.' (Site from DM).	(b) (4)	
Query 'Per DM CLR: Please note that there is no AE that matches this Con Med indication. Please review Con Med use and add a medical condition and all applicable details to the appropriate AE eCRF.' answered with 'AE added.' (Site from DM).	(b) (4), (b) (6)	16 Feb 2021 03:10:54
User opened query 'Per DM CLR: Please note that there is no AE that matches this Con Med indication. Please review Con Med use and add a medical condition and all applicable details to the appropriate AE eCRF.' (Site from DM).	Sarah Wiatrek (b) (4)	15 Feb 2021 17:26:21
DataPoint Verified.	(b) (4)	
User closed query 'Per DM CLR: Please note that there is no AE that matches this Con Med indication. Please review Con Med use and add a medical condition and all applicable details to the appropriate AE eCRF.' (Site from DM).	(b) (4), (b) (6)	21 Jan 2021 16:47:16
DataPoint Verified.	(b) (4), (b) (6)	10 Dec 2020 16:36:42
User closed query 'Per DM CLR: Please update the indication to reflect the location (bilateral, left, right) and/or type of ACUTE JOINT PAIN. Review and update indication and ensure to update MH/Adverse event eCRF as appropriate.' (Site from DM).	(b) (4), (b) (6)	02 Dec 2020 06:06:32
Query 'Per DM CLR: Please update the indication to reflect the location (bilateral, left, right) and/or type of ACUTE JOINT PAIN. Review and update indication and ensure to update MH/Adverse event eCRF as appropriate.' answered with 'amended' (Site from DM).	(b) (4), (b) (6)	30 Nov 2020 22:15:57
DataPoint Un-verified.	(b) (4), (b) (6)	30 Nov 2020 22:14:47

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 09:13:35

[Indication](#)

Audit	User	Time (GMT)
User entered 'ACUTE THUMB JOINT PAIN'	(b) (4), (b) (6)	30 Nov 2020 22:14:47
reason for change: Data Entry Error		
User opened query 'Per DM CLR: Please update the indication to reflect the location (bilateral, left, right) and/or type of ACUTE JOINT PAIN. Review and update indication and ensure to update MH/Adverse event eCRF as appropriate. ' (Site from DM).	(b) (4), (b) (6)	25 Nov 2020 14:37:49
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 17:53:16
User entered 'Acute Joint Pain'	Isaac Perez (b) (4)	13 Oct 2020 19:19:34
	(b) (4)	
DataPoint activated with code reason code Data required.	Isaac Perez (b) (4)	13 Oct 2020 19:17:34
	(b) (4)	
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	24 Sep 2020 15:13:11

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 09:13:35

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 06:51:30
User signature succeeded.	Colleen Kelley (b) (4)	12 Apr 2021 01:33:40
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	08 Apr 2021 19:42:29
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	08 Apr 2021 19:41:29
Signature has been broken.	(b) (4), (b) (6)	08 Apr 2021 19:41:29
User signature succeeded.	Colleen Kelley (b) (4)	02 Apr 2021 20:59:30
DataPoint Verified.	(b) (4), (b) (6)	10 Dec 2020 16:36:42
User closed query 'Per DM CLR: Please consider recording the number of applications instead (e.g. dose=1; unit=application). Review and amend as appropriate.' (Site from DM).	(b) (4), (b) (6)	02 Dec 2020 06:06:34
Query 'Per DM CLR: Please consider recording the number of applications instead (e.g. dose=1; unit=application). Review and amend as appropriate.' answered with 'updated' (Site from DM).	Christina Bacher (b) (4)	01 Dec 2020 14:32:07
DataPoint Un-verified.	Christina Bacher (b) (4)	01 Dec 2020 14:32:01
User entered '1' reason for change: Per Query Resolution	Christina Bacher (b) (4)	01 Dec 2020 14:32:01
User opened query 'Per DM CLR: Please consider recording the number of applications instead (e.g. dose=1; unit=application). Review and amend as appropriate.' (Site from DM).	(b) (4), (b) (6)	25 Nov 2020 14:37:10
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 17:53:18
User entered '0.5'	Isaac Perez (b) (4)	13 Oct 2020 19:19:34
DataPoint activated with code reason code Data required.	Isaac Perez (b) (4)	13 Oct 2020 19:17:34
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	24 Sep 2020 15:13:11

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 09:13:35

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 06:51:30
User signature succeeded.	Colleen Kelley (b) (4)	12 Apr 2021 01:33:40
DataPoint activated with code reason code Data required.	(b) (4)	08 Apr 2021 19:42:29
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	08 Apr 2021 19:41:29
Signature has been broken.	(b) (4), (b) (6)	08 Apr 2021 19:41:29
User signature succeeded.	Colleen Kelley (b) (4)	02 Apr 2021 20:59:30
DataPoint Verified.	(b) (4)	10 Dec 2020 16:36:42
DataPoint Un-verified.	Christina Bacher (b) (4)	01 Dec 2020 14:32:01
User entered 'Other (OTHER)' reason for change: Per Query Resolution	Christina Bacher (b) (4)	01 Dec 2020 14:32:01
DataPoint Verified.	(b) (4)	19 Nov 2020 17:53:20
User entered 'g (g)'	Isaac Perez (b) (4)	13 Oct 2020 19:19:34
DataPoint activated with code reason code Data required.	(b) (4)	13 Oct 2020 19:17:34
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	24 Sep 2020 15:13:11

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 09:13:35

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 06:51:30
User signature succeeded.	Colleen Kelley (b) (4)	12 Apr 2021 01:33:40
DataPoint activated with code reason code Data required.	(b) (4)	08 Apr 2021 19:42:29
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	08 Apr 2021 19:41:29
Signature has been broken.	(b) (4), (b) (6)	08 Apr 2021 19:41:29
User signature succeeded.	Colleen Kelley (b) (4)	02 Apr 2021 20:59:30
DataPoint Verified.	(b) (4)	10 Dec 2020 16:36:42
DataPoint Un-verified.	Christina Bacher (b) (4)	01 Dec 2020 14:32:01
User entered 'application' reason for change: Per Query Resolution	(b) (4)	01 Dec 2020 14:32:01
DataPoint Verified.	Christina Bacher (b) (4)	19 Nov 2020 17:53:22
User entered empty.	(b) (4)	13 Oct 2020 19:19:34
DataPoint activated with code reason code Data required.	Isaac Perez (b) (4)	13 Oct 2020 19:17:34
DataPoint inactivated with code reason code Data not required.	(b) (4)	24 Sep 2020 15:13:11

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 09:13:35

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 06:51:30
User signature succeeded.	Colleen Kelley (b) (4)	12 Apr 2021 01:33:40
DataPoint activated with code reason code Data required.	(b) (4)	08 Apr 2021 19:42:29
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	08 Apr 2021 19:41:29
Signature has been broken.	(b) (4), (b) (6)	08 Apr 2021 19:41:29
User signature succeeded.	Colleen Kelley (b) (4)	02 Apr 2021 20:59:30
DataPoint Verified.	(b) (4)	19 Nov 2020 17:53:27
User entered 'as needed (PRN)'	(b) (4), (b) (6)	
	Isaac Perez (b) (4)	13 Oct 2020 19:19:34
DataPoint activated with code reason code Data required.	(b) (4)	
	Isaac Perez (b) (4)	13 Oct 2020 19:17:34
DataPoint inactivated with code reason code Data not required.	(b) (4)	
	(b) (4), (b) (6)	24 Sep 2020 15:13:11

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 09:13:35

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 06:51:30
User signature succeeded.	Colleen Kelley (b) (4)	12 Apr 2021 01:33:40
DataPoint activated with code reason code Data required.	(b) (4)	08 Apr 2021 19:42:29
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	08 Apr 2021 19:41:29
Signature has been broken.	(b) (4), (b) (6)	08 Apr 2021 19:41:29
User signature succeeded.	Colleen Kelley (b) (4)	02 Apr 2021 20:59:30
DataPoint Verified.	(b) (4)	19 Nov 2020 17:53:29
User entered empty.	Isaac Perez (b) (4)	13 Oct 2020 19:19:34
DataPoint activated with code reason code Data required.	(b) (4)	13 Oct 2020 19:17:34
DataPoint inactivated with code reason code Data not required.	Isaac Perez (b) (4)	24 Sep 2020 15:13:11

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 09:13:35

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 06:51:30
User signature succeeded.	Colleen Kelley (b) (4)	12 Apr 2021 01:33:40
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	08 Apr 2021 19:42:29
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	08 Apr 2021 19:41:29
Signature has been broken.	(b) (4), (b) (6)	08 Apr 2021 19:41:29
User signature succeeded.	Colleen Kelley (b) (4)	02 Apr 2021 20:59:30
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 17:53:31
User entered 'Topical (TOPICAL)'	Isaac Perez (b) (4)	13 Oct 2020 19:19:34
DataPoint activated with code reason code Data required.	Isaac Perez (b) (4)	13 Oct 2020 19:17:34
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	24 Sep 2020 15:13:11



US3632052

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 09:13:35

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 06:51:30
User signature succeeded.	Colleen Kelley (b) (4)	12 Apr 2021 01:33:40
DataPoint activated with code reason code Data required.	(b) (4)	08 Apr 2021 19:42:29
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	08 Apr 2021 19:41:29
Signature has been broken.	(b) (4), (b) (6)	08 Apr 2021 19:41:29
User signature succeeded.	Colleen Kelley (b) (4)	02 Apr 2021 20:59:30
DataPoint Verified.	(b) (4)	19 Nov 2020 17:53:35
User entered empty.	Isaac Perez (b) (4)	13 Oct 2020 19:19:34
DataPoint activated with code reason code Data required.	(b) (4)	13 Oct 2020 19:17:34
DataPoint inactivated with code reason code Data not required.	Isaac Perez (b) (4)	24 Sep 2020 15:13:11

US3632052

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 09:13:35

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 06:51:30
User signature succeeded.	Colleen Kelley (b) (4)	12 Apr 2021 01:33:40
DataPoint activated with code reason code Data required.	(b) (4)	08 Apr 2021 19:42:29
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	08 Apr 2021 19:41:29
Signature has been broken.	(b) (4), (b) (6)	08 Apr 2021 19:41:29
User signature succeeded.	Colleen Kelley (b) (4)	02 Apr 2021 20:59:30
DataPoint Verified.	(b) (4)	19 Nov 2020 17:53:38
User entered '13 Oct 2020'	Isaac Perez (b) (4)	13 Oct 2020 19:19:34
DataPoint activated with code reason code Data required.	Isaac Perez (b) (4)	13 Oct 2020 19:17:34
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	24 Sep 2020 15:13:11

US3632052

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 09:13:35

Start date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 06:51:30
User signature succeeded.	Colleen Kelley (b) (4)	12 Apr 2021 01:33:40
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	08 Apr 2021 19:42:29
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	08 Apr 2021 19:41:29
Signature has been broken.	(b) (4), (b) (6)	08 Apr 2021 19:41:29
User signature succeeded.	Colleen Kelley (b) (4)	02 Apr 2021 20:59:30
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 17:53:42
User entered '0'	Isaac Perez (b) (4)	13 Oct 2020 19:19:34
DataPoint activated with code reason code Data required.	Isaac Perez (b) (4)	13 Oct 2020 19:17:34
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	24 Sep 2020 15:13:11

US3632052

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 09:13:35

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 06:51:30
User signature succeeded.	Colleen Kelley (b) (4)	12 Apr 2021 01:33:40
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 19:47:00
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	08 Apr 2021 19:42:29
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	08 Apr 2021 19:41:29
Signature has been broken.	(b) (4), (b) (6)	08 Apr 2021 19:41:29
User signature succeeded.	Colleen Kelley (b) (4)	02 Apr 2021 20:59:30
DataPoint Un-verified.	Sarah Wiatrek (b) (4)	05 Mar 2021 16:40:39
User entered 'No (N)' reason for change: Data Entry Error	Sarah Wiatrek (b) (4)	05 Mar 2021 16:40:39
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 17:53:45
User entered 'Yes (Y)'	Isaac Perez (b) (4)	13 Oct 2020 19:19:34
DataPoint activated with code reason code Data required.	Isaac Perez (b) (4)	13 Oct 2020 19:17:34
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	24 Sep 2020 15:13:11

US3632052

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 09:13:35

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 06:51:30
User signature succeeded.	Colleen Kelley (b) (4)	12 Apr 2021 01:33:40
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 19:47:04
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	08 Apr 2021 19:42:29
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	08 Apr 2021 19:41:29
Signature has been broken.	(b) (4), (b) (6)	08 Apr 2021 19:41:29
User signature succeeded.	Colleen Kelley (b) (4)	02 Apr 2021 20:59:30
DataPoint Un-verified.	Sarah Wiatrek (b) (4)	05 Mar 2021 16:40:39
User entered '15 Feb 2021' reason for change: New Information	Sarah Wiatrek (b) (4)	05 Mar 2021 16:40:39
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 17:53:52
User entered empty.	Isaac Perez (b) (4)	13 Oct 2020 19:19:34
DataPoint activated with code reason code Data required.	Isaac Perez (b) (4)	13 Oct 2020 19:17:34
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	24 Sep 2020 15:13:11

US3632052

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 09:13:35

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 06:51:30
User signature succeeded.	Colleen Kelley (b) (4)	12 Apr 2021 01:33:40
DataPoint activated with code reason code Data required.	(b) (4)	08 Apr 2021 19:42:29
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	08 Apr 2021 19:41:29
Signature has been broken.	(b) (4), (b) (6)	08 Apr 2021 19:41:29
User signature succeeded.	Colleen Kelley (b) (4)	02 Apr 2021 20:59:30
DataPoint Verified.	(b) (4)	19 Nov 2020 17:53:54
User entered 'No (N)'	(b) (4), (b) (6)	
	Isaac Perez (b) (4)	13 Oct 2020 19:19:34
DataPoint activated with code reason code Data required.	(b) (4)	
	Isaac Perez (b) (4)	13 Oct 2020 19:17:34
DataPoint inactivated with code reason code Data not required.	(b) (4)	
	(b) (4), (b) (6)	24 Sep 2020 15:13:11

US3632052

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 09:13:35

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 06:51:30
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	08 Apr 2021 19:42:29
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	08 Apr 2021 19:41:29
User entered empty.	System	13 Oct 2020 19:19:34
DataPoint activated with code reason code Data required.	Isaac Perez (b) (4)	13 Oct 2020 19:17:34
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	24 Sep 2020 15:13:11

US3632052

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 09:13:35

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 06:51:30
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	08 Apr 2021 19:42:29
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	08 Apr 2021 19:41:29
User entered empty.	System	13 Oct 2020 19:19:34
DataPoint activated with code reason code Data required.	Isaac Perez (b) (4)	13 Oct 2020 19:17:34
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	24 Sep 2020 15:13:11



US3632052

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 09:13:35

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 06:51:30
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	08 Apr 2021 19:42:29
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	08 Apr 2021 19:41:29
User entered empty.	System	13 Oct 2020 19:19:34
DataPoint activated with code reason code Data required.	Isaac Perez (b) (4)	13 Oct 2020 19:17:34
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	24 Sep 2020 15:13:11

US3632052

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 09:13:35

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 06:51:32
User signature succeeded.	Colleen Kelley (b) (4)	12 Apr 2021 01:33:40
User coded data point as ATC: NERVOUS SYSTEM, ATC: ANALGESICS, ATC: OTHER ANALGESICS AND ANTIPYRETICS, ATC: ANILIDES, PRODUCT: PARACETAMOL, PRODUCTSYNONYM: TYLENOL EXTRA STRENGTH - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	08 Apr 2021 19:43:49
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	08 Apr 2021 19:43:49
Data point term sent to Coder	System	08 Apr 2021 19:42:55
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	08 Apr 2021 19:42:29
Data point term sent to Coder	System	08 Apr 2021 19:41:46
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	08 Apr 2021 19:41:29
Signature has been broken.	(b) (4), (b) (6)	08 Apr 2021 19:41:29
User signature succeeded.	Colleen Kelley (b) (4)	02 Apr 2021 20:59:30
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 17:54:46
Query 'Per source, this medication is written as, "Tylenol". Please verify with source and update EDC accordingly.' canceled (Site from CRA).	(b) (4), (b) (6)	19 Nov 2020 17:54:43
User opened query 'Per source, this medication is written as, "Tylenol". Please verify with source and update EDC accordingly.' (Site from CRA).	(b) (4), (b) (6)	19 Nov 2020 17:54:37
User coded data point as ATC: NERVOUS SYSTEM, ATC: ANALGESICS, ATC: OTHER ANALGESICS AND ANTIPYRETICS, ATC: ANILIDES, PRODUCT: PARACETAMOL, PRODUCTSYNONYM: TYLENOL EXTRA STRENGTH - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	29 Sep 2020 05:58:57
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	29 Sep 2020 05:58:57

US3632052

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 09:13:35

[Name of Medication](#)

Audit	User	Time (GMT)
Data point term sent to Coder	System	21 Sep 2020 19:47:58
User closed query 'DM-Coding: Please add the active ingredient name(s) in brackets next to the drug name in the eCRF.' (Site from System).	System	21 Sep 2020 19:47:50
Query 'DM-Coding: Please add the active ingredient name(s) in brackets next to the drug name in the eCRF.' answered with 'Included active ingredient.' (Site from System).	Isaac Perez (b) (4)	21 Sep 2020 19:47:50
User entered 'EXTRA STRENGTH TYLENOL [ACETAMINOPHEN]' reason for change: Data Entry Error	Isaac Perez (b) (4)	21 Sep 2020 19:47:39
User opened query 'DM-Coding: Please add the active ingredient name(s) in brackets next to the drug name in the eCRF.' (Site from System).	Coder Import (b) (4)	18 Sep 2020 09:20:44
Data point term sent to Coder	System	15 Sep 2020 17:42:11
User entered 'Extra Strength Tylenol'	Bezuayehu Mandefro (b) (4)	15 Sep 2020 17:41:45

US3632052

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 09:13:35

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 06:51:32
User signature succeeded.	Colleen Kelley (b) (4)	12 Apr 2021 01:33:40
DataPoint activated with code reason code Data required.	(b) (4)	08 Apr 2021 19:42:29
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	08 Apr 2021 19:41:29
Signature has been broken.	(b) (4), (b) (6)	08 Apr 2021 19:41:29
User signature succeeded.	Colleen Kelley (b) (4)	02 Apr 2021 20:59:30
DataPoint Verified.	(b) (4)	19 Nov 2020 17:54:39
User entered 'No (N)'	Bezuayehu Mandefro (b) (4)	15 Sep 2020 17:41:45

US3632052

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 09:13:35

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 06:51:32
User signature succeeded.	Colleen Kelley (b) (4)	12 Apr 2021 01:33:40
DataPoint activated with code reason code Data required.	(b) (4)	08 Apr 2021 19:42:29
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	08 Apr 2021 19:41:29
Signature has been broken.	(b) (4), (b) (6)	08 Apr 2021 19:41:29
User signature succeeded.	Colleen Kelley (b) (4)	02 Apr 2021 20:59:30
DataPoint Verified.	(b) (4)	19 Nov 2020 17:54:51
User entered 'Mild Headache'	Bezuayehu Mandefro (b) (4)	15 Sep 2020 17:41:45

US3632052

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 09:13:35

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 06:51:32
User signature succeeded.	Colleen Kelley (b) (4)	12 Apr 2021 01:33:40
DataPoint activated with code reason code Data required.	(b) (4)	08 Apr 2021 19:42:29
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	08 Apr 2021 19:41:29
Signature has been broken.	(b) (4), (b) (6)	08 Apr 2021 19:41:29
User signature succeeded.	Colleen Kelley (b) (4)	02 Apr 2021 20:59:30
DataPoint Verified.	(b) (4)	19 Nov 2020 17:54:52
User entered '1000'	Bezuayehu Mandefro (b) (4)	15 Sep 2020 17:41:45

US3632052

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 09:13:35

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 06:51:32
User signature succeeded.	Colleen Kelley (b) (4)	12 Apr 2021 01:33:40
DataPoint activated with code reason code Data required.	(b) (4)	08 Apr 2021 19:42:29
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	08 Apr 2021 19:41:29
Signature has been broken.	(b) (4), (b) (6)	08 Apr 2021 19:41:29
User signature succeeded.	Colleen Kelley (b) (4)	02 Apr 2021 20:59:30
DataPoint Verified.	(b) (4)	19 Nov 2020 17:54:54
User entered 'mg (mg)'	Bezuayehu Mandefro (b) (4)	15 Sep 2020 17:41:45

US3632052

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 09:13:35

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 06:51:32
User signature succeeded.	Colleen Kelley (b) (4)	12 Apr 2021 01:33:40
DataPoint activated with code reason code Data required.	(b) (4)	08 Apr 2021 19:42:29
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	08 Apr 2021 19:41:29
Signature has been broken.	(b) (4), (b) (6)	08 Apr 2021 19:41:29
User signature succeeded.	Colleen Kelley (b) (4)	02 Apr 2021 20:59:30
DataPoint Verified.	(b) (4)	19 Nov 2020 17:55:02
User entered empty.	Bezuayehu Mandefro (b) (4)	15 Sep 2020 17:41:45



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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 09:13:35

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 06:51:32
User signature succeeded.	Colleen Kelley (b) (4)	12 Apr 2021 01:33:40
DataPoint activated with code reason code Data required.	(b) (4)	08 Apr 2021 19:42:29
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	08 Apr 2021 19:41:29
Signature has been broken.	(b) (4), (b) (6)	08 Apr 2021 19:41:29
User signature succeeded.	Colleen Kelley (b) (4)	02 Apr 2021 20:59:30
DataPoint Verified.	(b) (4)	19 Nov 2020 17:55:07
User entered 'once (ONCE)'	Bezuayehu Mandefro (b) (4)	15 Sep 2020 17:41:45

US3632052

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 09:13:35

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 06:51:32
User signature succeeded.	Colleen Kelley (b) (4)	12 Apr 2021 01:33:40
DataPoint activated with code reason code Data required.	(b) (4)	08 Apr 2021 19:42:29
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	08 Apr 2021 19:41:29
Signature has been broken.	(b) (4), (b) (6)	08 Apr 2021 19:41:29
User signature succeeded.	Colleen Kelley (b) (4)	02 Apr 2021 20:59:30
DataPoint Verified.	(b) (4)	19 Nov 2020 17:55:16
DataPoint Un-verified.	(b) (4), (b) (6)	19 Nov 2020 17:55:14
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 17:55:10
User entered empty.	Bezuayehu Mandefro (b) (4)	15 Sep 2020 17:41:45

US3632052

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 09:13:35

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 06:51:32
User signature succeeded.	Colleen Kelley (b) (4)	12 Apr 2021 01:33:40
DataPoint activated with code reason code Data required.	(b) (4)	08 Apr 2021 19:42:29
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	08 Apr 2021 19:41:29
Signature has been broken.	(b) (4), (b) (6)	08 Apr 2021 19:41:29
User signature succeeded.	Colleen Kelley (b) (4)	02 Apr 2021 20:59:30
DataPoint Verified.	(b) (4)	19 Nov 2020 17:55:20
User entered 'Oral (ORAL)'	Bezuayehu Mandefro (b) (4)	15 Sep 2020 17:41:45

US3632052

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 09:13:35

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 06:51:32
User signature succeeded.	Colleen Kelley (b) (4)	12 Apr 2021 01:33:40
DataPoint activated with code reason code Data required.	(b) (4)	08 Apr 2021 19:42:29
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	08 Apr 2021 19:41:29
Signature has been broken.	(b) (4), (b) (6)	08 Apr 2021 19:41:29
User signature succeeded.	Colleen Kelley (b) (4)	02 Apr 2021 20:59:30
DataPoint Verified.	(b) (4)	19 Nov 2020 17:55:22
User entered empty.	Bezuayehu Mandefro (b) (4)	15 Sep 2020 17:41:45

US3632052

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 09:13:35

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 06:51:32
User signature succeeded.	Colleen Kelley (b) (4)	12 Apr 2021 01:33:40
DataPoint activated with code reason code Data required.	(b) (4)	08 Apr 2021 19:42:29
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	08 Apr 2021 19:41:29
Signature has been broken.	(b) (4), (b) (6)	08 Apr 2021 19:41:29
User signature succeeded.	Colleen Kelley (b) (4)	02 Apr 2021 20:59:30
DataPoint Verified.	(b) (4)	19 Nov 2020 17:55:24
User entered '14 Sep 2020'	Bezuayehu Mandefro (b) (4)	15 Sep 2020 17:41:45

US3632052

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 09:13:35

Start date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 06:51:32
User signature succeeded.	Colleen Kelley (b) (4)	12 Apr 2021 01:33:40
DataPoint activated with code reason code Data required.	(b) (4)	08 Apr 2021 19:42:29
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	08 Apr 2021 19:41:29
Signature has been broken.	(b) (4), (b) (6)	08 Apr 2021 19:41:29
User signature succeeded.	Colleen Kelley (b) (4)	02 Apr 2021 20:59:30
DataPoint Verified.	(b) (4)	19 Nov 2020 17:55:26
User entered '0'	Bezuayehu Mandefro (b) (4)	15 Sep 2020 17:41:45

US3632052

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 09:13:35

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 06:51:32
User signature succeeded.	Colleen Kelley (b) (4)	12 Apr 2021 01:33:40
DataPoint activated with code reason code Data required.	(b) (4)	08 Apr 2021 19:42:29
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	08 Apr 2021 19:41:29
Signature has been broken.	(b) (4), (b) (6)	08 Apr 2021 19:41:29
User signature succeeded.	Colleen Kelley (b) (4)	02 Apr 2021 20:59:30
DataPoint Verified.	(b) (4)	19 Nov 2020 17:55:29
User entered 'No (N)'	Bezuayehu Mandefro (b) (4)	15 Sep 2020 17:41:45

US3632052

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 09:13:35

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 06:51:32
User signature succeeded.	Colleen Kelley (b) (4)	12 Apr 2021 01:33:40
DataPoint activated with code reason code Data required.	(b) (4)	08 Apr 2021 19:42:29
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	08 Apr 2021 19:41:29
Signature has been broken.	(b) (4), (b) (6)	08 Apr 2021 19:41:29
User signature succeeded.	Colleen Kelley (b) (4)	02 Apr 2021 20:59:30
DataPoint Verified.	(b) (4)	19 Nov 2020 17:55:32
User entered '14 Sep 2020'	Bezuayehu Mandefro (b) (4)	15 Sep 2020 17:41:45



US3632052

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 09:13:35

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 06:51:32
User signature succeeded.	Colleen Kelley (b) (4)	12 Apr 2021 01:33:40
DataPoint activated with code reason code Data required.	(b) (4)	
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	08 Apr 2021 19:42:29
Signature has been broken.	(b) (4), (b) (6)	08 Apr 2021 19:41:29
User signature succeeded.	Colleen Kelley (b) (4)	02 Apr 2021 20:59:30
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	19 Nov 2020 17:55:36
User closed query 'Per DM CLR: Please note that there is no AE that matches this Con Med indication during this timeframe. If the Mild Headache is considered a solicited local or systemic adverse reaction, and meets any of the following criteria: results in a visit to a healthcare provider (MAAE), leads to withdrawal from the study of study vaccination, or otherwise meets the definition of an SAE, please add an entry and applicable details to the AE ecrf as appropriate. Otherwise, please confirm in query response that the solicited adverse reaction of Mild Headache did not meet the AE reporting criteria.' (Site from DM).	(b) (4), (b) (6)	30 Oct 2020 12:54:31
Query 'Per DM CLR: Please note that there is no AE that matches this Con Med indication during this timeframe. If the Mild Headache is considered a solicited local or systemic adverse reaction, and meets any of the following criteria: results in a visit to a healthcare provider (MAAE), leads to withdrawal from the study of study vaccination, or otherwise meets the definition of an SAE, please add an entry and applicable details to the AE ecrf as appropriate. Otherwise, please confirm in query response that the solicited adverse reaction of Mild Headache did not meet the AE reporting criteria.' answered with 'the solicited adverse reaction of Mild Headache did not meet the AE reporting criteria' (Site from DM).	Bezuayehu Mandefro (b) (4)	29 Oct 2020 19:04:05

US3632052

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 09:13:35

Was this medication taken for solicited event?

Audit	User	Time (GMT)
User opened query 'Per DM CLR: Please note that there is no AE that matches this Con Med indication during this timeframe. If the Mild Headache is considered a solicited local or systemic adverse reaction, and meets any of the following criteria: results in a visit to a healthcare provider (MAAE), leads to withdrawal from the study of study vaccination, or otherwise meets the definition of an SAE, please add an entry and applicable details to the AE ecrf as appropriate. Otherwise, please confirm in query response that the solicited adverse reaction of Mild Headache did not meet the AE reporting criteria.' (Site from DM). User entered 'Yes (Y)'	(b) (4), (b) (6) Bezuayehu Mandefro (b) (4)	29 Oct 2020 18:39:49 15 Sep 2020 17:41:45

US3632052

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 09:13:35

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 06:51:32
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	08 Apr 2021 19:42:29
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	08 Apr 2021 19:41:29
User entered empty.	System	15 Sep 2020 17:41:45

US3632052

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 09:13:35

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 06:51:32
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	08 Apr 2021 19:42:29
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	08 Apr 2021 19:41:29
User entered empty.	System	15 Sep 2020 17:41:45

US3632052

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 09:13:35

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 06:51:32
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	08 Apr 2021 19:42:29
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	08 Apr 2021 19:41:29
User entered empty.	System	15 Sep 2020 17:41:45

US3632052

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 09:13:35

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 06:51:39
User signature succeeded.	Colleen Kelley (b) (4)	12 Apr 2021 01:33:40
User coded data point as ATC: NERVOUS SYSTEM, ATC: ANALGESICS, ATC: OTHER ANALGESICS AND ANTIPYRETICS, ATC: ANILIDES, PRODUCT: PARACETAMOL, PRODUCTSYNONYM: TYLENOL - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	08 Apr 2021 19:43:49
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	08 Apr 2021 19:43:49
Data point term sent to Coder	System	08 Apr 2021 19:42:54
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	08 Apr 2021 19:42:29
Data point term sent to Coder	System	08 Apr 2021 19:41:46
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	08 Apr 2021 19:41:29
Signature has been broken.	(b) (4), (b) (6)	08 Apr 2021 19:41:29
User signature succeeded.	Colleen Kelley (b) (4)	02 Apr 2021 20:59:30
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 17:55:46
User coded data point as ATC: NERVOUS SYSTEM, ATC: ANALGESICS, ATC: OTHER ANALGESICS AND ANTIPYRETICS, ATC: ANILIDES, PRODUCT: PARACETAMOL, PRODUCTSYNONYM: TYLENOL - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	13 Oct 2020 19:18:23
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	13 Oct 2020 19:18:23
Data point term sent to Coder	System	13 Oct 2020 19:17:35
User entered 'Tylenol'	Isaac Perez (b) (4)	13 Oct 2020 19:17:11

US3632052

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 09:13:35

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 06:51:39
User signature succeeded.	Colleen Kelley (b) (4)	12 Apr 2021 01:33:40
DataPoint activated with code reason code Data required.	(b) (4)	
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	08 Apr 2021 19:42:29
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	08 Apr 2021 19:41:29
Signature has been broken.	(b) (4), (b) (6)	08 Apr 2021 19:41:29
User signature succeeded.	Colleen Kelley (b) (4)	02 Apr 2021 20:59:30
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	19 Nov 2020 17:55:48
User entered 'No (N)'	Isaac Perez (b) (4)	13 Oct 2020 19:17:11
	(b) (4)	

US3632052

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 09:13:35

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 06:51:39
User signature succeeded.	Colleen Kelley (b) (4)	12 Apr 2021 01:33:40
DataPoint activated with code reason code Data required.	(b) (4)	08 Apr 2021 19:42:29
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	08 Apr 2021 19:41:29
Signature has been broken.	(b) (4), (b) (6)	08 Apr 2021 19:41:29
User signature succeeded.	Colleen Kelley (b) (4)	02 Apr 2021 20:59:30
User closed query 'Please note that there is no AE that matches this Con Med indication during this timeframe. If the PAIN AT INJECTION SITE is considered a solicited local or systemic adverse reaction, and meets any of the following criteria: results in a visit to a healthcare provider (MAAE), leads to withdrawal from the study of study vaccination, or otherwise meets the definition of an SAE, please add an entry and applicable details to the AE ecrf as appropriate. Otherwise, please confirm in query response that the solicited adverse reaction of PAIN AT INJECTION SITE did not meet the AE reporting criteria.' (Site from DM).	(b) (4)	02 Dec 2020 08:46:21
Query 'Please note that there is no AE that matches this Con Med indication during this timeframe. If the PAIN AT INJECTION SITE is considered a solicited local or systemic adverse reaction, and meets any of the following criteria: results in a visit to a healthcare provider (MAAE), leads to withdrawal from the study of study vaccination, or otherwise meets the definition of an SAE, please add an entry and applicable details to the AE ecrf as appropriate. Otherwise, please confirm in query response that the solicited adverse reaction of PAIN AT INJECTION SITE did not meet the AE reporting criteria.' answered with 'Pain at injection site did not meet AE reporting criteria' (Site from DM).	Isaac Perez (b) (4)	01 Dec 2020 14:41:52



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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 09:13:35

[Indication](#)

Audit	User	Time (GMT)
User opened query 'Please note that there is no AE that matches this Con Med indication during this timeframe. If the PAIN AT INJECTION SITE is considered a solicited local or systemic adverse reaction, and meets any of the following criteria: results in a visit to a healthcare provider (MAAE), leads to withdrawal from the study of study vaccination, or otherwise meets the definition of an SAE, please add an entry and applicable details to the AE ecrf as appropriate. Otherwise, please confirm in query response that the solicited adverse reaction of PAIN AT INJECTION SITE did not meet the AE reporting criteria.' (Site from DM). DataPoint Verified.	(b) (4), (b) (6)	25 Nov 2020 14:38:42
	(b) (4), (b) (6)	19 Nov 2020 17:55:55
User entered 'Pain at Injection Site'	Isaac Perez (b) (4)	13 Oct 2020 19:17:11
	(b) (4)	

US3632052

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 09:13:35

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 06:51:39
User signature succeeded.	Colleen Kelley (b) (4)	12 Apr 2021 01:33:40
DataPoint activated with code reason code Data required.	(b) (4)	
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	08 Apr 2021 19:42:29
Signature has been broken.	(b) (4), (b) (6)	08 Apr 2021 19:41:29
User signature succeeded.	Colleen Kelley (b) (4)	02 Apr 2021 20:59:30
DataPoint Verified.	(b) (4)	
User entered '650'	(b) (4), (b) (6)	19 Nov 2020 17:56:01
	Isaac Perez (b) (4)	13 Oct 2020 19:17:11
	(b) (4)	

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 09:13:35

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 06:51:39
User signature succeeded.	Colleen Kelley (b) (4)	12 Apr 2021 01:33:40
DataPoint activated with code reason code Data required.	(b) (4)	08 Apr 2021 19:42:29
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	08 Apr 2021 19:41:29
Signature has been broken.	(b) (4), (b) (6)	08 Apr 2021 19:41:29
User signature succeeded.	Colleen Kelley (b) (4)	02 Apr 2021 20:59:30
DataPoint Verified.	(b) (4)	19 Nov 2020 17:56:04
User entered 'mg (mg)'	Isaac Perez (b) (4)	13 Oct 2020 19:17:11
	(b) (4)	

US3632052

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 09:13:35

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 06:51:39
User signature succeeded.	Colleen Kelley (b) (4)	12 Apr 2021 01:33:40
DataPoint activated with code reason code Data required.	(b) (4)	08 Apr 2021 19:42:29
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	08 Apr 2021 19:41:29
Signature has been broken.	(b) (4), (b) (6)	08 Apr 2021 19:41:29
User signature succeeded.	Colleen Kelley (b) (4)	02 Apr 2021 20:59:30
DataPoint Verified.	(b) (4)	19 Nov 2020 17:56:06
User entered empty.	Isaac Perez (b) (4)	13 Oct 2020 19:17:11
	(b) (4)	

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 09:13:35

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 06:51:39
User signature succeeded.	Colleen Kelley (b) (4)	12 Apr 2021 01:33:40
DataPoint activated with code reason code Data required.	(b) (4)	
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	08 Apr 2021 19:42:29
Signature has been broken.	(b) (4), (b) (6)	08 Apr 2021 19:41:29
User signature succeeded.	Colleen Kelley (b) (4)	02 Apr 2021 20:59:30
DataPoint Verified.	(b) (4)	
User entered 'as needed (PRN)'	(b) (4), (b) (6)	19 Nov 2020 17:56:08
	Isaac Perez (b) (4)	13 Oct 2020 19:17:11
	(b) (4)	

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 09:13:35

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 06:51:39
User signature succeeded.	Colleen Kelley (b) (4)	12 Apr 2021 01:33:40
DataPoint activated with code reason code Data required.	(b) (4)	08 Apr 2021 19:42:29
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	08 Apr 2021 19:41:29
Signature has been broken.	(b) (4), (b) (6)	08 Apr 2021 19:41:29
User signature succeeded.	Colleen Kelley (b) (4)	02 Apr 2021 20:59:30
DataPoint Verified.	(b) (4)	19 Nov 2020 17:56:11
User entered empty.	Isaac Perez (b) (4)	13 Oct 2020 19:17:11
	(b) (4)	

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 09:13:35

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 06:51:39
User signature succeeded.	Colleen Kelley (b) (4)	12 Apr 2021 01:33:40
DataPoint activated with code reason code Data required.	(b) (4)	08 Apr 2021 19:42:29
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	08 Apr 2021 19:41:29
Signature has been broken.	(b) (4), (b) (6)	08 Apr 2021 19:41:29
User signature succeeded.	Colleen Kelley (b) (4)	02 Apr 2021 20:59:30
DataPoint Verified.	(b) (4)	19 Nov 2020 17:56:13
User entered 'Oral (ORAL)'	Isaac Perez (b) (4)	13 Oct 2020 19:17:11
	(b) (4)	

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 09:13:35

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 06:51:39
User signature succeeded.	Colleen Kelley (b) (4)	12 Apr 2021 01:33:40
DataPoint activated with code reason code Data required.	(b) (4)	
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	08 Apr 2021 19:42:29
Signature has been broken.	(b) (4), (b) (6)	08 Apr 2021 19:41:29
User signature succeeded.	Colleen Kelley (b) (4)	02 Apr 2021 20:59:30
DataPoint Verified.	(b) (4)	
User entered empty.	(b) (4), (b) (6)	19 Nov 2020 17:56:15
	Isaac Perez (b) (4)	13 Oct 2020 19:17:11
	(b) (4)	



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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 09:13:35

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 06:51:39
User signature succeeded.	Colleen Kelley (b) (4)	12 Apr 2021 01:33:40
DataPoint activated with code reason code Data required.	(b) (4)	
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	08 Apr 2021 19:42:29
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	08 Apr 2021 19:41:29
Signature has been broken.	(b) (4), (b) (6)	08 Apr 2021 19:41:29
User signature succeeded.	Colleen Kelley (b) (4)	02 Apr 2021 20:59:30
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	19 Nov 2020 17:56:18
User entered '6 Oct 2020'	Isaac Perez (b) (4)	13 Oct 2020 19:17:11
	(b) (4)	

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 09:13:35

Start date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 06:51:39
User signature succeeded.	Colleen Kelley (b) (4)	12 Apr 2021 01:33:40
DataPoint activated with code reason code Data required.	(b) (4)	
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	08 Apr 2021 19:42:29
Signature has been broken.	(b) (4), (b) (6)	08 Apr 2021 19:41:29
User signature succeeded.	Colleen Kelley (b) (4)	02 Apr 2021 20:59:30
DataPoint Verified.	(b) (4)	
User entered '0'	(b) (4), (b) (6)	19 Nov 2020 17:56:19
	Isaac Perez (b) (4)	13 Oct 2020 19:17:11
	(b) (4)	

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 09:13:35

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 06:51:39
User signature succeeded.	Colleen Kelley (b) (4)	12 Apr 2021 01:33:40
DataPoint activated with code reason code Data required.	(b) (4)	
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	08 Apr 2021 19:42:29
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	08 Apr 2021 19:41:29
Signature has been broken.	(b) (4), (b) (6)	08 Apr 2021 19:41:29
User signature succeeded.	Colleen Kelley (b) (4)	02 Apr 2021 20:59:30
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	19 Nov 2020 17:56:21
User entered 'No (N)'	Isaac Perez (b) (4)	13 Oct 2020 19:17:11
	(b) (4)	

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 09:13:35

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 06:51:39
User signature succeeded.	Colleen Kelley (b) (4)	12 Apr 2021 01:33:40
DataPoint activated with code reason code Data required.	(b) (4)	
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	08 Apr 2021 19:42:29
Signature has been broken.	(b) (4), (b) (6)	08 Apr 2021 19:41:29
User signature succeeded.	Colleen Kelley (b) (4)	02 Apr 2021 20:59:30
DataPoint Verified.	(b) (4)	
User entered '10 Oct 2020'	(b) (4), (b) (6)	19 Nov 2020 17:56:24
	Isaac Perez (b) (4)	13 Oct 2020 19:17:11
	(b) (4)	

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 09:13:35

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 06:51:39
User signature succeeded.	Colleen Kelley (b) (4)	12 Apr 2021 01:33:40
DataPoint activated with code reason code Data required.	(b) (4)	
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	08 Apr 2021 19:42:29
Signature has been broken.	(b) (4), (b) (6)	08 Apr 2021 19:41:29
User signature succeeded.	Colleen Kelley (b) (4)	02 Apr 2021 20:59:30
DataPoint Verified.	(b) (4)	
User entered 'Yes (Y)'	(b) (4), (b) (6)	19 Nov 2020 17:56:28
	Isaac Perez (b) (4)	13 Oct 2020 19:17:11
	(b) (4)	

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 09:13:35

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 06:51:39
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	08 Apr 2021 19:42:29
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	08 Apr 2021 19:41:29
User entered empty.	System	13 Oct 2020 19:17:11

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 09:13:35

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 06:51:39
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	08 Apr 2021 19:42:29
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	08 Apr 2021 19:41:29
User entered empty.	System	13 Oct 2020 19:17:11

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 09:13:35

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 06:51:39
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	08 Apr 2021 19:42:29
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	08 Apr 2021 19:41:29
User entered empty.	System	13 Oct 2020 19:17:11



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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 10 Jun 2021 09:13:35

Name of Medication

Audit	User	Time (GMT)
User signature succeeded.	Colleen Kelley (b) (4)	12 Apr 2021 01:33:40
User coded data point as ATC: MUSCULO-SKELETAL SYSTEM, ATC: ANTIINFLAMMATORY AND ANTIRHEUMATIC PRODUCTS, ATC: ANTIINFLAMMATORY AND ANTIRHEUMATIC PRODUCTS, NON-STERIODS, ATC: PROPIONIC ACID DERIVATIVES, PRODUCT: NAPROXEN SODIUM, PRODUCTSYNONYM: ALEVE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	08 Apr 2021 20:31:47
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	08 Apr 2021 20:31:47
Data point term sent to Coder	System	08 Apr 2021 19:42:54
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	08 Apr 2021 19:42:29
Data point term sent to Coder	System	08 Apr 2021 19:41:49
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	08 Apr 2021 19:41:29
Signature has been broken.	(b) (4), (b) (6)	08 Apr 2021 19:41:29
User signature succeeded.	Colleen Kelley (b) (4)	02 Apr 2021 20:59:30
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 17:56:44
User coded data point as ATC: MUSCULO-SKELETAL SYSTEM, ATC: ANTIINFLAMMATORY AND ANTIRHEUMATIC PRODUCTS, ATC: ANTIINFLAMMATORY AND ANTIRHEUMATIC PRODUCTS, NON-STERIODS, ATC: PROPIONIC ACID DERIVATIVES, PRODUCT: NAPROXEN SODIUM, PRODUCTSYNONYM: ALEVE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	27 Oct 2020 21:30:25
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	27 Oct 2020 21:30:25
Data point term sent to Coder	System	27 Oct 2020 20:06:20
User entered 'Aleve'	Sarah Wiatrek (b) (4)	27 Oct 2020 20:05:56

US3632052

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 10 Jun 2021 09:13:35

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Colleen Kelley (b) (4)	12 Apr 2021 01:33:40
DataPoint activated with code reason code Data required.	(b) (4)	
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	08 Apr 2021 19:42:29
Signature has been broken.	(b) (4), (b) (6)	08 Apr 2021 19:41:29
User signature succeeded.	Colleen Kelley (b) (4)	02 Apr 2021 20:59:30
DataPoint Verified.	(b) (4)	
User entered 'No (N)'	(b) (4), (b) (6)	19 Nov 2020 17:56:47
	Sarah Wiatrek (b) (4)	27 Oct 2020 20:05:56
	(b) (4)	

US3632052

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 10 Jun 2021 09:13:35

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Colleen Kelley (b) (4)	12 Apr 2021 01:33:40
DataPoint activated with code reason code Data required.	(b) (4)	
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	08 Apr 2021 19:42:29
Signature has been broken.	(b) (4), (b) (6)	08 Apr 2021 19:41:29
User signature succeeded.	Colleen Kelley (b) (4)	02 Apr 2021 20:59:30
User closed query 'Per DM CLR: Please note that there is no AE that matches this Con Med indication during this time frame. Please review Con Med use and add a medical condition and all applicable details to the AE eCRF as appropriate.' (Site from DM).	(b) (4)	
Query 'Per DM CLR: Please note that there is no AE that matches this Con Med indication during this time frame. Please review Con Med use and add a medical condition and all applicable details to the AE eCRF as appropriate.' answered with 'This is not an AE. ' (Site from DM).	(b) (4), (b) (6)	12 Jan 2021 05:27:47
User opened query 'Per DM CLR: Please note that there is no AE that matches this Con Med indication during this time frame. Please review Con Med use and add a medical condition and all applicable details to the AE eCRF as appropriate.' (Site from DM).	(b) (4), (b) (6)	11 Jan 2021 17:29:45
DataPoint Verified.	(b) (4), (b) (6)	23 Dec 2020 07:51:06
User entered 'Soreness from yard work'	(b) (4), (b) (6)	19 Nov 2020 17:56:58
	Sarah Wiatrek (b) (4)	27 Oct 2020 20:05:56
	(b) (4)	

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 10 Jun 2021 09:13:35

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Colleen Kelley (b) (4)	12 Apr 2021 01:33:40
DataPoint activated with code reason code Data required.	(b) (4)	
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	08 Apr 2021 19:42:29
Signature has been broken.	(b) (4), (b) (6)	08 Apr 2021 19:41:29
User signature succeeded.	Colleen Kelley (b) (4)	02 Apr 2021 20:59:30
User closed query 'Per source, dose taken was 500 mg. Please verify and update EDC accordingly.' (Site from CRA).	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	23 Feb 2021 03:21:40
Query 'Per source, dose taken was 500 mg. Please verify and update EDC accordingly.' answered with 'UPDATED' (Site from CRA).	(b) (4), (b) (6)	10 Dec 2020 16:36:42
User entered '500' reason for change: Data Entry Error	Kelly Likos (b) (4)	20 Nov 2020 16:10:41
User opened query 'Per source, dose taken was 500 mg. Please verify and update EDC accordingly.' (Site from CRA).	(b) (4)	
User entered '1000'	Kelly Likos (b) (4)	20 Nov 2020 16:10:36
	(b) (4), (b) (6)	19 Nov 2020 17:57:20
	Sarah Wiatrek (b) (4)	27 Oct 2020 20:05:56
	(b) (4)	

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 10 Jun 2021 09:13:35

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Colleen Kelley (b) (4)	12 Apr 2021 01:33:40
DataPoint activated with code reason code Data required.	(b) (4)	
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	08 Apr 2021 19:42:29
Signature has been broken.	(b) (4), (b) (6)	08 Apr 2021 19:41:29
User signature succeeded.	Colleen Kelley (b) (4)	02 Apr 2021 20:59:30
DataPoint Verified.	(b) (4)	
User entered 'mg (mg)'	(b) (4), (b) (6)	19 Nov 2020 17:57:22
	Sarah Wiatrek (b) (4)	27 Oct 2020 20:05:56
	(b) (4)	

US3632052

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 10 Jun 2021 09:13:35

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Colleen Kelley (b) (4)	12 Apr 2021 01:33:40
DataPoint activated with code reason code Data required.	(b) (4)	
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	08 Apr 2021 19:42:29
Signature has been broken.	(b) (4), (b) (6)	08 Apr 2021 19:41:29
User signature succeeded.	Colleen Kelley (b) (4)	02 Apr 2021 20:59:30
DataPoint Verified.	(b) (4)	
User entered empty.	(b) (4), (b) (6)	19 Nov 2020 17:57:25
	Sarah Wiatrek (b) (4)	27 Oct 2020 20:05:56
	(b) (4)	

US3632052

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 10 Jun 2021 09:13:35

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Colleen Kelley (b) (4)	12 Apr 2021 01:33:40
DataPoint activated with code reason code Data required.	(b) (4)	
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	08 Apr 2021 19:42:29
Signature has been broken.	(b) (4), (b) (6)	08 Apr 2021 19:41:29
User signature succeeded.	Colleen Kelley (b) (4)	02 Apr 2021 20:59:30
DataPoint Verified.	(b) (4)	
User entered 'as needed (PRN)' reason for change: New Information	(b) (4), (b) (6)	19 Nov 2020 17:57:38
User entered 'once (ONCE)'	Christina Bacher (b) (4)	16 Nov 2020 21:10:33
	(b) (4)	
	Sarah Wiatrek (b) (4)	27 Oct 2020 20:05:56
	(b) (4)	

US3632052

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 10 Jun 2021 09:13:35

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Colleen Kelley (b) (4)	12 Apr 2021 01:33:40
DataPoint activated with code reason code Data required.	(b) (4)	
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	08 Apr 2021 19:42:29
Signature has been broken.	(b) (4), (b) (6)	08 Apr 2021 19:41:29
User signature succeeded.	Colleen Kelley (b) (4)	02 Apr 2021 20:59:30
DataPoint Verified.	(b) (4)	
User entered empty.	(b) (4), (b) (6)	19 Nov 2020 17:57:35
	Sarah Wiatrek (b) (4)	27 Oct 2020 20:05:56
	(b) (4)	



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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 10 Jun 2021 09:13:35

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Colleen Kelley (b) (4)	12 Apr 2021 01:33:40
DataPoint activated with code reason code Data required.	(b) (4)	
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	08 Apr 2021 19:42:29
Signature has been broken.	(b) (4), (b) (6)	08 Apr 2021 19:41:29
User signature succeeded.	Colleen Kelley (b) (4)	02 Apr 2021 20:59:30
DataPoint Verified.	(b) (4)	
User entered 'Oral (ORAL)'	(b) (4), (b) (6)	19 Nov 2020 17:57:41
	Sarah Wiatrek (b) (4)	27 Oct 2020 20:05:56
	(b) (4)	

US3632052

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 10 Jun 2021 09:13:35

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Colleen Kelley (b) (4)	12 Apr 2021 01:33:40
DataPoint activated with code reason code Data required.	(b) (4)	
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	08 Apr 2021 19:42:29
Signature has been broken.	(b) (4), (b) (6)	08 Apr 2021 19:41:29
User signature succeeded.	Colleen Kelley (b) (4)	02 Apr 2021 20:59:30
DataPoint Verified.	(b) (4)	
User entered empty.	(b) (4), (b) (6)	19 Nov 2020 17:57:45
	Sarah Wiatrek (b) (4)	27 Oct 2020 20:05:56
	(b) (4)	

US3632052

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 10 Jun 2021 09:13:35

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Colleen Kelley (b) (4)	12 Apr 2021 01:33:40
DataPoint activated with code reason code Data required.	(b) (4)	
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	08 Apr 2021 19:42:29
Signature has been broken.	(b) (4), (b) (6)	08 Apr 2021 19:41:29
User signature succeeded.	Colleen Kelley (b) (4)	02 Apr 2021 20:59:30
DataPoint Verified.	(b) (4)	
User entered '24 Oct 2020'	(b) (4), (b) (6)	19 Nov 2020 17:57:49
	Sarah Wiatrek (b) (4)	27 Oct 2020 20:05:56
	(b) (4)	

US3632052

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 10 Jun 2021 09:13:35

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Colleen Kelley (b) (4)	12 Apr 2021 01:33:40
DataPoint activated with code reason code Data required.	(b) (4)	
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	08 Apr 2021 19:42:29
Signature has been broken.	(b) (4), (b) (6)	08 Apr 2021 19:41:29
User signature succeeded.	Colleen Kelley (b) (4)	02 Apr 2021 20:59:30
DataPoint Verified.	(b) (4)	
User entered '0'	(b) (4), (b) (6)	19 Nov 2020 17:57:51
	Sarah Wiatrek (b) (4)	27 Oct 2020 20:05:56
	(b) (4)	

US3632052

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 10 Jun 2021 09:13:35

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Colleen Kelley (b) (4)	12 Apr 2021 01:33:40
DataPoint activated with code reason code Data required.	(b) (4)	
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	08 Apr 2021 19:42:29
Signature has been broken.	(b) (4), (b) (6)	08 Apr 2021 19:41:29
User signature succeeded.	Colleen Kelley (b) (4)	02 Apr 2021 20:59:30
DataPoint Verified.	(b) (4)	
User entered 'Yes (Y)' reason for change: New Information	(b) (4), (b) (6)	19 Nov 2020 17:57:53
User entered 'No (N)'	Christina Bacher (b) (4)	16 Nov 2020 21:10:33
	(b) (4)	
	Sarah Wiatrek (b) (4)	27 Oct 2020 20:05:56
	(b) (4)	

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 10 Jun 2021 09:13:35

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Colleen Kelley (b) (4)	12 Apr 2021 01:33:40
DataPoint activated with code reason code Data required.	(b) (4)	
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	08 Apr 2021 19:42:29
Signature has been broken.	(b) (4), (b) (6)	08 Apr 2021 19:41:29
User signature succeeded.	Colleen Kelley (b) (4)	02 Apr 2021 20:59:30
DataPoint Verified.	(b) (4)	
User entered empty; reason for change New Information	(b) (4), (b) (6)	19 Nov 2020 17:57:55
User entered '24 Oct 2020'	Christina Bacher (b) (4)	16 Nov 2020 21:10:33
	(b) (4)	
	Sarah Wiatrek (b) (4)	27 Oct 2020 20:05:56
	(b) (4)	

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 10 Jun 2021 09:13:35

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Colleen Kelley (b) (4)	12 Apr 2021 01:33:40
DataPoint activated with code reason code Data required.	(b) (4)	
	(b) (4), (b) (6)	08 Apr 2021 19:42:29
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	08 Apr 2021 19:41:29
Signature has been broken.	(b) (4), (b) (6)	08 Apr 2021 19:41:29
User signature succeeded.	Colleen Kelley (b) (4)	02 Apr 2021 20:59:30
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	19 Nov 2020 17:57:57
User entered 'No (N)'	Sarah Wiatrek (b) (4)	27 Oct 2020 20:05:56
	(b) (4)	

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 10 Jun 2021 09:13:35

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	08 Apr 2021 19:42:29
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	08 Apr 2021 19:41:29
User entered empty.	System	27 Oct 2020 20:05:56



**US3632052**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (13)**

**Generated On: 10 Jun 2021 09:13:35**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	08 Apr 2021 19:42:29
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	08 Apr 2021 19:41:29
User entered empty.	System	27 Oct 2020 20:05:56

US3632052

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 10 Jun 2021 09:13:35

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	08 Apr 2021 19:42:29
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	08 Apr 2021 19:41:29
User entered empty.	System	27 Oct 2020 20:05:56

US3632052

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 10 Jun 2021 09:13:35

Name of Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 06:51:42
User signature succeeded.	Colleen Kelley (b) (4)	12 Apr 2021 01:33:40
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)	08 Apr 2021 19:43:50
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\202003.	(b) (4)	08 Apr 2021 19:43:50
Data point term sent to Coder	System	08 Apr 2021 19:42:54
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	08 Apr 2021 19:42:29
Data point term sent to Coder	System	08 Apr 2021 19:41:48
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	08 Apr 2021 19:41:29
Signature has been broken.	(b) (4), (b) (6)	08 Apr 2021 19:41:29
User signature succeeded.	Colleen Kelley (b) (4)	02 Apr 2021 20:59:30
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)	20 Nov 2020 16:42:45
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\202003.	(b) (4)	20 Nov 2020 16:42:45
Data point term sent to Coder	System	20 Nov 2020 16:11:11
Coding entries removed.	Kelly Likos (b) (4)	20 Nov 2020 16:10:59
DataPoint Verified.	(b) (4)	19 Nov 2020 17:58:09
User coded data point as ATC: ANTIINFECTIVES FOR SYSTEMIC USE, ATC: VACCINES, ATC: VIRAL VACCINES, ATC: INFLUENZA VACCINES, PRODUCT: INFLUENZA VACCINE - version WHODrug-Global-B3\202003.	(b) (4), (b) (6)	05 Nov 2020 12:04:24
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\202003.	Coder Import (b) (4)	05 Nov 2020 12:04:24

PRODUCTION RELEASE (v12.003  
EAB) (1725)

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**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (14)**

**Generated On: 10 Jun 2021 09:13:35**

[Name of Medication](#)

Audit	User	Time (GMT)
Data point term sent to Coder	System	02 Nov 2020 20:19:23
User entered 'Flu Vaccine'	Aastha KC (b) (4)	02 Nov 2020 20:18:33
	(b) (4)	

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 10 Jun 2021 09:13:35

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 06:51:42
User signature succeeded.	Colleen Kelley (b) (4)	12 Apr 2021 01:33:40
DataPoint activated with code reason code Data required.	(b) (4)	
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	08 Apr 2021 19:42:29
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	08 Apr 2021 19:41:29
Signature has been broken.	(b) (4), (b) (6)	08 Apr 2021 19:41:29
User signature succeeded.	Colleen Kelley (b) (4)	02 Apr 2021 20:59:30
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	19 Nov 2020 17:58:13
User entered 'Yes (Y)'	Aastha KC (b) (4)	02 Nov 2020 20:18:33
	(b) (4)	

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 10 Jun 2021 09:13:35

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 06:51:42
User signature succeeded.	Colleen Kelley (b) (4)	12 Apr 2021 01:33:40
DataPoint activated with code reason code Data required.	(b) (4)	
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	08 Apr 2021 19:42:29
Signature has been broken.	(b) (4), (b) (6)	08 Apr 2021 19:41:29
User signature succeeded.	Colleen Kelley (b) (4)	02 Apr 2021 20:59:30
User closed query 'Per source, indication for this medication is "General". Please verify with source and update EDC accordingly.' (Site from CRA).	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	23 Feb 2021 03:21:58
Query 'Per source, indication for this medication is "General". Please verify with source and update EDC accordingly.' answered with 'UPDATED' (Site from CRA).	(b) (4), (b) (6)	10 Dec 2020 16:36:42
User entered 'GENERAL HEALTH' reason for change: Data Entry Error	Kelly Likos (b) (4)	20 Nov 2020 16:11:05
User opened query 'Per source, indication for this medication is "General". Please verify with source and update EDC accordingly.' (Site from CRA).	(b) (4)	
DataPoint Un-verified.	(b) (4), (b) (6)	20 Nov 2020 16:10:59
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 17:59:05
User entered 'Seasonal Flu'	(b) (4), (b) (6)	19 Nov 2020 17:58:22
	(b) (4), (b) (6)	19 Nov 2020 17:58:20
	Aastha KC (b) (4)	02 Nov 2020 20:18:33
	(b) (4)	

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 10 Jun 2021 09:13:35

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 06:51:42
User signature succeeded.	Colleen Kelley (b) (4)	12 Apr 2021 01:33:40
DataPoint activated with code reason code Data required.	(b) (4)	08 Apr 2021 19:42:29
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	08 Apr 2021 19:41:29
Signature has been broken.	(b) (4), (b) (6)	08 Apr 2021 19:41:29
User signature succeeded.	Colleen Kelley (b) (4)	02 Apr 2021 20:59:30
DataPoint Verified.	(b) (4)	19 Nov 2020 17:59:10
User entered 'UNK'	Aastha KC (b) (4)	02 Nov 2020 20:18:33
	(b) (4)	

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 10 Jun 2021 09:13:35

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 06:51:42
User signature succeeded.	Colleen Kelley (b) (4)	12 Apr 2021 01:33:40
DataPoint activated with code reason code Data required.	(b) (4)	
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	08 Apr 2021 19:42:29
Signature has been broken.	(b) (4), (b) (6)	08 Apr 2021 19:41:29
User signature succeeded.	Colleen Kelley (b) (4)	02 Apr 2021 20:59:30
DataPoint Verified.	(b) (4)	
User entered 'Other (OTHER)'	(b) (4), (b) (6)	19 Nov 2020 17:59:12
	Aastha KC (b) (4)	02 Nov 2020 20:18:33
	(b) (4)	



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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 10 Jun 2021 09:13:35

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 06:51:42
User signature succeeded.	Colleen Kelley (b) (4)	12 Apr 2021 01:33:40
DataPoint activated with code reason code Data required.	(b) (4)	
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	08 Apr 2021 19:42:29
Signature has been broken.	(b) (4), (b) (6)	08 Apr 2021 19:41:29
User signature succeeded.	Colleen Kelley (b) (4)	02 Apr 2021 20:59:30
DataPoint Verified.	(b) (4)	
User entered 'Unknown'	(b) (4), (b) (6)	19 Nov 2020 17:59:15
	Aastha KC (b) (4)	02 Nov 2020 20:18:33
	(b) (4)	

US3632052

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 10 Jun 2021 09:13:35

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 06:51:42
User signature succeeded.	Colleen Kelley (b) (4)	12 Apr 2021 01:33:40
DataPoint activated with code reason code Data required.	(b) (4)	
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	08 Apr 2021 19:42:29
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	08 Apr 2021 19:41:29
Signature has been broken.	(b) (4), (b) (6)	08 Apr 2021 19:41:29
User signature succeeded.	Colleen Kelley (b) (4)	02 Apr 2021 20:59:30
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	19 Nov 2020 17:59:18
User entered 'once (ONCE)'	Aastha KC (b) (4)	02 Nov 2020 20:18:33
	(b) (4)	

US3632052

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 10 Jun 2021 09:13:35

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 06:51:42
User signature succeeded.	Colleen Kelley (b) (4)	12 Apr 2021 01:33:40
DataPoint activated with code reason code Data required.	(b) (4)	
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	08 Apr 2021 19:42:29
Signature has been broken.	(b) (4), (b) (6)	08 Apr 2021 19:41:29
User signature succeeded.	Colleen Kelley (b) (4)	02 Apr 2021 20:59:30
DataPoint Verified.	(b) (4)	
User entered empty.	(b) (4), (b) (6)	19 Nov 2020 17:59:20
	Aastha KC (b) (4)	02 Nov 2020 20:18:33
	(b) (4)	

US3632052

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 10 Jun 2021 09:13:35

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 06:51:42
User signature succeeded.	Colleen Kelley (b) (4)	12 Apr 2021 01:33:40
DataPoint activated with code reason code Data required.	(b) (4)	08 Apr 2021 19:42:29
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	08 Apr 2021 19:41:29
Signature has been broken.	(b) (4), (b) (6)	08 Apr 2021 19:41:29
User signature succeeded.	Colleen Kelley (b) (4)	02 Apr 2021 20:59:30
DataPoint Verified.	(b) (4)	19 Nov 2020 17:59:23
User entered 'Intramuscular (INTRAMUSCULAR)'	(b) (4), (b) (6)	02 Nov 2020 20:18:33
	(b) (4)	

US3632052

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 10 Jun 2021 09:13:35

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 06:51:42
User signature succeeded.	Colleen Kelley (b) (4)	12 Apr 2021 01:33:40
DataPoint activated with code reason code Data required.	(b) (4)	
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	08 Apr 2021 19:42:29
Signature has been broken.	(b) (4), (b) (6)	08 Apr 2021 19:41:29
User signature succeeded.	Colleen Kelley (b) (4)	02 Apr 2021 20:59:30
DataPoint Verified.	(b) (4)	
User entered empty.	(b) (4), (b) (6)	19 Nov 2020 17:59:26
	Aastha KC (b) (4)	02 Nov 2020 20:18:33
	(b) (4)	

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 10 Jun 2021 09:13:35

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 06:51:42
User signature succeeded.	Colleen Kelley (b) (4)	12 Apr 2021 01:33:40
DataPoint activated with code reason code Data required.	(b) (4)	
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	08 Apr 2021 19:42:29
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	08 Apr 2021 19:41:29
Signature has been broken.	(b) (4), (b) (6)	08 Apr 2021 19:41:29
User signature succeeded.	Colleen Kelley (b) (4)	02 Apr 2021 20:59:30
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	19 Nov 2020 17:59:30
User entered '28 Oct 2020'	Aastha KC (b) (4)	02 Nov 2020 20:18:33
	(b) (4)	

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 10 Jun 2021 09:13:35

Start date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 06:51:42
User signature succeeded.	Colleen Kelley (b) (4)	12 Apr 2021 01:33:40
DataPoint activated with code reason code Data required.	(b) (4)	08 Apr 2021 19:42:29
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	08 Apr 2021 19:41:29
Signature has been broken.	(b) (4), (b) (6)	08 Apr 2021 19:41:29
User signature succeeded.	Colleen Kelley (b) (4)	02 Apr 2021 20:59:30
DataPoint Verified.	(b) (4)	19 Nov 2020 17:59:32
User entered '0'	Aastha KC (b) (4)	02 Nov 2020 20:18:33
	(b) (4)	

US3632052

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 10 Jun 2021 09:13:35

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 06:51:42
User signature succeeded.	Colleen Kelley (b) (4)	12 Apr 2021 01:33:40
DataPoint activated with code reason code Data required.	(b) (4)	
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	08 Apr 2021 19:42:29
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	08 Apr 2021 19:41:29
Signature has been broken.	(b) (4), (b) (6)	08 Apr 2021 19:41:29
User signature succeeded.	Colleen Kelley (b) (4)	02 Apr 2021 20:59:30
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	19 Nov 2020 17:59:35
User entered 'No (N)'	Aastha KC (b) (4)	02 Nov 2020 20:18:33
	(b) (4)	



US3632052

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 10 Jun 2021 09:13:35

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 06:51:42
User signature succeeded.	Colleen Kelley (b) (4)	12 Apr 2021 01:33:40
DataPoint activated with code reason code Data required.	(b) (4)	
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	08 Apr 2021 19:42:29
Signature has been broken.	(b) (4), (b) (6)	08 Apr 2021 19:41:29
User signature succeeded.	Colleen Kelley (b) (4)	02 Apr 2021 20:59:30
DataPoint Verified.	(b) (4)	
User entered '28 Oct 2020'	(b) (4), (b) (6)	19 Nov 2020 17:59:36
	Aastha KC (b) (4)	02 Nov 2020 20:18:33
	(b) (4)	

US3632052

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 10 Jun 2021 09:13:35

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 06:51:42
User signature succeeded.	Colleen Kelley (b) (4)	12 Apr 2021 01:33:40
DataPoint activated with code reason code Data required.	(b) (4)	
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	08 Apr 2021 19:42:29
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	08 Apr 2021 19:41:29
Signature has been broken.	(b) (4), (b) (6)	08 Apr 2021 19:41:29
User signature succeeded.	Colleen Kelley (b) (4)	02 Apr 2021 20:59:30
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	19 Nov 2020 17:59:38
User entered 'No (N)'	Aastha KC (b) (4)	02 Nov 2020 20:18:33
	(b) (4)	

US3632052

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 10 Jun 2021 09:13:35

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 06:51:42
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	08 Apr 2021 19:42:29
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	08 Apr 2021 19:41:29
User entered empty.	System	02 Nov 2020 20:18:33

US3632052

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 10 Jun 2021 09:13:35

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 06:51:42
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	08 Apr 2021 19:42:29
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	08 Apr 2021 19:41:29
User entered empty.	System	02 Nov 2020 20:18:33

US3632052

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 10 Jun 2021 09:13:35

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 06:51:42
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	08 Apr 2021 19:42:29
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	08 Apr 2021 19:41:29
User entered empty.	System	02 Nov 2020 20:18:33

US3632052

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 10 Jun 2021 09:13:35

Name of Medication

Audit	User	Time (GMT)
User signature succeeded.	Colleen Kelley (b) (4)	12 Apr 2021 01:33:40
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: DRUGS FOR ACID RELATED DISORDERS, ATC: DRUGS FOR PEPTIC ULCER AND GASTRO-OESOPHAGEAL REFLUX DISEASE (GORD), ATC: PROTON PUMP INHIBITORS, PRODUCT: OMEPRAZOLE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	08 Apr 2021 19:43:50
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	08 Apr 2021 19:43:50
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 19:43:41
Data point term sent to Coder	System	08 Apr 2021 19:42:55
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	08 Apr 2021 19:42:29
Data point term sent to Coder	System	08 Apr 2021 19:41:48
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	08 Apr 2021 19:41:29
Signature has been broken.	(b) (4), (b) (6)	08 Apr 2021 19:41:29
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: DRUGS FOR ACID RELATED DISORDERS, ATC: DRUGS FOR PEPTIC ULCER AND GASTRO-OESOPHAGEAL REFLUX DISEASE (GORD), ATC: PROTON PUMP INHIBITORS, PRODUCT: OMEPRAZOLE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	05 Apr 2021 09:32:52
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	05 Apr 2021 09:32:52
User signature succeeded.	Colleen Kelley (b) (4)	02 Apr 2021 20:59:30
Data point term sent to Coder	System	01 Apr 2021 19:54:50
User entered 'omeprazole'	(b) (4), (b) (6)	01 Apr 2021 19:54:16

US3632052

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 10 Jun 2021 09:13:35

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Colleen Kelley (b) (4)	12 Apr 2021 01:33:40
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	08 Apr 2021 19:43:41
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	08 Apr 2021 19:42:29
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	08 Apr 2021 19:41:29
Signature has been broken.	(b) (4), (b) (6)	08 Apr 2021 19:41:29
User signature succeeded.	Colleen Kelley (b) (4)	02 Apr 2021 20:59:30
User entered 'No (N)'	(b) (4)	
	(b) (4), (b) (6)	01 Apr 2021 19:54:16

US3632052

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 10 Jun 2021 09:13:35

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Colleen Kelley (b) (4)	12 Apr 2021 01:33:40
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	08 Apr 2021 19:43:41
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	08 Apr 2021 19:42:29
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	08 Apr 2021 19:41:29
Signature has been broken.	(b) (4), (b) (6)	08 Apr 2021 19:41:29
User signature succeeded.	Colleen Kelley (b) (4)	02 Apr 2021 20:59:30
User entered 'globus pharyngeus'	(b) (4)	
	(b) (4), (b) (6)	01 Apr 2021 19:54:16



US3632052

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 10 Jun 2021 09:13:35

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Colleen Kelley (b) (4)	12 Apr 2021 01:33:40
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	08 Apr 2021 19:43:41
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	08 Apr 2021 19:42:29
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	08 Apr 2021 19:41:29
Signature has been broken.	(b) (4), (b) (6)	08 Apr 2021 19:41:29
User signature succeeded.	Colleen Kelley (b) (4)	02 Apr 2021 20:59:30
User entered '20'	(b) (4)	
	(b) (4), (b) (6)	01 Apr 2021 19:54:16

US3632052

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 10 Jun 2021 09:13:35

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Colleen Kelley (b) (4)	12 Apr 2021 01:33:40
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	08 Apr 2021 19:43:41
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	08 Apr 2021 19:42:29
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	08 Apr 2021 19:41:29
Signature has been broken.	(b) (4), (b) (6)	08 Apr 2021 19:41:29
User signature succeeded.	Colleen Kelley (b) (4)	02 Apr 2021 20:59:30
User entered 'mg (mg)'	(b) (4)	
	(b) (4), (b) (6)	01 Apr 2021 19:54:16

US3632052

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 10 Jun 2021 09:13:35

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Colleen Kelley (b) (4)	12 Apr 2021 01:33:40
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 19:43:41
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	08 Apr 2021 19:42:29
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	08 Apr 2021 19:41:29
Signature has been broken.	(b) (4), (b) (6)	08 Apr 2021 19:41:29
User signature succeeded.	Colleen Kelley (b) (4)	02 Apr 2021 20:59:30
	(b) (4)	
User entered empty.	(b) (4), (b) (6)	01 Apr 2021 19:54:16

US3632052

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 10 Jun 2021 09:13:35

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Colleen Kelley (b) (4)	12 Apr 2021 01:33:40
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	08 Apr 2021 19:43:41
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	08 Apr 2021 19:42:29
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	08 Apr 2021 19:41:29
Signature has been broken.	(b) (4), (b) (6)	08 Apr 2021 19:41:29
User signature succeeded.	Colleen Kelley (b) (4)	02 Apr 2021 20:59:30
User entered 'once daily (QD)'	(b) (4)	
	(b) (4), (b) (6)	01 Apr 2021 19:54:16

US3632052

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 10 Jun 2021 09:13:35

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Colleen Kelley (b) (4)	12 Apr 2021 01:33:40
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 19:43:41
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	08 Apr 2021 19:42:29
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	08 Apr 2021 19:41:29
Signature has been broken.	(b) (4), (b) (6)	08 Apr 2021 19:41:29
User signature succeeded.	Colleen Kelley (b) (4)	02 Apr 2021 20:59:30
	(b) (4)	
User entered empty.	(b) (4), (b) (6)	01 Apr 2021 19:54:16

US3632052

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 10 Jun 2021 09:13:35

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Colleen Kelley (b) (4)	12 Apr 2021 01:33:40
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	08 Apr 2021 19:43:41
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	08 Apr 2021 19:42:29
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	08 Apr 2021 19:41:29
Signature has been broken.	(b) (4), (b) (6)	08 Apr 2021 19:41:29
User signature succeeded.	Colleen Kelley (b) (4)	02 Apr 2021 20:59:30
User entered 'Oral (ORAL)'	(b) (4)	
	(b) (4), (b) (6)	01 Apr 2021 19:54:16

US3632052

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 10 Jun 2021 09:13:35

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Colleen Kelley (b) (4)	12 Apr 2021 01:33:40
DataPoint Verified.	(b) (4)	08 Apr 2021 19:43:41
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	08 Apr 2021 19:42:29
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	08 Apr 2021 19:41:29
Signature has been broken.	(b) (4), (b) (6)	08 Apr 2021 19:41:29
User signature succeeded.	Colleen Kelley (b) (4)	02 Apr 2021 20:59:30
User entered empty.	(b) (4)	01 Apr 2021 19:54:16
	(b) (4), (b) (6)	

US3632052

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 10 Jun 2021 09:13:35

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Colleen Kelley (b) (4)	12 Apr 2021 01:33:40
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	08 Apr 2021 19:43:41
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	08 Apr 2021 19:42:29
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	08 Apr 2021 19:41:29
Signature has been broken.	(b) (4), (b) (6)	08 Apr 2021 19:41:29
User signature succeeded.	Colleen Kelley (b) (4)	02 Apr 2021 20:59:30
User entered '12 Feb 2021' reason for change: Data Entry Error	(b) (4)	
	(b) (4), (b) (6)	02 Apr 2021 13:09:04
User entered 'un Feb 2021'	(b) (4), (b) (6)	01 Apr 2021 19:54:16



US3632052

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 10 Jun 2021 09:13:35

Start date completely unknown

Audit	User	Time (GMT)
User signature succeeded.	Colleen Kelley (b) (4)	12 Apr 2021 01:33:40
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	08 Apr 2021 19:43:41
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	08 Apr 2021 19:42:29
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	08 Apr 2021 19:41:29
Signature has been broken.	(b) (4), (b) (6)	08 Apr 2021 19:41:29
User signature succeeded.	Colleen Kelley (b) (4)	02 Apr 2021 20:59:30
User entered '0'	(b) (4)	
	(b) (4), (b) (6)	01 Apr 2021 19:54:16

US3632052

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 10 Jun 2021 09:13:35

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Colleen Kelley (b) (4)	12 Apr 2021 01:33:40
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	08 Apr 2021 19:43:41
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	08 Apr 2021 19:42:29
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	08 Apr 2021 19:41:29
Signature has been broken.	(b) (4), (b) (6)	08 Apr 2021 19:41:29
User signature succeeded.	Colleen Kelley (b) (4)	02 Apr 2021 20:59:30
User entered 'Yes (Y)'	(b) (4)	
	(b) (4), (b) (6)	01 Apr 2021 19:54:16

US3632052

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 10 Jun 2021 09:13:35

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Colleen Kelley (b) (4)	12 Apr 2021 01:33:40
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 19:43:41
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	08 Apr 2021 19:42:29
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	08 Apr 2021 19:41:29
Signature has been broken.	(b) (4), (b) (6)	08 Apr 2021 19:41:29
User signature succeeded.	Colleen Kelley (b) (4)	02 Apr 2021 20:59:30
	(b) (4)	
User entered empty.	(b) (4), (b) (6)	01 Apr 2021 19:54:16

US3632052

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 10 Jun 2021 09:13:35

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Colleen Kelley (b) (4)	12 Apr 2021 01:33:40
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	08 Apr 2021 19:43:41
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	08 Apr 2021 19:42:29
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	08 Apr 2021 19:41:29
Signature has been broken.	(b) (4), (b) (6)	08 Apr 2021 19:41:29
User signature succeeded.	Colleen Kelley (b) (4)	02 Apr 2021 20:59:30
User entered 'No (N)'	(b) (4)	
	(b) (4), (b) (6)	01 Apr 2021 19:54:16

US3632052

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 10 Jun 2021 09:13:35

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	08 Apr 2021 19:42:29
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	08 Apr 2021 19:41:29
User entered 'I'	System	01 Apr 2021 19:54:16

US3632052

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 10 Jun 2021 09:13:35

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	08 Apr 2021 19:42:29
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	08 Apr 2021 19:41:29
User entered 'I'	System	01 Apr 2021 19:54:16

US3632052

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 10 Jun 2021 09:13:35

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	08 Apr 2021 19:42:29
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	08 Apr 2021 19:41:29
User entered '804 (804)'	System	01 Apr 2021 19:54:16

US3632052

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures Summary

Generated On: 10 Jun 2021 09:13:35

[Were any concomitant procedures performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 09:04:15
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 19:27:14
User signature succeeded.	Colleen Kelley (b) (4)	02 Apr 2021 20:59:30
DataPoint Un-verified.	(b) (4), (b) (6)	01 Apr 2021 19:48:27
User entered 'Yes (Y)' reason for change: Data Entry Error	(b) (4), (b) (6)	01 Apr 2021 19:48:27
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 18:01:11
User entered 'No (N)'	(b) (4), (b) (6)	09 Sep 2020 13:41:44



**US3632052**

**Folder: Concomitant Procedures (1)**

**Form: Concomitant Procedures (1)**

**Generated On: 10 Jun 2021 09:13:35**

**Procedure/Surgery date** (*dd MMM yyyy*)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 19:27:42
User signature succeeded.	Colleen Kelley (b) (4)	02 Apr 2021 20:59:30
User entered '05 Feb 2021'	(b) (4), (b) (6)	01 Apr 2021 19:48:52

**US3632052**

**Folder: Concomitant Procedures (1)**

**Form: Concomitant Procedures (1)**

**Generated On: 10 Jun 2021 09:13:35**

[Procedure/Surgery](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 19:27:42
User signature succeeded.	Colleen Kelley (b) (4)	02 Apr 2021 20:59:30
User entered 'Endoscopy'	(b) (4), (b) (6)	01 Apr 2021 19:48:52

**US3632052**

**Folder: Concomitant Procedures (1)**

**Form: Concomitant Procedures (1)**

**Generated On: 10 Jun 2021 09:13:35**

[Indication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 19:27:42
User signature succeeded.	Colleen Kelley (b) (4)	02 Apr 2021 20:59:30
User entered 'Adverse Event (AE)'	(b) (4), (b) (6)	01 Apr 2021 19:48:52

US3632052

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (1)

Generated On: 10 Jun 2021 09:13:35

If indication is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 19:27:42
User signature succeeded.	Colleen Kelley (b) (4)	02 Apr 2021 20:59:30
User entered empty.	(b) (4), (b) (6)	01 Apr 2021 19:48:52

US3632052

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (2)

Generated On: 10 Jun 2021 09:13:35

Procedure/Surgery date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:52:33
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 19:27:42
User signature succeeded.	Colleen Kelley (b) (4)	02 Apr 2021 20:59:30
User entered '18 Feb 2021'	(b) (4), (b) (6)	01 Apr 2021 19:49:34

**US3632052**

**Folder: Concomitant Procedures (1)**

**Form: Concomitant Procedures (2)**

**Generated On: 10 Jun 2021 09:13:35**

[Procedure/Surgery](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:52:33
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 19:27:42
User signature succeeded.	Colleen Kelley (b) (4)	02 Apr 2021 20:59:30
User entered 'colonoscopy'	(b) (4), (b) (6)	01 Apr 2021 19:49:34

US3632052

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (2)

Generated On: 10 Jun 2021 09:13:35

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:52:33
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 19:27:42
User signature succeeded.	Colleen Kelley (b) (4)	02 Apr 2021 20:59:30
User entered 'Other (OTHER)'	(b) (4), (b) (6)	01 Apr 2021 19:49:34

US3632052

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (2)

Generated On: 10 Jun 2021 09:13:35

If indication is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:52:33
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 19:27:42
User signature succeeded.	Colleen Kelley (b) (4)	02 Apr 2021 20:59:30
User entered 'routine colonoscopy for age'	(b) (4), (b) (6)	01 Apr 2021 19:49:34



US3632052

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (3)

Generated On: 10 Jun 2021 09:13:35

Procedure/Surgery date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:52:37
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 19:27:42
User signature succeeded.	Colleen Kelley (b) (4)	02 Apr 2021 20:59:30
User entered '04 Mar 2021'	(b) (4), (b) (6)	01 Apr 2021 19:49:58

US3632052

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (3)

Generated On: 10 Jun 2021 09:13:35

[Procedure/Surgery](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:52:37
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 19:27:42
User signature succeeded.	Colleen Kelley (b) (4)	02 Apr 2021 20:59:30
User entered 'prostate biopsy'	(b) (4), (b) (6)	01 Apr 2021 19:49:58

**US3632052**

**Folder: Concomitant Procedures (1)**

**Form: Concomitant Procedures (3)**

**Generated On: 10 Jun 2021 09:13:35**

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:52:37
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 19:27:42
User signature succeeded.	Colleen Kelley (b) (4)	02 Apr 2021 20:59:30
User entered 'Diagnostic (DIAGNOSTIC)'	(b) (4), (b) (6)	01 Apr 2021 19:49:58

US3632052

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (3)

Generated On: 10 Jun 2021 09:13:35

If indication is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:52:37
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 19:27:42
User signature succeeded.	Colleen Kelley (b) (4)	02 Apr 2021 20:59:30
User entered empty.	(b) (4), (b) (6)	01 Apr 2021 19:49:58

**US3632052**

**Folder: SAE USA-US120-2021-MRNA-1273-P301000005**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:13:35**

[SAEID](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 19:49:16
User signature succeeded.	Colleen Kelley (b) (4)	02 Apr 2021 20:59:30
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	02 Apr 2021 16:53:09
User entered 'USA-US120-2021-MRNA-1273-P301000005'	System	02 Apr 2021 16:51:27

**US3632052**

**Folder: SAE USA-US120-2021-MRNA-1273-P301000005**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:13:35**

**Serious**

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 19:49:16
User signature succeeded.	Colleen Kelley (b) (4)	02 Apr 2021 20:59:30
Reviewed for Safety.	(b) (4), (b) (6)	02 Apr 2021 16:53:09
User entered 'Yes (Y)'	System	02 Apr 2021 16:51:27

**US3632052**

**Folder: SAE USA-US120-2021-MRNA-1273-P301000005**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:13:35**

[Death](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 19:49:16
User signature succeeded.	Colleen Kelley (b) (4)	02 Apr 2021 20:59:30
Reviewed for Safety.	(b) (4), (b) (6)	02 Apr 2021 16:53:09
User entered 'No (N)'	System	02 Apr 2021 16:51:27

**US3632052**

**Folder: SAE USA-US120-2021-MRNA-1273-P301000005**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:13:35**

[Life threatening](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 19:49:16
User signature succeeded.	Colleen Kelley (b) (4)	02 Apr 2021 20:59:30
Reviewed for Safety.	(b) (4), (b) (6)	02 Apr 2021 16:53:09
User entered 'No (N)'	System	02 Apr 2021 16:51:27



**US3632052**

**Folder: SAE USA-US120-2021-MRNA-1273-P301000005**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:13:35**

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 19:49:16
User signature succeeded.	Colleen Kelley (b) (4)	02 Apr 2021 20:59:30
Reviewed for Safety.	(b) (4), (b) (6)	02 Apr 2021 16:53:09
User entered 'No (N)'	System	02 Apr 2021 16:51:27

**US3632052**

**Folder: SAE USA-US120-2021-MRNA-1273-P301000005**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:13:35**

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 19:49:16
User signature succeeded.	Colleen Kelley (b) (4)	02 Apr 2021 20:59:30
Reviewed for Safety.	(b) (4), (b) (6)	02 Apr 2021 16:53:09
User entered 'No (N)'	System	02 Apr 2021 16:51:27

**US3632052**

**Folder: SAE USA-US120-2021-MRNA-1273-P301000005**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:13:35**

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 19:49:16
User signature succeeded.	Colleen Kelley (b) (4)	02 Apr 2021 20:59:30
Reviewed for Safety.	(b) (4), (b) (6)	02 Apr 2021 16:53:09
User entered 'No (N)'	System	02 Apr 2021 16:51:27

**US3632052**

**Folder: SAE USA-US120-2021-MRNA-1273-P301000005**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:13:35**

[Other medically important event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 19:49:16
User signature succeeded.	Colleen Kelley (b) (4)	02 Apr 2021 20:59:30
Reviewed for Safety.	(b) (4), (b) (6)	02 Apr 2021 16:53:09
User entered 'Yes (Y)'	System	02 Apr 2021 16:51:27

**US3632052**

**Folder: SAE USA-US120-2021-MRNA-1273-P301000005**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:13:35**

[Investigator's First Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 19:49:16
User signature succeeded.	Colleen Kelley (b) (4)	02 Apr 2021 20:59:30
Reviewed for Safety.	(b) (4), (b) (6)	02 Apr 2021 16:53:09
User entered 'Colleen'	System	02 Apr 2021 16:51:27

**US3632052**

**Folder: SAE USA-US120-2021-MRNA-1273-P301000005**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:13:35**

[Investigator's Last Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 19:49:16
User signature succeeded.	Colleen Kelley (b) (4)	02 Apr 2021 20:59:30
Reviewed for Safety.	(b) (4)	
	(b) (4), (b) (6)	02 Apr 2021 16:53:09
User entered 'Kelley'	System	02 Apr 2021 16:51:27

**US3632052**

**Folder: SAE USA-US120-2021-MRNA-1273-P301000005**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:13:35**

[Site Address: State](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 19:49:16
User signature succeeded.	Colleen Kelley (b) (4)	02 Apr 2021 20:59:30
Reviewed for Safety.	(b) (4), (b) (6)	02 Apr 2021 16:53:09
User entered 'GA'	System	02 Apr 2021 16:51:27

**US3632052**

**Folder: SAE USA-US120-2021-MRNA-1273-P301000005**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:13:35**

[Investigator Country](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 19:49:16
User signature succeeded.	Colleen Kelley (b) (4)	02 Apr 2021 20:59:30
Reviewed for Safety.	(b) (4), (b) (6)	02 Apr 2021 16:53:29
User entered 'US'	System	02 Apr 2021 16:53:25



**US3632052**

**Folder: SAE USA-US120-2021-MRNA-1273-P301000005**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:13:35**

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '2'	System	14 Apr 2021 13:17:03
User entered '1'	System	02 Apr 2021 16:53:25

**US3632052**

**Folder: SAE USA-US120-2021-MRNA-1273-P301000005**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:13:35**

[SAEID](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 19:49:16
User signature succeeded.	Colleen Kelley (b) (4)	02 Apr 2021 20:59:30
Reviewed for Safety.	(b) (4), (b) (6)	02 Apr 2021 16:53:09
User entered 'USA-US120-2021-MRNA-1273-P301000005'	System	02 Apr 2021 16:51:27

**US3632052**

**Folder: SAE USA-US120-2021-MRNA-1273-P301000005**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:13:35**

**Serious**

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 19:49:16
User signature succeeded.	Colleen Kelley (b) (4)	02 Apr 2021 20:59:30
Reviewed for Safety.	(b) (4), (b) (6)	02 Apr 2021 16:53:09
User entered 'Yes (Y)'	System	02 Apr 2021 16:51:27

**US3632052**

**Folder: SAE USA-US120-2021-MRNA-1273-P301000005**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:13:35**

[Death](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 19:49:16
User signature succeeded.	Colleen Kelley (b) (4)	02 Apr 2021 20:59:30
Reviewed for Safety.	(b) (4), (b) (6)	02 Apr 2021 16:53:09
User entered 'No (N)'	System	02 Apr 2021 16:51:27

**US3632052**

**Folder: SAE USA-US120-2021-MRNA-1273-P301000005**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:13:35**

[Life threatening](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 19:49:16
User signature succeeded.	Colleen Kelley (b) (4)	02 Apr 2021 20:59:30
Reviewed for Safety.	(b) (4), (b) (6)	02 Apr 2021 16:53:09
User entered 'No (N)'	System	02 Apr 2021 16:51:27

**US3632052**

**Folder: SAE USA-US120-2021-MRNA-1273-P301000005**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:13:35**

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 19:49:16
User signature succeeded.	Colleen Kelley (b) (4)	02 Apr 2021 20:59:30
Reviewed for Safety.	(b) (4), (b) (6)	02 Apr 2021 16:53:09
User entered 'No (N)'	System	02 Apr 2021 16:51:27

**US3632052**

**Folder: SAE USA-US120-2021-MRNA-1273-P301000005**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:13:35**

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 19:49:16
User signature succeeded.	Colleen Kelley (b) (4)	02 Apr 2021 20:59:30
Reviewed for Safety.	(b) (4), (b) (6)	02 Apr 2021 16:53:09
User entered 'No (N)'	System	02 Apr 2021 16:51:27

**US3632052**

**Folder: SAE USA-US120-2021-MRNA-1273-P301000005**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:13:35**

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 19:49:16
User signature succeeded.	Colleen Kelley (b) (4)	02 Apr 2021 20:59:30
Reviewed for Safety.	(b) (4), (b) (6)	02 Apr 2021 16:53:09
User entered 'No (N)'	System	02 Apr 2021 16:51:27



**US3632052**

**Folder: SAE USA-US120-2021-MRNA-1273-P301000005**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:13:35**

[Other medically important event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 19:49:16
User signature succeeded.	Colleen Kelley (b) (4)	02 Apr 2021 20:59:30
Reviewed for Safety.	(b) (4), (b) (6)	02 Apr 2021 16:53:09
User entered 'Yes (Y)'	System	02 Apr 2021 16:51:27

**US3632052**

**Folder: SAE USA-US120-2021-MRNA-1273-P301000005**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:13:35**

[Investigator's First Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 19:49:16
User signature succeeded.	Colleen Kelley (b) (4)	02 Apr 2021 20:59:30
Reviewed for Safety.	(b) (4), (b) (6)	02 Apr 2021 16:53:09
User entered 'Colleen'	System	02 Apr 2021 16:51:27

**US3632052**

**Folder: SAE USA-US120-2021-MRNA-1273-P301000005**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:13:35**

[Investigator's Last Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 19:49:16
User signature succeeded.	Colleen Kelley (b) (4)	02 Apr 2021 20:59:30
Reviewed for Safety.	(b) (4), (b) (6)	02 Apr 2021 16:53:09
User entered 'Kelley'	System	02 Apr 2021 16:51:27

**US3632052**

**Folder: SAE USA-US120-2021-MRNA-1273-P301000005**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:13:35**

[Site Address: State](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 19:49:16
User signature succeeded.	Colleen Kelley (b) (4)	02 Apr 2021 20:59:30
Reviewed for Safety.	(b) (4), (b) (6)	02 Apr 2021 16:53:09
User entered 'GA'	System	02 Apr 2021 16:51:27

**US3632052**

**Folder: SAE USA-US120-2021-MRNA-1273-P301000005**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:13:35**

[Investigator Country](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 19:49:16
User signature succeeded.	Colleen Kelley (b) (4)	02 Apr 2021 20:59:30
Reviewed for Safety.	(b) (4), (b) (6)	02 Apr 2021 16:53:29
User entered 'US'	System	02 Apr 2021 16:53:25

**US3632052**

**Folder: SAE USA-US120-2021-MRNA-1273-P301000005**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:13:35**

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '2'	System	14 Apr 2021 13:17:03
User entered '1'	System	02 Apr 2021 16:53:25

**US3632052**

**Folder: SAE USA-US120-2021-MRNA-1273-P301000005**

**Form: Safety Report Form (1)**

**Generated On: 10 Jun 2021 09:13:35**

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 19:49:16
User signature succeeded.	Colleen Kelley (b) (4)	02 Apr 2021 20:59:30
User entered '02/Apr/2021 12:53'	(b) (4) System	02 Apr 2021 16:53:25

US3632052

Folder: SAE USA-US120-2021-MRNA-1273-P301000005

Form: Safety Report Form (1)

Generated On: 10 Jun 2021 09:13:35

**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)	08 Apr 2021 19:49:16
User signature succeeded.	Colleen Kelley (b) (4)	02 Apr 2021 20:59:30
Reviewed for Safety.	(b) (4), (b) (6)	02 Apr 2021 16:53:29
User entered 'I'	(b) (4), (b) (6)	02 Apr 2021 16:53:25



**US3632052**

**Folder: SAE USA-US120-2021-MRNA-1273-P301000005**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:13:35**

[SAEID](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 19:49:16
User signature succeeded.	Colleen Kelley (b) (4)	02 Apr 2021 20:59:30
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	02 Apr 2021 16:53:09
User entered 'USA-US120-2021-MRNA-1273-P301000005'	System	02 Apr 2021 16:51:27

**US3632052**

**Folder: SAE USA-US120-2021-MRNA-1273-P301000005**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:13:35**

**Serious**

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 19:49:16
User signature succeeded.	Colleen Kelley (b) (4)	02 Apr 2021 20:59:30
Reviewed for Safety.	(b) (4), (b) (6)	02 Apr 2021 16:53:09
User entered 'Yes (Y)'	System	02 Apr 2021 16:51:27

**US3632052**

**Folder: SAE USA-US120-2021-MRNA-1273-P301000005**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:13:35**

[Death](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 19:49:16
User signature succeeded.	Colleen Kelley (b) (4)	02 Apr 2021 20:59:30
Reviewed for Safety.	(b) (4), (b) (6)	02 Apr 2021 16:53:09
User entered 'No (N)'	System	02 Apr 2021 16:51:27

**US3632052**

**Folder: SAE USA-US120-2021-MRNA-1273-P301000005**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:13:35**

[Life threatening](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 19:49:16
User signature succeeded.	Colleen Kelley (b) (4)	02 Apr 2021 20:59:30
Reviewed for Safety.	(b) (4), (b) (6)	02 Apr 2021 16:53:09
User entered 'No (N)'	System	02 Apr 2021 16:51:27

**US3632052**

**Folder: SAE USA-US120-2021-MRNA-1273-P301000005**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:13:35**

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 19:49:16
User signature succeeded.	Colleen Kelley (b) (4)	02 Apr 2021 20:59:30
Reviewed for Safety.	(b) (4), (b) (6)	02 Apr 2021 16:53:09
User entered 'No (N)'	System	02 Apr 2021 16:51:27

**US3632052**

**Folder: SAE USA-US120-2021-MRNA-1273-P301000005**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:13:35**

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 19:49:16
User signature succeeded.	Colleen Kelley (b) (4)	02 Apr 2021 20:59:30
Reviewed for Safety.	(b) (4), (b) (6)	02 Apr 2021 16:53:09
User entered 'No (N)'	System	02 Apr 2021 16:51:27

**US3632052**

**Folder: SAE USA-US120-2021-MRNA-1273-P301000005**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:13:35**

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 19:49:16
User signature succeeded.	Colleen Kelley (b) (4)	02 Apr 2021 20:59:30
Reviewed for Safety.	(b) (4), (b) (6)	02 Apr 2021 16:53:09
User entered 'No (N)'	System	02 Apr 2021 16:51:27

**US3632052**

**Folder: SAE USA-US120-2021-MRNA-1273-P301000005**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:13:35**

[Other medically important event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 19:49:16
User signature succeeded.	Colleen Kelley (b) (4)	02 Apr 2021 20:59:30
Reviewed for Safety.	(b) (4), (b) (6)	02 Apr 2021 16:53:09
User entered 'Yes (Y)'	System	02 Apr 2021 16:51:27



**US3632052**

**Folder: SAE USA-US120-2021-MRNA-1273-P301000005**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:13:35**

[Investigator's First Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 19:49:16
User signature succeeded.	Colleen Kelley (b) (4)	02 Apr 2021 20:59:30
Reviewed for Safety.	(b) (4), (b) (6)	02 Apr 2021 16:53:09
User entered 'Colleen'	System	02 Apr 2021 16:51:27

**US3632052**

**Folder: SAE USA-US120-2021-MRNA-1273-P301000005**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:13:35**

[Investigator's Last Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 19:49:16
User signature succeeded.	Colleen Kelley (b) (4)	02 Apr 2021 20:59:30
Reviewed for Safety.	(b) (4), (b) (6)	02 Apr 2021 16:53:09
User entered 'Kelley'	System	02 Apr 2021 16:51:27

**US3632052**

**Folder: SAE USA-US120-2021-MRNA-1273-P301000005**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:13:35**

[Site Address: State](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 19:49:16
User signature succeeded.	Colleen Kelley (b) (4)	02 Apr 2021 20:59:30
Reviewed for Safety.	(b) (4), (b) (6)	02 Apr 2021 16:53:09
User entered 'GA'	System	02 Apr 2021 16:51:27

**US3632052**

**Folder: SAE USA-US120-2021-MRNA-1273-P301000005**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:13:35**

[Investigator Country](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 19:49:16
User signature succeeded.	Colleen Kelley (b) (4)	02 Apr 2021 20:59:30
Reviewed for Safety.	(b) (4), (b) (6)	02 Apr 2021 16:53:29
User entered 'US'	System	02 Apr 2021 16:53:25

**US3632052**

**Folder: SAE USA-US120-2021-MRNA-1273-P301000005**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:13:35**

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '2'	System	14 Apr 2021 13:17:03
User entered '1'	System	02 Apr 2021 16:53:25

**US3632052**

**Folder: SAE USA-US120-2021-MRNA-1273-P301000005**

**Form: Safety Report Form (2)**

**Generated On: 10 Jun 2021 09:13:35**

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Colleen Kelley (b) (4)	22 Apr 2021 15:40:44
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Apr 2021 16:13:52
User entered '14/Apr/2021 06:17'	System	14 Apr 2021 13:17:03

US3632052

Folder: SAE USA-US120-2021-MRNA-1273-P301000005

Form: Safety Report Form (2)

Generated On: 10 Jun 2021 09:13:35

**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.	Colleen Kelley (b) (4)	22 Apr 2021 15:40:44
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	15 Apr 2021 16:13:52
User entered 'I'	(b) (4), (b) (6)	14 Apr 2021 13:17:03