

US3612005 (Prod: University of Texas- Galveston)

Generated By: KC Joubran

Generated On: 10 Jun 2021 09:15:23

All time stamps listed in this document are displayed in GMT

US3612005

Form: Participant Creation

Data signed: (b) (4) 26 Mar 2021 18:58:12

Generated On: 10 Jun 2021 09:15:23

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[Participant ID](#)

US3612005

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

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US3612005

Folder: Screening

Form: Visit Date

Data signed: (b) (4) 05 Mar 2021 19:39:44

Generated On: 10 Jun 2021 09:15:23

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	01 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

US3612005

Folder: Screening

Form: Demographics

Data signed: (b) (4) 05 Mar 2021 19:39:44

Generated On: 10 Jun 2021 09:15:23

Date of Birth (MMM yyyy)	(b) (6) 1945
Age	75
Age Units	YEARS
Age (Derived)	75
Sex	Female <input type="radio"/> Male <input checked="" type="radio"/>
Ethnicity	Hispanic or Latino <input type="radio"/> Not Hispanic or Latino <input checked="" type="radio"/> Not Reported <input type="radio"/> Unknown <input type="radio"/>
Race (Check All That Apply)	
White	True
Black	False
Asian	False
American Indian or Alaska Native	False
Native Hawaiian or other Pacific Islander	False
Other	False
If race is Other, specify _____	
Unknown	False
Not reported	False

US3612005

Folder: Screening

Form: Enrollment

Data signed: (b) (4) 05 Mar 2021 19:39:44

Generated On: 10 Jun 2021 09:15:23

Date of Informed Consent ( <i>dd MMM yyyy</i> )	01 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 checked="" type="radio"/>
	Amendment 3 <input type="radio"/>
	Amendment 4 <input type="radio"/>
	Amendment 5 <input type="radio"/>
Was participant enrolled in the study?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
If No, indicate reason for screen fail	Withdrew Consent <input type="radio"/>
	Inclusion/Exclusion <input type="radio"/>
	Cohort Full <input type="radio"/>
	Other <input type="radio"/>
If reason for screen fail is Other, specify	
Was this participant screened previously?	Yes <input type="radio"/>
	No <input checked="" type="radio"/>
If Yes, previous participant number	
Enrollment Trigger	1

US3612005

Folder: Screening

Form: Inclusion/Exclusion Criteria Summary

Data signed: (b) (4) 05 Mar 2021 19:39:44

Generated On: 10 Jun 2021 09:15:23

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Did the participant meet all eligibility criteria?

Yes ☒

No ☐

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US3612005

Folder: Screening

Form: Medical History Summary

Data signed: (b) (4) 05 Mar 2021 19:39:44

Generated On: 10 Jun 2021 09:15:23

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Were any significant conditions reported?

Yes ☒  
No ☐

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US3612005

Folder: Screening

Form: Medical History (1)

Data signed: (b) (4) 05 Mar 2021 19:39:44

Generated On: 10 Jun 2021 09:15:23

Condition	KIDNEY STONES
Start date (dd MMM yyyy)	15 JUL 1981
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)	JUL 1981
Start Year (derived)	1981
Stop Month and Year (derived)	_____
Stop Year (derived)	_____

US3612005

Folder: Screening

Form: Medical History (2)

Data signed: (b) (4) 05 Mar 2021 19:39:44

Generated On: 10 Jun 2021 09:15:23

Condition	BLOOD CLOTS
Start date (dd MMM yyyy)	15 JUL 2005
Start date completely unknown	False
Condition ongoing at study entry	Yes <input type="radio"/> No <input checked="" type="radio"/>
If No, please specify the stop date (dd MMM yyyy) _____	
Stop date completely unknown	True
Start Month and Year (derived)	JUL 2005
Start Year (derived)	2005
Stop Month and Year (derived)	_____
Stop Year (derived)	_____

US3612005

Folder: Screening

Form: Medical History (3)

Data signed: (b) (4) 05 Mar 2021 19:39:44

Generated On: 10 Jun 2021 09:15:23

Condition	HIGH CHOLESTEROL
Start date (dd MMM yyyy)	15 FEB 2019
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)	FEB 2019
Start Year (derived)	2019
Stop Month and Year (derived)	_____
Stop Year (derived)	_____

US3612005

Folder: Screening

Form: Medical History (4)

Data signed: (b) (4) 05 Mar 2021 19:39:44

Generated On: 10 Jun 2021 09:15:23

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

US3612005

Folder: Screening

Form: Medical History (5)

Data signed: (b) (4) 05 Mar 2021 19:39:44

Generated On: 10 Jun 2021 09:15:23

Condition	CARDIAC ARREST
Start date (dd MMM yyyy)	28 DEC 2007
Start date completely unknown	False
Condition ongoing at study entry	Yes <input type="radio"/> No <input checked="" type="radio"/>
If No, please specify the stop date (dd MMM yyyy)	28 DEC 2007
Stop date completely unknown	False
Start Month and Year (derived)	DEC 2007
Start Year (derived)	2007
Stop Month and Year (derived)	DEC 2007
Stop Year (derived)	2007

US3612005

Folder: Screening

Form: Medical History (6)

Data signed: (b) (4) 05 Mar 2021 19:39:44

Generated On: 10 Jun 2021 09:15:23

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

US3612005

Folder: Screening

Form: Medical History (7)

Data signed: (b) (4) 05 Mar 2021 19:39:44

Generated On: 10 Jun 2021 09:15:23

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

US3612005

Folder: Screening

Form: Medical History (8)

Data signed: (b) (4) 05 Mar 2021 19:39:44

Generated On: 10 Jun 2021 09:15:23

Condition	LEFT KNEE ARTHROSCOPY
Start date (dd MMM yyyy)	04 AUG 2010
Start date completely unknown	False
Condition ongoing at study entry	Yes <input type="radio"/> No <input checked="" type="radio"/>
If No, please specify the stop date (dd MMM yyyy)	04 AUG 2010
Stop date completely unknown	False
Start Month and Year (derived)	AUG 2010
Start Year (derived)	2010
Stop Month and Year (derived)	AUG 2010
Stop Year (derived)	2010

US3612005

Folder: Screening

Form: Medical History (9)

Data signed: (b) (4) 05 Mar 2021 19:39:44

Generated On: 10 Jun 2021 09:15:23

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

US3612005

Folder: Screening

Form: Medical History (10)

Data signed: (b) (4) 05 Mar 2021 19:39:44

Generated On: 10 Jun 2021 09:15:23

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

US3612005

Folder: Screening

Form: Vital Signs

Data signed: (b) (4) 05 Mar 2021 19:39:44

Generated On: 10 Jun 2021 09:15:23

Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment ( <i>dd MMM yyyy</i> )	01 SEP 2020
Time of assessment ( <i>00:00-23:59</i> )	09:25 (24 HR)
Vital Signs Date and Time (derived)	01 SEP 2020 09:25
Height ( <i>xxx.x</i> )	71 in
Weight ( <i>xxx.x</i> )	184.8 lb
BMI ( <i>xxx.x</i> )	25.82826 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)	

US3612005

Folder: Screening

Form: Physical Examination

Data signed: (b) (4) 05 Mar 2021 19:39:44

Generated On: 10 Jun 2021 09:15:23

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

01 SEP 2020

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

US3612005

Folder: Screening

Form: Risk of Exposure

Data signed: (b) (4) 05 Mar 2021 19:39:44

Generated On: 10 Jun 2021 09:15:23

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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** OVER 65

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

**No Risk Identified** True

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

US3612005

Folder: Screening

Form: Risk of Exposure

Data signed: (b) (4) 05 Mar 2021 19:39:44

Generated On: 10 Jun 2021 09:15:23

<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)	False
<b>Other</b>	False
<b>Specify</b>	

US3612005

Folder: Visit 1 Day 1

Form: Visit Date

Data signed: (b) (4) 05 Mar 2021 19:39:44

Generated On: 10 Jun 2021 09:15:23

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	1 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

US3612005

Folder: Visit 1 Day 1

Form: Randomization

Data signed: (b) (4) 05 Mar 2021 19:39:44

Generated On: 10 Jun 2021 09:15:23

What was the date of randomization? (dd MMM yyyy) 01 SEP 2020

What was the participant's randomization number? 189150

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 ☐

US3612005

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Data signed: (b) (4) 05 Mar 2021 19:39:44

Generated On: 10 Jun 2021 09:15:23

Height	ND - Not Done
Weight	ND - Not Done

US3612005

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Data signed: (b) (4) 05 Mar 2021 19:39:44

Generated On: 10 Jun 2021 09:15:23

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)	01 SEP 2020
Time of assessment (00:00-23:59)	09:25 (24 HR)
Vital Signs Date and Time (derived)	01 SEP 2020 09:25
Temperature (xxx.x)	97.9 F
Route of measurement	Oral <input checked="" type="radio"/> Axillary <input type="radio"/> Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	67 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	129 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	65 mmHg
Diastolic Blood Pressure units	MMHG

US3612005

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Data signed: (b) (4) 05 Mar 2021 19:39:44

Generated On: 10 Jun 2021 09:15:23

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)	1 SEP 2020
Time of assessment (00:00-23:59)	11:31 (24 HR)
Vital Signs Date and Time (derived)	1 SEP 2020 11:31
Temperature (xxx.x)	97.8 F
Route of measurement	Oral <input checked="" type="radio"/> Axillary <input type="radio"/> Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	54 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	133 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	75 mmHg
Diastolic Blood Pressure units	MMHG

US3612005

Folder: Visit 1 Day 1

Form: Physical Examination

Data signed: (b) (4) 05 Mar 2021 19:39:44

Generated On: 10 Jun 2021 09:15:23

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

01 SEP 2020

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

US3612005

Folder: Visit 1 Day 1

Form: Exposure

Data signed: (b) (4) 05 Mar 2021 19:39:44

Generated On: 10 Jun 2021 09:15:23

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) 1 SEP 2020

What was the treatment time? (00:00-23:59) 10:58 (24 HR)

Treatment Date and Time (derived) 1 SEP 2020 10:58

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

US3612005

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Data signed: (b) (4) 05 Mar 2021 19:39:44

Generated On: 10 Jun 2021 09:15:23

Was the sample collected?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Collection date (dd MMM yyyy)	1 SEP 2020
Collection time (00:00-23:59)	10:07 (24 HR)
Collection date and time (derived)	1 SEP 2020 10:07

US3612005

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab

Data signed: (b) (4) 05 Mar 2021 19:39:44

Generated On: 10 Jun 2021 09:15:23

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

US3612005

Folder: Visit 1 Day 1

Form: Continuing

Data signed: (b) (4) 05 Mar 2021 19:39:44

Generated On: 10 Jun 2021 09:15:23

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3612005

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/1)

Generated On: 10 Jun 2021 09:15:23

**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

97.8 °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

01 SEP 2020 11:34

PC Open Date & Time

01 SEP 2020 11:18

PC Close Date & Time

01 SEP 2020 13:48

US3612005

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/2)

Generated On: 10 Jun 2021 09:15:23

**TIMEPOINT**

DAY 1, AFTER VACCINATION  
(AT HOME)

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

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

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

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

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

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

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

Was **TEMPERATURE** taken? Yes ☒ No ☐

Please record your **TEMPERATURE** in °F 97.3 °F

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

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

PC Time Stamp	02 SEP 2020 00:03
PC Open Date & Time	01 SEP 2020 14:43
PC Close Date & Time	02 SEP 2020 11:59

US3612005

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(2)

Generated On: 10 Jun 2021 09:15:23

**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

02 SEP 2020 21:40

PC Open Date & Time

02 SEP 2020 12:00

PC Close Date & Time

03 SEP 2020 11:59

US3612005

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(3)

Generated On: 10 Jun 2021 09:15:23

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**TIMEPOINT**

DAY 3

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.3 °F

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

Yes ☐

No ☒

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

PC Time Stamp

03 SEP 2020 12:42

PC Open Date & Time

03 SEP 2020 12:00

PC Close Date & Time

04 SEP 2020 11:59

US3612005

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(4)

Generated On: 10 Jun 2021 09:15:23

**TIMEPOINT**

DAY 4

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

98.1 °F

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

Yes ☐

No ☒

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

PC Time Stamp

04 SEP 2020 17:03

PC Open Date & Time

04 SEP 2020 12:00

PC Close Date & Time

05 SEP 2020 11:59

US3612005

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(5)

Generated On: 10 Jun 2021 09:15:23

**TIMEPOINT**

DAY 5

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

98.0 °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

05 SEP 2020 20:54

PC Open Date & Time

05 SEP 2020 12:00

PC Close Date & Time

06 SEP 2020 11:59

US3612005

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(6)

Generated On: 10 Jun 2021 09:15:23

**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

96.0 °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

06 SEP 2020 22:51

PC Open Date & Time

06 SEP 2020 12:00

PC Close Date & Time

07 SEP 2020 11:59

US3612005

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(7)

Generated On: 10 Jun 2021 09:15:23

**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

97.0 °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

07 SEP 2020 17:05

PC Open Date & Time

07 SEP 2020 12:00

PC Close Date & Time

08 SEP 2020 11:59

US3612005

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/1)

Generated On: 10 Jun 2021 09:15:23

**TIMEPOINT**

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

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

Please select one response below

None ☒

Does not interfere with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

Please select one response below

None ☒

Does not interfere with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

PC Time Stamp

01 SEP 2020 11:34

PC Open Date & Time

01 SEP 2020 11:18

PC Close Date & Time

01 SEP 2020 13:48

US3612005

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/2)

Generated On: 10 Jun 2021 09:15:23

**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

02 SEP 2020 00:05

PC Open Date & Time

01 SEP 2020 14:43

PC Close Date & Time

02 SEP 2020 11:59

US3612005

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(2)

Generated On: 10 Jun 2021 09:15:23

**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

02 SEP 2020 12:01

PC Open Date & Time

02 SEP 2020 12:00

PC Close Date & Time

03 SEP 2020 11:59

US3612005

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(3)

Generated On: 10 Jun 2021 09:15:23

**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

03 SEP 2020 12:33

PC Open Date & Time

03 SEP 2020 12:00

PC Close Date & Time

04 SEP 2020 11:59

US3612005

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(4)

Generated On: 10 Jun 2021 09:15:23

**TIMEPOINT**

DAY 4

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

PC Time Stamp

04 SEP 2020 17:04

PC Open Date & Time

04 SEP 2020 12:00

PC Close Date & Time

05 SEP 2020 11:59

US3612005

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(5)

Generated On: 10 Jun 2021 09:15:23

**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

05 SEP 2020 20:54

PC Open Date & Time

05 SEP 2020 12:00

PC Close Date & Time

06 SEP 2020 11:59

US3612005

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(6)

Generated On: 10 Jun 2021 09:15:23

**TIMEPOINT**

DAY 6

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

PC Time Stamp

06 SEP 2020 22:52

PC Open Date & Time

06 SEP 2020 12:00

PC Close Date & Time

07 SEP 2020 11:59

US3612005

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(7)

Generated On: 10 Jun 2021 09:15:23

**TIMEPOINT**

DAY 7

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

PC Time Stamp

07 SEP 2020 17:05

PC Open Date & Time

07 SEP 2020 12:00

PC Close Date & Time

08 SEP 2020 11:59

US3612005

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 10 Jun 2021 09:15:23

**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 ☐

US3612005

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 10 Jun 2021 09:15:23

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

No ☒

Yes ☐

PC Time stamp	01 SEP 2020 11:35
PC Open Date & Time	01 SEP 2020 11:18
PC Close Date & Time	01 SEP 2020 13:48

US3612005

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 10 Jun 2021 09:15:23

**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 ☐

US3612005

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 10 Jun 2021 09:15:23

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

No ☒

Yes ☐

PC Time stamp	02 SEP 2020 00:05
PC Open Date & Time	01 SEP 2020 14:43
PC Close Date & Time	02 SEP 2020 11:59

US3612005

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 10 Jun 2021 09:15:23

**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

51 of 2285

EAB) (1725)

US3612005

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 10 Jun 2021 09:15:23

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

US3612005

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 10 Jun 2021 09:15:23

TIMEPOINT

DAY 3

HEADACHE

None ☒

No interference with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

FATIGUE

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

NAUSEA/VOMITING

None ☒

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

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

Prevents daily activity, requires  
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity  
not requiring medical attention ☐

Prevents daily activity and  
requires medical attention ☐

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

No ☒

PRODUCTION RELEASE (v12.003  
EAB) (1725)

53 of 2285

US3612005

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 10 Jun 2021 09:15:23

Yes <input type="checkbox"/>	
PC Time stamp	03 SEP 2020 12:34
PC Open Date & Time	03 SEP 2020 12:00
PC Close Date & Time	04 SEP 2020 11:59

US3612005

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 10 Jun 2021 09:15:23

**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

55 of 2285

EAB) (1725)

US3612005

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 10 Jun 2021 09:15:23

Yes <input type="checkbox"/>	
PC Time stamp	04 SEP 2020 17:03
PC Open Date & Time	04 SEP 2020 12:00
PC Close Date & Time	05 SEP 2020 11:59

US3612005

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 10 Jun 2021 09:15:23

TIMEPOINT

DAY 5

HEADACHE

None ☒

No interference with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

FATIGUE

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

NAUSEA/VOMITING

None ☒

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

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

Prevents daily activity, requires  
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity  
not requiring medical attention ☐

Prevents daily activity and  
requires medical attention ☐

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

No ☒

PRODUCTION RELEASE (v12.003  
EAB) (1725)

57 of 2285

US3612005

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 10 Jun 2021 09:15:23

Yes <input type="checkbox"/>	
PC Time stamp	05 SEP 2020 20:54
PC Open Date & Time	05 SEP 2020 12:00
PC Close Date & Time	06 SEP 2020 11:59

US3612005

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 10 Jun 2021 09:15:23

TIMEPOINT

DAY 6

HEADACHE

None ☒

No interference with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

FATIGUE

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

NAUSEA/VOMITING

None ☒

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

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

Prevents daily activity, requires  
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity  
not requiring medical attention ☐

Prevents daily activity and  
requires medical attention ☐

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

No ☒

PRODUCTION RELEASE (v12.003

59 of 2285

EAB) (1725)

US3612005

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 10 Jun 2021 09:15:23

Yes <input type="checkbox"/>	
PC Time stamp	06 SEP 2020 22:52
PC Open Date & Time	06 SEP 2020 12:00
PC Close Date & Time	07 SEP 2020 11:59

US3612005

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 10 Jun 2021 09:15:23

TIMEPOINT

DAY 7

HEADACHE

None ☒

No interference with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

FATIGUE

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

NAUSEA/VOMITING

None ☒

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

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

Prevents daily activity, requires  
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity  
not requiring medical attention ☐

Prevents daily activity and  
requires medical attention ☐

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

No ☒

PRODUCTION RELEASE (v12.003

61 of 2285

EAB) (1725)

US3612005

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 10 Jun 2021 09:15:23

Yes <input type="checkbox"/>	
PC Time stamp	07 SEP 2020 17:05
PC Open Date & Time	07 SEP 2020 12:00
PC Close Date & Time	08 SEP 2020 11:59

US3612005

Folder: Safety Call Day 8 (1)

Form: Safety Call

Data signed: (b) (4) 05 Mar 2021 19:39:44

Generated On: 10 Jun 2021 09:15:23

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

9 SEP 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

*If Contact Not Made, please provide Comments*

US3612005

Folder: Safety Call Day 8 (1)

Form: Continuing

Data signed: (b) (4) 05 Mar 2021 19:39:44

Generated On: 10 Jun 2021 09:15:23

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3612005

Folder: Safety Call Day 15 (1)

Form: Safety Call

Data signed: (b) (4) 05 Mar 2021 19:39:44

Generated On: 10 Jun 2021 09:15:23

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

16 SEP 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

*If Contact Not Made, please provide Comments*

US3612005

Folder: Safety Call Day 15 (1)

Form: Continuing

Data signed: (b) (4) 05 Mar 2021 19:39:44

Generated On: 10 Jun 2021 09:15:23

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3612005

Folder: Safety Call Day 22 (1)

Form: Safety Call

Data signed: (b) (4) 05 Mar 2021 19:39:44

Generated On: 10 Jun 2021 09:15:23

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*

US3612005

Folder: Safety Call Day 22 (1)

Form: Continuing

Data signed: (b) (4) 05 Mar 2021 19:39:44

Generated On: 10 Jun 2021 09:15:23

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3612005

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Data signed: (b) (4) 05 Mar 2021 19:39:45

Generated On: 10 Jun 2021 09:15:23

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	29 SEP 2020
Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>
Folder OID	VISIT2

US3612005

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Data signed: (b) (4) 05 Mar 2021 19:39:45

Generated On: 10 Jun 2021 09:15:23

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)	29 SEP 2020
Time of assessment (00:00-23:59)	09:17 (24 HR)
Vital Signs Date and Time (derived)	29 SEP 2020 09:17
Temperature (xxx.x)	98.1 F
Route of measurement	Oral <input checked="" type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	69 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	135 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	63 mmHg
Diastolic Blood Pressure units	MMHG

US3612005

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Data signed: (b) (4) 05 Mar 2021 19:39:45

Generated On: 10 Jun 2021 09:15:23

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)	29 SEP 2020
Time of assessment (00:00-23:59)	10:53 (24 HR)
Vital Signs Date and Time (derived)	29 SEP 2020 10:53
Temperature (xxx.x)	97.9 F
Route of measurement	Oral <input checked="" type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	51 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	137 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	65 mmHg
Diastolic Blood Pressure units	MMHG

US3612005

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Data signed: (b) (4) 05 Mar 2021 19:39:45

Generated On: 10 Jun 2021 09:15:23

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

29 SEP 2020

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

US3612005

Folder: Visit 2 Day 29 (1)

Form: Exposure

Data signed: (b) (4) 05 Mar 2021 19:39:45

Generated On: 10 Jun 2021 09:15:23

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) 29 SEP 2020

What was the treatment time? (00:00-23:59) 10:21 (24 HR)

Treatment Date and Time (derived) 29 SEP 2020 10:21

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

US3612005

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 05 Mar 2021 19:39:45

Generated On: 10 Jun 2021 09:15:23

Was the sample collected?

Yes ☒

No ☐

Collection date (dd MMM yyyy)

29 SEP 2020

Collection time (00:00-23:59)

09:30 (24 HR)

Collection date and time (derived)

29 SEP 2020 09:30

US3612005

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab

Data signed: (b) (4) 05 Mar 2021 19:39:45

Generated On: 10 Jun 2021 09:15:23

Collection date (dd MMM yyyy)			29 SEP 2020
Lab Test	Was the sample collected?	Collection time (00:00 - 23:59)	Collection date and time (derived)
Nasopharyngeal Swab 1	Yes	09:34	29 SEP 2020 09:34
Nasopharyngeal Swab 2	No		

US3612005

Folder: Visit 2 Day 29 (1)

Form: Continuing

Data signed: (b) (4) 05 Mar 2021 19:39:45

Generated On: 10 Jun 2021 09:15:23

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3612005

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/1)

Generated On: 10 Jun 2021 09:15:23

**TIMEPOINT**

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

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.9 °F

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

Yes ☐

No ☒

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

PC Time Stamp

29 SEP 2020 10:58

PC Open Date & Time

29 SEP 2020 10:41

PC Close Date & Time

29 SEP 2020 13:11

US3612005

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/2)

Generated On: 10 Jun 2021 09:15:23

**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

96.5 °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	29 SEP 2020 20:40
PC Open Date & Time	29 SEP 2020 14:06
PC Close Date & Time	30 SEP 2020 11:59

US3612005

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(2)

Generated On: 10 Jun 2021 09:15:23

**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

97.2 °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

30 SEP 2020 14:13

PC Open Date & Time

30 SEP 2020 12:00

PC Close Date & Time

01 OCT 2020 11:59

US3612005

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(3)

Generated On: 10 Jun 2021 09:15:23

**TIMEPOINT**

DAY 3

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.1 °F

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

Yes ☐

No ☒

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

PC Time Stamp

01 OCT 2020 17:51

PC Open Date & Time

01 OCT 2020 12:00

PC Close Date & Time

02 OCT 2020 11:59

US3612005

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(4)

Generated On: 10 Jun 2021 09:15:23

**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

96.7 °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

02 OCT 2020 14:44

PC Open Date & Time

02 OCT 2020 12:00

PC Close Date & Time

03 OCT 2020 11:59

US3612005

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(5)

Generated On: 10 Jun 2021 09:15:23

**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

97.3 °F

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

Yes ☐

No ☒

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

PC Time Stamp

03 OCT 2020 14:48

PC Open Date & Time

03 OCT 2020 12:00

PC Close Date & Time

04 OCT 2020 11:59

US3612005

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(6)

Generated On: 10 Jun 2021 09:15:23

**TIMEPOINT**

DAY 6

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

98.3 °F

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

Yes ☐

No ☒

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

PC Time Stamp

04 OCT 2020 21:01

PC Open Date & Time

04 OCT 2020 12:00

PC Close Date & Time

05 OCT 2020 11:59

US3612005

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(7)

Generated On: 10 Jun 2021 09:15:23

**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

97.4 °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

05 OCT 2020 14:33

PC Open Date & Time

05 OCT 2020 12:00

PC Close Date & Time

06 OCT 2020 11:59

US3612005

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/1)

Generated On: 10 Jun 2021 09:15:23

**TIMEPOINT**

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

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

Please select one response below

None ☒

Does not interfere with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

Please select one response below

None ☒

Does not interfere with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

PC Time Stamp

29 SEP 2020 10:59

PC Open Date & Time

29 SEP 2020 10:41

PC Close Date & Time

29 SEP 2020 13:11

US3612005

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/2)

Generated On: 10 Jun 2021 09:15:23

**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

29 SEP 2020 20:42

PC Open Date & Time

29 SEP 2020 14:06

PC Close Date & Time

30 SEP 2020 11:59

US3612005

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(2)

Generated On: 10 Jun 2021 09:15:23

**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

30 SEP 2020 14:13

PC Open Date & Time

30 SEP 2020 12:00

PC Close Date & Time

01 OCT 2020 11:59

US3612005

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(3)

Generated On: 10 Jun 2021 09:15:23

**TIMEPOINT**

DAY 3

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

PC Time Stamp

01 OCT 2020 17:51

PC Open Date & Time

01 OCT 2020 12:00

PC Close Date & Time

02 OCT 2020 11:59

US3612005

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(4)

Generated On: 10 Jun 2021 09:15:23

**TIMEPOINT**

DAY 4

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

PC Time Stamp

02 OCT 2020 14:51

PC Open Date & Time

02 OCT 2020 12:00

PC Close Date & Time

03 OCT 2020 11:59

US3612005

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(5)

Generated On: 10 Jun 2021 09:15:23

**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

03 OCT 2020 14:49

PC Open Date & Time

03 OCT 2020 12:00

PC Close Date & Time

04 OCT 2020 11:59

US3612005

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(6)

Generated On: 10 Jun 2021 09:15:23

**TIMEPOINT**

DAY 6

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

PC Time Stamp

04 OCT 2020 21:01

PC Open Date & Time

04 OCT 2020 12:00

PC Close Date & Time

05 OCT 2020 11:59

US3612005

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(7)

Generated On: 10 Jun 2021 09:15:23

**TIMEPOINT**

DAY 7

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

PC Time Stamp

05 OCT 2020 14:34

PC Open Date & Time

05 OCT 2020 12:00

PC Close Date & Time

06 OCT 2020 11:59

US3612005

Folder: Diary Dose 2 (1)

Form: General\_Day(1/1)

Generated On: 10 Jun 2021 09:15:23

**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 ☐

US3612005

Folder: Diary Dose 2 (1)

Form: General\_Day(1/1)

Generated On: 10 Jun 2021 09:15:23

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

No ☒

Yes ☐

PC Time stamp	29 SEP 2020 10:59
PC Open Date & Time	29 SEP 2020 10:41
PC Close Date & Time	29 SEP 2020 13:11

US3612005

Folder: Diary Dose 2 (1)

Form: General\_Day(1/2)

Generated On: 10 Jun 2021 09:15:23

**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 ☐

US3612005

Folder: Diary Dose 2 (1)

Form: General\_Day(1/2)

Generated On: 10 Jun 2021 09:15:23

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

No ☒

Yes ☐

PC Time stamp	29 SEP 2020 20:43
PC Open Date & Time	29 SEP 2020 14:06
PC Close Date & Time	30 SEP 2020 11:59

US3612005

Folder: Diary Dose 2 (1)

Form: General\_Day(2)

Generated On: 10 Jun 2021 09:15:23

**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

97 of 2285

EAB) (1725)

US3612005

Folder: Diary Dose 2 (1)

Form: General\_Day(2)

Generated On: 10 Jun 2021 09:15:23

Yes <input type="checkbox"/>	
PC Time stamp	30 SEP 2020 14:13
PC Open Date & Time	30 SEP 2020 12:00
PC Close Date & Time	01 OCT 2020 11:59

US3612005

Folder: Diary Dose 2 (1)

Form: General\_Day(3)

Generated On: 10 Jun 2021 09:15:23

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

99 of 2285

EAB) (1725)

US3612005

Folder: Diary Dose 2 (1)

Form: General\_Day(3)

Generated On: 10 Jun 2021 09:15:23

Yes <input type="checkbox"/>	
PC Time stamp	01 OCT 2020 17:52
PC Open Date & Time	01 OCT 2020 12:00
PC Close Date & Time	02 OCT 2020 11:59

US3612005

Folder: Diary Dose 2 (1)

Form: General\_Day(4)

Generated On: 10 Jun 2021 09:15:23

**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 ☒

US3612005

Folder: Diary Dose 2 (1)

Form: General\_Day(4)

Generated On: 10 Jun 2021 09:15:23

Yes <input type="checkbox"/>	
PC Time stamp	02 OCT 2020 14:51
PC Open Date & Time	02 OCT 2020 12:00
PC Close Date & Time	03 OCT 2020 11:59

US3612005

Folder: Diary Dose 2 (1)

Form: General\_Day(5)

Generated On: 10 Jun 2021 09:15:23

TIMEPOINT

DAY 5

HEADACHE

None ☒

No interference with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

FATIGUE

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

NAUSEA/VOMITING

None ☒

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

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

Prevents daily activity, requires  
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity  
not requiring medical attention ☐

Prevents daily activity and  
requires medical attention ☐

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

No ☒

PRODUCTION RELEASE (v12.003

103 of 2285

EAB) (1725)

US3612005

Folder: Diary Dose 2 (1)

Form: General\_Day(5)

Generated On: 10 Jun 2021 09:15:23

Yes <input type="checkbox"/>	
PC Time stamp	03 OCT 2020 14:49
PC Open Date & Time	03 OCT 2020 12:00
PC Close Date & Time	04 OCT 2020 11:59

US3612005

Folder: Diary Dose 2 (1)

Form: General\_Day(6)

Generated On: 10 Jun 2021 09:15:23

TIMEPOINT

DAY 6

HEADACHE

None ☒

No interference with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

FATIGUE

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

NAUSEA/VOMITING

None ☒

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

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

Prevents daily activity, requires  
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity  
not requiring medical attention ☐

Prevents daily activity and  
requires medical attention ☐

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

No ☒

PRODUCTION RELEASE (v12.003

105 of 2285

EAB) (1725)

US3612005

Folder: Diary Dose 2 (1)

Form: General\_Day(6)

Generated On: 10 Jun 2021 09:15:23

Yes <input type="checkbox"/>	
PC Time stamp	04 OCT 2020 21:02
PC Open Date & Time	04 OCT 2020 12:00
PC Close Date & Time	05 OCT 2020 11:59

US3612005

Folder: Diary Dose 2 (1)

Form: General\_Day(7)

Generated On: 10 Jun 2021 09:15:23

**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 ☒

US3612005

Folder: Diary Dose 2 (1)

Form: General\_Day(7)

Generated On: 10 Jun 2021 09:15:23

Yes <input type="checkbox"/>	
PC Time stamp	05 OCT 2020 14:34
PC Open Date & Time	05 OCT 2020 12:00
PC Close Date & Time	06 OCT 2020 11:59

US3612005

Folder: Safety Call Day 36 (1)

Form: Safety Call

Data signed: (b) (4) 05 Mar 2021 19:39:44

Generated On: 10 Jun 2021 09:15:23

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

07 OCT 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

*If Contact Not Made, please provide Comments*

US3612005

Folder: Safety Call Day 36 (1)

Form: Continuing

Data signed: (b) (4) 05 Mar 2021 19:39:44

Generated On: 10 Jun 2021 09:15:23

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3612005

Folder: Safety Call Day 43 (1)

Form: Safety Call

Data signed: (b) (4) 05 Mar 2021 19:39:44

Generated On: 10 Jun 2021 09:15:23

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*

US3612005

Folder: Safety Call Day 43 (1)

Form: Continuing

Data signed: (b) (4) 05 Mar 2021 19:39:44

Generated On: 10 Jun 2021 09:15:23

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3612005

Folder: Safety Call Day 50 (1)

Form: Safety Call

Data signed: (b) (4) 05 Mar 2021 19:39:44

Generated On: 10 Jun 2021 09:15:23

Was Contact Attempted? Yes ☒  
No ☐

Date of Contact or Contact Attempt (dd MMM yyyy) 22 OCT 2020

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

Comments

*If Contact Not Made, please provide Comments*

US3612005

Folder: Safety Call Day 50 (1)

Form: Continuing

Data signed: (b) (4) 05 Mar 2021 19:39:44

Generated On: 10 Jun 2021 09:15:23

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3612005

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Data signed: (b) (4) 05 Mar 2021 19:39:45

Generated On: 10 Jun 2021 09:15:23

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

Visit date (dd MMM yyyy)	27 OCT 2020
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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	VISIT3
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US3612005

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Data signed: (b) (4) 05 Mar 2021 19:39:45

Generated On: 10 Jun 2021 09:15:23

Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (dd MMM yyyy)	27 OCT 2020
Time of assessment (00:00-23:59)	11:33 (24 HR)
Vital Signs Date and Time (derived)	27 OCT 2020 11:33
Temperature (xxx.x)	97.7 F
Route of measurement	Oral <input checked="" type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	52 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	145 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	64 mmHg
Diastolic Blood Pressure units	MMHG
Height (derived)	
Weight (derived)	

US3612005

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Data signed: (b) (4) 05 Mar 2021 19:39:45

Generated On: 10 Jun 2021 09:15:23

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

27 OCT 2020

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

US3612005

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 05 Mar 2021 19:39:45

Generated On: 10 Jun 2021 09:15:23

Was the sample collected?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Collection date (dd MMM yyyy)	27 OCT 2020
Collection time (00:00-23:59)	11:42 (24 HR)
Collection date and time (derived)	27 OCT 2020 11:42

US3612005

Folder: Visit 3 Day 57 (1)

Form: Continuing

Data signed: (b) (4) 05 Mar 2021 19:39:45

Generated On: 10 Jun 2021 09:15:23

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3612005

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:15:23

TIMEPOINT	DAY 64
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <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"/>

**US3612005**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:15:23**

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

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

Date and time of submission

Patient Cloud Open Date & Time

01 NOV 2020 00:01

Patient Cloud Close Date & Time

05 NOV 2020 23:59

US3612005

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:15:23

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 <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"/>

**US3612005**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:15:23**

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

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

Date and time of submission

Patient Cloud Open Date & Time

08 NOV 2020 00:01

Patient Cloud Close Date & Time

12 NOV 2020 23:59

US3612005

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:15:23

TIMEPOINT	DAY 78
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input 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"/>

**US3612005**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:15:23**

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

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

Date and time of submission

Patient Cloud Open Date & Time

15 NOV 2020 00:01

Patient Cloud Close Date & Time

19 NOV 2020 23:59

US3612005

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:15:23

TIMEPOINT	DAY 82
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input 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"/>

**US3612005**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:15:23**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood 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 NOV 2020 00:01

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[Patient Cloud Close Date & Time](#)

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23 NOV 2020 23:59

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US3612005

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:15:23

**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 ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

26 NOV 2020 00:50:29

Patient Cloud Open Date & Time

26 NOV 2020 00:01

Patient Cloud Close Date & Time

30 NOV 2020 23:59

US3612005

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:15:23

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	03 DEC 2020 07:28:25
Patient Cloud Open Date & Time	03 DEC 2020 00:01
Patient Cloud Close Date & Time	07 DEC 2020 23:59

US3612005

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:15:23

**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

10 DEC 2020 11:28:14

Patient Cloud Open Date & Time

10 DEC 2020 00:01

Patient Cloud Close Date & Time

14 DEC 2020 23:59

US3612005

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:15:23

**TIMEPOINT**

DAY 110

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

17 DEC 2020 12:12:43

Patient Cloud Open Date & Time

17 DEC 2020 00:01

Patient Cloud Close Date & Time

21 DEC 2020 23:59

US3612005

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:15:23

**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

24 DEC 2020 09:41:53

Patient Cloud Open Date & Time

24 DEC 2020 00:01

Patient Cloud Close Date & Time

28 DEC 2020 23:59

US3612005

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:15:23

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 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"/>

**US3612005**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:15:23**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood 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](#)

31 DEC 2020 00:01

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[Patient Cloud Close Date & Time](#)

04 JAN 2021 23:59

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US3612005

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:15:23

TIMEPOINT	DAY 131
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	10 JAN 2021 18:22:44
Patient Cloud Open Date & Time	07 JAN 2021 00:01
Patient Cloud Close Date & Time	11 JAN 2021 23:59

US3612005

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:15:23

**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

14 JAN 2021 00:20:26

Patient Cloud Open Date & Time

14 JAN 2021 00:01

Patient Cloud Close Date & Time

18 JAN 2021 23:59

US3612005

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:15:23

**TIMEPOINT**

DAY 145

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

21 JAN 2021 07:37:33

Patient Cloud Open Date & Time

21 JAN 2021 00:01

Patient Cloud Close Date & Time

25 JAN 2021 23:59

US3612005

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:15:23

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

**US3612005**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:15:23**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood 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](#)

28 JAN 2021 00:01

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[Patient Cloud Close Date & Time](#)

01 FEB 2021 23:59

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US3612005

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:15:23

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	04 FEB 2021 07:20:55
Patient Cloud Open Date & Time	04 FEB 2021 00:01
Patient Cloud Close Date & Time	08 FEB 2021 23:59

US3612005

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:15:23

<b>TIMEPOINT</b>	DAY 166
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	11 FEB 2021 00:16:14
Patient Cloud Open Date & Time	11 FEB 2021 00:01
Patient Cloud Close Date & Time	15 FEB 2021 23:59

US3612005

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:15:23

TIMEPOINT	DAY 173
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input 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 00:02:34
Patient Cloud Open Date & Time	18 FEB 2021 00:01
Patient Cloud Close Date & Time	22 FEB 2021 23:59

US3612005

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:15:23

**TIMEPOINT**

DAY 180

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

25 FEB 2021 08:36:49

Patient Cloud Open Date & Time

25 FEB 2021 00:01

Patient Cloud Close Date & Time

01 MAR 2021 23:59

US3612005

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:15:23

TIMEPOINT	DAY 187
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input 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"/>

**US3612005**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:15:23**

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

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[Patient Cloud Close Date & Time](#)

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08 MAR 2021 23:59

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US3612005

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:15:23

TIMEPOINT	DAY 194
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input 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"/>

**US3612005**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:15:23**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood 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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11 MAR 2021 00:01

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[Patient Cloud Close Date & Time](#)

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15 MAR 2021 23:59

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US3612005

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:15:23

**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

19 MAR 2021 23:55:06

Patient Cloud Open Date & Time

18 MAR 2021 00:01

Patient Cloud Close Date & Time

22 MAR 2021 23:59

US3612005

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:15:23

**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

25 MAR 2021 06:49:25

Patient Cloud Open Date & Time

25 MAR 2021 00:01

Patient Cloud Close Date & Time

29 MAR 2021 23:59

US3612005

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:15:23

**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

03 APR 2021 12:00:48

Patient Cloud Open Date & Time

01 APR 2021 00:01

Patient Cloud Close Date & Time

05 APR 2021 23:59

US3612005

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:15:23

**TIMEPOINT**

DAY 222

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

08 APR 2021 11:39:32

Patient Cloud Open Date & Time

08 APR 2021 00:01

Patient Cloud Close Date & Time

12 APR 2021 23:59

US3612005

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:15:23

TIMEPOINT	DAY 229
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input checked="" type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input checked="" type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input checked="" type="radio"/>
Date and time of submission	19 APR 2021 23:30:08
Patient Cloud Open Date & Time	15 APR 2021 00:01
Patient Cloud Close Date & Time	19 APR 2021 23:59

US3612005

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:15:23

TIMEPOINT	DAY 236
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input checked="" type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input checked="" type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input checked="" type="radio"/>
Date and time of submission	22 APR 2021 09:25:36
Patient Cloud Open Date & Time	22 APR 2021 00:01
Patient Cloud Close Date & Time	26 APR 2021 23:59

US3612005

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:15:23

**TIMEPOINT**

DAY 243

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

29 APR 2021 00:41:50

Patient Cloud Open Date & Time

29 APR 2021 00:01

Patient Cloud Close Date & Time

03 MAY 2021 23:59

US3612005

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:15:23

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="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"/>

**US3612005**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:15:23**

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

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[Patient Cloud Close Date & Time](#)

10 MAY 2021 23:59

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US3612005

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:15:23

**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 ☐

**US3612005**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:15:23**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood 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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US3612005

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:15:23

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"/>

**US3612005**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:15:23**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood 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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US3612005

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:15:23

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 <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"/>

**US3612005**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:15:23**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood 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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US3612005

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:15:23

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 <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"/>

**US3612005**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:15:23**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood 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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US3612005

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:15:23

**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 ☐

**US3612005**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:15:23**

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

US3612005

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:15:23

**TIMEPOINT**

DAY 292

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

No ☐

Yes ☐

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

No ☐

Yes ☐

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

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

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

No ☐

Yes ☐

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

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

No ☐

Yes ☐

**US3612005**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:15:23**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood 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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US3612005

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:15:23

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"/>

**US3612005**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:15:23**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood 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](#)

24 JUN 2021 00:01

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[Patient Cloud Close Date & Time](#)

28 JUN 2021 23:59

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US3612005

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:15:23

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 <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"/>

**US3612005**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:15:23**

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

01 JUL 2021 00:01

[Patient Cloud Close Date & Time](#)

05 JUL 2021 23:59

US3612005

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:15:23

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"/>

**US3612005**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:15:23**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood 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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US3612005

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:15:23

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

**US3612005**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:15:23**

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

US3612005

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:15:23

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"/>

**US3612005**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:15:23**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood 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](#)

22 JUL 2021 00:01

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[Patient Cloud Close Date & Time](#)

26 JUL 2021 23:59

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US3612005

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:15:23

**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 ☐

**US3612005**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:15:23**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood 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](#)

29 JUL 2021 00:01

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[Patient Cloud Close Date & Time](#)

02 AUG 2021 23:59

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US3612005

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:15:23

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"/>

**US3612005**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:15:23**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood 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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US3612005

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:15:23

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"/>

**US3612005**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:15:23**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood 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>	12 AUG 2021 00:01
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<a href="#">Patient Cloud Close Date &amp; Time</a>	16 AUG 2021 23:59
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US3612005

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:15:23

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 <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"/>

**US3612005**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:15:23**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood 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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US3612005

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:15:23

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="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"/>

**US3612005**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:15:23**

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

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[Patient Cloud Close Date & Time](#)

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30 AUG 2021 23:59

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US3612005

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:15:23

**TIMEPOINT**

DAY 369

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

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

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

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

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

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

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

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

**US3612005**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:15:23**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood 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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US3612005

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:15:23

**TIMEPOINT**

DAY 376

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

**US3612005**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:15:23**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood 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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US3612005

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:15:23

**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 ☐

**US3612005**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:15:23**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood 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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US3612005

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:15:23

**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 ☐

**US3612005**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:15:23**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood 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](#)

23 SEP 2021 00:01

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[Patient Cloud Close Date & Time](#)

27 SEP 2021 23:59

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US3612005

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:15:23

**TIMEPOINT**

DAY 397

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

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

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

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

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

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

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

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

**US3612005**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:15:23**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood 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](#)

30 SEP 2021 00:01

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[Patient Cloud Close Date & Time](#)

04 OCT 2021 23:59

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US3612005

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:15:23

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"/>

**US3612005**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:15:23**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood 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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US3612005

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:15:23

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"/>

**US3612005**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:15:23**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood 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>	14 OCT 2021 00:01
<a href="#">Patient Cloud Close Date &amp; Time</a>	18 OCT 2021 23:59

US3612005

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:15:23

**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 ☐

**US3612005**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:15:23**

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

US3612005

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:15:23

**TIMEPOINT**

DAY 425

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

**US3612005**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:15:23**

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

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[Patient Cloud Close Date & Time](#)

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01 NOV 2021 23:59

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US3612005

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:15:23

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"/>

**US3612005**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:15:23**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood 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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US3612005

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:15:23

**TIMEPOINT**

DAY 439

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

**US3612005**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:15:23**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood 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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11 NOV 2021 00:01

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[Patient Cloud Close Date & Time](#)

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15 NOV 2021 23:59

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US3612005

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:15:23

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"/>

**US3612005**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:15:23**

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

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[Patient Cloud Close Date & Time](#)

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22 NOV 2021 23:59

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US3612005

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:15:23

**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 ☐

**US3612005**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:15:23**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood 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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US3612005

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:15:23

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="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"/>

**US3612005**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:15:23**

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

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[Patient Cloud Close Date & Time](#)

06 DEC 2021 23:59

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US3612005

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:15:23

**TIMEPOINT**

DAY 467

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

**US3612005**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:15:23**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood 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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US3612005

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:15:23

**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 ☐

**US3612005**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:15:23**

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

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[Patient Cloud Close Date & Time](#)

20 DEC 2021 23:59

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US3612005

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:15:23

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 <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"/>

**US3612005**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:15:23**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

23 DEC 2021 00:01

[Patient Cloud Close Date & Time](#)

27 DEC 2021 23:59

US3612005

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:15:23

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"/>

**US3612005**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:15:23**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood 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](#)

30 DEC 2021 00:01

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[Patient Cloud Close Date & Time](#)

03 JAN 2022 23:59

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US3612005

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:15:23

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="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"/>

**US3612005**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:15:23**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

06 JAN 2022 00:01

[Patient Cloud Close Date & Time](#)

10 JAN 2022 23:59

US3612005

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:15:23

**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 ☐

**US3612005**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:15:23**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood 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 JAN 2022 00:01

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[Patient Cloud Close Date & Time](#)

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17 JAN 2022 23:59

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US3612005

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:15:23

**TIMEPOINT**

DAY 509

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

**US3612005**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:15:23**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood 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 JAN 2022 00:01

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[Patient Cloud Close Date & Time](#)

24 JAN 2022 23:59

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US3612005

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:15:23

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 <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"/>

**US3612005**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:15:23**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood 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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US3612005

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:15:23

**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 ☐

**US3612005**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:15:23**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood 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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US3612005

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:15:23

**TIMEPOINT**

DAY 530

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

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

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

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

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

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

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 ☐

**US3612005**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:15:23**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood 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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US3612005

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:15:23

**TIMEPOINT**

DAY 537

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

**US3612005**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:15:23**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood 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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[Patient Cloud Close Date & Time](#)

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21 FEB 2022 23:59

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US3612005

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:15:23

**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 ☐

**US3612005**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:15:23**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood 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 FEB 2022 00:01

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[Patient Cloud Close Date & Time](#)

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28 FEB 2022 23:59

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US3612005

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:15:23

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 <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"/>

**US3612005**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:15:23**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood 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 MAR 2022 00:01

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[Patient Cloud Close Date & Time](#)

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07 MAR 2022 23:59

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US3612005

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:15:23

**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 ☐

**US3612005**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:15:23**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood 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 MAR 2022 00:01

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[Patient Cloud Close Date & Time](#)

14 MAR 2022 23:59

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US3612005

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:15:23

**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 ☐

**US3612005**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:15:23**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood 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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US3612005

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:15:23

**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 ☐

**US3612005**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:15:23**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood 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 MAR 2022 00:01

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[Patient Cloud Close Date & Time](#)

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28 MAR 2022 23:59

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US3612005

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:15:23

**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 ☐

**US3612005**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:15:23**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood 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](#)

31 MAR 2022 00:01

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[Patient Cloud Close Date & Time](#)

04 APR 2022 23:59

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US3612005

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:15:23

**TIMEPOINT**

DAY 586

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

**US3612005**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:15:23**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood 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](#)

07 APR 2022 00:01

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[Patient Cloud Close Date & Time](#)

11 APR 2022 23:59

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US3612005

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:15:23

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 <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"/>

**US3612005**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:15:23**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood 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 APR 2022 00:01

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[Patient Cloud Close Date & Time](#)

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18 APR 2022 23:59

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US3612005

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:15:23

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

**US3612005**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:15:23**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood 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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US3612005

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:15:23

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"/>

**US3612005**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:15:23**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood 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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US3612005

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:15:23

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"/>

**US3612005**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:15:23**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood 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 MAY 2022 00:01

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[Patient Cloud Close Date & Time](#)

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09 MAY 2022 23:59

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US3612005

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:15:23

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

**US3612005**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:15:23**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood 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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12 MAY 2022 00:01

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[Patient Cloud Close Date & Time](#)

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16 MAY 2022 23:59

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US3612005

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:15:23

**TIMEPOINT**

DAY 628

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

**US3612005**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:15:23**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood 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](#)

19 MAY 2022 00:01

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[Patient Cloud Close Date & Time](#)

23 MAY 2022 23:59

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US3612005

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:15:23

**TIMEPOINT**

DAY 635

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

No ☐

Yes ☐

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

No ☐

Yes ☐

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

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

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

No ☐

Yes ☐

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

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

Chills

Cough

Shortness of breath

Difficulty breathing

Fatigue

Muscle aches

Body aches

Headache

New loss of taste

New loss of smell

Sore throat

Congestion

Runny nose

Nausea

Vomiting

Diarrhea

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

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

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

No ☐

Yes ☐

**US3612005**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:15:23**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood 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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US3612005

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:15:23

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"/>

**US3612005**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:15:23**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood 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 JUN 2022 00:01

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[Patient Cloud Close Date & Time](#)

06 JUN 2022 23:59

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US3612005

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:15:23

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

**US3612005**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:15:23**

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

[Patient Cloud Open Date & Time](#)

09 JUN 2022 00:01

[Patient Cloud Close Date & Time](#)

13 JUN 2022 23:59

US3612005

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:15:23

**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 ☐

**US3612005**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:15:23**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood 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 JUN 2022 00:01

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[Patient Cloud Close Date & Time](#)

20 JUN 2022 23:59

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US3612005

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:15:23

**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 ☐

**US3612005**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:15:23**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood 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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US3612005

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:15:23

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"/>

**US3612005**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:15:23**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood 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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US3612005

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:15:23

**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 ☐

**US3612005**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:15:23**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood 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](#)

07 JUL 2022 00:01

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[Patient Cloud Close Date & Time](#)

11 JUL 2022 23:59

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US3612005

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:15:23

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

**US3612005**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:15:23**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood 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>	14 JUL 2022 00:01
<a href="#">Patient Cloud Close Date &amp; Time</a>	18 JUL 2022 23:59

US3612005

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:15:23

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="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"/>

**US3612005**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:15:23**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

21 JUL 2022 00:01

[Patient Cloud Close Date & Time](#)

25 JUL 2022 23:59

US3612005

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:15:23

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

**US3612005**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:15:23**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

28 JUL 2022 00:01

[Patient Cloud Close Date & Time](#)

01 AUG 2022 23:59

US3612005

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:15:23

**TIMEPOINT**

DAY 705

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

**US3612005**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:15:23**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood 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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US3612005

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:15:23

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

**US3612005**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:15:23**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

11 AUG 2022 00:01

[Patient Cloud Close Date & Time](#)

15 AUG 2022 23:59

US3612005

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:15:23

**TIMEPOINT**

DAY 719

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

**US3612005**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:15:23**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood 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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US3612005

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:15:23

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"/>

**US3612005**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:15:23**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood 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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US3612005

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:15:23

**TIMEPOINT**

DAY 733

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

**US3612005**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:15:23**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood 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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US3612005

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:15:23

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"/>

**US3612005**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:15:23**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood 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 SEP 2022 00:01

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[Patient Cloud Close Date & Time](#)

12 SEP 2022 23:59

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US3612005

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:15:23

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="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"/>

**US3612005**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:15:23**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood 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](#)

15 SEP 2022 00:01

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[Patient Cloud Close Date & Time](#)

19 SEP 2022 23:59

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US3612005

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:15:23

**TIMEPOINT**

DAY 754

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

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

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

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

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

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

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

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

**US3612005**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:15:23**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood 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>	22 SEP 2022 00:01
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<a href="#">Patient Cloud Close Date &amp; Time</a>	26 SEP 2022 23:59
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US3612005

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:15:23

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 <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"/>

**US3612005**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:15:23**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood 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 SEP 2022 00:01

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[Patient Cloud Close Date & Time](#)

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03 OCT 2022 23:59

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US3612005

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:15:23

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="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"/>

**US3612005**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:15:23**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

06 OCT 2022 00:01

[Patient Cloud Close Date & Time](#)

10 OCT 2022 23:59

US3612005

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:15:23

**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 ☐

**US3612005**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:15:23**

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

US3612005

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:15:23

**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 ☐

**US3612005**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:15:23**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood 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>	20 OCT 2022 00:01
<a href="#">Patient Cloud Close Date &amp; Time</a>	24 OCT 2022 23:59

US3612005

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:15:23

**TIMEPOINT**

DAY 789

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

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

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

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

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

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

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

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

**US3612005**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:15:23**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood 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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US3612005

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:15:23

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"/>

**US3612005**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:15:23**

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

---

Date and time of submission

---

[Patient Cloud Open Date & Time](#)

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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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**US3612005**

**Folder: Cosmetic Injections and Dermal Fillers**

**Form: Cosmetic Injection\_ Dermal Filler eDiary**

**Generated On: 10 Jun 2021 09:15:23**

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		19 MAR 2021 23:55:23

US3612005

Folder: Safety Call Day 85 (1)

Form: Safety Call

Data signed: (b) (4) 05 Mar 2021 19:39:44

Generated On: 10 Jun 2021 09:15:23

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

24 NOV 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

*If Contact Not Made, please provide Comments*

US3612005

Folder: Safety Call Day 85 (1)

Form: Continuing

Data signed: (b) (4) 05 Mar 2021 19:39:44

Generated On: 10 Jun 2021 09:15:23

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3612005

Folder: Safety Call Day 119 (1)

Form: Safety Call

Data signed: (b) (4) 26 Mar 2021 18:58:13

Generated On: 10 Jun 2021 09:15:23

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

30 DEC 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

*If Contact Not Made, please provide Comments*

US3612005

Folder: Safety Call Day 119 (1)

Form: Continuing

Data signed: (b) (4) 26 Mar 2021 18:58:13

Generated On: 10 Jun 2021 09:15:23

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3612005

Folder: Safety Call Day 149 (1)

Form: Safety Call

Data signed: (b) (4) 26 Mar 2021 18:58:13

Generated On: 10 Jun 2021 09:15:23

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

29 JAN 2021

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

*If Contact Not Made, please provide Comments*

US3612005

Folder: Safety Call Day 149 (1)

Form: Continuing

Data signed: (b) (4) 26 Mar 2021 18:58:13

Generated On: 10 Jun 2021 09:15:23

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3612005

Folder: Safety Call Day 179 (1)

Form: Safety Call

Data signed: (b) (4) 26 Mar 2021 18:58:32

Generated On: 10 Jun 2021 09:15:23

Was Contact Attempted? Yes ☒  
No ☐

Date of Contact or Contact Attempt (dd MMM yyyy) 26 FEB 2021

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

Comments

*If Contact Not Made, please provide Comments*

US3612005

Folder: Safety Call Day 179 (1)

Form: Continuing

Data signed: (b) (4) 26 Mar 2021 18:58:32

Generated On: 10 Jun 2021 09:15:23

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3612005

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Data signed: (b) (4) 26 Mar 2021 18:58:32

Generated On: 10 Jun 2021 09:15:23

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

Visit date (dd MMM yyyy)	23 MAR 2021
--------------------------	-------------

Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>

Folder OID	VISIT4
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US3612005

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Data signed: (b) (4) 31 Mar 2021 21:09:32

Generated On: 10 Jun 2021 09:15:23

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) \_\_\_\_\_

US3612005

Folder: Visit 4 Day 209 (1)

Form: Physical Examination

Data signed: (b) (4) 26 Mar 2021 18:58:32

Generated On: 10 Jun 2021 09:15:23

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.*

US3612005

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 26 Mar 2021 18:58:32

Generated On: 10 Jun 2021 09:15:23

Was the sample collected?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Collection date (dd MMM yyyy)	23 MAR 2021
Collection time (00:00-23:59)	09:20 (24 HR)
Collection date and time (derived)	23 MAR 2021 09:20

US3612005

Folder: Visit 4 Day 209 (1)

Form: Continuing

Data signed: (b) (4) 26 Mar 2021 18:58:32

Generated On: 10 Jun 2021 09:15:23

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

**US3612005**

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

**Form: Safety Call**

**Generated On: 10 Jun 2021 09:15:23**

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*

**US3612005**

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

**Form: Continuing**

**Generated On: 10 Jun 2021 09:15:23**

Is the participant continuing to the next visit?

Yes ☐

No ☐

Continuing Flag

**US3612005**

**Folder: Covid-19 Assessment (1)**

**Form: COVID-19 Contact**

**Generated On: 10 Jun 2021 09:15:23**

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

**US3612005**

**Folder: Covid-19 Assessment (1)**

**Form: Generate Next COVID-19 Assessment**

**Generated On: 10 Jun 2021 09:15:23**

---

Generate Next COVID-19 Assessment

Yes ☐

No ☐

---

US3612005

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

Form: Visit Date

Data signed: (b) (4) 26 Mar 2021 18:58:13

Generated On: 10 Jun 2021 09:15:23

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

US3612005

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

Form: Unblinding

Data signed: (b) (4) 26 Mar 2021 18:58:13

Generated On: 10 Jun 2021 09:15:23

Date of updated informed consent ( <i>dd MMM yyyy</i> )	4 JAN 2021
N/A - Subject Unblinded under Amendment 5 and Discontinued from Study	False
Was the participant unblinded?	Yes <input checked="" type="radio"/> No <input type="radio"/>
Under what version of the Protocol was the Participant unblinded?	Amendment 5 <input type="radio"/> Amendment 6 or later <input checked="" type="radio"/>
Date of unblinding ( <i>dd MMM yyyy</i> )	4 JAN 2021
Participant randomization assignment	mRNA-1273 <input type="radio"/> Placebo <input checked="" type="radio"/>
Actual Dose 1	mRNA-1273 <input type="radio"/> Placebo <input checked="" type="radio"/> Not Administered <input type="radio"/>
Actual Dose 2	mRNA-1273 <input type="radio"/> Placebo <input checked="" type="radio"/> Not Administered <input type="radio"/>
Will participant receive mRNA-1273?	Yes <input checked="" type="radio"/> No <input type="radio"/>
Placebo Only Flag	1
Continuing with mRNA-1273	1

US3612005

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

Form: Vital Signs - Dosing

Data signed: (b) (4) 26 Mar 2021 18:58:13

Generated On: 10 Jun 2021 09:15:23

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

US3612005

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

Form: Vital Signs - Dosing (1)

Data signed: (b) (4) 26 Mar 2021 18:58:13

Generated On: 10 Jun 2021 09:15:23

Height	ND - Not Done
Weight	ND - Not Done
BMI (xxx.x)	
Timepoint	Pre-Dose <input checked="" type="radio"/> Post-Dose <input type="radio"/>
Were vital signs assessed?	Yes <input checked="" type="radio"/> No <input type="radio"/>
Date of assessment (dd MMM yyyy)	4 JAN 2021
Time of assessment (00:00-23:59)	10:23 (24 HR)
Vital Signs Date and Time (derived)	4 JAN 2021 10:23
Temperature (xxx.x)	98.0 F
Route of measurement	Oral <input checked="" type="radio"/> Axillary <input type="radio"/> Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	55 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	18 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	126 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	72 mmHg
Diastolic Blood Pressure units	MMHG

US3612005

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

Form: Vital Signs - Dosing (2)

Data signed: (b) (4) 26 Mar 2021 18:58:13

Generated On: 10 Jun 2021 09:15:23

Height	ND - Not Done
Weight	ND - Not Done
BMI (xxx.x)	
Timepoint	Pre-Dose <input type="radio"/> Post-Dose <input checked="" type="radio"/>
Were vital signs assessed?	Yes <input checked="" type="radio"/> No <input type="radio"/>
Date of assessment (dd MMM yyyy)	4 JAN 2021
Time of assessment (00:00-23:59)	11:50 (24 HR)
Vital Signs Date and Time (derived)	4 JAN 2021 11:50
Temperature (xxx.x)	97.9 F
Route of measurement	Oral <input checked="" type="radio"/> Axillary <input type="radio"/> Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	56 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	136 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	73 mmHg
Diastolic Blood Pressure units	MMHG

US3612005

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

Form: Physical Examination

Data signed: (b) (4) 26 Mar 2021 18:58:13

Generated On: 10 Jun 2021 09:15:23

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

4 JAN 2021

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

US3612005

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

Form: Exposure

Data signed: (b) (4) 26 Mar 2021 18:58:13

Generated On: 10 Jun 2021 09:15:23

Was study treatment given? Yes ☒ No ☐

If No, reason not given

Participant declined due to Adverse Event ☐

Physician withheld dose due to Adverse Event ☐

Death ☐

Lost To Follow-Up ☐

Physician Decision ☐

Pregnancy ☐

Protocol Deviation ☐

Study Terminated by Sponsor ☐

Withdrawal of Consent by Participant ☐

Confirmed COVID-19 ☐

Other ☐

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

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

What was the treatment date? (dd MMM yyyy) 4 JAN 2021

What was the treatment time? (00:00-23:59) 11:17 (24 HR)

Treatment Date and Time (derived) 4 JAN 2021 11:17

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

What was the frequency of the study treatment dosing? ONCE

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

US3612005

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

Form: Immunogenicity Assessment

Data signed: (b) (4) 26 Mar 2021 18:58:13

Generated On: 10 Jun 2021 09:15:23

Was the sample collected?

Yes ☒

No ☐

Collection date (dd MMM yyyy)

4 JAN 2021

Collection time (00:00-23:59)

10:29 (24 HR)

Collection date and time (derived)

4 JAN 2021 10:29

US3612005

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

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Data signed: (b) (4) 26 Mar 2021 18:58:13

Generated On: 10 Jun 2021 09:15:23

Was the sample collected?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Collection date (dd MMM yyyy)	4 JAN 2021
Collection time (00:00 - 23:59)	10:33
Collection Date and Time (derived)	4 JAN 2021 10:33

US3612005

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

Form: Continuing

Data signed: (b) (4) 26 Mar 2021 18:58:13

Generated On: 10 Jun 2021 09:15:23

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3612005

Folder: Safety Call OL-D8 (1)

Form: Safety Call

Data signed: (b) (4) 26 Mar 2021 18:58:32

Generated On: 10 Jun 2021 09:15:23

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

11 JAN 2021

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

*If Contact Not Made, please provide Comments*

US3612005

Folder: Safety Call OL-D8 (1)

Form: Continuing

Data signed: (b) (4) 26 Mar 2021 18:58:32

Generated On: 10 Jun 2021 09:15:23

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

US3612005

Folder: OL-D29 (1)

Form: Visit Date

Data signed: (b) (4) 26 Mar 2021 18:58:12

Generated On: 10 Jun 2021 09:15:23

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	02 FEB 2021
Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>
Folder OID	OLD29

US3612005

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Data signed: (b) (4) 26 Mar 2021 18:58:12

Generated On: 10 Jun 2021 09:15:23

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)	02 FEB 2021
Time of assessment (00:00-23:59)	08:48 (24 HR)
Vital Signs Date and Time (derived)	02 FEB 2021 08:48
Temperature (xxx.x)	097.9 F
Route of measurement	Oral <input checked="" type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	058 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	018 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	131 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	77 mmHg
Diastolic Blood Pressure units	MMHG

US3612005

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Data signed: (b) (4) 26 Mar 2021 18:58:12

Generated On: 10 Jun 2021 09:15:23

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)	02 FEB 2021
Time of assessment (00:00-23:59)	09:54 (24 HR)
Vital Signs Date and Time (derived)	02 FEB 2021 09:54
Temperature (xxx.x)	098.2 F
Route of measurement	Oral <input checked="" type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	060 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	018 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	126 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	76 mmHg
Diastolic Blood Pressure units	MMHG

US3612005

Folder: OL-D29 (1)

Form: Physical Examination

Data signed: (b) (4) 26 Mar 2021 18:58:12

Generated On: 10 Jun 2021 09:15:23

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

02 FEB 2021

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

US3612005

Folder: OL-D29 (1)

Form: Exposure

Data signed: (b) (4) 26 Mar 2021 18:58:12

Generated On: 10 Jun 2021 09:15:23

Was study treatment given? Yes ☒ No ☐

If No, reason not given

Participant declined due to Adverse Event ☐

Physician withheld dose due to Adverse Event ☐

Death ☐

Lost To Follow-Up ☐

Physician Decision ☐

Pregnancy ☐

Protocol Deviation ☐

Study Terminated by Sponsor ☐

Withdrawal of Consent by Participant ☐

Confirmed COVID-19 ☐

Other ☐

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

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

What was the treatment date? (dd MMM yyyy) 02 FEB 2021

What was the treatment time? (00:00-23:59) 09:20 (24 HR)

Treatment Date and Time (derived) 02 FEB 2021 09:20

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

US3612005

Folder: OL-D29 (1)

Form: Continuing

Data signed: (b) (4) 26 Mar 2021 18:58:12

Generated On: 10 Jun 2021 09:15:23

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3612005

Folder: Safety Call OL-D36 (1)

Form: Safety Call

Data signed: (b) (4) 26 Mar 2021 18:58:32

Generated On: 10 Jun 2021 09:15:23

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

10 FEB 2021

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

*If Contact Not Made, please provide Comments*

US3612005

Folder: Safety Call OL-D36 (1)

Form: Continuing

Data signed: (b) (4) 26 Mar 2021 18:58:32

Generated On: 10 Jun 2021 09:15:23

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3612005

Folder: OL-D57 (1)

Form: Visit Date

Data signed: (b) (4) 26 Mar 2021 18:58:13

Generated On: 10 Jun 2021 09:15:23

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	01 MAR 2021
Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>
Folder OID	OLD57

US3612005

Folder: OL-D57 (1)

Form: Vital Signs

Data signed: (b) (4) 26 Mar 2021 18:58:13

Generated On: 10 Jun 2021 09:15:23

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) \_\_\_\_\_

US3612005

Folder: OL-D57 (1)

Form: Physical Examination

Data signed: (b) (4) 26 Mar 2021 18:58:13

Generated On: 10 Jun 2021 09:15:23

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.*

US3612005

Folder: OL-D57 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 26 Mar 2021 18:58:12

Generated On: 10 Jun 2021 09:15:23

Was the sample collected?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Collection date ( <i>dd MMM yyyy</i> )	01 MAR 2021
Collection time ( <i>00:00-23:59</i> )	09:50 (24 HR)
Collection date and time (derived)	01 MAR 2021 09:50

US3612005

Folder: Adverse Events

Form: Adverse Events Summary

Data signed: (b) (4) 09 Apr 2021 14:55:29

Generated On: 10 Jun 2021 09:15:23

---

Did the participant experience any adverse events?

Yes ☒

No ☐

---

If Yes, enter details on the Adverse Events form.

---

US3612005

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:15:23

AEID

Adverse event

OTITIS EXTERNA

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)

02 JAN 2021

Start time (00:00-23:59)

AE start date and time (derived)

Ongoing?

Yes ☐

No ☒

If not Ongoing, end date (dd MMM yyyy)

09 JAN 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

Persistent or significant disability or incapacity

False

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EAB) (1725)

356 of 2285

US3612005

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:15:23

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

US3612005

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:15:23

AEID	USA-US129-2021-MRNA-1273-P30 1000006
Adverse event	MYOCARDIAL INFARCTION
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)	13 APR 2021
Start time (00:00-23:59)	
AE start date and time (derived)	
Ongoing?	Yes <input type="radio"/> No <input checked="" type="radio"/>
If not Ongoing, end date (dd MMM yyyy)	17 APR 2021
End time (00:00-23:59)	
AE End Date and Time (derived)	
Severity	Grade 1/Mild <input type="radio"/> Grade 2/Moderate <input type="radio"/> Grade 3/Severe <input type="radio"/> Grade 4 <input checked="" 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	True
Requires inpatient or prolongation of existing Hospitalization	True
Hospital Admission Date (dd MMM yyyy)	13 APR 2021
Hospital Discharge Date (dd MMM yyyy)	17 APR 2021
Admitted to ICU?	Yes <input type="radio"/> No <input checked="" type="radio"/> Unknown <input type="radio"/>
Number of Days in ICU	

PRODUCTION RELEASE (v12.003  
EAB) (1725)

358 of 2285

US3612005

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:15:23

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	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	

US3612005

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:15:23

RECEIVED CALL FROM  
SUBJECT STATING HE WAS  
HOSPITALIZED 13APR2021 FOR  
A MYOCARDIAL INFARCTION  
WITH DISCHARGE ON  
17APR2021. PATIENT  
UNDERWENT CARDIAC  
CATHETERIZATION AND STENT  
PLACEMENT IN 13APR2021.  
SUBJECT IS SCHEDULED TO  
FOLLOW UP WITH  
CARDIOLOGIST 20APR2021.  
COVID-19 TESTING NO  
COMPLETED DURING  
HOSPITALIZATION. FOLLOW UP  
WITH CARDIOLOGIST ON  
20-APR-2021. PATIENT STATES  
THERE WERE NO CHANGES IN  
HEALTH, HOWEVER  
MEDICATIONS WERE  
CHANGED. THE CHANGES IN  
MEDICATIONS ARE REFLECTED  
IN CONCOMITANT  
MEDICATIONS.

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

US3612005

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination Summary

Data signed: (b) (4) 26 Mar 2021 18:58:12

Generated On: 10 Jun 2021 09:15:23

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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.

---

US3612005

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Data signed: (b) (4) 26 Apr 2021 20:27:17

Generated On: 10 Jun 2021 09:15:23

Name of Medication ALLOPURINOL

Prophylaxis Yes ☒  
No ☐

Indication KIDNEY STONES

Dose per administration 300

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)

362 of 2285

US3612005

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Data signed: (b) (4) 26 Apr 2021 20:27:17

Generated On: 10 Jun 2021 09:15:23

	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)		15 JUL 1981
Start date completely unknown		False
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)		14 APR 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"/>

US3612005

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Data signed: (b) (4) 26 Apr 2021 20:27:17

Generated On: 10 Jun 2021 09:15:23

Name of Medication HYDROCHLOROTHIAZIDE

Prophylaxis Yes ☒  
No ☐

Indication KIDNEY STONES

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 ☐

PRODUCTION RELEASE (v12.003  
EAB) (1725)

364 of 2285

US3612005

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Data signed: (b) (4) 26 Apr 2021 20:27:17

Generated On: 10 Jun 2021 09:15:23

	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)		15 JUL 1981
Start date completely unknown		False
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)		14 APR 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"/>

US3612005

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Data signed: (b) (4) 26 Apr 2021 20:27:17

Generated On: 10 Jun 2021 09:15:23

Name of Medication WARFARIN

Prophylaxis Yes ☒  
No ☐

Indication BLOOD CLOTS

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 ☐

PRODUCTION RELEASE (v12.003  
EAB) (1725)

366 of 2285

US3612005

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Data signed: (b) (4) 26 Apr 2021 20:27:17

Generated On: 10 Jun 2021 09:15:23

	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)	15 JUL 2005	
Start date completely unknown	False	
Ongoing?	Yes	<input checked="" type="radio"/>
	No	<input type="radio"/>
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived)	1	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input checked="" type="radio"/>

US3612005

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Data signed: (b) (4) 26 Apr 2021 20:27:17

Generated On: 10 Jun 2021 09:15:23

Name of Medication FENOFIBRATE

Prophylaxis Yes ☐  
No ☒

Indication HIGH CHOLESTEROL

Dose per administration 67

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)

368 of 2285

US3612005

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Data signed: (b) (4) 26 Apr 2021 20:27:17

Generated On: 10 Jun 2021 09:15:23

	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)	15 FEB 2019	
Start date completely unknown	False	
Ongoing?	Yes <input type="checkbox"/>	
	No <input checked="" type="radio"/>	
If not Ongoing, End date (dd MMM yyyy) 14 APR 2021		
Was this medication taken for solicited event?	Yes <input type="checkbox"/>	
	No <input checked="" type="radio"/>	
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="radio"/>	

US3612005

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Data signed: (b) (4) 26 Apr 2021 20:27:17

Generated On: 10 Jun 2021 09:15:23

Name of Medication CELEBREX

Prophylaxis Yes ☐  
No ☒

Indication BILATERAL KNEE ACES

Dose per administration 200

Dose unit mg ☒  
ug ☐  
mL ☐  
g ☐  
IU ☐  
tablet ☐  
capsule ☐  
puff ☐  
Other ☐

If dose unit is Other, specify

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

If frequency is Other, specify

Route of administration Oral ☒  
Topical ☐  
Subcutaneous ☐  
Transdermal ☐  
Intraocular ☐

PRODUCTION RELEASE (v12.003  
EAB) (1725)

370 of 2285

US3612005

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Data signed: (b) (4) 26 Apr 2021 20:27:17

Generated On: 10 Jun 2021 09:15:23

	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)		15 FEB 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"/>

US3612005

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Data signed: (b) (4) 26 Apr 2021 20:27:17

Generated On: 10 Jun 2021 09:15:23

Name of Medication INFLUENZA VACCINE

Prophylaxis Yes ☒  
No ☐

Indication IMMUNIZATION

Dose per administration 0.5

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 ☐

PRODUCTION RELEASE (v12.003  
EAB) (1725)

372 of 2285

US3612005

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Data signed: (b) (4) 26 Apr 2021 20:27:17

Generated On: 10 Jun 2021 09:15:23

	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)		04 NOV 2020
Start date completely unknown		False
Ongoing?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
If not Ongoing, End date (dd MMM yyyy)		04 NOV 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"/>

US3612005

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Data signed: (b) (4) 26 Apr 2021 20:27:17

Generated On: 10 Jun 2021 09:15:23

Name of Medication OFLOXACIN

Prophylaxis Yes ☐  
No ☒

Indication RIGHT OTITIS EXTERNA

Dose per administration 1

Dose unit mg ☐  
ug ☐  
mL ☐  
g ☐  
IU ☐  
tablet ☐  
capsule ☐  
puff ☐  
Other ☒

If dose unit is Other, specify DROP

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)

374 of 2285

US3612005

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Data signed: (b) (4) 26 Apr 2021 20:27:17

Generated On: 10 Jun 2021 09:15:23

	Intramuscular	<input type="radio"/>
	Respiratory (Inhalation)	<input type="radio"/>
	Intralesional	<input type="radio"/>
	Intraperitoneal	<input type="radio"/>
	Nasal	<input type="radio"/>
	Vaginal	<input type="radio"/>
	Rectal	<input type="radio"/>
	Intravenous	<input type="radio"/>
	Intravenous Bolus	<input type="radio"/>
	Intravenous Drip	<input type="radio"/>
	Other	<input checked="" type="radio"/>
If route of administration is Other, specify	INTRA AURICULAR	
Start date (dd MMM yyyy)	2 JAN 2021	
Start date completely unknown	False	
Ongoing?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
If not Ongoing, End date (dd MMM yyyy)	9 JAN 2021	
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived)	2	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input checked="" type="radio"/>

US3612005

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Data signed: (b) (4) 26 Apr 2021 20:27:17

Generated On: 10 Jun 2021 09:15:23

Name of Medication AMIODARONE

Prophylaxis Yes ☐  
No ☒

Indication MYOCARDIAL INFARCTION

Dose per administration 200

Dose unit mg ☒  
ug ☐  
mL ☐  
g ☐  
IU ☐  
tablet ☐  
capsule ☐  
puff ☐  
Other ☐

If dose unit is Other, specify

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

If frequency is Other, specify

Route of administration Oral ☒  
Topical ☐  
Subcutaneous ☐  
Transdermal ☐  
Intraocular ☐

PRODUCTION RELEASE (v12.003  
EAB) (1725)

376 of 2285

US3612005

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Data signed: (b) (4) 26 Apr 2021 20:27:17

Generated On: 10 Jun 2021 09:15:23

	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)	14 APR 2021	
Start date completely unknown	False	
Ongoing?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
If not Ongoing, End date (dd MMM yyyy)	20 APR 2021	
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived)	1	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input checked="" type="radio"/>

US3612005

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Data signed: (b) (4) 26 Apr 2021 20:27:17

Generated On: 10 Jun 2021 09:15:23

Name of Medication METOPROLOL SUCCINATE XL

Prophylaxis Yes ☐  
No ☒

Indication MYOCARDIAL INFARCTION

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 ☐

PRODUCTION RELEASE (v12.003  
EAB) (1725)

378 of 2285

US3612005

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Data signed: (b) (4) 26 Apr 2021 20:27:17

Generated On: 10 Jun 2021 09:15:23

	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 APR 2021	
Start date completely unknown	False	
Ongoing?	Yes <input type="checkbox"/>	
	No <input checked="" type="radio"/>	
If not Ongoing, End date (dd MMM yyyy)	20 APR 2021	
Was this medication taken for solicited event?	Yes <input type="checkbox"/>	
	No <input checked="" type="radio"/>	
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="radio"/>	

US3612005

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Data signed: (b) (4) 26 Apr 2021 20:27:17

Generated On: 10 Jun 2021 09:15:23

Name of Medication FUROSEMIDE

Prophylaxis Yes ☐  
No ☒

Indication MYOCARDIAL INFARCTION

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  
EAB) (1725)

380 of 2285

US3612005

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Data signed: (b) (4) 26 Apr 2021 20:27:17

Generated On: 10 Jun 2021 09:15:23

	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 APR 2021	
Start date completely unknown	False	
Ongoing?	Yes	<input checked="" type="radio"/>
	No	<input type="radio"/>
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived)	1	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input checked="" type="radio"/>

US3612005

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Data signed: (b) (4) 26 Apr 2021 20:27:17

Generated On: 10 Jun 2021 09:15:23

Name of Medication CLOPIDOGREL

Prophylaxis Yes ☐  
No ☒

Indication MYOCARDIAL INFARCTION

Dose per administration 75

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)

382 of 2285

US3612005

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Data signed: (b) (4) 26 Apr 2021 20:27:17

Generated On: 10 Jun 2021 09:15:23

	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 APR 2021	
Start date completely unknown	False	
Ongoing?	Yes	<input checked="" type="radio"/>
	No	<input type="radio"/>
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived)	1	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input checked="" type="radio"/>

US3612005

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Data signed: (b) (4) 26 Apr 2021 20:27:17

Generated On: 10 Jun 2021 09:15:23

Name of Medication ATORVASTATIN

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 ☐

PRODUCTION RELEASE (v12.003  
EAB) (1725)

384 of 2285

US3612005

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Data signed: (b) (4) 26 Apr 2021 20:27:17

Generated On: 10 Jun 2021 09:15:23

	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 APR 2021	
Start date completely unknown	False	
Ongoing?	Yes	<input checked="" type="radio"/>
	No	<input type="radio"/>
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived)	1	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input checked="" type="radio"/>

US3612005

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Data signed: (b) (4) 26 Apr 2021 20:27:17

Generated On: 10 Jun 2021 09:15:23

Name of Medication ASPIRIN

Prophylaxis Yes ☐  
No ☒

Indication MYOCARDIAL INFARCTION

Dose per administration 81

Dose unit mg ☒  
ug ☐  
mL ☐  
g ☐  
IU ☐  
tablet ☐  
capsule ☐  
puff ☐  
Other ☐

If dose unit is Other, specify

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

If frequency is Other, specify

Route of administration Oral ☒  
Topical ☐  
Subcutaneous ☐  
Transdermal ☐  
Intraocular ☐

PRODUCTION RELEASE (v12.003  
EAB) (1725)

386 of 2285

US3612005

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Data signed: (b) (4) 26 Apr 2021 20:27:17

Generated On: 10 Jun 2021 09:15:23

	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 APR 2021	
Start date completely unknown	False	
Ongoing?	Yes	<input checked="" type="radio"/>
	No	<input type="radio"/>
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived)	1	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input checked="" type="radio"/>

US3612005

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Data signed: (b) (4) 26 Apr 2021 20:27:17

Generated On: 10 Jun 2021 09:15:23

Name of Medication DILTIAZEM

Prophylaxis Yes ☐  
No ☒

Indication MYOCARDIAL INFARCTION

Dose per administration 30

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)

388 of 2285

US3612005

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Data signed: (b) (4) 26 Apr 2021 20:27:17

Generated On: 10 Jun 2021 09:15:23

	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)	20 APR 2021	
Start date completely unknown	False	
Ongoing?	Yes	<input checked="" type="radio"/>
	No	<input type="radio"/>
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived)	2	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input checked="" type="radio"/>

US3612005

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures Summary

Data signed: (b) (4) 22 Apr 2021 15:29:48

Generated On: 10 Jun 2021 09:15:23

---

Were any concomitant procedures performed?

Yes ☒

No ☐

---

If yes, please complete Concomitant Procedures form.

---

US3612005

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures

Data signed: (b) (4) 22 Apr 2021 15:29:48

Generated On: 10 Jun 2021 09:15:23

Procedure/Surgery date (dd MMM yyyy)	Procedure/Surgery	Indication	If indication is Other, specify
13 APR 2021	CARDIAC CATHETERIZATION WITH STENT PLACEMENT	Adverse Event	

US3612005

Folder: End of Study (1)

Form: Dosing Discontinuation

Generated On: 10 Jun 2021 09:15:23

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

US3612005

Folder: End of Study (1)

Form: End of Study / Study Discontinuation

Generated On: 10 Jun 2021 09:15:23

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 ☐

US3612005

Folder: SAE USA-US129-2021-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 10 Jun 2021 09:15:23

SAEID	USA-US129-2021-MRNA-1273-P301000006
Serious	Yes <input checked="" type="radio"/> No <input type="radio"/>
Death	Yes <input type="radio"/> No <input checked="" type="radio"/>
Life threatening	Yes <input checked="" type="radio"/> No <input type="radio"/>
Requires inpatient or prolongation of existing Hospitalization	Yes <input checked="" type="radio"/> No <input type="radio"/>
Persistent or significant disability or incapacity	Yes <input type="radio"/> No <input checked="" type="radio"/>
Congenital anomaly or birth defect	Yes <input type="radio"/> No <input checked="" type="radio"/>
Other medically important event	Yes <input type="radio"/> No <input checked="" type="radio"/>
Investigator's First Name	RICHARD
Investigator's Last Name	RUPP
Site Address: Street	301 UNIVERSITY BLVD
Site Address: City	GALVESTON
Site Address: State	TX
Site Address: Postal Code	77555
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	3

US3612005

Folder: SAE USA-US129-2021-MRNA-1273-P301000006

Form: Safety Report Form (1)

Generated On: 10 Jun 2021 09:15:23

SAEID	USA-US129-2021-MRNA-1273-P301000006
Serious	Yes <input checked="" type="radio"/> No <input type="radio"/>
Death	Yes <input type="radio"/> No <input checked="" type="radio"/>
Life threatening	Yes <input checked="" type="radio"/> No <input type="radio"/>
Requires inpatient or prolongation of existing Hospitalization	Yes <input checked="" type="radio"/> No <input type="radio"/>
Persistent or significant disability or incapacity	Yes <input type="radio"/> No <input checked="" type="radio"/>
Congenital anomaly or birth defect	Yes <input type="radio"/> No <input checked="" type="radio"/>
Other medically important event	Yes <input type="radio"/> No <input checked="" type="radio"/>
Investigator's First Name	RICHARD
Investigator's Last Name	RUPP
Site Address: Street	301 UNIVERSITY BLVD
Site Address: City	GALVESTON
Site Address: State	TX
Site Address: Postal Code	77555
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	3
Date of submission (Pre-filled from custom function)	21/APR/2021 10:26
Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.	True

US3612005

Folder: SAE USA-US129-2021-MRNA-1273-P301000006

Form: Safety Report Form (2)

Generated On: 10 Jun 2021 09:15:23

SAEID	USA-US129-2021-MRNA-1273-P301000006
Serious	Yes <input checked="" type="radio"/> No <input type="radio"/>
Death	Yes <input type="radio"/> No <input checked="" type="radio"/>
Life threatening	Yes <input checked="" type="radio"/> No <input type="radio"/>
Requires inpatient or prolongation of existing Hospitalization	Yes <input checked="" type="radio"/> No <input type="radio"/>
Persistent or significant disability or incapacity	Yes <input type="radio"/> No <input checked="" type="radio"/>
Congenital anomaly or birth defect	Yes <input type="radio"/> No <input checked="" type="radio"/>
Other medically important event	Yes <input type="radio"/> No <input checked="" type="radio"/>
Investigator's First Name	RICHARD
Investigator's Last Name	RUPP
Site Address: Street	301 UNIVERSITY BLVD
Site Address: City	GALVESTON
Site Address: State	TX
Site Address: Postal Code	77555
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	3
Date of submission (Pre-filled from custom function)	23/APR/2021 12:24
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

US3612005

Folder: SAE USA-US129-2021-MRNA-1273-P301000006

Form: Safety Report Form (3)

Generated On: 10 Jun 2021 09:15:23

SAEID	USA-US129-2021-MRNA-1273-P301000006
Serious	Yes <input checked="" type="radio"/> No <input type="radio"/>
Death	Yes <input type="radio"/> No <input checked="" type="radio"/>
Life threatening	Yes <input checked="" type="radio"/> No <input type="radio"/>
Requires inpatient or prolongation of existing Hospitalization	Yes <input checked="" type="radio"/> No <input type="radio"/>
Persistent or significant disability or incapacity	Yes <input type="radio"/> No <input checked="" type="radio"/>
Congenital anomaly or birth defect	Yes <input type="radio"/> No <input checked="" type="radio"/>
Other medically important event	Yes <input type="radio"/> No <input checked="" type="radio"/>
Investigator's First Name	RICHARD
Investigator's Last Name	RUPP
Site Address: Street	301 UNIVERSITY BLVD
Site Address: City	GALVESTON
Site Address: State	TX
Site Address: Postal Code	77555
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	3
Date of submission (Pre-filled from custom function)	03/MAY/2021 10:24
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

US3612005 (Prod: University of Texas- Galveston)

**US3612005**

**Form: Participant Creation**

**Generated On: 10 Jun 2021 09:15:23**

[Participant ID](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Rupp (b) (4)	26 Mar 2021 18:58:13
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Sep 2020 18:01:38
User entered 'US3612005'	RWS_ENDPOINT ENDPOINT (b) (4)	01 Sep 2020 15:13:51

**US3612005**

**Folder: Screening**

**Form: Visit Date**

**Generated On: 10 Jun 2021 09:15:23**

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:08:19
User signature succeeded.	Richard Rupp (b) (4)	05 Mar 2021 19:39:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Sep 2020 18:01:53
User entered 'Yes (Y)'	Gerianne Casey (b) (4) (b) (4)	01 Sep 2020 15:23:17

US3612005

Folder: Screening

Form: Visit Date

Generated On: 10 Jun 2021 09:15:23

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:08:19
User signature succeeded.	Richard Rupp (b) (4)	05 Mar 2021 19:39:45
DataPoint Verified.	(b) (4)	09 Sep 2020 18:01:53
User entered '01 SEP 2020'	RWS_ENDPOINT ENDPOINT (b) (4)	01 Sep 2020 15:13:52

**US3612005**

**Folder: Screening**

**Form: Visit Date**

**Generated On: 10 Jun 2021 09:15:23**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:08:19
User signature succeeded.	Richard Rupp (b) (4)	05 Mar 2021 19:39:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Sep 2020 18:01:53
User entered 'Clinic (Clinic)'	Gerianne Casey (b) (4) (b) (4)	01 Sep 2020 15:23:17

**US3612005**

**Folder: Screening**

**Form: Visit Date**

**Generated On: 10 Jun 2021 09:15:23**

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:08:19
User entered 'SCRN'	System	01 Sep 2020 15:23:17

**US3612005**

**Folder: Screening**

**Form: Demographics**

**Generated On: 10 Jun 2021 09:15:23**

[Date of Birth \(MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:08:19
User signature succeeded.	Richard Rupp (b) (4)	05 Mar 2021 19:39:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Sep 2020 18:02:04
User entered (b) (6) 1945'	RWS_ENDPOINT ENDPOINT (b) (4)	01 Sep 2020 15:13:53

**US3612005**

**Folder: Screening**

**Form: Demographics**

**Generated On: 10 Jun 2021 09:15:23**

[Age](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:08:19
User signature succeeded.	Richard Rupp (b) (4)	05 Mar 2021 19:39:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Sep 2020 18:02:04
User entered '75'	Gerianne Casey (b) (4) (b) (4)	01 Sep 2020 15:23:40

**US3612005**

**Folder: Screening**

**Form: Demographics**

**Generated On: 10 Jun 2021 09:15:23**

[Age Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:08:19
User entered 'YEARS'	System	01 Sep 2020 15:23:40

**US3612005**

**Folder: Screening**

**Form: Demographics**

**Generated On: 10 Jun 2021 09:15:23**

[Age \(Derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:08:19
User entered '75'	System	01 Sep 2020 15:25:27

**US3612005**

**Folder: Screening**

**Form: Demographics**

**Generated On: 10 Jun 2021 09:15:23**

[Sex](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:08:19
User signature succeeded.	Richard Rupp (b) (4)	05 Mar 2021 19:39:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Sep 2020 18:02:04
User entered 'Male (M)'	Gerianne Casey (b) (4) (b) (4)	01 Sep 2020 15:23:40

**US3612005**

**Folder: Screening**

**Form: Demographics**

**Generated On: 10 Jun 2021 09:15:23**

[Ethnicity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:08:19
User signature succeeded.	Richard Rupp (b) (4)	05 Mar 2021 19:39:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Sep 2020 18:02:04
User entered 'Not Hispanic or Latino (NOT HISPANIC OR LATINO)'	Gerianne Casey (b) (4) (b) (4)	01 Sep 2020 15:23:40

**US3612005**

**Folder: Screening**

**Form: Demographics**

**Generated On: 10 Jun 2021 09:15:23**

[White](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:08:19
User signature succeeded.	Richard Rupp (b) (4)	05 Mar 2021 19:39:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Sep 2020 18:02:04
User entered 'I'	Gerianne Casey (b) (4) (b) (4)	01 Sep 2020 15:23:40

**US3612005**

**Folder: Screening**

**Form: Demographics**

**Generated On: 10 Jun 2021 09:15:23**

[Black](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:08:19
User signature succeeded.	Richard Rupp (b) (4)	05 Mar 2021 19:39:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Sep 2020 18:02:04
User entered '0'	Gerianne Casey (b) (4) (b) (4)	01 Sep 2020 15:23:40

**US3612005**

**Folder: Screening**

**Form: Demographics**

**Generated On: 10 Jun 2021 09:15:23**

[Asian](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:08:19
User signature succeeded.	Richard Rupp (b) (4)	05 Mar 2021 19:39:45
DataPoint Verified.	(b) (4)	09 Sep 2020 18:02:04
User entered '0'	Gerianne Casey (b) (4)	01 Sep 2020 15:23:40

**US3612005**

**Folder: Screening**

**Form: Demographics**

**Generated On: 10 Jun 2021 09:15:23**

[American Indian or Alaska Native](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:08:19
User signature succeeded.	Richard Rupp (b) (4)	05 Mar 2021 19:39:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Sep 2020 18:02:04
User entered '0'	Gerianne Casey (b) (4) (b) (4)	01 Sep 2020 15:23:40

**US3612005**

**Folder: Screening**

**Form: Demographics**

**Generated On: 10 Jun 2021 09:15:23**

[Native Hawaiian or other Pacific Islander](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:08:19
User signature succeeded.	Richard Rupp (b) (4)	05 Mar 2021 19:39:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Sep 2020 18:02:04
User entered '0'	Gerianne Casey (b) (4) (b) (4)	01 Sep 2020 15:23:40

**US3612005**

**Folder: Screening**

**Form: Demographics**

**Generated On: 10 Jun 2021 09:15:23**

[Other](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:08:19
User signature succeeded.	Richard Rupp (b) (4)	05 Mar 2021 19:39:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Sep 2020 18:02:04
User entered '0'	Gerianne Casey (b) (4) (b) (4)	01 Sep 2020 15:23:40

**US3612005**

**Folder: Screening**

**Form: Demographics**

**Generated On: 10 Jun 2021 09:15:23**

[If race is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:08:19
User signature succeeded.	Richard Rupp (b) (4)	05 Mar 2021 19:39:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Sep 2020 18:02:04
User entered empty.	Gerianne Casey (b) (4) (b) (4)	01 Sep 2020 15:23:40

**US3612005**

**Folder: Screening**

**Form: Demographics**

**Generated On: 10 Jun 2021 09:15:23**

[Unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:08:19
User signature succeeded.	Richard Rupp (b) (4)	05 Mar 2021 19:39:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Sep 2020 18:02:04
User entered '0'	Gerianne Casey (b) (4) (b) (4)	01 Sep 2020 15:23:40

**US3612005**

**Folder: Screening**

**Form: Demographics**

**Generated On: 10 Jun 2021 09:15:23**

[Not reported](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:08:19
User signature succeeded.	Richard Rupp (b) (4)	05 Mar 2021 19:39:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Sep 2020 18:02:04
User entered '0'	Gerianne Casey (b) (4) (b) (4)	01 Sep 2020 15:23:40

**US3612005**

**Folder: Screening**

**Form: Enrollment**

**Generated On: 10 Jun 2021 09:15:23**

[Date of Informed Consent \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:08:19
User signature succeeded.	Richard Rupp (b) (4)	05 Mar 2021 19:39:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Sep 2020 18:02:41
User entered '01 Sep 2020'	Gerianne Casey (b) (4) (b) (4)	01 Sep 2020 15:25:27

**US3612005**

**Folder: Screening**

**Form: Enrollment**

**Generated On: 10 Jun 2021 09:15:23**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:08:19
User entered 'Sep 2020'	System	01 Sep 2020 15:25:27

**US3612005**

**Folder: Screening**

**Form: Enrollment**

**Generated On: 10 Jun 2021 09:15:23**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:08:19
User entered '2020'	System	01 Sep 2020 15:25:27

**US3612005**

**Folder: Screening**

**Form: Enrollment**

**Generated On: 10 Jun 2021 09:15:23**

[Protocol Version](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:08:19
User signature succeeded.	Richard Rupp (b) (4)	05 Mar 2021 19:39:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Sep 2020 18:02:41
User entered 'Amendment 2 (2)'	Gerianne Casey (b) (4) (b) (4)	01 Sep 2020 15:25:27

**US3612005**

**Folder: Screening**

**Form: Enrollment**

**Generated On: 10 Jun 2021 09:15:23**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:08:19
User signature succeeded.	Richard Rupp (b) (4)	05 Mar 2021 19:39:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Sep 2020 18:02:41
User entered 'Yes (Y)'	Gerianne Casey (b) (4) (b) (4)	01 Sep 2020 15:25:27

**US3612005**

**Folder: Screening**

**Form: Enrollment**

**Generated On: 10 Jun 2021 09:15:23**

[If No, indicate reason for screen fail](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:08:19
User signature succeeded.	Richard Rupp (b) (4)	05 Mar 2021 19:39:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Sep 2020 18:02:41
User entered empty.	Gerianne Casey (b) (4) (b) (4)	01 Sep 2020 15:25:27

**US3612005**

**Folder: Screening**

**Form: Enrollment**

**Generated On: 10 Jun 2021 09:15:23**

If reason for screen fail is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:08:19
User signature succeeded.	Richard Rupp (b) (4)	05 Mar 2021 19:39:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Sep 2020 18:02:41
User entered empty.	Gerianne Casey (b) (4) (b) (4)	01 Sep 2020 15:25:27

**US3612005**

**Folder: Screening**

**Form: Enrollment**

**Generated On: 10 Jun 2021 09:15:23**

[Was this participant screened previously?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:08:19
User signature succeeded.	Richard Rupp (b) (4)	05 Mar 2021 19:39:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Sep 2020 18:02:41
User entered 'No (N)'	Gerianne Casey (b) (4) (b) (4)	01 Sep 2020 15:25:27

**US3612005**

**Folder: Screening**

**Form: Enrollment**

**Generated On: 10 Jun 2021 09:15:23**

[If Yes, previous participant number](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:08:19
User signature succeeded.	Richard Rupp (b) (4)	05 Mar 2021 19:39:45
DataPoint Verified.	(b) (4)	09 Sep 2020 18:02:41
User entered empty.	RWS_ENDPOINT ENDPOINT (b) (4)	01 Sep 2020 15:13:52

**US3612005**

**Folder: Screening**

**Form: Enrollment**

**Generated On: 10 Jun 2021 09:15:23**

[Enrollment Trigger](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:08:19
User entered 'I'	System	01 Sep 2020 15:25:33

**US3612005**

**Folder: Screening**

**Form: Inclusion/Exclusion Criteria Summary**

**Generated On: 10 Jun 2021 09:15:23**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:08:19
User signature succeeded.	Richard Rupp (b) (4)	05 Mar 2021 19:39:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Sep 2020 18:02:50
User entered 'Yes (Y)'	Gerianne Casey (b) (4) (b) (4)	01 Sep 2020 15:25:33

**US3612005**

**Folder: Screening**

**Form: Medical History Summary**

**Generated On: 10 Jun 2021 09:15:23**

[Were any significant conditions reported?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:08:19
User signature succeeded.	Richard Rupp (b) (4)	05 Mar 2021 19:39:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Sep 2020 18:02:57
User entered 'Yes (Y)'	Gerianne Casey (b) (4) (b) (4)	01 Sep 2020 15:25:44

US3612005

Folder: Screening

Form: Medical History (1)

Generated On: 10 Jun 2021 09:15:23

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:08:19
User signature succeeded.	Richard Rupp (b) (4)	05 Mar 2021 19:39:45
User closed query 'Sepsis and Cardiac arrest noted in source but are lined through, also the patient has a surgery admission on 29DEC2007 with a cardiologist. should sepsis and cardiac arrest be listed in the patient's medical Hx?' (Site from CRA).	(b) (4) (b) (4), (b) (6)	16 Sep 2020 17:29:51
Query 'Sepsis and Cardiac arrest noted in source but are lined through, also the patient has a surgery admission on 29DEC2007 with a cardiologist. should sepsis and cardiac arrest be listed in the patient's medical Hx?' answered with 'Completed' (Site from CRA).	Amy McMahan (b) (4) (b) (4)	15 Sep 2020 19:18:19
User opened query 'Sepsis and Cardiac arrest noted in source but are lined through, also the patient has a surgery admission on 29DEC2007 with a cardiologist. should sepsis and cardiac arrest be listed in the patient's medical Hx?' (Site from CRA).	(b) (4), (b) (6)	09 Sep 2020 18:05:37
DataPoint Verified.	(b) (4), (b) (6)	09 Sep 2020 18:03:29
User coded data point as SOC: Renal and urinary disorders, HLT: Urolithiasis, HLT: Renal lithiasis, PT: Nephrolithiasis, LLT: Kidney stones - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	01 Sep 2020 16:07:47
User coded data point as Term Coded data point by User: Coder System - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	01 Sep 2020 16:07:47
Data point term sent to Coder	System	01 Sep 2020 16:06:37
User entered 'kidney stones'	Gerianne Casey (b) (4) (b) (4)	01 Sep 2020 16:06:11

**US3612005**

**Folder: Screening**

**Form: Medical History (1)**

**Generated On: 10 Jun 2021 09:15:23**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:08:19
User signature succeeded.	Richard Rupp (b) (4)	05 Mar 2021 19:39:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Sep 2020 18:03:29
User entered '15 Jul 1981'	Gerianne Casey (b) (4) (b) (4)	01 Sep 2020 16:06:11

**US3612005**

**Folder: Screening**

**Form: Medical History (1)**

**Generated On: 10 Jun 2021 09:15:23**

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:08:19
User signature succeeded.	Richard Rupp (b) (4)	05 Mar 2021 19:39:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Sep 2020 18:03:29
User entered '0'	Gerianne Casey (b) (4) (b) (4)	01 Sep 2020 16:06:11

**US3612005**

**Folder: Screening**

**Form: Medical History (1)**

**Generated On: 10 Jun 2021 09:15:23**

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:08:19
User signature succeeded.	Richard Rupp (b) (4)	05 Mar 2021 19:39:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Sep 2020 18:03:29
User entered 'Yes (Y)'	Gerianne Casey (b) (4) (b) (4)	01 Sep 2020 16:06:11

**US3612005**

**Folder: Screening**

**Form: Medical History (1)**

**Generated On: 10 Jun 2021 09:15:23**

[If No, please specify the stop date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:08:19
User signature succeeded.	Richard Rupp (b) (4)	05 Mar 2021 19:39:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Sep 2020 18:03:29
User entered empty.	Gerianne Casey (b) (4) (b) (4)	01 Sep 2020 16:06:11

**US3612005**

**Folder: Screening**

**Form: Medical History (1)**

**Generated On: 10 Jun 2021 09:15:23**

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:08:19
User signature succeeded.	Richard Rupp (b) (4)	05 Mar 2021 19:39:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Sep 2020 18:03:29
User entered '0'	Gerianne Casey (b) (4) (b) (4)	01 Sep 2020 16:06:11

**US3612005**

**Folder: Screening**

**Form: Medical History (1)**

**Generated On: 10 Jun 2021 09:15:23**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:08:19
User entered 'Jul 1981'	System	01 Sep 2020 16:06:11

**US3612005**

**Folder: Screening**

**Form: Medical History (1)**

**Generated On: 10 Jun 2021 09:15:23**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:08:19
User entered '1981'	System	01 Sep 2020 16:06:11

**US3612005**

**Folder: Screening**

**Form: Medical History (1)**

**Generated On: 10 Jun 2021 09:15:23**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:08:19
User entered empty.	System	01 Sep 2020 16:06:11

**US3612005**

**Folder: Screening**

**Form: Medical History (1)**

**Generated On: 10 Jun 2021 09:15:23**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:08:19
User entered empty.	System	01 Sep 2020 16:06:11

US3612005

Folder: Screening

Form: Medical History (2)

Generated On: 10 Jun 2021 09:15:23

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:08:19
User signature succeeded.	Richard Rupp (b) (4)	05 Mar 2021 19:39:45
DataPoint Verified.	(b) (4)	09 Sep 2020 18:03:29
User coded data point as SOC: Vascular disorders, HLGT: Embolism and thrombosis, HLT: Non-site specific embolism and thrombosis, PT: Thrombosis, LLT: Clot blood - version MedDRA\\23.0.	Coder Import (b) (4)	01 Sep 2020 16:10:51
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	01 Sep 2020 16:10:51
Data point term sent to Coder	System	01 Sep 2020 16:09:44
User entered 'Blood Clots'	Gerianne Casey (b) (4)	01 Sep 2020 16:09:35

**US3612005**

**Folder: Screening**

**Form: Medical History (2)**

**Generated On: 10 Jun 2021 09:15:23**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:08:19
User signature succeeded.	Richard Rupp (b) (4)	05 Mar 2021 19:39:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Sep 2020 18:03:29
User entered '15 Jul 2005'	Gerianne Casey (b) (4) (b) (4)	01 Sep 2020 16:09:35

**US3612005**

**Folder: Screening**

**Form: Medical History (2)**

**Generated On: 10 Jun 2021 09:15:23**

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:08:19
User signature succeeded.	Richard Rupp (b) (4)	05 Mar 2021 19:39:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Sep 2020 18:03:29
User entered '0'	Gerianne Casey (b) (4) (b) (4)	01 Sep 2020 16:09:35

**US3612005**

**Folder: Screening**

**Form: Medical History (2)**

**Generated On: 10 Jun 2021 09:15:23**

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:08:19
User signature succeeded.	Richard Rupp (b) (4)	05 Mar 2021 19:39:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Sep 2020 18:03:29
User entered 'No (N)'	Gerianne Casey (b) (4) (b) (4)	01 Sep 2020 16:09:35

**US3612005**

**Folder: Screening**

**Form: Medical History (2)**

**Generated On: 10 Jun 2021 09:15:23**

[If No, please specify the stop date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:08:19
User signature succeeded.	Richard Rupp (b) (4)	05 Mar 2021 19:39:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Sep 2020 18:03:29
User entered empty.	Gerianne Casey (b) (4) (b) (4)	01 Sep 2020 16:09:35

**US3612005**

**Folder: Screening**

**Form: Medical History (2)**

**Generated On: 10 Jun 2021 09:15:23**

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:08:19
User signature succeeded.	Richard Rupp (b) (4)	05 Mar 2021 19:39:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Sep 2020 18:03:29
User entered 'I'	Gerianne Casey (b) (4) (b) (4)	01 Sep 2020 16:09:35

**US3612005**

**Folder: Screening**

**Form: Medical History (2)**

**Generated On: 10 Jun 2021 09:15:23**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:08:19
User entered 'Jul 2005'	System	01 Sep 2020 16:09:35

**US3612005**

**Folder: Screening**

**Form: Medical History (2)**

**Generated On: 10 Jun 2021 09:15:23**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:08:19
User entered '2005'	System	01 Sep 2020 16:09:35

**US3612005**

**Folder: Screening**

**Form: Medical History (2)**

**Generated On: 10 Jun 2021 09:15:23**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:08:19
User entered empty.	System	01 Sep 2020 16:09:35

**US3612005**

**Folder: Screening**

**Form: Medical History (2)**

**Generated On: 10 Jun 2021 09:15:23**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:08:19
User entered empty.	System	01 Sep 2020 16:09:35

US3612005

Folder: Screening

Form: Medical History (3)

Generated On: 10 Jun 2021 09:15:23

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:08:19
User signature succeeded.	Richard Rupp (b) (4)	05 Mar 2021 19:39:45
DataPoint Verified.	(b) (4)	09 Sep 2020 18:03:29
User coded data point as SOC: Investigations, HLT: Lipid analyses, HLT: Cholesterol analyses, PT: Blood cholesterol increased, LLT: High cholesterol - version MedDRA\\23.0.	Coder Import (b) (4)	01 Sep 2020 16:11:46
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	01 Sep 2020 16:11:46
Data point term sent to Coder	System	01 Sep 2020 16:10:44
User entered 'high cholesterol'	Gerianne Casey (b) (4)	01 Sep 2020 16:10:18

US3612005

Folder: Screening

Form: Medical History (3)

Generated On: 10 Jun 2021 09:15:23

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:08:19
DataPoint Verified.	(b) (4), (b) (6)	11 Mar 2021 16:06:34
User signature succeeded.	Richard Rupp (b) (4)	05 Mar 2021 19:39:45
DataPoint Un-verified.	(b) (4)	
	Amber Stanford (b) (4)	28 Oct 2020 19:01:08
User entered '15 Feb 2019' reason for change: Data Entry Error	(b) (4)	28 Oct 2020 19:01:08
DataPoint Verified.	(b) (4), (b) (6)	09 Sep 2020 18:03:29
User entered '15 Jul 2019'	Gerianne Casey (b) (4)	01 Sep 2020 16:10:18
	(b) (4)	

**US3612005**

**Folder: Screening**

**Form: Medical History (3)**

**Generated On: 10 Jun 2021 09:15:23**

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:08:19
User signature succeeded.	Richard Rupp (b) (4)	05 Mar 2021 19:39:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Sep 2020 18:03:29
User entered '0'	Gerianne Casey (b) (4) (b) (4)	01 Sep 2020 16:10:18

**US3612005**

**Folder: Screening**

**Form: Medical History (3)**

**Generated On: 10 Jun 2021 09:15:23**

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:08:19
User signature succeeded.	Richard Rupp (b) (4)	05 Mar 2021 19:39:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Sep 2020 18:03:29
User entered 'Yes (Y)'	Gerianne Casey (b) (4) (b) (4)	01 Sep 2020 16:10:18

**US3612005**

**Folder: Screening**

**Form: Medical History (3)**

**Generated On: 10 Jun 2021 09:15:23**

[If No, please specify the stop date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:08:19
User signature succeeded.	Richard Rupp (b) (4)	05 Mar 2021 19:39:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Sep 2020 18:03:29
User entered empty.	Gerianne Casey (b) (4) (b) (4)	01 Sep 2020 16:10:18

**US3612005**

**Folder: Screening**

**Form: Medical History (3)**

**Generated On: 10 Jun 2021 09:15:23**

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:08:19
User signature succeeded.	Richard Rupp (b) (4)	05 Mar 2021 19:39:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Sep 2020 18:03:29
User entered '0'	Gerianne Casey (b) (4) (b) (4)	01 Sep 2020 16:10:18

**US3612005**

**Folder: Screening**

**Form: Medical History (3)**

**Generated On: 10 Jun 2021 09:15:23**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:08:19
User entered 'Feb 2019'	System	28 Oct 2020 19:01:08
User entered 'Jul 2019'	System	01 Sep 2020 16:10:18

**US3612005**

**Folder: Screening**

**Form: Medical History (3)**

**Generated On: 10 Jun 2021 09:15:23**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:08:19
User entered '2019'	System	01 Sep 2020 16:10:18

**US3612005**

**Folder: Screening**

**Form: Medical History (3)**

**Generated On: 10 Jun 2021 09:15:23**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:08:19
User entered empty.	System	01 Sep 2020 16:10:18

**US3612005**

**Folder: Screening**

**Form: Medical History (3)**

**Generated On: 10 Jun 2021 09:15:23**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:08:19
User entered empty.	System	01 Sep 2020 16:10:18

US3612005

Folder: Screening

Form: Medical History (4)

Generated On: 10 Jun 2021 09:15:23

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:08:19
User signature succeeded.	Richard Rupp (b) (4)	05 Mar 2021 19:39:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Sep 2020 17:30:46
User coded data point as SOC: Infections and infestations, HLGT: Infections - pathogen unspecified, HLT: Sepsis, bacteraemia, viraemia and fungaemia NEC, PT: Sepsis, LLT: Sepsis - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	10 Sep 2020 18:15:53
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	10 Sep 2020 18:15:53
Data point term sent to Coder	System	10 Sep 2020 18:14:55
User entered 'Sepsis'	Gerianne Casey (b) (4) (b) (4)	10 Sep 2020 18:14:44

**US3612005**

**Folder: Screening**

**Form: Medical History (4)**

**Generated On: 10 Jun 2021 09:15:23**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:08:19
User signature succeeded.	Richard Rupp (b) (4)	05 Mar 2021 19:39:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Sep 2020 17:30:48
User entered 'un UNK 2018'	Gerianne Casey (b) (4) (b) (4)	10 Sep 2020 18:14:44

**US3612005**

**Folder: Screening**

**Form: Medical History (4)**

**Generated On: 10 Jun 2021 09:15:23**

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:08:19
User signature succeeded.	Richard Rupp (b) (4)	05 Mar 2021 19:39:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Sep 2020 17:30:50
User entered '0'	Gerianne Casey (b) (4) (b) (4)	10 Sep 2020 18:14:44

**US3612005**

**Folder: Screening**

**Form: Medical History (4)**

**Generated On: 10 Jun 2021 09:15:23**

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:08:19
User signature succeeded.	Richard Rupp (b) (4)	05 Mar 2021 19:39:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Sep 2020 17:30:52
User entered 'No (N)'	Gerianne Casey (b) (4) (b) (4)	10 Sep 2020 18:14:44

**US3612005**

**Folder: Screening**

**Form: Medical History (4)**

**Generated On: 10 Jun 2021 09:15:23**

[If No, please specify the stop date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:08:19
User signature succeeded.	Richard Rupp (b) (4)	05 Mar 2021 19:39:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Sep 2020 17:30:54
User entered 'un UNK 2018'	Gerianne Casey (b) (4) (b) (4)	10 Sep 2020 18:14:44

**US3612005**

**Folder: Screening**

**Form: Medical History (4)**

**Generated On: 10 Jun 2021 09:15:23**

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:08:19
User signature succeeded.	Richard Rupp (b) (4)	05 Mar 2021 19:39:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Sep 2020 17:30:56
User entered '0'	Gerianne Casey (b) (4) (b) (4)	10 Sep 2020 18:14:44

**US3612005**

**Folder: Screening**

**Form: Medical History (4)**

**Generated On: 10 Jun 2021 09:15:23**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:08:19
User entered 'Jan 2018'	System	10 Sep 2020 18:14:44

**US3612005**

**Folder: Screening**

**Form: Medical History (4)**

**Generated On: 10 Jun 2021 09:15:23**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:08:19
User entered '2018'	System	10 Sep 2020 18:14:44

**US3612005**

**Folder: Screening**

**Form: Medical History (4)**

**Generated On: 10 Jun 2021 09:15:23**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:08:19
User entered 'Jan 2018'	System	10 Sep 2020 18:14:44

**US3612005**

**Folder: Screening**

**Form: Medical History (4)**

**Generated On: 10 Jun 2021 09:15:23**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:08:19
User entered '2018'	System	10 Sep 2020 18:14:44

US3612005

Folder: Screening

Form: Medical History (5)

Generated On: 10 Jun 2021 09:15:23

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:08:19
User signature succeeded.	Richard Rupp (b) (4)	05 Mar 2021 19:39:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Sep 2020 17:30:23
User coded data point as SOC: Cardiac disorders, HLGT: Cardiac arrhythmias, HLT: Ventricular arrhythmias and cardiac arrest, PT: Cardiac arrest, LLT: Cardiac arrest - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	10 Sep 2020 18:16:46
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	10 Sep 2020 18:16:46
Data point term sent to Coder	System	10 Sep 2020 18:15:58
User entered 'cardiac arrest'	Gerianne Casey (b) (4) (b) (4)	10 Sep 2020 18:15:22

US3612005

Folder: Screening

Form: Medical History (5)

Generated On: 10 Jun 2021 09:15:23

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:08:19
User signature succeeded.	Richard Rupp (b) (4)	05 Mar 2021 19:39:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Sep 2020 17:30:25
User closed query 'Data entered is non-conformant. Please correct.' (Site from System).	System	10 Sep 2020 18:15:51
User entered '28 Dec 2007' reason for change: Data Entry Error	Gerianne Casey (b) (4) (b) (4)	10 Sep 2020 18:15:51
User opened query 'Data entered is non-conformant. Please correct.' (Site from System).	System	10 Sep 2020 18:15:22
User entered '28 Dec ' (non-conformant).	Gerianne Casey (b) (4) (b) (4)	10 Sep 2020 18:15:22

**US3612005**

**Folder: Screening**

**Form: Medical History (5)**

**Generated On: 10 Jun 2021 09:15:23**

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:08:19
User signature succeeded.	Richard Rupp (b) (4)	05 Mar 2021 19:39:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Sep 2020 17:30:27
User entered '0'	Gerianne Casey (b) (4) (b) (4)	10 Sep 2020 18:15:22

US3612005

Folder: Screening

Form: Medical History (5)

Generated On: 10 Jun 2021 09:15:23

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:08:19
User signature succeeded.	Richard Rupp (b) (4)	05 Mar 2021 19:39:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Sep 2020 17:30:29
User closed query 'Data is required. Please complete.' (Site from System).	System	10 Sep 2020 18:25:38
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	10 Sep 2020 18:25:38
User entered 'No (N)' reason for change: Data Entry Error	Gerianne Casey (b) (4) (b) (4)	10 Sep 2020 18:25:38
User opened query 'Data is required. Please complete.' (Site from System).	System	10 Sep 2020 18:15:22
User entered empty.	Gerianne Casey (b) (4) (b) (4)	10 Sep 2020 18:15:22

**US3612005**

**Folder: Screening**

**Form: Medical History (5)**

**Generated On: 10 Jun 2021 09:15:23**

[If No, please specify the stop date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:08:19
User signature succeeded.	Richard Rupp (b) (4)	05 Mar 2021 19:39:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Sep 2020 17:30:31
User entered '28 Dec 2007' reason for change: Data Entry Error	Gerianne Casey (b) (4)	10 Sep 2020 18:15:51
User entered empty.	(b) (4) Gerianne Casey (b) (4) (b) (4)	10 Sep 2020 18:15:22

**US3612005**

**Folder: Screening**

**Form: Medical History (5)**

**Generated On: 10 Jun 2021 09:15:23**

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:08:19
User signature succeeded.	Richard Rupp (b) (4)	05 Mar 2021 19:39:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Sep 2020 17:30:34
User entered '0'	Gerianne Casey (b) (4) (b) (4)	10 Sep 2020 18:15:22

**US3612005**

**Folder: Screening**

**Form: Medical History (5)**

**Generated On: 10 Jun 2021 09:15:23**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:08:19
User entered 'Dec 2007'	System	10 Sep 2020 18:15:51
User entered empty.	System	10 Sep 2020 18:15:22

**US3612005**

**Folder: Screening**

**Form: Medical History (5)**

**Generated On: 10 Jun 2021 09:15:23**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:08:19
User entered '2007'	System	10 Sep 2020 18:15:51
User entered empty.	System	10 Sep 2020 18:15:22

**US3612005**

**Folder: Screening**

**Form: Medical History (5)**

**Generated On: 10 Jun 2021 09:15:23**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:08:19
User entered 'Dec 2007'	System	10 Sep 2020 18:15:51
User entered empty.	System	10 Sep 2020 18:15:22

**US3612005**

**Folder: Screening**

**Form: Medical History (5)**

**Generated On: 10 Jun 2021 09:15:23**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:08:19
User entered '2007'	System	10 Sep 2020 18:15:51
User entered empty.	System	10 Sep 2020 18:15:22

US3612005

Folder: Screening

Form: Medical History (6)

Generated On: 10 Jun 2021 09:15:23

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:08:19
User signature succeeded.	Richard Rupp (b) (4)	05 Mar 2021 19:39:45
User closed query 'Per DM CLR: Please review and ensure the associated condition which led to this procedure is also captured in the Med History eCRF. Please verify and update as appropriate.' (Site from DM).	(b) (4) (b) (4), (b) (6)	07 Oct 2020 12:55:34
Query 'Per DM CLR: Please review and ensure the associated condition which led to this procedure is also captured in the Med History eCRF. Please verify and update as appropriate.' answered with 'Updated' (Site from DM).	Amy McMahan (b) (4) (b) (4)	06 Oct 2020 14:52:50
User opened query 'Per DM CLR: Please review and ensure the associated condition which led to this procedure is also captured in the Med History eCRF. Please verify and update as appropriate.' (Site from DM).	(b) (4), (b) (6)	02 Oct 2020 08:22:17
DataPoint Verified.	(b) (4), (b) (6)	22 Sep 2020 14:49:55
User coded data point as SOC: Investigations, HLGT: Musculoskeletal and soft tissue investigations (excl enzyme tests), HLT: Musculoskeletal and soft tissue imaging procedures, PT: Arthroscopy, LLT: Arthroscopy R knee - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	10 Sep 2020 18:17:50
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	10 Sep 2020 18:17:50
Data point term sent to Coder	System	10 Sep 2020 18:17:02
User entered 'Right knee arthroscopy'	Gerianne Casey (b) (4) (b) (4)	10 Sep 2020 18:16:41

**US3612005**

**Folder: Screening**

**Form: Medical History (6)**

**Generated On: 10 Jun 2021 09:15:23**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:08:19
User signature succeeded.	Richard Rupp (b) (4)	05 Mar 2021 19:39:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Sep 2020 14:49:55
User entered 'un Jun 2010'	Gerianne Casey (b) (4) (b) (4)	10 Sep 2020 18:16:41

**US3612005**

**Folder: Screening**

**Form: Medical History (6)**

**Generated On: 10 Jun 2021 09:15:23**

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:08:19
User signature succeeded.	Richard Rupp (b) (4)	05 Mar 2021 19:39:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Sep 2020 14:49:55
User entered '0'	Gerianne Casey (b) (4) (b) (4)	10 Sep 2020 18:16:41

**US3612005**

**Folder: Screening**

**Form: Medical History (6)**

**Generated On: 10 Jun 2021 09:15:23**

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:08:19
User signature succeeded.	Richard Rupp (b) (4)	05 Mar 2021 19:39:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Sep 2020 14:49:55
User entered 'No (N)'	Gerianne Casey (b) (4) (b) (4)	10 Sep 2020 18:16:41

US3612005

Folder: Screening

Form: Medical History (6)

Generated On: 10 Jun 2021 09:15:23

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:08:19
User signature succeeded.	Richard Rupp (b) (4)	05 Mar 2021 19:39:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Sep 2020 14:49:55
User closed query 'Stop date is prior to Start date. Please correct.' (Site from System).	System	10 Sep 2020 18:25:13
User entered 'UN Jun 2010' reason for change: Data Entry Error	Gerianne Casey (b) (4) (b) (4)	10 Sep 2020 18:25:13
User opened query 'Stop date is prior to Start date. Please correct.' (Site from System).	System	10 Sep 2020 18:16:41
User entered 'un Jun 2007'	Gerianne Casey (b) (4) (b) (4)	10 Sep 2020 18:16:41

**US3612005**

**Folder: Screening**

**Form: Medical History (6)**

**Generated On: 10 Jun 2021 09:15:23**

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:08:19
User signature succeeded.	Richard Rupp (b) (4)	05 Mar 2021 19:39:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Sep 2020 14:49:55
User entered '0'	Gerianne Casey (b) (4) (b) (4)	10 Sep 2020 18:16:41

**US3612005**

**Folder: Screening**

**Form: Medical History (6)**

**Generated On: 10 Jun 2021 09:15:23**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:08:19
User entered 'Jun 2010'	System	10 Sep 2020 18:16:41

**US3612005**

**Folder: Screening**

**Form: Medical History (6)**

**Generated On: 10 Jun 2021 09:15:23**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:08:19
User entered '2010'	System	10 Sep 2020 18:16:41

**US3612005**

**Folder: Screening**

**Form: Medical History (6)**

**Generated On: 10 Jun 2021 09:15:23**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:08:19
User entered 'Jun 2010'	System	10 Sep 2020 18:25:13
User entered 'Jun 2007'	System	10 Sep 2020 18:16:41

**US3612005**

**Folder: Screening**

**Form: Medical History (6)**

**Generated On: 10 Jun 2021 09:15:23**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:08:19
User entered '2010'	System	10 Sep 2020 18:25:13
User entered '2007'	System	10 Sep 2020 18:16:41

**US3612005**

**Folder: Screening**

**Form: Medical History (7)**

**Generated On: 10 Jun 2021 09:15:23**

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:08:19

**US3612005**

**Folder: Screening**

**Form: Medical History (7)**

**Generated On: 10 Jun 2021 09:15:23**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:08:19

**US3612005**

**Folder: Screening**

**Form: Medical History (7)**

**Generated On: 10 Jun 2021 09:15:23**

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:08:19

**US3612005**

**Folder: Screening**

**Form: Medical History (7)**

**Generated On: 10 Jun 2021 09:15:23**

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:08:19

**US3612005**

**Folder: Screening**

**Form: Medical History (7)**

**Generated On: 10 Jun 2021 09:15:23**

[If No, please specify the stop date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:08:19

**US3612005**

**Folder: Screening**

**Form: Medical History (7)**

**Generated On: 10 Jun 2021 09:15:23**

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:08:19

**US3612005**

**Folder: Screening**

**Form: Medical History (7)**

**Generated On: 10 Jun 2021 09:15:23**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:08:19

**US3612005**

**Folder: Screening**

**Form: Medical History (7)**

**Generated On: 10 Jun 2021 09:15:23**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:08:19

**US3612005**

**Folder: Screening**

**Form: Medical History (7)**

**Generated On: 10 Jun 2021 09:15:23**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:08:19

**US3612005**

**Folder: Screening**

**Form: Medical History (7)**

**Generated On: 10 Jun 2021 09:15:23**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:08:19

US3612005

Folder: Screening

Form: Medical History (8)

Generated On: 10 Jun 2021 09:15:23

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:08:19
User signature succeeded.	Richard Rupp (b) (4)	05 Mar 2021 19:39:45
User closed query 'Per DM CLR: Please review and ensure the associated condition which led to this procedure is also captured in the Med History eCRF. Please verify and update as appropriate.' (Site from DM).	(b) (4) (b) (4), (b) (6)	07 Oct 2020 12:55:50
Query 'Per DM CLR: Please review and ensure the associated condition which led to this procedure is also captured in the Med History eCRF. Please verify and update as appropriate.' answered with 'Updated' (Site from DM).	Amy McMahan (b) (4) (b) (4)	06 Oct 2020 14:53:32
User opened query 'Per DM CLR: Please review and ensure the associated condition which led to this procedure is also captured in the Med History eCRF. Please verify and update as appropriate.' (Site from DM).	(b) (4), (b) (6)	02 Oct 2020 08:23:08
DataPoint Verified.	(b) (4), (b) (6)	22 Sep 2020 14:49:55
User coded data point as SOC: Investigations, HLGT: Musculoskeletal and soft tissue investigations (excl enzyme tests), HLT: Musculoskeletal and soft tissue imaging procedures, PT: Arthroscopy, LLT: Arthroscopy L knee - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	10 Sep 2020 18:18:51
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	10 Sep 2020 18:18:51
Data point term sent to Coder	System	10 Sep 2020 18:18:05
User entered 'Left knee arthroscopy'	Gerianne Casey (b) (4) (b) (4)	10 Sep 2020 18:17:26

**US3612005**

**Folder: Screening**

**Form: Medical History (8)**

**Generated On: 10 Jun 2021 09:15:23**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:08:19
User signature succeeded.	Richard Rupp (b) (4)	05 Mar 2021 19:39:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Sep 2020 14:49:55
User entered '04 Aug 2010'	Gerianne Casey (b) (4) (b) (4)	10 Sep 2020 18:17:26

**US3612005**

**Folder: Screening**

**Form: Medical History (8)**

**Generated On: 10 Jun 2021 09:15:23**

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:08:19
User signature succeeded.	Richard Rupp (b) (4)	05 Mar 2021 19:39:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Sep 2020 14:49:55
User entered '0'	Gerianne Casey (b) (4) (b) (4)	10 Sep 2020 18:17:26

**US3612005**

**Folder: Screening**

**Form: Medical History (8)**

**Generated On: 10 Jun 2021 09:15:23**

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:08:19
User signature succeeded.	Richard Rupp (b) (4)	05 Mar 2021 19:39:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Sep 2020 14:49:55
User entered 'No (N)'	Gerianne Casey (b) (4) (b) (4)	10 Sep 2020 18:17:26

**US3612005**

**Folder: Screening**

**Form: Medical History (8)**

**Generated On: 10 Jun 2021 09:15:23**

[If No, please specify the stop date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:08:19
User signature succeeded.	Richard Rupp (b) (4)	05 Mar 2021 19:39:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Sep 2020 14:49:55
User entered '04 Aug 2010'	Gerianne Casey (b) (4) (b) (4)	10 Sep 2020 18:17:26

**US3612005**

**Folder: Screening**

**Form: Medical History (8)**

**Generated On: 10 Jun 2021 09:15:23**

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:08:19
User signature succeeded.	Richard Rupp (b) (4)	05 Mar 2021 19:39:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Sep 2020 14:49:55
User entered '0'	Gerianne Casey (b) (4) (b) (4)	10 Sep 2020 18:17:26

**US3612005**

**Folder: Screening**

**Form: Medical History (8)**

**Generated On: 10 Jun 2021 09:15:23**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:08:19
User entered 'Aug 2010'	System	10 Sep 2020 18:17:26

**US3612005**

**Folder: Screening**

**Form: Medical History (8)**

**Generated On: 10 Jun 2021 09:15:23**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:08:19
User entered '2010'	System	10 Sep 2020 18:17:26

**US3612005**

**Folder: Screening**

**Form: Medical History (8)**

**Generated On: 10 Jun 2021 09:15:23**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:08:19
User entered 'Aug 2010'	System	10 Sep 2020 18:17:26

**US3612005**

**Folder: Screening**

**Form: Medical History (8)**

**Generated On: 10 Jun 2021 09:15:23**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:08:19
User entered '2010'	System	10 Sep 2020 18:17:26

US3612005

Folder: Screening

Form: Medical History (9)

Generated On: 10 Jun 2021 09:15:23

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:08:19
User signature succeeded.	Richard Rupp (b) (4)	05 Mar 2021 19:39:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Oct 2020 15:04:34
User coded data point as SOC: Musculoskeletal and connective tissue disorders, HLGT: Joint disorders, HLT: Joint related signs and symptoms, PT: Arthralgia, LLT: Knee pain - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	06 Oct 2020 14:55:15
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	06 Oct 2020 14:55:15
Data point term sent to Coder	System	06 Oct 2020 14:54:04
User entered 'LEFT KNEE PAIN'	Amy McMahan (b) (4) (b) (4)	06 Oct 2020 14:53:06

**US3612005**

**Folder: Screening**

**Form: Medical History (9)**

**Generated On: 10 Jun 2021 09:15:23**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:08:19
User signature succeeded.	Richard Rupp (b) (4)	05 Mar 2021 19:39:45
DataPoint Verified.	(b) (4)	06 Oct 2020 15:04:34
User entered empty.	Amy McMahan (b) (4)	06 Oct 2020 14:53:06

**US3612005**

**Folder: Screening**

**Form: Medical History (9)**

**Generated On: 10 Jun 2021 09:15:23**

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:08:19
User signature succeeded.	Richard Rupp (b) (4)	05 Mar 2021 19:39:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Oct 2020 15:04:34
User entered 'I'	Amy McMahan (b) (4) (b) (4)	06 Oct 2020 14:53:06

US3612005

Folder: Screening

Form: Medical History (9)

Generated On: 10 Jun 2021 09:15:23

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:08:19
User signature succeeded.	Richard Rupp (b) (4)	05 Mar 2021 19:39:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Oct 2020 17:34:55
User closed query 'Source states that condition is not active/ongoing. Please review and reconcile. ' (Site from CRA).	(b) (4), (b) (6)	09 Oct 2020 17:34:53
Query 'Source states that condition is not active/ongoing. Please review and reconcile. ' answered with 'Updated' (Site from CRA).	Amy McMahan (b) (4) (b) (4)	06 Oct 2020 15:07:17
User entered 'No (N)' reason for change: Data Entry Error	Amy McMahan (b) (4) (b) (4)	06 Oct 2020 15:07:11
User opened query 'Source states that condition is not active/ongoing. Please review and reconcile. ' (Site from CRA).	(b) (4), (b) (6)	06 Oct 2020 15:05:42
DataPoint Un-verified.	(b) (4), (b) (6)	06 Oct 2020 15:05:32
DataPoint Verified.	(b) (4), (b) (6)	06 Oct 2020 15:05:30
DataPoint Un-verified.	(b) (4), (b) (6)	06 Oct 2020 15:05:28
DataPoint Verified.	(b) (4), (b) (6)	06 Oct 2020 15:04:34
User entered 'Yes (Y)'	Amy McMahan (b) (4) (b) (4)	06 Oct 2020 14:53:06

**US3612005**

**Folder: Screening**

**Form: Medical History (9)**

**Generated On: 10 Jun 2021 09:15:23**

[If No, please specify the stop date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:08:19
User signature succeeded.	Richard Rupp (b) (4)	05 Mar 2021 19:39:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Oct 2020 15:04:34
User entered empty.	Amy McMahan (b) (4) (b) (4)	06 Oct 2020 14:53:06

US3612005

Folder: Screening

Form: Medical History (9)

Generated On: 10 Jun 2021 09:15:23

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:08:19
DataPoint Verified.	(b) (4), (b) (6)	11 Mar 2021 16:07:19
User signature succeeded.	Richard Rupp (b) (4)	05 Mar 2021 19:39:45
DataPoint Un-verified.	(b) (4) Amy McMahan (b) (4)	06 Oct 2020 15:07:11
User entered '1' reason for change: Data Entry Error	(b) (4) Amy McMahan (b) (4)	06 Oct 2020 15:07:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Oct 2020 15:04:34
User entered '0'	Amy McMahan (b) (4) (b) (4)	06 Oct 2020 14:53:06

**US3612005**

**Folder: Screening**

**Form: Medical History (9)**

**Generated On: 10 Jun 2021 09:15:23**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:08:19
User entered empty.	System	06 Oct 2020 14:53:06

**US3612005**

**Folder: Screening**

**Form: Medical History (9)**

**Generated On: 10 Jun 2021 09:15:23**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:08:19
User entered empty.	System	06 Oct 2020 14:53:06

**US3612005**

**Folder: Screening**

**Form: Medical History (9)**

**Generated On: 10 Jun 2021 09:15:23**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:08:19
User entered empty.	System	06 Oct 2020 14:53:06

**US3612005**

**Folder: Screening**

**Form: Medical History (9)**

**Generated On: 10 Jun 2021 09:15:23**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:08:19
User entered empty.	System	06 Oct 2020 14:53:06

US3612005

Folder: Screening

Form: Medical History (10)

Generated On: 10 Jun 2021 09:15:23

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:08:19
User signature succeeded.	Richard Rupp (b) (4)	05 Mar 2021 19:39:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Oct 2020 15:04:34
User coded data point as SOC: Musculoskeletal and connective tissue disorders, HLGT: Joint disorders, HLT: Joint related signs and symptoms, PT: Arthralgia, LLT: Knee pain - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	06 Oct 2020 14:55:15
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	06 Oct 2020 14:55:15
Data point term sent to Coder	System	06 Oct 2020 14:54:04
User entered 'RIGHT KNEE PAIN'	Amy McMahan (b) (4) (b) (4)	06 Oct 2020 14:53:19

**US3612005**

**Folder: Screening**

**Form: Medical History (10)**

**Generated On: 10 Jun 2021 09:15:23**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:08:19
User signature succeeded.	Richard Rupp (b) (4)	05 Mar 2021 19:39:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Oct 2020 15:04:34
User entered empty.	Amy McMahan (b) (4) (b) (4)	06 Oct 2020 14:53:19

**US3612005**

**Folder: Screening**

**Form: Medical History (10)**

**Generated On: 10 Jun 2021 09:15:23**

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:08:19
User signature succeeded.	Richard Rupp (b) (4)	05 Mar 2021 19:39:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Oct 2020 15:04:34
User entered 'I'	Amy McMahan (b) (4) (b) (4)	06 Oct 2020 14:53:19

US3612005

Folder: Screening

Form: Medical History (10)

Generated On: 10 Jun 2021 09:15:23

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:08:19
User signature succeeded.	Richard Rupp (b) (4)	05 Mar 2021 19:39:45
User closed query 'Source states that condition is not active/ongoing. Please review and reconcile. ' (Site from CRA).	(b) (4) (b) (4), (b) (6)	09 Oct 2020 17:35:06
DataPoint Verified.	(b) (4), (b) (6)	09 Oct 2020 17:35:04
Query 'Source states that condition is not active/ongoing. Please review and reconcile. ' answered with 'Updated' (Site from CRA).	Amy McMahan (b) (4) (b) (4)	06 Oct 2020 15:07:39
User entered 'No (N)' reason for change: Data Entry Error	Amy McMahan (b) (4) (b) (4)	06 Oct 2020 15:07:33
User opened query 'Source states that condition is not active/ongoing. Please review and reconcile. ' (Site from CRA).	(b) (4), (b) (6)	06 Oct 2020 15:05:23
DataPoint Un-verified.	(b) (4), (b) (6)	06 Oct 2020 15:04:48
DataPoint Verified.	(b) (4), (b) (6)	06 Oct 2020 15:04:34
User entered 'Yes (Y)'	Amy McMahan (b) (4) (b) (4)	06 Oct 2020 14:53:19

**US3612005**

**Folder: Screening**

**Form: Medical History (10)**

**Generated On: 10 Jun 2021 09:15:23**

[If No, please specify the stop date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:08:19
User signature succeeded.	Richard Rupp (b) (4)	05 Mar 2021 19:39:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Oct 2020 15:04:34
User entered empty.	Amy McMahan (b) (4) (b) (4)	06 Oct 2020 14:53:19

US3612005

Folder: Screening

Form: Medical History (10)

Generated On: 10 Jun 2021 09:15:23

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:08:19
DataPoint Verified.	(b) (4), (b) (6)	11 Mar 2021 16:07:22
User signature succeeded.	Richard Rupp (b) (4)	05 Mar 2021 19:39:45
DataPoint Un-verified.	(b) (4) Amy McMahan (b) (4)	06 Oct 2020 15:07:33
User entered '1' reason for change: Data Entry Error	(b) (4) Amy McMahan (b) (4)	06 Oct 2020 15:07:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Oct 2020 15:04:34
User entered '0'	Amy McMahan (b) (4) (b) (4)	06 Oct 2020 14:53:19

**US3612005**

**Folder: Screening**

**Form: Medical History (10)**

**Generated On: 10 Jun 2021 09:15:23**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:08:19
User entered empty.	System	06 Oct 2020 14:53:19

**US3612005**

**Folder: Screening**

**Form: Medical History (10)**

**Generated On: 10 Jun 2021 09:15:23**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:08:19
User entered empty.	System	06 Oct 2020 14:53:19

**US3612005**

**Folder: Screening**

**Form: Medical History (10)**

**Generated On: 10 Jun 2021 09:15:23**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:08:19
User entered empty.	System	06 Oct 2020 14:53:19

**US3612005**

**Folder: Screening**

**Form: Medical History (10)**

**Generated On: 10 Jun 2021 09:15:23**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:08:19
User entered empty.	System	06 Oct 2020 14:53:19

**US3612005**

**Folder: Screening**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 09:15:23**

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:08:19
User signature succeeded.	Richard Rupp (b) (4)	05 Mar 2021 19:39:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Sep 2020 18:08:03
User entered 'Yes (Y)'	Gerianne Casey (b) (4) (b) (4)	01 Sep 2020 15:27:24

**US3612005**

**Folder: Screening**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 09:15:23**

**Date of assessment** (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:08:19
User signature succeeded.	Richard Rupp (b) (4)	05 Mar 2021 19:39:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Sep 2020 18:08:03
User entered '01 Sep 2020'	Gerianne Casey (b) (4) (b) (4)	01 Sep 2020 15:27:24

**US3612005**

**Folder: Screening**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 09:15:23**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:08:19
User signature succeeded.	Richard Rupp (b) (4)	05 Mar 2021 19:39:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Sep 2020 18:08:03
User entered '09:25'	Gerianne Casey (b) (4) (b) (4)	01 Sep 2020 15:27:24

**US3612005**

**Folder: Screening**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 09:15:23**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:08:19
User entered '01 Sep 2020 09:25'	System	01 Sep 2020 15:27:24

US3612005

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 09:15:23

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:08:19
User signature succeeded.	Richard Rupp (b) (4)	05 Mar 2021 19:39:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Sep 2020 18:08:03
User entered '71' in	Gerianne Casey (b) (4)	01 Sep 2020 15:27:24
DataPoint set to visible.	(b) (4) System	01 Sep 2020 15:25:33

US3612005

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 09:15:23

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:08:19
User signature succeeded.	Richard Rupp (b) (4)	05 Mar 2021 19:39:45
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	09 Sep 2020 18:08:03
User entered '184.8' lb	Gerianne Casey (b) (4)	01 Sep 2020 15:27:24
DataPoint set to visible.	(b) (4)	
	System	01 Sep 2020 15:25:33

**US3612005**

**Folder: Screening**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 09:15:23**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:08:19
User entered '25.82826'	System	01 Sep 2020 15:27:24
DataPoint set to visible.	System	01 Sep 2020 15:25:33

**US3612005**

**Folder: Screening**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 09:15:23**

[BMI units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:08:19
User entered 'kg/m2'	System	01 Sep 2020 15:27:24
DataPoint set to visible.	System	01 Sep 2020 15:25:33

US3612005

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 09:15:23

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:08:19
User signature succeeded.	Richard Rupp (b) (4)	05 Mar 2021 19:39:45
User closed query 'Per CDM: thank you for response, however as Temperature is ND kindly consider keeping Route and Units blanks for those data fields.' (Site from DM).	(b) (4) (b) (4), (b) (6)	10 Sep 2020 04:39:55
DataPoint Verified.	(b) (4), (b) (6)	09 Sep 2020 18:08:03
Query 'Per CDM: thank you for response, however as Temperature is ND kindly consider keeping Route and Units blanks for those data fields.' answered with 'updated' (Site from DM).	Kristin Pollock (b) (4) (b) (4)	09 Sep 2020 15:47:31
User entered missing code ND - Not Done; reason for change Per Query Resolution	Kristin Pollock (b) (4) (b) (4)	09 Sep 2020 15:46:50
User opened query 'Per CDM: thank you for response, however as Temperature is ND kindly consider keeping Route and Units blanks for those data fields.' (Site from DM).	(b) (4), (b) (6)	09 Sep 2020 05:06:24
User closed query 'Per CDM: It has been noted that Screening and Visit Day1 have been done on the same day. Per CCGs pages 15-16, If a participant is screened, enrolled, randomized, and dose on the same day, ND should be recorded for TEMPERATURE, PULSE, RESPIRATORY RATE, SYSTOLIC BP, and DIASTOLIC BP. Please update accordingly.' (Site from DM).	(b) (4), (b) (6)	09 Sep 2020 05:06:24
Query 'Per CDM: It has been noted that Screening and Visit Day1 have been done on the same day. Per CCGs pages 15-16, If a participant is screened, enrolled, randomized, and dose on the same day, ND should be recorded for TEMPERATURE, PULSE, RESPIRATORY RATE, SYSTOLIC BP, and DIASTOLIC BP. Please update accordingly.' answered with 'updated as requested' (Site from DM).	Kristin Pollock (b) (4) (b) (4)	08 Sep 2020 23:00:04
User entered missing code ND - Not Done; reason for change Per Query Resolution	Kristin Pollock (b) (4) (b) (4)	08 Sep 2020 22:59:51

US3612005

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 09:15:23

Temperature (xxx.x)

Audit	User	Time (GMT)
User opened query 'Per CDM: It has been noted that Screening and Visit Day1 have been done on the same day. Per CCGs pages 15-16, If a participant is screened, enrolled, randomized, and dose on the same day, ND should be recorded for TEMPERATURE, PULSE, RESPIRATORY RATE, SYSTOLIC BP, and DIASTOLIC BP. Please update accordingly.' (Site from DM).	(b) (4), (b) (6)	07 Sep 2020 22:43:53
User entered '97.9' F	Gerianne Casey (b) (4)	01 Sep 2020 15:27:24

**US3612005**

**Folder: Screening**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 09:15:23**

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:08:19
User signature succeeded.	Richard Rupp (b) (4)	05 Mar 2021 19:39:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Sep 2020 18:08:03
User entered empty; reason for change Data Entry Error	Kristin Pollock (b) (4) (b) (4)	09 Sep 2020 15:46:50
User entered 'Oral (Oral)'	Gerianne Casey (b) (4) (b) (4)	01 Sep 2020 15:27:24

**US3612005**

**Folder: Screening**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 09:15:23**

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:08:19
User signature succeeded.	Richard Rupp (b) (4)	05 Mar 2021 19:39:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Sep 2020 18:08:03
User entered empty.	Gerianne Casey (b) (4) (b) (4)	01 Sep 2020 15:27:24

**US3612005**

**Folder: Screening**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 09:15:23**

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:08:19
User signature succeeded.	Richard Rupp (b) (4)	05 Mar 2021 19:39:45
DataPoint Verified.	(b) (4)	09 Sep 2020 18:08:03
User entered missing code ND - Not Done; reason for change Per Query Resolution	Kristin Pollock (b) (4)	08 Sep 2020 22:59:51
User entered '67'	Gerianne Casey (b) (4)	01 Sep 2020 15:27:24

**US3612005**

**Folder: Screening**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 09:15:23**

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:08:19
User entered 'bpm'	System	01 Sep 2020 15:27:24

US3612005

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 09:15:23

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:08:19
User signature succeeded.	Richard Rupp (b) (4)	05 Mar 2021 19:39:45
DataPoint Verified.	(b) (4)	09 Sep 2020 18:08:03
User entered missing code ND - Not Done; reason for change Per Query Resolution	Kristin Pollock (b) (4)	08 Sep 2020 22:59:51
User entered '16'	Gerianne Casey (b) (4)	01 Sep 2020 15:27:24

**US3612005**

**Folder: Screening**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 09:15:23**

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:08:19
User entered 'breaths/min'	System	01 Sep 2020 15:27:24

US3612005

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 09:15:23

[Systolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:08:19
User signature succeeded.	Richard Rupp (b) (4)	05 Mar 2021 19:39:45
DataPoint Verified.	(b) (4)	09 Sep 2020 18:08:03
User entered missing code ND - Not Done; reason for change Per Query Resolution	Kristin Pollock (b) (4)	08 Sep 2020 22:59:51
User entered '129'	Gerianne Casey (b) (4)	01 Sep 2020 15:27:24

**US3612005**

**Folder: Screening**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 09:15:23**

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:08:19
User entered 'mmHg'	System	01 Sep 2020 15:27:24

US3612005

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 09:15:23

[Diastolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:08:19
User signature succeeded.	Richard Rupp (b) (4)	05 Mar 2021 19:39:45
DataPoint Verified.	(b) (4)	09 Sep 2020 18:08:03
User entered missing code ND - Not Done; reason for change Per Query Resolution	Kristin Pollock (b) (4)	08 Sep 2020 22:59:51
User entered '65'	Gerianne Casey (b) (4)	01 Sep 2020 15:27:24

**US3612005**

**Folder: Screening**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 09:15:23**

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:08:19
User entered 'mmHg'	System	01 Sep 2020 15:27:24

**US3612005**

**Folder: Screening**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 09:15:23**

[Height \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:08:19

**US3612005**

**Folder: Screening**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 09:15:23**

[Weight \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:08:19

**US3612005**

**Folder: Screening**

**Form: Physical Examination**

**Generated On: 10 Jun 2021 09:15:23**

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:08:19
User signature succeeded.	Richard Rupp (b) (4)	05 Mar 2021 19:39:45
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	09 Sep 2020 18:08:15
User entered 'Yes (Y)'	Gerianne Casey (b) (4)	01 Sep 2020 15:27:53
	(b) (4)	

**US3612005**

**Folder: Screening**

**Form: Physical Examination**

**Generated On: 10 Jun 2021 09:15:23**

**Date of examination (dd MMM yyyy)**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:08:19
User signature succeeded.	Richard Rupp (b) (4)	05 Mar 2021 19:39:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Sep 2020 18:08:15
User entered '01 Sep 2020'	Gerianne Casey (b) (4) (b) (4)	01 Sep 2020 15:27:53

US3612005

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 09:15:23

[Healthcare workers](#) (e.g., doctors, nurses, dentists, hospital support staff, morgue/mortuary workers)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:08:19
User signature succeeded.	Richard Rupp (b) (4)	05 Mar 2021 19:39:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Sep 2020 18:27:53
User entered 'No (N)'	Gerianne Casey (b) (4) (b) (4)	01 Sep 2020 15:28:38

US3612005

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 09:15:23

**Emergency Response** (e.g., Law enforcement officers, Firefighters, emergency medical service workers)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:08:19
User signature succeeded.	Richard Rupp (b) (4)	05 Mar 2021 19:39:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Sep 2020 18:27:53
User entered 'No (N)'	Gerianne Casey (b) (4) (b) (4)	01 Sep 2020 15:28:38

US3612005

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 09:15:23

**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)	27 Apr 2021 23:08:19
User signature succeeded.	Richard Rupp (b) (4)	05 Mar 2021 19:39:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Sep 2020 18:27:53
User entered 'No (N)'	Gerianne Casey (b) (4) (b) (4)	01 Sep 2020 15:28:38

US3612005

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 09:15:23

**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)	27 Apr 2021 23:08:19
User signature succeeded.	Richard Rupp (b) (4)	05 Mar 2021 19:39:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Sep 2020 18:27:53
User entered 'No (N)'	Gerianne Casey (b) (4) (b) (4)	01 Sep 2020 15:28:38

US3612005

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 09:15:23

[Warehouse shipping and fulfillment centers and jobs \(e.g., Amazon facilities\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:08:19
User signature succeeded.	Richard Rupp (b) (4)	05 Mar 2021 19:39:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Sep 2020 18:27:53
User entered 'No (N)'	Gerianne Casey (b) (4) (b) (4)	01 Sep 2020 15:28:38

US3612005

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 09:15:23

[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)	27 Apr 2021 23:08:19
User signature succeeded.	Richard Rupp (b) (4)	05 Mar 2021 19:39:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Sep 2020 18:27:53
User entered 'No (N)'	Gerianne Casey (b) (4) (b) (4)	01 Sep 2020 15:28:38

US3612005

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 09:15:23

**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)	27 Apr 2021 23:08:19
User signature succeeded.	Richard Rupp (b) (4)	05 Mar 2021 19:39:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Sep 2020 18:27:53
User entered 'No (N)'	Gerianne Casey (b) (4) (b) (4)	01 Sep 2020 15:28:38

US3612005

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 09:15:23

[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)	27 Apr 2021 23:08:19
User signature succeeded.	Richard Rupp (b) (4)	05 Mar 2021 19:39:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Sep 2020 18:27:53
User entered 'No (N)'	Gerianne Casey (b) (4) (b) (4)	01 Sep 2020 15:28:38

US3612005

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 09:15:23

[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)	27 Apr 2021 23:08:19
User signature succeeded.	Richard Rupp (b) (4)	05 Mar 2021 19:39:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Sep 2020 18:27:53
User entered 'No (N)'	Gerianne Casey (b) (4) (b) (4)	01 Sep 2020 15:28:38

US3612005

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 09:15:23

**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)	27 Apr 2021 23:08:19
User signature succeeded.	Richard Rupp (b) (4)	05 Mar 2021 19:39:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Sep 2020 18:27:53
User entered 'No (N)'	Gerianne Casey (b) (4) (b) (4)	01 Sep 2020 15:28:38

US3612005

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 09:15:23

**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)	27 Apr 2021 23:08:19
User signature succeeded.	Richard Rupp (b) (4)	05 Mar 2021 19:39:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Sep 2020 18:27:53
User entered 'No (N)'	Gerianne Casey (b) (4) (b) (4)	01 Sep 2020 15:28:38

**US3612005**

**Folder: Screening**

**Form: Risk of Exposure**

**Generated On: 10 Jun 2021 09:15:23**

**Other**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:08:19
User signature succeeded.	Richard Rupp (b) (4)	05 Mar 2021 19:39:45
DataPoint Verified.	(b) (4)	09 Sep 2020 18:27:53
User entered 'Yes (Y)'	Gerianne Casey (b) (4)	01 Sep 2020 15:28:38

**US3612005**

**Folder: Screening**

**Form: Risk of Exposure**

**Generated On: 10 Jun 2021 09:15:23**

[Specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:08:19
User signature succeeded.	Richard Rupp (b) (4)	05 Mar 2021 19:39:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Sep 2020 18:27:53
User entered 'over 65'	Gerianne Casey (b) (4) (b) (4)	01 Sep 2020 15:28:38

**US3612005**

**Folder: Screening**

**Form: Risk of Exposure**

**Generated On: 10 Jun 2021 09:15:23**

**No Risk Identified**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:08:19
User signature succeeded.	Richard Rupp (b) (4)	05 Mar 2021 19:39:45
User entered 'I'	Gerianne Casey (b) (4)	01 Sep 2020 15:28:38

US3612005

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 09:15:23

[Resides in Nursing Home or Assisted Living Facility](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:08:19
User signature succeeded.	Richard Rupp (b) (4)	05 Mar 2021 19:39:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Sep 2020 18:27:53
User entered '0'	Gerianne Casey (b) (4) (b) (4)	01 Sep 2020 15:28:38

US3612005

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 09:15:23

**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)	27 Apr 2021 23:08:19
User signature succeeded.	Richard Rupp (b) (4)	05 Mar 2021 19:39:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Sep 2020 18:27:53
User entered '0'	Gerianne Casey (b) (4) (b) (4)	01 Sep 2020 15:28:38

US3612005

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 09:15:23

[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)	27 Apr 2021 23:08:19
User signature succeeded.	Richard Rupp (b) (4)	05 Mar 2021 19:39:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Sep 2020 18:27:53
User entered '0'	Gerianne Casey (b) (4) (b) (4)	01 Sep 2020 15:28:38

US3612005

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 09:15:23

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)	27 Apr 2021 23:08:19
User signature succeeded.	Richard Rupp (b) (4)	05 Mar 2021 19:39:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Sep 2020 18:27:53
User entered '0'	Gerianne Casey (b) (4) (b) (4)	01 Sep 2020 15:28:38

US3612005

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 09:15:23

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:08:19
User signature succeeded.	Richard Rupp (b) (4)	05 Mar 2021 19:39:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Sep 2020 18:27:53
User entered '0'	Gerianne Casey (b) (4) (b) (4)	01 Sep 2020 15:28:38

**US3612005**

**Folder: Screening**

**Form: Risk of Exposure**

**Generated On: 10 Jun 2021 09:15:23**

**Other**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:08:19
User signature succeeded.	Richard Rupp (b) (4)	05 Mar 2021 19:39:45
User entered '0'	Gerianne Casey (b) (4)	01 Sep 2020 15:28:38

**US3612005**

**Folder: Screening**

**Form: Risk of Exposure**

**Generated On: 10 Jun 2021 09:15:23**

[Specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:08:19
User signature succeeded.	Richard Rupp (b) (4)	05 Mar 2021 19:39:45
DataPoint Verified.	(b) (4)	09 Sep 2020 18:27:53
User entered empty.	Gerianne Casey (b) (4)	01 Sep 2020 15:28:38

**US3612005**

**Folder: Visit 1 Day 1**

**Form: Visit Date**

**Generated On: 10 Jun 2021 09:15:23**

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 22:42:32
User signature succeeded.	Richard Rupp (b) (4)	05 Mar 2021 19:39:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Sep 2020 18:08:42
User entered 'Yes (Y)'	Gerianne Casey (b) (4) (b) (4)	01 Sep 2020 15:20:22

**US3612005**

**Folder: Visit 1 Day 1**

**Form: Visit Date**

**Generated On: 10 Jun 2021 09:15:23**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 22:42:32
User signature succeeded.	Richard Rupp (b) (4)	05 Mar 2021 19:39:45
DataPoint Verified.	(b) (4)	09 Sep 2020 18:08:42
User entered '1 Sep 2020'	Gerianne Casey (b) (4)	01 Sep 2020 15:20:22

**US3612005**

**Folder: Visit 1 Day 1**

**Form: Visit Date**

**Generated On: 10 Jun 2021 09:15:23**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 22:42:32
User signature succeeded.	Richard Rupp (b) (4)	05 Mar 2021 19:39:45
DataPoint Verified.	(b) (4)	09 Sep 2020 18:08:42
User entered 'Clinic (Clinic)'	Gerianne Casey (b) (4)	01 Sep 2020 15:20:22

**US3612005**

**Folder: Visit 1 Day 1**

**Form: Visit Date**

**Generated On: 10 Jun 2021 09:15:23**

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 22:42:32
User entered 'VISIT1'	System	01 Sep 2020 15:20:22

US3612005

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 10 Jun 2021 09:15:23

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 22:42:32
User signature succeeded.	Richard Rupp (b) (4)	05 Mar 2021 19:39:45
DataPoint Verified.	(b) (4)	09 Sep 2020 18:09:48
User entered '01 SEP 2020'	RWS_ENDPOINT ENDPOINT (b) (4)	01 Sep 2020 15:13:58

US3612005

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 10 Jun 2021 09:15:23

What was the participant's randomization number?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 22:42:32
User signature succeeded.	Richard Rupp (b) (4)	05 Mar 2021 19:39:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Sep 2020 18:09:48
User entered '189150'	RWS_ENDPOINT ENDPOINT (b) (4)	01 Sep 2020 15:13:58

US3612005

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 10 Jun 2021 09:15:23

[In what Cohort was the participant enrolled?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 22:42:32
User signature succeeded.	Richard Rupp (b) (4)	05 Mar 2021 19:39:45
DataPoint Verified.	(b) (4)	09 Sep 2020 18:09:48
User entered '>=65 years (3)'	RWS_ENDPOINT ENDPOINT (b) (4)	01 Sep 2020 15:13:58

US3612005

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 10 Jun 2021 09:15:23

Chronic lung disease (eg, emphysema and chronic bronchitis, idiopathic pulmonary fibrosis and cystic fibrosis, or moderate to severe asthma)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 22:42:32
User signature succeeded.	Richard Rupp (b) (4)	05 Mar 2021 19:39:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Sep 2020 18:09:48
User entered 'No (N)'	Gerianne Casey (b) (4) (b) (4)	01 Sep 2020 15:21:52

US3612005

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 10 Jun 2021 09:15:23

Significant cardiac disease (eg, heart failure, coronary artery disease, congenital heart disease, cardiomyopathies, and pulmonary hypertension)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 22:42:32
User signature succeeded.	Richard Rupp (b) (4)	05 Mar 2021 19:39:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Sep 2020 14:46:16
User closed query 'cardiac arrest with diagnosis date of 28DEC2007 has been lined through and initialed and dated in source. Please review and reconcile as needed. ' (Site from CRA).	(b) (4), (b) (6)	15 Sep 2020 16:58:53
Query 'cardiac arrest with diagnosis date of 28DEC2007 has been lined through and initialed and dated in source. Please review and reconcile as needed. ' answered with 'Added to medical history in both source and ecrf' (Site from CRA).	Gerianne Casey (b) (4) (b) (4)	10 Sep 2020 18:30:58
User opened query 'cardiac arrest with diagnosis date of 28DEC2007 has been lined through and initialed and dated in source. Please review and reconcile as needed. ' (Site from CRA).	(b) (4), (b) (6)	09 Sep 2020 18:12:47
DataPoint Un-verified.	(b) (4), (b) (6)	09 Sep 2020 18:11:56
DataPoint Verified.	(b) (4), (b) (6)	09 Sep 2020 18:09:48
User entered 'Yes (Y)'	Gerianne Casey (b) (4) (b) (4)	01 Sep 2020 15:21:52

**US3612005**

**Folder: Visit 1 Day 1**

**Form: Randomization**

**Generated On: 10 Jun 2021 09:15:23**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 22:42:32
User signature succeeded.	Richard Rupp (b) (4)	05 Mar 2021 19:39:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Sep 2020 18:09:48
User entered 'No (N)'	Gerianne Casey (b) (4) (b) (4)	01 Sep 2020 15:21:52

**US3612005**

**Folder: Visit 1 Day 1**

**Form: Randomization**

**Generated On: 10 Jun 2021 09:15:23**

[Diabetes \(Type I, Type 2, or gestational\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 22:42:32
User signature succeeded.	Richard Rupp (b) (4)	05 Mar 2021 19:39:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Sep 2020 18:09:48
User entered 'No (N)'	Gerianne Casey (b) (4) (b) (4)	01 Sep 2020 15:21:52

**US3612005**

**Folder: Visit 1 Day 1**

**Form: Randomization**

**Generated On: 10 Jun 2021 09:15:23**

[Liver Disease](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 22:42:32
User signature succeeded.	Richard Rupp (b) (4)	05 Mar 2021 19:39:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Sep 2020 18:09:48
User entered 'No (N)'	Gerianne Casey (b) (4) (b) (4)	01 Sep 2020 15:21:52

**US3612005**

**Folder: Visit 1 Day 1**

**Form: Randomization**

**Generated On: 10 Jun 2021 09:15:23**

[Human Immunodeficiency Virus \(HIV\) infection](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 22:42:32
Amendment Manager: DataPoint set to visible.	System	19 Sep 2020 09:50:58
Amendment Manager inserted this DataPoint.	System	19 Sep 2020 08:55:16

US3612005

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 10 Jun 2021 09:15:23

Height

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 22:42:32
User signature succeeded.	Richard Rupp (b) (4)	05 Mar 2021 19:39:45
User closed query 'Per CDM: ND (not done) noted for HEIGHT and WEIGHT, however please also keep the Units blank for both the data-fields. Thank you. ' (Site from DM).	(b) (4) (b) (4), (b) (6)	10 Sep 2020 11:08:52
DataPoint Verified.	(b) (4), (b) (6)	09 Sep 2020 18:13:26
Query 'Per CDM: ND (not done) noted for HEIGHT and WEIGHT, however please also keep the Units blank for both the data-fields. Thank you. ' answered with 'updated' (Site from DM).	Kristin Pollock (b) (4) (b) (4)	09 Sep 2020 15:47:56
User entered missing code ND - Not Done; reason for change Per Query Resolution	Kristin Pollock (b) (4) (b) (4)	09 Sep 2020 15:47:50
User opened query 'Per CDM: ND (not done) noted for HEIGHT and WEIGHT, however please also keep the Units blank for both the data-fields. Thank you. ' (Site from DM).	(b) (4), (b) (6)	09 Sep 2020 10:20:50
User closed query 'Per CDM: It has been noted that Screening and Visit Day1 have been done on the same day. Per CCGs pages 15-16, If a participant is screened, enrolled, randomized, and dose on the same day, ND should be recorded HEIGHT and WEIGHT. Please update accordingly.' (Site from DM).	(b) (4), (b) (6)	09 Sep 2020 09:28:11
Query 'Per CDM: It has been noted that Screening and Visit Day1 have been done on the same day. Per CCGs pages 15-16, If a participant is screened, enrolled, randomized, and dose on the same day, ND should be recorded HEIGHT and WEIGHT. Please update accordingly.' answered with 'updated as requested' (Site from DM).	Kristin Pollock (b) (4) (b) (4)	08 Sep 2020 23:00:41
User entered missing code ND - Not Done; reason for change Per Query Resolution	Kristin Pollock (b) (4) (b) (4)	08 Sep 2020 23:00:32

US3612005

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 10 Jun 2021 09:15:23

Height

Audit	User	Time (GMT)
User opened query 'Per CDM: It has been noted that Screening and Visit Day1 have been done on the same day. Per CCGs pages 15-16, If a participant is screened, enrolled, randomized, and dose on the same day, ND should be recorded HEIGHT and WEIGHT. Please update accordingly.' (Site from DM).	(b) (4), (b) (6)	07 Sep 2020 22:44:13
User entered '71' in	Gerianne Casey (b) (4) (b) (4)	01 Sep 2020 15:30:15

US3612005

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 10 Jun 2021 09:15:23

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 22:42:32
User signature succeeded.	Richard Rupp (b) (4)	05 Mar 2021 19:39:45
DataPoint Verified.	(b) (4)	09 Sep 2020 18:13:26
User entered missing code ND - Not Done; reason for change Per Query Resolution	Kristin Pollock (b) (4)	09 Sep 2020 15:47:50
User entered missing code ND - Not Done; reason for change Per Query Resolution	Kristin Pollock (b) (4)	08 Sep 2020 23:00:32
User entered '184.8' lb	Gerianne Casey (b) (4)	01 Sep 2020 15:30:15

US3612005

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 10 Jun 2021 09:15:23

Height

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 22:42:32
User signature succeeded.	Richard Rupp (b) (4)	05 Mar 2021 19:39:45
User closed query 'Per CDM: ND (not done) noted for HEIGHT and WEIGHT, however please also keep the Units blank for both the data-fields. Thank you. ' (Site from DM).	(b) (4) (b) (4), (b) (6)	10 Sep 2020 11:08:52
DataPoint Verified.	(b) (4), (b) (6)	09 Sep 2020 18:13:26
Query 'Per CDM: ND (not done) noted for HEIGHT and WEIGHT, however please also keep the Units blank for both the data-fields. Thank you. ' answered with 'updated' (Site from DM).	Kristin Pollock (b) (4) (b) (4)	09 Sep 2020 15:47:56
User entered missing code ND - Not Done; reason for change Per Query Resolution	Kristin Pollock (b) (4) (b) (4)	09 Sep 2020 15:47:50
User opened query 'Per CDM: ND (not done) noted for HEIGHT and WEIGHT, however please also keep the Units blank for both the data-fields. Thank you. ' (Site from DM).	(b) (4), (b) (6)	09 Sep 2020 10:20:50
User closed query 'Per CDM: It has been noted that Screening and Visit Day1 have been done on the same day. Per CCGs pages 15-16, If a participant is screened, enrolled, randomized, and dose on the same day, ND should be recorded HEIGHT and WEIGHT. Please update accordingly.' (Site from DM).	(b) (4), (b) (6)	09 Sep 2020 09:28:11
Query 'Per CDM: It has been noted that Screening and Visit Day1 have been done on the same day. Per CCGs pages 15-16, If a participant is screened, enrolled, randomized, and dose on the same day, ND should be recorded HEIGHT and WEIGHT. Please update accordingly.' answered with 'updated as requested' (Site from DM).	Kristin Pollock (b) (4) (b) (4)	08 Sep 2020 23:00:41
User entered missing code ND - Not Done; reason for change Per Query Resolution	Kristin Pollock (b) (4) (b) (4)	08 Sep 2020 23:00:32

US3612005

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 10 Jun 2021 09:15:23

Height

Audit	User	Time (GMT)
User opened query 'Per CDM: It has been noted that Screening and Visit Day1 have been done on the same day. Per CCGs pages 15-16, If a participant is screened, enrolled, randomized, and dose on the same day, ND should be recorded HEIGHT and WEIGHT. Please update accordingly.' (Site from DM).	(b) (4), (b) (6)	07 Sep 2020 22:44:13
User entered '71' in	Gerianne Casey (b) (4) (b) (4)	01 Sep 2020 15:30:15

US3612005

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 10 Jun 2021 09:15:23

Weight

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 22:42:32
User signature succeeded.	Richard Rupp (b) (4)	05 Mar 2021 19:39:45
DataPoint Verified.	(b) (4)	09 Sep 2020 18:13:26
User entered missing code ND - Not Done; reason for change Per Query Resolution	(b) (4), (b) (6)	09 Sep 2020 15:47:50
User entered missing code ND - Not Done; reason for change Per Query Resolution	Kristin Pollock (b) (4)	08 Sep 2020 23:00:32
User entered '184.8' lb	(b) (4)	01 Sep 2020 15:30:15
	Gerianne Casey (b) (4)	
	(b) (4)	

US3612005

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:15:23

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 22:42:32
User accepted default value 'Pre-Dose (PREDOSE)'	Gerianne Casey (b) (4)	01 Sep 2020 15:30:15
	(b) (4)	

US3612005

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:15:23

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 22:42:32
User signature succeeded.	Richard Rupp (b) (4)	05 Mar 2021 19:39:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Sep 2020 18:13:26
User entered 'Yes (Y)'	Gerianne Casey (b) (4) (b) (4)	01 Sep 2020 15:30:15

**US3612005**

**Folder: Visit 1 Day 1**

**Form: Vital Signs - Dosing (1)**

**Generated On: 10 Jun 2021 09:15:23**

**Date of assessment** (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 22:42:32
User signature succeeded.	Richard Rupp (b) (4)	05 Mar 2021 19:39:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Sep 2020 18:13:26
User entered '01 Sep 2020'	Gerianne Casey (b) (4) (b) (4)	01 Sep 2020 15:30:15

**US3612005**

**Folder: Visit 1 Day 1**

**Form: Vital Signs - Dosing (1)**

**Generated On: 10 Jun 2021 09:15:23**

[Time of assessment \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 22:42:32
User signature succeeded.	Richard Rupp (b) (4)	05 Mar 2021 19:39:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Sep 2020 18:13:26
User entered '09:25'	Gerianne Casey (b) (4) (b) (4)	01 Sep 2020 15:30:15

**US3612005**

**Folder: Visit 1 Day 1**

**Form: Vital Signs - Dosing (1)**

**Generated On: 10 Jun 2021 09:15:23**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 22:42:32
User entered '01 Sep 2020 09:25'	System	01 Sep 2020 15:30:15

US3612005

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:15:23

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 22:42:32
User signature succeeded.	Richard Rupp (b) (4)	05 Mar 2021 19:39:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Sep 2020 18:13:26
User entered '97.9' F	Gerianne Casey (b) (4) (b) (4)	01 Sep 2020 15:30:15

US3612005

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:15:23

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 22:42:32
User signature succeeded.	Richard Rupp (b) (4)	05 Mar 2021 19:39:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Sep 2020 18:13:26
User entered 'Oral (Oral)'	Gerianne Casey (b) (4) (b) (4)	01 Sep 2020 15:30:15

US3612005

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:15:23

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 22:42:32
User signature succeeded.	Richard Rupp (b) (4)	05 Mar 2021 19:39:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Sep 2020 18:13:26
User entered empty.	Gerianne Casey (b) (4) (b) (4)	01 Sep 2020 15:30:15

US3612005

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:15:23

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 22:42:32
User signature succeeded.	Richard Rupp (b) (4)	05 Mar 2021 19:39:45
DataPoint Verified.	(b) (4)	09 Sep 2020 18:13:26
User closed query 'Data is required. Please provide.' (Site from System).	System	02 Sep 2020 15:38:57
Query 'Data is required. Please provide.' answered by System data change (Site from System).		02 Sep 2020 15:38:57
User entered '67' reason for change: Data Entry Error	Amy McMahan (b) (4)	02 Sep 2020 15:38:57
User opened query 'Data is required. Please provide.' (Site from System).	(b) (4)	01 Sep 2020 15:30:15
User entered empty.	Gerianne Casey (b) (4)	01 Sep 2020 15:30:15

**US3612005**

**Folder: Visit 1 Day 1**

**Form: Vital Signs - Dosing (1)**

**Generated On: 10 Jun 2021 09:15:23**

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 22:42:32
User entered 'bpm'	System	02 Sep 2020 15:38:57
User entered empty.	System	01 Sep 2020 15:30:15

US3612005

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:15:23

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 22:42:32
User signature succeeded.	Richard Rupp (b) (4)	05 Mar 2021 19:39:45
DataPoint Verified.	(b) (4)	09 Sep 2020 18:13:26
User closed query 'Data is required. Please provide.' (Site from System).	(b) (4), (b) (6)	02 Sep 2020 15:38:57
Query 'Data is required. Please provide.' answered by System data change (Site from System).	System	02 Sep 2020 15:38:57
User entered '16' reason for change: Data Entry Error	Amy McMahan (b) (4)	02 Sep 2020 15:38:57
User opened query 'Data is required. Please provide.' (Site from System).	(b) (4)	01 Sep 2020 15:30:15
User entered empty.	Gerianne Casey (b) (4)	01 Sep 2020 15:30:15

US3612005

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:15:23

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 22:42:32
User entered 'breaths/min'	System	02 Sep 2020 15:38:57
User entered empty.	System	01 Sep 2020 15:30:15

US3612005

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:15:23

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 22:42:32
User signature succeeded.	Richard Rupp (b) (4)	05 Mar 2021 19:39:45
DataPoint Verified.	(b) (4)	09 Sep 2020 18:13:26
User closed query 'Data is required. Please provide.' (Site from System).	System	02 Sep 2020 15:38:57
Query 'Data is required. Please provide.' answered by System data change (Site from System).		02 Sep 2020 15:38:57
User entered '129' reason for change: Data Entry Error	Amy McMahan (b) (4)	02 Sep 2020 15:38:57
User opened query 'Data is required. Please provide.' (Site from System).	(b) (4)	01 Sep 2020 15:30:15
User entered empty.	Gerianne Casey (b) (4)	01 Sep 2020 15:30:15

**US3612005**

**Folder: Visit 1 Day 1**

**Form: Vital Signs - Dosing (1)**

**Generated On: 10 Jun 2021 09:15:23**

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 22:42:32
User entered 'mmHg'	System	02 Sep 2020 15:38:57
User entered empty.	System	01 Sep 2020 15:30:15

US3612005

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:15:23

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 22:42:32
User signature succeeded.	Richard Rupp (b) (4)	05 Mar 2021 19:39:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Sep 2020 18:13:26
User closed query 'Data is required. Please provide.' (Site from System).	System	02 Sep 2020 15:38:57
Query 'Data is required. Please provide.' answered by System data change (Site from System).		02 Sep 2020 15:38:57
User entered '65' reason for change: Data Entry Error	Amy McMahan (b) (4) (b) (4)	02 Sep 2020 15:38:57
User opened query 'Data is required. Please provide.' (Site from System).	System	01 Sep 2020 15:30:15
User entered empty.	Gerianne Casey (b) (4) (b) (4)	01 Sep 2020 15:30:15

US3612005

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:15:23

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 22:42:32
User entered 'mmHg'	System	02 Sep 2020 15:38:57
User entered empty.	System	01 Sep 2020 15:30:15

US3612005

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 10 Jun 2021 09:15:23

Height

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 22:42:32
User signature succeeded.	Richard Rupp (b) (4)	05 Mar 2021 19:39:45
User closed query 'Per CDM: ND (not done) noted for HEIGHT and WEIGHT, however please also keep the Units blank for both the data-fields. Thank you. ' (Site from DM).	(b) (4) (b) (4), (b) (6)	10 Sep 2020 11:08:52
DataPoint Verified.	(b) (4), (b) (6)	09 Sep 2020 18:13:26
Query 'Per CDM: ND (not done) noted for HEIGHT and WEIGHT, however please also keep the Units blank for both the data-fields. Thank you. ' answered with 'updated' (Site from DM).	Kristin Pollock (b) (4) (b) (4)	09 Sep 2020 15:47:56
User entered missing code ND - Not Done; reason for change Per Query Resolution	Kristin Pollock (b) (4) (b) (4)	09 Sep 2020 15:47:50
User opened query 'Per CDM: ND (not done) noted for HEIGHT and WEIGHT, however please also keep the Units blank for both the data-fields. Thank you. ' (Site from DM).	(b) (4), (b) (6)	09 Sep 2020 10:20:50
User closed query 'Per CDM: It has been noted that Screening and Visit Day1 have been done on the same day. Per CCGs pages 15-16, If a participant is screened, enrolled, randomized, and dose on the same day, ND should be recorded HEIGHT and WEIGHT. Please update accordingly.' (Site from DM).	(b) (4), (b) (6)	09 Sep 2020 09:28:11
Query 'Per CDM: It has been noted that Screening and Visit Day1 have been done on the same day. Per CCGs pages 15-16, If a participant is screened, enrolled, randomized, and dose on the same day, ND should be recorded HEIGHT and WEIGHT. Please update accordingly.' answered with 'updated as requested' (Site from DM).	Kristin Pollock (b) (4) (b) (4)	08 Sep 2020 23:00:41
User entered missing code ND - Not Done; reason for change Per Query Resolution	Kristin Pollock (b) (4) (b) (4)	08 Sep 2020 23:00:32

US3612005

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 10 Jun 2021 09:15:23

Height

Audit	User	Time (GMT)
User opened query 'Per CDM: It has been noted that Screening and Visit Day1 have been done on the same day. Per CCGs pages 15-16, If a participant is screened, enrolled, randomized, and dose on the same day, ND should be recorded HEIGHT and WEIGHT. Please update accordingly.' (Site from DM).	(b) (4), (b) (6)	07 Sep 2020 22:44:13
User entered '71' in	Gerianne Casey (b) (4) (b) (4)	01 Sep 2020 15:30:15

US3612005

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 10 Jun 2021 09:15:23

Weight

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 22:42:32
User signature succeeded.	Richard Rupp (b) (4)	05 Mar 2021 19:39:45
DataPoint Verified.	(b) (4)	09 Sep 2020 18:13:26
User entered missing code ND - Not Done; reason for change Per Query Resolution	(b) (4), (b) (6)	09 Sep 2020 15:47:50
User entered missing code ND - Not Done; reason for change Per Query Resolution	Kristin Pollock (b) (4)	09 Sep 2020 15:47:50
User entered missing code ND - Not Done; reason for change Per Query Resolution	(b) (4)	08 Sep 2020 23:00:32
User entered '184.8' lb	Kristin Pollock (b) (4)	08 Sep 2020 23:00:32
	(b) (4)	01 Sep 2020 15:30:15
	Gerianne Casey (b) (4)	01 Sep 2020 15:30:15
	(b) (4)	

US3612005

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:15:23

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 22:42:32
User accepted default value 'Post-Dose (POSTDOSE)'	Gerianne Casey (b) (4) (b) (4)	01 Sep 2020 15:30:15

US3612005

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:15:23

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 22:42:32
User signature succeeded.	Richard Rupp (b) (4)	05 Mar 2021 19:39:45
DataPoint Verified.	(b) (4)	09 Sep 2020 18:13:26
User closed query 'Data is required. Please complete.' (Site from System).	System	01 Sep 2020 17:11:21
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	01 Sep 2020 17:11:21
User entered 'Yes (Y)' reason for change: New Information	Gerianne Casey (b) (4)	01 Sep 2020 17:11:21
User opened query 'Data is required. Please complete.' (Site from System).	System	01 Sep 2020 15:30:15
User entered empty.	Gerianne Casey (b) (4)	01 Sep 2020 15:30:15

US3612005

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:15:23

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 22:42:32
User signature succeeded.	Richard Rupp (b) (4)	05 Mar 2021 19:39:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Sep 2020 18:13:26
User entered '1 Sep 2020' reason for change: New Information	Gerianne Casey (b) (4) (b) (4)	01 Sep 2020 17:11:21
User entered empty.	Gerianne Casey (b) (4) (b) (4)	01 Sep 2020 15:30:15

**US3612005**

**Folder: Visit 1 Day 1**

**Form: Vital Signs - Dosing (2)**

**Generated On: 10 Jun 2021 09:15:23**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 22:42:32
User signature succeeded.	Richard Rupp (b) (4)	05 Mar 2021 19:39:45
DataPoint Verified.	(b) (4)	09 Sep 2020 18:13:26
User entered '11:31' reason for change: New Information	Gerianne Casey (b) (4)	01 Sep 2020 17:11:21
User entered empty.	Gerianne Casey (b) (4)	01 Sep 2020 15:30:15

**US3612005**

**Folder: Visit 1 Day 1**

**Form: Vital Signs - Dosing (2)**

**Generated On: 10 Jun 2021 09:15:23**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 22:42:32
User entered '1 Sep 2020 11:31'	System	01 Sep 2020 17:11:21
User entered empty.	System	01 Sep 2020 15:30:15

US3612005

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:15:23

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 22:42:32
User signature succeeded.	Richard Rupp (b) (4)	05 Mar 2021 19:39:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Sep 2020 18:13:26
User entered '97.8' F reason for change: New Information	Gerianne Casey (b) (4) (b) (4)	01 Sep 2020 17:11:21
User entered empty.	Gerianne Casey (b) (4) (b) (4)	01 Sep 2020 15:30:15

US3612005

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:15:23

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 22:42:32
User signature succeeded.	Richard Rupp (b) (4)	05 Mar 2021 19:39:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Sep 2020 18:13:26
User entered 'Oral (Oral)' reason for change: New Information	Gerianne Casey (b) (4) (b) (4)	01 Sep 2020 17:11:21
User entered empty.	Gerianne Casey (b) (4) (b) (4)	01 Sep 2020 15:30:15

US3612005

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:15:23

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 22:42:32
User signature succeeded.	Richard Rupp (b) (4)	05 Mar 2021 19:39:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Sep 2020 18:13:26
User entered empty.	Gerianne Casey (b) (4) (b) (4)	01 Sep 2020 15:30:15

US3612005

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:15:23

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 22:42:32
User signature succeeded.	Richard Rupp (b) (4)	05 Mar 2021 19:39:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Sep 2020 18:13:26
User closed query 'Data is required. Please provide.' (Site from System).	System	02 Sep 2020 15:38:57
Query 'Data is required. Please provide.' answered by System data change (Site from System).		02 Sep 2020 15:38:57
User entered '54' reason for change: Data Entry Error	Amy McMahan (b) (4) (b) (4)	02 Sep 2020 15:38:57
User opened query 'Data is required. Please provide.' (Site from System).	System	01 Sep 2020 17:11:21
User entered empty.	Gerianne Casey (b) (4) (b) (4)	01 Sep 2020 15:30:15

US3612005

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:15:23

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 22:42:32
User entered 'bpm'	System	02 Sep 2020 15:38:57
User entered empty.	System	01 Sep 2020 15:30:15

US3612005

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:15:23

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 22:42:32
User signature succeeded.	Richard Rupp (b) (4)	05 Mar 2021 19:39:45
DataPoint Verified.	(b) (4)	09 Sep 2020 18:13:26
User closed query 'Data is required. Please provide.' (Site from System).	(b) (4), (b) (6)	02 Sep 2020 15:38:57
Query 'Data is required. Please provide.' answered by System data change (Site from System).	System	02 Sep 2020 15:38:57
User entered '16' reason for change: Data Entry Error	Amy McMahan (b) (4)	02 Sep 2020 15:38:57
User opened query 'Data is required. Please provide.' (Site from System).	(b) (4)	01 Sep 2020 17:11:21
User entered empty.	Gerianne Casey (b) (4)	01 Sep 2020 15:30:15

US3612005

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:15:23

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 22:42:32
User entered 'breaths/min'	System	02 Sep 2020 15:38:57
User entered empty.	System	01 Sep 2020 15:30:15

US3612005

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:15:23

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 22:42:32
User signature succeeded.	Richard Rupp (b) (4)	05 Mar 2021 19:39:45
DataPoint Verified.	(b) (4)	09 Sep 2020 18:13:26
User closed query 'Data is required. Please provide.' (Site from System).	System	02 Sep 2020 15:38:57
Query 'Data is required. Please provide.' answered by System data change (Site from System).		02 Sep 2020 15:38:57
User entered '133' reason for change: Data Entry Error	Amy McMahan (b) (4)	02 Sep 2020 15:38:57
User opened query 'Data is required. Please provide.' (Site from System).	(b) (4)	01 Sep 2020 17:11:21
User entered empty.	Gerianne Casey (b) (4)	01 Sep 2020 15:30:15

**US3612005**

**Folder: Visit 1 Day 1**

**Form: Vital Signs - Dosing (2)**

**Generated On: 10 Jun 2021 09:15:23**

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 22:42:32
User entered 'mmHg'	System	02 Sep 2020 15:38:57
User entered empty.	System	01 Sep 2020 15:30:15

US3612005

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:15:23

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 22:42:32
User signature succeeded.	Richard Rupp (b) (4)	05 Mar 2021 19:39:45
DataPoint Verified.	(b) (4)	09 Sep 2020 18:13:26
User closed query 'Data is required. Please provide.' (Site from System).	System	02 Sep 2020 15:38:57
Query 'Data is required. Please provide.' answered by System data change (Site from System).		02 Sep 2020 15:38:57
User entered '75' reason for change: Data Entry Error	Amy McMahan (b) (4)	02 Sep 2020 15:38:57
User opened query 'Data is required. Please provide.' (Site from System).	(b) (4)	01 Sep 2020 17:11:21
User entered empty.	Gerianne Casey (b) (4)	01 Sep 2020 15:30:15

US3612005

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:15:23

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 22:42:32
User entered 'mmHg'	System	02 Sep 2020 15:38:57
User entered empty.	System	01 Sep 2020 15:30:15

US3612005

Folder: Visit 1 Day 1

Form: Physical Examination

Generated On: 10 Jun 2021 09:15:23

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 22:42:32
User signature succeeded.	Richard Rupp (b) (4)	05 Mar 2021 19:39:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Sep 2020 18:24:19
User entered 'Yes (Y)'	Gerianne Casey (b) (4) (b) (4)	01 Sep 2020 15:31:47

US3612005

Folder: Visit 1 Day 1

Form: Physical Examination

Generated On: 10 Jun 2021 09:15:23

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 22:42:32
User signature succeeded.	Richard Rupp (b) (4)	05 Mar 2021 19:39:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Sep 2020 18:24:19
User entered '01 Sep 2020'	Gerianne Casey (b) (4) (b) (4)	01 Sep 2020 15:31:47

US3612005

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 10 Jun 2021 09:15:23

[Was study treatment given?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 22:42:32
User signature succeeded.	Richard Rupp (b) (4)	05 Mar 2021 19:39:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Sep 2020 18:09:32
User entered 'Yes (Y)'	Gerianne Casey (b) (4) (b) (4)	01 Sep 2020 16:12:18

**US3612005**

**Folder: Visit 1 Day 1**

**Form: Exposure**

**Generated On: 10 Jun 2021 09:15:23**

[If No, reason not given](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 22:42:32
User signature succeeded.	Richard Rupp (b) (4)	05 Mar 2021 19:39:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Sep 2020 18:09:32
User entered empty.	Gerianne Casey (b) (4) (b) (4)	01 Sep 2020 16:12:18

US3612005

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 10 Jun 2021 09:15:23

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 22:42:32
User signature succeeded.	Richard Rupp (b) (4)	05 Mar 2021 19:39:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Sep 2020 18:09:32
User entered empty.	Gerianne Casey (b) (4) (b) (4)	01 Sep 2020 16:12:18

**US3612005**

**Folder: Visit 1 Day 1**

**Form: Exposure**

**Generated On: 10 Jun 2021 09:15:23**

[What was the study treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 22:42:32
User entered 'MRNA-1273 OR PLACEBO'	System	01 Sep 2020 16:12:18

US3612005

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 10 Jun 2021 09:15:23

What was the treatment date? (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 22:42:32
User signature succeeded.	Richard Rupp (b) (4)	05 Mar 2021 19:39:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Sep 2020 18:09:32
User entered '1 Sep 2020'	Gerianne Casey (b) (4) (b) (4)	01 Sep 2020 16:12:18

US3612005

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 10 Jun 2021 09:15:23

[What was the treatment time? \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 22:42:32
User signature succeeded.	Richard Rupp (b) (4)	05 Mar 2021 19:39:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Sep 2020 18:09:32
User entered '10:58'	Gerianne Casey (b) (4) (b) (4)	01 Sep 2020 16:12:18

**US3612005**

**Folder: Visit 1 Day 1**

**Form: Exposure**

**Generated On: 10 Jun 2021 09:15:23**

[Treatment Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 22:42:32
User entered '1 Sep 2020 10:58'	System	01 Sep 2020 16:12:18

US3612005

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 10 Jun 2021 09:15:23

[Which arm was used to give treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 22:42:32
User signature succeeded.	Richard Rupp (b) (4)	05 Mar 2021 19:39:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Sep 2020 18:09:32
User entered 'Left Arm (LEFT ARM)'	Gerianne Casey (b) (4) (b) (4)	01 Sep 2020 16:12:18

**US3612005**

**Folder: Visit 1 Day 1**

**Form: Exposure**

**Generated On: 10 Jun 2021 09:15:23**

[What was the frequency of the study treatment dosing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 22:42:32
DataPoint Verified.	(b) (4), (b) (6)	09 Sep 2020 18:09:32
User entered 'ONCE'	System	01 Sep 2020 16:12:18

**US3612005**

**Folder: Visit 1 Day 1**

**Form: Exposure**

**Generated On: 10 Jun 2021 09:15:23**

[What was the route of administration for the study treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 22:42:32
User entered 'INTRAMUSCULAR'	System	01 Sep 2020 16:12:18

US3612005

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 09:15:23

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 22:42:32
User signature succeeded.	Richard Rupp (b) (4)	05 Mar 2021 19:39:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Sep 2020 18:08:53
User entered 'Yes (Y)'	Gerianne Casey (b) (4) (b) (4)	01 Sep 2020 15:32:21

US3612005

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 09:15:23

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 22:42:32
User signature succeeded.	Richard Rupp (b) (4)	05 Mar 2021 19:39:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Sep 2020 18:08:53
User entered '1 Sep 2020'	Gerianne Casey (b) (4) (b) (4)	01 Sep 2020 15:32:21

**US3612005**

**Folder: Visit 1 Day 1**

**Form: Immunogenicity Assessment**

**Generated On: 10 Jun 2021 09:15:23**

[Collection time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 22:42:32
User signature succeeded.	Richard Rupp (b) (4)	05 Mar 2021 19:39:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Sep 2020 18:08:53
User entered '10:07'	Gerianne Casey (b) (4) (b) (4)	01 Sep 2020 15:32:21

**US3612005**

**Folder: Visit 1 Day 1**

**Form: Immunogenicity Assessment**

**Generated On: 10 Jun 2021 09:15:23**

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 22:42:32
User entered '1 Sep 2020 10:07'	System	01 Sep 2020 15:32:21

**US3612005**

**Folder: Visit 1 Day 1**

**Form: Central Laboratory - Nasopharyngeal Swab**

**Generated On: 10 Jun 2021 09:15:23**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 22:42:32
User signature succeeded.	Richard Rupp (b) (4)	05 Mar 2021 19:39:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Sep 2020 18:09:05
User entered '1 Sep 2020'	Gerianne Casey (b) (4) (b) (4)	01 Sep 2020 15:32:56

**US3612005**

**Folder: Visit 1 Day 1**

**Form: Central Laboratory - Nasopharyngeal Swab (1)**

**Generated On: 10 Jun 2021 09:15:23**

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 22:42:32
User accepted default value 'Nasopharyngeal Swab 1 (NASAL1)'	Gerianne Casey (b) (4)	01 Sep 2020 15:32:56

**US3612005**

**Folder: Visit 1 Day 1**

**Form: Central Laboratory - Nasopharyngeal Swab (1)**

**Generated On: 10 Jun 2021 09:15:23**

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 22:42:32
User signature succeeded.	Richard Rupp (b) (4)	05 Mar 2021 19:39:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Sep 2020 18:09:05
User entered 'Yes (Y)'	Gerianne Casey (b) (4) (b) (4)	01 Sep 2020 15:32:56

**US3612005**

**Folder: Visit 1 Day 1**

**Form: Central Laboratory - Nasopharyngeal Swab (1)**

**Generated On: 10 Jun 2021 09:15:23**

[Collection time \(00:00 - 23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 22:42:32
User signature succeeded.	Richard Rupp (b) (4)	05 Mar 2021 19:39:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Sep 2020 18:09:05
User entered '09:59'	Gerianne Casey (b) (4) (b) (4)	01 Sep 2020 15:32:56

**US3612005**

**Folder: Visit 1 Day 1**

**Form: Central Laboratory - Nasopharyngeal Swab (1)**

**Generated On: 10 Jun 2021 09:15:23**

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 22:42:32
User entered '1 Sep 2020 09:59'	System	01 Sep 2020 15:32:56

**US3612005**

**Folder: Visit 1 Day 1**

**Form: Central Laboratory - Nasopharyngeal Swab (2)**

**Generated On: 10 Jun 2021 09:15:23**

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 22:42:32
User accepted default value 'Nasopharyngeal Swab 2 (NASAL2)'	Gerianne Casey (b) (4)	01 Sep 2020 15:32:56

US3612005

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 10 Jun 2021 09:15:23

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 22:42:32
User signature succeeded.	Richard Rupp (b) (4)	05 Mar 2021 19:39:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Sep 2020 18:09:05
User closed query 'Data is required. Please complete.' (Site from System).	System	01 Sep 2020 16:12:46
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	01 Sep 2020 16:12:46
User entered 'No (N)' reason for change: Data Entry Error	Gerianne Casey (b) (4) (b) (4)	01 Sep 2020 16:12:46
User opened query 'Data is required. Please complete.' (Site from System).	System	01 Sep 2020 15:32:56
User entered empty.	Gerianne Casey (b) (4) (b) (4)	01 Sep 2020 15:32:56

**US3612005**

**Folder: Visit 1 Day 1**

**Form: Central Laboratory - Nasopharyngeal Swab (2)**

**Generated On: 10 Jun 2021 09:15:23**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 22:42:32
User signature succeeded.	Richard Rupp (b) (4)	05 Mar 2021 19:39:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Sep 2020 18:09:05
User entered empty.	Gerianne Casey (b) (4) (b) (4)	01 Sep 2020 15:32:56

**US3612005**

**Folder: Visit 1 Day 1**

**Form: Central Laboratory - Nasopharyngeal Swab (2)**

**Generated On: 10 Jun 2021 09:15:23**

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 22:42:32
User entered empty.	System	01 Sep 2020 15:32:56

**US3612005**

**Folder: Visit 1 Day 1**

**Form: Continuing**

**Generated On: 10 Jun 2021 09:15:23**

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 22:42:32
User signature succeeded.	Richard Rupp (b) (4)	05 Mar 2021 19:39:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Sep 2020 15:20:41
User entered 'Yes (Y)'	Gerianne Casey (b) (4) (b) (4)	01 Sep 2020 15:33:14

**US3612005**

**Folder: Visit 1 Day 1**

**Form: Continuing**

**Generated On: 10 Jun 2021 09:15:23**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 22:42:32
User entered 'I'	System	01 Sep 2020 15:33:14

US3612005

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/1)

Generated On: 10 Jun 2021 09:15:23

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:05:06
Data entry locked.	System	01 Sep 2020 16:12:18
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	01 Sep 2020 16:12:18

US3612005

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/1)

Generated On: 10 Jun 2021 09:15:23

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:05:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a19c168458d97dd9)', Time: '2020-09-01T11:33:35', User OID: 'PatientReportedOutcome (US3612005)', ODM File OID: 'b9749031-5ed1-45f2-adba-7078db4ae945'	System	01 Sep 2020 16:34:07
User entered 'Yes (Y)'	System	01 Sep 2020 16:34:07

US3612005

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/1)

Generated On: 10 Jun 2021 09:15:23

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:05:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a19c168458d97dd9)', Time: '2020-09-01T11:33:43', User OID: 'PatientReportedOutcome (US3612005)', ODM File OID: 'b9749031-5ed1-45f2-adba-7078db4ae945'	System	01 Sep 2020 16:34:07
User entered '97.8'	System	01 Sep 2020 16:34:07

US3612005

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/1)

Generated On: 10 Jun 2021 09:15:23

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:05:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a19c168458d97dd9)', Time: '2020-09-01T11:33:51', User OID: 'PatientReportedOutcome (US3612005)', ODM File OID: 'b9749031-5ed1-45f2-adba-7078db4ae945'	System	01 Sep 2020 16:34:07
User entered 'No (N)'	System	01 Sep 2020 16:34:07

**US3612005**

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(1/1)**

**Generated On: 10 Jun 2021 09:15:23**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:05:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a19c168458d97dd9)', Time: '2020-09-01T11:34:03', User OID: 'PatientReportedOutcome (US3612005)', ODM File OID: 'b9749031-5ed1-45f2-adba-7078db4ae945'	System	01 Sep 2020 16:34:07
User entered '01 Sep 2020 11:34'	System	01 Sep 2020 16:34:07

**US3612005**

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(1/1)**

**Generated On: 10 Jun 2021 09:15:23**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:05:06
User entered '01 Sep 2020 11:18'	System	01 Sep 2020 16:12:18

**US3612005**

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(1/1)**

**Generated On: 10 Jun 2021 09:15:23**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:05:06
User entered '01 Sep 2020 13:48'	System	01 Sep 2020 16:12:18

US3612005

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/2)

Generated On: 10 Jun 2021 09:15:23

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:05:06
Data entry locked.	System	01 Sep 2020 16:12:18
User entered 'Day 1, after vaccination (at home)'	System	01 Sep 2020 16:12:18

US3612005

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/2)

Generated On: 10 Jun 2021 09:15:23

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:05:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a19c168458d97dd9)', Time: '2020-09-02T00:02:43', User OID: 'PatientReportedOutcome (US3612005)', ODM File OID: '1a4091c9-b252-415f-873f-49e1ff7605d7'	System	02 Sep 2020 05:03:59
User entered 'Yes (Y)'	System	02 Sep 2020 05:03:59

US3612005

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/2)

Generated On: 10 Jun 2021 09:15:23

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:05:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a19c168458d97dd9)', Time: '2020-09-02T00:03:41', User OID: 'PatientReportedOutcome (US3612005)', ODM File OID: '1a4091c9-b252-415f-873f-49e1ff7605d7'	System	02 Sep 2020 05:03:59
User entered '97.3'	System	02 Sep 2020 05:03:59

US3612005

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/2)

Generated On: 10 Jun 2021 09:15:23

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:05:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a19c168458d97dd9)', Time: '2020-09-02T00:03:46', User OID: 'PatientReportedOutcome (US3612005)', ODM File OID: '1a4091c9-b252-415f-873f-49e1ff7605d7'	System	02 Sep 2020 05:03:59
User entered 'No (N)'	System	02 Sep 2020 05:03:59

**US3612005**

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(1/2)**

**Generated On: 10 Jun 2021 09:15:23**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:05:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a19c168458d97dd9)', Time: '2020-09-02T00:03:57', User OID: 'PatientReportedOutcome (US3612005)', ODM File OID: '1a4091c9-b252-415f-873f-49e1ff7605d7'	System	02 Sep 2020 05:03:59
User entered '02 Sep 2020 00:03'	System	02 Sep 2020 05:03:59

**US3612005**

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(1/2)**

**Generated On: 10 Jun 2021 09:15:23**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:05:06
User entered '01 Sep 2020 14:43'	System	01 Sep 2020 16:12:18

**US3612005**

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(1/2)**

**Generated On: 10 Jun 2021 09:15:23**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:05:06
User entered '02 Sep 2020 11:59'	System	01 Sep 2020 16:12:18

**US3612005**

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(2)**

**Generated On: 10 Jun 2021 09:15:23**

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:05:06
Data entry locked.	System	01 Sep 2020 16:12:18
User entered 'Day 2'	System	01 Sep 2020 16:12:18

US3612005

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(2)

Generated On: 10 Jun 2021 09:15:23

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:05:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a19c168458d97dd9)', Time: '2020-09-02T21:39:55', User OID: 'PatientReportedOutcome (US3612005)', ODM File OID: '101e42bf-e643-4f25-9b34-294b7e014f54'	System	03 Sep 2020 02:40:34
User entered 'Yes (Y)'	System	03 Sep 2020 02:40:34

US3612005

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(2)

Generated On: 10 Jun 2021 09:15:23

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:05:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a19c168458d97dd9)', Time: '2020-09-02T21:40:07', User OID: 'PatientReportedOutcome (US3612005)', ODM File OID: '101e42bf-e643-4f25-9b34-294b7e014f54'	System	03 Sep 2020 02:40:34
User entered '97.8'	System	03 Sep 2020 02:40:34

US3612005

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(2)

Generated On: 10 Jun 2021 09:15:23

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:05:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a19c168458d97dd9)', Time: '2020-09-02T21:40:13', User OID: 'PatientReportedOutcome (US3612005)', ODM File OID: '101e42bf-e643-4f25-9b34-294b7e014f54'	System	03 Sep 2020 02:40:34
User entered 'No (N)'	System	03 Sep 2020 02:40:34

**US3612005**

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(2)**

**Generated On: 10 Jun 2021 09:15:23**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:05:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a19c168458d97dd9)', Time: '2020-09-02T21:40:27', User OID: 'PatientReportedOutcome (US3612005)', ODM File OID: '101e42bf-e643-4f25-9b34-294b7e014f54'	System	03 Sep 2020 02:40:34
User entered '02 Sep 2020 21:40'	System	03 Sep 2020 02:40:34

**US3612005**

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(2)**

**Generated On: 10 Jun 2021 09:15:23**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:05:06
User entered '02 Sep 2020 12:00'	System	01 Sep 2020 16:12:18

**US3612005**

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(2)**

**Generated On: 10 Jun 2021 09:15:23**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:05:06
User entered '03 Sep 2020 11:59'	System	01 Sep 2020 16:12:18

**US3612005**

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(3)**

**Generated On: 10 Jun 2021 09:15:23**

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:05:06
Data entry locked.	System	01 Sep 2020 16:12:18
User entered 'Day 3'	System	01 Sep 2020 16:12:18

US3612005

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(3)

Generated On: 10 Jun 2021 09:15:23

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:05:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a19c168458d97dd9)', Time: '2020-09-03T12:41:37', User OID: 'PatientReportedOutcome (US3612005)', ODM File OID: '84e3679d-c754-47f4-b3c9-269cde875027'	System	03 Sep 2020 17:42:15
User entered 'Yes (Y)'	System	03 Sep 2020 17:42:15

US3612005

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(3)

Generated On: 10 Jun 2021 09:15:23

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:05:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a19c168458d97dd9)', Time: '2020-09-03T12:41:45', User OID: 'PatientReportedOutcome (US3612005)', ODM File OID: '84e3679d-c754-47f4-b3c9-269cde875027' User entered '97.3'	System	03 Sep 2020 17:42:15
	System	03 Sep 2020 17:42:15

US3612005

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(3)

Generated On: 10 Jun 2021 09:15:23

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:05:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a19c168458d97dd9)', Time: '2020-09-03T12:41:52', User OID: 'PatientReportedOutcome (US3612005)', ODM File OID: '84e3679d-c754-47f4-b3c9-269cde875027'	System	03 Sep 2020 17:42:15
User entered 'No (N)'	System	03 Sep 2020 17:42:15

**US3612005**

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(3)**

**Generated On: 10 Jun 2021 09:15:23**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:05:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a19c168458d97dd9)', Time: '2020-09-03T12:42:12', User OID: 'PatientReportedOutcome (US3612005)', ODM File OID: '84e3679d-c754-47f4-b3c9-269cde875027'	System	03 Sep 2020 17:42:15
User entered '03 Sep 2020 12:42'	System	03 Sep 2020 17:42:15

**US3612005**

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(3)**

**Generated On: 10 Jun 2021 09:15:23**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:05:06
User entered '03 Sep 2020 12:00'	System	01 Sep 2020 16:12:18

**US3612005**

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(3)**

**Generated On: 10 Jun 2021 09:15:23**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:05:06
User entered '04 Sep 2020 11:59'	System	01 Sep 2020 16:12:18

**US3612005**

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(4)**

**Generated On: 10 Jun 2021 09:15:23**

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:05:06
Data entry locked.	System	01 Sep 2020 16:12:18
User entered 'Day 4'	System	01 Sep 2020 16:12:18

US3612005

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(4)

Generated On: 10 Jun 2021 09:15:23

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:05:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a19c168458d97dd9)', Time: '2020-09-04T17:02:47', User OID: 'PatientReportedOutcome (US3612005)', ODM File OID: '5cb18148-b286-490f-9a22-20192046e11b'	System	04 Sep 2020 22:03:14
User entered 'Yes (Y)'	System	04 Sep 2020 22:03:14

US3612005

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(4)

Generated On: 10 Jun 2021 09:15:23

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:05:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a19c168458d97dd9)', Time: '2020-09-04T17:02:56', User OID: 'PatientReportedOutcome (US3612005)', ODM File OID: '5cb18148-b286-490f-9a22-20192046e11b'	System	04 Sep 2020 22:03:14
User entered '98.1'	System	04 Sep 2020 22:03:14

US3612005

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(4)

Generated On: 10 Jun 2021 09:15:23

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:05:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a19c168458d97dd9)', Time: '2020-09-04T17:03:01', User OID: 'PatientReportedOutcome (US3612005)', ODM File OID: '5cb18148-b286-490f-9a22-20192046e11b'	System	04 Sep 2020 22:03:14
User entered 'No (N)'	System	04 Sep 2020 22:03:14

**US3612005**

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(4)**

**Generated On: 10 Jun 2021 09:15:23**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:05:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a19c168458d97dd9)', Time: '2020-09-04T17:03:07', User OID: 'PatientReportedOutcome (US3612005)', ODM File OID: '5cb18148-b286-490f-9a22-20192046e11b'	System	04 Sep 2020 22:03:14
User entered '04 Sep 2020 17:03'	System	04 Sep 2020 22:03:14

**US3612005**

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(4)**

**Generated On: 10 Jun 2021 09:15:23**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:05:06
User entered '04 Sep 2020 12:00'	System	01 Sep 2020 16:12:18

**US3612005**

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(4)**

**Generated On: 10 Jun 2021 09:15:23**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:05:06
User entered '05 Sep 2020 11:59'	System	01 Sep 2020 16:12:18

US3612005

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(5)

Generated On: 10 Jun 2021 09:15:23

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:05:06
Data entry locked.	System	01 Sep 2020 16:12:18
User entered 'Day 5'	System	01 Sep 2020 16:12:18

US3612005

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(5)

Generated On: 10 Jun 2021 09:15:23

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:05:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a19c168458d97dd9)', Time: '2020-09-05T20:53:44', User OID: 'PatientReportedOutcome (US3612005)', ODM File OID: '7c577538-9e92-4797-950f-2a1eb236f32c'	System	06 Sep 2020 01:54:06
User entered 'Yes (Y)'	System	06 Sep 2020 01:54:06

US3612005

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(5)

Generated On: 10 Jun 2021 09:15:23

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:05:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a19c168458d97dd9)', Time: '2020-09-05T20:53:51', User OID: 'PatientReportedOutcome (US3612005)', ODM File OID: '7c577538-9e92-4797-950f-2a1eb236f32c'	System	06 Sep 2020 01:54:06
User entered '98.0'	System	06 Sep 2020 01:54:06

US3612005

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(5)

Generated On: 10 Jun 2021 09:15:23

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:05:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a19c168458d97dd9)', Time: '2020-09-05T20:53:55', User OID: 'PatientReportedOutcome (US3612005)', ODM File OID: '7c577538-9e92-4797-950f-2a1eb236f32c'	System	06 Sep 2020 01:54:06
User entered 'No (N)'	System	06 Sep 2020 01:54:06

**US3612005**

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(5)**

**Generated On: 10 Jun 2021 09:15:23**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:05:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a19c168458d97dd9)', Time: '2020-09-05T20:54:01', User OID: 'PatientReportedOutcome (US3612005)', ODM File OID: '7c577538-9e92-4797-950f-2a1eb236f32c'	System	06 Sep 2020 01:54:06
User entered '05 Sep 2020 20:54'	System	06 Sep 2020 01:54:06

**US3612005**

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(5)**

**Generated On: 10 Jun 2021 09:15:23**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:05:06
User entered '05 Sep 2020 12:00'	System	01 Sep 2020 16:12:18

**US3612005**

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(5)**

**Generated On: 10 Jun 2021 09:15:23**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:05:06
User entered '06 Sep 2020 11:59'	System	01 Sep 2020 16:12:18

US3612005

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(6)

Generated On: 10 Jun 2021 09:15:23

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:05:06
Data entry locked.	System	01 Sep 2020 16:12:18
User entered 'Day 6'	System	01 Sep 2020 16:12:18

US3612005

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(6)

Generated On: 10 Jun 2021 09:15:23

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:05:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a19c168458d97dd9)', Time: '2020-09-06T22:51:29', User OID: 'PatientReportedOutcome (US3612005)', ODM File OID: '363be077-bd49-4b75-bbcc-24a96abb0d7e'	System	07 Sep 2020 03:51:52
User entered 'Yes (Y)'	System	07 Sep 2020 03:51:52

US3612005

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(6)

Generated On: 10 Jun 2021 09:15:23

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:05:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a19c168458d97dd9)', Time: '2020-09-06T22:51:36', User OID: 'PatientReportedOutcome (US3612005)', ODM File OID: '363be077-bd49-4b75-bbcc-24a96abb0d7e' User entered '96.0'	System	07 Sep 2020 03:51:52
	System	07 Sep 2020 03:51:52

US3612005

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(6)

Generated On: 10 Jun 2021 09:15:23

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:05:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a19c168458d97dd9)', Time: '2020-09-06T22:51:41', User OID: 'PatientReportedOutcome (US3612005)', ODM File OID: '363be077-bd49-4b75-bbcc-24a96abb0d7e'	System	07 Sep 2020 03:51:52
User entered 'No (N)'	System	07 Sep 2020 03:51:52

**US3612005**

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(6)**

**Generated On: 10 Jun 2021 09:15:23**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:05:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a19c168458d97dd9)', Time: '2020-09-06T22:51:49', User OID: 'PatientReportedOutcome (US3612005)', ODM File OID: '363be077-bd49-4b75-bbcc-24a96abb0d7e'	System	07 Sep 2020 03:51:52
User entered '06 Sep 2020 22:51'	System	07 Sep 2020 03:51:52

**US3612005**

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(6)**

**Generated On: 10 Jun 2021 09:15:23**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:05:06
User entered '06 Sep 2020 12:00'	System	01 Sep 2020 16:12:18

**US3612005**

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(6)**

**Generated On: 10 Jun 2021 09:15:23**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:05:06
User entered '07 Sep 2020 11:59'	System	01 Sep 2020 16:12:18

US3612005

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(7)

Generated On: 10 Jun 2021 09:15:23

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:05:06
Data entry locked.	System	01 Sep 2020 16:12:18
User entered 'Day 7'	System	01 Sep 2020 16:12:18

US3612005

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(7)

Generated On: 10 Jun 2021 09:15:23

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:05:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a19c168458d97dd9)', Time: '2020-09-07T17:04:45', User OID: 'PatientReportedOutcome (US3612005)', ODM File OID: '59700cad-f9e7-4ff3-ade7-fdf6560112fb'	System	07 Sep 2020 22:05:06
User entered 'Yes (Y)'	System	07 Sep 2020 22:05:06

US3612005

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(7)

Generated On: 10 Jun 2021 09:15:23

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:05:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a19c168458d97dd9)', Time: '2020-09-07T17:04:51', User OID: 'PatientReportedOutcome (US3612005)', ODM File OID: '59700cad-f9e7-4ff3-ade7-fdf6560112fb' User entered '97.0'	System	07 Sep 2020 22:05:06
	System	07 Sep 2020 22:05:06

US3612005

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(7)

Generated On: 10 Jun 2021 09:15:23

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:05:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a19c168458d97dd9)', Time: '2020-09-07T17:04:54', User OID: 'PatientReportedOutcome (US3612005)', ODM File OID: '59700cad-f9e7-4ff3-ade7-fdf6560112fb'	System	07 Sep 2020 22:05:06
User entered 'No (N)'	System	07 Sep 2020 22:05:06

**US3612005**

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(7)**

**Generated On: 10 Jun 2021 09:15:23**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:05:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a19c168458d97dd9)', Time: '2020-09-07T17:05:00', User OID: 'PatientReportedOutcome (US3612005)', ODM File OID: '59700cad-f9e7-4ff3-ade7-fdf6560112fb'	System	07 Sep 2020 22:05:06
User entered '07 Sep 2020 17:05'	System	07 Sep 2020 22:05:06

**US3612005**

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(7)**

**Generated On: 10 Jun 2021 09:15:23**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:05:06
User entered '07 Sep 2020 12:00'	System	01 Sep 2020 16:12:18

**US3612005**

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(7)**

**Generated On: 10 Jun 2021 09:15:23**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:05:06
User entered '08 Sep 2020 11:59'	System	01 Sep 2020 16:12:18

US3612005

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/1)

Generated On: 10 Jun 2021 09:15:23

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:05:06
Data entry locked.	System	01 Sep 2020 16:12:18
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	01 Sep 2020 16:12:18

US3612005

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/1)

Generated On: 10 Jun 2021 09:15:23

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 16:05:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a19c168458d97dd9)', Time: '2020-09-01T11:34:24', User OID: 'PatientReportedOutcome (US3612005)', ODM File OID: 'd1b702ef-6736-4f41-b162-4035baf05626'	System	01 Sep 2020 16:34:58
User entered 'None (1)'	System	01 Sep 2020 16:34:58

US3612005

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/1)

Generated On: 10 Jun 2021 09:15:23

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:05:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a19c168458d97dd9)', Time: '2020-09-01T11:34:30', User OID: 'PatientReportedOutcome (US3612005)', ODM File OID: 'd1b702ef-6736-4f41-b162-4035baf05626'	System	01 Sep 2020 16:34:58
User entered 'No (N)'	System	01 Sep 2020 16:34:58

US3612005

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/1)

Generated On: 10 Jun 2021 09:15:23

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:05:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a19c168458d97dd9)', Time: '2020-09-01T11:34:34', User OID: 'PatientReportedOutcome (US3612005)', ODM File OID: 'd1b702ef-6736-4f41-b162-4035baf05626'	System	01 Sep 2020 16:34:58
User entered 'No (N)'	System	01 Sep 2020 16:34:58

US3612005

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/1)

Generated On: 10 Jun 2021 09:15:23

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 16:05:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a19c168458d97dd9)', Time: '2020-09-01T11:34:42', User OID: 'PatientReportedOutcome (US3612005)', ODM File OID: 'd1b702ef-6736-4f41-b162-4035baf05626'	System	01 Sep 2020 16:34:58
User entered 'None (1)'	System	01 Sep 2020 16:34:58

**US3612005**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(1/1)**

**Generated On: 10 Jun 2021 09:15:23**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:05:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a19c168458d97dd9)', Time: '2020-09-01T11:34:56', User OID: 'PatientReportedOutcome (US3612005)', ODM File OID: 'd1b702ef-6736-4f41-b162-4035baf05626'	System	01 Sep 2020 16:34:58
User entered '01 Sep 2020 11:34'	System	01 Sep 2020 16:34:58

**US3612005**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(1/1)**

**Generated On: 10 Jun 2021 09:15:23**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:05:06
User entered '01 Sep 2020 11:18'	System	01 Sep 2020 16:12:18

**US3612005**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(1/1)**

**Generated On: 10 Jun 2021 09:15:23**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:05:06
User entered '01 Sep 2020 13:48'	System	01 Sep 2020 16:12:18

US3612005

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/2)

Generated On: 10 Jun 2021 09:15:23

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:05:06
Data entry locked.	System	01 Sep 2020 16:12:18
User entered 'Day 1, after vaccination (at home)'	System	01 Sep 2020 16:12:18

US3612005

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/2)

Generated On: 10 Jun 2021 09:15:23

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 16:05:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a19c168458d97dd9)', Time: '2020-09-02T00:04:51', User OID: 'PatientReportedOutcome (US3612005)', ODM File OID: 'f017f17a-688b-4de9-be5f-827b86c3c70b'	System	02 Sep 2020 05:05:21
User entered 'None (1)'	System	02 Sep 2020 05:05:21

US3612005

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/2)

Generated On: 10 Jun 2021 09:15:23

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:05:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a19c168458d97dd9)', Time: '2020-09-02T00:04:55', User OID: 'PatientReportedOutcome (US3612005)', ODM File OID: 'f017f17a-688b-4de9-be5f-827b86c3c70b'	System	02 Sep 2020 05:05:21
User entered 'No (N)'	System	02 Sep 2020 05:05:21

US3612005

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/2)

Generated On: 10 Jun 2021 09:15:23

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:05:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a19c168458d97dd9)', Time: '2020-09-02T00:05:05', User OID: 'PatientReportedOutcome (US3612005)', ODM File OID: 'f017f17a-688b-4de9-be5f-827b86c3c70b'	System	02 Sep 2020 05:05:21
User entered 'No (N)'	System	02 Sep 2020 05:05:21

US3612005

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/2)

Generated On: 10 Jun 2021 09:15:23

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 16:05:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a19c168458d97dd9)', Time: '2020-09-02T00:05:10', User OID: 'PatientReportedOutcome (US3612005)', ODM File OID: 'f017f17a-688b-4de9-be5f-827b86c3c70b'	System	02 Sep 2020 05:05:21
User entered 'None (1)'	System	02 Sep 2020 05:05:21

**US3612005**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(1/2)**

**Generated On: 10 Jun 2021 09:15:23**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:05:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a19c168458d97dd9)', Time: '2020-09-02T00:05:18', User OID: 'PatientReportedOutcome (US3612005)', ODM File OID: 'f017f17a-688b-4de9-be5f-827b86c3c70b'	System	02 Sep 2020 05:05:21
User entered '02 Sep 2020 00:05'	System	02 Sep 2020 05:05:21

**US3612005**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(1/2)**

**Generated On: 10 Jun 2021 09:15:23**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:05:06
User entered '01 Sep 2020 14:43'	System	01 Sep 2020 16:12:18

**US3612005**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(1/2)**

**Generated On: 10 Jun 2021 09:15:23**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:05:06
User entered '02 Sep 2020 11:59'	System	01 Sep 2020 16:12:18

**US3612005**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(2)**

**Generated On: 10 Jun 2021 09:15:23**

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:05:06
Data entry locked.	System	01 Sep 2020 16:12:18
User entered 'Day 2'	System	01 Sep 2020 16:12:18

US3612005

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(2)

Generated On: 10 Jun 2021 09:15:23

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 16:05:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a19c168458d97dd9)', Time: '2020-09-02T12:01:39', User OID: 'PatientReportedOutcome (US3612005)', ODM File OID: 'd882ef89-9909-4ebd-a0db-a4fb25877c34'	System	02 Sep 2020 17:02:17
User entered 'None (1)'	System	02 Sep 2020 17:02:17

US3612005

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(2)

Generated On: 10 Jun 2021 09:15:23

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:05:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a19c168458d97dd9)', Time: '2020-09-02T12:01:44', User OID: 'PatientReportedOutcome (US3612005)', ODM File OID: 'd882ef89-9909-4ebd-a0db-a4fb25877c34'	System	02 Sep 2020 17:02:17
User entered 'No (N)'	System	02 Sep 2020 17:02:17

US3612005

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(2)

Generated On: 10 Jun 2021 09:15:23

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:05:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a19c168458d97dd9)', Time: '2020-09-02T12:01:47', User OID: 'PatientReportedOutcome (US3612005)', ODM File OID: 'd882ef89-9909-4ebd-a0db-a4fb25877c34'	System	02 Sep 2020 17:02:17
User entered 'No (N)'	System	02 Sep 2020 17:02:17

US3612005

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(2)

Generated On: 10 Jun 2021 09:15:23

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 16:05:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a19c168458d97dd9)', Time: '2020-09-02T12:01:51', User OID: 'PatientReportedOutcome (US3612005)', ODM File OID: 'd882ef89-9909-4ebd-a0db-a4fb25877c34'	System	02 Sep 2020 17:02:17
User entered 'None (1)'	System	02 Sep 2020 17:02:17

**US3612005**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(2)**

**Generated On: 10 Jun 2021 09:15:23**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:05:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a19c168458d97dd9)', Time: '2020-09-02T12:01:58', User OID: 'PatientReportedOutcome (US3612005)', ODM File OID: 'd882ef89-9909-4ebd-a0db-a4fb25877c34'	System	02 Sep 2020 17:02:17
User entered '02 Sep 2020 12:01'	System	02 Sep 2020 17:02:17

**US3612005**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(2)**

**Generated On: 10 Jun 2021 09:15:23**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:05:06
User entered '02 Sep 2020 12:00'	System	01 Sep 2020 16:12:18

**US3612005**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(2)**

**Generated On: 10 Jun 2021 09:15:23**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:05:06
User entered '03 Sep 2020 11:59'	System	01 Sep 2020 16:12:18

US3612005

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(3)

Generated On: 10 Jun 2021 09:15:23

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:05:06
Data entry locked.	System	01 Sep 2020 16:12:18
User entered 'Day 3'	System	01 Sep 2020 16:12:18

US3612005

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(3)

Generated On: 10 Jun 2021 09:15:23

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 16:05:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a19c168458d97dd9)', Time: '2020-09-03T12:33:25', User OID: 'PatientReportedOutcome (US3612005)', ODM File OID: '8aa766ee-2182-4f5a-93ba-4eede28dde72'	System	03 Sep 2020 17:33:57
User entered 'None (1)'	System	03 Sep 2020 17:33:57

US3612005

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(3)

Generated On: 10 Jun 2021 09:15:23

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:05:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a19c168458d97dd9)', Time: '2020-09-03T12:33:41', User OID: 'PatientReportedOutcome (US3612005)', ODM File OID: '8aa766ee-2182-4f5a-93ba-4eede28dde72'	System	03 Sep 2020 17:33:57
User entered 'No (N)'	System	03 Sep 2020 17:33:57

US3612005

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(3)

Generated On: 10 Jun 2021 09:15:23

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:05:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a19c168458d97dd9)', Time: '2020-09-03T12:33:44', User OID: 'PatientReportedOutcome (US3612005)', ODM File OID: '8aa766ee-2182-4f5a-93ba-4eede28dde72'	System	03 Sep 2020 17:33:57
User entered 'No (N)'	System	03 Sep 2020 17:33:57

US3612005

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(3)

Generated On: 10 Jun 2021 09:15:23

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 16:05:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a19c168458d97dd9)', Time: '2020-09-03T12:33:48', User OID: 'PatientReportedOutcome (US3612005)', ODM File OID: '8aa766ee-2182-4f5a-93ba-4eede28dde72'	System	03 Sep 2020 17:33:57
User entered 'None (1)'	System	03 Sep 2020 17:33:57

**US3612005**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(3)**

**Generated On: 10 Jun 2021 09:15:23**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:05:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a19c168458d97dd9)', Time: '2020-09-03T12:33:52', User OID: 'PatientReportedOutcome (US3612005)', ODM File OID: '8aa766ee-2182-4f5a-93ba-4eede28dde72'	System	03 Sep 2020 17:33:57
User entered '03 Sep 2020 12:33'	System	03 Sep 2020 17:33:57

**US3612005**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(3)**

**Generated On: 10 Jun 2021 09:15:23**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:05:06
User entered '03 Sep 2020 12:00'	System	01 Sep 2020 16:12:18

**US3612005**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(3)**

**Generated On: 10 Jun 2021 09:15:23**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:05:06
User entered '04 Sep 2020 11:59'	System	01 Sep 2020 16:12:18

**US3612005**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(4)**

**Generated On: 10 Jun 2021 09:15:23**

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:05:06
Data entry locked.	System	01 Sep 2020 16:12:18
User entered 'Day 4'	System	01 Sep 2020 16:12:18

US3612005

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(4)

Generated On: 10 Jun 2021 09:15:23

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 16:05:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a19c168458d97dd9)', Time: '2020-09-04T17:04:02', User OID: 'PatientReportedOutcome (US3612005)', ODM File OID: 'fae93808-a31d-4ce6-adb0-4e8f34ff9b1f'	System	04 Sep 2020 22:04:18
User entered 'None (1)'	System	04 Sep 2020 22:04:18

US3612005

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(4)

Generated On: 10 Jun 2021 09:15:23

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:05:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a19c168458d97dd9)', Time: '2020-09-04T17:04:06', User OID: 'PatientReportedOutcome (US3612005)', ODM File OID: 'fae93808-a31d-4ce6-adb0-4e8f34ff9b1f'	System	04 Sep 2020 22:04:18
User entered 'No (N)'	System	04 Sep 2020 22:04:18

US3612005

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(4)

Generated On: 10 Jun 2021 09:15:23

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:05:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a19c168458d97dd9)', Time: '2020-09-04T17:04:09', User OID: 'PatientReportedOutcome (US3612005)', ODM File OID: 'fae93808-a31d-4ce6-adb0-4e8f34ff9b1f'	System	04 Sep 2020 22:04:18
User entered 'No (N)'	System	04 Sep 2020 22:04:18

US3612005

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(4)

Generated On: 10 Jun 2021 09:15:23

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 16:05:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a19c168458d97dd9)', Time: '2020-09-04T17:04:12', User OID: 'PatientReportedOutcome (US3612005)', ODM File OID: 'fae93808-a31d-4ce6-adb0-4e8f34ff9b1f'	System	04 Sep 2020 22:04:18
User entered 'None (1)'	System	04 Sep 2020 22:04:18

**US3612005**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(4)**

**Generated On: 10 Jun 2021 09:15:23**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:05:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a19c168458d97dd9)', Time: '2020-09-04T17:04:15', User OID: 'PatientReportedOutcome (US3612005)', ODM File OID: 'fae93808-a31d-4ce6-adb0-4e8f34ff9b1f' User entered '04 Sep 2020 17:04'	System	04 Sep 2020 22:04:18
	System	04 Sep 2020 22:04:18

**US3612005**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(4)**

**Generated On: 10 Jun 2021 09:15:23**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:05:06
User entered '04 Sep 2020 12:00'	System	01 Sep 2020 16:12:18

**US3612005**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(4)**

**Generated On: 10 Jun 2021 09:15:23**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:05:06
User entered '05 Sep 2020 11:59'	System	01 Sep 2020 16:12:18

**US3612005**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(5)**

**Generated On: 10 Jun 2021 09:15:23**

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:05:06
Data entry locked.	System	01 Sep 2020 16:12:18
User entered 'Day 5'	System	01 Sep 2020 16:12:18

US3612005

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(5)

Generated On: 10 Jun 2021 09:15:23

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 16:05:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a19c168458d97dd9)', Time: '2020-09-05T20:54:15', User OID: 'PatientReportedOutcome (US3612005)', ODM File OID: '23c369d2-ea7d-4e8f-84b6-26a55ed6d58d'	System	06 Sep 2020 01:54:34
User entered 'None (1)'	System	06 Sep 2020 01:54:34

US3612005

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(5)

Generated On: 10 Jun 2021 09:15:23

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:05:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a19c168458d97dd9)', Time: '2020-09-05T20:54:19', User OID: 'PatientReportedOutcome (US3612005)', ODM File OID: '23c369d2-ea7d-4e8f-84b6-26a55ed6d58d'	System	06 Sep 2020 01:54:34
User entered 'No (N)'	System	06 Sep 2020 01:54:34

US3612005

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(5)

Generated On: 10 Jun 2021 09:15:23

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:05:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a19c168458d97dd9)', Time: '2020-09-05T20:54:21', User OID: 'PatientReportedOutcome (US3612005)', ODM File OID: '23c369d2-ea7d-4e8f-84b6-26a55ed6d58d'	System	06 Sep 2020 01:54:34
User entered 'No (N)'	System	06 Sep 2020 01:54:34

US3612005

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(5)

Generated On: 10 Jun 2021 09:15:23

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 16:05:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a19c168458d97dd9)', Time: '2020-09-05T20:54:25', User OID: 'PatientReportedOutcome (US3612005)', ODM File OID: '23c369d2-ea7d-4e8f-84b6-26a55ed6d58d'	System	06 Sep 2020 01:54:34
User entered 'None (1)'	System	06 Sep 2020 01:54:34

**US3612005**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(5)**

**Generated On: 10 Jun 2021 09:15:23**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:05:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a19c168458d97dd9)', Time: '2020-09-05T20:54:30', User OID: 'PatientReportedOutcome (US3612005)', ODM File OID: '23c369d2-ea7d-4e8f-84b6-26a55ed6d58d'	System	06 Sep 2020 01:54:34
User entered '05 Sep 2020 20:54'	System	06 Sep 2020 01:54:34

**US3612005**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(5)**

**Generated On: 10 Jun 2021 09:15:23**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:05:06
User entered '05 Sep 2020 12:00'	System	01 Sep 2020 16:12:18

**US3612005**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(5)**

**Generated On: 10 Jun 2021 09:15:23**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:05:06
User entered '06 Sep 2020 11:59'	System	01 Sep 2020 16:12:18

**US3612005**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(6)**

**Generated On: 10 Jun 2021 09:15:23**

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:05:06
Data entry locked.	System	01 Sep 2020 16:12:18
User entered 'Day 6'	System	01 Sep 2020 16:12:18

US3612005

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(6)

Generated On: 10 Jun 2021 09:15:23

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 16:05:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a19c168458d97dd9)', Time: '2020-09-06T22:51:56', User OID: 'PatientReportedOutcome (US3612005)', ODM File OID: 'e0017aeb-88a7-4a3d-8e62-8e994b740a16'	System	07 Sep 2020 03:52:19
User entered 'None (1)'	System	07 Sep 2020 03:52:19

US3612005

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(6)

Generated On: 10 Jun 2021 09:15:23

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:05:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a19c168458d97dd9)', Time: '2020-09-06T22:52:01', User OID: 'PatientReportedOutcome (US3612005)', ODM File OID: 'e0017aeb-88a7-4a3d-8e62-8e994b740a16'	System	07 Sep 2020 03:52:19
User entered 'No (N)'	System	07 Sep 2020 03:52:19

US3612005

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(6)

Generated On: 10 Jun 2021 09:15:23

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:05:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a19c168458d97dd9)', Time: '2020-09-06T22:52:04', User OID: 'PatientReportedOutcome (US3612005)', ODM File OID: 'e0017aeb-88a7-4a3d-8e62-8e994b740a16'	System	07 Sep 2020 03:52:19
User entered 'No (N)'	System	07 Sep 2020 03:52:19

US3612005

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(6)

Generated On: 10 Jun 2021 09:15:23

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 16:05:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a19c168458d97dd9)', Time: '2020-09-06T22:52:09', User OID: 'PatientReportedOutcome (US3612005)', ODM File OID: 'e0017aeb-88a7-4a3d-8e62-8e994b740a16'	System	07 Sep 2020 03:52:19
User entered 'None (1)'	System	07 Sep 2020 03:52:19

**US3612005**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(6)**

**Generated On: 10 Jun 2021 09:15:23**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:05:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a19c168458d97dd9)', Time: '2020-09-06T22:52:14', User OID: 'PatientReportedOutcome (US3612005)', ODM File OID: 'e0017aeb-88a7-4a3d-8e62-8e994b740a16'	System	07 Sep 2020 03:52:19
User entered '06 Sep 2020 22:52'	System	07 Sep 2020 03:52:19

**US3612005**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(6)**

**Generated On: 10 Jun 2021 09:15:23**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:05:06
User entered '06 Sep 2020 12:00'	System	01 Sep 2020 16:12:18

**US3612005**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(6)**

**Generated On: 10 Jun 2021 09:15:23**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:05:06
User entered '07 Sep 2020 11:59'	System	01 Sep 2020 16:12:18

US3612005

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(7)

Generated On: 10 Jun 2021 09:15:23

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:05:06
Data entry locked.	System	01 Sep 2020 16:12:18
User entered 'Day 7'	System	01 Sep 2020 16:12:18

US3612005

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(7)

Generated On: 10 Jun 2021 09:15:23

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 16:05:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a19c168458d97dd9)', Time: '2020-09-07T17:05:08', User OID: 'PatientReportedOutcome (US3612005)', ODM File OID: 'da9d5496-78a5-41f7-9d26-77c7b9d9717c'	System	07 Sep 2020 22:05:28
User entered 'None (1)'	System	07 Sep 2020 22:05:28

US3612005

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(7)

Generated On: 10 Jun 2021 09:15:23

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:05:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a19c168458d97dd9)', Time: '2020-09-07T17:05:11', User OID: 'PatientReportedOutcome (US3612005)', ODM File OID: 'da9d5496-78a5-41f7-9d26-77c7b9d9717c'	System	07 Sep 2020 22:05:28
User entered 'No (N)'	System	07 Sep 2020 22:05:28

US3612005

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(7)

Generated On: 10 Jun 2021 09:15:23

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:05:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a19c168458d97dd9)', Time: '2020-09-07T17:05:14', User OID: 'PatientReportedOutcome (US3612005)', ODM File OID: 'da9d5496-78a5-41f7-9d26-77c7b9d9717c'	System	07 Sep 2020 22:05:28
User entered 'No (N)'	System	07 Sep 2020 22:05:28

US3612005

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(7)

Generated On: 10 Jun 2021 09:15:23

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 16:05:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a19c168458d97dd9)', Time: '2020-09-07T17:05:17', User OID: 'PatientReportedOutcome (US3612005)', ODM File OID: 'da9d5496-78a5-41f7-9d26-77c7b9d9717c'	System	07 Sep 2020 22:05:28
User entered 'None (1)'	System	07 Sep 2020 22:05:28

**US3612005**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(7)**

**Generated On: 10 Jun 2021 09:15:23**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:05:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a19c168458d97dd9)', Time: '2020-09-07T17:05:25', User OID: 'PatientReportedOutcome (US3612005)', ODM File OID: 'da9d5496-78a5-41f7-9d26-77c7b9d9717c'	System	07 Sep 2020 22:05:28
User entered '07 Sep 2020 17:05'	System	07 Sep 2020 22:05:28

**US3612005**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(7)**

**Generated On: 10 Jun 2021 09:15:23**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:05:06
User entered '07 Sep 2020 12:00'	System	01 Sep 2020 16:12:18

**US3612005**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(7)**

**Generated On: 10 Jun 2021 09:15:23**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:05:06
User entered '08 Sep 2020 11:59'	System	01 Sep 2020 16:12:18

**US3612005**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(1/1)**

**Generated On: 10 Jun 2021 09:15:23**

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:05:06
Data entry locked.	System	01 Sep 2020 16:12:18
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	01 Sep 2020 16:12:18

**US3612005**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(1/1)**

**Generated On: 10 Jun 2021 09:15:23**

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:05:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a19c168458d97dd9)', Time: '2020-09-01T11:35:06', User OID: 'PatientReportedOutcome (US3612005)', ODM File OID: 'c892ab6c-6b0a-4507-ab10-4a103676149e' User entered 'None (0)'	System	01 Sep 2020 16:35:54
	System	01 Sep 2020 16:35:54

**US3612005**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(1/1)**

**Generated On: 10 Jun 2021 09:15:23**

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:05:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a19c168458d97dd9)', Time: '2020-09-01T11:35:14', User OID: 'PatientReportedOutcome (US3612005)', ODM File OID: 'c892ab6c-6b0a-4507-ab10-4a103676149e' User entered 'None (0)'	System	01 Sep 2020 16:35:54
	System	01 Sep 2020 16:35:54

US3612005

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 10 Jun 2021 09:15:23

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:05:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a19c168458d97dd9)', Time: '2020-09-01T11:35:20', User OID: 'PatientReportedOutcome (US3612005)', ODM File OID: 'c892ab6c-6b0a-4507-ab10-4a103676149e'	System	01 Sep 2020 16:35:54
User entered 'None (0)'	System	01 Sep 2020 16:35:54

US3612005

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 10 Jun 2021 09:15:23

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:05:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a19c168458d97dd9)', Time: '2020-09-01T11:35:26', User OID: 'PatientReportedOutcome (US3612005)', ODM File OID: 'c892ab6c-6b0a-4507-ab10-4a103676149e' User entered 'None (0)'	System	01 Sep 2020 16:35:54
	System	01 Sep 2020 16:35:54

**US3612005**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(1/1)**

**Generated On: 10 Jun 2021 09:15:23**

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:05:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a19c168458d97dd9)', Time: '2020-09-01T11:35:29', User OID: 'PatientReportedOutcome (US3612005)', ODM File OID: 'c892ab6c-6b0a-4507-ab10-4a103676149e' User entered 'None (0)'	System	01 Sep 2020 16:35:54
	System	01 Sep 2020 16:35:54

**US3612005**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(1/1)**

**Generated On: 10 Jun 2021 09:15:23**

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:05:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a19c168458d97dd9)', Time: '2020-09-01T11:35:32', User OID: 'PatientReportedOutcome (US3612005)', ODM File OID: 'c892ab6c-6b0a-4507-ab10-4a103676149e' User entered 'None (0)'	System	01 Sep 2020 16:35:54
	System	01 Sep 2020 16:35:54

US3612005

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 10 Jun 2021 09:15:23

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 16:05:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a19c168458d97dd9)', Time: '2020-09-01T11:35:40', User OID: 'PatientReportedOutcome (US3612005)', ODM File OID: 'c892ab6c-6b0a-4507-ab10-4a103676149e'	System	01 Sep 2020 16:35:54
User entered 'No (N)'	System	01 Sep 2020 16:35:54

**US3612005**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(1/1)**

**Generated On: 10 Jun 2021 09:15:23**

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:05:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a19c168458d97dd9)', Time: '2020-09-01T11:35:50', User OID: 'PatientReportedOutcome (US3612005)', ODM File OID: 'c892ab6c-6b0a-4507-ab10-4a103676149e'	System	01 Sep 2020 16:35:54
User entered '01 Sep 2020 11:35'	System	01 Sep 2020 16:35:54

**US3612005**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(1/1)**

**Generated On: 10 Jun 2021 09:15:23**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:05:06
User entered '01 Sep 2020 11:18'	System	01 Sep 2020 16:12:18

**US3612005**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(1/1)**

**Generated On: 10 Jun 2021 09:15:23**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:05:06
User entered '01 Sep 2020 13:48'	System	01 Sep 2020 16:12:18

**US3612005**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(1/2)**

**Generated On: 10 Jun 2021 09:15:23**

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:05:06
Data entry locked.	System	01 Sep 2020 16:12:18
User entered 'Day 1, after vaccination (at home)'	System	01 Sep 2020 16:12:18

**US3612005**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(1/2)**

**Generated On: 10 Jun 2021 09:15:23**

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:05:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a19c168458d97dd9)', Time: '2020-09-02T00:05:24', User OID: 'PatientReportedOutcome (US3612005)', ODM File OID: 'f07ee886-7c4f-46e3-911d-d0ee2c12b1d8'	System	02 Sep 2020 05:05:56
User entered 'None (0)'	System	02 Sep 2020 05:05:56

US3612005

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 10 Jun 2021 09:15:23

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:05:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a19c168458d97dd9)', Time: '2020-09-02T00:05:28', User OID: 'PatientReportedOutcome (US3612005)', ODM File OID: 'f07ee886-7c4f-46e3-911d-d0ee2c12b1d8'	System	02 Sep 2020 05:05:56
User entered 'None (0)'	System	02 Sep 2020 05:05:56

**US3612005**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(1/2)**

**Generated On: 10 Jun 2021 09:15:23**

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:05:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a19c168458d97dd9)', Time: '2020-09-02T00:05:31', User OID: 'PatientReportedOutcome (US3612005)', ODM File OID: 'f07ee886-7c4f-46e3-911d-d0ee2c12b1d8'	System	02 Sep 2020 05:05:56
User entered 'None (0)'	System	02 Sep 2020 05:05:56

US3612005

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 10 Jun 2021 09:15:23

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:05:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a19c168458d97dd9)', Time: '2020-09-02T00:05:35', User OID: 'PatientReportedOutcome (US3612005)', ODM File OID: 'f07ee886-7c4f-46e3-911d-d0ee2c12b1d8'	System	02 Sep 2020 05:05:56
User entered 'None (0)'	System	02 Sep 2020 05:05:56

**US3612005**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(1/2)**

**Generated On: 10 Jun 2021 09:15:23**

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:05:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a19c168458d97dd9)', Time: '2020-09-02T00:05:38', User OID: 'PatientReportedOutcome (US3612005)', ODM File OID: 'f07ee886-7c4f-46e3-911d-d0ee2c12b1d8'	System	02 Sep 2020 05:05:56
User entered 'None (0)'	System	02 Sep 2020 05:05:56

**US3612005**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(1/2)**

**Generated On: 10 Jun 2021 09:15:23**

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:05:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a19c168458d97dd9)', Time: '2020-09-02T00:05:41', User OID: 'PatientReportedOutcome (US3612005)', ODM File OID: 'f07ee886-7c4f-46e3-911d-d0ee2c12b1d8'	System	02 Sep 2020 05:05:56
User entered 'None (0)'	System	02 Sep 2020 05:05:56

US3612005

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 10 Jun 2021 09:15:23

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 16:05:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a19c168458d97dd9)', Time: '2020-09-02T00:05:45', User OID: 'PatientReportedOutcome (US3612005)', ODM File OID: 'f07ee886-7c4f-46e3-911d-d0ee2c12b1d8'	System	02 Sep 2020 05:05:56
User entered 'No (N)'	System	02 Sep 2020 05:05:56

**US3612005**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(1/2)**

**Generated On: 10 Jun 2021 09:15:23**

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:05:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a19c168458d97dd9)', Time: '2020-09-02T00:05:54', User OID: 'PatientReportedOutcome (US3612005)', ODM File OID: 'f07ee886-7c4f-46e3-911d-d0ee2c12b1d8'	System	02 Sep 2020 05:05:56
User entered '02 Sep 2020 00:05'	System	02 Sep 2020 05:05:56

**US3612005**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(1/2)**

**Generated On: 10 Jun 2021 09:15:23**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:05:06
User entered '01 Sep 2020 14:43'	System	01 Sep 2020 16:12:18

**US3612005**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(1/2)**

**Generated On: 10 Jun 2021 09:15:23**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:05:06
User entered '02 Sep 2020 11:59'	System	01 Sep 2020 16:12:18

**US3612005**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(2)**

**Generated On: 10 Jun 2021 09:15:23**

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:05:06
Data entry locked.	System	01 Sep 2020 16:12:18
User entered 'Day 2'	System	01 Sep 2020 16:12:18

**US3612005**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(2)**

**Generated On: 10 Jun 2021 09:15:23**

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:05:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a19c168458d97dd9)', Time: '2020-09-02T12:02:07', User OID: 'PatientReportedOutcome (US3612005)', ODM File OID: '50eb05e0-c7c7-45be-9284-44bca990c88a'	System	02 Sep 2020 17:02:38
User entered 'None (0)'	System	02 Sep 2020 17:02:38

**US3612005**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(2)**

**Generated On: 10 Jun 2021 09:15:23**

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:05:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a19c168458d97dd9)', Time: '2020-09-02T12:02:10', User OID: 'PatientReportedOutcome (US3612005)', ODM File OID: '50eb05e0-c7c7-45be-9284-44bca990c88a'	System	02 Sep 2020 17:02:38
User entered 'None (0)'	System	02 Sep 2020 17:02:38

US3612005

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 10 Jun 2021 09:15:23

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:05:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a19c168458d97dd9)', Time: '2020-09-02T12:02:13', User OID: 'PatientReportedOutcome (US3612005)', ODM File OID: '50eb05e0-c7c7-45be-9284-44bca990c88a'	System	02 Sep 2020 17:02:38
User entered 'None (0)'	System	02 Sep 2020 17:02:38

US3612005

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 10 Jun 2021 09:15:23

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:05:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a19c168458d97dd9)', Time: '2020-09-02T12:02:16', User OID: 'PatientReportedOutcome (US3612005)', ODM File OID: '50eb05e0-c7c7-45be-9284-44bca990c88a'	System	02 Sep 2020 17:02:38
User entered 'None (0)'	System	02 Sep 2020 17:02:38

**US3612005**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(2)**

**Generated On: 10 Jun 2021 09:15:23**

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:05:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a19c168458d97dd9)', Time: '2020-09-02T12:02:19', User OID: 'PatientReportedOutcome (US3612005)', ODM File OID: '50eb05e0-c7c7-45be-9284-44bca990c88a'	System	02 Sep 2020 17:02:38
User entered 'None (0)'	System	02 Sep 2020 17:02:38

**US3612005**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(2)**

**Generated On: 10 Jun 2021 09:15:23**

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:05:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a19c168458d97dd9)', Time: '2020-09-02T12:02:22', User OID: 'PatientReportedOutcome (US3612005)', ODM File OID: '50eb05e0-c7c7-45be-9284-44bca990c88a'	System	02 Sep 2020 17:02:38
User entered 'None (0)'	System	02 Sep 2020 17:02:38

US3612005

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 10 Jun 2021 09:15:23

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 16:05:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a19c168458d97dd9)', Time: '2020-09-02T12:02:25', User OID: 'PatientReportedOutcome (US3612005)', ODM File OID: '50eb05e0-c7c7-45be-9284-44bca990c88a'	System	02 Sep 2020 17:02:38
User entered 'No (N)'	System	02 Sep 2020 17:02:38

**US3612005**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(2)**

**Generated On: 10 Jun 2021 09:15:23**

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:05:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a19c168458d97dd9)', Time: '2020-09-02T12:02:32', User OID: 'PatientReportedOutcome (US3612005)', ODM File OID: '50eb05e0-c7c7-45be-9284-44bca990c88a'	System	02 Sep 2020 17:02:38
User entered '02 Sep 2020 12:02'	System	02 Sep 2020 17:02:38

**US3612005**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(2)**

**Generated On: 10 Jun 2021 09:15:23**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:05:06
User entered '02 Sep 2020 12:00'	System	01 Sep 2020 16:12:18

**US3612005**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(2)**

**Generated On: 10 Jun 2021 09:15:23**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:05:06
User entered '03 Sep 2020 11:59'	System	01 Sep 2020 16:12:18

**US3612005**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(3)**

**Generated On: 10 Jun 2021 09:15:23**

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:05:06
Data entry locked.	System	01 Sep 2020 16:12:18
User entered 'Day 3'	System	01 Sep 2020 16:12:18

**US3612005**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(3)**

**Generated On: 10 Jun 2021 09:15:23**

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:05:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a19c168458d97dd9)', Time: '2020-09-03T12:34:00', User OID: 'PatientReportedOutcome (US3612005)', ODM File OID: '9a88989a-3903-4906-9679-f83509776880'	System	03 Sep 2020 17:34:33
User entered 'None (0)'	System	03 Sep 2020 17:34:33

US3612005

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 10 Jun 2021 09:15:23

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:05:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a19c168458d97dd9)', Time: '2020-09-03T12:34:03', User OID: 'PatientReportedOutcome (US3612005)', ODM File OID: '9a88989a-3903-4906-9679-f83509776880'	System	03 Sep 2020 17:34:33
User entered 'None (0)'	System	03 Sep 2020 17:34:33

US3612005

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 10 Jun 2021 09:15:23

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:05:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a19c168458d97dd9)', Time: '2020-09-03T12:34:06', User OID: 'PatientReportedOutcome (US3612005)', ODM File OID: '9a88989a-3903-4906-9679-f83509776880'	System	03 Sep 2020 17:34:33
User entered 'None (0)'	System	03 Sep 2020 17:34:33

US3612005

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 10 Jun 2021 09:15:23

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:05:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a19c168458d97dd9)', Time: '2020-09-03T12:34:09', User OID: 'PatientReportedOutcome (US3612005)', ODM File OID: '9a88989a-3903-4906-9679-f83509776880' User entered 'None (0)'	System	03 Sep 2020 17:34:33
	System	03 Sep 2020 17:34:33

**US3612005**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(3)**

**Generated On: 10 Jun 2021 09:15:23**

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:05:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a19c168458d97dd9)', Time: '2020-09-03T12:34:12', User OID: 'PatientReportedOutcome (US3612005)', ODM File OID: '9a88989a-3903-4906-9679-f83509776880'	System	03 Sep 2020 17:34:33
User entered 'None (0)'	System	03 Sep 2020 17:34:33

US3612005

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 10 Jun 2021 09:15:23

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:05:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a19c168458d97dd9)', Time: '2020-09-03T12:34:15', User OID: 'PatientReportedOutcome (US3612005)', ODM File OID: '9a88989a-3903-4906-9679-f83509776880'	System	03 Sep 2020 17:34:33
User entered 'None (0)'	System	03 Sep 2020 17:34:33

US3612005

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 10 Jun 2021 09:15:23

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 16:05:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a19c168458d97dd9)', Time: '2020-09-03T12:34:18', User OID: 'PatientReportedOutcome (US3612005)', ODM File OID: '9a88989a-3903-4906-9679-f83509776880'	System	03 Sep 2020 17:34:33
User entered 'No (N)'	System	03 Sep 2020 17:34:33

**US3612005**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(3)**

**Generated On: 10 Jun 2021 09:15:23**

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:05:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a19c168458d97dd9)', Time: '2020-09-03T12:34:27', User OID: 'PatientReportedOutcome (US3612005)', ODM File OID: '9a88989a-3903-4906-9679-f83509776880'	System	03 Sep 2020 17:34:33
User entered '03 Sep 2020 12:34'	System	03 Sep 2020 17:34:33

**US3612005**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(3)**

**Generated On: 10 Jun 2021 09:15:23**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:05:06
User entered '03 Sep 2020 12:00'	System	01 Sep 2020 16:12:18

**US3612005**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(3)**

**Generated On: 10 Jun 2021 09:15:23**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:05:06
User entered '04 Sep 2020 11:59'	System	01 Sep 2020 16:12:18

US3612005

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 10 Jun 2021 09:15:23

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:05:06
Data entry locked.	System	01 Sep 2020 16:12:18
User entered 'Day 4'	System	01 Sep 2020 16:12:18

**US3612005**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(4)**

**Generated On: 10 Jun 2021 09:15:23**

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:05:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a19c168458d97dd9)', Time: '2020-09-04T17:03:14', User OID: 'PatientReportedOutcome (US3612005)', ODM File OID: '5cd6863a-9787-41ce-9a84-58fb27334409' User entered 'None (0)'	System	04 Sep 2020 22:03:45
	System	04 Sep 2020 22:03:45

**US3612005**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(4)**

**Generated On: 10 Jun 2021 09:15:23**

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:05:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a19c168458d97dd9)', Time: '2020-09-04T17:03:17', User OID: 'PatientReportedOutcome (US3612005)', ODM File OID: '5cd6863a-9787-41ce-9a84-58fb27334409' User entered 'None (0)'	System	04 Sep 2020 22:03:45
	System	04 Sep 2020 22:03:45

**US3612005**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(4)**

**Generated On: 10 Jun 2021 09:15:23**

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:05:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a19c168458d97dd9)', Time: '2020-09-04T17:03:20', User OID: 'PatientReportedOutcome (US3612005)', ODM File OID: '5cd6863a-9787-41ce-9a84-58fb27334409' User entered 'None (0)'	System	04 Sep 2020 22:03:45
	System	04 Sep 2020 22:03:45

US3612005

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 10 Jun 2021 09:15:23

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:05:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a19c168458d97dd9)', Time: '2020-09-04T17:03:24', User OID: 'PatientReportedOutcome (US3612005)', ODM File OID: '5cd6863a-9787-41ce-9a84-58fb27334409' User entered 'None (0)'	System	04 Sep 2020 22:03:45
	System	04 Sep 2020 22:03:45

**US3612005**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(4)**

**Generated On: 10 Jun 2021 09:15:23**

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:05:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a19c168458d97dd9)', Time: '2020-09-04T17:03:27', User OID: 'PatientReportedOutcome (US3612005)', ODM File OID: '5cd6863a-9787-41ce-9a84-58fb27334409' User entered 'None (0)'	System	04 Sep 2020 22:03:45
	System	04 Sep 2020 22:03:45

**US3612005**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(4)**

**Generated On: 10 Jun 2021 09:15:23**

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:05:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a19c168458d97dd9)', Time: '2020-09-04T17:03:30', User OID: 'PatientReportedOutcome (US3612005)', ODM File OID: '5cd6863a-9787-41ce-9a84-58fb27334409' User entered 'None (0)'	System	04 Sep 2020 22:03:45
	System	04 Sep 2020 22:03:45

US3612005

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 10 Jun 2021 09:15:23

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 16:05:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a19c168458d97dd9)', Time: '2020-09-04T17:03:33', User OID: 'PatientReportedOutcome (US3612005)', ODM File OID: '5cd6863a-9787-41ce-9a84-58fb27334409'	System	04 Sep 2020 22:03:45
User entered 'No (N)'	System	04 Sep 2020 22:03:45

**US3612005**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(4)**

**Generated On: 10 Jun 2021 09:15:23**

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:05:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a19c168458d97dd9)', Time: '2020-09-04T17:03:39', User OID: 'PatientReportedOutcome (US3612005)', ODM File OID: '5cd6863a-9787-41ce-9a84-58fb27334409'	System	04 Sep 2020 22:03:45
User entered '04 Sep 2020 17:03'	System	04 Sep 2020 22:03:45

**US3612005**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(4)**

**Generated On: 10 Jun 2021 09:15:23**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:05:06
User entered '04 Sep 2020 12:00'	System	01 Sep 2020 16:12:18

**US3612005**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(4)**

**Generated On: 10 Jun 2021 09:15:23**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:05:06
User entered '05 Sep 2020 11:59'	System	01 Sep 2020 16:12:18

**US3612005**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(5)**

**Generated On: 10 Jun 2021 09:15:23**

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:05:06
Data entry locked.	System	01 Sep 2020 16:12:18
User entered 'Day 5'	System	01 Sep 2020 16:12:18

**US3612005**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(5)**

**Generated On: 10 Jun 2021 09:15:23**

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:05:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a19c168458d97dd9)', Time: '2020-09-05T20:54:35', User OID: 'PatientReportedOutcome (US3612005)', ODM File OID: '0e5fd4e9-3041-414e-aa4d-13bdae624825'	System	06 Sep 2020 01:55:03
User entered 'None (0)'	System	06 Sep 2020 01:55:03

**US3612005**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(5)**

**Generated On: 10 Jun 2021 09:15:23**

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:05:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a19c168458d97dd9)', Time: '2020-09-05T20:54:38', User OID: 'PatientReportedOutcome (US3612005)', ODM File OID: '0e5fd4e9-3041-414e-aa4d-13bdae624825'	System	06 Sep 2020 01:55:03
User entered 'None (0)'	System	06 Sep 2020 01:55:03

US3612005

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 10 Jun 2021 09:15:23

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:05:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a19c168458d97dd9)', Time: '2020-09-05T20:54:41', User OID: 'PatientReportedOutcome (US3612005)', ODM File OID: '0e5fd4e9-3041-414e-aa4d-13bdae624825'	System	06 Sep 2020 01:55:03
User entered 'None (0)'	System	06 Sep 2020 01:55:03

US3612005

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 10 Jun 2021 09:15:23

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:05:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a19c168458d97dd9)', Time: '2020-09-05T20:54:44', User OID: 'PatientReportedOutcome (US3612005)', ODM File OID: '0e5fd4e9-3041-414e-aa4d-13bdae624825'	System	06 Sep 2020 01:55:03
User entered 'None (0)'	System	06 Sep 2020 01:55:03

**US3612005**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(5)**

**Generated On: 10 Jun 2021 09:15:23**

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:05:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a19c168458d97dd9)', Time: '2020-09-05T20:54:47', User OID: 'PatientReportedOutcome (US3612005)', ODM File OID: '0e5fd4e9-3041-414e-aa4d-13bdae624825'	System	06 Sep 2020 01:55:03
User entered 'None (0)'	System	06 Sep 2020 01:55:03

**US3612005**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(5)**

**Generated On: 10 Jun 2021 09:15:23**

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:05:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a19c168458d97dd9)', Time: '2020-09-05T20:54:50', User OID: 'PatientReportedOutcome (US3612005)', ODM File OID: '0e5fd4e9-3041-414e-aa4d-13bdae624825'	System	06 Sep 2020 01:55:03
User entered 'None (0)'	System	06 Sep 2020 01:55:03

US3612005

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 10 Jun 2021 09:15:23

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 16:05:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a19c168458d97dd9)', Time: '2020-09-05T20:54:53', User OID: 'PatientReportedOutcome (US3612005)', ODM File OID: '0e5fd4e9-3041-414e-aa4d-13bdae624825'	System	06 Sep 2020 01:55:03
User entered 'No (N)'	System	06 Sep 2020 01:55:03

**US3612005**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(5)**

**Generated On: 10 Jun 2021 09:15:23**

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:05:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a19c168458d97dd9)', Time: '2020-09-05T20:54:59', User OID: 'PatientReportedOutcome (US3612005)', ODM File OID: '0e5fd4e9-3041-414e-aa4d-13bdae624825'	System	06 Sep 2020 01:55:03
User entered '05 Sep 2020 20:54'	System	06 Sep 2020 01:55:03

**US3612005**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(5)**

**Generated On: 10 Jun 2021 09:15:23**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:05:06
User entered '05 Sep 2020 12:00'	System	01 Sep 2020 16:12:18

**US3612005**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(5)**

**Generated On: 10 Jun 2021 09:15:23**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:05:06
User entered '06 Sep 2020 11:59'	System	01 Sep 2020 16:12:18

**US3612005**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(6)**

**Generated On: 10 Jun 2021 09:15:23**

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:05:06
Data entry locked.	System	01 Sep 2020 16:12:18
User entered 'Day 6'	System	01 Sep 2020 16:12:18

US3612005

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 10 Jun 2021 09:15:23

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:05:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a19c168458d97dd9)', Time: '2020-09-06T22:52:19', User OID: 'PatientReportedOutcome (US3612005)', ODM File OID: 'ec12b6a8-bae5-4a23-a7b5-7273e8557b58'	System	07 Sep 2020 03:52:47
User entered 'None (0)'	System	07 Sep 2020 03:52:47

**US3612005**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(6)**

**Generated On: 10 Jun 2021 09:15:23**

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:05:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a19c168458d97dd9)', Time: '2020-09-06T22:52:22', User OID: 'PatientReportedOutcome (US3612005)', ODM File OID: 'ec12b6a8-bae5-4a23-a7b5-7273e8557b58'	System	07 Sep 2020 03:52:47
User entered 'None (0)'	System	07 Sep 2020 03:52:47

US3612005

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 10 Jun 2021 09:15:23

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:05:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a19c168458d97dd9)', Time: '2020-09-06T22:52:24', User OID: 'PatientReportedOutcome (US3612005)', ODM File OID: 'ec12b6a8-bae5-4a23-a7b5-7273e8557b58'	System	07 Sep 2020 03:52:47
User entered 'None (0)'	System	07 Sep 2020 03:52:47

US3612005

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 10 Jun 2021 09:15:23

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:05:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a19c168458d97dd9)', Time: '2020-09-06T22:52:27', User OID: 'PatientReportedOutcome (US3612005)', ODM File OID: 'ec12b6a8-bae5-4a23-a7b5-7273e8557b58'	System	07 Sep 2020 03:52:47
User entered 'None (0)'	System	07 Sep 2020 03:52:47

**US3612005**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(6)**

**Generated On: 10 Jun 2021 09:15:23**

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:05:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a19c168458d97dd9)', Time: '2020-09-06T22:52:29', User OID: 'PatientReportedOutcome (US3612005)', ODM File OID: 'ec12b6a8-bae5-4a23-a7b5-7273e8557b58'	System	07 Sep 2020 03:52:47
User entered 'None (0)'	System	07 Sep 2020 03:52:47

**US3612005**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(6)**

**Generated On: 10 Jun 2021 09:15:23**

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:05:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a19c168458d97dd9)', Time: '2020-09-06T22:52:32', User OID: 'PatientReportedOutcome (US3612005)', ODM File OID: 'ec12b6a8-bae5-4a23-a7b5-7273e8557b58'	System	07 Sep 2020 03:52:47
User entered 'None (0)'	System	07 Sep 2020 03:52:47

US3612005

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 10 Jun 2021 09:15:23

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 16:05:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a19c168458d97dd9)', Time: '2020-09-06T22:52:36', User OID: 'PatientReportedOutcome (US3612005)', ODM File OID: 'ec12b6a8-bae5-4a23-a7b5-7273e8557b58'	System	07 Sep 2020 03:52:47
User entered 'No (N)'	System	07 Sep 2020 03:52:47

**US3612005**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(6)**

**Generated On: 10 Jun 2021 09:15:23**

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:05:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a19c168458d97dd9)', Time: '2020-09-06T22:52:44', User OID: 'PatientReportedOutcome (US3612005)', ODM File OID: 'ec12b6a8-bae5-4a23-a7b5-7273e8557b58'	System	07 Sep 2020 03:52:47
User entered '06 Sep 2020 22:52'	System	07 Sep 2020 03:52:47

**US3612005**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(6)**

**Generated On: 10 Jun 2021 09:15:23**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:05:06
User entered '06 Sep 2020 12:00'	System	01 Sep 2020 16:12:18

**US3612005**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(6)**

**Generated On: 10 Jun 2021 09:15:23**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:05:06
User entered '07 Sep 2020 11:59'	System	01 Sep 2020 16:12:18

**US3612005**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(7)**

**Generated On: 10 Jun 2021 09:15:23**

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:05:06
Data entry locked.	System	01 Sep 2020 16:12:18
User entered 'Day 7'	System	01 Sep 2020 16:12:18

US3612005

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 10 Jun 2021 09:15:23

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:05:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a19c168458d97dd9)', Time: '2020-09-07T17:05:29', User OID: 'PatientReportedOutcome (US3612005)', ODM File OID: 'a0e5a42d-9ba7-48cb-91ed-a4a85d58ea12'	System	07 Sep 2020 22:05:52
User entered 'None (0)'	System	07 Sep 2020 22:05:52

US3612005

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 10 Jun 2021 09:15:23

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:05:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a19c168458d97dd9)', Time: '2020-09-07T17:05:31', User OID: 'PatientReportedOutcome (US3612005)', ODM File OID: 'a0e5a42d-9ba7-48cb-91ed-a4a85d58ea12'	System	07 Sep 2020 22:05:52
User entered 'None (0)'	System	07 Sep 2020 22:05:52

US3612005

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 10 Jun 2021 09:15:23

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:05:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a19c168458d97dd9)', Time: '2020-09-07T17:05:33', User OID: 'PatientReportedOutcome (US3612005)', ODM File OID: 'a0e5a42d-9ba7-48cb-91ed-a4a85d58ea12'	System	07 Sep 2020 22:05:52
User entered 'None (0)'	System	07 Sep 2020 22:05:52

US3612005

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 10 Jun 2021 09:15:23

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:05:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a19c168458d97dd9)', Time: '2020-09-07T17:05:36', User OID: 'PatientReportedOutcome (US3612005)', ODM File OID: 'a0e5a42d-9ba7-48cb-91ed-a4a85d58ea12'	System	07 Sep 2020 22:05:52
User entered 'None (0)'	System	07 Sep 2020 22:05:52

**US3612005**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(7)**

**Generated On: 10 Jun 2021 09:15:23**

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:05:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a19c168458d97dd9)', Time: '2020-09-07T17:05:38', User OID: 'PatientReportedOutcome (US3612005)', ODM File OID: 'a0e5a42d-9ba7-48cb-91ed-a4a85d58ea12'	System	07 Sep 2020 22:05:52
User entered 'None (0)'	System	07 Sep 2020 22:05:52

US3612005

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 10 Jun 2021 09:15:23

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:05:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a19c168458d97dd9)', Time: '2020-09-07T17:05:40', User OID: 'PatientReportedOutcome (US3612005)', ODM File OID: 'a0e5a42d-9ba7-48cb-91ed-a4a85d58ea12'	System	07 Sep 2020 22:05:52
User entered 'None (0)'	System	07 Sep 2020 22:05:52

US3612005

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 10 Jun 2021 09:15:23

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 16:05:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a19c168458d97dd9)', Time: '2020-09-07T17:05:43', User OID: 'PatientReportedOutcome (US3612005)', ODM File OID: 'a0e5a42d-9ba7-48cb-91ed-a4a85d58ea12'	System	07 Sep 2020 22:05:52
User entered 'No (N)'	System	07 Sep 2020 22:05:52

**US3612005**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(7)**

**Generated On: 10 Jun 2021 09:15:23**

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:05:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a19c168458d97dd9)', Time: '2020-09-07T17:05:48', User OID: 'PatientReportedOutcome (US3612005)', ODM File OID: 'a0e5a42d-9ba7-48cb-91ed-a4a85d58ea12'	System	07 Sep 2020 22:05:52
User entered '07 Sep 2020 17:05'	System	07 Sep 2020 22:05:52

**US3612005**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(7)**

**Generated On: 10 Jun 2021 09:15:23**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:05:06
User entered '07 Sep 2020 12:00'	System	01 Sep 2020 16:12:18

**US3612005**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(7)**

**Generated On: 10 Jun 2021 09:15:23**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:05:06
User entered '08 Sep 2020 11:59'	System	01 Sep 2020 16:12:18

**US3612005**

**Folder: Safety Call Day 8 (1)**

**Form: Safety Call**

**Generated On: 10 Jun 2021 09:15:23**

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 22:42:32
User signature succeeded.	Richard Rupp (b) (4)	05 Mar 2021 19:39:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Sep 2020 14:55:14
User entered 'Yes (Y)'	Kristin Pollock (b) (4) (b) (4)	09 Sep 2020 23:54:13

**US3612005**

**Folder: Safety Call Day 8 (1)**

**Form: Safety Call**

**Generated On: 10 Jun 2021 09:15:23**

[Date of Contact or Contact Attempt \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 22:42:32
User signature succeeded.	Richard Rupp (b) (4)	05 Mar 2021 19:39:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Sep 2020 14:55:14
User entered '9 Sep 2020'	Kristin Pollock (b) (4) (b) (4)	09 Sep 2020 23:54:13

**US3612005**

**Folder: Safety Call Day 8 (1)**

**Form: Safety Call**

**Generated On: 10 Jun 2021 09:15:23**

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 22:42:32
User signature succeeded.	Richard Rupp (b) (4)	05 Mar 2021 19:39:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Sep 2020 14:55:14
User entered 'Contact Made (CONTACT MADE)'	Kristin Pollock (b) (4) (b) (4)	09 Sep 2020 23:54:13

**US3612005**

**Folder: Safety Call Day 8 (1)**

**Form: Safety Call**

**Generated On: 10 Jun 2021 09:15:23**

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 22:42:32
User signature succeeded.	Richard Rupp (b) (4)	05 Mar 2021 19:39:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Sep 2020 14:55:14
User entered empty.	Kristin Pollock (b) (4) (b) (4)	09 Sep 2020 23:54:13

**US3612005**

**Folder: Safety Call Day 8 (1)**

**Form: Continuing**

**Generated On: 10 Jun 2021 09:15:23**

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 22:42:32
User signature succeeded.	Richard Rupp (b) (4)	05 Mar 2021 19:39:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Sep 2020 14:55:29
User entered 'Yes (Y)'	Kristin Pollock (b) (4) (b) (4)	09 Sep 2020 23:54:19

**US3612005**

**Folder: Safety Call Day 8 (1)**

**Form: Continuing**

**Generated On: 10 Jun 2021 09:15:23**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 22:42:32
User entered 'I'	System	09 Sep 2020 23:54:19

**US3612005**

**Folder: Safety Call Day 15 (1)**

**Form: Safety Call**

**Generated On: 10 Jun 2021 09:15:23**

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 22:42:32
User signature succeeded.	Richard Rupp (b) (4)	05 Mar 2021 19:39:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Sep 2020 15:17:25
User entered 'Yes (Y)'	Kristin Pollock (b) (4) (b) (4)	16 Sep 2020 19:36:47

**US3612005**

**Folder: Safety Call Day 15 (1)**

**Form: Safety Call**

**Generated On: 10 Jun 2021 09:15:23**

[Date of Contact or Contact Attempt \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 22:42:32
User signature succeeded.	Richard Rupp (b) (4)	05 Mar 2021 19:39:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Sep 2020 15:17:25
User entered '16 Sep 2020'	Kristin Pollock (b) (4) (b) (4)	16 Sep 2020 19:36:47

**US3612005**

**Folder: Safety Call Day 15 (1)**

**Form: Safety Call**

**Generated On: 10 Jun 2021 09:15:23**

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 22:42:32
User signature succeeded.	Richard Rupp (b) (4)	05 Mar 2021 19:39:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Sep 2020 15:17:25
User entered 'Contact Made (CONTACT MADE)'	Kristin Pollock (b) (4) (b) (4)	16 Sep 2020 19:36:47

**US3612005**

**Folder: Safety Call Day 15 (1)**

**Form: Safety Call**

**Generated On: 10 Jun 2021 09:15:23**

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 22:42:32
User signature succeeded.	Richard Rupp (b) (4)	05 Mar 2021 19:39:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Sep 2020 15:17:25
User entered empty.	Kristin Pollock (b) (4) (b) (4)	16 Sep 2020 19:36:47

US3612005

Folder: Safety Call Day 15 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:15:23

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 22:42:32
User signature succeeded.	Richard Rupp (b) (4)	05 Mar 2021 19:39:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Sep 2020 15:17:46
User entered 'Yes (Y)'	Kristin Pollock (b) (4) (b) (4)	16 Sep 2020 19:37:09

**US3612005**

**Folder: Safety Call Day 15 (1)**

**Form: Continuing**

**Generated On: 10 Jun 2021 09:15:23**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 22:42:32
User entered 'I'	System	16 Sep 2020 19:37:09

**US3612005**

**Folder: Safety Call Day 22 (1)**

**Form: Safety Call**

**Generated On: 10 Jun 2021 09:15:23**

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 22:42:32
User signature succeeded.	Richard Rupp (b) (4)	05 Mar 2021 19:39:45
DataPoint Verified.	(b) (4)	06 Oct 2020 15:12:32
User entered 'Yes (Y)'	Amy McMahan (b) (4)	23 Sep 2020 16:39:06

**US3612005**

**Folder: Safety Call Day 22 (1)**

**Form: Safety Call**

**Generated On: 10 Jun 2021 09:15:23**

[Date of Contact or Contact Attempt \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 22:42:32
User signature succeeded.	Richard Rupp (b) (4)	05 Mar 2021 19:39:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Oct 2020 15:12:32
User entered '22 Sep 2020'	Amy McMahan (b) (4) (b) (4)	23 Sep 2020 16:39:06

**US3612005**

**Folder: Safety Call Day 22 (1)**

**Form: Safety Call**

**Generated On: 10 Jun 2021 09:15:23**

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 22:42:32
User signature succeeded.	Richard Rupp (b) (4)	05 Mar 2021 19:39:45
DataPoint Verified.	(b) (4)	06 Oct 2020 15:12:32
User entered 'Contact Made (CONTACT MADE)'	Amy McMahan (b) (4)	23 Sep 2020 16:39:06

**US3612005**

**Folder: Safety Call Day 22 (1)**

**Form: Safety Call**

**Generated On: 10 Jun 2021 09:15:23**

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 22:42:32
User signature succeeded.	Richard Rupp (b) (4)	05 Mar 2021 19:39:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Oct 2020 15:12:32
User entered empty.	Amy McMahan (b) (4) (b) (4)	23 Sep 2020 16:39:06

**US3612005**

**Folder: Safety Call Day 22 (1)**

**Form: Continuing**

**Generated On: 10 Jun 2021 09:15:23**

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 22:42:32
User signature succeeded.	Richard Rupp (b) (4)	05 Mar 2021 19:39:45
DataPoint Verified.	(b) (4)	06 Oct 2020 15:12:49
User entered 'Yes (Y)'	Amy McMahan (b) (4)	23 Sep 2020 16:39:11

**US3612005**

**Folder: Safety Call Day 22 (1)**

**Form: Continuing**

**Generated On: 10 Jun 2021 09:15:23**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 22:42:32
User entered 'I'	System	23 Sep 2020 16:39:11

**US3612005**

**Folder: Visit 2 Day 29 (1)**

**Form: Visit Date**

**Generated On: 10 Jun 2021 09:15:23**

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 22:42:32
User signature succeeded.	Richard Rupp (b) (4)	05 Mar 2021 19:39:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Oct 2020 15:13:41
User entered 'Yes (Y)'	Kristin Pollock (b) (4) (b) (4)	29 Sep 2020 15:45:25

**US3612005**

**Folder: Visit 2 Day 29 (1)**

**Form: Visit Date**

**Generated On: 10 Jun 2021 09:15:23**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 22:42:32
User signature succeeded.	Richard Rupp (b) (4)	05 Mar 2021 19:39:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Oct 2020 15:13:41
User entered '29 Sep 2020'	Kristin Pollock (b) (4) (b) (4)	29 Sep 2020 15:45:25

**US3612005**

**Folder: Visit 2 Day 29 (1)**

**Form: Visit Date**

**Generated On: 10 Jun 2021 09:15:23**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 22:42:32
User signature succeeded.	Richard Rupp (b) (4)	05 Mar 2021 19:39:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Oct 2020 15:13:41
User entered 'Clinic (Clinic)'	Kristin Pollock (b) (4) (b) (4)	29 Sep 2020 15:45:25

**US3612005**

**Folder: Visit 2 Day 29 (1)**

**Form: Visit Date**

**Generated On: 10 Jun 2021 09:15:23**

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 22:42:32
User entered 'VISIT2'	System	29 Sep 2020 15:45:25

US3612005

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:15:23

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 22:42:32
User accepted default value 'Pre-Dose (PREDOSE)'	Kristin Pollock (b) (4)	29 Sep 2020 20:30:27
	(b) (4)	

US3612005

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:15:23

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 22:42:32
User signature succeeded.	Richard Rupp (b) (4)	05 Mar 2021 19:39:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Oct 2020 15:14:17
User entered 'Yes (Y)'	Kristin Pollock (b) (4) (b) (4)	29 Sep 2020 20:30:27

US3612005

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:15:23

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 22:42:32
User signature succeeded.	Richard Rupp (b) (4)	05 Mar 2021 19:39:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Oct 2020 15:14:17
User entered '29 Sep 2020'	Kristin Pollock (b) (4) (b) (4)	29 Sep 2020 20:30:27

US3612005

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:15:23

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 22:42:32
User signature succeeded.	Richard Rupp (b) (4)	05 Mar 2021 19:39:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Oct 2020 15:14:17
User entered '09:17'	Kristin Pollock (b) (4) (b) (4)	29 Sep 2020 20:30:27

**US3612005**

**Folder: Visit 2 Day 29 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 10 Jun 2021 09:15:23**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 22:42:32
User entered '29 Sep 2020 09:17'	System	29 Sep 2020 20:30:27

US3612005

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:15:23

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 22:42:32
User signature succeeded.	Richard Rupp (b) (4)	05 Mar 2021 19:39:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Oct 2020 15:14:17
User entered '98.1' F	Kristin Pollock (b) (4) (b) (4)	29 Sep 2020 20:30:27

US3612005

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:15:23

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 22:42:32
User signature succeeded.	Richard Rupp (b) (4)	05 Mar 2021 19:39:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Oct 2020 15:14:17
User entered 'Oral (Oral)'	Kristin Pollock (b) (4) (b) (4)	29 Sep 2020 20:30:27

**US3612005**

**Folder: Visit 2 Day 29 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 10 Jun 2021 09:15:23**

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 22:42:32
User signature succeeded.	Richard Rupp (b) (4)	05 Mar 2021 19:39:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Oct 2020 15:14:17
User entered empty.	Kristin Pollock (b) (4) (b) (4)	29 Sep 2020 20:30:27

US3612005

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:15:23

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 22:42:32
User signature succeeded.	Richard Rupp (b) (4)	05 Mar 2021 19:39:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Oct 2020 15:14:17
User entered '69'	Kristin Pollock (b) (4) (b) (4)	29 Sep 2020 20:30:27

**US3612005**

**Folder: Visit 2 Day 29 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 10 Jun 2021 09:15:23**

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 22:42:32
User entered 'bpm'	System	29 Sep 2020 20:30:27

US3612005

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:15:23

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 22:42:32
User signature succeeded.	Richard Rupp (b) (4)	05 Mar 2021 19:39:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Oct 2020 15:14:17
User entered '16'	Kristin Pollock (b) (4) (b) (4)	29 Sep 2020 20:30:27

US3612005

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:15:23

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 22:42:32
User entered 'breaths/min'	System	29 Sep 2020 20:30:27

US3612005

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:15:23

[Systolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 22:42:32
User signature succeeded.	Richard Rupp (b) (4)	05 Mar 2021 19:39:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Oct 2020 15:14:17
User entered '135'	Kristin Pollock (b) (4) (b) (4)	29 Sep 2020 20:30:27

**US3612005**

**Folder: Visit 2 Day 29 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 10 Jun 2021 09:15:23**

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 22:42:32
User entered 'mmHg'	System	29 Sep 2020 20:30:27

US3612005

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:15:23

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 22:42:32
User signature succeeded.	Richard Rupp (b) (4)	05 Mar 2021 19:39:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Oct 2020 15:14:17
User entered '63'	Kristin Pollock (b) (4) (b) (4)	29 Sep 2020 20:30:27

**US3612005**

**Folder: Visit 2 Day 29 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 10 Jun 2021 09:15:23**

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 22:42:32
User entered 'mmHg'	System	29 Sep 2020 20:30:27

US3612005

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:15:23

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 22:42:32
User accepted default value 'Post-Dose (POSTDOSE)'	Kristin Pollock (b) (4) (b) (4)	29 Sep 2020 20:30:27

US3612005

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:15:23

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 22:42:32
User signature succeeded.	Richard Rupp (b) (4)	05 Mar 2021 19:39:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Oct 2020 15:14:17
User entered 'Yes (Y)'	Kristin Pollock (b) (4) (b) (4)	29 Sep 2020 20:30:27

US3612005

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:15:23

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 22:42:32
User signature succeeded.	Richard Rupp (b) (4)	05 Mar 2021 19:39:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Oct 2020 15:14:17
User entered '29 Sep 2020'	Kristin Pollock (b) (4) (b) (4)	29 Sep 2020 20:30:27

**US3612005**

**Folder: Visit 2 Day 29 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 10 Jun 2021 09:15:23**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 22:42:32
User signature succeeded.	Richard Rupp (b) (4)	05 Mar 2021 19:39:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Oct 2020 15:14:17
User entered '10:53'	Kristin Pollock (b) (4) (b) (4)	29 Sep 2020 20:30:27

**US3612005**

**Folder: Visit 2 Day 29 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 10 Jun 2021 09:15:23**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 22:42:32
User entered '29 Sep 2020 10:53'	System	29 Sep 2020 20:30:27

US3612005

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:15:23

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 22:42:32
User signature succeeded.	Richard Rupp (b) (4)	05 Mar 2021 19:39:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Oct 2020 15:14:17
User entered '97.9' F	Kristin Pollock (b) (4) (b) (4)	29 Sep 2020 20:30:27

US3612005

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:15:23

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 22:42:32
User signature succeeded.	Richard Rupp (b) (4)	05 Mar 2021 19:39:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Oct 2020 15:14:17
User entered 'Oral (Oral)'	Kristin Pollock (b) (4) (b) (4)	29 Sep 2020 20:30:27

US3612005

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:15:23

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 22:42:32
User signature succeeded.	Richard Rupp (b) (4)	05 Mar 2021 19:39:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Oct 2020 15:14:17
User entered empty.	Kristin Pollock (b) (4) (b) (4)	29 Sep 2020 20:30:27

US3612005

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:15:23

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 22:42:32
User signature succeeded.	Richard Rupp (b) (4)	05 Mar 2021 19:39:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Oct 2020 15:14:17
User entered '51'	Kristin Pollock (b) (4) (b) (4)	29 Sep 2020 20:30:27

**US3612005**

**Folder: Visit 2 Day 29 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 10 Jun 2021 09:15:23**

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 22:42:32
User entered 'bpm'	System	29 Sep 2020 20:30:27

US3612005

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:15:23

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 22:42:32
User signature succeeded.	Richard Rupp (b) (4)	05 Mar 2021 19:39:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Oct 2020 15:14:17
User entered '16'	Kristin Pollock (b) (4) (b) (4)	29 Sep 2020 20:30:27

US3612005

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:15:23

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 22:42:32
User entered 'breaths/min'	System	29 Sep 2020 20:30:27

US3612005

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:15:23

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 22:42:32
User signature succeeded.	Richard Rupp (b) (4)	05 Mar 2021 19:39:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Oct 2020 15:14:17
User entered '137'	Kristin Pollock (b) (4) (b) (4)	29 Sep 2020 20:30:27

**US3612005**

**Folder: Visit 2 Day 29 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 10 Jun 2021 09:15:23**

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 22:42:32
User entered 'mmHg'	System	29 Sep 2020 20:30:27

US3612005

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:15:23

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 22:42:32
User signature succeeded.	Richard Rupp (b) (4)	05 Mar 2021 19:39:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Oct 2020 15:14:17
User entered '65'	Kristin Pollock (b) (4) (b) (4)	29 Sep 2020 20:30:27

US3612005

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:15:23

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 22:42:32
User entered 'mmHg'	System	29 Sep 2020 20:30:27

US3612005

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Generated On: 10 Jun 2021 09:15:23

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 22:42:32
User signature succeeded.	Richard Rupp (b) (4)	05 Mar 2021 19:39:45
DataPoint Verified.	(b) (4)	06 Oct 2020 15:14:49
User entered 'Yes (Y)'	Kristin Pollock (b) (4)	29 Sep 2020 20:30:37

US3612005

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Generated On: 10 Jun 2021 09:15:23

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 22:42:32
User signature succeeded.	Richard Rupp (b) (4)	05 Mar 2021 19:39:45
DataPoint Verified.	(b) (4)	06 Oct 2020 15:14:49
User entered '29 Sep 2020'	Kristin Pollock (b) (4)	29 Sep 2020 20:30:37

US3612005

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 10 Jun 2021 09:15:23

[Was study treatment given?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 22:42:32
User signature succeeded.	Richard Rupp (b) (4)	05 Mar 2021 19:39:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Oct 2020 15:16:07
User entered 'Yes (Y)'	Kristin Pollock (b) (4) (b) (4)	29 Sep 2020 15:46:04

**US3612005**

**Folder: Visit 2 Day 29 (1)**

**Form: Exposure**

**Generated On: 10 Jun 2021 09:15:23**

[If No, reason not given](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 22:42:32
User signature succeeded.	Richard Rupp (b) (4)	05 Mar 2021 19:39:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Oct 2020 15:16:07
User entered empty.	Kristin Pollock (b) (4) (b) (4)	29 Sep 2020 15:46:04

US3612005

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 10 Jun 2021 09:15:23

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 22:42:32
User signature succeeded.	Richard Rupp (b) (4)	05 Mar 2021 19:39:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Oct 2020 15:16:07
User entered empty.	Kristin Pollock (b) (4) (b) (4)	29 Sep 2020 15:46:04

**US3612005**

**Folder: Visit 2 Day 29 (1)**

**Form: Exposure**

**Generated On: 10 Jun 2021 09:15:23**

[What was the study treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 22:42:32
User entered 'MRNA-1273 OR PLACEBO'	System	29 Sep 2020 15:46:04

US3612005

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 10 Jun 2021 09:15:23

What was the treatment date? (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 22:42:32
User signature succeeded.	Richard Rupp (b) (4)	05 Mar 2021 19:39:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Oct 2020 15:16:07
User entered '29 Sep 2020'	Kristin Pollock (b) (4) (b) (4)	29 Sep 2020 15:46:04

**US3612005**

**Folder: Visit 2 Day 29 (1)**

**Form: Exposure**

**Generated On: 10 Jun 2021 09:15:23**

[What was the treatment time? \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 22:42:32
User signature succeeded.	Richard Rupp (b) (4)	05 Mar 2021 19:39:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Oct 2020 15:16:07
User entered '10:21'	Kristin Pollock (b) (4) (b) (4)	29 Sep 2020 15:46:04

**US3612005**

**Folder: Visit 2 Day 29 (1)**

**Form: Exposure**

**Generated On: 10 Jun 2021 09:15:23**

[Treatment Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 22:42:32
User entered '29 Sep 2020 10:21'	System	29 Sep 2020 15:46:04

US3612005

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 10 Jun 2021 09:15:23

[Which arm was used to give treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 22:42:32
User signature succeeded.	Richard Rupp (b) (4)	05 Mar 2021 19:39:45
DataPoint Verified.	(b) (4)	06 Oct 2020 15:16:07
User entered 'Left Arm (LEFT ARM)'	Kristin Pollock (b) (4)	29 Sep 2020 15:46:04

**US3612005**

**Folder: Visit 2 Day 29 (1)**

**Form: Exposure**

**Generated On: 10 Jun 2021 09:15:23**

[What was the frequency of the study treatment dosing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 22:42:32
DataPoint Verified.	(b) (4), (b) (6)	06 Oct 2020 15:16:07
User entered 'ONCE'	System	29 Sep 2020 15:46:04

**US3612005**

**Folder: Visit 2 Day 29 (1)**

**Form: Exposure**

**Generated On: 10 Jun 2021 09:15:23**

[What was the route of administration for the study treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 22:42:32
User entered 'INTRAMUSCULAR'	System	29 Sep 2020 15:46:04

US3612005

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 09:15:23

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 22:42:32
User signature succeeded.	Richard Rupp (b) (4)	05 Mar 2021 19:39:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Oct 2020 15:15:03
User entered 'Yes (Y)'	Kristin Pollock (b) (4) (b) (4)	29 Sep 2020 20:30:58

US3612005

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 09:15:23

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 22:42:32
User signature succeeded.	Richard Rupp (b) (4)	05 Mar 2021 19:39:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Oct 2020 15:15:03
User entered '29 Sep 2020'	Kristin Pollock (b) (4) (b) (4)	29 Sep 2020 20:30:58

**US3612005**

**Folder: Visit 2 Day 29 (1)**

**Form: Immunogenicity Assessment**

**Generated On: 10 Jun 2021 09:15:23**

[Collection time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 22:42:32
User signature succeeded.	Richard Rupp (b) (4)	05 Mar 2021 19:39:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Oct 2020 15:15:03
User entered '09:30'	Kristin Pollock (b) (4) (b) (4)	29 Sep 2020 20:30:58

**US3612005**

**Folder: Visit 2 Day 29 (1)**

**Form: Immunogenicity Assessment**

**Generated On: 10 Jun 2021 09:15:23**

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 22:42:32
User entered '29 Sep 2020 09:30'	System	29 Sep 2020 20:30:58

**US3612005**

**Folder: Visit 2 Day 29 (1)**

**Form: Central Laboratory - Nasopharyngeal Swab**

**Generated On: 10 Jun 2021 09:15:23**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 22:42:32
User signature succeeded.	Richard Rupp (b) (4)	05 Mar 2021 19:39:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Oct 2020 15:15:13
User entered '29 Sep 2020'	Kristin Pollock (b) (4) (b) (4)	29 Sep 2020 20:31:24

**US3612005**

**Folder: Visit 2 Day 29 (1)**

**Form: Central Laboratory - Nasopharyngeal Swab (1)**

**Generated On: 10 Jun 2021 09:15:23**

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 22:42:32
User accepted default value 'Nasopharyngeal Swab 1 (NASAL1)'	Kristin Pollock (b) (4) (b) (4)	29 Sep 2020 20:31:24

**US3612005**

**Folder: Visit 2 Day 29 (1)**

**Form: Central Laboratory - Nasopharyngeal Swab (1)**

**Generated On: 10 Jun 2021 09:15:23**

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 22:42:32
User signature succeeded.	Richard Rupp (b) (4)	05 Mar 2021 19:39:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Oct 2020 15:15:13
User entered 'Yes (Y)'	Kristin Pollock (b) (4) (b) (4)	29 Sep 2020 20:31:24

**US3612005**

**Folder: Visit 2 Day 29 (1)**

**Form: Central Laboratory - Nasopharyngeal Swab (1)**

**Generated On: 10 Jun 2021 09:15:23**

[Collection time \(00:00 - 23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 22:42:32
User signature succeeded.	Richard Rupp (b) (4)	05 Mar 2021 19:39:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Oct 2020 15:15:13
User entered '09:34'	Kristin Pollock (b) (4) (b) (4)	29 Sep 2020 20:31:24

**US3612005**

**Folder: Visit 2 Day 29 (1)**

**Form: Central Laboratory - Nasopharyngeal Swab (1)**

**Generated On: 10 Jun 2021 09:15:23**

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 22:42:32
User entered '29 Sep 2020 09:34'	System	29 Sep 2020 20:31:24

**US3612005**

**Folder: Visit 2 Day 29 (1)**

**Form: Central Laboratory - Nasopharyngeal Swab (2)**

**Generated On: 10 Jun 2021 09:15:23**

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 22:42:32
User accepted default value 'Nasopharyngeal Swab 2 (NASAL2)'	Kristin Pollock (b) (4) (b) (4)	29 Sep 2020 20:31:24

**US3612005**

**Folder: Visit 2 Day 29 (1)**

**Form: Central Laboratory - Nasopharyngeal Swab (2)**

**Generated On: 10 Jun 2021 09:15:23**

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 22:42:32
User signature succeeded.	Richard Rupp (b) (4)	05 Mar 2021 19:39:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Oct 2020 15:15:13
User entered 'No (N)'	Kristin Pollock (b) (4) (b) (4)	29 Sep 2020 20:31:24

**US3612005**

**Folder: Visit 2 Day 29 (1)**

**Form: Central Laboratory - Nasopharyngeal Swab (2)**

**Generated On: 10 Jun 2021 09:15:23**

[Collection time \(00:00 - 23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 22:42:32
User signature succeeded.	Richard Rupp (b) (4)	05 Mar 2021 19:39:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Oct 2020 15:15:13
User entered empty.	Kristin Pollock (b) (4) (b) (4)	29 Sep 2020 20:31:24

**US3612005**

**Folder: Visit 2 Day 29 (1)**

**Form: Central Laboratory - Nasopharyngeal Swab (2)**

**Generated On: 10 Jun 2021 09:15:23**

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 22:42:32
User entered empty.	System	29 Sep 2020 20:31:24

US3612005

Folder: Visit 2 Day 29 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:15:23

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 22:42:32
User signature succeeded.	Richard Rupp (b) (4)	05 Mar 2021 19:39:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Oct 2020 15:15:21
User entered 'Yes (Y)'	Kristin Pollock (b) (4) (b) (4)	29 Sep 2020 20:31:32

**US3612005**

**Folder: Visit 2 Day 29 (1)**

**Form: Continuing**

**Generated On: 10 Jun 2021 09:15:23**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 22:42:32
User entered 'I'	System	29 Sep 2020 20:31:32

US3612005

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/1)

Generated On: 10 Jun 2021 09:15:23

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:05:06
Data entry locked.	System	29 Sep 2020 15:46:04
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	29 Sep 2020 15:46:04

US3612005

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/1)

Generated On: 10 Jun 2021 09:15:23

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:05:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a19c168458d97dd9)', Time: '2020-09-29T10:58:21', User OID: 'PatientReportedOutcome (US3612005)', ODM File OID: '47c63b48-760d-40f6-95c3-0888eb09cee7'	System	29 Sep 2020 15:58:30
User entered 'Yes (Y)'	System	29 Sep 2020 15:58:30

US3612005

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/1)

Generated On: 10 Jun 2021 09:15:23

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:05:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a19c168458d97dd9)', Time: '2020-09-29T10:58:09', User OID: 'PatientReportedOutcome (US3612005)', ODM File OID: '47c63b48-760d-40f6-95c3-0888eb09cee7' User entered '97.9'	System	29 Sep 2020 15:58:30
	System	29 Sep 2020 15:58:30

US3612005

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/1)

Generated On: 10 Jun 2021 09:15:23

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:05:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a19c168458d97dd9)', Time: '2020-09-29T10:58:15', User OID: 'PatientReportedOutcome (US3612005)', ODM File OID: '47c63b48-760d-40f6-95c3-0888eb09cee7'	System	29 Sep 2020 15:58:30
User entered 'No (N)'	System	29 Sep 2020 15:58:30

**US3612005**

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(1/1)**

**Generated On: 10 Jun 2021 09:15:23**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:05:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a19c168458d97dd9)', Time: '2020-09-29T10:58:28', User OID: 'PatientReportedOutcome (US3612005)', ODM File OID: '47c63b48-760d-40f6-95c3-0888eb09cee7'	System	29 Sep 2020 15:58:30
User entered '29 Sep 2020 10:58'	System	29 Sep 2020 15:58:30

**US3612005**

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(1/1)**

**Generated On: 10 Jun 2021 09:15:23**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:05:06
User entered '29 Sep 2020 10:41'	System	29 Sep 2020 15:46:04

**US3612005**

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(1/1)**

**Generated On: 10 Jun 2021 09:15:23**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:05:06
User entered '29 Sep 2020 13:11'	System	29 Sep 2020 15:46:04

US3612005

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/2)

Generated On: 10 Jun 2021 09:15:23

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:05:06
Data entry locked.	System	29 Sep 2020 15:46:04
User entered 'Day 1, after vaccination (at home)'	System	29 Sep 2020 15:46:04

US3612005

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/2)

Generated On: 10 Jun 2021 09:15:23

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:05:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a19c168458d97dd9)', Time: '2020-09-29T20:40:00', User OID: 'PatientReportedOutcome (US3612005)', ODM File OID: 'b24fbc04-f497-466b-bce4-de8b56d5a24c'	System	30 Sep 2020 01:40:26
User entered 'Yes (Y)'	System	30 Sep 2020 01:40:26

US3612005

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/2)

Generated On: 10 Jun 2021 09:15:23

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:05:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a19c168458d97dd9)', Time: '2020-09-29T20:40:06', User OID: 'PatientReportedOutcome (US3612005)', ODM File OID: 'b24fbc04-f497-466b-bce4-de8b56d5a24c'	System	30 Sep 2020 01:40:26
User entered '96.5'	System	30 Sep 2020 01:40:26

US3612005

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/2)

Generated On: 10 Jun 2021 09:15:23

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:05:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a19c168458d97dd9)', Time: '2020-09-29T20:40:12', User OID: 'PatientReportedOutcome (US3612005)', ODM File OID: 'b24fbc04-f497-466b-bce4-de8b56d5a24c'	System	30 Sep 2020 01:40:26
User entered 'No (N)'	System	30 Sep 2020 01:40:26

**US3612005**

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(1/2)**

**Generated On: 10 Jun 2021 09:15:23**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:05:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a19c168458d97dd9)', Time: '2020-09-29T20:40:24', User OID: 'PatientReportedOutcome (US3612005)', ODM File OID: 'b24fbc04-f497-466b-bce4-de8b56d5a24c'	System	30 Sep 2020 01:40:26
User entered '29 Sep 2020 20:40'	System	30 Sep 2020 01:40:26

**US3612005**

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(1/2)**

**Generated On: 10 Jun 2021 09:15:23**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:05:06
User entered '29 Sep 2020 14:06'	System	29 Sep 2020 15:46:04

**US3612005**

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(1/2)**

**Generated On: 10 Jun 2021 09:15:23**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:05:06
User entered '30 Sep 2020 11:59'	System	29 Sep 2020 15:46:04

**US3612005**

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(2)**

**Generated On: 10 Jun 2021 09:15:23**

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:05:06
Data entry locked.	System	29 Sep 2020 15:46:04
User entered 'Day 2'	System	29 Sep 2020 15:46:04

US3612005

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(2)

Generated On: 10 Jun 2021 09:15:23

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:05:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a19c168458d97dd9)', Time: '2020-09-30T14:12:50', User OID: 'PatientReportedOutcome (US3612005)', ODM File OID: '583b4b20-66e6-48d9-9a1d-78a52cd7deaf'	System	30 Sep 2020 19:13:08
User entered 'Yes (Y)'	System	30 Sep 2020 19:13:08

US3612005

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(2)

Generated On: 10 Jun 2021 09:15:23

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:05:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a19c168458d97dd9)', Time: '2020-09-30T14:12:56', User OID: 'PatientReportedOutcome (US3612005)', ODM File OID: '583b4b20-66e6-48d9-9a1d-78a52cd7deaf'	System	30 Sep 2020 19:13:08
User entered '97.2'	System	30 Sep 2020 19:13:08

US3612005

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(2)

Generated On: 10 Jun 2021 09:15:23

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:05:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a19c168458d97dd9)', Time: '2020-09-30T14:13:00', User OID: 'PatientReportedOutcome (US3612005)', ODM File OID: '583b4b20-66e6-48d9-9a1d-78a52cd7deaf'	System	30 Sep 2020 19:13:08
User entered 'No (N)'	System	30 Sep 2020 19:13:08

**US3612005**

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(2)**

**Generated On: 10 Jun 2021 09:15:23**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:05:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a19c168458d97dd9)', Time: '2020-09-30T14:13:06', User OID: 'PatientReportedOutcome (US3612005)', ODM File OID: '583b4b20-66e6-48d9-9a1d-78a52cd7deaf'	System	30 Sep 2020 19:13:08
User entered '30 Sep 2020 14:13'	System	30 Sep 2020 19:13:08

**US3612005**

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(2)**

**Generated On: 10 Jun 2021 09:15:23**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:05:06
User entered '30 Sep 2020 12:00'	System	29 Sep 2020 15:46:04

**US3612005**

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(2)**

**Generated On: 10 Jun 2021 09:15:23**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:05:06
User entered '01 Oct 2020 11:59'	System	29 Sep 2020 15:46:04

US3612005

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(3)

Generated On: 10 Jun 2021 09:15:23

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:05:06
Data entry locked.	System	29 Sep 2020 15:46:04
User entered 'Day 3'	System	29 Sep 2020 15:46:04

US3612005

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(3)

Generated On: 10 Jun 2021 09:15:23

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:05:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a19c168458d97dd9)', Time: '2020-10-01T17:50:51', User OID: 'PatientReportedOutcome (US3612005)', ODM File OID: '302920f6-1dff-4733-9569-cb1805ecc5c6'	System	01 Oct 2020 22:51:09
User entered 'Yes (Y)'	System	01 Oct 2020 22:51:09

US3612005

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(3)

Generated On: 10 Jun 2021 09:15:23

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:05:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a19c168458d97dd9)', Time: '2020-10-01T17:50:56', User OID: 'PatientReportedOutcome (US3612005)', ODM File OID: '302920f6-1dff-4733-9569-cb1805ecc5c6'	System	01 Oct 2020 22:51:09
User entered '97.1'	System	01 Oct 2020 22:51:09

US3612005

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(3)

Generated On: 10 Jun 2021 09:15:23

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:05:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a19c168458d97dd9)', Time: '2020-10-01T17:50:59', User OID: 'PatientReportedOutcome (US3612005)', ODM File OID: '302920f6-1dff-4733-9569-cb1805ecc5c6'	System	01 Oct 2020 22:51:09
User entered 'No (N)'	System	01 Oct 2020 22:51:09

**US3612005**

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(3)**

**Generated On: 10 Jun 2021 09:15:23**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:05:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a19c168458d97dd9)', Time: '2020-10-01T17:51:04', User OID: 'PatientReportedOutcome (US3612005)', ODM File OID: '302920f6-1dff-4733-9569-cb1805ecc5c6'	System	01 Oct 2020 22:51:09
User entered '01 Oct 2020 17:51'	System	01 Oct 2020 22:51:09

**US3612005**

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(3)**

**Generated On: 10 Jun 2021 09:15:23**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:05:06
User entered '01 Oct 2020 12:00'	System	29 Sep 2020 15:46:04

**US3612005**

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(3)**

**Generated On: 10 Jun 2021 09:15:23**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:05:06
User entered '02 Oct 2020 11:59'	System	29 Sep 2020 15:46:04

US3612005

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(4)

Generated On: 10 Jun 2021 09:15:23

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:05:06
Data entry locked.	System	29 Sep 2020 15:46:04
User entered 'Day 4'	System	29 Sep 2020 15:46:04

US3612005

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(4)

Generated On: 10 Jun 2021 09:15:23

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:05:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a19c168458d97dd9)', Time: '2020-10-02T14:44:20', User OID: 'PatientReportedOutcome (US3612005)', ODM File OID: 'ccb5fd9f-8251-4e17-b953-e4ae94b66e0c'	System	02 Oct 2020 19:44:46
User entered 'Yes (Y)'	System	02 Oct 2020 19:44:46

US3612005

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(4)

Generated On: 10 Jun 2021 09:15:23

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:05:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a19c168458d97dd9)', Time: '2020-10-02T14:44:26', User OID: 'PatientReportedOutcome (US3612005)', ODM File OID: 'ccb5fd9f-8251-4e17-b953-e4ae94b66e0c'	System	02 Oct 2020 19:44:46
User entered '96.7'	System	02 Oct 2020 19:44:46

US3612005

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(4)

Generated On: 10 Jun 2021 09:15:23

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:05:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a19c168458d97dd9)', Time: '2020-10-02T14:44:30', User OID: 'PatientReportedOutcome (US3612005)', ODM File OID: 'ccb5fd9f-8251-4e17-b953-e4ae94b66e0c'	System	02 Oct 2020 19:44:46
User entered 'No (N)'	System	02 Oct 2020 19:44:46

**US3612005**

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(4)**

**Generated On: 10 Jun 2021 09:15:23**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:05:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a19c168458d97dd9)', Time: '2020-10-02T14:44:41', User OID: 'PatientReportedOutcome (US3612005)', ODM File OID: 'ccb5fd9f-8251-4e17-b953-e4ae94b66e0c'	System	02 Oct 2020 19:44:46
User entered '02 Oct 2020 14:44'	System	02 Oct 2020 19:44:46

**US3612005**

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(4)**

**Generated On: 10 Jun 2021 09:15:23**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:05:06
User entered '02 Oct 2020 12:00'	System	29 Sep 2020 15:46:04

**US3612005**

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(4)**

**Generated On: 10 Jun 2021 09:15:23**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:05:06
User entered '03 Oct 2020 11:59'	System	29 Sep 2020 15:46:04

US3612005

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(5)

Generated On: 10 Jun 2021 09:15:23

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:05:06
Data entry locked.	System	29 Sep 2020 15:46:04
User entered 'Day 5'	System	29 Sep 2020 15:46:04

**US3612005**

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(5)**

**Generated On: 10 Jun 2021 09:15:23**

**Was TEMPERATURE taken?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:05:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a19c168458d97dd9)', Time: '2020-10-03T14:48:14', User OID: 'PatientReportedOutcome (US3612005)', ODM File OID: '07d3c457-52b8-42fd-b24d-8ebfb8f2c4c7'	System	03 Oct 2020 19:48:39
User entered 'Yes (Y)'	System	03 Oct 2020 19:48:39

US3612005

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(5)

Generated On: 10 Jun 2021 09:15:23

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:05:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a19c168458d97dd9)', Time: '2020-10-03T14:48:27', User OID: 'PatientReportedOutcome (US3612005)', ODM File OID: '07d3c457-52b8-42fd-b24d-8ebfb8f2c4c7'	System	03 Oct 2020 19:48:39
User entered '97.3'	System	03 Oct 2020 19:48:39

US3612005

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(5)

Generated On: 10 Jun 2021 09:15:23

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:05:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a19c168458d97dd9)', Time: '2020-10-03T14:48:31', User OID: 'PatientReportedOutcome (US3612005)', ODM File OID: '07d3c457-52b8-42fd-b24d-8ebfb8f2c4c7'	System	03 Oct 2020 19:48:39
User entered 'No (N)'	System	03 Oct 2020 19:48:39

**US3612005**

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(5)**

**Generated On: 10 Jun 2021 09:15:23**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:05:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a19c168458d97dd9)', Time: '2020-10-03T14:48:34', User OID: 'PatientReportedOutcome (US3612005)', ODM File OID: '07d3c457-52b8-42fd-b24d-8ebfb8f2c4c7'	System	03 Oct 2020 19:48:39
User entered '03 Oct 2020 14:48'	System	03 Oct 2020 19:48:39

**US3612005**

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(5)**

**Generated On: 10 Jun 2021 09:15:23**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:05:06
User entered '03 Oct 2020 12:00'	System	29 Sep 2020 15:46:04

**US3612005**

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(5)**

**Generated On: 10 Jun 2021 09:15:23**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:05:06
User entered '04 Oct 2020 11:59'	System	29 Sep 2020 15:46:04

US3612005

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(6)

Generated On: 10 Jun 2021 09:15:23

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:05:06
Data entry locked.	System	29 Sep 2020 15:46:04
User entered 'Day 6'	System	29 Sep 2020 15:46:04

US3612005

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(6)

Generated On: 10 Jun 2021 09:15:23

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:05:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a19c168458d97dd9)', Time: '2020-10-04T21:00:57', User OID: 'PatientReportedOutcome (US3612005)', ODM File OID: '82cd14ff-dfc2-4e55-a1c6-a2137f5f01cb'	System	05 Oct 2020 02:01:23
User entered 'Yes (Y)'	System	05 Oct 2020 02:01:23

US3612005

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(6)

Generated On: 10 Jun 2021 09:15:23

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:05:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a19c168458d97dd9)', Time: '2020-10-04T21:01:11', User OID: 'PatientReportedOutcome (US3612005)', ODM File OID: '82cd14ff-dfc2-4e55-a1c6-a2137f5f01cb'	System	05 Oct 2020 02:01:23
User entered '98.3'	System	05 Oct 2020 02:01:23

US3612005

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(6)

Generated On: 10 Jun 2021 09:15:23

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:05:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a19c168458d97dd9)', Time: '2020-10-04T21:01:14', User OID: 'PatientReportedOutcome (US3612005)', ODM File OID: '82cd14ff-dfc2-4e55-a1c6-a2137f5f01cb'	System	05 Oct 2020 02:01:23
User entered 'No (N)'	System	05 Oct 2020 02:01:23

**US3612005**

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(6)**

**Generated On: 10 Jun 2021 09:15:23**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:05:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a19c168458d97dd9)', Time: '2020-10-04T21:01:21', User OID: 'PatientReportedOutcome (US3612005)', ODM File OID: '82cd14ff-dfc2-4e55-a1c6-a2137f5f01cb'	System	05 Oct 2020 02:01:23
User entered '04 Oct 2020 21:01'	System	05 Oct 2020 02:01:23

**US3612005**

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(6)**

**Generated On: 10 Jun 2021 09:15:23**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:05:06
User entered '04 Oct 2020 12:00'	System	29 Sep 2020 15:46:04

**US3612005**

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(6)**

**Generated On: 10 Jun 2021 09:15:23**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:05:06
User entered '05 Oct 2020 11:59'	System	29 Sep 2020 15:46:04

US3612005

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(7)

Generated On: 10 Jun 2021 09:15:23

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:05:06
Data entry locked.	System	29 Sep 2020 15:46:04
User entered 'Day 7'	System	29 Sep 2020 15:46:04

US3612005

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(7)

Generated On: 10 Jun 2021 09:15:23

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:05:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a19c168458d97dd9)', Time: '2020-10-05T14:33:03', User OID: 'PatientReportedOutcome (US3612005)', ODM File OID: '0ed45d42-0499-44af-aef9-0246eb3fed3d'	System	05 Oct 2020 19:33:25
User entered 'Yes (Y)'	System	05 Oct 2020 19:33:25

US3612005

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(7)

Generated On: 10 Jun 2021 09:15:23

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:05:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a19c168458d97dd9)', Time: '2020-10-05T14:33:13', User OID: 'PatientReportedOutcome (US3612005)', ODM File OID: '0ed45d42-0499-44af-aef9-0246eb3fed3d'	System	05 Oct 2020 19:33:25
User entered '97.4'	System	05 Oct 2020 19:33:25

US3612005

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(7)

Generated On: 10 Jun 2021 09:15:23

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:05:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a19c168458d97dd9)', Time: '2020-10-05T14:33:17', User OID: 'PatientReportedOutcome (US3612005)', ODM File OID: '0ed45d42-0499-44af-aef9-0246eb3fed3d'	System	05 Oct 2020 19:33:25
User entered 'No (N)'	System	05 Oct 2020 19:33:25

**US3612005**

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(7)**

**Generated On: 10 Jun 2021 09:15:23**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:05:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a19c168458d97dd9)', Time: '2020-10-05T14:33:22', User OID: 'PatientReportedOutcome (US3612005)', ODM File OID: '0ed45d42-0499-44af-aef9-0246eb3fed3d'	System	05 Oct 2020 19:33:25
User entered '05 Oct 2020 14:33'	System	05 Oct 2020 19:33:25

**US3612005**

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(7)**

**Generated On: 10 Jun 2021 09:15:23**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:05:06
User entered '05 Oct 2020 12:00'	System	29 Sep 2020 15:46:04

**US3612005**

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(7)**

**Generated On: 10 Jun 2021 09:15:23**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:05:06
User entered '06 Oct 2020 11:59'	System	29 Sep 2020 15:46:04

US3612005

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/1)

Generated On: 10 Jun 2021 09:15:23

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:05:06
Data entry locked.	System	29 Sep 2020 15:46:04
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	29 Sep 2020 15:46:04

US3612005

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/1)

Generated On: 10 Jun 2021 09:15:23

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 16:05:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a19c168458d97dd9)', Time: '2020-09-29T10:59:11', User OID: 'PatientReportedOutcome (US3612005)', ODM File OID: 'e6e058db-fa51-408b-96ea-51b58bfe1534'	System	29 Sep 2020 15:59:32
User entered 'None (1)'	System	29 Sep 2020 15:59:32

US3612005

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/1)

Generated On: 10 Jun 2021 09:15:23

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:05:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a19c168458d97dd9)', Time: '2020-09-29T10:59:15', User OID: 'PatientReportedOutcome (US3612005)', ODM File OID: 'e6e058db-fa51-408b-96ea-51b58bfe1534'	System	29 Sep 2020 15:59:32
User entered 'No (N)'	System	29 Sep 2020 15:59:32

US3612005

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/1)

Generated On: 10 Jun 2021 09:15:23

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:05:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a19c168458d97dd9)', Time: '2020-09-29T10:59:19', User OID: 'PatientReportedOutcome (US3612005)', ODM File OID: 'e6e058db-fa51-408b-96ea-51b58bfe1534'	System	29 Sep 2020 15:59:32
User entered 'No (N)'	System	29 Sep 2020 15:59:32

US3612005

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/1)

Generated On: 10 Jun 2021 09:15:23

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 16:05:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a19c168458d97dd9)', Time: '2020-09-29T10:59:23', User OID: 'PatientReportedOutcome (US3612005)', ODM File OID: 'e6e058db-fa51-408b-96ea-51b58bfe1534'	System	29 Sep 2020 15:59:32
User entered 'None (1)'	System	29 Sep 2020 15:59:32

**US3612005**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(1/1)**

**Generated On: 10 Jun 2021 09:15:23**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:05:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a19c168458d97dd9)', Time: '2020-09-29T10:59:28', User OID: 'PatientReportedOutcome (US3612005)', ODM File OID: 'e6e058db-fa51-408b-96ea-51b58bfe1534'	System	29 Sep 2020 15:59:32
User entered '29 Sep 2020 10:59'	System	29 Sep 2020 15:59:32

**US3612005**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(1/1)**

**Generated On: 10 Jun 2021 09:15:23**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:05:06
User entered '29 Sep 2020 10:41'	System	29 Sep 2020 15:46:04

**US3612005**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(1/1)**

**Generated On: 10 Jun 2021 09:15:23**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:05:06
User entered '29 Sep 2020 13:11'	System	29 Sep 2020 15:46:04

US3612005

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/2)

Generated On: 10 Jun 2021 09:15:23

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:05:06
Data entry locked.	System	29 Sep 2020 15:46:04
User entered 'Day 1, after vaccination (at home)'	System	29 Sep 2020 15:46:04

US3612005

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/2)

Generated On: 10 Jun 2021 09:15:23

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 16:05:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a19c168458d97dd9)', Time: '2020-09-29T20:42:17', User OID: 'PatientReportedOutcome (US3612005)', ODM File OID: '20b1d3de-3775-4b21-aa28-d096fdad3841'	System	30 Sep 2020 01:42:45
User entered 'None (1)'	System	30 Sep 2020 01:42:45

US3612005

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/2)

Generated On: 10 Jun 2021 09:15:23

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:05:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a19c168458d97dd9)', Time: '2020-09-29T20:42:21', User OID: 'PatientReportedOutcome (US3612005)', ODM File OID: '20b1d3de-3775-4b21-aa28-d096fdad3841'	System	30 Sep 2020 01:42:45
User entered 'No (N)'	System	30 Sep 2020 01:42:45

US3612005

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/2)

Generated On: 10 Jun 2021 09:15:23

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:05:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a19c168458d97dd9)', Time: '2020-09-29T20:42:24', User OID: 'PatientReportedOutcome (US3612005)', ODM File OID: '20b1d3de-3775-4b21-aa28-d096fdad3841'	System	30 Sep 2020 01:42:45
User entered 'No (N)'	System	30 Sep 2020 01:42:45

US3612005

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/2)

Generated On: 10 Jun 2021 09:15:23

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 16:05:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a19c168458d97dd9)', Time: '2020-09-29T20:42:31', User OID: 'PatientReportedOutcome (US3612005)', ODM File OID: '20b1d3de-3775-4b21-aa28-d096fdad3841'	System	30 Sep 2020 01:42:45
User entered 'None (1)'	System	30 Sep 2020 01:42:45

**US3612005**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(1/2)**

**Generated On: 10 Jun 2021 09:15:23**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:05:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a19c168458d97dd9)', Time: '2020-09-29T20:42:41', User OID: 'PatientReportedOutcome (US3612005)', ODM File OID: '20b1d3de-3775-4b21-aa28-d096fdad3841'	System	30 Sep 2020 01:42:45
User entered '29 Sep 2020 20:42'	System	30 Sep 2020 01:42:45

**US3612005**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(1/2)**

**Generated On: 10 Jun 2021 09:15:23**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:05:06
User entered '29 Sep 2020 14:06'	System	29 Sep 2020 15:46:04

**US3612005**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(1/2)**

**Generated On: 10 Jun 2021 09:15:23**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:05:06
User entered '30 Sep 2020 11:59'	System	29 Sep 2020 15:46:04

US3612005

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(2)

Generated On: 10 Jun 2021 09:15:23

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:05:06
Data entry locked.	System	29 Sep 2020 15:46:04
User entered 'Day 2'	System	29 Sep 2020 15:46:04

US3612005

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(2)

Generated On: 10 Jun 2021 09:15:23

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 16:05:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a19c168458d97dd9)', Time: '2020-09-30T14:13:10', User OID: 'PatientReportedOutcome (US3612005)', ODM File OID: 'c155ec5c-f888-4573-85e3-9fdf8caefb9f'	System	30 Sep 2020 19:13:37
User entered 'None (1)'	System	30 Sep 2020 19:13:37

US3612005

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(2)

Generated On: 10 Jun 2021 09:15:23

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:05:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a19c168458d97dd9)', Time: '2020-09-30T14:13:14', User OID: 'PatientReportedOutcome (US3612005)', ODM File OID: 'c155ec5c-f888-4573-85e3-9fdf8caefb9f'	System	30 Sep 2020 19:13:37
User entered 'No (N)'	System	30 Sep 2020 19:13:37

US3612005

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(2)

Generated On: 10 Jun 2021 09:15:23

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:05:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a19c168458d97dd9)', Time: '2020-09-30T14:13:19', User OID: 'PatientReportedOutcome (US3612005)', ODM File OID: 'c155ec5c-f888-4573-85e3-9fdf8caefb9f'	System	30 Sep 2020 19:13:37
User entered 'No (N)'	System	30 Sep 2020 19:13:37

US3612005

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(2)

Generated On: 10 Jun 2021 09:15:23

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 16:05:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a19c168458d97dd9)', Time: '2020-09-30T14:13:23', User OID: 'PatientReportedOutcome (US3612005)', ODM File OID: 'c155ec5c-f888-4573-85e3-9fdf8caefb9f'	System	30 Sep 2020 19:13:37
User entered 'None (1)'	System	30 Sep 2020 19:13:37

**US3612005**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(2)**

**Generated On: 10 Jun 2021 09:15:23**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:05:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a19c168458d97dd9)', Time: '2020-09-30T14:13:28', User OID: 'PatientReportedOutcome (US3612005)', ODM File OID: 'c155ec5c-f888-4573-85e3-9fdf8caefb9f'	System	30 Sep 2020 19:13:37
User entered '30 Sep 2020 14:13'	System	30 Sep 2020 19:13:37

**US3612005**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(2)**

**Generated On: 10 Jun 2021 09:15:23**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:05:06
User entered '30 Sep 2020 12:00'	System	29 Sep 2020 15:46:04

**US3612005**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(2)**

**Generated On: 10 Jun 2021 09:15:23**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:05:06
User entered '01 Oct 2020 11:59'	System	29 Sep 2020 15:46:04

US3612005

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(3)

Generated On: 10 Jun 2021 09:15:23

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:05:06
Data entry locked.	System	29 Sep 2020 15:46:04
User entered 'Day 3'	System	29 Sep 2020 15:46:04

US3612005

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(3)

Generated On: 10 Jun 2021 09:15:23

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 16:05:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a19c168458d97dd9)', Time: '2020-10-01T17:51:27', User OID: 'PatientReportedOutcome (US3612005)', ODM File OID: '7c3c91ff-5a13-4303-9b2a-4fdddb4d81fa'	System	01 Oct 2020 22:51:53
User entered 'None (1)'	System	01 Oct 2020 22:51:53

US3612005

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(3)

Generated On: 10 Jun 2021 09:15:23

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:05:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a19c168458d97dd9)', Time: '2020-10-01T17:51:30', User OID: 'PatientReportedOutcome (US3612005)', ODM File OID: '7c3c91ff-5a13-4303-9b2a-4fdddb4d81fa'	System	01 Oct 2020 22:51:53
User entered 'No (N)'	System	01 Oct 2020 22:51:53

US3612005

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(3)

Generated On: 10 Jun 2021 09:15:23

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:05:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a19c168458d97dd9)', Time: '2020-10-01T17:51:39', User OID: 'PatientReportedOutcome (US3612005)', ODM File OID: '7c3c91ff-5a13-4303-9b2a-4fdddb4d81fa'	System	01 Oct 2020 22:51:53
User entered 'No (N)'	System	01 Oct 2020 22:51:53

US3612005

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(3)

Generated On: 10 Jun 2021 09:15:23

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 16:05:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a19c168458d97dd9)', Time: '2020-10-01T17:51:44', User OID: 'PatientReportedOutcome (US3612005)', ODM File OID: '7c3c91ff-5a13-4303-9b2a-4fdddb4d81fa'	System	01 Oct 2020 22:51:53
User entered 'None (1)'	System	01 Oct 2020 22:51:53

**US3612005**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(3)**

**Generated On: 10 Jun 2021 09:15:23**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:05:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a19c168458d97dd9)', Time: '2020-10-01T17:51:48', User OID: 'PatientReportedOutcome (US3612005)', ODM File OID: '7c3c91ff-5a13-4303-9b2a-4fdddb4d81fa'	System	01 Oct 2020 22:51:53
User entered '01 Oct 2020 17:51'	System	01 Oct 2020 22:51:53

**US3612005**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(3)**

**Generated On: 10 Jun 2021 09:15:23**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:05:06
User entered '01 Oct 2020 12:00'	System	29 Sep 2020 15:46:04

**US3612005**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(3)**

**Generated On: 10 Jun 2021 09:15:23**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:05:06
User entered '02 Oct 2020 11:59'	System	29 Sep 2020 15:46:04

US3612005

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(4)

Generated On: 10 Jun 2021 09:15:23

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:05:06
Data entry locked.	System	29 Sep 2020 15:46:04
User entered 'Day 4'	System	29 Sep 2020 15:46:04

US3612005

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(4)

Generated On: 10 Jun 2021 09:15:23

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 16:05:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a19c168458d97dd9)', Time: '2020-10-02T14:51:01', User OID: 'PatientReportedOutcome (US3612005)', ODM File OID: 'c3a498b7-edd5-49ca-b47e-0f5789c72838'	System	02 Oct 2020 19:51:23
User entered 'None (1)'	System	02 Oct 2020 19:51:23

US3612005

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(4)

Generated On: 10 Jun 2021 09:15:23

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:05:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a19c168458d97dd9)', Time: '2020-10-02T14:51:04', User OID: 'PatientReportedOutcome (US3612005)', ODM File OID: 'c3a498b7-edd5-49ca-b47e-0f5789c72838'	System	02 Oct 2020 19:51:23
User entered 'No (N)'	System	02 Oct 2020 19:51:23

US3612005

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(4)

Generated On: 10 Jun 2021 09:15:23

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:05:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a19c168458d97dd9)', Time: '2020-10-02T14:51:10', User OID: 'PatientReportedOutcome (US3612005)', ODM File OID: 'c3a498b7-edd5-49ca-b47e-0f5789c72838'	System	02 Oct 2020 19:51:23
User entered 'No (N)'	System	02 Oct 2020 19:51:23

US3612005

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(4)

Generated On: 10 Jun 2021 09:15:23

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 16:05:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a19c168458d97dd9)', Time: '2020-10-02T14:51:13', User OID: 'PatientReportedOutcome (US3612005)', ODM File OID: 'c3a498b7-edd5-49ca-b47e-0f5789c72838'	System	02 Oct 2020 19:51:23
User entered 'None (1)'	System	02 Oct 2020 19:51:23

**US3612005**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(4)**

**Generated On: 10 Jun 2021 09:15:23**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:05:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a19c168458d97dd9)', Time: '2020-10-02T14:51:21', User OID: 'PatientReportedOutcome (US3612005)', ODM File OID: 'c3a498b7-edd5-49ca-b47e-0f5789c72838'	System	02 Oct 2020 19:51:23
User entered '02 Oct 2020 14:51'	System	02 Oct 2020 19:51:23

**US3612005**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(4)**

**Generated On: 10 Jun 2021 09:15:23**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:05:06
User entered '02 Oct 2020 12:00'	System	29 Sep 2020 15:46:04

**US3612005**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(4)**

**Generated On: 10 Jun 2021 09:15:23**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:05:06
User entered '03 Oct 2020 11:59'	System	29 Sep 2020 15:46:04

**US3612005**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(5)**

**Generated On: 10 Jun 2021 09:15:23**

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:05:06
Data entry locked.	System	29 Sep 2020 15:46:04
User entered 'Day 5'	System	29 Sep 2020 15:46:04

US3612005

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(5)

Generated On: 10 Jun 2021 09:15:23

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 16:05:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a19c168458d97dd9)', Time: '2020-10-03T14:48:50', User OID: 'PatientReportedOutcome (US3612005)', ODM File OID: 'de7b7daf-5cff-4d0c-bc9c-157445e8bbd6'	System	03 Oct 2020 19:49:14
User entered 'None (1)'	System	03 Oct 2020 19:49:14

US3612005

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(5)

Generated On: 10 Jun 2021 09:15:23

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:05:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a19c168458d97dd9)', Time: '2020-10-03T14:48:55', User OID: 'PatientReportedOutcome (US3612005)', ODM File OID: 'de7b7daf-5cff-4d0c-bc9c-157445e8bbd6'	System	03 Oct 2020 19:49:14
User entered 'No (N)'	System	03 Oct 2020 19:49:14

US3612005

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(5)

Generated On: 10 Jun 2021 09:15:23

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:05:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a19c168458d97dd9)', Time: '2020-10-03T14:48:59', User OID: 'PatientReportedOutcome (US3612005)', ODM File OID: 'de7b7daf-5cff-4d0c-bc9c-157445e8bbd6'	System	03 Oct 2020 19:49:14
User entered 'No (N)'	System	03 Oct 2020 19:49:14

US3612005

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(5)

Generated On: 10 Jun 2021 09:15:23

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 16:05:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a19c168458d97dd9)', Time: '2020-10-03T14:49:07', User OID: 'PatientReportedOutcome (US3612005)', ODM File OID: 'de7b7daf-5cff-4d0c-bc9c-157445e8bbd6'	System	03 Oct 2020 19:49:14
User entered 'None (1)'	System	03 Oct 2020 19:49:14

**US3612005**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(5)**

**Generated On: 10 Jun 2021 09:15:23**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:05:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a19c168458d97dd9)', Time: '2020-10-03T14:49:11', User OID: 'PatientReportedOutcome (US3612005)', ODM File OID: 'de7b7daf-5cff-4d0c-bc9c-157445e8bbd6'	System	03 Oct 2020 19:49:14
User entered '03 Oct 2020 14:49'	System	03 Oct 2020 19:49:14

**US3612005**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(5)**

**Generated On: 10 Jun 2021 09:15:23**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:05:06
User entered '03 Oct 2020 12:00'	System	29 Sep 2020 15:46:04

**US3612005**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(5)**

**Generated On: 10 Jun 2021 09:15:23**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:05:06
User entered '04 Oct 2020 11:59'	System	29 Sep 2020 15:46:04

US3612005

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(6)

Generated On: 10 Jun 2021 09:15:23

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:05:06
Data entry locked.	System	29 Sep 2020 15:46:04
User entered 'Day 6'	System	29 Sep 2020 15:46:04

US3612005

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(6)

Generated On: 10 Jun 2021 09:15:23

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 16:05:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a19c168458d97dd9)', Time: '2020-10-04T21:01:41', User OID: 'PatientReportedOutcome (US3612005)', ODM File OID: '39a10f4d-2099-462d-9040-94631381c0a1'	System	05 Oct 2020 02:01:59
User entered 'None (1)'	System	05 Oct 2020 02:01:59

US3612005

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(6)

Generated On: 10 Jun 2021 09:15:23

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:05:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a19c168458d97dd9)', Time: '2020-10-04T21:01:44', User OID: 'PatientReportedOutcome (US3612005)', ODM File OID: '39a10f4d-2099-462d-9040-94631381c0a1'	System	05 Oct 2020 02:01:59
User entered 'No (N)'	System	05 Oct 2020 02:01:59

US3612005

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(6)

Generated On: 10 Jun 2021 09:15:23

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:05:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a19c168458d97dd9)', Time: '2020-10-04T21:01:48', User OID: 'PatientReportedOutcome (US3612005)', ODM File OID: '39a10f4d-2099-462d-9040-94631381c0a1'	System	05 Oct 2020 02:01:59
User entered 'No (N)'	System	05 Oct 2020 02:01:59

US3612005

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(6)

Generated On: 10 Jun 2021 09:15:23

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 16:05:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a19c168458d97dd9)', Time: '2020-10-04T21:01:51', User OID: 'PatientReportedOutcome (US3612005)', ODM File OID: '39a10f4d-2099-462d-9040-94631381c0a1'	System	05 Oct 2020 02:01:59
User entered 'None (1)'	System	05 Oct 2020 02:01:59

**US3612005**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(6)**

**Generated On: 10 Jun 2021 09:15:23**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:05:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a19c168458d97dd9)', Time: '2020-10-04T21:01:56', User OID: 'PatientReportedOutcome (US3612005)', ODM File OID: '39a10f4d-2099-462d-9040-94631381c0a1'	System	05 Oct 2020 02:01:59
User entered '04 Oct 2020 21:01'	System	05 Oct 2020 02:01:59

**US3612005**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(6)**

**Generated On: 10 Jun 2021 09:15:23**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:05:06
User entered '04 Oct 2020 12:00'	System	29 Sep 2020 15:46:04

**US3612005**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(6)**

**Generated On: 10 Jun 2021 09:15:23**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:05:06
User entered '05 Oct 2020 11:59'	System	29 Sep 2020 15:46:04

US3612005

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(7)

Generated On: 10 Jun 2021 09:15:23

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:05:06
Data entry locked.	System	29 Sep 2020 15:46:04
User entered 'Day 7'	System	29 Sep 2020 15:46:04

US3612005

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(7)

Generated On: 10 Jun 2021 09:15:23

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 16:05:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a19c168458d97dd9)', Time: '2020-10-05T14:34:01', User OID: 'PatientReportedOutcome (US3612005)', ODM File OID: 'dd85abe9-6ec1-4989-a0f0-6da7a800721f'	System	05 Oct 2020 19:34:27
User entered 'None (1)'	System	05 Oct 2020 19:34:27

US3612005

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(7)

Generated On: 10 Jun 2021 09:15:23

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:05:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a19c168458d97dd9)', Time: '2020-10-05T14:34:04', User OID: 'PatientReportedOutcome (US3612005)', ODM File OID: 'dd85abe9-6ec1-4989-a0f0-6da7a800721f'	System	05 Oct 2020 19:34:27
User entered 'No (N)'	System	05 Oct 2020 19:34:27

US3612005

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(7)

Generated On: 10 Jun 2021 09:15:23

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:05:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a19c168458d97dd9)', Time: '2020-10-05T14:34:09', User OID: 'PatientReportedOutcome (US3612005)', ODM File OID: 'dd85abe9-6ec1-4989-a0f0-6da7a800721f'	System	05 Oct 2020 19:34:27
User entered 'No (N)'	System	05 Oct 2020 19:34:27

US3612005

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(7)

Generated On: 10 Jun 2021 09:15:23

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 16:05:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a19c168458d97dd9)', Time: '2020-10-05T14:34:13', User OID: 'PatientReportedOutcome (US3612005)', ODM File OID: 'dd85abe9-6ec1-4989-a0f0-6da7a800721f'	System	05 Oct 2020 19:34:27
User entered 'None (1)'	System	05 Oct 2020 19:34:27

**US3612005**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(7)**

**Generated On: 10 Jun 2021 09:15:23**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:05:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a19c168458d97dd9)', Time: '2020-10-05T14:34:24', User OID: 'PatientReportedOutcome (US3612005)', ODM File OID: 'dd85abe9-6ec1-4989-a0f0-6da7a800721f'	System	05 Oct 2020 19:34:27
User entered '05 Oct 2020 14:34'	System	05 Oct 2020 19:34:27

**US3612005**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(7)**

**Generated On: 10 Jun 2021 09:15:23**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:05:06
User entered '05 Oct 2020 12:00'	System	29 Sep 2020 15:46:04

**US3612005**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(7)**

**Generated On: 10 Jun 2021 09:15:23**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:05:06
User entered '06 Oct 2020 11:59'	System	29 Sep 2020 15:46:04

US3612005

Folder: Diary Dose 2 (1)

Form: General\_Day(1/1)

Generated On: 10 Jun 2021 09:15:23

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:05:06
Data entry locked.	System	29 Sep 2020 15:46:04
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	29 Sep 2020 15:46:04

US3612005

Folder: Diary Dose 2 (1)

Form: General\_Day(1/1)

Generated On: 10 Jun 2021 09:15:23

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:05:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a19c168458d97dd9)', Time: '2020-09-29T10:59:33', User OID: 'PatientReportedOutcome (US3612005)', ODM File OID: '57b04d3d-62eb-4c28-beb7-b8cf2647aba1'	System	29 Sep 2020 16:00:05
User entered 'None (0)'	System	29 Sep 2020 16:00:05

**US3612005**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(1/1)**

**Generated On: 10 Jun 2021 09:15:23**

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:05:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a19c168458d97dd9)', Time: '2020-09-29T10:59:36', User OID: 'PatientReportedOutcome (US3612005)', ODM File OID: '57b04d3d-62eb-4c28-beb7-b8cf2647aba1'	System	29 Sep 2020 16:00:05
User entered 'None (0)'	System	29 Sep 2020 16:00:05

US3612005

Folder: Diary Dose 2 (1)

Form: General\_Day(1/1)

Generated On: 10 Jun 2021 09:15:23

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:05:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a19c168458d97dd9)', Time: '2020-09-29T10:59:39', User OID: 'PatientReportedOutcome (US3612005)', ODM File OID: '57b04d3d-62eb-4c28-beb7-b8cf2647aba1'	System	29 Sep 2020 16:00:05
User entered 'None (0)'	System	29 Sep 2020 16:00:05

US3612005

Folder: Diary Dose 2 (1)

Form: General\_Day(1/1)

Generated On: 10 Jun 2021 09:15:23

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:05:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a19c168458d97dd9)', Time: '2020-09-29T10:59:42', User OID: 'PatientReportedOutcome (US3612005)', ODM File OID: '57b04d3d-62eb-4c28-beb7-b8cf2647aba1'	System	29 Sep 2020 16:00:05
User entered 'None (0)'	System	29 Sep 2020 16:00:05

**US3612005**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(1/1)**

**Generated On: 10 Jun 2021 09:15:23**

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:05:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a19c168458d97dd9)', Time: '2020-09-29T10:59:45', User OID: 'PatientReportedOutcome (US3612005)', ODM File OID: '57b04d3d-62eb-4c28-beb7-b8cf2647aba1'	System	29 Sep 2020 16:00:05
User entered 'None (0)'	System	29 Sep 2020 16:00:05

**US3612005**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(1/1)**

**Generated On: 10 Jun 2021 09:15:23**

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:05:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a19c168458d97dd9)', Time: '2020-09-29T10:59:47', User OID: 'PatientReportedOutcome (US3612005)', ODM File OID: '57b04d3d-62eb-4c28-beb7-b8cf2647aba1'	System	29 Sep 2020 16:00:05
User entered 'None (0)'	System	29 Sep 2020 16:00:05

US3612005

Folder: Diary Dose 2 (1)

Form: General\_Day(1/1)

Generated On: 10 Jun 2021 09:15:23

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 16:05:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a19c168458d97dd9)', Time: '2020-09-29T10:59:51', User OID: 'PatientReportedOutcome (US3612005)', ODM File OID: '57b04d3d-62eb-4c28-beb7-b8cf2647aba1'	System	29 Sep 2020 16:00:05
User entered 'No (N)'	System	29 Sep 2020 16:00:05

**US3612005**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(1/1)**

**Generated On: 10 Jun 2021 09:15:23**

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:05:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a19c168458d97dd9)', Time: '2020-09-29T10:59:58', User OID: 'PatientReportedOutcome (US3612005)', ODM File OID: '57b04d3d-62eb-4c28-beb7-b8cf2647aba1'	System	29 Sep 2020 16:00:05
User entered '29 Sep 2020 10:59'	System	29 Sep 2020 16:00:05

**US3612005**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(1/1)**

**Generated On: 10 Jun 2021 09:15:23**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:05:06
User entered '29 Sep 2020 10:41'	System	29 Sep 2020 15:46:04

**US3612005**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(1/1)**

**Generated On: 10 Jun 2021 09:15:23**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:05:06
User entered '29 Sep 2020 13:11'	System	29 Sep 2020 15:46:04

US3612005

Folder: Diary Dose 2 (1)

Form: General\_Day(1/2)

Generated On: 10 Jun 2021 09:15:23

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:05:06
Data entry locked.	System	29 Sep 2020 15:46:04
User entered 'Day 1, after vaccination (at home)'	System	29 Sep 2020 15:46:04

US3612005

Folder: Diary Dose 2 (1)

Form: General\_Day(1/2)

Generated On: 10 Jun 2021 09:15:23

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:05:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a19c168458d97dd9)', Time: '2020-09-29T20:42:49', User OID: 'PatientReportedOutcome (US3612005)', ODM File OID: 'edb75287-83cb-4008-aa2e-ce9024035651' User entered 'None (0)'	System	30 Sep 2020 01:43:19
	System	30 Sep 2020 01:43:19

**US3612005**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(1/2)**

**Generated On: 10 Jun 2021 09:15:23**

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:05:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a19c168458d97dd9)', Time: '2020-09-29T20:42:53', User OID: 'PatientReportedOutcome (US3612005)', ODM File OID: 'edb75287-83cb-4008-aa2e-ce9024035651'	System	30 Sep 2020 01:43:19
User entered 'None (0)'	System	30 Sep 2020 01:43:19

US3612005

Folder: Diary Dose 2 (1)

Form: General\_Day(1/2)

Generated On: 10 Jun 2021 09:15:23

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:05:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a19c168458d97dd9)', Time: '2020-09-29T20:42:58', User OID: 'PatientReportedOutcome (US3612005)', ODM File OID: 'edb75287-83cb-4008-aa2e-ce9024035651'	System	30 Sep 2020 01:43:19
User entered 'None (0)'	System	30 Sep 2020 01:43:19

US3612005

Folder: Diary Dose 2 (1)

Form: General\_Day(1/2)

Generated On: 10 Jun 2021 09:15:23

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:05:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a19c168458d97dd9)', Time: '2020-09-29T20:43:01', User OID: 'PatientReportedOutcome (US3612005)', ODM File OID: 'edb75287-83cb-4008-aa2e-ce9024035651' User entered 'None (0)'	System	30 Sep 2020 01:43:19
	System	30 Sep 2020 01:43:19

**US3612005**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(1/2)**

**Generated On: 10 Jun 2021 09:15:23**

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:05:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a19c168458d97dd9)', Time: '2020-09-29T20:43:04', User OID: 'PatientReportedOutcome (US3612005)', ODM File OID: 'edb75287-83cb-4008-aa2e-ce9024035651'	System	30 Sep 2020 01:43:19
User entered 'None (0)'	System	30 Sep 2020 01:43:19

**US3612005**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(1/2)**

**Generated On: 10 Jun 2021 09:15:23**

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:05:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a19c168458d97dd9)', Time: '2020-09-29T20:43:07', User OID: 'PatientReportedOutcome (US3612005)', ODM File OID: 'edb75287-83cb-4008-aa2e-ce9024035651'	System	30 Sep 2020 01:43:19
User entered 'None (0)'	System	30 Sep 2020 01:43:19

US3612005

Folder: Diary Dose 2 (1)

Form: General\_Day(1/2)

Generated On: 10 Jun 2021 09:15:23

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 16:05:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a19c168458d97dd9)', Time: '2020-09-29T20:43:09', User OID: 'PatientReportedOutcome (US3612005)', ODM File OID: 'edb75287-83cb-4008-aa2e-ce9024035651'	System	30 Sep 2020 01:43:19
User entered 'No (N)'	System	30 Sep 2020 01:43:19

**US3612005**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(1/2)**

**Generated On: 10 Jun 2021 09:15:23**

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:05:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a19c168458d97dd9)', Time: '2020-09-29T20:43:14', User OID: 'PatientReportedOutcome (US3612005)', ODM File OID: 'edb75287-83cb-4008-aa2e-ce9024035651'	System	30 Sep 2020 01:43:19
User entered '29 Sep 2020 20:43'	System	30 Sep 2020 01:43:19

**US3612005**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(1/2)**

**Generated On: 10 Jun 2021 09:15:23**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:05:06
User entered '29 Sep 2020 14:06'	System	29 Sep 2020 15:46:04

**US3612005**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(1/2)**

**Generated On: 10 Jun 2021 09:15:23**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:05:06
User entered '30 Sep 2020 11:59'	System	29 Sep 2020 15:46:04

**US3612005**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(2)**

**Generated On: 10 Jun 2021 09:15:23**

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:05:06
Data entry locked.	System	29 Sep 2020 15:46:04
User entered 'Day 2'	System	29 Sep 2020 15:46:04

US3612005

Folder: Diary Dose 2 (1)

Form: General\_Day(2)

Generated On: 10 Jun 2021 09:15:23

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:05:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a19c168458d97dd9)', Time: '2020-09-30T14:13:32', User OID: 'PatientReportedOutcome (US3612005)', ODM File OID: 'b01913b2-ebfc-4892-a475-14afb6f6cebd'	System	30 Sep 2020 19:14:00
User entered 'None (0)'	System	30 Sep 2020 19:14:00

**US3612005**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(2)**

**Generated On: 10 Jun 2021 09:15:23**

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:05:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a19c168458d97dd9)', Time: '2020-09-30T14:13:35', User OID: 'PatientReportedOutcome (US3612005)', ODM File OID: 'b01913b2-ebfc-4892-a475-14afb6f6cebd'	System	30 Sep 2020 19:14:00
User entered 'None (0)'	System	30 Sep 2020 19:14:00

US3612005

Folder: Diary Dose 2 (1)

Form: General\_Day(2)

Generated On: 10 Jun 2021 09:15:23

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:05:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a19c168458d97dd9)', Time: '2020-09-30T14:13:38', User OID: 'PatientReportedOutcome (US3612005)', ODM File OID: 'b01913b2-ebfc-4892-a475-14afb6f6cebd'	System	30 Sep 2020 19:14:00
User entered 'None (0)'	System	30 Sep 2020 19:14:00

US3612005

Folder: Diary Dose 2 (1)

Form: General\_Day(2)

Generated On: 10 Jun 2021 09:15:23

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:05:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a19c168458d97dd9)', Time: '2020-09-30T14:13:41', User OID: 'PatientReportedOutcome (US3612005)', ODM File OID: 'b01913b2-ebfc-4892-a475-14afb6f6cebd'	System	30 Sep 2020 19:14:00
User entered 'None (0)'	System	30 Sep 2020 19:14:00

**US3612005**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(2)**

**Generated On: 10 Jun 2021 09:15:23**

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:05:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a19c168458d97dd9)', Time: '2020-09-30T14:13:44', User OID: 'PatientReportedOutcome (US3612005)', ODM File OID: 'b01913b2-ebfc-4892-a475-14afb6f6cebd'	System	30 Sep 2020 19:14:00
User entered 'None (0)'	System	30 Sep 2020 19:14:00

**US3612005**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(2)**

**Generated On: 10 Jun 2021 09:15:23**

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:05:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a19c168458d97dd9)', Time: '2020-09-30T14:13:46', User OID: 'PatientReportedOutcome (US3612005)', ODM File OID: 'b01913b2-ebfc-4892-a475-14afb6f6cebd'	System	30 Sep 2020 19:14:00
User entered 'None (0)'	System	30 Sep 2020 19:14:00

US3612005

Folder: Diary Dose 2 (1)

Form: General\_Day(2)

Generated On: 10 Jun 2021 09:15:23

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 16:05:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a19c168458d97dd9)', Time: '2020-09-30T14:13:50', User OID: 'PatientReportedOutcome (US3612005)', ODM File OID: 'b01913b2-ebfc-4892-a475-14afb6f6cebd'	System	30 Sep 2020 19:14:00
User entered 'No (N)'	System	30 Sep 2020 19:14:00

**US3612005**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(2)**

**Generated On: 10 Jun 2021 09:15:23**

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:05:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a19c168458d97dd9)', Time: '2020-09-30T14:13:56', User OID: 'PatientReportedOutcome (US3612005)', ODM File OID: 'b01913b2-ebfc-4892-a475-14afb6f6cebd'	System	30 Sep 2020 19:14:00
User entered '30 Sep 2020 14:13'	System	30 Sep 2020 19:14:00

**US3612005**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(2)**

**Generated On: 10 Jun 2021 09:15:23**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:05:06
User entered '30 Sep 2020 12:00'	System	29 Sep 2020 15:46:04

**US3612005**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(2)**

**Generated On: 10 Jun 2021 09:15:23**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:05:06
User entered '01 Oct 2020 11:59'	System	29 Sep 2020 15:46:04

**US3612005**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(3)**

**Generated On: 10 Jun 2021 09:15:23**

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:05:06
Data entry locked.	System	29 Sep 2020 15:46:04
User entered 'Day 3'	System	29 Sep 2020 15:46:04

US3612005

Folder: Diary Dose 2 (1)

Form: General\_Day(3)

Generated On: 10 Jun 2021 09:15:23

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:05:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a19c168458d97dd9)', Time: '2020-10-01T17:51:53', User OID: 'PatientReportedOutcome (US3612005)', ODM File OID: '62d83e7b-f009-4e36-b902-9f4ffdd8c489'	System	01 Oct 2020 22:52:20
User entered 'None (0)'	System	01 Oct 2020 22:52:20

**US3612005**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(3)**

**Generated On: 10 Jun 2021 09:15:23**

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:05:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a19c168458d97dd9)', Time: '2020-10-01T17:51:55', User OID: 'PatientReportedOutcome (US3612005)', ODM File OID: '62d83e7b-f009-4e36-b902-9f4ffdd8c489'	System	01 Oct 2020 22:52:20
User entered 'None (0)'	System	01 Oct 2020 22:52:20

US3612005

Folder: Diary Dose 2 (1)

Form: General\_Day(3)

Generated On: 10 Jun 2021 09:15:23

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:05:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a19c168458d97dd9)', Time: '2020-10-01T17:51:58', User OID: 'PatientReportedOutcome (US3612005)', ODM File OID: '62d83e7b-f009-4e36-b902-9f4ffdd8c489'	System	01 Oct 2020 22:52:20
User entered 'None (0)'	System	01 Oct 2020 22:52:20

**US3612005**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(3)**

**Generated On: 10 Jun 2021 09:15:23**

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:05:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a19c168458d97dd9)', Time: '2020-10-01T17:52:01', User OID: 'PatientReportedOutcome (US3612005)', ODM File OID: '62d83e7b-f009-4e36-b902-9f4ffdd8c489'	System	01 Oct 2020 22:52:20
User entered 'None (0)'	System	01 Oct 2020 22:52:20

**US3612005**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(3)**

**Generated On: 10 Jun 2021 09:15:23**

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:05:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a19c168458d97dd9)', Time: '2020-10-01T17:52:03', User OID: 'PatientReportedOutcome (US3612005)', ODM File OID: '62d83e7b-f009-4e36-b902-9f4ffdd8c489'	System	01 Oct 2020 22:52:20
User entered 'None (0)'	System	01 Oct 2020 22:52:20

**US3612005**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(3)**

**Generated On: 10 Jun 2021 09:15:23**

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:05:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a19c168458d97dd9)', Time: '2020-10-01T17:52:05', User OID: 'PatientReportedOutcome (US3612005)', ODM File OID: '62d83e7b-f009-4e36-b902-9f4ffdd8c489'	System	01 Oct 2020 22:52:20
User entered 'None (0)'	System	01 Oct 2020 22:52:20

US3612005

Folder: Diary Dose 2 (1)

Form: General\_Day(3)

Generated On: 10 Jun 2021 09:15:23

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 16:05:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a19c168458d97dd9)', Time: '2020-10-01T17:52:09', User OID: 'PatientReportedOutcome (US3612005)', ODM File OID: '62d83e7b-f009-4e36-b902-9f4ffdd8c489'	System	01 Oct 2020 22:52:20
User entered 'No (N)'	System	01 Oct 2020 22:52:20

**US3612005**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(3)**

**Generated On: 10 Jun 2021 09:15:23**

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:05:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a19c168458d97dd9)', Time: '2020-10-01T17:52:17', User OID: 'PatientReportedOutcome (US3612005)', ODM File OID: '62d83e7b-f009-4e36-b902-9f4ffdd8c489'	System	01 Oct 2020 22:52:20
User entered '01 Oct 2020 17:52'	System	01 Oct 2020 22:52:20

**US3612005**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(3)**

**Generated On: 10 Jun 2021 09:15:23**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:05:06
User entered '01 Oct 2020 12:00'	System	29 Sep 2020 15:46:04

**US3612005**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(3)**

**Generated On: 10 Jun 2021 09:15:23**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:05:06
User entered '02 Oct 2020 11:59'	System	29 Sep 2020 15:46:04

**US3612005**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(4)**

**Generated On: 10 Jun 2021 09:15:23**

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:05:06
Data entry locked.	System	29 Sep 2020 15:46:04
User entered 'Day 4'	System	29 Sep 2020 15:46:04

**US3612005**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(4)**

**Generated On: 10 Jun 2021 09:15:23**

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:05:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a19c168458d97dd9)', Time: '2020-10-02T14:51:25', User OID: 'PatientReportedOutcome (US3612005)', ODM File OID: '2eda81e3-1485-436d-b29f-2b88b90b18db'	System	02 Oct 2020 19:51:55
User entered 'None (0)'	System	02 Oct 2020 19:51:55

**US3612005**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(4)**

**Generated On: 10 Jun 2021 09:15:23**

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:05:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a19c168458d97dd9)', Time: '2020-10-02T14:51:28', User OID: 'PatientReportedOutcome (US3612005)', ODM File OID: '2eda81e3-1485-436d-b29f-2b88b90b18db'	System	02 Oct 2020 19:51:55
User entered 'None (0)'	System	02 Oct 2020 19:51:55

US3612005

Folder: Diary Dose 2 (1)

Form: General\_Day(4)

Generated On: 10 Jun 2021 09:15:23

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:05:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a19c168458d97dd9)', Time: '2020-10-02T14:51:31', User OID: 'PatientReportedOutcome (US3612005)', ODM File OID: '2eda81e3-1485-436d-b29f-2b88b90b18db' User entered 'None (0)'	System	02 Oct 2020 19:51:55
	System	02 Oct 2020 19:51:55

US3612005

Folder: Diary Dose 2 (1)

Form: General\_Day(4)

Generated On: 10 Jun 2021 09:15:23

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:05:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a19c168458d97dd9)', Time: '2020-10-02T14:51:34', User OID: 'PatientReportedOutcome (US3612005)', ODM File OID: '2eda81e3-1485-436d-b29f-2b88b90b18db'	System	02 Oct 2020 19:51:55
User entered 'None (0)'	System	02 Oct 2020 19:51:55

**US3612005**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(4)**

**Generated On: 10 Jun 2021 09:15:23**

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:05:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a19c168458d97dd9)', Time: '2020-10-02T14:51:37', User OID: 'PatientReportedOutcome (US3612005)', ODM File OID: '2eda81e3-1485-436d-b29f-2b88b90b18db'	System	02 Oct 2020 19:51:55
User entered 'None (0)'	System	02 Oct 2020 19:51:55

**US3612005**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(4)**

**Generated On: 10 Jun 2021 09:15:23**

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:05:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a19c168458d97dd9)', Time: '2020-10-02T14:51:39', User OID: 'PatientReportedOutcome (US3612005)', ODM File OID: '2eda81e3-1485-436d-b29f-2b88b90b18db'	System	02 Oct 2020 19:51:55
User entered 'None (0)'	System	02 Oct 2020 19:51:55

US3612005

Folder: Diary Dose 2 (1)

Form: General\_Day(4)

Generated On: 10 Jun 2021 09:15:23

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 16:05:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a19c168458d97dd9)', Time: '2020-10-02T14:51:43', User OID: 'PatientReportedOutcome (US3612005)', ODM File OID: '2eda81e3-1485-436d-b29f-2b88b90b18db'	System	02 Oct 2020 19:51:55
User entered 'No (N)'	System	02 Oct 2020 19:51:55

**US3612005**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(4)**

**Generated On: 10 Jun 2021 09:15:23**

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:05:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a19c168458d97dd9)', Time: '2020-10-02T14:51:51', User OID: 'PatientReportedOutcome (US3612005)', ODM File OID: '2eda81e3-1485-436d-b29f-2b88b90b18db'	System	02 Oct 2020 19:51:55
User entered '02 Oct 2020 14:51'	System	02 Oct 2020 19:51:55

**US3612005**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(4)**

**Generated On: 10 Jun 2021 09:15:23**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:05:06
User entered '02 Oct 2020 12:00'	System	29 Sep 2020 15:46:04

**US3612005**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(4)**

**Generated On: 10 Jun 2021 09:15:23**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:05:06
User entered '03 Oct 2020 11:59'	System	29 Sep 2020 15:46:04

US3612005

Folder: Diary Dose 2 (1)

Form: General\_Day(5)

Generated On: 10 Jun 2021 09:15:23

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:05:06
Data entry locked.	System	29 Sep 2020 15:46:04
User entered 'Day 5'	System	29 Sep 2020 15:46:04

**US3612005**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(5)**

**Generated On: 10 Jun 2021 09:15:23**

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:05:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a19c168458d97dd9)', Time: '2020-10-03T14:49:16', User OID: 'PatientReportedOutcome (US3612005)', ODM File OID: '86097f8e-2580-4b9b-87a8-0889dc96db53'	System	03 Oct 2020 19:49:54
User entered 'None (0)'	System	03 Oct 2020 19:49:54

**US3612005**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(5)**

**Generated On: 10 Jun 2021 09:15:23**

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:05:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a19c168458d97dd9)', Time: '2020-10-03T14:49:18', User OID: 'PatientReportedOutcome (US3612005)', ODM File OID: '86097f8e-2580-4b9b-87a8-0889dc96db53'	System	03 Oct 2020 19:49:54
User entered 'None (0)'	System	03 Oct 2020 19:49:54

US3612005

Folder: Diary Dose 2 (1)

Form: General\_Day(5)

Generated On: 10 Jun 2021 09:15:23

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:05:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a19c168458d97dd9)', Time: '2020-10-03T14:49:21', User OID: 'PatientReportedOutcome (US3612005)', ODM File OID: '86097f8e-2580-4b9b-87a8-0889dc96db53'	System	03 Oct 2020 19:49:54
User entered 'None (0)'	System	03 Oct 2020 19:49:54

US3612005

Folder: Diary Dose 2 (1)

Form: General\_Day(5)

Generated On: 10 Jun 2021 09:15:23

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:05:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a19c168458d97dd9)', Time: '2020-10-03T14:49:23', User OID: 'PatientReportedOutcome (US3612005)', ODM File OID: '86097f8e-2580-4b9b-87a8-0889dc96db53'	System	03 Oct 2020 19:49:54
User entered 'None (0)'	System	03 Oct 2020 19:49:54

**US3612005**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(5)**

**Generated On: 10 Jun 2021 09:15:23**

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:05:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a19c168458d97dd9)', Time: '2020-10-03T14:49:27', User OID: 'PatientReportedOutcome (US3612005)', ODM File OID: '86097f8e-2580-4b9b-87a8-0889dc96db53'	System	03 Oct 2020 19:49:54
User entered 'None (0)'	System	03 Oct 2020 19:49:54

**US3612005**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(5)**

**Generated On: 10 Jun 2021 09:15:23**

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:05:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a19c168458d97dd9)', Time: '2020-10-03T14:49:34', User OID: 'PatientReportedOutcome (US3612005)', ODM File OID: '86097f8e-2580-4b9b-87a8-0889dc96db53'	System	03 Oct 2020 19:49:54
User entered 'None (0)'	System	03 Oct 2020 19:49:54

US3612005

Folder: Diary Dose 2 (1)

Form: General\_Day(5)

Generated On: 10 Jun 2021 09:15:23

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 16:05:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a19c168458d97dd9)', Time: '2020-10-03T14:49:38', User OID: 'PatientReportedOutcome (US3612005)', ODM File OID: '86097f8e-2580-4b9b-87a8-0889dc96db53'	System	03 Oct 2020 19:49:54
User entered 'No (N)'	System	03 Oct 2020 19:49:54

**US3612005**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(5)**

**Generated On: 10 Jun 2021 09:15:23**

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:05:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a19c168458d97dd9)', Time: '2020-10-03T14:49:51', User OID: 'PatientReportedOutcome (US3612005)', ODM File OID: '86097f8e-2580-4b9b-87a8-0889dc96db53'	System	03 Oct 2020 19:49:54
User entered '03 Oct 2020 14:49'	System	03 Oct 2020 19:49:54

**US3612005**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(5)**

**Generated On: 10 Jun 2021 09:15:23**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:05:06
User entered '03 Oct 2020 12:00'	System	29 Sep 2020 15:46:04

**US3612005**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(5)**

**Generated On: 10 Jun 2021 09:15:23**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:05:06
User entered '04 Oct 2020 11:59'	System	29 Sep 2020 15:46:04

**US3612005**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(6)**

**Generated On: 10 Jun 2021 09:15:23**

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:05:06
Data entry locked.	System	29 Sep 2020 15:46:04
User entered 'Day 6'	System	29 Sep 2020 15:46:04

**US3612005**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(6)**

**Generated On: 10 Jun 2021 09:15:23**

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:05:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a19c168458d97dd9)', Time: '2020-10-04T21:02:00', User OID: 'PatientReportedOutcome (US3612005)', ODM File OID: '1f028bc1-18a2-4989-9f85-01546eb7cdd7'	System	05 Oct 2020 02:02:37
User entered 'None (0)'	System	05 Oct 2020 02:02:37

**US3612005**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(6)**

**Generated On: 10 Jun 2021 09:15:23**

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:05:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a19c168458d97dd9)', Time: '2020-10-04T21:02:03', User OID: 'PatientReportedOutcome (US3612005)', ODM File OID: '1f028bc1-18a2-4989-9f85-01546eb7cdd7'	System	05 Oct 2020 02:02:37
User entered 'None (0)'	System	05 Oct 2020 02:02:37

US3612005

Folder: Diary Dose 2 (1)

Form: General\_Day(6)

Generated On: 10 Jun 2021 09:15:23

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:05:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a19c168458d97dd9)', Time: '2020-10-04T21:02:06', User OID: 'PatientReportedOutcome (US3612005)', ODM File OID: '1f028bc1-18a2-4989-9f85-01546eb7cdd7'	System	05 Oct 2020 02:02:37
User entered 'None (0)'	System	05 Oct 2020 02:02:37

US3612005

Folder: Diary Dose 2 (1)

Form: General\_Day(6)

Generated On: 10 Jun 2021 09:15:23

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:05:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a19c168458d97dd9)', Time: '2020-10-04T21:02:13', User OID: 'PatientReportedOutcome (US3612005)', ODM File OID: '1f028bc1-18a2-4989-9f85-01546eb7cdd7'	System	05 Oct 2020 02:02:37
User entered 'None (0)'	System	05 Oct 2020 02:02:37

**US3612005**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(6)**

**Generated On: 10 Jun 2021 09:15:23**

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:05:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a19c168458d97dd9)', Time: '2020-10-04T21:02:17', User OID: 'PatientReportedOutcome (US3612005)', ODM File OID: '1f028bc1-18a2-4989-9f85-01546eb7cdd7'	System	05 Oct 2020 02:02:37
User entered 'None (0)'	System	05 Oct 2020 02:02:37

**US3612005**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(6)**

**Generated On: 10 Jun 2021 09:15:23**

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:05:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a19c168458d97dd9)', Time: '2020-10-04T21:02:20', User OID: 'PatientReportedOutcome (US3612005)', ODM File OID: '1f028bc1-18a2-4989-9f85-01546eb7cdd7'	System	05 Oct 2020 02:02:37
User entered 'None (0)'	System	05 Oct 2020 02:02:37

US3612005

Folder: Diary Dose 2 (1)

Form: General\_Day(6)

Generated On: 10 Jun 2021 09:15:23

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 16:05:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a19c168458d97dd9)', Time: '2020-10-04T21:02:24', User OID: 'PatientReportedOutcome (US3612005)', ODM File OID: '1f028bc1-18a2-4989-9f85-01546eb7cdd7'	System	05 Oct 2020 02:02:37
User entered 'No (N)'	System	05 Oct 2020 02:02:37

**US3612005**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(6)**

**Generated On: 10 Jun 2021 09:15:23**

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:05:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a19c168458d97dd9)', Time: '2020-10-04T21:02:33', User OID: 'PatientReportedOutcome (US3612005)', ODM File OID: '1f028bc1-18a2-4989-9f85-01546eb7cdd7'	System	05 Oct 2020 02:02:37
User entered '04 Oct 2020 21:02'	System	05 Oct 2020 02:02:37

**US3612005**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(6)**

**Generated On: 10 Jun 2021 09:15:23**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:05:06
User entered '04 Oct 2020 12:00'	System	29 Sep 2020 15:46:04

**US3612005**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(6)**

**Generated On: 10 Jun 2021 09:15:23**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:05:06
User entered '05 Oct 2020 11:59'	System	29 Sep 2020 15:46:04

**US3612005**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(7)**

**Generated On: 10 Jun 2021 09:15:23**

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:05:06
Data entry locked.	System	29 Sep 2020 15:46:04
User entered 'Day 7'	System	29 Sep 2020 15:46:04

**US3612005**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(7)**

**Generated On: 10 Jun 2021 09:15:23**

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:05:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a19c168458d97dd9)', Time: '2020-10-05T14:34:29', User OID: 'PatientReportedOutcome (US3612005)', ODM File OID: '6f8f64a7-bf48-4b87-980d-44e6781a5c96'	System	05 Oct 2020 19:34:59
User entered 'None (0)'	System	05 Oct 2020 19:34:59

**US3612005**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(7)**

**Generated On: 10 Jun 2021 09:15:23**

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:05:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a19c168458d97dd9)', Time: '2020-10-05T14:34:32', User OID: 'PatientReportedOutcome (US3612005)', ODM File OID: '6f8f64a7-bf48-4b87-980d-44e6781a5c96'	System	05 Oct 2020 19:34:59
User entered 'None (0)'	System	05 Oct 2020 19:34:59

US3612005

Folder: Diary Dose 2 (1)

Form: General\_Day(7)

Generated On: 10 Jun 2021 09:15:23

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:05:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a19c168458d97dd9)', Time: '2020-10-05T14:34:35', User OID: 'PatientReportedOutcome (US3612005)', ODM File OID: '6f8f64a7-bf48-4b87-980d-44e6781a5c96'	System	05 Oct 2020 19:34:59
User entered 'None (0)'	System	05 Oct 2020 19:34:59

US3612005

Folder: Diary Dose 2 (1)

Form: General\_Day(7)

Generated On: 10 Jun 2021 09:15:23

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:05:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a19c168458d97dd9)', Time: '2020-10-05T14:34:39', User OID: 'PatientReportedOutcome (US3612005)', ODM File OID: '6f8f64a7-bf48-4b87-980d-44e6781a5c96'	System	05 Oct 2020 19:34:59
User entered 'None (0)'	System	05 Oct 2020 19:34:59

**US3612005**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(7)**

**Generated On: 10 Jun 2021 09:15:23**

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:05:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a19c168458d97dd9)', Time: '2020-10-05T14:34:41', User OID: 'PatientReportedOutcome (US3612005)', ODM File OID: '6f8f64a7-bf48-4b87-980d-44e6781a5c96'	System	05 Oct 2020 19:34:59
User entered 'None (0)'	System	05 Oct 2020 19:34:59

**US3612005**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(7)**

**Generated On: 10 Jun 2021 09:15:23**

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:05:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a19c168458d97dd9)', Time: '2020-10-05T14:34:44', User OID: 'PatientReportedOutcome (US3612005)', ODM File OID: '6f8f64a7-bf48-4b87-980d-44e6781a5c96'	System	05 Oct 2020 19:34:59
User entered 'None (0)'	System	05 Oct 2020 19:34:59

US3612005

Folder: Diary Dose 2 (1)

Form: General\_Day(7)

Generated On: 10 Jun 2021 09:15:23

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 16:05:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a19c168458d97dd9)', Time: '2020-10-05T14:34:49', User OID: 'PatientReportedOutcome (US3612005)', ODM File OID: '6f8f64a7-bf48-4b87-980d-44e6781a5c96'	System	05 Oct 2020 19:34:59
User entered 'No (N)'	System	05 Oct 2020 19:34:59

**US3612005**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(7)**

**Generated On: 10 Jun 2021 09:15:23**

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:05:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a19c168458d97dd9)', Time: '2020-10-05T14:34:57', User OID: 'PatientReportedOutcome (US3612005)', ODM File OID: '6f8f64a7-bf48-4b87-980d-44e6781a5c96'	System	05 Oct 2020 19:34:59
User entered '05 Oct 2020 14:34'	System	05 Oct 2020 19:34:59

**US3612005**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(7)**

**Generated On: 10 Jun 2021 09:15:23**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:05:06
User entered '05 Oct 2020 12:00'	System	29 Sep 2020 15:46:04

**US3612005**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(7)**

**Generated On: 10 Jun 2021 09:15:23**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:05:06
User entered '06 Oct 2020 11:59'	System	29 Sep 2020 15:46:04

**US3612005**

**Folder: Safety Call Day 36 (1)**

**Form: Safety Call**

**Generated On: 10 Jun 2021 09:15:23**

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 22:42:32
User signature succeeded.	Richard Rupp (b) (4)	05 Mar 2021 19:39:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Oct 2020 15:55:43
User entered 'Yes (Y)'	Amber Stanford (b) (4) (b) (4)	07 Oct 2020 14:46:19

**US3612005**

**Folder: Safety Call Day 36 (1)**

**Form: Safety Call**

**Generated On: 10 Jun 2021 09:15:23**

[Date of Contact or Contact Attempt \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 22:42:32
User signature succeeded.	Richard Rupp (b) (4)	05 Mar 2021 19:39:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Oct 2020 15:55:43
User entered '07 Oct 2020'	Amber Stanford (b) (4) (b) (4)	07 Oct 2020 14:46:19

**US3612005**

**Folder: Safety Call Day 36 (1)**

**Form: Safety Call**

**Generated On: 10 Jun 2021 09:15:23**

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 22:42:32
User signature succeeded.	Richard Rupp (b) (4)	05 Mar 2021 19:39:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Oct 2020 15:55:43
User entered 'Contact Made (CONTACT MADE)'	Amber Stanford (b) (4) (b) (4)	07 Oct 2020 14:46:19

**US3612005**

**Folder: Safety Call Day 36 (1)**

**Form: Safety Call**

**Generated On: 10 Jun 2021 09:15:23**

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 22:42:32
User signature succeeded.	Richard Rupp (b) (4)	05 Mar 2021 19:39:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Oct 2020 15:55:43
User entered empty.	Amber Stanford (b) (4) (b) (4)	07 Oct 2020 14:46:19

US3612005

Folder: Safety Call Day 36 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:15:23

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 22:42:32
User signature succeeded.	Richard Rupp (b) (4)	05 Mar 2021 19:39:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Oct 2020 15:55:53
User entered 'Yes (Y)'	Amber Stanford (b) (4) (b) (4)	07 Oct 2020 14:46:26

**US3612005**

**Folder: Safety Call Day 36 (1)**

**Form: Continuing**

**Generated On: 10 Jun 2021 09:15:23**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 22:42:32
User entered 'I'	System	07 Oct 2020 14:46:26

**US3612005**

**Folder: Safety Call Day 43 (1)**

**Form: Safety Call**

**Generated On: 10 Jun 2021 09:15:23**

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 22:42:32
User signature succeeded.	Richard Rupp (b) (4)	05 Mar 2021 19:39:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Oct 2020 15:56:23
User entered 'Yes (Y)'	Amber Stanford (b) (4) (b) (4)	13 Oct 2020 19:14:58

**US3612005**

**Folder: Safety Call Day 43 (1)**

**Form: Safety Call**

**Generated On: 10 Jun 2021 09:15:23**

[Date of Contact or Contact Attempt \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 22:42:32
User signature succeeded.	Richard Rupp (b) (4)	05 Mar 2021 19:39:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Oct 2020 15:56:23
User entered '13 Oct 2020'	Amber Stanford (b) (4) (b) (4)	13 Oct 2020 19:14:58

**US3612005**

**Folder: Safety Call Day 43 (1)**

**Form: Safety Call**

**Generated On: 10 Jun 2021 09:15:23**

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 22:42:32
User signature succeeded.	Richard Rupp (b) (4)	05 Mar 2021 19:39:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Oct 2020 15:56:23
User entered 'Contact Made (CONTACT MADE)'	Amber Stanford (b) (4) (b) (4)	13 Oct 2020 19:14:58

**US3612005**

**Folder: Safety Call Day 43 (1)**

**Form: Safety Call**

**Generated On: 10 Jun 2021 09:15:23**

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 22:42:32
User signature succeeded.	Richard Rupp (b) (4)	05 Mar 2021 19:39:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Oct 2020 15:56:23
User entered empty.	Amber Stanford (b) (4) (b) (4)	13 Oct 2020 19:14:58

US3612005

Folder: Safety Call Day 43 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:15:23

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 22:42:32
User signature succeeded.	Richard Rupp (b) (4)	05 Mar 2021 19:39:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Oct 2020 15:56:32
User entered 'Yes (Y)'	Amber Stanford (b) (4) (b) (4)	13 Oct 2020 19:15:04

**US3612005**

**Folder: Safety Call Day 43 (1)**

**Form: Continuing**

**Generated On: 10 Jun 2021 09:15:23**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 22:42:32
User entered 'I'	System	13 Oct 2020 19:15:04

**US3612005**

**Folder: Safety Call Day 50 (1)**

**Form: Safety Call**

**Generated On: 10 Jun 2021 09:15:23**

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 22:42:32
User signature succeeded.	Richard Rupp (b) (4)	05 Mar 2021 19:39:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Nov 2020 16:54:05
User entered 'Yes (Y)'	Kristin Pollock (b) (4) (b) (4)	22 Oct 2020 15:30:06

**US3612005**

**Folder: Safety Call Day 50 (1)**

**Form: Safety Call**

**Generated On: 10 Jun 2021 09:15:23**

[Date of Contact or Contact Attempt \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 22:42:32
User signature succeeded.	Richard Rupp (b) (4)	05 Mar 2021 19:39:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Nov 2020 16:54:05
User entered '22 Oct 2020'	Kristin Pollock (b) (4) (b) (4)	22 Oct 2020 15:30:06

**US3612005**

**Folder: Safety Call Day 50 (1)**

**Form: Safety Call**

**Generated On: 10 Jun 2021 09:15:23**

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 22:42:32
User signature succeeded.	Richard Rupp (b) (4)	05 Mar 2021 19:39:45
DataPoint Verified.	(b) (4)	03 Nov 2020 16:54:05
User entered 'Contact Made (CONTACT MADE)'	Kristin Pollock (b) (4)	22 Oct 2020 15:30:06

**US3612005**

**Folder: Safety Call Day 50 (1)**

**Form: Safety Call**

**Generated On: 10 Jun 2021 09:15:23**

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 22:42:32
User signature succeeded.	Richard Rupp (b) (4)	05 Mar 2021 19:39:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Nov 2020 16:54:05
User entered empty.	Kristin Pollock (b) (4) (b) (4)	22 Oct 2020 15:30:06

US3612005

Folder: Safety Call Day 50 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:15:23

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 22:42:32
User signature succeeded.	Richard Rupp (b) (4)	05 Mar 2021 19:39:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Nov 2020 16:54:31
User entered 'Yes (Y)'	Kristin Pollock (b) (4) (b) (4)	22 Oct 2020 15:30:12

**US3612005**

**Folder: Safety Call Day 50 (1)**

**Form: Continuing**

**Generated On: 10 Jun 2021 09:15:23**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 22:42:32
User entered 'I'	System	22 Oct 2020 15:30:12

**US3612005**

**Folder: Visit 3 Day 57 (1)**

**Form: Visit Date**

**Generated On: 10 Jun 2021 09:15:23**

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 22:42:32
User signature succeeded.	Richard Rupp (b) (4)	05 Mar 2021 19:39:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 16:15:53
User entered 'Yes (Y)'	Kristin Pollock (b) (4) (b) (4)	27 Oct 2020 17:24:28

**US3612005**

**Folder: Visit 3 Day 57 (1)**

**Form: Visit Date**

**Generated On: 10 Jun 2021 09:15:23**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 22:42:32
User signature succeeded.	Richard Rupp (b) (4)	05 Mar 2021 19:39:45
DataPoint Verified.	(b) (4)	17 Nov 2020 16:15:53
User entered '27 Oct 2020'	Kristin Pollock (b) (4)	27 Oct 2020 17:24:28

**US3612005**

**Folder: Visit 3 Day 57 (1)**

**Form: Visit Date**

**Generated On: 10 Jun 2021 09:15:23**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 22:42:32
User signature succeeded.	Richard Rupp (b) (4)	05 Mar 2021 19:39:45
DataPoint Verified.	(b) (4)	17 Nov 2020 16:15:53
User entered 'Clinic (Clinic)'	Kristin Pollock (b) (4)	27 Oct 2020 17:24:28

**US3612005**

**Folder: Visit 3 Day 57 (1)**

**Form: Visit Date**

**Generated On: 10 Jun 2021 09:15:23**

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 22:42:32
User entered 'VISIT3'	System	27 Oct 2020 17:24:28

US3612005

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:15:23

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 22:42:32
User signature succeeded.	Richard Rupp (b) (4)	05 Mar 2021 19:39:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 16:16:12
User entered 'Yes (Y)'	Kristin Pollock (b) (4) (b) (4)	27 Oct 2020 17:25:01

**US3612005**

**Folder: Visit 3 Day 57 (1)**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 09:15:23**

**Date of assessment** (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 22:42:32
User signature succeeded.	Richard Rupp (b) (4)	05 Mar 2021 19:39:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 16:16:12
User entered '27 Oct 2020'	Kristin Pollock (b) (4) (b) (4)	27 Oct 2020 17:25:01

**US3612005**

**Folder: Visit 3 Day 57 (1)**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 09:15:23**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 22:42:32
User signature succeeded.	Richard Rupp (b) (4)	05 Mar 2021 19:39:45
DataPoint Verified.	(b) (4)	17 Nov 2020 16:16:12
User entered '11:33'	Kristin Pollock (b) (4)	27 Oct 2020 17:25:01

**US3612005**

**Folder: Visit 3 Day 57 (1)**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 09:15:23**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 22:42:32
User entered '27 Oct 2020 11:33'	System	27 Oct 2020 17:25:01

US3612005

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:15:23

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 22:42:32
User signature succeeded.	Richard Rupp (b) (4)	05 Mar 2021 19:39:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 16:16:12
User closed query 'Data entered is non-conformant. Please correct.' (Site from System).	System	27 Oct 2020 17:25:07
User entered '97.7' F reason for change: Data Entry Error	Kristin Pollock (b) (4) (b) (4)	27 Oct 2020 17:25:07
User opened query 'Data entered is non-conformant. Please correct.' (Site from System).	System	27 Oct 2020 17:25:01
User entered '97.7' (non-conformant).	Kristin Pollock (b) (4) (b) (4)	27 Oct 2020 17:25:01

US3612005

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:15:23

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 22:42:32
User signature succeeded.	Richard Rupp (b) (4)	05 Mar 2021 19:39:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 16:16:12
User entered 'Oral (Oral)'	Kristin Pollock (b) (4) (b) (4)	27 Oct 2020 17:25:01

US3612005

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:15:23

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 22:42:32
User signature succeeded.	Richard Rupp (b) (4)	05 Mar 2021 19:39:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 16:16:12
User entered empty.	Kristin Pollock (b) (4) (b) (4)	27 Oct 2020 17:25:01

US3612005

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:15:23

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 22:42:32
User signature succeeded.	Richard Rupp (b) (4)	05 Mar 2021 19:39:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 16:16:12
User entered '52'	Kristin Pollock (b) (4) (b) (4)	27 Oct 2020 17:25:01

**US3612005**

**Folder: Visit 3 Day 57 (1)**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 09:15:23**

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 22:42:32
User entered 'bpm'	System	27 Oct 2020 17:25:01

US3612005

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:15:23

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 22:42:32
User signature succeeded.	Richard Rupp (b) (4)	05 Mar 2021 19:39:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 16:16:12
User entered '16'	Kristin Pollock (b) (4) (b) (4)	27 Oct 2020 17:25:01

**US3612005**

**Folder: Visit 3 Day 57 (1)**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 09:15:23**

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 22:42:32
User entered 'breaths/min'	System	27 Oct 2020 17:25:01

US3612005

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:15:23

[Systolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 22:42:32
User signature succeeded.	Richard Rupp (b) (4)	05 Mar 2021 19:39:45
DataPoint Verified.	(b) (4)	17 Nov 2020 16:16:12
User entered '145'	Kristin Pollock (b) (4)	27 Oct 2020 17:25:01

**US3612005**

**Folder: Visit 3 Day 57 (1)**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 09:15:23**

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 22:42:32
User entered 'mmHg'	System	27 Oct 2020 17:25:01

US3612005

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:15:23

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 22:42:32
User signature succeeded.	Richard Rupp (b) (4)	05 Mar 2021 19:39:45
DataPoint Verified.	(b) (4)	17 Nov 2020 16:16:12
User entered '64'	Kristin Pollock (b) (4)	27 Oct 2020 17:25:01

**US3612005**

**Folder: Visit 3 Day 57 (1)**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 09:15:23**

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 22:42:32
User entered 'mmHg'	System	27 Oct 2020 17:25:01

**US3612005**

**Folder: Visit 3 Day 57 (1)**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 09:15:23**

[Height \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 22:42:32

**US3612005**

**Folder: Visit 3 Day 57 (1)**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 09:15:23**

[Weight \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 22:42:32

US3612005

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Generated On: 10 Jun 2021 09:15:23

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 22:42:32
User signature succeeded.	Richard Rupp (b) (4)	05 Mar 2021 19:39:45
DataPoint Verified.	(b) (4)	17 Nov 2020 16:16:26
User entered 'Yes (Y)'	Kristin Pollock (b) (4)	27 Oct 2020 17:25:16

US3612005

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Generated On: 10 Jun 2021 09:15:23

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 22:42:32
User signature succeeded.	Richard Rupp (b) (4)	05 Mar 2021 19:39:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 16:16:26
User closed query 'Was the physical examination performed is Yes, however Date of examination is missing. Please provide.' (Site from System).	System	27 Oct 2020 20:09:16
User entered '27 Oct 2020' reason for change: Data Entry Error	Kristin Pollock (b) (4) (b) (4)	27 Oct 2020 20:09:16
User opened query 'Was the physical examination performed is Yes, however Date of examination is missing. Please provide.' (Site from System).	System	27 Oct 2020 17:25:16
User entered empty.	Kristin Pollock (b) (4) (b) (4)	27 Oct 2020 17:25:16

**US3612005**

**Folder: Visit 3 Day 57 (1)**

**Form: Immunogenicity Assessment**

**Generated On: 10 Jun 2021 09:15:23**

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 22:42:32
User signature succeeded.	Richard Rupp (b) (4)	05 Mar 2021 19:39:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 16:16:34
User entered 'Yes (Y)'	Kristin Pollock (b) (4) (b) (4)	27 Oct 2020 17:25:38

US3612005

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 09:15:23

Collection date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 22:42:32
User signature succeeded.	Richard Rupp (b) (4)	05 Mar 2021 19:39:45
User closed query 'Per GCL Lab Reconciliation: Antibody-mediated Immunogenicity: Sample dated 27OCT2020 is recorded under Visit 3 Day 57 in EDC, however immunogenicity sample is reported under UNSCHEDULED visit in PPD portal. Please reconcile the correct Visit and update if applicable, else clarify.' (Site from DM).	(b) (4) (b) (4), (b) (6)	30 Nov 2020 09:11:12
Query 'Per GCL Lab Reconciliation: Antibody-mediated Immunogenicity: Sample dated 27OCT2020 is recorded under Visit 3 Day 57 in EDC, however immunogenicity sample is reported under UNSCHEDULED visit in PPD portal. Please reconcile the correct Visit and update if applicable, else clarify.' answered with 'PPD had a shortage of kits for visit 3 and sites were told to use UNSCHEDULED kits.' (Site from DM).	Amy McMahan (b) (4) (b) (4)	17 Nov 2020 16:53:18
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 16:16:34
User opened query 'Per GCL Lab Reconciliation: Antibody-mediated Immunogenicity: Sample dated 27OCT2020 is recorded under Visit 3 Day 57 in EDC, however immunogenicity sample is reported under UNSCHEDULED visit in PPD portal. Please reconcile the correct Visit and update if applicable, else clarify.' (Site from DM).	(b) (4), (b) (6)	17 Nov 2020 07:38:37
User entered '27 Oct 2020'	Kristin Pollock (b) (4) (b) (4)	27 Oct 2020 17:25:38

**US3612005**

**Folder: Visit 3 Day 57 (1)**

**Form: Immunogenicity Assessment**

**Generated On: 10 Jun 2021 09:15:23**

[Collection time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 22:42:32
User signature succeeded.	Richard Rupp (b) (4)	05 Mar 2021 19:39:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 16:16:34
User entered '11:42'	Kristin Pollock (b) (4) (b) (4)	27 Oct 2020 17:25:38

**US3612005**

**Folder: Visit 3 Day 57 (1)**

**Form: Immunogenicity Assessment**

**Generated On: 10 Jun 2021 09:15:23**

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 22:42:32
User entered '27 Oct 2020 11:42'	System	27 Oct 2020 17:25:38

US3612005

Folder: Visit 3 Day 57 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:15:23

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 22:42:32
User signature succeeded.	Richard Rupp (b) (4)	05 Mar 2021 19:39:45
DataPoint Verified.	(b) (4)	17 Nov 2020 16:19:00
User entered 'Yes (Y)'	Kristin Pollock (b) (4)	27 Oct 2020 17:25:43
	(b) (4)	

**US3612005**

**Folder: Visit 3 Day 57 (1)**

**Form: Continuing**

**Generated On: 10 Jun 2021 09:15:23**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 22:42:32
User entered 'I'	System	27 Oct 2020 17:25:43

**US3612005**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:15:23**

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:49:15
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 21:39:34
Data entry locked.	System	01 Sep 2020 16:12:18
User entered 'Day 64'	System	01 Sep 2020 16:12:18

**US3612005**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:15:23**

[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)	24 Apr 2021 14:49:15
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 21:39:34

**US3612005**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:15:23**

[Have you been exposed to someone with 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)	24 Apr 2021 14:49:15
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 21:39:34

**US3612005**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:15:23**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:49:15
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 21:39:34

**US3612005**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:15:23**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:49:15
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 21:39:34

**US3612005**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:15:23**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:49:15
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 21:39:34

**US3612005**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:15:23**

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:49:15
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 21:39:34

**US3612005**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:15:23**

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:49:15
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 21:39:34

**US3612005**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:15:23**

[Shortness of breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:49:15
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 21:39:34

**US3612005**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:15:23**

[Difficulty breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:49:15
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 21:39:34

**US3612005**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:15:23**

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:49:15
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 21:39:34

**US3612005**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:15:23**

[Muscle aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:49:15
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 21:39:34

**US3612005**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:15:23**

[Body aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:49:15
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 21:39:34

**US3612005**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:15:23**

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:49:15
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 21:39:34

**US3612005**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:15:23**

[New loss of taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:49:15
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 21:39:34

**US3612005**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:15:23**

[New loss of smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:49:15
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 21:39:34

**US3612005**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:15:23**

[Sore throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:49:15
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 21:39:34

**US3612005**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:15:23**

[Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:49:15
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 21:39:34

**US3612005**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:15:23**

[Runny nose](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:49:15
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 21:39:34

**US3612005**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:15:23**

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:49:15
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 21:39:34

**US3612005**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:15:23**

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:49:15
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 21:39:34

**US3612005**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:15:23**

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:49:15
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 21:39:34

**US3612005**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:15:23**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:49:15
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 21:39:34

**US3612005**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:15:23**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:49:15
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 21:39:34

**US3612005**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:15:23**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:49:15
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 21:39:34

**US3612005**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:15:23**

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:49:15
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 21:39:34

**US3612005**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:15:23**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:49:15
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 21:39:34
Data entry locked.	System	01 Sep 2020 16:12:18
User entered '01 Nov 2020 00:01'	System	01 Sep 2020 16:12:18

**US3612005**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:15:23**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:49:15
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 21:39:34
Data entry locked.	System	01 Sep 2020 16:12:18
User entered '05 Nov 2020 23:59'	System	01 Sep 2020 16:12:18

**US3612005**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:15:23**

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:49:15
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 21:39:34
Data entry locked.	System	01 Sep 2020 16:12:18
User entered 'Day 71'	System	01 Sep 2020 16:12:18

**US3612005**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:15:23**

[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)	24 Apr 2021 14:49:15
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 21:39:34

**US3612005**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:15:23**

[Have you been exposed to someone with 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)	24 Apr 2021 14:49:15
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 21:39:34

**US3612005**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:15:23**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:49:15
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 21:39:34

**US3612005**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:15:23**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:49:15
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 21:39:34

**US3612005**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:15:23**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:49:15
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 21:39:34

**US3612005**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:15:23**

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:49:15
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 21:39:34

**US3612005**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:15:23**

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:49:15
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 21:39:34

**US3612005**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:15:23**

[Shortness of breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:49:15
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 21:39:34

**US3612005**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:15:23**

[Difficulty breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:49:15
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 21:39:34

**US3612005**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:15:23**

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:49:15
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 21:39:34

**US3612005**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:15:23**

[Muscle aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:49:15
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 21:39:34

**US3612005**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:15:23**

[Body aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:49:15
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 21:39:34

**US3612005**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:15:23**

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:49:15
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 21:39:34

**US3612005**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:15:23**

[New loss of taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:49:15
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 21:39:34

**US3612005**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:15:23**

[New loss of smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:49:15
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 21:39:34

**US3612005**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:15:23**

[Sore throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:49:15
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 21:39:34

**US3612005**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:15:23**

[Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:49:15
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 21:39:34

**US3612005**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:15:23**

[Runny nose](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:49:15
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 21:39:34

**US3612005**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:15:23**

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:49:15
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 21:39:34

**US3612005**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:15:23**

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:49:15
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 21:39:34

**US3612005**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:15:23**

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:49:15
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 21:39:34

**US3612005**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:15:23**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:49:15
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 21:39:34

**US3612005**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:15:23**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:49:15
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 21:39:34

**US3612005**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:15:23**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:49:15
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 21:39:34

**US3612005**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:15:23**

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:49:15
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 21:39:34

**US3612005**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:15:23**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:49:15
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 21:39:34
Data entry locked.	System	01 Sep 2020 16:12:18
User entered '08 Nov 2020 00:01'	System	01 Sep 2020 16:12:18

**US3612005**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:15:23**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:49:15
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 21:39:34
Data entry locked.	System	01 Sep 2020 16:12:18
User entered '12 Nov 2020 23:59'	System	01 Sep 2020 16:12:18

**US3612005**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:15:23**

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:49:15
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 21:39:34
Data entry locked.	System	01 Sep 2020 16:12:18
User entered 'Day 78'	System	01 Sep 2020 16:12:18

**US3612005**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:15:23**

[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)	24 Apr 2021 14:49:15
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 21:39:34

**US3612005**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:15:23**

[Have you been exposed to someone with 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)	24 Apr 2021 14:49:15
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 21:39:34

**US3612005**

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

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**Generated On: 10 Jun 2021 09:15:23**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:49:15
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 21:39:34

**US3612005**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:15:23**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:49:15
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 21:39:34

**US3612005**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:15:23**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:49:15
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 21:39:34

**US3612005**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:15:23**

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:49:15
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 21:39:34

**US3612005**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:15:23**

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:49:15
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 21:39:34

**US3612005**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:15:23**

[Shortness of breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:49:15
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 21:39:34

**US3612005**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:15:23**

[Difficulty breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:49:15
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 21:39:34

**US3612005**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:15:23**

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:49:15
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 21:39:34

**US3612005**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:15:23**

[Muscle aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:49:15
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 21:39:34

**US3612005**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:15:23**

[Body aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:49:15
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 21:39:34

**US3612005**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:15:23**

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:49:15
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 21:39:34

**US3612005**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:15:23**

[New loss of taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:49:15
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 21:39:34

**US3612005**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:15:23**

[New loss of smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:49:15
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 21:39:34

**US3612005**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:15:23**

[Sore throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:49:15
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 21:39:34

**US3612005**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:15:23**

[Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:49:15
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 21:39:34

**US3612005**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:15:23**

[Runny nose](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:49:15
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 21:39:34

**US3612005**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:15:23**

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:49:15
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 21:39:34

**US3612005**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:15:23**

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:49:15
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 21:39:34

**US3612005**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:15:23**

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:49:15
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 21:39:34

**US3612005**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:15:23**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:49:15
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 21:39:34

**US3612005**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:15:23**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:49:15
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 21:39:34

**US3612005**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:15:23**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:49:15
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 21:39:34

**US3612005**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:15:23**

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:49:15
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 21:39:34

**US3612005**

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

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**Generated On: 10 Jun 2021 09:15:23**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:49:15
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 21:39:34
Data entry locked.	System	01 Sep 2020 16:12:18
User entered '15 Nov 2020 00:01'	System	01 Sep 2020 16:12:18

**US3612005**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:15:23**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:49:15
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 21:39:34
Data entry locked.	System	01 Sep 2020 16:12:18
User entered '19 Nov 2020 23:59'	System	01 Sep 2020 16:12:18

**US3612005**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:15:23**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:39:34
Amendment Manager: User entered 'Day 82'	System	19 Nov 2020 21:39:34

**US3612005**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:15:23**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:39:34
Amendment Manager: User entered '19 Nov 2020 00:01'	System	19 Nov 2020 21:39:34

**US3612005**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:15:23**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:39:34
Amendment Manager: User entered '23 Nov 2020 23:59'	System	19 Nov 2020 21:39:34

**US3612005**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:15:23**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:39:34
Amendment Manager: User entered 'Day 89'	System	19 Nov 2020 21:39:34

**US3612005**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:15:23**

[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 (a19c168458d97dd9)', Time: '2020-11-26T00:49:58', User OID: 'PatientReportedOutcome (US3612005)', ODM File OID: 'e403d1c1-2a07-41ae-af9f-af47bba5ab3b'	System	26 Nov 2020 06:50:32
User entered 'No (N)'	System	26 Nov 2020 06:50:32

**US3612005**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:15:23**

Have you been exposed to someone with 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 (a19c168458d97dd9)', Time: '2020-11-26T00:50:10', User OID: 'PatientReportedOutcome (US3612005)', ODM File OID: 'e403d1c1-2a07-41ae-af9f-af47bba5ab3b'	System	26 Nov 2020 06:50:32
User entered 'No (N)'	System	26 Nov 2020 06:50:32

**US3612005**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:15:23**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a19c168458d97dd9)', Time: '2020-11-26T00:50:29', User OID: 'PatientReportedOutcome (US3612005)', ODM File OID: 'e403d1c1-2a07-41ae-af9f-af47bba5ab3b'	System	26 Nov 2020 06:50:32
User entered '26 Nov 2020 00:50:29'	System	26 Nov 2020 06:50:32

**US3612005**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:15:23**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:39:34
Amendment Manager: User entered '26 Nov 2020 00:01'	System	19 Nov 2020 21:39:34

**US3612005**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:15:23**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:39:34
Amendment Manager: User entered '30 Nov 2020 23:59'	System	19 Nov 2020 21:39:34

**US3612005**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:15:23**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:39:34
Amendment Manager: User entered 'Day 96'	System	19 Nov 2020 21:39:34

**US3612005**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:15:23**

[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 (a19c168458d97dd9)', Time: '2020-12-03T07:27:44', User OID: 'PatientReportedOutcome (US3612005)', ODM File OID: '21048317-8bd1-4112-ac41-21a32ca39025'	System	03 Dec 2020 13:28:28
User entered 'No (N)'	System	03 Dec 2020 13:28:28

**US3612005**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:15:23**

Have you been exposed to someone with 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 (a19c168458d97dd9)', Time: '2020-12-03T07:28:00', User OID: 'PatientReportedOutcome (US3612005)', ODM File OID: '21048317-8bd1-4112-ac41-21a32ca39025'	System	03 Dec 2020 13:28:28
User entered 'No (N)'	System	03 Dec 2020 13:28:28

**US3612005**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:15:23**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a19c168458d97dd9)', Time: '2020-12-03T07:28:25', User OID: 'PatientReportedOutcome (US3612005)', ODM File OID: '21048317-8bd1-4112-ac41-21a32ca39025'	System	03 Dec 2020 13:28:28
User entered '03 Dec 2020 07:28:25'	System	03 Dec 2020 13:28:28

**US3612005**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:15:23**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:39:34
Amendment Manager: User entered '03 Dec 2020 00:01'	System	19 Nov 2020 21:39:34

**US3612005**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:15:23**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:39:34
Amendment Manager: User entered '07 Dec 2020 23:59'	System	19 Nov 2020 21:39:34

**US3612005**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:15:23**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:39:34
Amendment Manager: User entered 'Day 103'	System	19 Nov 2020 21:39:34

**US3612005**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:15:23**

[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 (a19c168458d97dd9)', Time: '2020-12-10T11:27:58', User OID: 'PatientReportedOutcome (US3612005)', ODM File OID: '067c6fe3-2232-42fc-98d2-8a56cc7a786b'	System	10 Dec 2020 17:28:19
User entered 'No (N)'	System	10 Dec 2020 17:28:19

**US3612005**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:15:23**

Have you been exposed to someone with 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 (a19c168458d97dd9)', Time: '2020-12-10T11:28:06', User OID: 'PatientReportedOutcome (US3612005)', ODM File OID: '067c6fe3-2232-42fc-98d2-8a56cc7a786b'	System	10 Dec 2020 17:28:19
User entered 'No (N)'	System	10 Dec 2020 17:28:19

**US3612005**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:15:23**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a19c168458d97dd9)', Time: '2020-12-10T11:28:14', User OID: 'PatientReportedOutcome (US3612005)', ODM File OID: '067c6fe3-2232-42fc-98d2-8a56cc7a786b'	System	10 Dec 2020 17:28:19
User entered '10 Dec 2020 11:28:14'	System	10 Dec 2020 17:28:19

**US3612005**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:15:23**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:39:34
Amendment Manager: User entered '10 Dec 2020 00:01'	System	19 Nov 2020 21:39:34

**US3612005**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:15:23**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:39:34
Amendment Manager: User entered '14 Dec 2020 23:59'	System	19 Nov 2020 21:39:34

**US3612005**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:15:23**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:39:34
Amendment Manager: User entered 'Day 110'	System	19 Nov 2020 21:39:34

**US3612005**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:15:23**

[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 (a19c168458d97dd9)', Time: '2020-12-17T12:12:33', User OID: 'PatientReportedOutcome (US3612005)', ODM File OID: 'b16ab831-993e-4055-9fa9-97d6241e5800'	System	17 Dec 2020 18:12:48
User entered 'No (N)'	System	17 Dec 2020 18:12:48

**US3612005**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:15:23**

Have you been exposed to someone with 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 (a19c168458d97dd9)', Time: '2020-12-17T12:12:38', User OID: 'PatientReportedOutcome (US3612005)', ODM File OID: 'b16ab831-993e-4055-9fa9-97d6241e5800'	System	17 Dec 2020 18:12:48
User entered 'No (N)'	System	17 Dec 2020 18:12:48

**US3612005**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:15:23**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a19c168458d97dd9)', Time: '2020-12-17T12:12:43', User OID: 'PatientReportedOutcome (US3612005)', ODM File OID: 'b16ab831-993e-4055-9fa9-97d6241e5800'	System	17 Dec 2020 18:12:48
User entered '17 Dec 2020 12:12:43'	System	17 Dec 2020 18:12:48

**US3612005**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:15:23**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:39:34
Amendment Manager: User entered '17 Dec 2020 00:01'	System	19 Nov 2020 21:39:34

**US3612005**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:15:23**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:39:34
Amendment Manager: User entered '21 Dec 2020 23:59'	System	19 Nov 2020 21:39:34

**US3612005**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:15:23**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:39:34
Amendment Manager: User entered 'Day 117'	System	19 Nov 2020 21:39:34

**US3612005**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:15:23**

[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 (a19c168458d97dd9)', Time: '2020-12-24T09:41:39', User OID: 'PatientReportedOutcome (US3612005)', ODM File OID: '3b5f5d7f-18d0-47f2-be81-35183f029976'	System	24 Dec 2020 15:41:56
User entered 'No (N)'	System	24 Dec 2020 15:41:56

**US3612005**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:15:23**

Have you been exposed to someone with 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 (a19c168458d97dd9)', Time: '2020-12-24T09:41:45', User OID: 'PatientReportedOutcome (US3612005)', ODM File OID: '3b5f5d7f-18d0-47f2-be81-35183f029976'	System	24 Dec 2020 15:41:56
User entered 'No (N)'	System	24 Dec 2020 15:41:56

**US3612005**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:15:23**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a19c168458d97dd9)', Time: '2020-12-24T09:41:53', User OID: 'PatientReportedOutcome (US3612005)', ODM File OID: '3b5f5d7f-18d0-47f2-be81-35183f029976'	System	24 Dec 2020 15:41:56
User entered '24 Dec 2020 09:41:53'	System	24 Dec 2020 15:41:56

**US3612005**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:15:23**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:39:34
Amendment Manager: User entered '24 Dec 2020 00:01'	System	19 Nov 2020 21:39:34

**US3612005**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:15:23**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:39:34
Amendment Manager: User entered '28 Dec 2020 23:59'	System	19 Nov 2020 21:39:34

**US3612005**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:15:23**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:39:34
Amendment Manager: User entered 'Day 124'	System	19 Nov 2020 21:39:34

**US3612005**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:15:23**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:39:34
Amendment Manager: User entered '31 Dec 2020 00:01'	System	19 Nov 2020 21:39:34

**US3612005**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:15:23**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:39:34
Amendment Manager: User entered '04 Jan 2021 23:59'	System	19 Nov 2020 21:39:34

**US3612005**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:15:23**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:39:34
Amendment Manager: User entered 'Day 131'	System	19 Nov 2020 21:39:34

**US3612005**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:15:23**

[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 (a19c168458d97dd9)', Time: '2021-01-10T18:22:33', User OID: 'PatientReportedOutcome (US3612005)', ODM File OID: '9b64e3b7-e0ca-4130-be09-312e3c9b2f6b'	System	11 Jan 2021 00:22:50
User entered 'No (N)'	System	11 Jan 2021 00:22:50

**US3612005**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:15:23**

[Have you been exposed to someone with 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 (a19c168458d97dd9)', Time: '2021-01-10T18:22:39', User OID: 'PatientReportedOutcome (US3612005)', ODM File OID: '9b64e3b7-e0ca-4130-be09-312e3c9b2f6b'	System	11 Jan 2021 00:22:50
User entered 'No (N)'	System	11 Jan 2021 00:22:50

**US3612005**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:15:23**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a19c168458d97dd9)', Time: '2021-01-10T18:22:44', User OID: 'PatientReportedOutcome (US3612005)', ODM File OID: '9b64e3b7-e0ca-4130-be09-312e3c9b2f6b'	System	11 Jan 2021 00:22:50
User entered '10 Jan 2021 18:22:44'	System	11 Jan 2021 00:22:50

**US3612005**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:15:23**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:39:34
Amendment Manager: User entered '07 Jan 2021 00:01'	System	19 Nov 2020 21:39:34

**US3612005**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:15:23**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:39:34
Amendment Manager: User entered '11 Jan 2021 23:59'	System	19 Nov 2020 21:39:34

**US3612005**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:15:23**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:39:34
Amendment Manager: User entered 'Day 138'	System	19 Nov 2020 21:39:34

**US3612005**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:15:23**

[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 (a19c168458d97dd9)', Time: '2021-01-14T00:20:09', User OID: 'PatientReportedOutcome (US3612005)', ODM File OID: '04e59d05-f845-465b-a8e6-aa33ffda294f'	System	14 Jan 2021 06:20:28
User entered 'No (N)'	System	14 Jan 2021 06:20:28

**US3612005**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:15:23**

Have you been exposed to someone with 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 (a19c168458d97dd9)', Time: '2021-01-14T00:20:16', User OID: 'PatientReportedOutcome (US3612005)', ODM File OID: '04e59d05-f845-465b-a8e6-aa33ffda294f'	System	14 Jan 2021 06:20:28
User entered 'No (N)'	System	14 Jan 2021 06:20:28

**US3612005**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:15:23**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a19c168458d97dd9)', Time: '2021-01-14T00:20:26', User OID: 'PatientReportedOutcome (US3612005)', ODM File OID: '04e59d05-f845-465b-a8e6-aa33ffda294f'	System	14 Jan 2021 06:20:28
User entered '14 Jan 2021 00:20:26'	System	14 Jan 2021 06:20:28

**US3612005**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:15:23**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:39:34
Amendment Manager: User entered '14 Jan 2021 00:01'	System	19 Nov 2020 21:39:34

**US3612005**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:15:23**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:39:34
Amendment Manager: User entered '18 Jan 2021 23:59'	System	19 Nov 2020 21:39:34

**US3612005**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:15:23**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:39:34
Amendment Manager: User entered 'Day 145'	System	19 Nov 2020 21:39:34

**US3612005**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:15:23**

[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 (a19c168458d97dd9)', Time: '2021-01-21T07:37:10', User OID: 'PatientReportedOutcome (US3612005)', ODM File OID: 'e6fc4f8d-1d67-44b3-a71d-9e9120c04e5a'	System	21 Jan 2021 13:37:36
User entered 'No (N)'	System	21 Jan 2021 13:37:36

**US3612005**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:15:23**

[Have you been exposed to someone with 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 (a19c168458d97dd9)', Time: '2021-01-21T07:37:24', User OID: 'PatientReportedOutcome (US3612005)', ODM File OID: 'e6fc4f8d-1d67-44b3-a71d-9e9120c04e5a'	System	21 Jan 2021 13:37:36
User entered 'No (N)'	System	21 Jan 2021 13:37:36

**US3612005**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:15:23**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a19c168458d97dd9)', Time: '2021-01-21T07:37:33', User OID: 'PatientReportedOutcome (US3612005)', ODM File OID: 'e6fc4f8d-1d67-44b3-a71d-9e9120c04e5a'	System	21 Jan 2021 13:37:36
User entered '21 Jan 2021 07:37:33'	System	21 Jan 2021 13:37:36

**US3612005**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:15:23**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:39:34
Amendment Manager: User entered '21 Jan 2021 00:01'	System	19 Nov 2020 21:39:34

**US3612005**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:15:23**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:39:34
Amendment Manager: User entered '25 Jan 2021 23:59'	System	19 Nov 2020 21:39:34

**US3612005**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:15:23**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:39:34
Amendment Manager: User entered 'Day 152'	System	19 Nov 2020 21:39:34

**US3612005**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:15:23**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:39:34
Amendment Manager: User entered '28 Jan 2021 00:01'	System	19 Nov 2020 21:39:34

**US3612005**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:15:23**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:39:34
Amendment Manager: User entered '01 Feb 2021 23:59'	System	19 Nov 2020 21:39:34

**US3612005**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:15:23**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:39:34
Amendment Manager: User entered 'Day 159'	System	19 Nov 2020 21:39:34

**US3612005**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:15:23**

[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 (a19c168458d97dd9)', Time: '2021-02-04T07:20:38', User OID: 'PatientReportedOutcome (US3612005)', ODM File OID: '45deac7b-5707-42d4-b478-6cedd2a6add5'	System	04 Feb 2021 13:21:00
User entered 'No (N)'	System	04 Feb 2021 13:21:00

**US3612005**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:15:23**

[Have you been exposed to someone with 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 (a19c168458d97dd9)', Time: '2021-02-04T07:20:28', User OID: 'PatientReportedOutcome (US3612005)', ODM File OID: '45deac7b-5707-42d4-b478-6cedd2a6add5'	System	04 Feb 2021 13:21:00
User entered 'No (N)'	System	04 Feb 2021 13:21:00

**US3612005**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:15:23**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a19c168458d97dd9)', Time: '2021-02-04T07:20:55', User OID: 'PatientReportedOutcome (US3612005)', ODM File OID: '45deac7b-5707-42d4-b478-6cedd2a6add5'	System	04 Feb 2021 13:21:00
User entered '04 Feb 2021 07:20:55'	System	04 Feb 2021 13:21:00

**US3612005**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:15:23**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:39:34
Amendment Manager: User entered '04 Feb 2021 00:01'	System	19 Nov 2020 21:39:34

**US3612005**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:15:23**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:39:34
Amendment Manager: User entered '08 Feb 2021 23:59'	System	19 Nov 2020 21:39:34

**US3612005**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:15:23**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:39:34
Amendment Manager: User entered 'Day 166'	System	19 Nov 2020 21:39:34

**US3612005**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:15:23**

[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 (a19c168458d97dd9)', Time: '2021-02-11T00:15:50', User OID: 'PatientReportedOutcome (US3612005)', ODM File OID: 'fd0c8c84-d524-4b38-97f4-5932cd917f51'	System	11 Feb 2021 06:16:20
User entered 'No (N)'	System	11 Feb 2021 06:16:20

**US3612005**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:15:23**

Have you been exposed to someone with 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 (a19c168458d97dd9)', Time: '2021-02-11T00:15:58', User OID: 'PatientReportedOutcome (US3612005)', ODM File OID: 'fd0c8c84-d524-4b38-97f4-5932cd917f51'	System	11 Feb 2021 06:16:20
User entered 'No (N)'	System	11 Feb 2021 06:16:20

**US3612005**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:15:23**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a19c168458d97dd9)', Time: '2021-02-11T00:16:14', User OID: 'PatientReportedOutcome (US3612005)', ODM File OID: 'fd0c8c84-d524-4b38-97f4-5932cd917f51'	System	11 Feb 2021 06:16:20
User entered '11 Feb 2021 00:16:14'	System	11 Feb 2021 06:16:20

**US3612005**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:15:23**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:39:34
Amendment Manager: User entered '11 Feb 2021 00:01'	System	19 Nov 2020 21:39:34

**US3612005**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:15:23**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:39:34
Amendment Manager: User entered '15 Feb 2021 23:59'	System	19 Nov 2020 21:39:34

**US3612005**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:15:23**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:39:34
Amendment Manager: User entered 'Day 173'	System	19 Nov 2020 21:39:34

**US3612005**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:15:23**

[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 (a19c168458d97dd9)', Time: '2021-02-18T00:01:54', User OID: 'PatientReportedOutcome (US3612005)', ODM File OID: 'e8521e38-d0cf-4be5-9b21-d06ad0fe5feb'	System	18 Feb 2021 06:02:45
User entered 'No (N)'	System	18 Feb 2021 06:02:45

**US3612005**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:15:23**

Have you been exposed to someone with 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 (a19c168458d97dd9)', Time: '2021-02-18T00:02:02', User OID: 'PatientReportedOutcome (US3612005)', ODM File OID: 'e8521e38-d0cf-4be5-9b21-d06ad0fe5feb'	System	18 Feb 2021 06:02:45
User entered 'Yes (Y)'	System	18 Feb 2021 06:02:45

**US3612005**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:15:23**

[Please 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 (a19c168458d97dd9)', Time: '2021-02-18T00:02:23', User OID: 'PatientReportedOutcome (US3612005)', ODM File OID: 'e8521e38-d0cf-4be5-9b21-d06ad0fe5feb'	System	18 Feb 2021 06:02:45
User entered 'I confirm I have read this message and will call the study clinic immediately (9)'	System	18 Feb 2021 06:02:45

**US3612005**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:15:23**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a19c168458d97dd9)', Time: '2021-02-18T00:02:34', User OID: 'PatientReportedOutcome (US3612005)', ODM File OID: 'e8521e38-d0cf-4be5-9b21-d06ad0fe5feb'	System	18 Feb 2021 06:02:45
User entered '18 Feb 2021 00:02:34'	System	18 Feb 2021 06:02:45

**US3612005**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:15:23**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:39:34
Amendment Manager: User entered '18 Feb 2021 00:01'	System	19 Nov 2020 21:39:34

**US3612005**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:15:23**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:39:34
Amendment Manager: User entered '22 Feb 2021 23:59'	System	19 Nov 2020 21:39:34

**US3612005**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:15:23**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:39:34
Amendment Manager: User entered 'Day 180'	System	19 Nov 2020 21:39:34

**US3612005**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:15:23**

[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 (a19c168458d97dd9)', Time: '2021-02-25T08:36:30-06:00', User OID: 'PatientReportedOutcome (US3612005)', ODM File OID: '51cf0849-4d3e-43e2-a567-167bc2308649' User entered 'No (N)'	System	25 Feb 2021 17:11:27
	System	25 Feb 2021 17:11:27

**US3612005**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:15:23**

Have you been exposed to someone with 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 (a19c168458d97dd9)', Time: '2021-02-25T08:36:39-06:00', User OID: 'PatientReportedOutcome (US3612005)', ODM File OID: '51cf0849-4d3e-43e2-a567-167bc2308649'	System	25 Feb 2021 17:11:27
User entered 'No (N)'	System	25 Feb 2021 17:11:27

**US3612005**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:15:23**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a19c168458d97dd9)', Time: '2021-02-25T08:36:49-06:00', User OID: 'PatientReportedOutcome (US3612005)', ODM File OID: '51cf0849-4d3e-43e2-a567-167bc2308649' User entered '25 Feb 2021 08:36:49'	System	25 Feb 2021 17:11:27
	System	25 Feb 2021 17:11:27

**US3612005**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:15:23**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:39:34
Amendment Manager: User entered '25 Feb 2021 00:01'	System	19 Nov 2020 21:39:34

**US3612005**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:15:23**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:39:34
Amendment Manager: User entered '01 Mar 2021 23:59'	System	19 Nov 2020 21:39:34

**US3612005**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:15:23**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:39:34
Amendment Manager: User entered 'Day 187'	System	19 Nov 2020 21:39:34

**US3612005**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:15:23**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:39:34
Amendment Manager: User entered '04 Mar 2021 00:01'	System	19 Nov 2020 21:39:34

**US3612005**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:15:23**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:39:34
Amendment Manager: User entered '08 Mar 2021 23:59'	System	19 Nov 2020 21:39:34

**US3612005**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:15:23**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:39:34
Amendment Manager: User entered 'Day 194'	System	19 Nov 2020 21:39:34

**US3612005**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:15:23**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:39:34
Amendment Manager: User entered '11 Mar 2021 00:01'	System	19 Nov 2020 21:39:34

**US3612005**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:15:23**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:39:34
Amendment Manager: User entered '15 Mar 2021 23:59'	System	19 Nov 2020 21:39:34

**US3612005**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:15:23**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:39:34
Amendment Manager: User entered 'Day 201'	System	19 Nov 2020 21:39:34

**US3612005**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:15:23**

[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 (a19c168458d97dd9)', Time: '2021-03-19T23:54:48-05:00', User OID: 'PatientReportedOutcome (US3612005)', ODM File OID: '69425ae3-f37d-440a-85d9-c98c72b19780'	System	20 Mar 2021 04:55:10
User entered 'No (N)'	System	20 Mar 2021 04:55:10

**US3612005**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:15:23**

[Have you been exposed to someone with 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 (a19c168458d97dd9)', Time: '2021-03-19T23:54:58-05:00', User OID: 'PatientReportedOutcome (US3612005)', ODM File OID: '69425ae3-f37d-440a-85d9-c98c72b19780'	System	20 Mar 2021 04:55:10
User entered 'No (N)'	System	20 Mar 2021 04:55:10

**US3612005**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:15:23**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a19c168458d97dd9)', Time: '2021-03-19T23:55:06-05:00', User OID: 'PatientReportedOutcome (US3612005)', ODM File OID: '69425ae3-f37d-440a-85d9-c98c72b19780'	System	20 Mar 2021 04:55:10
User entered '19 Mar 2021 23:55:06'	System	20 Mar 2021 04:55:10

**US3612005**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:15:23**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:39:34
Amendment Manager: User entered '18 Mar 2021 00:01'	System	19 Nov 2020 21:39:34

**US3612005**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:15:23**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:39:34
Amendment Manager: User entered '22 Mar 2021 23:59'	System	19 Nov 2020 21:39:34

**US3612005**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:15:23**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:39:34
Amendment Manager: User entered 'Day 208'	System	19 Nov 2020 21:39:34

**US3612005**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:15:23**

[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 (a19c168458d97dd9)', Time: '2021-03-25T06:48:57-05:00', User OID: 'PatientReportedOutcome (US3612005)', ODM File OID: 'eb454100-2eca-45b3-bea0-a30a2c91956b'	System	25 Mar 2021 11:49:30
User entered 'No (N)'	System	25 Mar 2021 11:49:30

**US3612005**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:15:23**

Have you been exposed to someone with 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 (a19c168458d97dd9)', Time: '2021-03-25T06:49:10-05:00', User OID: 'PatientReportedOutcome (US3612005)', ODM File OID: 'eb454100-2eca-45b3-bea0-a30a2c91956b'	System	25 Mar 2021 11:49:30
User entered 'No (N)'	System	25 Mar 2021 11:49:30

**US3612005**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:15:23**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a19c168458d97dd9)', Time: '2021-03-25T06:49:25-05:00', User OID: 'PatientReportedOutcome (US3612005)', ODM File OID: 'eb454100-2eca-45b3-bea0-a30a2c91956b' User entered '25 Mar 2021 06:49:25'	System	25 Mar 2021 11:49:30
	System	25 Mar 2021 11:49:30

**US3612005**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:15:23**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:39:34
Amendment Manager: User entered '25 Mar 2021 00:01'	System	19 Nov 2020 21:39:34

**US3612005**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:15:23**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:39:34
Amendment Manager: User entered '29 Mar 2021 23:59'	System	19 Nov 2020 21:39:34

**US3612005**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:15:23**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:39:34
Amendment Manager: User entered 'Day 215'	System	19 Nov 2020 21:39:34

**US3612005**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:15:23**

[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 (a19c168458d97dd9)', Time: '2021-04-03T12:00:31-05:00', User OID: 'PatientReportedOutcome (US3612005)', ODM File OID: '95e06ccd-e4ba-4113-aa89-3127c0f48cf3'	System	03 Apr 2021 17:01:10
User entered 'No (N)'	System	03 Apr 2021 17:01:10

**US3612005**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:15:23**

Have you been exposed to someone with 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 (a19c168458d97dd9)', Time: '2021-04-03T12:00:43-05:00', User OID: 'PatientReportedOutcome (US3612005)', ODM File OID: '95e06ccd-e4ba-4113-aa89-3127c0f48cf3'	System	03 Apr 2021 17:01:10
User entered 'No (N)'	System	03 Apr 2021 17:01:10

**US3612005**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:15:23**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a19c168458d97dd9)', Time: '2021-04-03T12:00:48-05:00', User OID: 'PatientReportedOutcome (US3612005)', ODM File OID: '95e06ccd-e4ba-4113-aa89-3127c0f48cf3'	System	03 Apr 2021 17:01:10
User entered '03 Apr 2021 12:00:48'	System	03 Apr 2021 17:01:10

**US3612005**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:15:23**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:39:34
Amendment Manager: User entered '01 Apr 2021 00:01'	System	19 Nov 2020 21:39:34

**US3612005**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:15:23**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:39:34
Amendment Manager: User entered '05 Apr 2021 23:59'	System	19 Nov 2020 21:39:34

**US3612005**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:15:23**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:39:34
Amendment Manager: User entered 'Day 222'	System	19 Nov 2020 21:39:34

**US3612005**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:15:23**

[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 (a19c168458d97dd9)', Time: '2021-04-08T11:39:15-05:00', User OID: 'PatientReportedOutcome (US3612005)', ODM File OID: '990289c0-ac22-440a-a992-2118002120fd' User entered 'No (N)'	System	08 Apr 2021 16:39:36
	System	08 Apr 2021 16:39:36

**US3612005**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:15:23**

Have you been exposed to someone with 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 (a19c168458d97dd9)', Time: '2021-04-08T11:39:26-05:00', User OID: 'PatientReportedOutcome (US3612005)', ODM File OID: '990289c0-ac22-440a-a992-2118002120fd' User entered 'No (N)'	System	08 Apr 2021 16:39:36

**US3612005**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:15:23**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a19c168458d97dd9)', Time: '2021-04-08T11:39:32-05:00', User OID: 'PatientReportedOutcome (US3612005)', ODM File OID: '990289c0-ac22-440a-a992-2118002120fd' User entered '08 Apr 2021 11:39:32'	System	08 Apr 2021 16:39:36
	System	08 Apr 2021 16:39:36

**US3612005**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:15:23**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:39:34
Amendment Manager: User entered '08 Apr 2021 00:01'	System	19 Nov 2020 21:39:34

**US3612005**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:15:23**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:39:34
Amendment Manager: User entered '12 Apr 2021 23:59'	System	19 Nov 2020 21:39:34

**US3612005**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:15:23**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:39:34
Amendment Manager: User entered 'Day 229'	System	19 Nov 2020 21:39:34

**US3612005**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:15:23**

[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 (a19c168458d97dd9)', Time: '2021-04-19T23:28:59-05:00', User OID: 'PatientReportedOutcome (US3612005)', ODM File OID: '4011fd54-a051-480c-9afc-1847aa8105f3'	System	20 Apr 2021 04:30:19
User entered 'Yes (Y)'	System	20 Apr 2021 04:30:19

**US3612005**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:15:23**

Have you been exposed to someone with 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 (a19c168458d97dd9)', Time: '2021-04-19T23:29:09-05:00', User OID: 'PatientReportedOutcome (US3612005)', ODM File OID: '4011fd54-a051-480c-9afc-1847aa8105f3'	System	20 Apr 2021 04:30:19
User entered 'No (N)'	System	20 Apr 2021 04:30:19

**US3612005**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:15:23**

[Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a19c168458d97dd9)', Time: '2021-04-19T23:29:17-05:00', User OID: 'PatientReportedOutcome (US3612005)', ODM File OID: '4011fd54-a051-480c-9afc-1847aa8105f3'	System	20 Apr 2021 04:30:19
User entered 'No (N)'	System	20 Apr 2021 04:30:19

**US3612005**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:15:23**

[Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a19c168458d97dd9)', Time: '2021-04-19T23:29:28-05:00', User OID: 'PatientReportedOutcome (US3612005)', ODM File OID: '4011fd54-a051-480c-9afc-1847aa8105f3'	System	20 Apr 2021 04:30:19
User entered 'Yes (Y)'	System	20 Apr 2021 04:30:19

**US3612005**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:15:23**

[Please 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 (a19c168458d97dd9)', Time: '2021-04-19T23:29:41-05:00', User OID: 'PatientReportedOutcome (US3612005)', ODM File OID: '4011fd54-a051-480c-9afc-1847aa8105f3'	System	20 Apr 2021 04:30:19
User entered 'I confirm I have read this message and will call the study clinic immediately (9)'	System	20 Apr 2021 04:30:19

**US3612005**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:15:23**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a19c168458d97dd9)', Time: '2021-04-19T23:30:08-05:00', User OID: 'PatientReportedOutcome (US3612005)', ODM File OID: '4011fd54-a051-480c-9afc-1847aa8105f3'	System	20 Apr 2021 04:30:19
User entered '19 Apr 2021 23:30:08'	System	20 Apr 2021 04:30:19

**US3612005**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:15:23**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:39:34
Amendment Manager: User entered '15 Apr 2021 00:01'	System	19 Nov 2020 21:39:34

**US3612005**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:15:23**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:39:34
Amendment Manager: User entered '19 Apr 2021 23:59'	System	19 Nov 2020 21:39:34

**US3612005**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:15:23**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:39:34
Amendment Manager: User entered 'Day 236'	System	19 Nov 2020 21:39:34

**US3612005**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:15:23**

[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 (a19c168458d97dd9)', Time: '2021-04-22T09:24:33-05:00', User OID: 'PatientReportedOutcome (US3612005)', ODM File OID: '36dab004-d805-41d3-90b6-0197cff562a7'	System	22 Apr 2021 14:25:48
User entered 'Yes (Y)'	System	22 Apr 2021 14:25:48

**US3612005**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:15:23**

Have you been exposed to someone with 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 (a19c168458d97dd9)', Time: '2021-04-22T09:24:23-05:00', User OID: 'PatientReportedOutcome (US3612005)', ODM File OID: '36dab004-d805-41d3-90b6-0197cff562a7'	System	22 Apr 2021 14:25:48
User entered 'No (N)'	System	22 Apr 2021 14:25:48

**US3612005**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:15:23**

[Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a19c168458d97dd9)', Time: '2021-04-22T09:24:21-05:00', User OID: 'PatientReportedOutcome (US3612005)', ODM File OID: '36dab004-d805-41d3-90b6-0197cff562a7'	System	22 Apr 2021 14:25:48
User entered 'No (N)'	System	22 Apr 2021 14:25:48

**US3612005**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:15:23**

[Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a19c168458d97dd9)', Time: '2021-04-22T09:24:42-05:00', User OID: 'PatientReportedOutcome (US3612005)', ODM File OID: '36dab004-d805-41d3-90b6-0197cff562a7'	System	22 Apr 2021 14:25:48
User entered 'Yes (Y)'	System	22 Apr 2021 14:25:48

**US3612005**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:15:23**

[Please 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 (a19c168458d97dd9)', Time: '2021-04-22T09:24:47-05:00', User OID: 'PatientReportedOutcome (US3612005)', ODM File OID: '36dab004-d805-41d3-90b6-0197cff562a7'	System	22 Apr 2021 14:25:48
User entered 'I confirm I have read this message and will call the study clinic immediately (9)'	System	22 Apr 2021 14:25:48

**US3612005**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:15:23**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a19c168458d97dd9)', Time: '2021-04-22T09:25:36-05:00', User OID: 'PatientReportedOutcome (US3612005)', ODM File OID: '36dab004-d805-41d3-90b6-0197cff562a7'	System	22 Apr 2021 14:25:48
User entered '22 Apr 2021 09:25:36'	System	22 Apr 2021 14:25:48

**US3612005**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:15:23**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:39:34
Amendment Manager: User entered '22 Apr 2021 00:01'	System	19 Nov 2020 21:39:34

**US3612005**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:15:23**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:39:34
Amendment Manager: User entered '26 Apr 2021 23:59'	System	19 Nov 2020 21:39:34

**US3612005**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:15:23**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:39:34
Amendment Manager: User entered 'Day 243'	System	19 Nov 2020 21:39:34

**US3612005**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:15:23**

[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 (a19c168458d97dd9)', Time: '2021-04-29T00:41:32-05:00', User OID: 'PatientReportedOutcome (US3612005)', ODM File OID: 'c7e8a0ad-cedf-49f2-901c-3da6abdd55ed' User entered 'No (N)'	System	29 Apr 2021 05:41:54

**US3612005**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:15:23**

Have you been exposed to someone with 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 (a19c168458d97dd9)', Time: '2021-04-29T00:41:41-05:00', User OID: 'PatientReportedOutcome (US3612005)', ODM File OID: 'c7e8a0ad-cedf-49f2-901c-3da6abdd55ed'	System	29 Apr 2021 05:41:54
User entered 'No (N)'	System	29 Apr 2021 05:41:54

**US3612005**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:15:23**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a19c168458d97dd9)', Time: '2021-04-29T00:41:50-05:00', User OID: 'PatientReportedOutcome (US3612005)', ODM File OID: 'c7e8a0ad-cedf-49f2-901c-3da6abdd55ed' User entered '29 Apr 2021 00:41:50'	System	29 Apr 2021 05:41:54
	System	29 Apr 2021 05:41:54

**US3612005**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:15:23**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:39:34
Amendment Manager: User entered '29 Apr 2021 00:01'	System	19 Nov 2020 21:39:34

**US3612005**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:15:23**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:39:34
Amendment Manager: User entered '03 May 2021 23:59'	System	19 Nov 2020 21:39:34

**US3612005**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:15:23**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:39:34
Amendment Manager: User entered 'Day 250'	System	19 Nov 2020 21:39:34

**US3612005**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:15:23**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:39:34
Amendment Manager: User entered '06 May 2021 00:01'	System	19 Nov 2020 21:39:34

**US3612005**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:15:23**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:39:34
Amendment Manager: User entered '10 May 2021 23:59'	System	19 Nov 2020 21:39:34

**US3612005**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:15:23**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:39:34
Amendment Manager: User entered 'Day 257'	System	19 Nov 2020 21:39:34

**US3612005**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:15:23**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:39:34
Amendment Manager: User entered '13 May 2021 00:01'	System	19 Nov 2020 21:39:34

**US3612005**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:15:23**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:39:34
Amendment Manager: User entered '17 May 2021 23:59'	System	19 Nov 2020 21:39:34

**US3612005**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:15:23**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:39:34
Amendment Manager: User entered 'Day 264'	System	19 Nov 2020 21:39:34

**US3612005**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:15:23**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:39:34
Amendment Manager: User entered '20 May 2021 00:01'	System	19 Nov 2020 21:39:34

**US3612005**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:15:23**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:39:34
Amendment Manager: User entered '24 May 2021 23:59'	System	19 Nov 2020 21:39:34

**US3612005**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:15:23**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:39:34
Amendment Manager: User entered 'Day 271'	System	19 Nov 2020 21:39:34

**US3612005**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:15:23**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:39:34
Amendment Manager: User entered '27 May 2021 00:01'	System	19 Nov 2020 21:39:34

**US3612005**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:15:23**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:39:34
Amendment Manager: User entered '31 May 2021 23:59'	System	19 Nov 2020 21:39:34

**US3612005**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:15:23**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:39:34
Amendment Manager: User entered 'Day 278'	System	19 Nov 2020 21:39:34

**US3612005**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:15:23**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:39:34
Amendment Manager: User entered '03 Jun 2021 00:01'	System	19 Nov 2020 21:39:34

**US3612005**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:15:23**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:39:34
Amendment Manager: User entered '07 Jun 2021 23:59'	System	19 Nov 2020 21:39:34

**US3612005**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:15:23**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:39:34
Amendment Manager: User entered 'Day 285'	System	19 Nov 2020 21:39:34

**US3612005**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:15:23**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:39:34
Amendment Manager: User entered '10 Jun 2021 00:01'	System	19 Nov 2020 21:39:34

**US3612005**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:15:23**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:39:34
Amendment Manager: User entered '14 Jun 2021 23:59'	System	19 Nov 2020 21:39:34

**US3612005**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:15:23**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:39:34
Amendment Manager: User entered 'Day 292'	System	19 Nov 2020 21:39:34

**US3612005**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:15:23**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:39:34
Amendment Manager: User entered '17 Jun 2021 00:01'	System	19 Nov 2020 21:39:34

**US3612005**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:15:23**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:39:34
Amendment Manager: User entered '21 Jun 2021 23:59'	System	19 Nov 2020 21:39:34

**US3612005**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:15:23**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:39:34
Amendment Manager: User entered 'Day 299'	System	19 Nov 2020 21:39:34

**US3612005**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:15:23**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:39:34
Amendment Manager: User entered '24 Jun 2021 00:01'	System	19 Nov 2020 21:39:34

**US3612005**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:15:23**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:39:34
Amendment Manager: User entered '28 Jun 2021 23:59'	System	19 Nov 2020 21:39:34

**US3612005**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:15:23**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:39:34
Amendment Manager: User entered 'Day 306'	System	19 Nov 2020 21:39:34

**US3612005**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:15:23**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:39:34
Amendment Manager: User entered '01 Jul 2021 00:01'	System	19 Nov 2020 21:39:34

**US3612005**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:15:23**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:39:34
Amendment Manager: User entered '05 Jul 2021 23:59'	System	19 Nov 2020 21:39:34

**US3612005**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:15:23**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:39:34
Amendment Manager: User entered 'Day 313'	System	19 Nov 2020 21:39:34

**US3612005**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:15:23**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:39:34
Amendment Manager: User entered '08 Jul 2021 00:01'	System	19 Nov 2020 21:39:34

**US3612005**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:15:23**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:39:34
Amendment Manager: User entered '12 Jul 2021 23:59'	System	19 Nov 2020 21:39:34

**US3612005**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:15:23**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:39:34
Amendment Manager: User entered 'Day 320'	System	19 Nov 2020 21:39:34

**US3612005**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:15:23**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:39:34
Amendment Manager: User entered '15 Jul 2021 00:01'	System	19 Nov 2020 21:39:34

**US3612005**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:15:23**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:39:34
Amendment Manager: User entered '19 Jul 2021 23:59'	System	19 Nov 2020 21:39:34

**US3612005**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:15:23**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:39:34
Amendment Manager: User entered 'Day 327'	System	19 Nov 2020 21:39:34

**US3612005**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:15:23**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:39:34
Amendment Manager: User entered '22 Jul 2021 00:01'	System	19 Nov 2020 21:39:34

**US3612005**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:15:23**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:39:34
Amendment Manager: User entered '26 Jul 2021 23:59'	System	19 Nov 2020 21:39:34

**US3612005**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:15:23**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:39:34
Amendment Manager: User entered 'Day 334'	System	19 Nov 2020 21:39:34

**US3612005**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:15:23**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:39:34
Amendment Manager: User entered '29 Jul 2021 00:01'	System	19 Nov 2020 21:39:34

**US3612005**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:15:23**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:39:34
Amendment Manager: User entered '02 Aug 2021 23:59'	System	19 Nov 2020 21:39:34

**US3612005**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:15:23**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:39:34
Amendment Manager: User entered 'Day 341'	System	19 Nov 2020 21:39:34

**US3612005**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:15:23**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:39:34
Amendment Manager: User entered '05 Aug 2021 00:01'	System	19 Nov 2020 21:39:34

**US3612005**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:15:23**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:39:34
Amendment Manager: User entered '09 Aug 2021 23:59'	System	19 Nov 2020 21:39:34

**US3612005**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:15:23**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:39:34
Amendment Manager: User entered 'Day 348'	System	19 Nov 2020 21:39:34

**US3612005**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:15:23**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:39:34
Amendment Manager: User entered '12 Aug 2021 00:01'	System	19 Nov 2020 21:39:34

**US3612005**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:15:23**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:39:34
Amendment Manager: User entered '16 Aug 2021 23:59'	System	19 Nov 2020 21:39:34

**US3612005**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:15:23**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:39:34
Amendment Manager: User entered 'Day 355'	System	19 Nov 2020 21:39:34

**US3612005**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:15:23**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:39:34
Amendment Manager: User entered '19 Aug 2021 00:01'	System	19 Nov 2020 21:39:34

**US3612005**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:15:23**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:39:34
Amendment Manager: User entered '23 Aug 2021 23:59'	System	19 Nov 2020 21:39:34

**US3612005**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:15:23**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:39:34
Amendment Manager: User entered 'Day 362'	System	19 Nov 2020 21:39:34

**US3612005**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:15:23**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:39:34
Amendment Manager: User entered '26 Aug 2021 00:01'	System	19 Nov 2020 21:39:34

**US3612005**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:15:23**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:39:34
Amendment Manager: User entered '30 Aug 2021 23:59'	System	19 Nov 2020 21:39:34

**US3612005**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:15:23**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:39:34
Amendment Manager: User entered 'Day 369'	System	19 Nov 2020 21:39:34

**US3612005**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:15:23**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:39:34
Amendment Manager: User entered '02 Sep 2021 00:01'	System	19 Nov 2020 21:39:34

**US3612005**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:15:23**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:39:34
Amendment Manager: User entered '06 Sep 2021 23:59'	System	19 Nov 2020 21:39:34

**US3612005**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:15:23**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:39:34
Amendment Manager: User entered 'Day 376'	System	19 Nov 2020 21:39:34

**US3612005**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:15:23**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:39:34
Amendment Manager: User entered '09 Sep 2021 00:01'	System	19 Nov 2020 21:39:34

**US3612005**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:15:23**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:39:34
Amendment Manager: User entered '13 Sep 2021 23:59'	System	19 Nov 2020 21:39:34

**US3612005**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:15:23**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:39:34
Amendment Manager: User entered 'Day 383'	System	19 Nov 2020 21:39:34

**US3612005**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:15:23**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:39:34
Amendment Manager: User entered '16 Sep 2021 00:01'	System	19 Nov 2020 21:39:34

**US3612005**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:15:23**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:39:34
Amendment Manager: User entered '20 Sep 2021 23:59'	System	19 Nov 2020 21:39:34

**US3612005**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:15:23**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:39:34
Amendment Manager: User entered 'Day 390'	System	19 Nov 2020 21:39:34

**US3612005**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:15:23**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:39:34
Amendment Manager: User entered '23 Sep 2021 00:01'	System	19 Nov 2020 21:39:34

**US3612005**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:15:23**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:39:34
Amendment Manager: User entered '27 Sep 2021 23:59'	System	19 Nov 2020 21:39:34

**US3612005**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:15:23**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:39:34
Amendment Manager: User entered 'Day 397'	System	19 Nov 2020 21:39:34

**US3612005**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:15:23**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:39:34
Amendment Manager: User entered '30 Sep 2021 00:01'	System	19 Nov 2020 21:39:34

**US3612005**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:15:23**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:39:34
Amendment Manager: User entered '04 Oct 2021 23:59'	System	19 Nov 2020 21:39:34

**US3612005**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:15:23**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:39:34
Amendment Manager: User entered 'Day 404'	System	19 Nov 2020 21:39:34

**US3612005**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:15:23**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:39:34
Amendment Manager: User entered '07 Oct 2021 00:01'	System	19 Nov 2020 21:39:34

**US3612005**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:15:23**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:39:34
Amendment Manager: User entered '11 Oct 2021 23:59'	System	19 Nov 2020 21:39:34

**US3612005**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:15:23**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:39:34
Amendment Manager: User entered 'Day 411'	System	19 Nov 2020 21:39:34

**US3612005**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:15:23**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:39:34
Amendment Manager: User entered '14 Oct 2021 00:01'	System	19 Nov 2020 21:39:34

**US3612005**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:15:23**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:39:34
Amendment Manager: User entered '18 Oct 2021 23:59'	System	19 Nov 2020 21:39:34

**US3612005**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:15:23**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:39:34
Amendment Manager: User entered 'Day 418'	System	19 Nov 2020 21:39:34

**US3612005**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:15:23**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:39:34
Amendment Manager: User entered '21 Oct 2021 00:01'	System	19 Nov 2020 21:39:34

**US3612005**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:15:23**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:39:34
Amendment Manager: User entered '25 Oct 2021 23:59'	System	19 Nov 2020 21:39:34

**US3612005**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:15:23**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:39:34
Amendment Manager: User entered 'Day 425'	System	19 Nov 2020 21:39:34

**US3612005**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:15:23**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:39:34
Amendment Manager: User entered '28 Oct 2021 00:01'	System	19 Nov 2020 21:39:34

**US3612005**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:15:23**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:39:34
Amendment Manager: User entered '01 Nov 2021 23:59'	System	19 Nov 2020 21:39:34

**US3612005**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:15:23**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:39:34
Amendment Manager: User entered 'Day 432'	System	19 Nov 2020 21:39:34

**US3612005**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:15:23**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:39:34
Amendment Manager: User entered '04 Nov 2021 00:01'	System	19 Nov 2020 21:39:34

**US3612005**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:15:23**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:39:34
Amendment Manager: User entered '08 Nov 2021 23:59'	System	19 Nov 2020 21:39:34

**US3612005**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:15:23**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:39:34
Amendment Manager: User entered 'Day 439'	System	19 Nov 2020 21:39:34

**US3612005**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:15:23**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:39:34
Amendment Manager: User entered '11 Nov 2021 00:01'	System	19 Nov 2020 21:39:34

**US3612005**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:15:23**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:39:34
Amendment Manager: User entered '15 Nov 2021 23:59'	System	19 Nov 2020 21:39:34

**US3612005**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:15:23**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:39:34
Amendment Manager: User entered 'Day 446'	System	19 Nov 2020 21:39:34

**US3612005**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:15:23**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:39:34
Amendment Manager: User entered '18 Nov 2021 00:01'	System	19 Nov 2020 21:39:34

**US3612005**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:15:23**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:39:34
Amendment Manager: User entered '22 Nov 2021 23:59'	System	19 Nov 2020 21:39:34

**US3612005**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:15:23**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:39:34
Amendment Manager: User entered 'Day 453'	System	19 Nov 2020 21:39:34

**US3612005**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:15:23**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:39:34
Amendment Manager: User entered '25 Nov 2021 00:01'	System	19 Nov 2020 21:39:34

**US3612005**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:15:23**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:39:34
Amendment Manager: User entered '29 Nov 2021 23:59'	System	19 Nov 2020 21:39:34

**US3612005**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:15:23**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:39:34
Amendment Manager: User entered 'Day 460'	System	19 Nov 2020 21:39:34

**US3612005**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:15:23**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:39:34
Amendment Manager: User entered '02 Dec 2021 00:01'	System	19 Nov 2020 21:39:34

**US3612005**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:15:23**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:39:34
Amendment Manager: User entered '06 Dec 2021 23:59'	System	19 Nov 2020 21:39:34

**US3612005**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:15:23**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:39:34
Amendment Manager: User entered 'Day 467'	System	19 Nov 2020 21:39:34

**US3612005**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:15:23**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:39:34
Amendment Manager: User entered '09 Dec 2021 00:01'	System	19 Nov 2020 21:39:34

**US3612005**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:15:23**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:39:34
Amendment Manager: User entered '13 Dec 2021 23:59'	System	19 Nov 2020 21:39:34

**US3612005**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:15:23**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:39:34
Amendment Manager: User entered 'Day 474'	System	19 Nov 2020 21:39:34

**US3612005**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:15:23**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:39:34
Amendment Manager: User entered '16 Dec 2021 00:01'	System	19 Nov 2020 21:39:34

**US3612005**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:15:23**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:39:34
Amendment Manager: User entered '20 Dec 2021 23:59'	System	19 Nov 2020 21:39:34

**US3612005**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:15:23**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:39:34
Amendment Manager: User entered 'Day 481'	System	19 Nov 2020 21:39:34

**US3612005**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:15:23**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:39:34
Amendment Manager: User entered '23 Dec 2021 00:01'	System	19 Nov 2020 21:39:34

**US3612005**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:15:23**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:39:34
Amendment Manager: User entered '27 Dec 2021 23:59'	System	19 Nov 2020 21:39:34

**US3612005**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:15:23**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:39:34
Amendment Manager: User entered 'Day 488'	System	19 Nov 2020 21:39:34

**US3612005**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:15:23**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:39:34
Amendment Manager: User entered '30 Dec 2021 00:01'	System	19 Nov 2020 21:39:34

**US3612005**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:15:23**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:39:34
Amendment Manager: User entered '03 Jan 2022 23:59'	System	19 Nov 2020 21:39:34

**US3612005**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:15:23**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:39:34
Amendment Manager: User entered 'Day 495'	System	19 Nov 2020 21:39:34

**US3612005**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:15:23**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:39:34
Amendment Manager: User entered '06 Jan 2022 00:01'	System	19 Nov 2020 21:39:34

**US3612005**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:15:23**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:39:34
Amendment Manager: User entered '10 Jan 2022 23:59'	System	19 Nov 2020 21:39:34

**US3612005**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:15:23**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:39:34
Amendment Manager: User entered 'Day 502'	System	19 Nov 2020 21:39:34

**US3612005**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:15:23**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:39:34
Amendment Manager: User entered '13 Jan 2022 00:01'	System	19 Nov 2020 21:39:34

**US3612005**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:15:23**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:39:34
Amendment Manager: User entered '17 Jan 2022 23:59'	System	19 Nov 2020 21:39:34

**US3612005**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:15:23**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:39:34
Amendment Manager: User entered 'Day 509'	System	19 Nov 2020 21:39:34

**US3612005**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:15:23**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:39:34
Amendment Manager: User entered '20 Jan 2022 00:01'	System	19 Nov 2020 21:39:34

**US3612005**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:15:23**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:39:34
Amendment Manager: User entered '24 Jan 2022 23:59'	System	19 Nov 2020 21:39:34

**US3612005**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:15:23**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:39:34
Amendment Manager: User entered 'Day 516'	System	19 Nov 2020 21:39:34

**US3612005**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:15:23**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:39:34
Amendment Manager: User entered '27 Jan 2022 00:01'	System	19 Nov 2020 21:39:34

**US3612005**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:15:23**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:39:34
Amendment Manager: User entered '31 Jan 2022 23:59'	System	19 Nov 2020 21:39:34

**US3612005**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:15:23**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:39:34
Amendment Manager: User entered 'Day 523'	System	19 Nov 2020 21:39:34

**US3612005**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:15:23**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:39:34
Amendment Manager: User entered '03 Feb 2022 00:01'	System	19 Nov 2020 21:39:34

**US3612005**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:15:23**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:39:34
Amendment Manager: User entered '07 Feb 2022 23:59'	System	19 Nov 2020 21:39:34

**US3612005**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:15:23**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:39:34
Amendment Manager: User entered 'Day 530'	System	19 Nov 2020 21:39:34

**US3612005**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:15:23**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:39:34
Amendment Manager: User entered '10 Feb 2022 00:01'	System	19 Nov 2020 21:39:34

**US3612005**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:15:23**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:39:34
Amendment Manager: User entered '14 Feb 2022 23:59'	System	19 Nov 2020 21:39:34

**US3612005**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:15:23**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:39:34
Amendment Manager: User entered 'Day 537'	System	19 Nov 2020 21:39:34

**US3612005**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:15:23**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:39:34
Amendment Manager: User entered '17 Feb 2022 00:01'	System	19 Nov 2020 21:39:34

**US3612005**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:15:23**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:39:34
Amendment Manager: User entered '21 Feb 2022 23:59'	System	19 Nov 2020 21:39:34

**US3612005**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:15:23**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:39:34
Amendment Manager: User entered 'Day 544'	System	19 Nov 2020 21:39:34

**US3612005**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:15:23**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:39:34
Amendment Manager: User entered '24 Feb 2022 00:01'	System	19 Nov 2020 21:39:34

**US3612005**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:15:23**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:39:34
Amendment Manager: User entered '28 Feb 2022 23:59'	System	19 Nov 2020 21:39:34

**US3612005**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:15:23**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:39:34
Amendment Manager: User entered 'Day 551'	System	19 Nov 2020 21:39:34

**US3612005**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:15:23**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:39:34
Amendment Manager: User entered '03 Mar 2022 00:01'	System	19 Nov 2020 21:39:34

**US3612005**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:15:23**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:39:34
Amendment Manager: User entered '07 Mar 2022 23:59'	System	19 Nov 2020 21:39:34

**US3612005**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:15:23**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:39:34
Amendment Manager: User entered 'Day 558'	System	19 Nov 2020 21:39:34

**US3612005**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:15:23**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:39:34
Amendment Manager: User entered '10 Mar 2022 00:01'	System	19 Nov 2020 21:39:34

**US3612005**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:15:23**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:39:34
Amendment Manager: User entered '14 Mar 2022 23:59'	System	19 Nov 2020 21:39:34

**US3612005**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:15:23**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:39:34
Amendment Manager: User entered 'Day 565'	System	19 Nov 2020 21:39:34

**US3612005**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:15:23**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:39:34
Amendment Manager: User entered '17 Mar 2022 00:01'	System	19 Nov 2020 21:39:34

**US3612005**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:15:23**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:39:34
Amendment Manager: User entered '21 Mar 2022 23:59'	System	19 Nov 2020 21:39:34

**US3612005**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:15:23**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:39:34
Amendment Manager: User entered 'Day 572'	System	19 Nov 2020 21:39:34

**US3612005**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:15:23**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:39:34
Amendment Manager: User entered '24 Mar 2022 00:01'	System	19 Nov 2020 21:39:34

**US3612005**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:15:23**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:39:34
Amendment Manager: User entered '28 Mar 2022 23:59'	System	19 Nov 2020 21:39:34

**US3612005**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:15:23**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:39:34
Amendment Manager: User entered 'Day 579'	System	19 Nov 2020 21:39:34

**US3612005**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:15:23**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:39:34
Amendment Manager: User entered '31 Mar 2022 00:01'	System	19 Nov 2020 21:39:34

**US3612005**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:15:23**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:39:34
Amendment Manager: User entered '04 Apr 2022 23:59'	System	19 Nov 2020 21:39:34

**US3612005**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:15:23**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:39:34
Amendment Manager: User entered 'Day 586'	System	19 Nov 2020 21:39:34

**US3612005**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:15:23**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:39:34
Amendment Manager: User entered '07 Apr 2022 00:01'	System	19 Nov 2020 21:39:34

**US3612005**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:15:23**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:39:34
Amendment Manager: User entered '11 Apr 2022 23:59'	System	19 Nov 2020 21:39:34

**US3612005**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:15:23**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:39:34
Amendment Manager: User entered 'Day 593'	System	19 Nov 2020 21:39:34

**US3612005**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:15:23**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:39:34
Amendment Manager: User entered '14 Apr 2022 00:01'	System	19 Nov 2020 21:39:34

**US3612005**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:15:23**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:39:34
Amendment Manager: User entered '18 Apr 2022 23:59'	System	19 Nov 2020 21:39:34

**US3612005**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:15:23**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:39:34
Amendment Manager: User entered 'Day 600'	System	19 Nov 2020 21:39:34

**US3612005**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:15:23**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:39:34
Amendment Manager: User entered '21 Apr 2022 00:01'	System	19 Nov 2020 21:39:34

**US3612005**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:15:23**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:39:34
Amendment Manager: User entered '25 Apr 2022 23:59'	System	19 Nov 2020 21:39:34

**US3612005**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:15:23**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:39:34
Amendment Manager: User entered 'Day 607'	System	19 Nov 2020 21:39:34

**US3612005**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:15:23**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:39:34
Amendment Manager: User entered '28 Apr 2022 00:01'	System	19 Nov 2020 21:39:34

**US3612005**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:15:23**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:39:34
Amendment Manager: User entered '02 May 2022 23:59'	System	19 Nov 2020 21:39:34

**US3612005**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:15:23**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:39:34
Amendment Manager: User entered 'Day 614'	System	19 Nov 2020 21:39:34

**US3612005**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:15:23**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:39:34
Amendment Manager: User entered '05 May 2022 00:01'	System	19 Nov 2020 21:39:34

**US3612005**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:15:23**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:39:34
Amendment Manager: User entered '09 May 2022 23:59'	System	19 Nov 2020 21:39:34

**US3612005**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:15:23**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:39:34
Amendment Manager: User entered 'Day 621'	System	19 Nov 2020 21:39:34

**US3612005**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:15:23**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:39:34
Amendment Manager: User entered '12 May 2022 00:01'	System	19 Nov 2020 21:39:34

**US3612005**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:15:23**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:39:34
Amendment Manager: User entered '16 May 2022 23:59'	System	19 Nov 2020 21:39:34

**US3612005**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:15:23**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:39:34
Amendment Manager: User entered 'Day 628'	System	19 Nov 2020 21:39:34

**US3612005**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:15:23**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:39:34
Amendment Manager: User entered '19 May 2022 00:01'	System	19 Nov 2020 21:39:34

**US3612005**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:15:23**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:39:34
Amendment Manager: User entered '23 May 2022 23:59'	System	19 Nov 2020 21:39:34

**US3612005**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:15:23**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:39:34
Amendment Manager: User entered 'Day 635'	System	19 Nov 2020 21:39:34

**US3612005**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:15:23**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:39:34
Amendment Manager: User entered '26 May 2022 00:01'	System	19 Nov 2020 21:39:34

**US3612005**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:15:23**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:39:34
Amendment Manager: User entered '30 May 2022 23:59'	System	19 Nov 2020 21:39:34

**US3612005**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:15:23**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:39:34
Amendment Manager: User entered 'Day 642'	System	19 Nov 2020 21:39:34

**US3612005**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:15:23**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:39:34
Amendment Manager: User entered '02 Jun 2022 00:01'	System	19 Nov 2020 21:39:34

**US3612005**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:15:23**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:39:34
Amendment Manager: User entered '06 Jun 2022 23:59'	System	19 Nov 2020 21:39:34

**US3612005**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:15:23**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:39:34
Amendment Manager: User entered 'Day 649'	System	19 Nov 2020 21:39:34

**US3612005**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:15:23**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:39:34
Amendment Manager: User entered '09 Jun 2022 00:01'	System	19 Nov 2020 21:39:34

**US3612005**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:15:23**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:39:34
Amendment Manager: User entered '13 Jun 2022 23:59'	System	19 Nov 2020 21:39:34

**US3612005**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:15:23**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:39:34
Amendment Manager: User entered 'Day 656'	System	19 Nov 2020 21:39:34

**US3612005**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:15:23**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:39:34
Amendment Manager: User entered '16 Jun 2022 00:01'	System	19 Nov 2020 21:39:34

**US3612005**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:15:23**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:39:34
Amendment Manager: User entered '20 Jun 2022 23:59'	System	19 Nov 2020 21:39:34

**US3612005**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:15:23**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:39:34
Amendment Manager: User entered 'Day 663'	System	19 Nov 2020 21:39:34

**US3612005**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:15:23**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:39:34
Amendment Manager: User entered '23 Jun 2022 00:01'	System	19 Nov 2020 21:39:34

**US3612005**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:15:23**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:39:34
Amendment Manager: User entered '27 Jun 2022 23:59'	System	19 Nov 2020 21:39:34

**US3612005**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:15:23**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:39:34
Amendment Manager: User entered 'Day 670'	System	19 Nov 2020 21:39:34

**US3612005**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:15:23**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:39:34
Amendment Manager: User entered '30 Jun 2022 00:01'	System	19 Nov 2020 21:39:34

**US3612005**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:15:23**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:39:34
Amendment Manager: User entered '04 Jul 2022 23:59'	System	19 Nov 2020 21:39:34

**US3612005**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:15:23**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:39:34
Amendment Manager: User entered 'Day 677'	System	19 Nov 2020 21:39:34

**US3612005**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:15:23**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:39:34
Amendment Manager: User entered '07 Jul 2022 00:01'	System	19 Nov 2020 21:39:34

**US3612005**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:15:23**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:39:34
Amendment Manager: User entered '11 Jul 2022 23:59'	System	19 Nov 2020 21:39:34

**US3612005**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:15:23**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:39:34
Amendment Manager: User entered 'Day 684'	System	19 Nov 2020 21:39:34

**US3612005**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:15:23**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:39:34
Amendment Manager: User entered '14 Jul 2022 00:01'	System	19 Nov 2020 21:39:34

**US3612005**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:15:23**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:39:34
Amendment Manager: User entered '18 Jul 2022 23:59'	System	19 Nov 2020 21:39:34

**US3612005**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:15:23**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:39:34
Amendment Manager: User entered 'Day 691'	System	19 Nov 2020 21:39:34

**US3612005**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:15:23**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:39:34
Amendment Manager: User entered '21 Jul 2022 00:01'	System	19 Nov 2020 21:39:34

**US3612005**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:15:23**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:39:34
Amendment Manager: User entered '25 Jul 2022 23:59'	System	19 Nov 2020 21:39:34

**US3612005**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:15:23**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:39:34
Amendment Manager: User entered 'Day 698'	System	19 Nov 2020 21:39:34

**US3612005**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:15:23**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:39:34
Amendment Manager: User entered '28 Jul 2022 00:01'	System	19 Nov 2020 21:39:34

**US3612005**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:15:23**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:39:34
Amendment Manager: User entered '01 Aug 2022 23:59'	System	19 Nov 2020 21:39:34

**US3612005**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:15:23**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:39:34
Amendment Manager: User entered 'Day 705'	System	19 Nov 2020 21:39:34

**US3612005**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:15:23**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:39:34
Amendment Manager: User entered '04 Aug 2022 00:01'	System	19 Nov 2020 21:39:34

**US3612005**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:15:23**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:39:34
Amendment Manager: User entered '08 Aug 2022 23:59'	System	19 Nov 2020 21:39:34

**US3612005**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:15:23**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:39:34
Amendment Manager: User entered 'Day 712'	System	19 Nov 2020 21:39:34

**US3612005**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:15:23**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:39:34
Amendment Manager: User entered '11 Aug 2022 00:01'	System	19 Nov 2020 21:39:34

**US3612005**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:15:23**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:39:34
Amendment Manager: User entered '15 Aug 2022 23:59'	System	19 Nov 2020 21:39:34

**US3612005**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:15:23**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:39:34
Amendment Manager: User entered 'Day 719'	System	19 Nov 2020 21:39:34

**US3612005**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:15:23**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:39:34
Amendment Manager: User entered '18 Aug 2022 00:01'	System	19 Nov 2020 21:39:34

**US3612005**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:15:23**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:39:34
Amendment Manager: User entered '22 Aug 2022 23:59'	System	19 Nov 2020 21:39:34

**US3612005**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:15:23**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:39:34
Amendment Manager: User entered 'Day 726'	System	19 Nov 2020 21:39:34

**US3612005**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:15:23**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:39:34
Amendment Manager: User entered '25 Aug 2022 00:01'	System	19 Nov 2020 21:39:34

**US3612005**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:15:23**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:39:34
Amendment Manager: User entered '29 Aug 2022 23:59'	System	19 Nov 2020 21:39:34

**US3612005**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:15:23**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:39:34
Amendment Manager: User entered 'Day 733'	System	19 Nov 2020 21:39:34

**US3612005**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:15:23**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:39:34
Amendment Manager: User entered '01 Sep 2022 00:01'	System	19 Nov 2020 21:39:34

**US3612005**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:15:23**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:39:34
Amendment Manager: User entered '05 Sep 2022 23:59'	System	19 Nov 2020 21:39:34

**US3612005**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:15:23**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:39:34
Amendment Manager: User entered 'Day 740'	System	19 Nov 2020 21:39:34

**US3612005**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:15:23**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:39:34
Amendment Manager: User entered '08 Sep 2022 00:01'	System	19 Nov 2020 21:39:34

**US3612005**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:15:23**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:39:34
Amendment Manager: User entered '12 Sep 2022 23:59'	System	19 Nov 2020 21:39:34

**US3612005**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:15:23**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:39:34
Amendment Manager: User entered 'Day 747'	System	19 Nov 2020 21:39:34

**US3612005**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:15:23**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:39:34
Amendment Manager: User entered '15 Sep 2022 00:01'	System	19 Nov 2020 21:39:34

**US3612005**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:15:23**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:39:34
Amendment Manager: User entered '19 Sep 2022 23:59'	System	19 Nov 2020 21:39:34

**US3612005**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:15:23**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:39:34
Amendment Manager: User entered 'Day 754'	System	19 Nov 2020 21:39:34

**US3612005**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:15:23**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:39:34
Amendment Manager: User entered '22 Sep 2022 00:01'	System	19 Nov 2020 21:39:34

**US3612005**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:15:23**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:39:34
Amendment Manager: User entered '26 Sep 2022 23:59'	System	19 Nov 2020 21:39:34

**US3612005**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:15:23**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:39:34
Amendment Manager: User entered 'Day 761'	System	19 Nov 2020 21:39:34

**US3612005**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:15:23**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:39:34
Amendment Manager: User entered '29 Sep 2022 00:01'	System	19 Nov 2020 21:39:34

**US3612005**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:15:23**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:39:34
Amendment Manager: User entered '03 Oct 2022 23:59'	System	19 Nov 2020 21:39:34

**US3612005**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:15:23**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:39:34
Amendment Manager: User entered 'Day 768'	System	19 Nov 2020 21:39:34

**US3612005**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:15:23**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:39:34
Amendment Manager: User entered '06 Oct 2022 00:01'	System	19 Nov 2020 21:39:34

**US3612005**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:15:23**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:39:34
Amendment Manager: User entered '10 Oct 2022 23:59'	System	19 Nov 2020 21:39:34

**US3612005**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:15:23**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:39:34
Amendment Manager: User entered 'Day 775'	System	19 Nov 2020 21:39:34

**US3612005**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:15:23**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:39:34
Amendment Manager: User entered '13 Oct 2022 00:01'	System	19 Nov 2020 21:39:34

**US3612005**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:15:23**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:39:34
Amendment Manager: User entered '17 Oct 2022 23:59'	System	19 Nov 2020 21:39:34

**US3612005**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:15:23**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:39:34
Amendment Manager: User entered 'Day 782'	System	19 Nov 2020 21:39:34

**US3612005**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:15:23**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:39:34
Amendment Manager: User entered '20 Oct 2022 00:01'	System	19 Nov 2020 21:39:34

**US3612005**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:15:23**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:39:34
Amendment Manager: User entered '24 Oct 2022 23:59'	System	19 Nov 2020 21:39:34

**US3612005**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:15:23**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:39:34
Amendment Manager: User entered 'Day 789'	System	19 Nov 2020 21:39:34

**US3612005**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:15:23**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:39:34
Amendment Manager: User entered '27 Oct 2022 00:01'	System	19 Nov 2020 21:39:34

**US3612005**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:15:23**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:39:34
Amendment Manager: User entered '31 Oct 2022 23:59'	System	19 Nov 2020 21:39:34

**US3612005**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:15:23**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:39:34
Amendment Manager: User entered 'Day 796'	System	19 Nov 2020 21:39:34

**US3612005**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:15:23**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:39:34
Amendment Manager: User entered '03 Nov 2022 00:01'	System	19 Nov 2020 21:39:34

**US3612005**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:15:23**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:39:34
Amendment Manager: User entered '07 Nov 2022 23:59'	System	19 Nov 2020 21:39:34

US3612005

Folder: Cosmetic Injections and Dermal Fillers

Form: Cosmetic Injection\_ Dermal Filler eDiary (1)

Generated On: 10 Jun 2021 09:15:23

Have you ever received facial cosmetic injections, such as Juvederm, Voluma, Radiesse, Restylane, Botox or other?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:49:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a19c168458d97dd9)', Time: '2021-03-19T23:55:17-05:00', User OID: 'PatientReportedOutcome (US3612005)', ODM File OID: 'c0b68aa7-77dd-4672-901a-89670baf5e9a'	System	20 Mar 2021 04:55:27
User entered 'No (N)'	System	20 Mar 2021 04:55:27

**US3612005**

**Folder: Cosmetic Injections and Dermal Fillers**

**Form: Cosmetic Injection\_ Dermal Filler eDiary (1)**

**Generated On: 10 Jun 2021 09:15:23**

[Date & Time of Submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:49:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a19c168458d97dd9)', Time: '2021-03-19T23:55:23-05:00', User OID: 'PatientReportedOutcome (US3612005)', ODM File OID: 'c0b68aa7-77dd-4672-901a-89670baf5e9a' User entered '19 Mar 2021 23:55:23'	System	20 Mar 2021 04:55:27
	System	20 Mar 2021 04:55:27

**US3612005**

**Folder: Safety Call Day 85 (1)**

**Form: Safety Call**

**Generated On: 10 Jun 2021 09:15:23**

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 22:42:32
User signature succeeded.	Richard Rupp (b) (4)	05 Mar 2021 19:39:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Dec 2020 16:18:45
User entered 'Yes (Y)'	Amber Stanford (b) (4) (b) (4)	24 Nov 2020 21:50:28

**US3612005**

**Folder: Safety Call Day 85 (1)**

**Form: Safety Call**

**Generated On: 10 Jun 2021 09:15:23**

[Date of Contact or Contact Attempt \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 22:42:32
User signature succeeded.	Richard Rupp (b) (4)	05 Mar 2021 19:39:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Dec 2020 16:18:45
User entered '24 Nov 2020'	Amber Stanford (b) (4) (b) (4)	24 Nov 2020 21:50:28

**US3612005**

**Folder: Safety Call Day 85 (1)**

**Form: Safety Call**

**Generated On: 10 Jun 2021 09:15:23**

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 22:42:32
User signature succeeded.	Richard Rupp (b) (4)	05 Mar 2021 19:39:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Dec 2020 16:18:45
User entered 'Contact Made (CONTACT MADE)'	Amber Stanford (b) (4) (b) (4)	24 Nov 2020 21:50:28

**US3612005**

**Folder: Safety Call Day 85 (1)**

**Form: Safety Call**

**Generated On: 10 Jun 2021 09:15:23**

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 22:42:32
User signature succeeded.	Richard Rupp (b) (4)	05 Mar 2021 19:39:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Dec 2020 16:18:45
User entered empty.	Amber Stanford (b) (4) (b) (4)	24 Nov 2020 21:50:28

**US3612005**

**Folder: Safety Call Day 85 (1)**

**Form: Continuing**

**Generated On: 10 Jun 2021 09:15:23**

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 22:42:32
User signature succeeded.	Richard Rupp (b) (4)	05 Mar 2021 19:39:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Dec 2020 16:22:31
User entered 'Yes (Y)'	Amber Stanford (b) (4) (b) (4)	24 Nov 2020 21:50:32

**US3612005**

**Folder: Safety Call Day 85 (1)**

**Form: Continuing**

**Generated On: 10 Jun 2021 09:15:23**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 22:42:32
User entered 'I'	System	24 Nov 2020 21:50:32

**US3612005**

**Folder: Safety Call Day 119 (1)**

**Form: Safety Call**

**Generated On: 10 Jun 2021 09:15:23**

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 17:27:48
User signature succeeded.	Richard Rupp (b) (4)	26 Mar 2021 18:58:13
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Mar 2021 16:43:29
User entered 'Yes (Y)'	Amber Stanford (b) (4) (b) (4)	31 Dec 2020 23:01:09

**US3612005**

**Folder: Safety Call Day 119 (1)**

**Form: Safety Call**

**Generated On: 10 Jun 2021 09:15:23**

[Date of Contact or Contact Attempt \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 17:27:48
User signature succeeded.	Richard Rupp (b) (4)	26 Mar 2021 18:58:13
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Mar 2021 16:43:29
User entered '30 Dec 2020'	Amber Stanford (b) (4) (b) (4)	31 Dec 2020 23:01:09

**US3612005**

**Folder: Safety Call Day 119 (1)**

**Form: Safety Call**

**Generated On: 10 Jun 2021 09:15:23**

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 17:27:48
User signature succeeded.	Richard Rupp (b) (4)	26 Mar 2021 18:58:13
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Mar 2021 16:43:29
User entered 'Contact Made (CONTACT MADE)'	Amber Stanford (b) (4) (b) (4)	31 Dec 2020 23:01:09

**US3612005**

**Folder: Safety Call Day 119 (1)**

**Form: Safety Call**

**Generated On: 10 Jun 2021 09:15:23**

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 17:27:48
User signature succeeded.	Richard Rupp (b) (4)	26 Mar 2021 18:58:13
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Mar 2021 16:43:29
User entered empty.	Amber Stanford (b) (4) (b) (4)	31 Dec 2020 23:01:09

**US3612005**

**Folder: Safety Call Day 119 (1)**

**Form: Continuing**

**Generated On: 10 Jun 2021 09:15:23**

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 17:27:48
User signature succeeded.	Richard Rupp (b) (4)	26 Mar 2021 18:58:13
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Mar 2021 16:46:49
User entered 'Yes (Y)'	Amber Stanford (b) (4) (b) (4)	31 Dec 2020 23:01:13

**US3612005**

**Folder: Safety Call Day 119 (1)**

**Form: Continuing**

**Generated On: 10 Jun 2021 09:15:23**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 17:27:48
User entered 'I'	System	31 Dec 2020 23:01:13

**US3612005**

**Folder: Safety Call Day 149 (1)**

**Form: Safety Call**

**Generated On: 10 Jun 2021 09:15:23**

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 17:27:48
User signature succeeded.	Richard Rupp (b) (4)	26 Mar 2021 18:58:13
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Feb 2021 20:22:45
User entered 'Yes (Y)'	Amber Stanford (b) (4) (b) (4)	29 Jan 2021 21:02:23

**US3612005**

**Folder: Safety Call Day 149 (1)**

**Form: Safety Call**

**Generated On: 10 Jun 2021 09:15:23**

**Date of Contact or Contact Attempt (dd MMM yyyy)**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 17:27:48
User signature succeeded.	Richard Rupp (b) (4)	26 Mar 2021 18:58:13
DataPoint Verified.	(b) (4)	09 Feb 2021 20:22:45
User entered '29 Jan 2021'	Amber Stanford (b) (4)	29 Jan 2021 21:02:23

**US3612005**

**Folder: Safety Call Day 149 (1)**

**Form: Safety Call**

**Generated On: 10 Jun 2021 09:15:23**

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 17:27:48
User signature succeeded.	Richard Rupp (b) (4)	26 Mar 2021 18:58:13
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Feb 2021 20:22:45
User entered 'Contact Made (CONTACT MADE)'	Amber Stanford (b) (4) (b) (4)	29 Jan 2021 21:02:23

**US3612005**

**Folder: Safety Call Day 149 (1)**

**Form: Safety Call**

**Generated On: 10 Jun 2021 09:15:23**

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 17:27:48
User signature succeeded.	Richard Rupp (b) (4)	26 Mar 2021 18:58:13
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Feb 2021 20:22:45
User entered empty.	Amber Stanford (b) (4) (b) (4)	29 Jan 2021 21:02:23

**US3612005**

**Folder: Safety Call Day 149 (1)**

**Form: Continuing**

**Generated On: 10 Jun 2021 09:15:23**

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 17:27:48
User signature succeeded.	Richard Rupp (b) (4)	26 Mar 2021 18:58:13
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Feb 2021 20:22:49
User entered 'Yes (Y)'	Amber Stanford (b) (4) (b) (4)	29 Jan 2021 21:03:05

**US3612005**

**Folder: Safety Call Day 149 (1)**

**Form: Continuing**

**Generated On: 10 Jun 2021 09:15:23**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 17:27:48
User entered 'I'	System	29 Jan 2021 21:03:05

**US3612005**

**Folder: Safety Call Day 179 (1)**

**Form: Safety Call**

**Generated On: 10 Jun 2021 09:15:23**

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 17:27:48
User signature succeeded.	Richard Rupp (b) (4)	26 Mar 2021 18:58:32
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	11 Mar 2021 16:49:27
User entered 'Yes (Y)'	Amber Stanford (b) (4)	26 Feb 2021 21:33:31
	(b) (4)	

**US3612005**

**Folder: Safety Call Day 179 (1)**

**Form: Safety Call**

**Generated On: 10 Jun 2021 09:15:23**

[Date of Contact or Contact Attempt \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 17:27:48
User signature succeeded.	Richard Rupp (b) (4)	26 Mar 2021 18:58:32
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	11 Mar 2021 16:49:27
User entered '26 Feb 2021'	Amber Stanford (b) (4)	26 Feb 2021 21:33:31
	(b) (4)	

**US3612005**

**Folder: Safety Call Day 179 (1)**

**Form: Safety Call**

**Generated On: 10 Jun 2021 09:15:23**

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 17:27:48
User signature succeeded.	Richard Rupp (b) (4)	26 Mar 2021 18:58:32
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Mar 2021 16:49:27
User entered 'Contact Made (CONTACT MADE)'	Amber Stanford (b) (4) (b) (4)	26 Feb 2021 21:33:31

**US3612005**

**Folder: Safety Call Day 179 (1)**

**Form: Safety Call**

**Generated On: 10 Jun 2021 09:15:23**

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 17:27:48
User signature succeeded.	Richard Rupp (b) (4)	26 Mar 2021 18:58:32
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Mar 2021 16:49:27
User entered empty.	Amber Stanford (b) (4) (b) (4)	26 Feb 2021 21:33:31

**US3612005**

**Folder: Safety Call Day 179 (1)**

**Form: Continuing**

**Generated On: 10 Jun 2021 09:15:23**

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 17:27:48
User signature succeeded.	Richard Rupp (b) (4)	26 Mar 2021 18:58:32
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Mar 2021 16:49:33
User entered 'Yes (Y)'	Amber Stanford (b) (4) (b) (4)	26 Feb 2021 21:34:08

**US3612005**

**Folder: Safety Call Day 179 (1)**

**Form: Continuing**

**Generated On: 10 Jun 2021 09:15:23**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 17:27:48
User entered 'I'	System	26 Feb 2021 21:34:08

**US3612005**

**Folder: Visit 4 Day 209 (1)**

**Form: Visit Date**

**Generated On: 10 Jun 2021 09:15:23**

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 17:27:48
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 17:04:52
User signature succeeded.	Richard Rupp (b) (4)	26 Mar 2021 18:58:32
User entered 'Yes (Y)'	(b) (4) Kristin Pollock (b) (4) (b) (4)	23 Mar 2021 17:00:18

**US3612005**

**Folder: Visit 4 Day 209 (1)**

**Form: Visit Date**

**Generated On: 10 Jun 2021 09:15:23**

[Visit date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 17:27:48
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 17:04:52
User signature succeeded.	Richard Rupp (b) (4)	26 Mar 2021 18:58:32
User entered '23 Mar 2021'	(b) (4) Kristin Pollock (b) (4) (b) (4)	23 Mar 2021 17:00:18

**US3612005**

**Folder: Visit 4 Day 209 (1)**

**Form: Visit Date**

**Generated On: 10 Jun 2021 09:15:23**

[Was visit performed at the participant's home or at the clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 17:27:48
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 17:04:52
User signature succeeded.	Richard Rupp (b) (4)	26 Mar 2021 18:58:32
User entered 'Clinic (Clinic)'	(b) (4) Kristin Pollock (b) (4) (b) (4)	23 Mar 2021 17:00:18

**US3612005**

**Folder: Visit 4 Day 209 (1)**

**Form: Visit Date**

**Generated On: 10 Jun 2021 09:15:23**

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 17:27:48
User entered 'VISIT4'	System	23 Mar 2021 17:00:18

**US3612005**

**Folder: Visit 4 Day 209 (1)**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 09:15:23**

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 17:27:48
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 17:05:26
User signature succeeded.	Richard Rupp (b) (4)	31 Mar 2021 21:09:32
User entered 'No (N)'	(b) (4) Amber Stanford (b) (4) (b) (4)	30 Mar 2021 17:50:53

US3612005

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:15:23

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 17:27:48
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 17:05:26
User signature succeeded.	Richard Rupp (b) (4)	31 Mar 2021 21:09:32
User entered empty.	(b) (4) Amber Stanford (b) (4) (b) (4)	30 Mar 2021 17:50:53

**US3612005**

**Folder: Visit 4 Day 209 (1)**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 09:15:23**

**Time of assessment (00:00-23:59)**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 17:27:48
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 17:05:26
User signature succeeded.	Richard Rupp (b) (4)	31 Mar 2021 21:09:32
User entered empty.	(b) (4) Amber Stanford (b) (4) (b) (4)	30 Mar 2021 17:50:53

**US3612005**

**Folder: Visit 4 Day 209 (1)**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 09:15:23**

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 17:27:48
User entered empty.	System	30 Mar 2021 17:50:53

US3612005

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:15:23

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 17:27:48
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 17:05:26
User signature succeeded.	Richard Rupp (b) (4)	31 Mar 2021 21:09:32
User entered empty.	(b) (4) Amber Stanford (b) (4) (b) (4)	30 Mar 2021 17:50:53

**US3612005**

**Folder: Visit 4 Day 209 (1)**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 09:15:23**

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 17:27:48
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 17:05:26
User signature succeeded.	Richard Rupp (b) (4)	31 Mar 2021 21:09:32
User entered empty.	(b) (4) Amber Stanford (b) (4) (b) (4)	30 Mar 2021 17:50:53

**US3612005**

**Folder: Visit 4 Day 209 (1)**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 09:15:23**

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 17:27:48
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 17:05:26
User signature succeeded.	Richard Rupp (b) (4)	31 Mar 2021 21:09:32
User entered empty.	(b) (4) Amber Stanford (b) (4) (b) (4)	30 Mar 2021 17:50:53

**US3612005**

**Folder: Visit 4 Day 209 (1)**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 09:15:23**

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 17:27:48
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 17:05:26
User signature succeeded.	Richard Rupp (b) (4)	31 Mar 2021 21:09:32
User entered empty.	(b) (4) Amber Stanford (b) (4) (b) (4)	30 Mar 2021 17:50:53

**US3612005**

**Folder: Visit 4 Day 209 (1)**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 09:15:23**

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 17:27:48
User entered empty.	System	30 Mar 2021 17:50:53

US3612005

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:15:23

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 17:27:48
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 17:05:26
User signature succeeded.	Richard Rupp (b) (4)	31 Mar 2021 21:09:32
User entered empty.	(b) (4) Amber Stanford (b) (4) (b) (4)	30 Mar 2021 17:50:53

**US3612005**

**Folder: Visit 4 Day 209 (1)**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 09:15:23**

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 17:27:48
User entered empty.	System	30 Mar 2021 17:50:53

US3612005

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:15:23

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 17:27:48
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 17:05:26
User signature succeeded.	Richard Rupp (b) (4)	31 Mar 2021 21:09:32
User entered empty.	(b) (4) Amber Stanford (b) (4) (b) (4)	30 Mar 2021 17:50:53

**US3612005**

**Folder: Visit 4 Day 209 (1)**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 09:15:23**

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 17:27:48
User entered empty.	System	30 Mar 2021 17:50:53

US3612005

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:15:23

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 17:27:48
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 17:05:26
User signature succeeded.	Richard Rupp (b) (4)	31 Mar 2021 21:09:32
User entered empty.	(b) (4) Amber Stanford (b) (4) (b) (4)	30 Mar 2021 17:50:53

**US3612005**

**Folder: Visit 4 Day 209 (1)**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 09:15:23**

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 17:27:48
User entered empty.	System	30 Mar 2021 17:50:53

**US3612005**

**Folder: Visit 4 Day 209 (1)**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 09:15:23**

[Height \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 17:27:48

**US3612005**

**Folder: Visit 4 Day 209 (1)**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 09:15:23**

[Weight \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 17:27:48

US3612005

Folder: Visit 4 Day 209 (1)

Form: Physical Examination

Generated On: 10 Jun 2021 09:15:23

Was the physical examination performed?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 17:27:48
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 17:05:50
User signature succeeded.	Richard Rupp (b) (4)	26 Mar 2021 18:58:32
User closed query 'Was the physical examination performed is No, however Date of examination is provided. Please correct.' (Site from System).	(b) (4)	23 Mar 2021 17:00:45
User opened query 'Was the physical examination performed is No, however Date of examination is provided. Please correct.' (Site from System).	System	23 Mar 2021 17:00:32
User entered 'No (N)'	Kristin Pollock (b) (4)	23 Mar 2021 17:00:32
	(b) (4)	

**US3612005**

**Folder: Visit 4 Day 209 (1)**

**Form: Physical Examination**

**Generated On: 10 Jun 2021 09:15:23**

**Date of examination (dd MMM yyyy)**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 17:27:48
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 17:05:50
User signature succeeded.	Richard Rupp (b) (4)	26 Mar 2021 18:58:32
User entered empty; reason for change Data Entry Error	Kristin Pollock (b) (4)	23 Mar 2021 17:00:45
User entered '23 Mar 2021'	Kristin Pollock (b) (4)	23 Mar 2021 17:00:32

**US3612005**

**Folder: Visit 4 Day 209 (1)**

**Form: Immunogenicity Assessment**

**Generated On: 10 Jun 2021 09:15:23**

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 17:27:48
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 17:06:06
User signature succeeded.	Richard Rupp (b) (4)	26 Mar 2021 18:58:32
User entered 'Yes (Y)'	(b) (4) Kristin Pollock (b) (4) (b) (4)	23 Mar 2021 17:01:17

**US3612005**

**Folder: Visit 4 Day 209 (1)**

**Form: Immunogenicity Assessment**

**Generated On: 10 Jun 2021 09:15:23**

**Collection date** (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 17:27:48
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 17:06:06
User signature succeeded.	Richard Rupp (b) (4)	26 Mar 2021 18:58:32
User entered '23 Mar 2021'	(b) (4) Kristin Pollock (b) (4) (b) (4)	23 Mar 2021 17:01:17

**US3612005**

**Folder: Visit 4 Day 209 (1)**

**Form: Immunogenicity Assessment**

**Generated On: 10 Jun 2021 09:15:23**

[Collection time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 17:27:48
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 17:06:06
User signature succeeded.	Richard Rupp (b) (4)	26 Mar 2021 18:58:32
User entered '09:20'	(b) (4) Kristin Pollock (b) (4) (b) (4)	23 Mar 2021 17:01:17

**US3612005**

**Folder: Visit 4 Day 209 (1)**

**Form: Immunogenicity Assessment**

**Generated On: 10 Jun 2021 09:15:23**

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 17:27:48
User entered '23 Mar 2021 09:20'	System	23 Mar 2021 17:01:17

US3612005

Folder: Visit 4 Day 209 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:15:23

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 17:27:48
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 17:06:14
User signature succeeded.	Richard Rupp (b) (4)	26 Mar 2021 18:58:32
User entered 'Yes (Y)'	(b) (4) Kristin Pollock (b) (4) (b) (4)	23 Mar 2021 17:01:22

**US3612005**

**Folder: Visit 4 Day 209 (1)**

**Form: Continuing**

**Generated On: 10 Jun 2021 09:15:23**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 17:27:48
User entered 'I'	System	23 Mar 2021 17:01:22

**US3612005**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Visit Date**

**Generated On: 10 Jun 2021 09:15:23**

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 02:43:13
User signature succeeded.	Richard Rupp (b) (4)	26 Mar 2021 18:58:13
DataPoint Verified.	(b) (4)	11 Mar 2021 16:25:59
User entered 'Yes (Y)'	Kristin Pollock (b) (4)	04 Jan 2021 21:33:31
	(b) (4)	

**US3612005**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Visit Date**

**Generated On: 10 Jun 2021 09:15:23**

[Visit date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 02:43:13
User signature succeeded.	Richard Rupp (b) (4)	26 Mar 2021 18:58:13
DataPoint Verified.	(b) (4)	11 Mar 2021 16:25:59
User entered '4 Jan 2021'	Kristin Pollock (b) (4)	04 Jan 2021 21:33:31

**US3612005**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Visit Date**

**Generated On: 10 Jun 2021 09:15:23**

[Was visit performed at the participant's home or at the clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 02:43:13
User signature succeeded.	Richard Rupp (b) (4)	26 Mar 2021 18:58:13
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	11 Mar 2021 16:25:59
User entered 'Clinic (Clinic)'	Kristin Pollock (b) (4)	04 Jan 2021 21:33:31
	(b) (4)	

**US3612005**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Visit Date**

**Generated On: 10 Jun 2021 09:15:23**

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 02:43:13
User entered 'UNBLND_DECIDE'	System	04 Jan 2021 21:33:31

**US3612005**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Unblinding**

**Generated On: 10 Jun 2021 09:15:23**

[Date of updated informed consent \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 02:43:13
User signature succeeded.	Richard Rupp (b) (4)	26 Mar 2021 18:58:13
DataPoint Verified.	(b) (4)	11 Mar 2021 16:26:15
User entered '4 Jan 2021'	Kristin Pollock (b) (4)	04 Jan 2021 21:33:52

**US3612005**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Unblinding**

**Generated On: 10 Jun 2021 09:15:23**

[N/A - Subject Unblinded under Amendment 5 and Discontinued from Study](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 02:43:13
User signature succeeded.	Richard Rupp (b) (4)	26 Mar 2021 18:58:13
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Mar 2021 16:26:15
User entered '0'	Amber Stanford (b) (4)	08 Mar 2021 19:31:26
Amendment Manager inserted this DataPoint.	(b) (4) System	06 Mar 2021 18:12:27

**US3612005**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Unblinding**

**Generated On: 10 Jun 2021 09:15:23**

[Was the participant unblinded?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 02:43:13
User signature succeeded.	Richard Rupp (b) (4)	26 Mar 2021 18:58:13
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	11 Mar 2021 16:26:15
User entered 'Yes (Y)'	Kristin Pollock (b) (4)	04 Jan 2021 21:33:52
	(b) (4)	

**US3612005**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Unblinding**

**Generated On: 10 Jun 2021 09:15:23**

[Under what version of the Protocol was the Participant unblinded?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 02:43:13
User signature succeeded.	Richard Rupp (b) (4)	26 Mar 2021 18:58:13
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Mar 2021 16:26:15
User entered 'Amendment 6 or later (Amendment 6 or later)'	Amber Stanford (b) (4)	08 Mar 2021 19:31:26
Amendment Manager inserted this DataPoint.	(b) (4) System	06 Mar 2021 18:12:27

**US3612005**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Unblinding**

**Generated On: 10 Jun 2021 09:15:23**

**Date of unblinding (dd MMM yyyy)**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 02:43:13
User signature succeeded.	Richard Rupp (b) (4)	26 Mar 2021 18:58:13
DataPoint Verified.	(b) (4)	11 Mar 2021 16:26:15
User entered '4 Jan 2021'	Kristin Pollock (b) (4)	04 Jan 2021 21:33:52

US3612005

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 10 Jun 2021 09:15:23

[Participant randomization assignment](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 02:43:13
User signature succeeded.	Richard Rupp (b) (4)	26 Mar 2021 18:58:13
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	11 Mar 2021 16:26:15
User entered 'Placebo (Placebo)'	Kristin Pollock (b) (4)	04 Jan 2021 21:33:52
	(b) (4)	

**US3612005**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Unblinding**

**Generated On: 10 Jun 2021 09:15:23**

[Actual Dose 1](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 02:43:13
User signature succeeded.	Richard Rupp (b) (4)	26 Mar 2021 18:58:13
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Mar 2021 16:26:15
Amendment Manager: User entered 'Placebo (Placebo)'	System	20 Jan 2021 13:37:44
User entered 'Placebo (Placebo)'	Kristin Pollock (b) (4) (b) (4)	04 Jan 2021 21:33:52

**US3612005**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Unblinding**

**Generated On: 10 Jun 2021 09:15:23**

[Actual Dose 2](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 02:43:13
User signature succeeded.	Richard Rupp (b) (4)	26 Mar 2021 18:58:13
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Mar 2021 16:26:15
Amendment Manager: User entered 'Placebo (Placebo)'	System	20 Jan 2021 13:37:44
User entered 'Placebo (Placebo)'	Kristin Pollock (b) (4) (b) (4)	04 Jan 2021 21:33:52

**US3612005**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Unblinding**

**Generated On: 10 Jun 2021 09:15:23**

[Will participant receive mRNA-1273?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 02:43:13
User signature succeeded.	Richard Rupp (b) (4)	26 Mar 2021 18:58:13
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	11 Mar 2021 16:26:15
User entered 'Yes (Y)'	Kristin Pollock (b) (4)	04 Jan 2021 21:33:52
	(b) (4)	

**US3612005**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Unblinding**

**Generated On: 10 Jun 2021 09:15:23**

[Placebo Only Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 02:43:13
User entered '1'	System	04 Jan 2021 21:33:52

**US3612005**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Unblinding**

**Generated On: 10 Jun 2021 09:15:23**

[Continuing with mRNA-1273](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 02:43:13
User entered 'I'	System	04 Jan 2021 21:33:52

**US3612005**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Vital Signs - Dosing**

**Generated On: 10 Jun 2021 09:15:23**

[Height](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 02:43:13
User signature succeeded.	Richard Rupp (b) (4)	26 Mar 2021 18:58:13
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	11 Mar 2021 16:26:53
User entered missing code ND - Not Done.	Kristin Pollock (b) (4)	04 Jan 2021 21:35:10
	(b) (4)	

**US3612005**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Vital Signs - Dosing**

**Generated On: 10 Jun 2021 09:15:23**

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 02:43:13
User signature succeeded.	Richard Rupp (b) (4)	26 Mar 2021 18:58:13
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Mar 2021 16:26:53
User entered missing code ND - Not Done.	Kristin Pollock (b) (4) (b) (4)	04 Jan 2021 21:35:10

**US3612005**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Vital Signs - Dosing**

**Generated On: 10 Jun 2021 09:15:23**

**BMI (xxx.x)**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 02:43:13
User entered empty.	System	04 Jan 2021 21:35:10
DataPoint set to visible.	System	04 Jan 2021 21:33:52

**US3612005**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Vital Signs - Dosing**

**Generated On: 10 Jun 2021 09:15:23**

[Height](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 02:43:13
User signature succeeded.	Richard Rupp (b) (4)	26 Mar 2021 18:58:13
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Mar 2021 16:26:53
User entered missing code ND - Not Done.	Kristin Pollock (b) (4) (b) (4)	04 Jan 2021 21:35:10

**US3612005**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Vital Signs - Dosing**

**Generated On: 10 Jun 2021 09:15:23**

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 02:43:13
User signature succeeded.	Richard Rupp (b) (4)	26 Mar 2021 18:58:13
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	11 Mar 2021 16:26:53
User entered missing code ND - Not Done.	Kristin Pollock (b) (4)	04 Jan 2021 21:35:10
	(b) (4)	

**US3612005**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Vital Signs - Dosing**

**Generated On: 10 Jun 2021 09:15:23**

**BMI (xxx.x)**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 02:43:13
User entered empty.	System	04 Jan 2021 21:35:10
DataPoint set to visible.	System	04 Jan 2021 21:33:52

**US3612005**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 10 Jun 2021 09:15:23**

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 02:43:13
User accepted default value 'Pre-Dose (PREDOSE)'	Kristin Pollock (b) (4)	04 Jan 2021 21:35:10
	(b) (4)	

US3612005

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:15:23

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 02:43:13
User signature succeeded.	Richard Rupp (b) (4)	26 Mar 2021 18:58:13
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	11 Mar 2021 16:26:53
User entered 'Yes (Y)'	Kristin Pollock (b) (4)	04 Jan 2021 21:35:10
	(b) (4)	

US3612005

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:15:23

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 02:43:13
User signature succeeded.	Richard Rupp (b) (4)	26 Mar 2021 18:58:13
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	11 Mar 2021 16:26:53
User entered '4 Jan 2021'	Kristin Pollock (b) (4)	04 Jan 2021 21:35:10
	(b) (4)	

**US3612005**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 10 Jun 2021 09:15:23**

[Time of assessment \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 02:43:13
User signature succeeded.	Richard Rupp (b) (4)	26 Mar 2021 18:58:13
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	11 Mar 2021 16:26:53
User entered '10:23'	Kristin Pollock (b) (4)	04 Jan 2021 21:35:10
	(b) (4)	

**US3612005**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 10 Jun 2021 09:15:23**

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 02:43:13
User entered '4 Jan 2021 10:23'	System	04 Jan 2021 21:35:10

**US3612005**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 10 Jun 2021 09:15:23**

[Temperature \(xxx.x\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 02:43:13
User signature succeeded.	Richard Rupp (b) (4)	26 Mar 2021 18:58:13
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	11 Mar 2021 16:26:53
User entered '98.0' F	Kristin Pollock (b) (4)	04 Jan 2021 21:35:10
	(b) (4)	

**US3612005**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 10 Jun 2021 09:15:23**

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 02:43:13
User signature succeeded.	Richard Rupp (b) (4)	26 Mar 2021 18:58:13
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	11 Mar 2021 16:26:53
User entered 'Oral (Oral)'	Kristin Pollock (b) (4)	04 Jan 2021 21:35:10
	(b) (4)	

**US3612005**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 10 Jun 2021 09:15:23**

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 02:43:13
User signature succeeded.	Richard Rupp (b) (4)	26 Mar 2021 18:58:13
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	11 Mar 2021 16:26:53
User entered empty.	Kristin Pollock (b) (4)	04 Jan 2021 21:35:10
	(b) (4)	

**US3612005**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 10 Jun 2021 09:15:23**

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 02:43:13
User signature succeeded.	Richard Rupp (b) (4)	26 Mar 2021 18:58:13
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	11 Mar 2021 16:26:53
User entered '55'	Kristin Pollock (b) (4)	04 Jan 2021 21:35:10
	(b) (4)	

**US3612005**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 10 Jun 2021 09:15:23**

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 02:43:13
User entered 'bpm'	System	04 Jan 2021 21:35:10

**US3612005**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 10 Jun 2021 09:15:23**

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 02:43:13
User signature succeeded.	Richard Rupp (b) (4)	26 Mar 2021 18:58:13
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	11 Mar 2021 16:26:53
User entered '18'	Kristin Pollock (b) (4)	04 Jan 2021 21:35:10
	(b) (4)	

US3612005

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:15:23

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 02:43:13
User entered 'breaths/min'	System	04 Jan 2021 21:35:10

**US3612005**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 10 Jun 2021 09:15:23**

[Systolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 02:43:13
User signature succeeded.	Richard Rupp (b) (4)	26 Mar 2021 18:58:13
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	11 Mar 2021 16:26:53
User entered '126'	Kristin Pollock (b) (4)	04 Jan 2021 21:35:10
	(b) (4)	

**US3612005**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 10 Jun 2021 09:15:23**

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 02:43:13
User entered 'mmHg'	System	04 Jan 2021 21:35:10

**US3612005**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 10 Jun 2021 09:15:23**

[Diastolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 02:43:13
User signature succeeded.	Richard Rupp (b) (4)	26 Mar 2021 18:58:13
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	11 Mar 2021 16:26:53
User entered '72'	Kristin Pollock (b) (4)	04 Jan 2021 21:35:10
	(b) (4)	

**US3612005**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 10 Jun 2021 09:15:23**

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 02:43:13
User entered 'mmHg'	System	04 Jan 2021 21:35:10

US3612005

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing

Generated On: 10 Jun 2021 09:15:23

[Height](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 02:43:13
User signature succeeded.	Richard Rupp (b) (4)	26 Mar 2021 18:58:13
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Mar 2021 16:26:53
User entered missing code ND - Not Done.	Kristin Pollock (b) (4) (b) (4)	04 Jan 2021 21:35:10

**US3612005**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Vital Signs - Dosing**

**Generated On: 10 Jun 2021 09:15:23**

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 02:43:13
User signature succeeded.	Richard Rupp (b) (4)	26 Mar 2021 18:58:13
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	11 Mar 2021 16:26:53
User entered missing code ND - Not Done.	Kristin Pollock (b) (4)	04 Jan 2021 21:35:10
	(b) (4)	

**US3612005**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Vital Signs - Dosing**

**Generated On: 10 Jun 2021 09:15:23**

**BMI (xxx.x)**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 02:43:13
User entered empty.	System	04 Jan 2021 21:35:10
DataPoint set to visible.	System	04 Jan 2021 21:33:52

**US3612005**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 10 Jun 2021 09:15:23**

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 02:43:13
User accepted default value 'Post-Dose (POSTDOSE)'	Kristin Pollock (b) (4) (b) (4)	04 Jan 2021 21:35:48

US3612005

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:15:23

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 02:43:13
User signature succeeded.	Richard Rupp (b) (4)	26 Mar 2021 18:58:13
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	11 Mar 2021 16:26:53
User entered 'Yes (Y)'	Kristin Pollock (b) (4)	04 Jan 2021 21:35:48
	(b) (4)	

**US3612005**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 10 Jun 2021 09:15:23**

**Date of assessment (dd MMM yyyy)**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 02:43:13
User signature succeeded.	Richard Rupp (b) (4)	26 Mar 2021 18:58:13
DataPoint Verified.	(b) (4)	11 Mar 2021 16:26:53
User entered '4 Jan 2021'	Kristin Pollock (b) (4)	04 Jan 2021 21:35:48

**US3612005**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 10 Jun 2021 09:15:23**

[Time of assessment \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 02:43:13
User signature succeeded.	Richard Rupp (b) (4)	26 Mar 2021 18:58:13
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	11 Mar 2021 16:26:53
User entered '11:50'	Kristin Pollock (b) (4)	04 Jan 2021 21:35:48
	(b) (4)	

**US3612005**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 10 Jun 2021 09:15:23**

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 02:43:13
User entered '4 Jan 2021 11:50'	System	04 Jan 2021 21:35:48

US3612005

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:15:23

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 02:43:13
User signature succeeded.	Richard Rupp (b) (4)	26 Mar 2021 18:58:13
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	11 Mar 2021 16:26:53
User entered '97.9' F	Kristin Pollock (b) (4)	04 Jan 2021 21:35:48
	(b) (4)	

**US3612005**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 10 Jun 2021 09:15:23**

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 02:43:13
User signature succeeded.	Richard Rupp (b) (4)	26 Mar 2021 18:58:13
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	11 Mar 2021 16:26:53
User entered 'Oral (Oral)'	Kristin Pollock (b) (4)	04 Jan 2021 21:35:48
	(b) (4)	

**US3612005**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 10 Jun 2021 09:15:23**

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 02:43:13
User signature succeeded.	Richard Rupp (b) (4)	26 Mar 2021 18:58:13
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	11 Mar 2021 16:26:53
User entered empty.	Kristin Pollock (b) (4)	04 Jan 2021 21:35:48
	(b) (4)	

US3612005

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:15:23

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 02:43:13
User signature succeeded.	Richard Rupp (b) (4)	26 Mar 2021 18:58:13
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	11 Mar 2021 16:26:53
User entered '56'	Kristin Pollock (b) (4)	04 Jan 2021 21:35:48
	(b) (4)	

**US3612005**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 10 Jun 2021 09:15:23**

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 02:43:13
User entered 'bpm'	System	04 Jan 2021 21:35:48

**US3612005**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 10 Jun 2021 09:15:23**

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 02:43:13
User signature succeeded.	Richard Rupp (b) (4)	26 Mar 2021 18:58:13
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	11 Mar 2021 16:26:53
User entered '16'	Kristin Pollock (b) (4)	04 Jan 2021 21:35:48
	(b) (4)	

US3612005

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:15:23

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 02:43:13
User entered 'breaths/min'	System	04 Jan 2021 21:35:48

**US3612005**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 10 Jun 2021 09:15:23**

[Systolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 02:43:13
User signature succeeded.	Richard Rupp (b) (4)	26 Mar 2021 18:58:13
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	11 Mar 2021 16:26:53
User entered '136'	Kristin Pollock (b) (4)	04 Jan 2021 21:35:48
	(b) (4)	

**US3612005**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 10 Jun 2021 09:15:23**

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 02:43:13
User entered 'mmHg'	System	04 Jan 2021 21:35:48

US3612005

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:15:23

[Diastolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 02:43:13
User signature succeeded.	Richard Rupp (b) (4)	26 Mar 2021 18:58:13
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	11 Mar 2021 16:26:53
User entered '73'	Kristin Pollock (b) (4)	04 Jan 2021 21:35:48
	(b) (4)	

**US3612005**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 10 Jun 2021 09:15:23**

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 02:43:13
User entered 'mmHg'	System	04 Jan 2021 21:35:48

**US3612005**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Physical Examination**

**Generated On: 10 Jun 2021 09:15:23**

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 02:43:13
User signature succeeded.	Richard Rupp (b) (4)	26 Mar 2021 18:58:13
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	11 Mar 2021 16:27:37
User entered 'Yes (Y)'	Kristin Pollock (b) (4)	04 Jan 2021 21:36:03
	(b) (4)	

**US3612005**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Physical Examination**

**Generated On: 10 Jun 2021 09:15:23**

**Date of examination (dd MMM yyyy)**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 02:43:13
User signature succeeded.	Richard Rupp (b) (4)	26 Mar 2021 18:58:13
DataPoint Verified.	(b) (4)	11 Mar 2021 16:27:37
User entered '4 Jan 2021'	Kristin Pollock (b) (4)	04 Jan 2021 21:36:03

**US3612005**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Exposure**

**Generated On: 10 Jun 2021 09:15:23**

[Was study treatment given?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 02:43:13
User signature succeeded.	Richard Rupp (b) (4)	26 Mar 2021 18:58:13
DataPoint Verified.	(b) (4)	11 Mar 2021 16:27:41
User entered 'Yes (Y)'	Kristin Pollock (b) (4)	04 Jan 2021 21:38:01
	(b) (4)	

**US3612005**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Exposure**

**Generated On: 10 Jun 2021 09:15:23**

[If No, reason not given](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 02:43:13
User signature succeeded.	Richard Rupp (b) (4)	26 Mar 2021 18:58:13
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Mar 2021 16:27:41
User entered empty.	Kristin Pollock (b) (4) (b) (4)	04 Jan 2021 21:38:01

US3612005

Folder: Participant Decision Visit / OL-D1 (1)

Form: Exposure

Generated On: 10 Jun 2021 09:15:23

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)	25 Apr 2021 02:43:13
User signature succeeded.	Richard Rupp (b) (4)	26 Mar 2021 18:58:13
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Mar 2021 16:27:41
User entered empty.	Kristin Pollock (b) (4) (b) (4)	04 Jan 2021 21:38:01

**US3612005**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Exposure**

**Generated On: 10 Jun 2021 09:15:23**

[What was the study treatment? \(Unblinded\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 02:43:13
User entered 'mRNA-1273'	System	04 Jan 2021 21:38:01
DataPoint set to visible.	System	04 Jan 2021 21:33:52

US3612005

Folder: Participant Decision Visit / OL-D1 (1)

Form: Exposure

Generated On: 10 Jun 2021 09:15:23

What was the treatment date? (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 02:43:13
User signature succeeded.	Richard Rupp (b) (4)	26 Mar 2021 18:58:13
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	11 Mar 2021 16:27:41
User entered '4 Jan 2021'	Kristin Pollock (b) (4)	04 Jan 2021 21:38:01
	(b) (4)	

**US3612005**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Exposure**

**Generated On: 10 Jun 2021 09:15:23**

[What was the treatment time? \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 02:43:13
User signature succeeded.	Richard Rupp (b) (4)	26 Mar 2021 18:58:13
DataPoint Verified.	(b) (4)	11 Mar 2021 16:27:41
User entered '11:17'	Kristin Pollock (b) (4)	04 Jan 2021 21:38:01

**US3612005**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Exposure**

**Generated On: 10 Jun 2021 09:15:23**

[Treatment Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 02:43:13
User entered '4 Jan 2021 11:17'	System	04 Jan 2021 21:38:01

**US3612005**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Exposure**

**Generated On: 10 Jun 2021 09:15:23**

[Which arm was used to give treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 02:43:13
User signature succeeded.	Richard Rupp (b) (4)	26 Mar 2021 18:58:13
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	11 Mar 2021 16:27:41
User entered 'Left Arm (LEFT ARM)'	Kristin Pollock (b) (4)	04 Jan 2021 21:38:01
	(b) (4)	

**US3612005**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Exposure**

**Generated On: 10 Jun 2021 09:15:23**

[What was the frequency of the study treatment dosing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 02:43:13
DataPoint Verified.	(b) (4), (b) (6)	11 Mar 2021 16:27:41
User entered 'ONCE'	System	04 Jan 2021 21:38:01

**US3612005**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Exposure**

**Generated On: 10 Jun 2021 09:15:23**

[What was the route of administration for the study treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 02:43:13
User entered 'INTRAMUSCULAR'	System	04 Jan 2021 21:38:01

**US3612005**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Immunogenicity Assessment**

**Generated On: 10 Jun 2021 09:15:23**

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 02:43:13
User signature succeeded.	Richard Rupp (b) (4)	26 Mar 2021 18:58:13
DataPoint Verified.	(b) (4)	11 Mar 2021 16:27:53
User entered 'Yes (Y)'	Kristin Pollock (b) (4)	04 Jan 2021 21:38:18

US3612005

Folder: Participant Decision Visit / OL-D1 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 09:15:23

Collection date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 02:43:13
User signature succeeded.	Richard Rupp (b) (4)	26 Mar 2021 18:58:13
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Mar 2021 16:27:53
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.' canceled (Site from DM).	(b) (4), (b) (6)	13 Jan 2021 22:32:58
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 21:16:10
User entered '4 Jan 2021'	Kristin Pollock (b) (4) (b) (4)	04 Jan 2021 21:38:18

**US3612005**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Immunogenicity Assessment**

**Generated On: 10 Jun 2021 09:15:23**

[Collection time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 02:43:13
User signature succeeded.	Richard Rupp (b) (4)	26 Mar 2021 18:58:13
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	11 Mar 2021 16:27:53
User entered '10:29'	Kristin Pollock (b) (4)	04 Jan 2021 21:38:18
	(b) (4)	

**US3612005**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Immunogenicity Assessment**

**Generated On: 10 Jun 2021 09:15:23**

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 02:43:13
User entered '4 Jan 2021 10:29'	System	04 Jan 2021 21:38:18

US3612005

Folder: Participant Decision Visit / OL-D1 (1)

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 10 Jun 2021 09:15:23

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 02:43:13
User signature succeeded.	Richard Rupp (b) (4)	26 Mar 2021 18:58:13
DataPoint Verified.	(b) (4)	11 Mar 2021 16:27:59
User entered 'Yes (Y)'	Kristin Pollock (b) (4)	04 Jan 2021 21:38:29

**US3612005**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Central Laboratory - Nasopharyngeal Swab (Single)**

**Generated On: 10 Jun 2021 09:15:23**

[Collection date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 02:43:13
User signature succeeded.	Richard Rupp (b) (4)	26 Mar 2021 18:58:13
DataPoint Verified.	(b) (4)	11 Mar 2021 16:27:59
User entered '4 Jan 2021'	Kristin Pollock (b) (4)	04 Jan 2021 21:38:29

**US3612005**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Central Laboratory - Nasopharyngeal Swab (Single)**

**Generated On: 10 Jun 2021 09:15:23**

[Collection time \(00:00 - 23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 02:43:13
User signature succeeded.	Richard Rupp (b) (4)	26 Mar 2021 18:58:13
DataPoint Verified.	(b) (4)	11 Mar 2021 16:27:59
User entered '10:33'	Kristin Pollock (b) (4)	04 Jan 2021 21:38:29

**US3612005**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Central Laboratory - Nasopharyngeal Swab (Single)**

**Generated On: 10 Jun 2021 09:15:23**

[Collection Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 02:43:13
User entered '4 Jan 2021 10:33'	System	04 Jan 2021 21:38:29

**US3612005**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Continuing**

**Generated On: 10 Jun 2021 09:15:23**

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 02:43:13
User signature succeeded.	Richard Rupp (b) (4)	26 Mar 2021 18:58:13
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	11 Mar 2021 16:28:09
User entered 'Yes (Y)'	Kristin Pollock (b) (4)	04 Jan 2021 21:38:34
	(b) (4)	

**US3612005**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Continuing**

**Generated On: 10 Jun 2021 09:15:23**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 02:43:13
User entered 'I'	System	04 Jan 2021 21:38:34

**US3612005**

**Folder: Safety Call OL-D8 (1)**

**Form: Safety Call**

**Generated On: 10 Jun 2021 09:15:23**

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 02:43:13
User signature succeeded.	Richard Rupp (b) (4)	26 Mar 2021 18:58:32
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	11 Mar 2021 16:34:38
User entered 'Yes (Y)'	Amber Stanford (b) (4)	12 Jan 2021 17:51:17
	(b) (4)	

US3612005

Folder: Safety Call OL-D8 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:15:23

Date of Contact or Contact Attempt (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 02:43:13
User signature succeeded.	Richard Rupp (b) (4)	26 Mar 2021 18:58:32
User closed query 'Per visit source and date of SC signature, the visit took place on 11JAN2021. Please review ad reconcile as needed.' (Site from CRA).	(b) (4)	12 Mar 2021 16:53:10
DataPoint Verified.	(b) (4), (b) (6)	12 Mar 2021 16:53:08
Query 'Per visit source and date of SC signature, the visit took place on 11JAN2021. Please review ad reconcile as needed.' answered with 'updated' (Site from CRA).	Kristin Pollock (b) (4)	11 Mar 2021 17:42:01
User entered '11 Jan 2021' reason for change: Data Entry Error	(b) (4)	11 Mar 2021 17:41:53
User opened query 'Per visit source and date of SC signature, the visit took place on 11JAN2021. Please review ad reconcile as needed.' (Site from CRA).	(b) (4), (b) (6)	11 Mar 2021 16:35:20
User entered '12 Jan 2021'	Amber Stanford (b) (4)	12 Jan 2021 17:51:17

**US3612005**

**Folder: Safety Call OL-D8 (1)**

**Form: Safety Call**

**Generated On: 10 Jun 2021 09:15:23**

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 02:43:13
User signature succeeded.	Richard Rupp (b) (4)	26 Mar 2021 18:58:32
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	11 Mar 2021 16:34:40
User entered 'Contact Made (CONTACT MADE)'	Amber Stanford (b) (4)	12 Jan 2021 17:51:17
	(b) (4)	

**US3612005**

**Folder: Safety Call OL-D8 (1)**

**Form: Safety Call**

**Generated On: 10 Jun 2021 09:15:23**

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 02:43:13
User signature succeeded.	Richard Rupp (b) (4)	26 Mar 2021 18:58:32
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Mar 2021 16:34:41
User entered empty.	Amber Stanford (b) (4) (b) (4)	12 Jan 2021 17:51:17

**US3612005**

**Folder: Safety Call OL-D8 (1)**

**Form: Continuing**

**Generated On: 10 Jun 2021 09:15:23**

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 02:43:13
User signature succeeded.	Richard Rupp (b) (4)	26 Mar 2021 18:58:32
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	11 Mar 2021 16:35:25
User entered 'Yes (Y)'	Amber Stanford (b) (4)	12 Jan 2021 17:51:24
	(b) (4)	

**US3612005**

**Folder: Safety Call OL-D8 (1)**

**Form: Continuing**

**Generated On: 10 Jun 2021 09:15:23**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 02:43:13
User entered 'I'	System	12 Jan 2021 17:51:24

**US3612005**

**Folder: Safety Call OL-D8 (1)**

**Form: Continuing**

**Generated On: 10 Jun 2021 09:15:23**

[OLD29 Placebo Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 02:43:13
User entered '1'	System	12 Jan 2021 17:51:24
DataPoint set to visible.	System	12 Jan 2021 17:51:24

**US3612005**

**Folder: OL-D29 (1)**

**Form: Visit Date**

**Generated On: 10 Jun 2021 09:15:23**

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 02:43:13
User signature succeeded.	Richard Rupp (b) (4)	26 Mar 2021 18:58:13
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	11 Mar 2021 16:35:43
User entered 'Yes (Y)'	Amber Stanford (b) (4)	02 Feb 2021 17:40:25
	(b) (4)	

**US3612005**

**Folder: OL-D29 (1)**

**Form: Visit Date**

**Generated On: 10 Jun 2021 09:15:23**

[Visit date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 02:43:13
User signature succeeded.	Richard Rupp (b) (4)	26 Mar 2021 18:58:13
DataPoint Verified.	(b) (4)	11 Mar 2021 16:35:43
User entered '02 Feb 2021'	Amber Stanford (b) (4)	02 Feb 2021 17:40:25

**US3612005**

**Folder: OL-D29 (1)**

**Form: Visit Date**

**Generated On: 10 Jun 2021 09:15:23**

[Was visit performed at the participant's home or at the clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 02:43:13
User signature succeeded.	Richard Rupp (b) (4)	26 Mar 2021 18:58:13
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	11 Mar 2021 16:35:43
User entered 'Clinic (Clinic)'	Amber Stanford (b) (4)	02 Feb 2021 17:40:25
	(b) (4)	

**US3612005**

**Folder: OL-D29 (1)**

**Form: Visit Date**

**Generated On: 10 Jun 2021 09:15:23**

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 02:43:13
User entered 'OLD29'	System	02 Feb 2021 17:40:25

**US3612005**

**Folder: OL-D29 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 10 Jun 2021 09:15:23**

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 02:43:13
User accepted default value 'Pre-Dose (PREDOSE)'	Amber Stanford (b) (4)	02 Feb 2021 17:42:48
	(b) (4)	

**US3612005**

**Folder: OL-D29 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 10 Jun 2021 09:15:23**

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 02:43:13
User signature succeeded.	Richard Rupp (b) (4)	26 Mar 2021 18:58:13
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	11 Mar 2021 16:37:11
User entered 'Yes (Y)'	Amber Stanford (b) (4)	02 Feb 2021 17:42:48
	(b) (4)	

**US3612005**

**Folder: OL-D29 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 10 Jun 2021 09:15:23**

**Date of assessment (dd MMM yyyy)**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 02:43:13
User signature succeeded.	Richard Rupp (b) (4)	26 Mar 2021 18:58:13
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	11 Mar 2021 16:37:11
User entered '02 Feb 2021'	Amber Stanford (b) (4)	02 Feb 2021 17:42:48
	(b) (4)	

**US3612005**

**Folder: OL-D29 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 10 Jun 2021 09:15:23**

[Time of assessment \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 02:43:13
User signature succeeded.	Richard Rupp (b) (4)	26 Mar 2021 18:58:13
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	11 Mar 2021 16:37:11
User entered '08:48'	Amber Stanford (b) (4)	02 Feb 2021 17:42:48
	(b) (4)	

**US3612005**

**Folder: OL-D29 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 10 Jun 2021 09:15:23**

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 02:43:13
User entered '02 Feb 2021 08:48'	System	02 Feb 2021 17:42:48

US3612005

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:15:23

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 02:43:13
User signature succeeded.	Richard Rupp (b) (4)	26 Mar 2021 18:58:13
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	11 Mar 2021 16:37:11
User entered '097.9' F	Amber Stanford (b) (4)	02 Feb 2021 17:42:48
	(b) (4)	

**US3612005**

**Folder: OL-D29 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 10 Jun 2021 09:15:23**

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 02:43:13
User signature succeeded.	Richard Rupp (b) (4)	26 Mar 2021 18:58:13
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	11 Mar 2021 16:37:11
User entered 'Oral (Oral)'	Amber Stanford (b) (4)	02 Feb 2021 17:42:48
	(b) (4)	

**US3612005**

**Folder: OL-D29 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 10 Jun 2021 09:15:23**

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 02:43:13
User signature succeeded.	Richard Rupp (b) (4)	26 Mar 2021 18:58:13
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	11 Mar 2021 16:37:11
User entered empty.	Amber Stanford (b) (4)	02 Feb 2021 17:42:48
	(b) (4)	

**US3612005**

**Folder: OL-D29 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 10 Jun 2021 09:15:23**

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 02:43:13
User signature succeeded.	Richard Rupp (b) (4)	26 Mar 2021 18:58:13
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	11 Mar 2021 16:37:11
User entered '058'	Amber Stanford (b) (4)	02 Feb 2021 17:42:48
	(b) (4)	

**US3612005**

**Folder: OL-D29 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 10 Jun 2021 09:15:23**

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 02:43:13
User entered 'bpm'	System	02 Feb 2021 17:42:48

**US3612005**

**Folder: OL-D29 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 10 Jun 2021 09:15:23**

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 02:43:13
User signature succeeded.	Richard Rupp (b) (4)	26 Mar 2021 18:58:13
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	11 Mar 2021 16:37:11
User entered '018'	Amber Stanford (b) (4)	02 Feb 2021 17:42:48
	(b) (4)	

**US3612005**

**Folder: OL-D29 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 10 Jun 2021 09:15:23**

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 02:43:13
User entered 'breaths/min'	System	02 Feb 2021 17:42:48

US3612005

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:15:23

[Systolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 02:43:13
User signature succeeded.	Richard Rupp (b) (4)	26 Mar 2021 18:58:13
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	11 Mar 2021 16:37:11
User entered '131'	Amber Stanford (b) (4)	02 Feb 2021 17:42:48
	(b) (4)	

**US3612005**

**Folder: OL-D29 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 10 Jun 2021 09:15:23**

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 02:43:13
User entered 'mmHg'	System	02 Feb 2021 17:42:48

**US3612005**

**Folder: OL-D29 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 10 Jun 2021 09:15:23**

[Diastolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 02:43:13
User signature succeeded.	Richard Rupp (b) (4)	26 Mar 2021 18:58:13
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	11 Mar 2021 16:37:11
User entered '77'	Amber Stanford (b) (4)	02 Feb 2021 17:42:48
	(b) (4)	

**US3612005**

**Folder: OL-D29 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 10 Jun 2021 09:15:23**

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 02:43:13
User entered 'mmHg'	System	02 Feb 2021 17:42:48

**US3612005**

**Folder: OL-D29 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 10 Jun 2021 09:15:23**

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 02:43:13
User accepted default value 'Post-Dose (POSTDOSE)'	Amber Stanford (b) (4) (b) (4)	02 Feb 2021 17:42:48

**US3612005**

**Folder: OL-D29 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 10 Jun 2021 09:15:23**

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 02:43:13
User signature succeeded.	Richard Rupp (b) (4)	26 Mar 2021 18:58:13
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	11 Mar 2021 16:37:11
User entered 'Yes (Y)'	Amber Stanford (b) (4)	02 Feb 2021 17:42:48
	(b) (4)	

**US3612005**

**Folder: OL-D29 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 10 Jun 2021 09:15:23**

**Date of assessment** (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 02:43:13
User signature succeeded.	Richard Rupp (b) (4)	26 Mar 2021 18:58:13
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	11 Mar 2021 16:37:11
User entered '02 Feb 2021'	Amber Stanford (b) (4)	02 Feb 2021 17:42:48
	(b) (4)	

**US3612005**

**Folder: OL-D29 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 10 Jun 2021 09:15:23**

[Time of assessment \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 02:43:13
User signature succeeded.	Richard Rupp (b) (4)	26 Mar 2021 18:58:13
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	11 Mar 2021 16:37:11
User entered '09:54'	Amber Stanford (b) (4)	02 Feb 2021 17:42:48
	(b) (4)	

**US3612005**

**Folder: OL-D29 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 10 Jun 2021 09:15:23**

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 02:43:13
User entered '02 Feb 2021 09:54'	System	02 Feb 2021 17:42:48

**US3612005**

**Folder: OL-D29 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 10 Jun 2021 09:15:23**

[Temperature \(xxx.x\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 02:43:13
User signature succeeded.	Richard Rupp (b) (4)	26 Mar 2021 18:58:13
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	11 Mar 2021 16:37:11
User entered '098.2' F	Amber Stanford (b) (4)	02 Feb 2021 17:42:48
	(b) (4)	

**US3612005**

**Folder: OL-D29 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 10 Jun 2021 09:15:23**

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 02:43:13
User signature succeeded.	Richard Rupp (b) (4)	26 Mar 2021 18:58:13
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	11 Mar 2021 16:37:11
User entered 'Oral (Oral)'	Amber Stanford (b) (4)	02 Feb 2021 17:42:48
	(b) (4)	

**US3612005**

**Folder: OL-D29 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 10 Jun 2021 09:15:23**

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 02:43:13
User signature succeeded.	Richard Rupp (b) (4)	26 Mar 2021 18:58:13
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	11 Mar 2021 16:37:11
User entered empty.	Amber Stanford (b) (4)	02 Feb 2021 17:42:48
	(b) (4)	

**US3612005**

**Folder: OL-D29 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 10 Jun 2021 09:15:23**

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 02:43:13
User signature succeeded.	Richard Rupp (b) (4)	26 Mar 2021 18:58:13
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	11 Mar 2021 16:37:11
User entered '060'	Amber Stanford (b) (4)	02 Feb 2021 17:42:48
	(b) (4)	

**US3612005**

**Folder: OL-D29 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 10 Jun 2021 09:15:23**

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 02:43:13
User entered 'bpm'	System	02 Feb 2021 17:42:48

US3612005

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:15:23

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 02:43:13
User signature succeeded.	Richard Rupp (b) (4)	26 Mar 2021 18:58:13
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	11 Mar 2021 16:37:11
User entered '018'	Amber Stanford (b) (4)	02 Feb 2021 17:42:48
	(b) (4)	

**US3612005**

**Folder: OL-D29 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 10 Jun 2021 09:15:23**

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 02:43:13
User entered 'breaths/min'	System	02 Feb 2021 17:42:48

US3612005

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:15:23

[Systolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 02:43:13
User signature succeeded.	Richard Rupp (b) (4)	26 Mar 2021 18:58:13
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	11 Mar 2021 16:37:11
User entered '126'	Amber Stanford (b) (4)	02 Feb 2021 17:42:48
	(b) (4)	

**US3612005**

**Folder: OL-D29 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 10 Jun 2021 09:15:23**

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 02:43:13
User entered 'mmHg'	System	02 Feb 2021 17:42:48

US3612005

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:15:23

[Diastolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 02:43:13
User signature succeeded.	Richard Rupp (b) (4)	26 Mar 2021 18:58:13
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	11 Mar 2021 16:37:11
User entered '76'	Amber Stanford (b) (4)	02 Feb 2021 17:42:48
	(b) (4)	

**US3612005**

**Folder: OL-D29 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 10 Jun 2021 09:15:23**

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 02:43:13
User entered 'mmHg'	System	02 Feb 2021 17:42:48

**US3612005**

**Folder: OL-D29 (1)**

**Form: Physical Examination**

**Generated On: 10 Jun 2021 09:15:23**

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 02:43:13
User signature succeeded.	Richard Rupp (b) (4)	26 Mar 2021 18:58:13
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	11 Mar 2021 16:37:54
User entered 'Yes (Y)'	Amber Stanford (b) (4)	02 Feb 2021 17:42:55
	(b) (4)	

**US3612005**

**Folder: OL-D29 (1)**

**Form: Physical Examination**

**Generated On: 10 Jun 2021 09:15:23**

**Date of examination (dd MMM yyyy)**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 02:43:13
User signature succeeded.	Richard Rupp (b) (4)	26 Mar 2021 18:58:13
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	11 Mar 2021 16:37:54
User entered '02 Feb 2021'	Amber Stanford (b) (4)	02 Feb 2021 17:42:55
	(b) (4)	

**US3612005**

**Folder: OL-D29 (1)**

**Form: Exposure**

**Generated On: 10 Jun 2021 09:15:23**

[Was study treatment given?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 02:43:13
User signature succeeded.	Richard Rupp (b) (4)	26 Mar 2021 18:58:13
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	11 Mar 2021 16:37:58
User entered 'Yes (Y)'	Amber Stanford (b) (4)	02 Feb 2021 17:43:21
	(b) (4)	

**US3612005**

**Folder: OL-D29 (1)**

**Form: Exposure**

**Generated On: 10 Jun 2021 09:15:23**

[If No, reason not given](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 02:43:13
User signature succeeded.	Richard Rupp (b) (4)	26 Mar 2021 18:58:13
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	11 Mar 2021 16:37:58
User entered empty.	Amber Stanford (b) (4)	02 Feb 2021 17:43:21
	(b) (4)	

US3612005

Folder: OL-D29 (1)

Form: Exposure

Generated On: 10 Jun 2021 09:15:23

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)	25 Apr 2021 02:43:13
User signature succeeded.	Richard Rupp (b) (4)	26 Mar 2021 18:58:13
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	11 Mar 2021 16:37:58
User entered empty.	Amber Stanford (b) (4)	02 Feb 2021 17:43:21
	(b) (4)	

**US3612005**

**Folder: OL-D29 (1)**

**Form: Exposure**

**Generated On: 10 Jun 2021 09:15:23**

[What was the study treatment? \(Unblinded\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 02:43:13
User entered 'mRNA-1273'	System	02 Feb 2021 17:43:21
DataPoint set to visible.	System	12 Jan 2021 17:51:24

US3612005

Folder: OL-D29 (1)

Form: Exposure

Generated On: 10 Jun 2021 09:15:23

What was the treatment date? (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 02:43:13
User signature succeeded.	Richard Rupp (b) (4)	26 Mar 2021 18:58:13
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	11 Mar 2021 16:37:58
User entered '02 Feb 2021'	Amber Stanford (b) (4)	02 Feb 2021 17:43:21
	(b) (4)	

**US3612005**

**Folder: OL-D29 (1)**

**Form: Exposure**

**Generated On: 10 Jun 2021 09:15:23**

[What was the treatment time? \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 02:43:13
User signature succeeded.	Richard Rupp (b) (4)	26 Mar 2021 18:58:13
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	11 Mar 2021 16:37:58
User entered '09:20'	Amber Stanford (b) (4)	02 Feb 2021 17:43:21
	(b) (4)	

**US3612005**

**Folder: OL-D29 (1)**

**Form: Exposure**

**Generated On: 10 Jun 2021 09:15:23**

[Treatment Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 02:43:13
User entered '02 Feb 2021 09:20'	System	02 Feb 2021 17:43:21

**US3612005**

**Folder: OL-D29 (1)**

**Form: Exposure**

**Generated On: 10 Jun 2021 09:15:23**

[Which arm was used to give treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 02:43:13
User signature succeeded.	Richard Rupp (b) (4)	26 Mar 2021 18:58:13
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	11 Mar 2021 16:37:58
User entered 'Left Arm (LEFT ARM)'	Amber Stanford (b) (4)	02 Feb 2021 17:43:21
	(b) (4)	

**US3612005**

**Folder: OL-D29 (1)**

**Form: Exposure**

**Generated On: 10 Jun 2021 09:15:23**

[What was the frequency of the study treatment dosing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 02:43:13
DataPoint Verified.	(b) (4), (b) (6)	11 Mar 2021 16:37:58
User entered 'ONCE'	System	02 Feb 2021 17:43:21

**US3612005**

**Folder: OL-D29 (1)**

**Form: Exposure**

**Generated On: 10 Jun 2021 09:15:23**

[What was the route of administration for the study treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 02:43:13
User entered 'INTRAMUSCULAR'	System	02 Feb 2021 17:43:21

**US3612005**

**Folder: OL-D29 (1)**

**Form: Continuing**

**Generated On: 10 Jun 2021 09:15:23**

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 02:43:13
User signature succeeded.	Richard Rupp (b) (4)	26 Mar 2021 18:58:13
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	11 Mar 2021 16:38:07
User entered 'Yes (Y)'	Amber Stanford (b) (4)	02 Feb 2021 17:43:25
	(b) (4)	

**US3612005**

**Folder: OL-D29 (1)**

**Form: Continuing**

**Generated On: 10 Jun 2021 09:15:23**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 02:43:13
User entered 'I'	System	02 Feb 2021 17:43:25

**US3612005**

**Folder: Safety Call OL-D36 (1)**

**Form: Safety Call**

**Generated On: 10 Jun 2021 09:15:23**

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 02:43:13
User signature succeeded.	Richard Rupp (b) (4)	26 Mar 2021 18:58:32
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	11 Mar 2021 16:40:54
User entered 'Yes (Y)'	Amber Stanford (b) (4)	10 Feb 2021 17:30:54
	(b) (4)	

**US3612005**

**Folder: Safety Call OL-D36 (1)**

**Form: Safety Call**

**Generated On: 10 Jun 2021 09:15:23**

[Date of Contact or Contact Attempt \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 02:43:13
User signature succeeded.	Richard Rupp (b) (4)	26 Mar 2021 18:58:32
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	11 Mar 2021 16:40:54
User entered '10 Feb 2021'	Amber Stanford (b) (4)	10 Feb 2021 17:30:54
	(b) (4)	

**US3612005**

**Folder: Safety Call OL-D36 (1)**

**Form: Safety Call**

**Generated On: 10 Jun 2021 09:15:23**

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 02:43:13
User signature succeeded.	Richard Rupp (b) (4)	26 Mar 2021 18:58:32
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	11 Mar 2021 16:40:54
User entered 'Contact Made (CONTACT MADE)'	Amber Stanford (b) (4)	10 Feb 2021 17:30:54
	(b) (4)	

**US3612005**

**Folder: Safety Call OL-D36 (1)**

**Form: Safety Call**

**Generated On: 10 Jun 2021 09:15:23**

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 02:43:13
User signature succeeded.	Richard Rupp (b) (4)	26 Mar 2021 18:58:32
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	11 Mar 2021 16:40:54
User entered empty.	Amber Stanford (b) (4)	10 Feb 2021 17:30:54
	(b) (4)	

**US3612005**

**Folder: Safety Call OL-D36 (1)**

**Form: Continuing**

**Generated On: 10 Jun 2021 09:15:23**

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 02:43:13
User signature succeeded.	Richard Rupp (b) (4)	26 Mar 2021 18:58:32
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	11 Mar 2021 16:40:57
User entered 'Yes (Y)'	Amber Stanford (b) (4)	10 Feb 2021 17:31:00
	(b) (4)	

**US3612005**

**Folder: Safety Call OL-D36 (1)**

**Form: Continuing**

**Generated On: 10 Jun 2021 09:15:23**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 02:43:13
User entered 'I'	System	10 Feb 2021 17:31:00

**US3612005**

**Folder: OL-D57 (1)**

**Form: Visit Date**

**Generated On: 10 Jun 2021 09:15:23**

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 02:43:13
User signature succeeded.	Richard Rupp (b) (4)	26 Mar 2021 18:58:13
DataPoint Verified.	(b) (4)	11 Mar 2021 16:41:16
User entered 'Yes (Y)'	Amber Stanford (b) (4)	01 Mar 2021 16:56:57

**US3612005**

**Folder: OL-D57 (1)**

**Form: Visit Date**

**Generated On: 10 Jun 2021 09:15:23**

[Visit date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 02:43:13
User signature succeeded.	Richard Rupp (b) (4)	26 Mar 2021 18:58:13
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	11 Mar 2021 16:41:16
User entered '01 Mar 2021'	Amber Stanford (b) (4)	01 Mar 2021 16:56:57
	(b) (4)	

**US3612005**

**Folder: OL-D57 (1)**

**Form: Visit Date**

**Generated On: 10 Jun 2021 09:15:23**

[Was visit performed at the participant's home or at the clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 02:43:13
User signature succeeded.	Richard Rupp (b) (4)	26 Mar 2021 18:58:13
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	11 Mar 2021 16:41:16
User entered 'Clinic (Clinic)'	Amber Stanford (b) (4)	01 Mar 2021 16:56:57
	(b) (4)	

**US3612005**

**Folder: OL-D57 (1)**

**Form: Visit Date**

**Generated On: 10 Jun 2021 09:15:23**

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 02:43:13
User entered 'OLD57'	System	01 Mar 2021 16:56:57

**US3612005**

**Folder: OL-D57 (1)**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 09:15:23**

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 02:43:13
User signature succeeded.	Richard Rupp (b) (4)	26 Mar 2021 18:58:13
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	11 Mar 2021 16:41:33
User entered 'No (N)'	Amber Stanford (b) (4)	01 Mar 2021 16:57:06
	(b) (4)	

**US3612005**

**Folder: OL-D57 (1)**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 09:15:23**

**Date of assessment** (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 02:43:13
User signature succeeded.	Richard Rupp (b) (4)	26 Mar 2021 18:58:13
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	11 Mar 2021 16:41:33
User entered empty.	Amber Stanford (b) (4)	01 Mar 2021 16:57:06
	(b) (4)	

**US3612005**

**Folder: OL-D57 (1)**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 09:15:23**

[Time of assessment \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 02:43:13
User signature succeeded.	Richard Rupp (b) (4)	26 Mar 2021 18:58:13
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	11 Mar 2021 16:41:33
User entered empty.	Amber Stanford (b) (4)	01 Mar 2021 16:57:06
	(b) (4)	

**US3612005**

**Folder: OL-D57 (1)**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 09:15:23**

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 02:43:13
User entered empty.	System	01 Mar 2021 16:57:06

**US3612005**

**Folder: OL-D57 (1)**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 09:15:23**

[Temperature \(xxx.x\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 02:43:13
User signature succeeded.	Richard Rupp (b) (4)	26 Mar 2021 18:58:13
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	11 Mar 2021 16:41:33
User entered empty.	Amber Stanford (b) (4)	01 Mar 2021 16:57:06
	(b) (4)	

**US3612005**

**Folder: OL-D57 (1)**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 09:15:23**

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 02:43:13
User signature succeeded.	Richard Rupp (b) (4)	26 Mar 2021 18:58:13
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	11 Mar 2021 16:41:33
User entered empty.	Amber Stanford (b) (4)	01 Mar 2021 16:57:06
	(b) (4)	

**US3612005**

**Folder: OL-D57 (1)**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 09:15:23**

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 02:43:13
User signature succeeded.	Richard Rupp (b) (4)	26 Mar 2021 18:58:13
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	11 Mar 2021 16:41:33
User entered empty.	Amber Stanford (b) (4)	01 Mar 2021 16:57:06
	(b) (4)	

**US3612005**

**Folder: OL-D57 (1)**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 09:15:23**

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 02:43:13
User signature succeeded.	Richard Rupp (b) (4)	26 Mar 2021 18:58:13
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	11 Mar 2021 16:41:33
User entered empty.	Amber Stanford (b) (4)	01 Mar 2021 16:57:06
	(b) (4)	

**US3612005**

**Folder: OL-D57 (1)**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 09:15:23**

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 02:43:13
User entered empty.	System	01 Mar 2021 16:57:06

**US3612005**

**Folder: OL-D57 (1)**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 09:15:23**

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 02:43:13
User signature succeeded.	Richard Rupp (b) (4)	26 Mar 2021 18:58:13
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	11 Mar 2021 16:41:33
User entered empty.	Amber Stanford (b) (4)	01 Mar 2021 16:57:06
	(b) (4)	

**US3612005**

**Folder: OL-D57 (1)**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 09:15:23**

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 02:43:13
User entered empty.	System	01 Mar 2021 16:57:06

**US3612005**

**Folder: OL-D57 (1)**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 09:15:23**

[Systolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 02:43:13
User signature succeeded.	Richard Rupp (b) (4)	26 Mar 2021 18:58:13
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	11 Mar 2021 16:41:33
User entered empty.	Amber Stanford (b) (4)	01 Mar 2021 16:57:06
	(b) (4)	

**US3612005**

**Folder: OL-D57 (1)**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 09:15:23**

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 02:43:13
User entered empty.	System	01 Mar 2021 16:57:06

**US3612005**

**Folder: OL-D57 (1)**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 09:15:23**

[Diastolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 02:43:13
User signature succeeded.	Richard Rupp (b) (4)	26 Mar 2021 18:58:13
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	11 Mar 2021 16:41:33
User entered empty.	Amber Stanford (b) (4)	01 Mar 2021 16:57:06
	(b) (4)	

**US3612005**

**Folder: OL-D57 (1)**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 09:15:23**

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 02:43:13
User entered empty.	System	01 Mar 2021 16:57:06

**US3612005**

**Folder: OL-D57 (1)**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 09:15:23**

[Height \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 02:43:13

**US3612005**

**Folder: OL-D57 (1)**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 09:15:23**

[Weight \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 02:43:13

**US3612005**

**Folder: OL-D57 (1)**

**Form: Physical Examination**

**Generated On: 10 Jun 2021 09:15:23**

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 02:43:13
User signature succeeded.	Richard Rupp (b) (4)	26 Mar 2021 18:58:13
DataPoint Verified.	(b) (4)	11 Mar 2021 16:41:24
User entered 'No (N)'	Amber Stanford (b) (4)	01 Mar 2021 16:57:10

**US3612005**

**Folder: OL-D57 (1)**

**Form: Physical Examination**

**Generated On: 10 Jun 2021 09:15:23**

**Date of examination (dd MMM yyyy)**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 02:43:13
User signature succeeded.	Richard Rupp (b) (4)	26 Mar 2021 18:58:13
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	11 Mar 2021 16:41:24
User entered empty.	Amber Stanford (b) (4)	01 Mar 2021 16:57:10
	(b) (4)	

**US3612005**

**Folder: OL-D57 (1)**

**Form: Immunogenicity Assessment**

**Generated On: 10 Jun 2021 09:15:23**

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 02:43:13
User signature succeeded.	Richard Rupp (b) (4)	26 Mar 2021 18:58:13
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	11 Mar 2021 16:41:19
User entered 'Yes (Y)'	Amber Stanford (b) (4)	01 Mar 2021 16:56:47
	(b) (4)	

**US3612005**

**Folder: OL-D57 (1)**

**Form: Immunogenicity Assessment**

**Generated On: 10 Jun 2021 09:15:23**

**Collection date** (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 02:43:13
User signature succeeded.	Richard Rupp (b) (4)	26 Mar 2021 18:58:13
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	11 Mar 2021 16:41:19
User entered '01 Mar 2021'	Amber Stanford (b) (4)	01 Mar 2021 16:56:47
	(b) (4)	

**US3612005**

**Folder: OL-D57 (1)**

**Form: Immunogenicity Assessment**

**Generated On: 10 Jun 2021 09:15:23**

[Collection time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 02:43:13
User signature succeeded.	Richard Rupp (b) (4)	26 Mar 2021 18:58:13
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	11 Mar 2021 16:41:19
User entered '09:50'	Amber Stanford (b) (4)	01 Mar 2021 16:56:47
	(b) (4)	

**US3612005**

**Folder: OL-D57 (1)**

**Form: Immunogenicity Assessment**

**Generated On: 10 Jun 2021 09:15:23**

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 02:43:13
User entered '01 Mar 2021 09:50'	System	01 Mar 2021 16:56:47

US3612005

Folder: Adverse Events

Form: Adverse Events Summary

Generated On: 10 Jun 2021 09:15:23

[Did the participant experience any adverse events?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 08:50:12
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 15:54:19
User signature succeeded.	Richard Rupp (b) (4)	09 Apr 2021 14:55:29
DataPoint Un-verified.	(b) (4)	
	Kristin Pollock (b) (4)	06 Apr 2021 16:28:21
Signature has been broken.	(b) (4)	
	Kristin Pollock (b) (4)	06 Apr 2021 16:28:21
User entered 'Yes (Y)' reason for change: New Information	(b) (4)	
	Kristin Pollock (b) (4)	06 Apr 2021 16:28:21
User signature succeeded.	Richard Rupp (b) (4)	19 Mar 2021 16:13:30
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	11 Mar 2021 16:09:16
	(b) (4), (b) (6)	
DataPoint Un-verified.	(b) (4), (b) (6)	11 Mar 2021 16:08:42
	(b) (4), (b) (6)	
DataPoint Verified.	(b) (4), (b) (6)	11 Mar 2021 16:08:33
	(b) (4), (b) (6)	
User entered 'No (N)'	Amy McMahan (b) (4)	04 Feb 2021 15:57:45
	(b) (4)	

**US3612005**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 10 Jun 2021 09:15:23**

[AEID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:35:55

US3612005

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:15:23

[Adverse event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:35:55
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 15:54:26
User signature succeeded.	Richard Rupp (b) (4)	09 Apr 2021 14:55:29
User coded data point as SOC: Infections and infestations, HLGT: Infections - pathogen unspecified, HLT: Ear infections, PT: Otitis externa, LLT: Otitis externa - version MedDRA\23.0.	Coder Import (b) (4)	08 Apr 2021 14:21:58
User coded data point as Term Coded data point by User: Coder System - version MedDRA\23.0.	Coder Import (b) (4)	08 Apr 2021 14:21:58
Data point term sent to Coder	System	08 Apr 2021 14:20:17
User coded data point as SOC: Infections and infestations, HLGT: Infections - pathogen unspecified, HLT: Ear infections, PT: Otitis externa, LLT: Otitis externa - version MedDRA\23.0.	Coder Import (b) (4)	08 Apr 2021 14:19:45
User coded data point as Term Coded data point by User: Coder System - version MedDRA\23.0.	Coder Import (b) (4)	08 Apr 2021 14:19:45
Query 'CDM-Coding: RIGHT EAR DRAINAGE is a medical and surgical procedure and not appropriate as an adverse event. Please enter the diagnosis for which this procedure was performed and amend /update the term accordingly. Thank you. ' canceled (Site from System).	Coder Import (b) (4)	08 Apr 2021 14:19:40
Data point term sent to Coder	System	08 Apr 2021 14:18:15
DataPoint Un-verified.	Kristin Pollock (b) (4)	08 Apr 2021 14:18:00
User entered 'Otitis Externa' reason for change: Per Query Resolution	Kristin Pollock (b) (4)	08 Apr 2021 14:18:00
User opened query 'CDM-Coding: RIGHT EAR DRAINAGE is a medical and surgical procedure and not appropriate as an adverse event. Please enter the diagnosis for which this procedure was performed and amend /update the term accordingly. Thank you. ' (Site from System).	Coder Import (b) (4)	08 Apr 2021 09:44:36
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 18:13:34
Data point term sent to Coder	System	06 Apr 2021 16:29:45
User entered 'Right Ear Drainage'	Kristin Pollock (b) (4)	06 Apr 2021 16:29:20

**US3612005**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 10 Jun 2021 09:15:23**

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:35:55
User signature succeeded.	Richard Rupp (b) (4)	09 Apr 2021 14:55:29
DataPoint Verified.	(b) (4)	06 Apr 2021 18:13:34
User entered 'Yes (Y)'	Kristin Pollock (b) (4)	06 Apr 2021 16:29:20

**US3612005**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 10 Jun 2021 09:15:23**

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:35:55
User signature succeeded.	Richard Rupp (b) (4)	09 Apr 2021 14:55:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Apr 2021 18:13:34
User entered 'No (N)'	Kristin Pollock (b) (4) (b) (4)	06 Apr 2021 16:29:20

**US3612005**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 10 Jun 2021 09:15:23**

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:35:55
User signature succeeded.	Richard Rupp (b) (4)	09 Apr 2021 14:55:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Apr 2021 18:13:34
User entered 'No (N)'	Kristin Pollock (b) (4) (b) (4)	06 Apr 2021 16:29:20

**US3612005**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 10 Jun 2021 09:15:23**

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:35:55
User signature succeeded.	Richard Rupp (b) (4)	09 Apr 2021 14:55:29
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	06 Apr 2021 18:13:34
User entered '02 Jan 2021'	Kristin Pollock (b) (4)	06 Apr 2021 16:29:20
	(b) (4)	

**US3612005**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 10 Jun 2021 09:15:23**

[Start time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:35:55
User signature succeeded.	Richard Rupp (b) (4)	09 Apr 2021 14:55:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Apr 2021 18:13:34
User entered empty.	Kristin Pollock (b) (4) (b) (4)	06 Apr 2021 16:29:20

**US3612005**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 10 Jun 2021 09:15:23**

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:35:55
User entered empty.	System	06 Apr 2021 16:29:20

**US3612005**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 10 Jun 2021 09:15:23**

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:35:55
User signature succeeded.	Richard Rupp (b) (4)	09 Apr 2021 14:55:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Apr 2021 18:13:34
User entered 'No (N)'	Kristin Pollock (b) (4) (b) (4)	06 Apr 2021 16:29:20

**US3612005**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 10 Jun 2021 09:15:23**

*If not Ongoing, end date (dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:35:55
User signature succeeded.	Richard Rupp (b) (4)	09 Apr 2021 14:55:29
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	06 Apr 2021 18:13:34
User entered '09 Jan 2021'	Kristin Pollock (b) (4)	06 Apr 2021 16:29:20
	(b) (4)	

**US3612005**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 10 Jun 2021 09:15:23**

**End time (00:00-23:59)**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:35:55
User signature succeeded.	Richard Rupp (b) (4)	09 Apr 2021 14:55:29
DataPoint Verified.	(b) (4)	06 Apr 2021 18:13:34
User entered empty.	Kristin Pollock (b) (4)	06 Apr 2021 16:29:20

**US3612005**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 10 Jun 2021 09:15:23**

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:35:55
User entered empty.	System	06 Apr 2021 16:29:20

**US3612005**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 10 Jun 2021 09:15:23**

[Severity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:35:55
User signature succeeded.	Richard Rupp (b) (4)	09 Apr 2021 14:55:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Apr 2021 18:13:34
User entered 'Grade 1/Mild (Grade 1/Mild)'	Kristin Pollock (b) (4) (b) (4)	06 Apr 2021 16:29:20

**US3612005**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 10 Jun 2021 09:15:23**

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:35:55
User signature succeeded.	Richard Rupp (b) (4)	09 Apr 2021 14:55:29
DataPoint Verified.	(b) (4)	06 Apr 2021 18:13:34
User entered 'No (N)'	Kristin Pollock (b) (4)	06 Apr 2021 16:29:20

**US3612005**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 10 Jun 2021 09:15:23**

[Death](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:35:55
User signature succeeded.	Richard Rupp (b) (4)	09 Apr 2021 14:55:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Apr 2021 18:13:34
User entered '0'	Kristin Pollock (b) (4) (b) (4)	06 Apr 2021 16:29:20

**US3612005**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 10 Jun 2021 09:15:23**

[Life threatening](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:35:55
User signature succeeded.	Richard Rupp (b) (4)	09 Apr 2021 14:55:29
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	06 Apr 2021 18:13:34
User entered '0'	Kristin Pollock (b) (4)	06 Apr 2021 16:29:20
	(b) (4)	

**US3612005**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 10 Jun 2021 09:15:23**

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:35:55
User signature succeeded.	Richard Rupp (b) (4)	09 Apr 2021 14:55:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Apr 2021 18:13:34
User entered '0'	Kristin Pollock (b) (4) (b) (4)	06 Apr 2021 16:29:20

**US3612005**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 10 Jun 2021 09:15:23**

**Hospital Admission Date** (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:35:55
User signature succeeded.	Richard Rupp (b) (4)	09 Apr 2021 14:55:29
DataPoint Verified.	(b) (4)	06 Apr 2021 18:13:34
User entered empty.	Kristin Pollock (b) (4)	06 Apr 2021 16:29:20

**US3612005**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 10 Jun 2021 09:15:23**

[Hospital Discharge Date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:35:55
User signature succeeded.	Richard Rupp (b) (4)	09 Apr 2021 14:55:29
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	06 Apr 2021 18:13:34
User entered empty.	Kristin Pollock (b) (4)	06 Apr 2021 16:29:20
	(b) (4)	

**US3612005**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 10 Jun 2021 09:15:23**

[Admitted to ICU?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:35:55
User signature succeeded.	Richard Rupp (b) (4)	09 Apr 2021 14:55:29
DataPoint Verified.	(b) (4)	06 Apr 2021 18:13:34
User entered empty.	Kristin Pollock (b) (4)	06 Apr 2021 16:29:20

**US3612005**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 10 Jun 2021 09:15:23**

[Number of Days in ICU](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:35:55
User signature succeeded.	Richard Rupp (b) (4)	09 Apr 2021 14:55:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Apr 2021 18:13:34
User entered empty.	Kristin Pollock (b) (4) (b) (4)	06 Apr 2021 16:29:20

**US3612005**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 10 Jun 2021 09:15:23**

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:35:55
User signature succeeded.	Richard Rupp (b) (4)	09 Apr 2021 14:55:29
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	06 Apr 2021 18:13:34
User entered '0'	Kristin Pollock (b) (4)	06 Apr 2021 16:29:20
	(b) (4)	

**US3612005**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 10 Jun 2021 09:15:23**

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:35:55
User signature succeeded.	Richard Rupp (b) (4)	09 Apr 2021 14:55:29
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	06 Apr 2021 18:13:34
User entered '0'	Kristin Pollock (b) (4)	06 Apr 2021 16:29:20
	(b) (4)	

**US3612005**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 10 Jun 2021 09:15:23**

[Other medically important event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:35:55
User signature succeeded.	Richard Rupp (b) (4)	09 Apr 2021 14:55:29
DataPoint Verified.	(b) (4)	06 Apr 2021 18:13:34
User entered '0'	Kristin Pollock (b) (4)	06 Apr 2021 16:29:20

**US3612005**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 10 Jun 2021 09:15:23**

[Relationship to investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:35:55
User signature succeeded.	Richard Rupp (b) (4)	09 Apr 2021 14:55:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Apr 2021 18:13:34
User entered 'Not Related (NOT RELATED)'	Kristin Pollock (b) (4) (b) (4)	06 Apr 2021 16:29:20

**US3612005**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 10 Jun 2021 09:15:23**

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:35:55
User signature succeeded.	Richard Rupp (b) (4)	09 Apr 2021 14:55:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Apr 2021 18:13:34
User entered 'Not Related (NOT RELATED)'	Kristin Pollock (b) (4) (b) (4)	06 Apr 2021 16:29:20

**US3612005**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 10 Jun 2021 09:15:23**

[Action taken with investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:35:55
User signature succeeded.	Richard Rupp (b) (4)	09 Apr 2021 14:55:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Apr 2021 18:13:34
User entered 'Not Applicable (NOT APPLICABLE)'	Kristin Pollock (b) (4) (b) (4)	06 Apr 2021 16:29:20

**US3612005**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 10 Jun 2021 09:15:23**

[None](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:35:55
User signature succeeded.	Richard Rupp (b) (4)	09 Apr 2021 14:55:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Apr 2021 18:13:34
User entered '0'	Kristin Pollock (b) (4) (b) (4)	06 Apr 2021 16:29:20

**US3612005**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 10 Jun 2021 09:15:23**

[Concomitant Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:35:55
User signature succeeded.	Richard Rupp (b) (4)	09 Apr 2021 14:55:29
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	06 Apr 2021 18:13:34
User entered 'l'	Kristin Pollock (b) (4)	06 Apr 2021 16:29:20
	(b) (4)	

**US3612005**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 10 Jun 2021 09:15:23**

[Concomitant Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:35:55
User signature succeeded.	Richard Rupp (b) (4)	09 Apr 2021 14:55:29
DataPoint Verified.	(b) (4)	06 Apr 2021 18:13:34
User entered '0'	Kristin Pollock (b) (4)	06 Apr 2021 16:29:20

**US3612005**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 10 Jun 2021 09:15:23**

[Outcome](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:35:55
User signature succeeded.	Richard Rupp (b) (4)	09 Apr 2021 14:55:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Apr 2021 18:13:34
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)'	Kristin Pollock (b) (4) (b) (4)	06 Apr 2021 16:29:20

**US3612005**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 10 Jun 2021 09:15:23**

[If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:35:55
User signature succeeded.	Richard Rupp (b) (4)	09 Apr 2021 14:55:29
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	06 Apr 2021 18:13:34
User entered empty.	Kristin Pollock (b) (4)	06 Apr 2021 16:29:20
	(b) (4)	

**US3612005**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 10 Jun 2021 09:15:23**

[Narrative](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:35:55
User signature succeeded.	Richard Rupp (b) (4)	09 Apr 2021 14:55:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Apr 2021 18:13:34
User entered empty.	Kristin Pollock (b) (4) (b) (4)	06 Apr 2021 16:29:20

**US3612005**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 10 Jun 2021 09:15:23**

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:35:55
User entered '0'	System	06 Apr 2021 16:29:20

**US3612005**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 10 Jun 2021 09:15:23**

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:35:55
User entered '1'	System	06 Apr 2021 16:29:20

**US3612005**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 10 Jun 2021 09:15:23**

[Admitted to ICU Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:35:55

**US3612005**

**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 10 Jun 2021 09:15:23**

[AEID](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 14:43:20
User signature succeeded.	Richard Rupp (b) (4)	22 Apr 2021 15:29:49
Reviewed for Safety.	(b) (4)	
	(b) (4), (b) (6)	21 Apr 2021 15:26:17
User entered		
'USA-US129-2021-mRNA-1273-P301000006'	System	21 Apr 2021 15:26:12
User entered 'New'	(b) (4), (b) (6)	21 Apr 2021 15:26:12

US3612005

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:15:23

[Adverse event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 14:43:23
User signature succeeded.	Richard Rupp (b) (4)	20 Apr 2021 18:27:14
User coded data point as SOC: Cardiac disorders, HLGT: Coronary artery disorders, HLT: Ischaemic coronary artery disorders, PT: Myocardial infarction, LLT: Myocardial infarction - version MedDRA\\23.0.	Coder Import (b) (4)	20 Apr 2021 16:12:40
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	20 Apr 2021 16:12:40
Data point term sent to Coder	System	20 Apr 2021 16:11:58
User entered 'Myocardial Infarction'	Amy McMahan (b) (4)	20 Apr 2021 16:11:42

**US3612005**

**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 10 Jun 2021 09:15:23**

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 14:43:23
User signature succeeded.	Richard Rupp (b) (4)	20 Apr 2021 18:27:14
User entered 'Yes (Y)'	Amy McMahan (b) (4)	20 Apr 2021 16:11:42

**US3612005**

**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 10 Jun 2021 09:15:23**

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 14:43:23
User signature succeeded.	Richard Rupp (b) (4)	20 Apr 2021 18:27:14
User entered 'No (N)'	Amy McMahan (b) (4)	20 Apr 2021 16:11:42

**US3612005**

**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 10 Jun 2021 09:15:23**

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 14:43:23
User signature succeeded.	Richard Rupp (b) (4)	20 Apr 2021 18:27:14
User entered 'No (N)'	Amy McMahan (b) (4)	20 Apr 2021 16:11:42

**US3612005**

**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 10 Jun 2021 09:15:23**

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 14:43:23
User signature succeeded.	Richard Rupp (b) (4)	20 Apr 2021 18:27:14
User entered '13 Apr 2021'	Amy McMahan (b) (4)	20 Apr 2021 16:11:42

**US3612005**

**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 10 Jun 2021 09:15:23**

[Start time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 14:43:23
User signature succeeded.	Richard Rupp (b) (4)	20 Apr 2021 18:27:14
User entered empty.	Amy McMahan (b) (4)	20 Apr 2021 16:11:42

**US3612005**

**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 10 Jun 2021 09:15:23**

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	20 Apr 2021 16:11:42

**US3612005**

**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 10 Jun 2021 09:15:23**

[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 14:43:23
User signature succeeded.	Richard Rupp (b) (4)	20 Apr 2021 18:27:14
User entered 'No (N)'	Amy McMahan (b) (4)	20 Apr 2021 16:11:42

US3612005

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:15:23

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Richard Rupp (b) (4)	23 Apr 2021 17:48:37
Query 'Stop date per source is 17APR2021.' canceled (Site from CRA).	(b) (4)	23 Apr 2021 15:16:03
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 15:16:00
DataPoint Un-verified.	(b) (4), (b) (6)	23 Apr 2021 15:15:52
Signature has been broken.	Amy McMahan (b) (4)	23 Apr 2021 15:15:52
User entered '17 Apr 2021' reason for change: Data Entry Error	(b) (4)	23 Apr 2021 15:15:52
User opened query 'Stop date per source is 17APR2021.' (Site from CRA).	Amy McMahan (b) (4)	23 Apr 2021 14:44:14
Query 'Per study team review, "Hospital discharge date is after illness visit end date. Can you please reconfirm the end date and reconcile dates in EDC and/or source, if needed." ' canceled (Site from CRA).	(b) (4), (b) (6)	23 Apr 2021 14:43:44
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 14:43:23
User opened query 'Per study team review, "Hospital discharge date is after illness visit end date. Can you please reconfirm the end date and reconcile dates in EDC and/or source, if needed." ' (Site from CRA).	(b) (4), (b) (6)	22 Apr 2021 16:24:53
User signature succeeded.	Richard Rupp (b) (4)	20 Apr 2021 18:27:14
User entered '16 Apr 2021'	(b) (4)	20 Apr 2021 16:11:42
	Amy McMahan (b) (4)	
	(b) (4)	

**US3612005**

**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 10 Jun 2021 09:15:23**

[End time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 14:43:23
User signature succeeded.	Richard Rupp (b) (4)	20 Apr 2021 18:27:14
User entered empty.	Amy McMahan (b) (4)	20 Apr 2021 16:11:42

**US3612005**

**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 10 Jun 2021 09:15:23**

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	20 Apr 2021 16:11:42

**US3612005**

**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 10 Jun 2021 09:15:23**

[Severity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 14:43:23
User signature succeeded.	Richard Rupp (b) (4)	20 Apr 2021 18:27:14
User entered 'Grade 4 (Grade 4)'	Amy McMahan (b) (4)	20 Apr 2021 16:11:42

**US3612005**

**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 10 Jun 2021 09:15:23**

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 14:43:23
User signature succeeded.	Richard Rupp (b) (4)	20 Apr 2021 18:27:14
User entered 'Yes (Y)'	Amy McMahan (b) (4)	20 Apr 2021 16:11:42

**US3612005**

**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 10 Jun 2021 09:15:23**

[Death](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 14:43:23
User signature succeeded.	Richard Rupp (b) (4)	20 Apr 2021 18:27:14
User entered '0'	Amy McMahan (b) (4)	20 Apr 2021 16:11:42

**US3612005**

**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 10 Jun 2021 09:15:23**

[Life threatening](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 14:43:23
User signature succeeded.	Richard Rupp (b) (4)	20 Apr 2021 18:27:14
User entered 'I'	Amy McMahan (b) (4)	20 Apr 2021 16:11:42

**US3612005**

**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 10 Jun 2021 09:15:23**

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 14:43:23
User signature succeeded.	Richard Rupp (b) (4)	20 Apr 2021 18:27:14
User entered 'I'	Amy McMahan (b) (4)	20 Apr 2021 16:11:42

US3612005

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:15:23

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 14:43:23
User signature succeeded.	Richard Rupp (b) (4)	20 Apr 2021 18:27:14
User entered '13 Apr 2021'	Amy McMahan (b) (4)	20 Apr 2021 16:11:42

**US3612005**

**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 10 Jun 2021 09:15:23**

**Hospital Discharge Date (dd MMM yyyy)**

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 14:43:23
User signature succeeded.	Richard Rupp (b) (4)	20 Apr 2021 18:27:14
User entered '17 Apr 2021'	Amy McMahan (b) (4)	20 Apr 2021 16:11:42

US3612005

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:15:23

[Admitted to ICU?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 14:43:23
User signature succeeded.	Richard Rupp (b) (4)	20 Apr 2021 18:27:14
User closed query 'Admitted to ICU?' is Unknown. However, this data must be collected. Please leave this query open until the response can be updated to Yes or No.' (Site from System).	(b) (4) System	20 Apr 2021 16:12:06
Query 'Admitted to ICU?' is Unknown. However, this System data must be collected. Please leave this query open until the response can be updated to Yes or No.' answered by data change (Site from System).		20 Apr 2021 16:12:06
User entered 'No (N)' reason for change: Data Entry Error	Amy McMahan (b) (4) (b) (4)	20 Apr 2021 16:12:06
User opened query 'Admitted to ICU?' is Unknown. However, this data must be collected. Please leave this query open until the response can be updated to Yes or No.' (Site from System).	System	20 Apr 2021 16:11:42
User entered 'Unknown (UNK)'	Amy McMahan (b) (4) (b) (4)	20 Apr 2021 16:11:42

**US3612005**

**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 10 Jun 2021 09:15:23**

[Number of Days in ICU](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 14:43:23
User signature succeeded.	Richard Rupp (b) (4)	20 Apr 2021 18:27:14
User entered empty.	Amy McMahan (b) (4)	20 Apr 2021 16:11:42

**US3612005**

**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 10 Jun 2021 09:15:23**

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 14:43:23
User signature succeeded.	Richard Rupp (b) (4)	20 Apr 2021 18:27:14
User entered '0'	Amy McMahan (b) (4)	20 Apr 2021 16:11:42

**US3612005**

**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 10 Jun 2021 09:15:23**

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 14:43:23
User signature succeeded.	Richard Rupp (b) (4)	20 Apr 2021 18:27:14
User entered '0'	Amy McMahan (b) (4)	20 Apr 2021 16:11:42

**US3612005**

**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 10 Jun 2021 09:15:23**

[Other medically important event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 14:43:23
User signature succeeded.	Richard Rupp (b) (4)	20 Apr 2021 18:27:14
User entered '0'	Amy McMahan (b) (4)	20 Apr 2021 16:11:42

**US3612005**

**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 10 Jun 2021 09:15:23**

[Relationship to investigational product](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 14:43:23
User signature succeeded.	Richard Rupp (b) (4)	20 Apr 2021 18:27:14
User entered 'Not Related (NOT RELATED)'	Amy McMahan (b) (4)	20 Apr 2021 16:11:42

**US3612005**

**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 10 Jun 2021 09:15:23**

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 14:43:23
User signature succeeded.	Richard Rupp (b) (4)	20 Apr 2021 18:27:14
User entered 'Not Related (NOT RELATED)'	Amy McMahan (b) (4)	20 Apr 2021 16:11:42

**US3612005**

**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 10 Jun 2021 09:15:23**

[Action taken with investigational product](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 14:43:23
User signature succeeded.	Richard Rupp (b) (4)	20 Apr 2021 18:27:14
User entered 'Not Applicable (NOT APPLICABLE)'	Amy McMahan (b) (4)	20 Apr 2021 16:11:42

**US3612005**

**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 10 Jun 2021 09:15:23**

[None](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 14:43:23
User signature succeeded.	Richard Rupp (b) (4)	20 Apr 2021 18:27:14
User entered '0'	Amy McMahan (b) (4)	20 Apr 2021 16:11:42

**US3612005**

**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 10 Jun 2021 09:15:23**

[Concomitant Medication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 14:43:23
User signature succeeded.	Richard Rupp (b) (4)	20 Apr 2021 18:27:14
User entered 'I'	Amy McMahan (b) (4)	20 Apr 2021 16:11:42

**US3612005**

**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 10 Jun 2021 09:15:23**

[Concomitant Procedure](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 14:43:23
User signature succeeded.	Richard Rupp (b) (4)	20 Apr 2021 18:27:14
User entered 'I'	Amy McMahan (b) (4)	20 Apr 2021 16:11:42

**US3612005**

**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 10 Jun 2021 09:15:23**

[Outcome](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 14:43:23
User signature succeeded.	Richard Rupp (b) (4)	20 Apr 2021 18:27:14
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)'	(b) (4) Amy McMahan (b) (4)	20 Apr 2021 16:11:42

**US3612005**

**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 10 Jun 2021 09:15:23**

[If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 14:43:23
User signature succeeded.	Richard Rupp (b) (4)	20 Apr 2021 18:27:14
User entered empty.	Amy McMahan (b) (4)	20 Apr 2021 16:11:42

US3612005

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:15:23

[Narrative](#)

Audit	User	Time (GMT)
User closed query 'PV Query: Please provide the results of any COVID-19 testing performed during hospital admission, including date of collection and type of testing.? If not done, please state so.' (Site from Safety).	(b) (4), (b) (6)	03 May 2021 14:24:07
User closed query 'PV Query: Please provide any relevant laboratory and diagnostic test results. Please include units and reference ranges if applicable. If needed, results with patient identifiers redacted and subject ID added can be sent to Safety_Moderna@iqvia.com or fax to 866.599.1342. If no results are available, please confirm in your response.' (Site from Safety).	(b) (4), (b) (6)	03 May 2021 14:24:04
User closed query 'PV Query: If available, please provide cardiologist follow-up information from 20 Apr 2021. Please keep query open until reports become available.' (Site from Safety).	(b) (4), (b) (6)	03 May 2021 14:23:58
Query 'PV Query: Please provide any relevant laboratory and diagnostic test results. Please include units and reference ranges if applicable. If needed, results with patient identifiers redacted and subject ID added can be sent to Safety_Moderna@iqvia.com or fax to 866.599.1342. If no results are available, please confirm in your response.' answered with 'Completed' (Site from Safety).	Amy McMahan (b) (4) (b) (4)	30 Apr 2021 20:01:23
Query 'PV Query: If available, please provide cardiologist follow-up information from 20 Apr 2021. Please keep query open until reports become available.' answered with 'completed' (Site from Safety).	Amy McMahan (b) (4) (b) (4)	30 Apr 2021 19:09:53

US3612005

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:15:23

[Narrative](#)

Audit	User	Time (GMT)
User entered 'RECEIVED CALL FROM SUBJECT STATING HE WAS HOSPITALIZED 13APR2021 FOR A MYOCARDIAL INFARCTION WITH DISCHARGE ON 17APR2021. PATIENT UNDERWENT CARDIAC CATHETERIZATION AND STENT PLACEMENT IN 13APR2021. SUBJECT IS SCHEDULED TO FOLLOW UP WITH CARDIOLOGIST 20APR2021. COVID-19 TESTING NO COMPLETED DURING HOSPITALIZATION. Follow up with cardiologist on 20-Apr-2021. Patient states there were no changes in health, however medications were changed. The changes in medications are reflected in concomitant medications.' reason for change: Data Entry Error	Amy McMahan (b) (4)	30 Apr 2021 19:09:20
Query 'PV Query: Please provide the results of any COVID-19 testing performed during hospital admission, including date of collection and type of testing.? If not done, please state so.' answered with 'completed' (Site from Safety).	Amy McMahan (b) (4)	30 Apr 2021 19:05:06
DataPoint Un-verified.	Amy McMahan (b) (4)	30 Apr 2021 19:04:34
Signature has been broken.	Amy McMahan (b) (4)	30 Apr 2021 19:04:34
User entered 'RECEIVED CALL FROM SUBJECT STATING HE WAS HOSPITALIZED 13APR2021 FOR A MYOCARDIAL INFARCTION WITH DISCHARGE ON 17APR2021. PATIENT UNDERWENT CARDIAC CATHETERIZATION AND STENT PLACEMENT IN 13APR2021. SUBJECT IS SCHEDULED TO FOLLOW UP WITH CARDIOLOGIST 20APR2021. Covid-19 testing no completed during hospitalization. WILL FOLLOW UP WITH SUBJECT WHEN MORE INFORMATION IS AVAILABLE.' reason for change: Data Entry Error	Amy McMahan (b) (4)	30 Apr 2021 19:04:34
User opened query 'PV Query: If available, please provide cardiologist follow-up information from 20 Apr 2021. Please keep query open until reports become available.' (Site from Safety).	(b) (4), (b) (6)	30 Apr 2021 13:47:45

US3612005

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:15:23

[Narrative](#)

Audit	User	Time (GMT)
User opened query 'PV Query: Please provide any relevant laboratory and diagnostic test results. Please include units and reference ranges if applicable. If needed, results with patient identifiers redacted and subject ID added can be sent to Safety_Moderna@iqvia.com or fax to 866.599.1342. If no results are available, please confirm in your response.' (Site from Safety).	(b) (4), (b) (6)	30 Apr 2021 13:47:29
User opened query 'PV Query: Please provide the results of any COVID-19 testing performed during hospital admission, including date of collection and type of testing.? If not done, please state so.' (Site from Safety).	(b) (4), (b) (6)	30 Apr 2021 13:47:14
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 14:43:23
User signature succeeded.	Richard Rupp (b) (4)	20 Apr 2021 18:27:14
User entered 'Received call from subject stating he was hospitalized 13Apr2021 for a Myocardial Infarction with discharge on 17Apr2021. Patient underwent cardiac catheterization and stent placement in 13Apr2021. Subject is scheduled to follow up with cardiologist 20Apr2021. Will follow up with subject when more information is available.'	Amy McMahan (b) (4)	20 Apr 2021 16:11:42

**US3612005**

**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 10 Jun 2021 09:15:23**

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '1'	System	20 Apr 2021 16:11:42

**US3612005**

**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 10 Jun 2021 09:15:23**

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '1'	System	20 Apr 2021 16:11:42

**US3612005**

**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 10 Jun 2021 09:15:23**

[Admitted to ICU Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '0'	System	20 Apr 2021 16:11:42

US3612005

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination Summary

Generated On: 10 Jun 2021 09:15:23

[Were any prior/concomitant medications and/or vaccinations taken?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 08:50:12
User signature succeeded.	Richard Rupp (b) (4)	26 Mar 2021 18:58:13
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	09 Sep 2020 18:30:53
User entered 'Yes (Y)'	Gerianne Casey (b) (4)	01 Sep 2020 16:13:11
	(b) (4)	

US3612005

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 09:15:23

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Rupp (b) (4)	26 Mar 2021 18:58:13
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	09 Sep 2020 18:31:34
User coded data point as ATC: MUSCULO-SKELETAL SYSTEM, ATC: ANTIGOUT PREPARATIONS, ATC: ANTIGOUT PREPARATIONS, ATC: PREPARATIONS INHIBITING URIC ACID PRODUCTION, PRODUCT: ALLOPURINOL - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	01 Sep 2020 16:24:55
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	01 Sep 2020 16:24:55
Data point term sent to Coder	System	01 Sep 2020 16:23:18
User entered 'allopurinol'	Gerianne Casey (b) (4) (b) (4)	01 Sep 2020 16:23:06

**US3612005**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 10 Jun 2021 09:15:23**

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Rupp (b) (4)	26 Mar 2021 18:58:13
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Sep 2020 18:31:34
User entered 'Yes (Y)'	Gerianne Casey (b) (4) (b) (4)	01 Sep 2020 16:23:06

US3612005

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 09:15:23

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Rupp (b) (4)	26 Mar 2021 18:58:13
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	22 Sep 2020 15:27:08
User closed query 'No indication noted in source. Please update source. ' (Site from CRA).	(b) (4), (b) (6)	16 Sep 2020 17:27:10
Query 'No indication noted in source. Please update source. ' answered with 'Completed in source.' (Site from CRA).	Amy McMahan (b) (4)	15 Sep 2020 19:28:02
	(b) (4)	
User opened query 'No indication noted in source. Please update source. ' (Site from CRA).	(b) (4), (b) (6)	09 Sep 2020 18:32:10
DataPoint Un-verified.	(b) (4), (b) (6)	09 Sep 2020 18:31:49
DataPoint Verified.	(b) (4), (b) (6)	09 Sep 2020 18:31:34
User entered 'kidney stones'	Gerianne Casey (b) (4)	01 Sep 2020 16:23:06
	(b) (4)	

**US3612005**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 10 Jun 2021 09:15:23**

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Rupp (b) (4)	26 Mar 2021 18:58:13
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Sep 2020 18:31:34
User entered '300'	Gerianne Casey (b) (4) (b) (4)	01 Sep 2020 16:23:06

US3612005

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 09:15:23

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Rupp (b) (4)	26 Mar 2021 18:58:13
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Sep 2020 18:31:34
User entered 'mg (mg)'	Gerianne Casey (b) (4) (b) (4)	01 Sep 2020 16:23:06

US3612005

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 09:15:23

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Richard Rupp (b) (4)	26 Mar 2021 18:58:13
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Sep 2020 18:31:34
User entered empty.	Gerianne Casey (b) (4) (b) (4)	01 Sep 2020 16:23:06

US3612005

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 09:15:23

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Rupp (b) (4)	26 Mar 2021 18:58:13
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Sep 2020 18:31:34
User entered 'once daily (QD)'	Gerianne Casey (b) (4) (b) (4)	01 Sep 2020 16:23:06

US3612005

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 09:15:23

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Richard Rupp (b) (4)	26 Mar 2021 18:58:13
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Sep 2020 18:31:34
User entered empty.	Gerianne Casey (b) (4) (b) (4)	01 Sep 2020 16:23:06

**US3612005**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 10 Jun 2021 09:15:23**

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Rupp (b) (4)	26 Mar 2021 18:58:13
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Sep 2020 18:31:34
User entered 'Oral (ORAL)'	Gerianne Casey (b) (4) (b) (4)	01 Sep 2020 16:23:06

US3612005

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 09:15:23

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Richard Rupp (b) (4)	26 Mar 2021 18:58:13
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Sep 2020 18:31:34
User entered empty.	Gerianne Casey (b) (4) (b) (4)	01 Sep 2020 16:23:06

US3612005

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 09:15:23

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Richard Rupp (b) (4)	26 Mar 2021 18:58:13
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Sep 2020 18:31:34
User closed query 'Start date is missing and Start date completely unknown is not checked. Please provide.' (Site from System).	System	01 Sep 2020 17:13:57
User entered '15 Jul 1981' reason for change: New Information	Gerianne Casey (b) (4) (b) (4)	01 Sep 2020 17:13:57
User opened query 'Start date is missing and Start date completely unknown is not checked. Please provide.' (Site from System).	System	01 Sep 2020 16:23:06
User entered empty.	Gerianne Casey (b) (4) (b) (4)	01 Sep 2020 16:23:06

**US3612005**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 10 Jun 2021 09:15:23**

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Rupp (b) (4)	26 Mar 2021 18:58:13
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Sep 2020 18:31:34
User entered '0'	Gerianne Casey (b) (4) (b) (4)	01 Sep 2020 16:23:06

US3612005

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 09:15:23

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Rupp (b) (4)	22 Apr 2021 15:29:49
DataPoint Un-verified.	(b) (4)	
	Kristin Pollock (b) (4)	20 Apr 2021 19:43:10
	(b) (4)	
Signature has been broken.	Kristin Pollock (b) (4)	20 Apr 2021 19:43:10
	(b) (4)	
User entered 'No (N)' reason for change: New Information	Kristin Pollock (b) (4)	20 Apr 2021 19:43:10
	(b) (4)	
User signature succeeded.	Richard Rupp (b) (4)	26 Mar 2021 18:58:13
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	09 Sep 2020 18:31:34
User closed query 'Data is required. Please complete.' (Site from System).	System	01 Sep 2020 17:13:57
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	01 Sep 2020 17:13:57
User entered 'Yes (Y)' reason for change: New Information	Gerianne Casey (b) (4)	01 Sep 2020 17:13:57
	(b) (4)	
User opened query 'Data is required. Please complete.' (Site from System).	System	01 Sep 2020 16:23:06
User entered empty.	Gerianne Casey (b) (4)	01 Sep 2020 16:23:06
	(b) (4)	

US3612005

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 09:15:23

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Richard Rupp (b) (4)	22 Apr 2021 15:29:49
DataPoint Un-verified.	(b) (4)	
	Kristin Pollock (b) (4)	20 Apr 2021 19:43:10
	(b) (4)	
Signature has been broken.	Kristin Pollock (b) (4)	20 Apr 2021 19:43:10
	(b) (4)	
User entered '14 Apr 2021' reason for change: Data Entry Error	Kristin Pollock (b) (4)	20 Apr 2021 19:43:10
	(b) (4)	
User signature succeeded.	Richard Rupp (b) (4)	26 Mar 2021 18:58:13
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	09 Sep 2020 18:31:34
User closed query 'Ongoing is Yes, however End date is provided. Please correct.' (Site from System).	System	01 Sep 2020 17:14:15
User entered empty; reason for change Data Entry Error	Gerianne Casey (b) (4)	01 Sep 2020 17:14:15
	(b) (4)	
User opened query 'Ongoing is Yes, however End date is provided. Please correct.' (Site from System).	System	01 Sep 2020 17:13:57
User entered '15 Jul 1981'	Gerianne Casey (b) (4)	01 Sep 2020 16:23:06
	(b) (4)	

**US3612005**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 10 Jun 2021 09:15:23**

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Rupp (b) (4)	26 Mar 2021 18:58:13
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Sep 2020 18:31:34
User entered 'No (N)'	Gerianne Casey (b) (4) (b) (4)	01 Sep 2020 16:23:06

**US3612005**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 10 Jun 2021 09:15:23**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	01 Sep 2020 16:23:06

**US3612005**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 10 Jun 2021 09:15:23**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	01 Sep 2020 16:23:06

**US3612005**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 10 Jun 2021 09:15:23**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	01 Sep 2020 16:23:06

US3612005

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 09:15:23

Name of Medication

Audit	User	Time (GMT)
User signature succeeded.	Richard Rupp (b) (4)	26 Mar 2021 18:58:13
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	09 Sep 2020 18:31:34
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) (b) (4)	01 Sep 2020 16:27:54
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	01 Sep 2020 16:27:54
Data point term sent to Coder	System	01 Sep 2020 16:27:29
User entered 'hydrochlorothiazide' reason for change: Per Query Resolution	Gerianne Casey (b) (4) (b) (4)	01 Sep 2020 16:26:47
Data point term sent to Coder	System	01 Sep 2020 16:26:26
User entered 'HCTZ'	Gerianne Casey (b) (4) (b) (4)	01 Sep 2020 16:25:48

**US3612005**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 10 Jun 2021 09:15:23**

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Rupp (b) (4)	26 Mar 2021 18:58:13
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Sep 2020 18:31:34
User entered 'Yes (Y)'	Gerianne Casey (b) (4) (b) (4)	01 Sep 2020 16:25:48

US3612005

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 09:15:23

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Rupp (b) (4)	26 Mar 2021 18:58:13
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	22 Sep 2020 15:29:11
User closed query 'No indication noted in source. Please update source. ' (Site from CRA).	(b) (4), (b) (6)	16 Sep 2020 17:27:06
Query 'No indication noted in source. Please update source. ' answered with 'Completed in source.' (Site from CRA).	Amy McMahan (b) (4)	15 Sep 2020 19:28:23
	(b) (4)	
User opened query 'No indication noted in source. Please update source. ' (Site from CRA).	(b) (4), (b) (6)	09 Sep 2020 18:34:12
DataPoint Un-verified.	(b) (4), (b) (6)	09 Sep 2020 18:33:52
DataPoint Verified.	(b) (4), (b) (6)	09 Sep 2020 18:31:34
User entered 'kidney stones'	Gerianne Casey (b) (4)	01 Sep 2020 16:25:48
	(b) (4)	

**US3612005**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 10 Jun 2021 09:15:23**

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Rupp (b) (4)	26 Mar 2021 18:58:13
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Sep 2020 18:31:34
User entered '12.5'	Gerianne Casey (b) (4) (b) (4)	01 Sep 2020 16:25:48

US3612005

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 09:15:23

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Rupp (b) (4)	26 Mar 2021 18:58:13
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Sep 2020 18:31:34
User entered 'mg (mg)'	Gerianne Casey (b) (4) (b) (4)	01 Sep 2020 16:25:48

**US3612005**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 10 Jun 2021 09:15:23**

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Rupp (b) (4)	26 Mar 2021 18:58:13
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Sep 2020 18:31:34
User entered empty.	Gerianne Casey (b) (4) (b) (4)	01 Sep 2020 16:25:48

US3612005

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 09:15:23

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Rupp (b) (4)	26 Mar 2021 18:58:13
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Sep 2020 18:31:34
User closed query 'Data is required. Please complete.' (Site from System).	System	01 Sep 2020 16:27:47
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	01 Sep 2020 16:27:47
User entered 'once daily (QD)' reason for change: Data Entry Error	Gerianne Casey (b) (4) (b) (4)	01 Sep 2020 16:27:47
User opened query 'Data is required. Please complete.' (Site from System).	System	01 Sep 2020 16:25:48
User entered empty.	Gerianne Casey (b) (4) (b) (4)	01 Sep 2020 16:25:48

**US3612005**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 10 Jun 2021 09:15:23**

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Rupp (b) (4)	26 Mar 2021 18:58:13
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Sep 2020 18:31:34
User entered empty.	Gerianne Casey (b) (4) (b) (4)	01 Sep 2020 16:25:48

**US3612005**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 10 Jun 2021 09:15:23**

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Rupp (b) (4)	26 Mar 2021 18:58:13
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Sep 2020 18:31:34
User entered 'Oral (ORAL)'	Gerianne Casey (b) (4) (b) (4)	01 Sep 2020 16:25:48

US3612005

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 10 Jun 2021 09:15:23**

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Richard Rupp (b) (4)	26 Mar 2021 18:58:13
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Sep 2020 18:31:34
User entered empty.	Gerianne Casey (b) (4) (b) (4)	01 Sep 2020 16:25:48

US3612005

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 09:15:23

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Richard Rupp (b) (4)	26 Mar 2021 18:58:13
User closed query 'Source states 15JUL1981. Please review and reconcile as needed. ' (Site from CRA). DataPoint Verified.	(b) (4) (b) (4), (b) (6) (b) (4), (b) (6)	16 Sep 2020 17:28:58 16 Sep 2020 17:28:56
Query 'Source states 15JUL1981. Please review and reconcile as needed. ' answered with 'Corrected.' (Site from CRA).	Amy McMahan (b) (4) (b) (4)	15 Sep 2020 19:29:10
User entered '15 Jul 1981' reason for change: Data Entry Error	Amy McMahan (b) (4) (b) (4)	15 Sep 2020 19:29:02
User opened query 'Source states 15JUL1981. Please review and reconcile as needed. ' (Site from CRA). DataPoint Un-verified.	(b) (4), (b) (6) (b) (4), (b) (6)	09 Sep 2020 18:35:01 09 Sep 2020 18:34:33
DataPoint Verified.	(b) (4), (b) (6)	09 Sep 2020 18:31:34
User entered '15 Jul 2005'	Gerianne Casey (b) (4) (b) (4)	01 Sep 2020 16:25:48

**US3612005**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 10 Jun 2021 09:15:23**

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Rupp (b) (4)	26 Mar 2021 18:58:13
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Sep 2020 18:31:34
User entered '0'	Gerianne Casey (b) (4) (b) (4)	01 Sep 2020 16:25:48

US3612005

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 09:15:23

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Rupp (b) (4)	22 Apr 2021 15:29:49
DataPoint Un-verified.	(b) (4)	
	Kristin Pollock (b) (4)	20 Apr 2021 19:43:43
	(b) (4)	
Signature has been broken.	Kristin Pollock (b) (4)	20 Apr 2021 19:43:43
	(b) (4)	
User entered 'No (N)' reason for change: New Information	Kristin Pollock (b) (4)	20 Apr 2021 19:43:43
	(b) (4)	
User signature succeeded.	Richard Rupp (b) (4)	26 Mar 2021 18:58:13
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	09 Sep 2020 18:31:34
User entered 'Yes (Y)'	Gerianne Casey (b) (4)	01 Sep 2020 16:25:48
	(b) (4)	

US3612005

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 09:15:23

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Richard Rupp (b) (4)	22 Apr 2021 15:29:49
DataPoint Un-verified.	(b) (4)	
	Kristin Pollock (b) (4)	20 Apr 2021 19:43:43
	(b) (4)	
Signature has been broken.	Kristin Pollock (b) (4)	20 Apr 2021 19:43:43
	(b) (4)	
User entered '14 Apr 2021' reason for change: Data Entry Error	Kristin Pollock (b) (4)	20 Apr 2021 19:43:43
	(b) (4)	
User signature succeeded.	Richard Rupp (b) (4)	26 Mar 2021 18:58:13
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	09 Sep 2020 18:31:34
User entered empty.	Gerianne Casey (b) (4)	01 Sep 2020 16:25:48
	(b) (4)	

**US3612005**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 10 Jun 2021 09:15:23**

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Rupp (b) (4)	26 Mar 2021 18:58:13
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Sep 2020 18:31:34
User entered 'No (N)'	Gerianne Casey (b) (4) (b) (4)	01 Sep 2020 16:25:48

**US3612005**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 10 Jun 2021 09:15:23**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	01 Sep 2020 16:27:47
User entered empty.	System	01 Sep 2020 16:25:48

**US3612005**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 10 Jun 2021 09:15:23**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	01 Sep 2020 16:27:47
User entered empty.	System	01 Sep 2020 16:25:48

**US3612005**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 10 Jun 2021 09:15:23**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	01 Sep 2020 16:27:47
User entered empty.	System	01 Sep 2020 16:25:48

US3612005

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 09:15:23

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Rupp (b) (4)	26 Mar 2021 18:58:13
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Sep 2020 18:31:34
User coded data point as ATC: BLOOD AND BLOOD FORMING ORGANS, ATC: ANTITHROMBOTIC AGENTS, ATC: ANTITHROMBOTIC AGENTS, ATC: VITAMIN K ANTAGONISTS, PRODUCT: WARFARIN - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	01 Sep 2020 17:18:55
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	01 Sep 2020 17:18:55
Data point term sent to Coder	System	01 Sep 2020 17:18:28
User entered 'warfarin'	Gerianne Casey (b) (4) (b) (4)	01 Sep 2020 17:17:30

**US3612005**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 10 Jun 2021 09:15:23**

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Rupp (b) (4)	26 Mar 2021 18:58:13
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Sep 2020 18:31:34
User entered 'Yes (Y)'	Gerianne Casey (b) (4) (b) (4)	01 Sep 2020 17:17:30

US3612005

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 09:15:23

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Rupp (b) (4)	26 Mar 2021 18:58:13
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	22 Sep 2020 15:29:31
User closed query 'No indication noted in source. Please update source. ' (Site from CRA).	(b) (4), (b) (6)	16 Sep 2020 17:27:35
Query 'No indication noted in source. Please update source. ' answered with 'Completed in source.' (Site from CRA).	Amy McMahan (b) (4)	15 Sep 2020 19:29:43
	(b) (4)	
User opened query 'No indication noted in source. Please update source. ' (Site from CRA).	(b) (4), (b) (6)	09 Sep 2020 18:36:13
DataPoint Un-verified.	(b) (4), (b) (6)	09 Sep 2020 18:35:42
DataPoint Verified.	(b) (4), (b) (6)	09 Sep 2020 18:31:34
User entered 'blood clots'	Gerianne Casey (b) (4)	01 Sep 2020 17:17:30
	(b) (4)	

US3612005

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 09:15:23

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Rupp (b) (4)	22 Apr 2021 15:29:49
DataPoint Un-verified.	(b) (4)	
	Kristin Pollock (b) (4)	20 Apr 2021 19:44:31
	(b) (4)	
Signature has been broken.	Kristin Pollock (b) (4)	20 Apr 2021 19:44:31
	(b) (4)	
User entered '5' reason for change: New Information	Kristin Pollock (b) (4)	20 Apr 2021 19:44:31
	(b) (4)	
User signature succeeded.	Richard Rupp (b) (4)	26 Mar 2021 18:58:13
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	09 Sep 2020 18:31:34
User entered '6'	Gerianne Casey (b) (4)	01 Sep 2020 17:17:30
	(b) (4)	

US3612005

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 09:15:23

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Rupp (b) (4)	26 Mar 2021 18:58:13
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Sep 2020 18:31:34
User entered 'mg (mg)'	Gerianne Casey (b) (4) (b) (4)	01 Sep 2020 17:17:30

**US3612005**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 10 Jun 2021 09:15:23**

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Richard Rupp (b) (4)	26 Mar 2021 18:58:13
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Sep 2020 18:31:34
User entered empty.	Gerianne Casey (b) (4) (b) (4)	01 Sep 2020 17:17:30

US3612005

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 09:15:23

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Rupp (b) (4)	26 Mar 2021 18:58:13
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Sep 2020 18:31:34
User entered 'once daily (QD)'	Gerianne Casey (b) (4) (b) (4)	01 Sep 2020 17:17:30

**US3612005**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 10 Jun 2021 09:15:23**

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Rupp (b) (4)	26 Mar 2021 18:58:13
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Sep 2020 18:31:34
User entered empty.	Gerianne Casey (b) (4) (b) (4)	01 Sep 2020 17:17:30

**US3612005**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 10 Jun 2021 09:15:23**

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Rupp (b) (4)	26 Mar 2021 18:58:13
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Sep 2020 18:31:34
User entered 'Oral (ORAL)'	Gerianne Casey (b) (4) (b) (4)	01 Sep 2020 17:17:30

**US3612005**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 10 Jun 2021 09:15:23**

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Richard Rupp (b) (4)	26 Mar 2021 18:58:13
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Sep 2020 18:31:34
User entered empty.	Gerianne Casey (b) (4) (b) (4)	01 Sep 2020 17:17:30

**US3612005**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 10 Jun 2021 09:15:23**

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Rupp (b) (4)	26 Mar 2021 18:58:13
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Sep 2020 18:31:34
User entered '15 Jul 2005'	Gerianne Casey (b) (4) (b) (4)	01 Sep 2020 17:17:30

**US3612005**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 10 Jun 2021 09:15:23**

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Rupp (b) (4)	26 Mar 2021 18:58:13
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Sep 2020 18:31:34
User entered '0'	Gerianne Casey (b) (4) (b) (4)	01 Sep 2020 17:17:30

**US3612005**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 10 Jun 2021 09:15:23**

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Rupp (b) (4)	26 Mar 2021 18:58:13
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Sep 2020 18:31:34
User entered 'Yes (Y)'	Gerianne Casey (b) (4) (b) (4)	01 Sep 2020 17:17:30

**US3612005**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 10 Jun 2021 09:15:23**

*If not Ongoing, End date (dd MMM yyyy)*

Audit	User	Time (GMT)
User signature succeeded.	Richard Rupp (b) (4)	26 Mar 2021 18:58:13
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Sep 2020 18:31:34
User entered empty.	Gerianne Casey (b) (4) (b) (4)	01 Sep 2020 17:17:30

**US3612005**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 10 Jun 2021 09:15:23**

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Rupp (b) (4)	26 Mar 2021 18:58:13
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Sep 2020 18:31:34
User entered 'No (N)'	Gerianne Casey (b) (4) (b) (4)	01 Sep 2020 17:17:30

**US3612005**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 10 Jun 2021 09:15:23**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	01 Sep 2020 17:17:30

**US3612005**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 10 Jun 2021 09:15:23**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	01 Sep 2020 17:17:30

**US3612005**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 10 Jun 2021 09:15:23**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	01 Sep 2020 17:17:30

US3612005

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 09:15:23

Name of Medication

Audit	User	Time (GMT)
User signature succeeded.	Richard Rupp (b) (4)	26 Mar 2021 18:58:13
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	09 Sep 2020 18:31:34
User coded data point as ATC: CARDIOVASCULAR SYSTEM, ATC: LIPID MODIFYING AGENTS, ATC: LIPID MODIFYING AGENTS, PLAIN, ATC: FIBRATES, PRODUCT: FENOFIBRATE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	01 Sep 2020 17:21:49
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	(b) (4)	01 Sep 2020 17:21:49
Data point term sent to Coder	System	01 Sep 2020 17:20:34
Data point term sent to Coder	System	01 Sep 2020 17:19:33
User entered 'fenofibrate'	Gerianne Casey (b) (4)	01 Sep 2020 17:18:38
	(b) (4)	

US3612005

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 09:15:23

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Rupp (b) (4)	26 Mar 2021 18:58:13
User closed query 'Per DM CLR: Prophylaxis is marked as YES. However, there is an actual condition recorded in the MH eCRF. Please review if the prophylaxis indication should be changed as appropriate. Otherwise, provide clarification. ' (Site from DM).	(b) (4) (b) (4), (b) (6)	24 Dec 2020 08:22:21
DataPoint Verified.	(b) (4), (b) (6)	23 Dec 2020 18:42:17
Query 'Per DM CLR: Prophylaxis is marked as YES. However, there is an actual condition recorded in the MH eCRF. Please review if the prophylaxis indication should be changed as appropriate. Otherwise, provide clarification. ' answered with 'Updated' (Site from DM).	Amber Stanford (b) (4) (b) (4)	23 Dec 2020 16:25:16
DataPoint Un-verified.	Amber Stanford (b) (4) (b) (4)	23 Dec 2020 16:25:09
User entered 'No (N)' reason for change: Data Entry Error	Amber Stanford (b) (4) (b) (4)	23 Dec 2020 16:25:09
User opened query 'Per DM CLR: Prophylaxis is marked as YES. However, there is an actual condition recorded in the MH eCRF. Please review if the prophylaxis indication should be changed as appropriate. Otherwise, provide clarification. ' (Site from DM).	(b) (4), (b) (6)	22 Dec 2020 08:35:13
DataPoint Verified.	(b) (4), (b) (6)	09 Sep 2020 18:31:34
User entered 'Yes (Y)'	Gerianne Casey (b) (4) (b) (4)	01 Sep 2020 17:18:38

US3612005

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 09:15:23

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Rupp (b) (4)	26 Mar 2021 18:58:13
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	22 Sep 2020 15:29:49
User closed query 'No indication noted in source. Please update source. ' (Site from CRA).	(b) (4), (b) (6)	16 Sep 2020 17:27:48
Query 'No indication noted in source. Please update source. ' answered with 'Completed in source.' (Site from CRA).	Amy McMahan (b) (4)	15 Sep 2020 19:37:58
	(b) (4)	
User opened query 'No indication noted in source. Please update source. ' (Site from CRA).	(b) (4), (b) (6)	09 Sep 2020 18:36:57
DataPoint Un-verified.	(b) (4), (b) (6)	09 Sep 2020 18:36:49
DataPoint Verified.	(b) (4), (b) (6)	09 Sep 2020 18:31:34
User entered 'high cholesterol'	Gerianne Casey (b) (4)	01 Sep 2020 17:18:38
	(b) (4)	

US3612005

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 09:15:23

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Rupp (b) (4)	26 Mar 2021 18:58:13
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	22 Dec 2020 16:24:17
User closed query 'Per DM CLR: Please provide the actual dose for this medication (e.g., 40 MG, 100 MG, etc) instead of tablet count, as there are multiple dosage options for this drug. Update the Dose and Dose Unit fields as appropriate.' (Site from DM).	(b) (4), (b) (6)	29 Oct 2020 20:35:09
Query 'Per DM CLR: Please provide the actual dose for this medication (e.g., 40 MG, 100 MG, etc) instead of tablet count, as there are multiple dosage options for this drug. Update the Dose and Dose Unit fields as appropriate.' answered with 'Updated dose' (Site from DM).	Amber Stanford (b) (4)	28 Oct 2020 19:00:25
DataPoint Un-verified.	(b) (4)	
	Amber Stanford (b) (4)	28 Oct 2020 19:00:17
User entered '67' reason for change: Data Entry Error	(b) (4)	
	Amber Stanford (b) (4)	28 Oct 2020 19:00:17
User opened query 'Per DM CLR: Please provide the actual dose for this medication (e.g., 40 MG, 100 MG, etc) instead of tablet count, as there are multiple dosage options for this drug. Update the Dose and Dose Unit fields as appropriate.' (Site from DM).	(b) (4), (b) (6)	28 Oct 2020 09:19:43
DataPoint Verified.	(b) (4), (b) (6)	09 Sep 2020 18:31:34
User entered 'I'	Gerianne Casey (b) (4)	01 Sep 2020 17:18:38
	(b) (4)	

US3612005

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 09:15:23

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Rupp (b) (4)	26 Mar 2021 18:58:13
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Dec 2020 16:24:20
DataPoint Un-verified.	Amber Stanford (b) (4) (b) (4)	28 Oct 2020 19:00:17
User entered 'mg (mg)' reason for change: Data Entry Error	Amber Stanford (b) (4) (b) (4)	28 Oct 2020 19:00:17
DataPoint Verified.	(b) (4), (b) (6)	09 Sep 2020 18:31:34
User entered 'tablet (TABLET)'	Gerianne Casey (b) (4) (b) (4)	01 Sep 2020 17:18:38

US3612005

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 09:15:23

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Richard Rupp (b) (4)	26 Mar 2021 18:58:13
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Sep 2020 18:31:34
User entered empty.	Gerianne Casey (b) (4) (b) (4)	01 Sep 2020 17:18:38

**US3612005**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (4)**

**Generated On: 10 Jun 2021 09:15:23**

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Rupp (b) (4)	26 Mar 2021 18:58:13
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Sep 2020 18:31:34
User entered 'once daily (QD)'	Gerianne Casey (b) (4) (b) (4)	01 Sep 2020 17:18:38

US3612005

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 09:15:23

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Richard Rupp (b) (4)	26 Mar 2021 18:58:13
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Sep 2020 18:31:34
User entered empty.	Gerianne Casey (b) (4) (b) (4)	01 Sep 2020 17:18:38

US3612005

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 09:15:23

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Rupp (b) (4)	26 Mar 2021 18:58:13
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Sep 2020 18:31:34
User closed query 'Data is required. Please complete.' (Site from System).	System	01 Sep 2020 17:19:42
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	01 Sep 2020 17:19:42
User entered 'Oral (ORAL)' reason for change: Data Entry Error	Gerianne Casey (b) (4) (b) (4)	01 Sep 2020 17:19:42
User opened query 'Data is required. Please complete.' (Site from System).	System	01 Sep 2020 17:18:38
User entered empty.	Gerianne Casey (b) (4) (b) (4)	01 Sep 2020 17:18:38

US3612005

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 09:15:23

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Richard Rupp (b) (4)	26 Mar 2021 18:58:13
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Sep 2020 18:31:34
User entered empty.	Gerianne Casey (b) (4) (b) (4)	01 Sep 2020 17:18:38

US3612005

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 09:15:23

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Richard Rupp (b) (4)	26 Mar 2021 18:58:13
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) (4), (b) (6)	29 Oct 2020 20:35:45
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 'Dates reviewed and reconciled' (Site from DM).	Amber Stanford (b) (4) (b) (4)	28 Oct 2020 19:00:41
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)	28 Oct 2020 09:19:54
DataPoint Verified.	(b) (4), (b) (6)	09 Sep 2020 18:31:34
User entered '15 Feb 2019'	Gerianne Casey (b) (4) (b) (4)	01 Sep 2020 17:18:38

**US3612005**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (4)**

**Generated On: 10 Jun 2021 09:15:23**

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Rupp (b) (4)	26 Mar 2021 18:58:13
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Sep 2020 18:31:34
User entered '0'	Gerianne Casey (b) (4) (b) (4)	01 Sep 2020 17:18:38

US3612005

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 09:15:23

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Rupp (b) (4)	22 Apr 2021 15:29:49
DataPoint Un-verified.	(b) (4)	
	Kristin Pollock (b) (4)	20 Apr 2021 19:42:20
	(b) (4)	
Signature has been broken.	Kristin Pollock (b) (4)	20 Apr 2021 19:42:20
	(b) (4)	
User entered 'No (N)' reason for change: New Information	Kristin Pollock (b) (4)	20 Apr 2021 19:42:20
	(b) (4)	
User signature succeeded.	Richard Rupp (b) (4)	26 Mar 2021 18:58:13
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	09 Sep 2020 18:31:34
User entered 'Yes (Y)'	Gerianne Casey (b) (4)	01 Sep 2020 17:18:38
	(b) (4)	

US3612005

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 09:15:23

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Richard Rupp (b) (4)	22 Apr 2021 15:29:49
	(b) (4)	
DataPoint Un-verified.	Kristin Pollock (b) (4)	20 Apr 2021 19:42:20
	(b) (4)	
Signature has been broken.	Kristin Pollock (b) (4)	20 Apr 2021 19:42:20
	(b) (4)	
User entered '14 Apr 2021' reason for change: New Information	Kristin Pollock (b) (4)	20 Apr 2021 19:42:20
	(b) (4)	
User signature succeeded.	Richard Rupp (b) (4)	26 Mar 2021 18:58:13
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	09 Sep 2020 18:31:34
User entered empty.	Gerianne Casey (b) (4)	01 Sep 2020 17:18:38
	(b) (4)	

US3612005

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 09:15:23

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Rupp (b) (4)	26 Mar 2021 18:58:13
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Sep 2020 18:31:34
User entered 'No (N)'	Gerianne Casey (b) (4) (b) (4)	01 Sep 2020 17:18:38

**US3612005**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (4)**

**Generated On: 10 Jun 2021 09:15:23**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	01 Sep 2020 17:18:38

**US3612005**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (4)**

**Generated On: 10 Jun 2021 09:15:23**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	01 Sep 2020 17:18:38

**US3612005**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (4)**

**Generated On: 10 Jun 2021 09:15:23**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	01 Sep 2020 17:18:38

US3612005

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 09:15:23

Name of Medication

Audit	User	Time (GMT)
User signature succeeded.	Richard Rupp (b) (4)	26 Mar 2021 18:58:13
User closed query 'Per source, patient received 0.5mL flu vaccine on 04NOV2020. vaccine administered IM, prophylactically.' (Site from CRA).	(b) (4) (b) (4), (b) (6)	23 Dec 2020 18:42:42
User coded data point as ATC: MUSCULO-SKELETAL SYSTEM, ATC: ANTIINFLAMMATORY AND ANTIRHEUMATIC PRODUCTS, ATC: ANTIINFLAMMATORY AND ANTIRHEUMATIC PRODUCTS, NON-STEROIDS, ATC: COXIBS, PRODUCT: CELECOXIB, PRODUCTSYNONYM: CELEBREX - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	23 Dec 2020 17:14:41
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	23 Dec 2020 17:14:41
Query 'Per source, patient received 0.5mL flu vaccine on 04NOV2020. vaccine administered IM, prophylactically.' answered with 'updated' (Site from CRA).	Amber Stanford (b) (4) (b) (4)	23 Dec 2020 16:25:55
Data point term sent to Coder	System	23 Dec 2020 16:23:40
Coding entries removed.	Amber Stanford (b) (4) (b) (4)	23 Dec 2020 16:23:33
User opened query 'Per source, patient received 0.5mL flu vaccine on 04NOV2020. vaccine administered IM, prophylactically.' (Site from CRA).	(b) (4), (b) (6)	22 Dec 2020 16:36:26
User coded data point as ATC: MUSCULO-SKELETAL SYSTEM, ATC: ANTIINFLAMMATORY AND ANTIRHEUMATIC PRODUCTS, ATC: ANTIINFLAMMATORY AND ANTIRHEUMATIC PRODUCTS, NON-STEROIDS, ATC: COXIBS, PRODUCT: CELECOXIB, PRODUCTSYNONYM: CELEBREX - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	30 Oct 2020 02:53:58
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	30 Oct 2020 02:53:58
Data point term sent to Coder	System	28 Oct 2020 19:03:38
Coding entries removed.	Amber Stanford (b) (4) (b) (4)	28 Oct 2020 19:02:47
DataPoint Verified.	(b) (4), (b) (6)	09 Sep 2020 18:31:34

US3612005

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 09:15:23

[Name of Medication](#)

Audit	User	Time (GMT)
User coded data point as ATC: MUSCULO-SKELETAL SYSTEM, ATC: ANTIINFLAMMATORY AND ANTIRHEUMATIC PRODUCTS, ATC: ANTIINFLAMMATORY AND ANTIRHEUMATIC PRODUCTS, NON-STEROIDS, ATC: COXIBS, PRODUCT: CELECOXIB, PRODUCTSYNONYM: CELEBREX - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	01 Sep 2020 23:20:34
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	01 Sep 2020 23:20:34
Data point term sent to Coder	System	01 Sep 2020 17:21:40
User entered 'Celebrex'	Gerianne Casey (b) (4) (b) (4)	01 Sep 2020 17:20:54

US3612005

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 09:15:23

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Rupp (b) (4)	26 Mar 2021 18:58:13
User closed query 'Per DM CLR: Prophylaxis is marked as YES. However, this medication is not expected to be given as a prophylaxis. It is typically used to treat a medical diagnosis. Please review if the prophylaxis indication should be changed as appropriate. Otherwise, provide clarification. ' (Site from DM).	(b) (4) (b) (4), (b) (6)	24 Dec 2020 10:39:19
DataPoint Verified.	(b) (4), (b) (6)	23 Dec 2020 18:42:17
Query 'Per DM CLR: Prophylaxis is marked as YES. However, this medication is not expected to be given as a prophylaxis. It is typically used to treat a medical diagnosis. Please review if the prophylaxis indication should be changed as appropriate. Otherwise, provide clarification. ' answered with 'updated' (Site from DM).	Amber Stanford (b) (4) (b) (4)	23 Dec 2020 16:26:01
DataPoint Un-verified.	Amber Stanford (b) (4) (b) (4)	23 Dec 2020 16:23:33
User entered 'No (N)' reason for change: Data Entry Error	Amber Stanford (b) (4) (b) (4)	23 Dec 2020 16:23:33
User opened query 'Per DM CLR: Prophylaxis is marked as YES. However, this medication is not expected to be given as a prophylaxis. It is typically used to treat a medical diagnosis. Please review if the prophylaxis indication should be changed as appropriate. Otherwise, provide clarification. ' (Site from DM).	(b) (4), (b) (6)	22 Dec 2020 08:35:41
DataPoint Verified.	(b) (4), (b) (6)	09 Sep 2020 18:31:34
User entered 'Yes (Y)'	Gerianne Casey (b) (4) (b) (4)	01 Sep 2020 17:20:54

US3612005

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 09:15:23

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Rupp (b) (4)	26 Mar 2021 18:58:13
User closed query 'Per source, indication is B knee aches. please reconcile.' (Site from CRA).	(b) (4)	23 Dec 2020 18:45:19
DataPoint Verified.	(b) (4), (b) (6)	23 Dec 2020 18:42:17
Query 'Per source, indication is B knee aches. please reconcile.' answered with 'Reconciled' (Site from CRA).	(b) (4), (b) (6)	23 Dec 2020 16:26:07
User entered 'BILATERAL KNEE aches' reason for change: Data Entry Error	Amber Stanford (b) (4)	23 Dec 2020 16:23:33
User opened query 'Per source, indication is B knee aches. please reconcile.' (Site from CRA).	(b) (4)	22 Dec 2020 16:25:38
User closed query 'Per DM CLR: Please update the indication to reflect the location and type of Aches. Review and update indication and ensure to update MH/Adverse event eCRF as appropriate.' (Site from DM).	(b) (4), (b) (6)	29 Oct 2020 20:36:03
Query 'Per DM CLR: Please update the indication to reflect the location and type of Aches. Review and update indication and ensure to update MH/Adverse event eCRF as appropriate.' answered with 'Updated indication' (Site from DM).	(b) (4), (b) (6)	
DataPoint Un-verified.	Amber Stanford (b) (4)	28 Oct 2020 19:03:07
User entered 'Bilateral knee pain' reason for change: Data Entry Error	(b) (4)	28 Oct 2020 19:02:47
User opened query 'Per DM CLR: Please update the indication to reflect the location and type of Aches. Review and update indication and ensure to update MH/Adverse event eCRF as appropriate.' (Site from DM).	Amber Stanford (b) (4)	28 Oct 2020 19:02:47
DataPoint Verified.	(b) (4)	28 Oct 2020 09:20:21
User closed query 'No indication noted in source. Please update source.' (Site from CRA).	(b) (4), (b) (6)	22 Sep 2020 15:31:24
Query 'No indication noted in source. Please update source.' answered with 'Completed in source.' (Site from CRA).	(b) (4), (b) (6)	16 Sep 2020 17:28:31
User opened query 'No indication noted in source. Please update source.' (Site from CRA).	Amy McMahan (b) (4)	15 Sep 2020 19:38:06
	(b) (4)	09 Sep 2020 18:37:58

**US3612005**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (5)**

**Generated On: 10 Jun 2021 09:15:23**

[Indication](#)

Audit	User	Time (GMT)
DataPoint Un-verified.	(b) (4), (b) (6)	09 Sep 2020 18:37:38
DataPoint Verified.	(b) (4), (b) (6)	09 Sep 2020 18:31:34
User entered 'aches'	Gerianne Casey (b) (4) (b) (4)	01 Sep 2020 17:20:54

US3612005

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 09:15:23

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Rupp (b) (4)	26 Mar 2021 18:58:13
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	22 Dec 2020 16:24:59
User closed query 'Per DM CLR: Please provide the actual dose for this medication (e.g., 100 MG, 200 MG, etc) instead of tablet count, as there are multiple dosage options for this drug. Update the Dose and Dose Unit fields as appropriate.' (Site from DM).	(b) (4), (b) (6)	29 Oct 2020 20:36:11
Query 'Per DM CLR: Please provide the actual dose for this medication (e.g., 100 MG, 200 MG, etc) instead of tablet count, as there are multiple dosage options for this drug. Update the Dose and Dose Unit fields as appropriate.' answered with 'Clarified with subject dosing and updated' (Site from DM).	Amber Stanford (b) (4)	28 Oct 2020 19:03:41
DataPoint Un-verified.	(b) (4)	
	Amber Stanford (b) (4)	28 Oct 2020 19:02:47
User entered '200' reason for change: Data Entry Error	(b) (4)	
	Amber Stanford (b) (4)	28 Oct 2020 19:02:47
User opened query 'Per DM CLR: Please provide the actual dose for this medication (e.g., 100 MG, 200 MG, etc) instead of tablet count, as there are multiple dosage options for this drug. Update the Dose and Dose Unit fields as appropriate.' (Site from DM).	(b) (4), (b) (6)	28 Oct 2020 09:20:27
DataPoint Verified.	(b) (4), (b) (6)	09 Sep 2020 18:31:34
User entered '1'	Gerianne Casey (b) (4)	01 Sep 2020 17:20:54
	(b) (4)	

US3612005

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 09:15:23

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Rupp (b) (4)	26 Mar 2021 18:58:13
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Dec 2020 16:25:42
DataPoint Un-verified.	Amber Stanford (b) (4) (b) (4)	28 Oct 2020 19:02:47
User entered 'mg (mg)' reason for change: Data Entry Error	Amber Stanford (b) (4) (b) (4)	28 Oct 2020 19:02:47
DataPoint Verified.	(b) (4), (b) (6)	09 Sep 2020 18:31:34
User entered 'tablet (TABLET)'	Gerianne Casey (b) (4) (b) (4)	01 Sep 2020 17:20:54

US3612005

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 09:15:23

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Richard Rupp (b) (4)	26 Mar 2021 18:58:13
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Sep 2020 18:31:34
User entered empty.	Gerianne Casey (b) (4) (b) (4)	01 Sep 2020 17:20:54

US3612005

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 09:15:23

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Rupp (b) (4)	26 Mar 2021 18:58:13
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Sep 2020 18:31:34
User entered 'as needed (PRN)'	Gerianne Casey (b) (4) (b) (4)	01 Sep 2020 17:20:54

**US3612005**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (5)**

**Generated On: 10 Jun 2021 09:15:23**

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Rupp (b) (4)	26 Mar 2021 18:58:13
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Sep 2020 18:31:34
User entered empty.	Gerianne Casey (b) (4) (b) (4)	01 Sep 2020 17:20:54

**US3612005**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (5)**

**Generated On: 10 Jun 2021 09:15:23**

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Rupp (b) (4)	26 Mar 2021 18:58:13
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Sep 2020 18:31:34
User entered 'Oral (ORAL)'	Gerianne Casey (b) (4) (b) (4)	01 Sep 2020 17:20:54

**US3612005**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (5)**

**Generated On: 10 Jun 2021 09:15:23**

[If route of administration is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Rupp (b) (4)	26 Mar 2021 18:58:13
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Sep 2020 18:31:34
User entered empty.	Gerianne Casey (b) (4) (b) (4)	01 Sep 2020 17:20:54

US3612005

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 09:15:23

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Richard Rupp (b) (4)	26 Mar 2021 18:58:13
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Sep 2020 18:31:34
User closed query 'Data entered is non-conformant. Please correct.' (Site from System).	System	01 Sep 2020 17:21:17
User entered '15 Feb 2019' reason for change: Data Entry Error	Gerianne Casey (b) (4) (b) (4)	01 Sep 2020 17:21:17
User opened query 'Data entered is non-conformant. Please correct.' (Site from System).	System	01 Sep 2020 17:20:54
User entered '15 Feb ' (non-conformant).	Gerianne Casey (b) (4) (b) (4)	01 Sep 2020 17:20:54

**US3612005**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (5)**

**Generated On: 10 Jun 2021 09:15:23**

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Rupp (b) (4)	26 Mar 2021 18:58:13
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Sep 2020 18:31:34
User entered '0'	Gerianne Casey (b) (4) (b) (4)	01 Sep 2020 17:20:54

**US3612005**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (5)**

**Generated On: 10 Jun 2021 09:15:23**

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Rupp (b) (4)	26 Mar 2021 18:58:13
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Sep 2020 18:31:34
User entered 'Yes (Y)'	Gerianne Casey (b) (4) (b) (4)	01 Sep 2020 17:20:54

**US3612005**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (5)**

**Generated On: 10 Jun 2021 09:15:23**

*If not Ongoing, End date (dd MMM yyyy)*

Audit	User	Time (GMT)
User signature succeeded.	Richard Rupp (b) (4)	26 Mar 2021 18:58:13
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Sep 2020 18:31:34
User entered empty.	Gerianne Casey (b) (4) (b) (4)	01 Sep 2020 17:20:54

US3612005

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 09:15:23

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Rupp (b) (4)	26 Mar 2021 18:58:13
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Sep 2020 18:31:34
User entered 'No (N)'	Gerianne Casey (b) (4) (b) (4)	01 Sep 2020 17:20:54

**US3612005**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (5)**

**Generated On: 10 Jun 2021 09:15:23**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	01 Sep 2020 17:20:54

**US3612005**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (5)**

**Generated On: 10 Jun 2021 09:15:23**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	01 Sep 2020 17:20:54

**US3612005**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (5)**

**Generated On: 10 Jun 2021 09:15:23**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	01 Sep 2020 17:20:54

US3612005

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 09:15:23

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Rupp (b) (4)	26 Mar 2021 18:58:13
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	23 Dec 2020 18:42:17
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)	23 Dec 2020 16:25:42
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\202003.	Coder Import (b) (4)	23 Dec 2020 16:25:42
Data point term sent to Coder	System	23 Dec 2020 16:24:42
User entered 'Influenza vaccine'	Amber Stanford (b) (4)	23 Dec 2020 16:24:36
	(b) (4)	

**US3612005**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (6)**

**Generated On: 10 Jun 2021 09:15:23**

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Rupp (b) (4)	26 Mar 2021 18:58:13
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Dec 2020 18:42:17
User entered 'Yes (Y)'	Amber Stanford (b) (4) (b) (4)	23 Dec 2020 16:24:36

**US3612005**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (6)**

**Generated On: 10 Jun 2021 09:15:23**

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Rupp (b) (4)	26 Mar 2021 18:58:13
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Dec 2020 18:42:17
User entered 'Immunization'	Amber Stanford (b) (4) (b) (4)	23 Dec 2020 16:24:36

**US3612005**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (6)**

**Generated On: 10 Jun 2021 09:15:23**

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Rupp (b) (4)	26 Mar 2021 18:58:13
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Dec 2020 18:42:17
User entered '0.5'	Amber Stanford (b) (4) (b) (4)	23 Dec 2020 16:24:36

US3612005

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 09:15:23

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Rupp (b) (4)	26 Mar 2021 18:58:13
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Dec 2020 18:42:17
User entered 'mL (mL)'	Amber Stanford (b) (4) (b) (4)	23 Dec 2020 16:24:36

US3612005

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 09:15:23

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Richard Rupp (b) (4)	26 Mar 2021 18:58:13
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Dec 2020 18:42:17
User entered empty.	Amber Stanford (b) (4) (b) (4)	23 Dec 2020 16:24:36

**US3612005**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (6)**

**Generated On: 10 Jun 2021 09:15:23**

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Rupp (b) (4)	26 Mar 2021 18:58:13
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Dec 2020 18:42:17
User entered 'once (ONCE)'	Amber Stanford (b) (4) (b) (4)	23 Dec 2020 16:24:36

US3612005

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 09:15:23

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Richard Rupp (b) (4)	26 Mar 2021 18:58:13
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Dec 2020 18:42:17
User entered empty.	Amber Stanford (b) (4) (b) (4)	23 Dec 2020 16:24:36

**US3612005**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (6)**

**Generated On: 10 Jun 2021 09:15:23**

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Rupp (b) (4)	26 Mar 2021 18:58:13
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Dec 2020 18:42:17
User entered 'Intramuscular (INTRAMUSCULAR)'	Amber Stanford (b) (4) (b) (4)	23 Dec 2020 16:24:36

**US3612005**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (6)**

**Generated On: 10 Jun 2021 09:15:23**

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Richard Rupp (b) (4)	26 Mar 2021 18:58:13
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Dec 2020 18:42:17
User entered empty.	Amber Stanford (b) (4) (b) (4)	23 Dec 2020 16:24:36

**US3612005**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (6)**

**Generated On: 10 Jun 2021 09:15:23**

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Rupp (b) (4)	26 Mar 2021 18:58:13
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Dec 2020 18:42:17
User entered '04 Nov 2020'	Amber Stanford (b) (4) (b) (4)	23 Dec 2020 16:24:36

**US3612005**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (6)**

**Generated On: 10 Jun 2021 09:15:23**

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Rupp (b) (4)	26 Mar 2021 18:58:13
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Dec 2020 18:42:17
User entered '0'	Amber Stanford (b) (4) (b) (4)	23 Dec 2020 16:24:36

**US3612005**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (6)**

**Generated On: 10 Jun 2021 09:15:23**

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Rupp (b) (4)	26 Mar 2021 18:58:13
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Dec 2020 18:42:17
User entered 'No (N)'	Amber Stanford (b) (4) (b) (4)	23 Dec 2020 16:24:36

**US3612005**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (6)**

**Generated On: 10 Jun 2021 09:15:23**

**If not Ongoing, End date (*dd MMM yyyy*)**

Audit	User	Time (GMT)
User signature succeeded.	Richard Rupp (b) (4)	26 Mar 2021 18:58:13
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Dec 2020 18:42:17
User entered '04 Nov 2020'	Amber Stanford (b) (4) (b) (4)	23 Dec 2020 16:24:36

**US3612005**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (6)**

**Generated On: 10 Jun 2021 09:15:23**

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Rupp (b) (4)	26 Mar 2021 18:58:13
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Dec 2020 18:42:17
User entered 'No (N)'	Amber Stanford (b) (4) (b) (4)	23 Dec 2020 16:24:36

**US3612005**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (6)**

**Generated On: 10 Jun 2021 09:15:23**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	23 Dec 2020 16:24:36

**US3612005**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (6)**

**Generated On: 10 Jun 2021 09:15:23**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	23 Dec 2020 16:24:36

**US3612005**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (6)**

**Generated On: 10 Jun 2021 09:15:23**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	23 Dec 2020 16:24:36

US3612005

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 09:15:23

Name of Medication

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 15:55:27
DataPoint Un-verified.	(b) (4), (b) (6)	12 Apr 2021 15:55:23
User coded data point as ATC: SENSORY ORGANS, ATC: OTOLOGICALS, ATC: ANTIINFECTIVES, ATC: ANTIINFECTIVES, PRODUCT: OFLOXACIN - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	08 Apr 2021 15:10:56
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 Apr 2021 15:10:56
Data point term sent to Coder	System	08 Apr 2021 14:35:29
Coding entries removed.	Amber Stanford (b) (4)	08 Apr 2021 14:34:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Apr 2021 17:58:16
User signature succeeded.	Richard Rupp (b) (4) (b) (4)	31 Mar 2021 21:09:32
User coded data point as ATC: SENSORY ORGANS, ATC: OTOLOGICALS, ATC: ANTIINFECTIVES, ATC: ANTIINFECTIVES, PRODUCT: OFLOXACIN - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	30 Mar 2021 09:45:12
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	30 Mar 2021 09:45:12
Data point term sent to Coder	System	29 Mar 2021 20:00:57
User entered 'Ofloxacin'	Kristin Pollock (b) (4) (b) (4)	29 Mar 2021 20:00:06

**US3612005**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (7)**

**Generated On: 10 Jun 2021 09:15:23**

[Prophylaxis](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 17:58:19
User signature succeeded.	Richard Rupp (b) (4)	31 Mar 2021 21:09:32
User entered 'No (N)'	Kristin Pollock (b) (4)	29 Mar 2021 20:00:06

US3612005

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 09:15:23

[Indication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 15:55:32
User signature succeeded.	Richard Rupp (b) (4)	09 Apr 2021 14:55:29
DataPoint Un-verified.	(b) (4)	
	Amber Stanford (b) (4)	08 Apr 2021 14:34:29
Signature has been broken.	(b) (4)	
	Amber Stanford (b) (4)	08 Apr 2021 14:34:29
User entered 'RIGHT otitis externa' reason for change: Data Entry Error	(b) (4)	
User closed query 'Per DM CLR: Please note that there is no AE or ConProc that matches this Con Med indication during this time frame. Please review Con Med use and add a medical condition and all applicable details as appropriate.	Amber Stanford (b) (4)	08 Apr 2021 14:34:29
' (Site from DM).	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 15:19:50
Query 'Per DM CLR: Please note that there is no AE or ConProc that matches this Con Med indication during this time frame. Please review Con Med use and add a medical condition and all applicable details as appropriate.	(b) (4), (b) (6)	
' answered with 'updated AE page' (Site from DM).		
User opened query 'Per DM CLR: Please note that there is no AE or ConProc that matches this Con Med indication during this time frame. Please review Con Med use and add a medical condition and all applicable details as appropriate.	Kristin Pollock (b) (4)	06 Apr 2021 16:28:04
' (Site from DM).	(b) (4)	
User signature succeeded.	(b) (4), (b) (6)	06 Apr 2021 08:46:22
User entered 'Right ear drainage'	(b) (4)	
	Richard Rupp (b) (4)	31 Mar 2021 21:09:32
	(b) (4)	
	Kristin Pollock (b) (4)	29 Mar 2021 20:00:06
	(b) (4)	

**US3612005**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (7)**

**Generated On: 10 Jun 2021 09:15:23**

[Dose per administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 17:58:36
User signature succeeded.	Richard Rupp (b) (4)	31 Mar 2021 21:09:32
User entered 'I'	Kristin Pollock (b) (4)	29 Mar 2021 20:00:06

**US3612005**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (7)**

**Generated On: 10 Jun 2021 09:15:23**

[Dose unit](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 17:58:38
User signature succeeded.	Richard Rupp (b) (4)	31 Mar 2021 21:09:32
User entered 'Other (OTHER)'	Kristin Pollock (b) (4)	29 Mar 2021 20:00:06

**US3612005**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (7)**

**Generated On: 10 Jun 2021 09:15:23**

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 17:58:40
User signature succeeded.	Richard Rupp (b) (4)	31 Mar 2021 21:09:32
User entered 'drop'	Kristin Pollock (b) (4)	29 Mar 2021 20:00:06

**US3612005**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (7)**

**Generated On: 10 Jun 2021 09:15:23**

[Frequency](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 17:58:42
User signature succeeded.	Richard Rupp (b) (4)	31 Mar 2021 21:09:32
User entered 'twice daily (BID)'	Kristin Pollock (b) (4)	29 Mar 2021 20:00:06

US3612005

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 09:15:23

If frequency is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 17:58:43
User signature succeeded.	Richard Rupp (b) (4)	31 Mar 2021 21:09:32
User entered empty.	Kristin Pollock (b) (4)	29 Mar 2021 20:00:06

**US3612005**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (7)**

**Generated On: 10 Jun 2021 09:15:23**

[Route of administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 17:58:46
User signature succeeded.	Richard Rupp (b) (4)	31 Mar 2021 21:09:32
User entered 'Other (OTHER)'	Kristin Pollock (b) (4)	29 Mar 2021 20:00:06

**US3612005**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (7)**

**Generated On: 10 Jun 2021 09:15:23**

[If route of administration is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 17:58:48
User signature succeeded.	Richard Rupp (b) (4)	31 Mar 2021 21:09:32
User entered 'intra auricular'	Kristin Pollock (b) (4)	29 Mar 2021 20:00:06

**US3612005**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (7)**

**Generated On: 10 Jun 2021 09:15:23**

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 17:58:50
User signature succeeded.	Richard Rupp (b) (4)	31 Mar 2021 21:09:32
User entered '2 Jan 2021'	Kristin Pollock (b) (4)	29 Mar 2021 20:00:06

**US3612005**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (7)**

**Generated On: 10 Jun 2021 09:15:23**

[Start date completely unknown](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 17:58:53
User signature succeeded.	Richard Rupp (b) (4)	31 Mar 2021 21:09:32
User entered '0'	Kristin Pollock (b) (4)	29 Mar 2021 20:00:06

**US3612005**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (7)**

**Generated On: 10 Jun 2021 09:15:23**

[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 17:58:55
User signature succeeded.	Richard Rupp (b) (4)	31 Mar 2021 21:09:32
User entered 'No (N)'	Kristin Pollock (b) (4)	29 Mar 2021 20:00:06

**US3612005**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (7)**

**Generated On: 10 Jun 2021 09:15:23**

**If not Ongoing, End date (*dd MMM yyyy*)**

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 17:58:52
User signature succeeded.	Richard Rupp (b) (4)	31 Mar 2021 21:09:32
User entered '9 Jan 2021'	Kristin Pollock (b) (4)	29 Mar 2021 20:00:06

US3612005

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 09:15:23

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 17:58:57
User signature succeeded.	Richard Rupp (b) (4)	31 Mar 2021 21:09:32
User entered 'No (N)'	Kristin Pollock (b) (4)	29 Mar 2021 20:00:06

**US3612005**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (7)**

**Generated On: 10 Jun 2021 09:15:23**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '2'	System	29 Mar 2021 20:00:06

**US3612005**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (7)**

**Generated On: 10 Jun 2021 09:15:23**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	29 Mar 2021 20:00:06

**US3612005**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (7)**

**Generated On: 10 Jun 2021 09:15:23**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	29 Mar 2021 20:00:06

US3612005

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 09:15:23

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Rupp (b) (4)	22 Apr 2021 15:29:49
User coded data point as ATC: CARDIOVASCULAR SYSTEM, ATC: CARDIAC THERAPY, ATC: ANTIARRHYTHMICS, CLASS I AND III, ATC: ANTIARRHYTHMICS, CLASS III, PRODUCT: AMIODARONE - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4)	20 Apr 2021 19:42:43
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	20 Apr 2021 19:42:43
Data point term sent to Coder	System	20 Apr 2021 19:41:29
User entered 'Amiodarone'	Kristin Pollock (b) (4) (b) (4)	20 Apr 2021 19:41:22

**US3612005**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (8)**

**Generated On: 10 Jun 2021 09:15:23**

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Rupp (b) (4)	22 Apr 2021 15:29:49
User entered 'No (N)'	(b) (4) Kristin Pollock (b) (4) (b) (4)	20 Apr 2021 19:41:22

**US3612005**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (8)**

**Generated On: 10 Jun 2021 09:15:23**

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Rupp (b) (4)	22 Apr 2021 15:29:49
User entered 'Myocardial infarction'	(b) (4) Kristin Pollock (b) (4) (b) (4)	20 Apr 2021 19:41:22

**US3612005**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (8)**

**Generated On: 10 Jun 2021 09:15:23**

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Rupp (b) (4)	22 Apr 2021 15:29:49
User entered '200'	(b) (4) Kristin Pollock (b) (4) (b) (4)	20 Apr 2021 19:41:22

**US3612005**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (8)**

**Generated On: 10 Jun 2021 09:15:23**

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Rupp (b) (4)	22 Apr 2021 15:29:49
User entered 'mg (mg)'	(b) (4) Kristin Pollock (b) (4) (b) (4)	20 Apr 2021 19:41:22

US3612005

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 09:15:23

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Richard Rupp (b) (4)	22 Apr 2021 15:29:49
User entered empty.	(b) (4) Kristin Pollock (b) (4) (b) (4)	20 Apr 2021 19:41:22

**US3612005**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (8)**

**Generated On: 10 Jun 2021 09:15:23**

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Rupp (b) (4)	22 Apr 2021 15:29:49
User entered 'once daily (QD)'	(b) (4) Kristin Pollock (b) (4) (b) (4)	20 Apr 2021 19:41:22

US3612005

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 09:15:23

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Rupp (b) (4)	22 Apr 2021 15:29:49
User entered empty.	(b) (4) Kristin Pollock (b) (4) (b) (4)	20 Apr 2021 19:41:22

**US3612005**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (8)**

**Generated On: 10 Jun 2021 09:15:23**

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Rupp (b) (4)	22 Apr 2021 15:29:49
User entered 'Oral (ORAL)'	(b) (4) Kristin Pollock (b) (4) (b) (4)	20 Apr 2021 19:41:22

US3612005

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (8)**

**Generated On: 10 Jun 2021 09:15:23**

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Richard Rupp (b) (4)	22 Apr 2021 15:29:49
User entered empty.	(b) (4) Kristin Pollock (b) (4) (b) (4)	20 Apr 2021 19:41:22

**US3612005**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (8)**

**Generated On: 10 Jun 2021 09:15:23**

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Rupp (b) (4)	22 Apr 2021 15:29:49
User entered '14 Apr 2021'	(b) (4) Kristin Pollock (b) (4) (b) (4)	20 Apr 2021 19:41:22

**US3612005**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (8)**

**Generated On: 10 Jun 2021 09:15:23**

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Rupp (b) (4)	22 Apr 2021 15:29:49
User entered '0'	(b) (4) Kristin Pollock (b) (4) (b) (4)	20 Apr 2021 19:41:22

**US3612005**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (8)**

**Generated On: 10 Jun 2021 09:15:23**

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Rupp (b) (4)	26 Apr 2021 20:27:17
Signature has been broken.	(b) (4)	
	Kristin Pollock (b) (4)	26 Apr 2021 19:15:53
	(b) (4)	
User entered 'No (N)' reason for change: New Information	Kristin Pollock (b) (4)	26 Apr 2021 19:15:53
	(b) (4)	
User signature succeeded.	Richard Rupp (b) (4)	22 Apr 2021 15:29:49
	(b) (4)	
User entered 'Yes (Y)'	Kristin Pollock (b) (4)	20 Apr 2021 19:41:22
	(b) (4)	

US3612005

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 09:15:23

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Richard Rupp (b) (4)	26 Apr 2021 20:27:17
Signature has been broken.	(b) (4)	
	Kristin Pollock (b) (4)	26 Apr 2021 19:15:53
	(b) (4)	
User entered '20 Apr 2021' reason for change: New Information	Kristin Pollock (b) (4)	26 Apr 2021 19:15:53
	(b) (4)	
User signature succeeded.	Richard Rupp (b) (4)	22 Apr 2021 15:29:49
	(b) (4)	
User entered empty.	Kristin Pollock (b) (4)	20 Apr 2021 19:41:22
	(b) (4)	

**US3612005**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (8)**

**Generated On: 10 Jun 2021 09:15:23**

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Rupp (b) (4)	22 Apr 2021 15:29:49
User entered 'No (N)'	(b) (4) Kristin Pollock (b) (4) (b) (4)	20 Apr 2021 19:41:22

**US3612005**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (8)**

**Generated On: 10 Jun 2021 09:15:23**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	20 Apr 2021 19:41:22

**US3612005**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (8)**

**Generated On: 10 Jun 2021 09:15:23**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	20 Apr 2021 19:41:22

**US3612005**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (8)**

**Generated On: 10 Jun 2021 09:15:23**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	20 Apr 2021 19:41:22

US3612005

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 09:15:23

Name of Medication

Audit	User	Time (GMT)
User signature succeeded.	Richard Rupp (b) (4)	22 Apr 2021 15:29:49
User coded data point as ATC: CARDIOVASCULAR SYSTEM, ATC: BETA BLOCKING AGENTS, ATC: BETA BLOCKING AGENTS, ATC: BETA BLOCKING AGENTS, SELECTIVE, PRODUCT: METOPROLOL SUCCINATE - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4) (b) (4)	20 Apr 2021 21:30:21
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	20 Apr 2021 21:30:21
Data point term sent to Coder	System	20 Apr 2021 19:46:39
User entered 'Metoprolol Succinate XL'	Kristin Pollock (b) (4) (b) (4)	20 Apr 2021 19:45:47

**US3612005**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (9)**

**Generated On: 10 Jun 2021 09:15:23**

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Rupp (b) (4)	22 Apr 2021 15:29:49
User entered 'No (N)'	(b) (4) Kristin Pollock (b) (4) (b) (4)	20 Apr 2021 19:45:47

**US3612005**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (9)**

**Generated On: 10 Jun 2021 09:15:23**

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Rupp (b) (4)	22 Apr 2021 15:29:49
User entered 'Myocardial Infarction'	(b) (4) Kristin Pollock (b) (4) (b) (4)	20 Apr 2021 19:45:47

**US3612005**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (9)**

**Generated On: 10 Jun 2021 09:15:23**

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Rupp (b) (4)	22 Apr 2021 15:29:49
User entered '12.5'	(b) (4) Kristin Pollock (b) (4) (b) (4)	20 Apr 2021 19:45:47

US3612005

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 09:15:23

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Rupp (b) (4)	22 Apr 2021 15:29:49
User entered 'mg (mg)'	(b) (4) Kristin Pollock (b) (4) (b) (4)	20 Apr 2021 19:45:47

**US3612005**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (9)**

**Generated On: 10 Jun 2021 09:15:23**

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Rupp (b) (4)	22 Apr 2021 15:29:49
User entered empty.	(b) (4) Kristin Pollock (b) (4) (b) (4)	20 Apr 2021 19:45:47

**US3612005**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (9)**

**Generated On: 10 Jun 2021 09:15:23**

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Rupp (b) (4)	22 Apr 2021 15:29:49
User entered 'once daily (QD)'	(b) (4) Kristin Pollock (b) (4) (b) (4)	20 Apr 2021 19:45:47

**US3612005**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (9)**

**Generated On: 10 Jun 2021 09:15:23**

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Rupp (b) (4)	22 Apr 2021 15:29:49
User entered empty.	(b) (4) Kristin Pollock (b) (4) (b) (4)	20 Apr 2021 19:45:47

**US3612005**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (9)**

**Generated On: 10 Jun 2021 09:15:23**

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Rupp (b) (4)	22 Apr 2021 15:29:49
User entered 'Oral (ORAL)'	(b) (4) Kristin Pollock (b) (4) (b) (4)	20 Apr 2021 19:45:47

**US3612005**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (9)**

**Generated On: 10 Jun 2021 09:15:23**

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Richard Rupp (b) (4)	22 Apr 2021 15:29:49
User entered empty.	(b) (4) Kristin Pollock (b) (4) (b) (4)	20 Apr 2021 19:45:47

**US3612005**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (9)**

**Generated On: 10 Jun 2021 09:15:23**

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Rupp (b) (4)	22 Apr 2021 15:29:49
User entered '14 Apr 2021'	(b) (4) Kristin Pollock (b) (4) (b) (4)	20 Apr 2021 19:45:47

**US3612005**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (9)**

**Generated On: 10 Jun 2021 09:15:23**

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Rupp (b) (4)	22 Apr 2021 15:29:49
User entered '0'	(b) (4) Kristin Pollock (b) (4) (b) (4)	20 Apr 2021 19:45:47

**US3612005**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (9)**

**Generated On: 10 Jun 2021 09:15:23**

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Rupp (b) (4)	26 Apr 2021 20:27:17
Signature has been broken.	(b) (4)	
	Kristin Pollock (b) (4)	26 Apr 2021 19:18:57
	(b) (4)	
User entered 'No (N)' reason for change: New Information	Kristin Pollock (b) (4)	26 Apr 2021 19:18:57
	(b) (4)	
User signature succeeded.	Richard Rupp (b) (4)	22 Apr 2021 15:29:49
	(b) (4)	
User entered 'Yes (Y)'	Kristin Pollock (b) (4)	20 Apr 2021 19:45:47
	(b) (4)	

US3612005

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 09:15:23

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Richard Rupp (b) (4)	26 Apr 2021 20:27:17
Signature has been broken.	(b) (4)	
	Kristin Pollock (b) (4)	26 Apr 2021 19:18:57
	(b) (4)	
User entered '20 Apr 2021' reason for change: New Information	Kristin Pollock (b) (4)	26 Apr 2021 19:18:57
	(b) (4)	
User signature succeeded.	Richard Rupp (b) (4)	22 Apr 2021 15:29:49
	(b) (4)	
User entered empty.	Kristin Pollock (b) (4)	20 Apr 2021 19:45:47
	(b) (4)	

**US3612005**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (9)**

**Generated On: 10 Jun 2021 09:15:23**

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Rupp (b) (4)	22 Apr 2021 15:29:49
User entered 'No (N)'	(b) (4) Kristin Pollock (b) (4) (b) (4)	20 Apr 2021 19:45:47

**US3612005**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (9)**

**Generated On: 10 Jun 2021 09:15:23**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	20 Apr 2021 19:45:47

**US3612005**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (9)**

**Generated On: 10 Jun 2021 09:15:23**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	20 Apr 2021 19:45:47

**US3612005**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (9)**

**Generated On: 10 Jun 2021 09:15:23**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	20 Apr 2021 19:45:47

US3612005

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 09:15:23

Name of Medication

Audit	User	Time (GMT)
User signature succeeded.	Richard Rupp (b) (4)	22 Apr 2021 15:29:49
User coded data point as ATC: CARDIOVASCULAR SYSTEM, ATC: DIURETICS, ATC: HIGH-CEILING DIURETICS, ATC: SULFONAMIDES, PLAIN, PRODUCT: FUROSEMIDE - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4) (b) (4)	20 Apr 2021 20:05:43
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	20 Apr 2021 20:05:43
Data point term sent to Coder	System	20 Apr 2021 19:47:41
User entered 'Furosemide'	Kristin Pollock (b) (4) (b) (4)	20 Apr 2021 19:46:44

**US3612005**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (10)**

**Generated On: 10 Jun 2021 09:15:23**

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Rupp (b) (4)	22 Apr 2021 15:29:49
User entered 'No (N)'	(b) (4) Kristin Pollock (b) (4) (b) (4)	20 Apr 2021 19:46:44

**US3612005**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (10)**

**Generated On: 10 Jun 2021 09:15:23**

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Rupp (b) (4)	22 Apr 2021 15:29:49
User entered 'Myocardial Infarction'	(b) (4) Kristin Pollock (b) (4) (b) (4)	20 Apr 2021 19:46:44

**US3612005**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (10)**

**Generated On: 10 Jun 2021 09:15:23**

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Rupp (b) (4)	22 Apr 2021 15:29:49
User entered '20'	(b) (4) Kristin Pollock (b) (4) (b) (4)	20 Apr 2021 19:46:44

US3612005

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 09:15:23

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Rupp (b) (4)	22 Apr 2021 15:29:49
User entered 'mg (mg)'	(b) (4) Kristin Pollock (b) (4) (b) (4)	20 Apr 2021 19:46:44

**US3612005**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (10)**

**Generated On: 10 Jun 2021 09:15:23**

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Rupp (b) (4)	22 Apr 2021 15:29:49
User entered empty.	(b) (4) Kristin Pollock (b) (4) (b) (4)	20 Apr 2021 19:46:44

**US3612005**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (10)**

**Generated On: 10 Jun 2021 09:15:23**

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Rupp (b) (4)	22 Apr 2021 15:29:49
User entered 'once daily (QD)'	(b) (4) Kristin Pollock (b) (4) (b) (4)	20 Apr 2021 19:46:44

US3612005

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 09:15:23

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Richard Rupp (b) (4)	22 Apr 2021 15:29:49
User entered empty.	(b) (4) Kristin Pollock (b) (4) (b) (4)	20 Apr 2021 19:46:44

**US3612005**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (10)**

**Generated On: 10 Jun 2021 09:15:23**

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Rupp (b) (4)	22 Apr 2021 15:29:49
User entered 'Oral (ORAL)'	(b) (4) Kristin Pollock (b) (4) (b) (4)	20 Apr 2021 19:46:44

**US3612005**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (10)**

**Generated On: 10 Jun 2021 09:15:23**

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Richard Rupp (b) (4)	22 Apr 2021 15:29:49
User entered empty.	(b) (4) Kristin Pollock (b) (4) (b) (4)	20 Apr 2021 19:46:44

**US3612005**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (10)**

**Generated On: 10 Jun 2021 09:15:23**

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Rupp (b) (4)	22 Apr 2021 15:29:49
User entered '14 Apr 2021'	(b) (4) Kristin Pollock (b) (4) (b) (4)	20 Apr 2021 19:46:44

**US3612005**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (10)**

**Generated On: 10 Jun 2021 09:15:23**

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Rupp (b) (4)	22 Apr 2021 15:29:49
User entered '0'	(b) (4) Kristin Pollock (b) (4) (b) (4)	20 Apr 2021 19:46:44

**US3612005**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (10)**

**Generated On: 10 Jun 2021 09:15:23**

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Rupp (b) (4)	22 Apr 2021 15:29:49
User entered 'Yes (Y)'	(b) (4) Kristin Pollock (b) (4) (b) (4)	20 Apr 2021 19:46:44

**US3612005**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (10)**

**Generated On: 10 Jun 2021 09:15:23**

*If not Ongoing, End date (dd MMM yyyy)*

Audit	User	Time (GMT)
User signature succeeded.	Richard Rupp (b) (4)	22 Apr 2021 15:29:49
User entered empty.	(b) (4) Kristin Pollock (b) (4) (b) (4)	20 Apr 2021 19:46:44

**US3612005**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (10)**

**Generated On: 10 Jun 2021 09:15:23**

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Rupp (b) (4)	22 Apr 2021 15:29:49
User entered 'No (N)'	(b) (4) Kristin Pollock (b) (4) (b) (4)	20 Apr 2021 19:46:44

**US3612005**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (10)**

**Generated On: 10 Jun 2021 09:15:23**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	20 Apr 2021 19:46:44

**US3612005**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (10)**

**Generated On: 10 Jun 2021 09:15:23**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	20 Apr 2021 19:46:44

**US3612005**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (10)**

**Generated On: 10 Jun 2021 09:15:23**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	20 Apr 2021 19:46:44

US3612005

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 09:15:23

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Rupp (b) (4)	22 Apr 2021 15:29:49
User coded data point as ATC: BLOOD AND BLOOD FORMING ORGANS, ATC: ANTITHROMBOTIC AGENTS, ATC: ANTITHROMBOTIC AGENTS, ATC: PLATELET AGGREGATION INHIBITORS EXCL. HEPARIN, PRODUCT: CLOPIDOGREL - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4)	20 Apr 2021 19:49:41
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	20 Apr 2021 19:49:41
Data point term sent to Coder	System	20 Apr 2021 19:48:43
User entered 'Clopidogrel'	Kristin Pollock (b) (4) (b) (4)	20 Apr 2021 19:47:55

**US3612005**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (11)**

**Generated On: 10 Jun 2021 09:15:23**

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Rupp (b) (4)	22 Apr 2021 15:29:49
User entered 'No (N)'	(b) (4) Kristin Pollock (b) (4) (b) (4)	20 Apr 2021 19:47:55

**US3612005**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (11)**

**Generated On: 10 Jun 2021 09:15:23**

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Rupp (b) (4)	22 Apr 2021 15:29:49
User entered 'Myocardial Infarction'	(b) (4) Kristin Pollock (b) (4) (b) (4)	20 Apr 2021 19:47:55

**US3612005**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (11)**

**Generated On: 10 Jun 2021 09:15:23**

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Rupp (b) (4)	22 Apr 2021 15:29:49
User entered '75'	(b) (4) Kristin Pollock (b) (4) (b) (4)	20 Apr 2021 19:47:55

US3612005

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 09:15:23

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Rupp (b) (4)	22 Apr 2021 15:29:49
User entered 'mg (mg)'	(b) (4) Kristin Pollock (b) (4) (b) (4)	20 Apr 2021 19:47:55

US3612005

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (11)**

**Generated On: 10 Jun 2021 09:15:23**

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Richard Rupp (b) (4)	22 Apr 2021 15:29:49
User entered empty.	(b) (4) Kristin Pollock (b) (4) (b) (4)	20 Apr 2021 19:47:55

**US3612005**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (11)**

**Generated On: 10 Jun 2021 09:15:23**

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Rupp (b) (4)	22 Apr 2021 15:29:49
User entered 'once daily (QD)'	(b) (4) Kristin Pollock (b) (4) (b) (4)	20 Apr 2021 19:47:55

**US3612005**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (11)**

**Generated On: 10 Jun 2021 09:15:23**

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Rupp (b) (4)	22 Apr 2021 15:29:49
User entered empty.	(b) (4) Kristin Pollock (b) (4) (b) (4)	20 Apr 2021 19:47:55

**US3612005**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (11)**

**Generated On: 10 Jun 2021 09:15:23**

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Rupp (b) (4)	22 Apr 2021 15:29:49
User entered 'Oral (ORAL)'	(b) (4) Kristin Pollock (b) (4) (b) (4)	20 Apr 2021 19:47:55

US3612005

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (11)**

**Generated On: 10 Jun 2021 09:15:23**

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Richard Rupp (b) (4)	22 Apr 2021 15:29:49
User entered empty.	(b) (4) Kristin Pollock (b) (4) (b) (4)	20 Apr 2021 19:47:55

**US3612005**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (11)**

**Generated On: 10 Jun 2021 09:15:23**

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Rupp (b) (4)	22 Apr 2021 15:29:49
User entered '14 Apr 2021'	(b) (4) Kristin Pollock (b) (4) (b) (4)	20 Apr 2021 19:47:55

**US3612005**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (11)**

**Generated On: 10 Jun 2021 09:15:23**

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Rupp (b) (4)	22 Apr 2021 15:29:49
User entered '0'	(b) (4) Kristin Pollock (b) (4) (b) (4)	20 Apr 2021 19:47:55

**US3612005**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (11)**

**Generated On: 10 Jun 2021 09:15:23**

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Rupp (b) (4)	22 Apr 2021 15:29:49
User entered 'Yes (Y)'	(b) (4) Kristin Pollock (b) (4) (b) (4)	20 Apr 2021 19:47:55

**US3612005**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (11)**

**Generated On: 10 Jun 2021 09:15:23**

*If not Ongoing, End date (dd MMM yyyy)*

Audit	User	Time (GMT)
User signature succeeded.	Richard Rupp (b) (4)	22 Apr 2021 15:29:49
User entered empty.	(b) (4) Kristin Pollock (b) (4) (b) (4)	20 Apr 2021 19:47:55

US3612005

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (11)**

**Generated On: 10 Jun 2021 09:15:23**

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Rupp (b) (4)	22 Apr 2021 15:29:49
User entered 'No (N)'	(b) (4) Kristin Pollock (b) (4) (b) (4)	20 Apr 2021 19:47:55

**US3612005**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (11)**

**Generated On: 10 Jun 2021 09:15:23**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	20 Apr 2021 19:47:55

**US3612005**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (11)**

**Generated On: 10 Jun 2021 09:15:23**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	20 Apr 2021 19:47:55

**US3612005**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (11)**

**Generated On: 10 Jun 2021 09:15:23**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	20 Apr 2021 19:47:55

US3612005

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 09:15:23

Name of Medication

Audit	User	Time (GMT)
User signature succeeded.	Richard Rupp (b) (4)	22 Apr 2021 15:29:49
User coded data point as ATC: CARDIOVASCULAR SYSTEM, ATC: LIPID MODIFYING AGENTS, ATC: LIPID MODIFYING AGENTS, PLAIN, ATC: HMG COA REDUCTASE INHIBITORS, PRODUCT: ATORVASTATIN - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4)	20 Apr 2021 19:50:43
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	20 Apr 2021 19:50:43
Data point term sent to Coder	System	20 Apr 2021 19:49:44
User entered 'Atorvastatin'	Kristin Pollock (b) (4) (b) (4)	20 Apr 2021 19:49:08

**US3612005**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (12)**

**Generated On: 10 Jun 2021 09:15:23**

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Rupp (b) (4)	22 Apr 2021 15:29:49
User entered 'No (N)'	(b) (4) Kristin Pollock (b) (4) (b) (4)	20 Apr 2021 19:49:08

**US3612005**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (12)**

**Generated On: 10 Jun 2021 09:15:23**

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Rupp (b) (4)	22 Apr 2021 15:29:49
User entered 'hypercholesterolemia'	(b) (4) Kristin Pollock (b) (4) (b) (4)	20 Apr 2021 19:49:08

**US3612005**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (12)**

**Generated On: 10 Jun 2021 09:15:23**

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Rupp (b) (4)	22 Apr 2021 15:29:49
User entered '40'	(b) (4) Kristin Pollock (b) (4) (b) (4)	20 Apr 2021 19:49:08

US3612005

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 09:15:23

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Rupp (b) (4)	22 Apr 2021 15:29:49
User entered 'mg (mg)'	(b) (4) Kristin Pollock (b) (4) (b) (4)	20 Apr 2021 19:49:08

US3612005

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (12)**

**Generated On: 10 Jun 2021 09:15:23**

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Richard Rupp (b) (4)	22 Apr 2021 15:29:49
User entered empty.	(b) (4) Kristin Pollock (b) (4) (b) (4)	20 Apr 2021 19:49:08

**US3612005**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (12)**

**Generated On: 10 Jun 2021 09:15:23**

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Rupp (b) (4)	22 Apr 2021 15:29:49
User entered 'once daily (QD)'	(b) (4) Kristin Pollock (b) (4) (b) (4)	20 Apr 2021 19:49:08

US3612005

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (12)**

**Generated On: 10 Jun 2021 09:15:23**

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Rupp (b) (4)	22 Apr 2021 15:29:49
User entered empty.	(b) (4) Kristin Pollock (b) (4) (b) (4)	20 Apr 2021 19:49:08

**US3612005**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (12)**

**Generated On: 10 Jun 2021 09:15:23**

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Rupp (b) (4)	22 Apr 2021 15:29:49
User entered 'Oral (ORAL)'	(b) (4) Kristin Pollock (b) (4) (b) (4)	20 Apr 2021 19:49:08

**US3612005**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (12)**

**Generated On: 10 Jun 2021 09:15:23**

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Richard Rupp (b) (4)	22 Apr 2021 15:29:49
User entered empty.	(b) (4) Kristin Pollock (b) (4) (b) (4)	20 Apr 2021 19:49:08

**US3612005**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (12)**

**Generated On: 10 Jun 2021 09:15:23**

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Rupp (b) (4)	22 Apr 2021 15:29:49
User entered '14 Apr 2021'	(b) (4) Kristin Pollock (b) (4) (b) (4)	20 Apr 2021 19:49:08

**US3612005**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (12)**

**Generated On: 10 Jun 2021 09:15:23**

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Rupp (b) (4)	22 Apr 2021 15:29:49
User entered '0'	(b) (4) Kristin Pollock (b) (4) (b) (4)	20 Apr 2021 19:49:08

**US3612005**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (12)**

**Generated On: 10 Jun 2021 09:15:23**

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Rupp (b) (4)	22 Apr 2021 15:29:49
User entered 'Yes (Y)'	(b) (4) Kristin Pollock (b) (4) (b) (4)	20 Apr 2021 19:49:08

**US3612005**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (12)**

**Generated On: 10 Jun 2021 09:15:23**

*If not Ongoing, End date (dd MMM yyyy)*

Audit	User	Time (GMT)
User signature succeeded.	Richard Rupp (b) (4)	22 Apr 2021 15:29:49
User entered empty.	(b) (4) Kristin Pollock (b) (4) (b) (4)	20 Apr 2021 19:49:08

**US3612005**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (12)**

**Generated On: 10 Jun 2021 09:15:23**

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Rupp (b) (4)	22 Apr 2021 15:29:49
User entered 'No (N)'	(b) (4) Kristin Pollock (b) (4) (b) (4)	20 Apr 2021 19:49:08

**US3612005**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (12)**

**Generated On: 10 Jun 2021 09:15:23**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	20 Apr 2021 19:49:08

**US3612005**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (12)**

**Generated On: 10 Jun 2021 09:15:23**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	20 Apr 2021 19:49:08

**US3612005**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (12)**

**Generated On: 10 Jun 2021 09:15:23**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	20 Apr 2021 19:49:08

US3612005

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 10 Jun 2021 09:15:23

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Rupp (b) (4)	22 Apr 2021 15:29:49
User coded data point as ATC: BLOOD AND BLOOD FORMING ORGANS, ATC: ANTITHROMBOTIC AGENTS, ATC: ANTITHROMBOTIC AGENTS, ATC: PLATELET AGGREGATION INHIBITORS EXCL. HEPARIN, PRODUCT: ACETYLSALICYLIC ACID, PRODUCTSYNONYM: ASPIRIN [ACETYLSALICYLIC ACID] - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	20 Apr 2021 19:51:31
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	20 Apr 2021 19:51:31
Data point term sent to Coder	System	20 Apr 2021 19:50:44
User entered 'Aspirin'	Kristin Pollock (b) (4)	20 Apr 2021 19:50:20

**US3612005**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (13)**

**Generated On: 10 Jun 2021 09:15:23**

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Rupp (b) (4)	22 Apr 2021 15:29:49
User entered 'No (N)'	(b) (4) Kristin Pollock (b) (4) (b) (4)	20 Apr 2021 19:50:20

**US3612005**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (13)**

**Generated On: 10 Jun 2021 09:15:23**

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Rupp (b) (4)	22 Apr 2021 15:29:49
User entered 'myocardial infarction'	(b) (4) Kristin Pollock (b) (4) (b) (4)	20 Apr 2021 19:50:20

**US3612005**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (13)**

**Generated On: 10 Jun 2021 09:15:23**

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Rupp (b) (4)	22 Apr 2021 15:29:49
User entered '81'	(b) (4) Kristin Pollock (b) (4) (b) (4)	20 Apr 2021 19:50:20

US3612005

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 10 Jun 2021 09:15:23

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Rupp (b) (4)	22 Apr 2021 15:29:49
User entered 'mg (mg)'	(b) (4) Kristin Pollock (b) (4) (b) (4)	20 Apr 2021 19:50:20

US3612005

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (13)**

**Generated On: 10 Jun 2021 09:15:23**

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Richard Rupp (b) (4)	22 Apr 2021 15:29:49
	(b) (4)	
User entered empty.	Kristin Pollock (b) (4)	20 Apr 2021 19:50:20
	(b) (4)	

**US3612005**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (13)**

**Generated On: 10 Jun 2021 09:15:23**

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Rupp (b) (4)	22 Apr 2021 15:29:49
User entered 'once daily (QD)'	(b) (4) Kristin Pollock (b) (4) (b) (4)	20 Apr 2021 19:50:20

US3612005

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 10 Jun 2021 09:15:23

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Richard Rupp (b) (4)	22 Apr 2021 15:29:49
User entered empty.	(b) (4) Kristin Pollock (b) (4) (b) (4)	20 Apr 2021 19:50:20

**US3612005**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (13)**

**Generated On: 10 Jun 2021 09:15:23**

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Rupp (b) (4)	22 Apr 2021 15:29:49
User entered 'Oral (ORAL)'	(b) (4) Kristin Pollock (b) (4) (b) (4)	20 Apr 2021 19:50:20

**US3612005**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (13)**

**Generated On: 10 Jun 2021 09:15:23**

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Richard Rupp (b) (4)	22 Apr 2021 15:29:49
User entered empty.	(b) (4) Kristin Pollock (b) (4) (b) (4)	20 Apr 2021 19:50:20

**US3612005**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (13)**

**Generated On: 10 Jun 2021 09:15:23**

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Rupp (b) (4)	22 Apr 2021 15:29:49
User entered '14 Apr 2021'	(b) (4) Kristin Pollock (b) (4) (b) (4)	20 Apr 2021 19:50:20

**US3612005**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (13)**

**Generated On: 10 Jun 2021 09:15:23**

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Rupp (b) (4)	22 Apr 2021 15:29:49
User entered '0'	(b) (4) Kristin Pollock (b) (4) (b) (4)	20 Apr 2021 19:50:20

**US3612005**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (13)**

**Generated On: 10 Jun 2021 09:15:23**

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Rupp (b) (4)	22 Apr 2021 15:29:49
User entered 'Yes (Y)'	(b) (4) Kristin Pollock (b) (4) (b) (4)	20 Apr 2021 19:50:20

**US3612005**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (13)**

**Generated On: 10 Jun 2021 09:15:23**

*If not Ongoing, End date (dd MMM yyyy)*

Audit	User	Time (GMT)
User signature succeeded.	Richard Rupp (b) (4)	22 Apr 2021 15:29:49
User entered empty.	(b) (4) Kristin Pollock (b) (4) (b) (4)	20 Apr 2021 19:50:20

**US3612005**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (13)**

**Generated On: 10 Jun 2021 09:15:23**

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Rupp (b) (4)	22 Apr 2021 15:29:49
User entered 'No (N)'	(b) (4) Kristin Pollock (b) (4) (b) (4)	20 Apr 2021 19:50:20

**US3612005**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (13)**

**Generated On: 10 Jun 2021 09:15:23**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	20 Apr 2021 19:50:20

**US3612005**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (13)**

**Generated On: 10 Jun 2021 09:15:23**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	20 Apr 2021 19:50:20

**US3612005**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (13)**

**Generated On: 10 Jun 2021 09:15:23**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	20 Apr 2021 19:50:20

US3612005

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 10 Jun 2021 09:15:23

Name of Medication

Audit	User	Time (GMT)
User coded data point as ATC: CARDIOVASCULAR SYSTEM, ATC: CALCIUM CHANNEL BLOCKERS, ATC: SELECTIVE CALCIUM CHANNEL BLOCKERS WITH DIRECT CARDIAC EFFECTS, ATC: BENZOTHIAZEPINE DERIVATIVES, PRODUCT: DILTIAZEM - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	26 Apr 2021 21:02:01
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	26 Apr 2021 21:02:01
User signature succeeded.	Richard Rupp (b) (4) (b) (4)	26 Apr 2021 20:27:17
Data point term sent to Coder	System	26 Apr 2021 19:29:48
User entered 'Diltiazem'	Kristin Pollock (b) (4) (b) (4)	26 Apr 2021 19:29:04

**US3612005**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (14)**

**Generated On: 10 Jun 2021 09:15:23**

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Rupp (b) (4)	26 Apr 2021 20:27:17
User entered 'No (N)'	(b) (4) Kristin Pollock (b) (4) (b) (4)	26 Apr 2021 19:29:04

**US3612005**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (14)**

**Generated On: 10 Jun 2021 09:15:23**

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Rupp (b) (4)	26 Apr 2021 20:27:17
User entered 'myocardial infarction'	(b) (4) Kristin Pollock (b) (4) (b) (4)	26 Apr 2021 19:29:04

US3612005

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 10 Jun 2021 09:15:23

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Rupp (b) (4)	26 Apr 2021 20:27:17
User entered '30'	(b) (4) Kristin Pollock (b) (4) (b) (4)	26 Apr 2021 19:29:04

US3612005

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 10 Jun 2021 09:15:23

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Rupp (b) (4)	26 Apr 2021 20:27:17
User entered 'mg (mg)'	(b) (4) Kristin Pollock (b) (4) (b) (4)	26 Apr 2021 19:29:04

US3612005

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (14)**

**Generated On: 10 Jun 2021 09:15:23**

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Richard Rupp (b) (4)	26 Apr 2021 20:27:17
User entered empty.	(b) (4) Kristin Pollock (b) (4) (b) (4)	26 Apr 2021 19:29:04

**US3612005**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (14)**

**Generated On: 10 Jun 2021 09:15:23**

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Rupp (b) (4)	26 Apr 2021 20:27:17
User entered 'twice daily (BID)'	(b) (4) Kristin Pollock (b) (4) (b) (4)	26 Apr 2021 19:29:04

US3612005

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 10 Jun 2021 09:15:23

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Richard Rupp (b) (4)	26 Apr 2021 20:27:17
User entered empty.	(b) (4) Kristin Pollock (b) (4) (b) (4)	26 Apr 2021 19:29:04

**US3612005**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (14)**

**Generated On: 10 Jun 2021 09:15:23**

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Rupp (b) (4)	26 Apr 2021 20:27:17
User entered 'Oral (ORAL)'	(b) (4) Kristin Pollock (b) (4) (b) (4)	26 Apr 2021 19:29:04

US3612005

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (14)**

**Generated On: 10 Jun 2021 09:15:23**

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Richard Rupp (b) (4)	26 Apr 2021 20:27:17
User entered empty.	(b) (4) Kristin Pollock (b) (4) (b) (4)	26 Apr 2021 19:29:04

**US3612005**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (14)**

**Generated On: 10 Jun 2021 09:15:23**

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Rupp (b) (4)	26 Apr 2021 20:27:17
User entered '20 Apr 2021'	(b) (4) Kristin Pollock (b) (4) (b) (4)	26 Apr 2021 19:29:04

**US3612005**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (14)**

**Generated On: 10 Jun 2021 09:15:23**

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Rupp (b) (4)	26 Apr 2021 20:27:17
User entered '0'	(b) (4) Kristin Pollock (b) (4) (b) (4)	26 Apr 2021 19:29:04

**US3612005**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (14)**

**Generated On: 10 Jun 2021 09:15:23**

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Rupp (b) (4)	26 Apr 2021 20:27:17
User entered 'Yes (Y)'	(b) (4) Kristin Pollock (b) (4) (b) (4)	26 Apr 2021 19:29:04

**US3612005**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (14)**

**Generated On: 10 Jun 2021 09:15:23**

*If not Ongoing, End date (dd MMM yyyy)*

Audit	User	Time (GMT)
User signature succeeded.	Richard Rupp (b) (4)	26 Apr 2021 20:27:17
User entered empty.	(b) (4) Kristin Pollock (b) (4) (b) (4)	26 Apr 2021 19:29:04

**US3612005**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (14)**

**Generated On: 10 Jun 2021 09:15:23**

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Rupp (b) (4)	26 Apr 2021 20:27:17
User entered 'No (N)'	(b) (4) Kristin Pollock (b) (4) (b) (4)	26 Apr 2021 19:29:04

**US3612005**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (14)**

**Generated On: 10 Jun 2021 09:15:23**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '2'	System	26 Apr 2021 19:29:04

**US3612005**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (14)**

**Generated On: 10 Jun 2021 09:15:23**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	26 Apr 2021 19:29:04

**US3612005**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (14)**

**Generated On: 10 Jun 2021 09:15:23**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	26 Apr 2021 19:29:04

US3612005

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures Summary

Generated On: 10 Jun 2021 09:15:23

[Were any concomitant procedures performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 08:50:12
User signature succeeded.	Richard Rupp (b) (4)	22 Apr 2021 15:29:49
User closed query 'Please update to YES and enter CARDIAC CATHETERIZATION AND STENT PLACEMENT that patient received on 13APR2021 due MI.' (Site from CRA).	(b) (4) (b) (4), (b) (6)	21 Apr 2021 15:38:29
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 15:38:08
Query 'Please update to YES and enter CARDIAC CATHETERIZATION AND STENT PLACEMENT that patient received on 13APR2021 due MI.' answered with 'updated' (Site from CRA).	Kristin Pollock (b) (4) (b) (4)	20 Apr 2021 19:51:41
DataPoint Un-verified.	Kristin Pollock (b) (4) (b) (4)	20 Apr 2021 19:51:28
Signature has been broken.	Kristin Pollock (b) (4) (b) (4)	20 Apr 2021 19:51:28
User entered 'Yes (Y)' reason for change: New Information	Kristin Pollock (b) (4) (b) (4)	20 Apr 2021 19:51:28
User opened query 'Please update to YES and enter CARDIAC CATHETERIZATION AND STENT PLACEMENT that patient received on 13APR2021 due MI.' (Site from CRA).	(b) (4), (b) (6)	20 Apr 2021 19:01:35
User signature succeeded.	Richard Rupp (b) (4) (b) (4)	26 Mar 2021 18:58:13
DataPoint Verified.	(b) (4), (b) (6)	11 Mar 2021 16:41:47
User entered 'No (N)'	Amy McMahan (b) (4) (b) (4)	04 Feb 2021 15:57:38

US3612005

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (1)

Generated On: 10 Jun 2021 09:15:23

Procedure/Surgery date (*dd MMM yyyy*)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 14:51:49
User signature succeeded.	Richard Rupp (b) (4)	22 Apr 2021 15:29:49
User entered '13 Apr 2021'	Kristin Pollock (b) (4)	20 Apr 2021 19:52:22

US3612005

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (1)

Generated On: 10 Jun 2021 09:15:23

[Procedure/Surgery](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 14:51:49
User signature succeeded.	Richard Rupp (b) (4)	22 Apr 2021 15:29:49
User entered 'Cardiac Catheterization with Stent placement'	Kristin Pollock (b) (4)	20 Apr 2021 19:52:22

**US3612005**

**Folder: Concomitant Procedures (1)**

**Form: Concomitant Procedures (1)**

**Generated On: 10 Jun 2021 09:15:23**

[Indication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 14:51:49
User signature succeeded.	Richard Rupp (b) (4)	22 Apr 2021 15:29:49
User entered 'Adverse Event (AE)'	Kristin Pollock (b) (4)	20 Apr 2021 19:52:22

US3612005

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (1)

Generated On: 10 Jun 2021 09:15:23

If indication is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 14:51:49
User signature succeeded.	Richard Rupp (b) (4)	22 Apr 2021 15:29:49
User entered empty.	Kristin Pollock (b) (4)	20 Apr 2021 19:52:22

**US3612005**

**Folder: SAE USA-US129-2021-MRNA-1273-P301000006**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:15:23**

[SAEID](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 16:22:14
User signature succeeded.	Richard Rupp (b) (4)	22 Apr 2021 15:29:49
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	21 Apr 2021 15:26:31
User entered 'USA-US129-2021-MRNA-1273-P301000006'	System	21 Apr 2021 15:26:12

**US3612005**

**Folder: SAE USA-US129-2021-MRNA-1273-P301000006**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:15:23**

**Serious**

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 16:22:14
User signature succeeded.	Richard Rupp (b) (4)	22 Apr 2021 15:29:49
Reviewed for Safety.	(b) (4)	21 Apr 2021 15:26:31
User entered 'Yes (Y)'	System	21 Apr 2021 15:26:12

**US3612005**

**Folder: SAE USA-US129-2021-MRNA-1273-P301000006**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:15:23**

[Death](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 16:22:14
User signature succeeded.	Richard Rupp (b) (4)	22 Apr 2021 15:29:49
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	21 Apr 2021 15:26:31
User entered 'No (N)'	System	21 Apr 2021 15:26:12

**US3612005**

**Folder: SAE USA-US129-2021-MRNA-1273-P301000006**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:15:23**

[Life threatening](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 16:22:14
User signature succeeded.	Richard Rupp (b) (4)	22 Apr 2021 15:29:49
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	21 Apr 2021 15:26:31
User entered 'Yes (Y)'	System	21 Apr 2021 15:26:12

**US3612005**

**Folder: SAE USA-US129-2021-MRNA-1273-P301000006**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:15:23**

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 16:22:14
User signature succeeded.	Richard Rupp (b) (4)	22 Apr 2021 15:29:49
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	21 Apr 2021 15:26:31
User entered 'Yes (Y)'	System	21 Apr 2021 15:26:12

**US3612005**

**Folder: SAE USA-US129-2021-MRNA-1273-P301000006**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:15:23**

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 16:22:14
User signature succeeded.	Richard Rupp (b) (4)	22 Apr 2021 15:29:49
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	21 Apr 2021 15:26:31
User entered 'No (N)'	System	21 Apr 2021 15:26:12

**US3612005**

**Folder: SAE USA-US129-2021-MRNA-1273-P301000006**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:15:23**

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 16:22:14
User signature succeeded.	Richard Rupp (b) (4)	22 Apr 2021 15:29:49
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	21 Apr 2021 15:26:31
User entered 'No (N)'	System	21 Apr 2021 15:26:12

**US3612005**

**Folder: SAE USA-US129-2021-MRNA-1273-P301000006**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:15:23**

[Other medically important event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 16:22:14
User signature succeeded.	Richard Rupp (b) (4)	22 Apr 2021 15:29:49
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	21 Apr 2021 15:26:31
User entered 'No (N)'	System	21 Apr 2021 15:26:12

**US3612005**

**Folder: SAE USA-US129-2021-MRNA-1273-P301000006**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:15:23**

[Investigator's First Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 16:22:14
User signature succeeded.	Richard Rupp (b) (4)	22 Apr 2021 15:29:49
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	21 Apr 2021 15:26:31
User entered 'Richard'	System	21 Apr 2021 15:26:12

**US3612005**

**Folder: SAE USA-US129-2021-MRNA-1273-P301000006**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:15:23**

[Investigator's Last Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 16:22:14
User signature succeeded.	Richard Rupp (b) (4)	22 Apr 2021 15:29:49
Reviewed for Safety.	(b) (4)	
	(b) (4), (b) (6)	21 Apr 2021 15:26:31
User entered 'Rupp'	System	21 Apr 2021 15:26:12

**US3612005**

**Folder: SAE USA-US129-2021-MRNA-1273-P301000006**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:15:23**

[Site Address: Street](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 16:22:14
User signature succeeded.	Richard Rupp (b) (4)	22 Apr 2021 15:29:49
Reviewed for Safety.	(b) (4)	
	(b) (4), (b) (6)	21 Apr 2021 15:26:31
User entered '301 University Blvd'	System	21 Apr 2021 15:26:12

**US3612005**

**Folder: SAE USA-US129-2021-MRNA-1273-P301000006**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:15:23**

[Site Address: City](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 16:22:14
User signature succeeded.	Richard Rupp (b) (4)	22 Apr 2021 15:29:49
Reviewed for Safety.	(b) (4)	21 Apr 2021 15:26:31
User entered 'Galveston'	System	21 Apr 2021 15:26:12

**US3612005**

**Folder: SAE USA-US129-2021-MRNA-1273-P301000006**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:15:23**

[Site Address: State](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 16:22:14
User signature succeeded.	Richard Rupp (b) (4)	22 Apr 2021 15:29:49
Reviewed for Safety.	(b) (4)	21 Apr 2021 15:26:31
User entered 'TX'	System	21 Apr 2021 15:26:12

**US3612005**

**Folder: SAE USA-US129-2021-MRNA-1273-P301000006**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:15:23**

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 16:22:14
User signature succeeded.	Richard Rupp (b) (4)	22 Apr 2021 15:29:49
Reviewed for Safety.	(b) (4)	21 Apr 2021 15:26:31
User entered '77555'	System	21 Apr 2021 15:26:12

**US3612005**

**Folder: SAE USA-US129-2021-MRNA-1273-P301000006**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:15:23**

[Investigator Country](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 16:22:14
User signature succeeded.	Richard Rupp (b) (4)	22 Apr 2021 15:29:49
User entered 'US'	(b) (4) System	21 Apr 2021 15:26:42

**US3612005**

**Folder: SAE USA-US129-2021-MRNA-1273-P301000006**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:15:23**

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '3'	System	03 May 2021 14:24:31
User entered '2'	System	23 Apr 2021 19:24:05
User entered '1'	System	21 Apr 2021 15:26:42

**US3612005**

**Folder: SAE USA-US129-2021-MRNA-1273-P301000006**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:15:23**

[SAEID](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 16:22:14
User signature succeeded.	Richard Rupp (b) (4)	22 Apr 2021 15:29:49
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	21 Apr 2021 15:26:31
User entered 'USA-US129-2021-MRNA-1273-P301000006'	System	21 Apr 2021 15:26:12

**US3612005**

**Folder: SAE USA-US129-2021-MRNA-1273-P301000006**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:15:23**

**Serious**

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 16:22:14
User signature succeeded.	Richard Rupp (b) (4)	22 Apr 2021 15:29:49
Reviewed for Safety.	(b) (4)	
	(b) (4), (b) (6)	21 Apr 2021 15:26:31
User entered 'Yes (Y)'	System	21 Apr 2021 15:26:12

**US3612005**

**Folder: SAE USA-US129-2021-MRNA-1273-P301000006**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:15:23**

[Death](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 16:22:14
User signature succeeded.	Richard Rupp (b) (4)	22 Apr 2021 15:29:49
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	21 Apr 2021 15:26:31
User entered 'No (N)'	System	21 Apr 2021 15:26:12

**US3612005**

**Folder: SAE USA-US129-2021-MRNA-1273-P301000006**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:15:23**

[Life threatening](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 16:22:14
User signature succeeded.	Richard Rupp (b) (4)	22 Apr 2021 15:29:49
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	21 Apr 2021 15:26:31
User entered 'Yes (Y)'	System	21 Apr 2021 15:26:12

**US3612005**

**Folder: SAE USA-US129-2021-MRNA-1273-P301000006**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:15:23**

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 16:22:14
User signature succeeded.	Richard Rupp (b) (4)	22 Apr 2021 15:29:49
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	21 Apr 2021 15:26:31
User entered 'Yes (Y)'	System	21 Apr 2021 15:26:12

**US3612005**

**Folder: SAE USA-US129-2021-MRNA-1273-P301000006**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:15:23**

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 16:22:14
User signature succeeded.	Richard Rupp (b) (4)	22 Apr 2021 15:29:49
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	21 Apr 2021 15:26:31
User entered 'No (N)'	System	21 Apr 2021 15:26:12

**US3612005**

**Folder: SAE USA-US129-2021-MRNA-1273-P301000006**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:15:23**

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 16:22:14
User signature succeeded.	Richard Rupp (b) (4)	22 Apr 2021 15:29:49
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	21 Apr 2021 15:26:31
User entered 'No (N)'	System	21 Apr 2021 15:26:12

**US3612005**

**Folder: SAE USA-US129-2021-MRNA-1273-P301000006**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:15:23**

[Other medically important event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 16:22:14
User signature succeeded.	Richard Rupp (b) (4)	22 Apr 2021 15:29:49
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	21 Apr 2021 15:26:31
User entered 'No (N)'	System	21 Apr 2021 15:26:12

**US3612005**

**Folder: SAE USA-US129-2021-MRNA-1273-P301000006**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:15:23**

[Investigator's First Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 16:22:14
User signature succeeded.	Richard Rupp (b) (4)	22 Apr 2021 15:29:49
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	21 Apr 2021 15:26:31
User entered 'Richard'	System	21 Apr 2021 15:26:12

**US3612005**

**Folder: SAE USA-US129-2021-MRNA-1273-P301000006**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:15:23**

[Investigator's Last Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 16:22:14
User signature succeeded.	Richard Rupp (b) (4)	22 Apr 2021 15:29:49
Reviewed for Safety.	(b) (4)	
	(b) (4), (b) (6)	21 Apr 2021 15:26:31
User entered 'Rupp'	System	21 Apr 2021 15:26:12

**US3612005**

**Folder: SAE USA-US129-2021-MRNA-1273-P301000006**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:15:23**

[Site Address: Street](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 16:22:14
User signature succeeded.	Richard Rupp (b) (4)	22 Apr 2021 15:29:49
Reviewed for Safety.	(b) (4)	
	(b) (4), (b) (6)	21 Apr 2021 15:26:31
User entered '301 University Blvd'	System	21 Apr 2021 15:26:12

**US3612005**

**Folder: SAE USA-US129-2021-MRNA-1273-P301000006**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:15:23**

[Site Address: City](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 16:22:14
User signature succeeded.	Richard Rupp (b) (4)	22 Apr 2021 15:29:49
Reviewed for Safety.	(b) (4)	21 Apr 2021 15:26:31
User entered 'Galveston'	System	21 Apr 2021 15:26:12

**US3612005**

**Folder: SAE USA-US129-2021-MRNA-1273-P301000006**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:15:23**

[Site Address: State](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 16:22:14
User signature succeeded.	Richard Rupp (b) (4)	22 Apr 2021 15:29:49
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	21 Apr 2021 15:26:31
User entered 'TX'	System	21 Apr 2021 15:26:12

**US3612005**

**Folder: SAE USA-US129-2021-MRNA-1273-P301000006**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:15:23**

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 16:22:14
User signature succeeded.	Richard Rupp (b) (4)	22 Apr 2021 15:29:49
Reviewed for Safety.	(b) (4)	21 Apr 2021 15:26:31
User entered '77555'	System	21 Apr 2021 15:26:12

**US3612005**

**Folder: SAE USA-US129-2021-MRNA-1273-P301000006**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:15:23**

[Investigator Country](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 16:22:14
User signature succeeded.	Richard Rupp (b) (4)	22 Apr 2021 15:29:49
User entered 'US'	(b) (4) System	21 Apr 2021 15:26:42

**US3612005**

**Folder: SAE USA-US129-2021-MRNA-1273-P301000006**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:15:23**

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '3'	System	03 May 2021 14:24:31
User entered '2'	System	23 Apr 2021 19:24:05
User entered '1'	System	21 Apr 2021 15:26:42

**US3612005**

**Folder: SAE USA-US129-2021-MRNA-1273-P301000006**

**Form: Safety Report Form (1)**

**Generated On: 10 Jun 2021 09:15:23**

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 16:22:14
User signature succeeded.	Richard Rupp (b) (4)	22 Apr 2021 15:29:49
User entered '21/Apr/2021 10:26'	(b) (4) System	21 Apr 2021 15:26:42

US3612005

Folder: SAE USA-US129-2021-MRNA-1273-P301000006

Form: Safety Report Form (1)

Generated On: 10 Jun 2021 09:15:23

**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)	22 Apr 2021 16:22:14
User signature succeeded.	Richard Rupp (b) (4)	22 Apr 2021 15:29:49
User entered 'I'	(b) (4), (b) (6)	21 Apr 2021 15:26:42

**US3612005**

**Folder: SAE USA-US129-2021-MRNA-1273-P301000006**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:15:23**

[SAEID](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 16:22:14
User signature succeeded.	Richard Rupp (b) (4)	22 Apr 2021 15:29:49
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	21 Apr 2021 15:26:31
User entered 'USA-US129-2021-MRNA-1273-P301000006'	System	21 Apr 2021 15:26:12

**US3612005**

**Folder: SAE USA-US129-2021-MRNA-1273-P301000006**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:15:23**

**Serious**

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 16:22:14
User signature succeeded.	Richard Rupp (b) (4)	22 Apr 2021 15:29:49
Reviewed for Safety.	(b) (4)	21 Apr 2021 15:26:31
User entered 'Yes (Y)'	System	21 Apr 2021 15:26:12

**US3612005**

**Folder: SAE USA-US129-2021-MRNA-1273-P301000006**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:15:23**

[Death](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 16:22:14
User signature succeeded.	Richard Rupp (b) (4)	22 Apr 2021 15:29:49
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	21 Apr 2021 15:26:31
User entered 'No (N)'	System	21 Apr 2021 15:26:12

**US3612005**

**Folder: SAE USA-US129-2021-MRNA-1273-P301000006**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:15:23**

[Life threatening](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 16:22:14
User signature succeeded.	Richard Rupp (b) (4)	22 Apr 2021 15:29:49
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	21 Apr 2021 15:26:31
User entered 'Yes (Y)'	System	21 Apr 2021 15:26:12

**US3612005**

**Folder: SAE USA-US129-2021-MRNA-1273-P301000006**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:15:23**

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 16:22:14
User signature succeeded.	Richard Rupp (b) (4)	22 Apr 2021 15:29:49
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	21 Apr 2021 15:26:31
User entered 'Yes (Y)'	System	21 Apr 2021 15:26:12

**US3612005**

**Folder: SAE USA-US129-2021-MRNA-1273-P301000006**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:15:23**

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 16:22:14
User signature succeeded.	Richard Rupp (b) (4)	22 Apr 2021 15:29:49
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	21 Apr 2021 15:26:31
User entered 'No (N)'	System	21 Apr 2021 15:26:12

**US3612005**

**Folder: SAE USA-US129-2021-MRNA-1273-P301000006**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:15:23**

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 16:22:14
User signature succeeded.	Richard Rupp (b) (4)	22 Apr 2021 15:29:49
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	21 Apr 2021 15:26:31
User entered 'No (N)'	System	21 Apr 2021 15:26:12

**US3612005**

**Folder: SAE USA-US129-2021-MRNA-1273-P301000006**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:15:23**

[Other medically important event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 16:22:14
User signature succeeded.	Richard Rupp (b) (4)	22 Apr 2021 15:29:49
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	21 Apr 2021 15:26:31
User entered 'No (N)'	System	21 Apr 2021 15:26:12

**US3612005**

**Folder: SAE USA-US129-2021-MRNA-1273-P301000006**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:15:23**

[Investigator's First Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 16:22:14
User signature succeeded.	Richard Rupp (b) (4)	22 Apr 2021 15:29:49
Reviewed for Safety.	(b) (4)	
	(b) (4), (b) (6)	21 Apr 2021 15:26:31
User entered 'Richard'	System	21 Apr 2021 15:26:12

**US3612005**

**Folder: SAE USA-US129-2021-MRNA-1273-P301000006**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:15:23**

[Investigator's Last Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 16:22:14
User signature succeeded.	Richard Rupp (b) (4)	22 Apr 2021 15:29:49
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	21 Apr 2021 15:26:31
User entered 'Rupp'	System	21 Apr 2021 15:26:12

**US3612005**

**Folder: SAE USA-US129-2021-MRNA-1273-P301000006**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:15:23**

[Site Address: Street](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 16:22:14
User signature succeeded.	Richard Rupp (b) (4)	22 Apr 2021 15:29:49
Reviewed for Safety.	(b) (4)	
	(b) (4), (b) (6)	21 Apr 2021 15:26:31
User entered '301 University Blvd'	System	21 Apr 2021 15:26:12

**US3612005**

**Folder: SAE USA-US129-2021-MRNA-1273-P301000006**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:15:23**

[Site Address: City](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 16:22:14
User signature succeeded.	Richard Rupp (b) (4)	22 Apr 2021 15:29:49
Reviewed for Safety.	(b) (4)	21 Apr 2021 15:26:31
User entered 'Galveston'	System	21 Apr 2021 15:26:12

**US3612005**

**Folder: SAE USA-US129-2021-MRNA-1273-P301000006**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:15:23**

[Site Address: State](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 16:22:14
User signature succeeded.	Richard Rupp (b) (4)	22 Apr 2021 15:29:49
Reviewed for Safety.	(b) (4)	21 Apr 2021 15:26:31
User entered 'TX'	System	21 Apr 2021 15:26:12

**US3612005**

**Folder: SAE USA-US129-2021-MRNA-1273-P301000006**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:15:23**

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 16:22:14
User signature succeeded.	Richard Rupp (b) (4)	22 Apr 2021 15:29:49
Reviewed for Safety.	(b) (4)	21 Apr 2021 15:26:31
User entered '77555'	System	21 Apr 2021 15:26:12

**US3612005**

**Folder: SAE USA-US129-2021-MRNA-1273-P301000006**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:15:23**

[Investigator Country](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 16:22:14
User signature succeeded.	Richard Rupp (b) (4)	22 Apr 2021 15:29:49
User entered 'US'	(b) (4) System	21 Apr 2021 15:26:42

**US3612005**

**Folder: SAE USA-US129-2021-MRNA-1273-P301000006**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:15:23**

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '3'	System	03 May 2021 14:24:31
User entered '2'	System	23 Apr 2021 19:24:05
User entered '1'	System	21 Apr 2021 15:26:42

**US3612005**

**Folder: SAE USA-US129-2021-MRNA-1273-P301000006**

**Form: Safety Report Form (2)**

**Generated On: 10 Jun 2021 09:15:23**

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	28 Apr 2021 15:27:51
User signature succeeded.	Richard Rupp (b) (4)	26 Apr 2021 20:27:17
User entered '23/Apr/2021 12:24'	(b) (4) System	23 Apr 2021 19:24:05

US3612005

Folder: SAE USA-US129-2021-MRNA-1273-P301000006

Form: Safety Report Form (2)

Generated On: 10 Jun 2021 09:15:23

**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)	28 Apr 2021 15:27:52
User signature succeeded.	Richard Rupp (b) (4)	26 Apr 2021 20:27:17
User entered 'I'	(b) (4) (b) (4), (b) (6)	23 Apr 2021 19:24:05

**US3612005**

**Folder: SAE USA-US129-2021-MRNA-1273-P301000006**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:15:23**

[SAEID](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 16:22:14
User signature succeeded.	Richard Rupp (b) (4)	22 Apr 2021 15:29:49
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	21 Apr 2021 15:26:31
User entered 'USA-US129-2021-MRNA-1273-P301000006'	System	21 Apr 2021 15:26:12

**US3612005**

**Folder: SAE USA-US129-2021-MRNA-1273-P301000006**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:15:23**

**Serious**

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 16:22:14
User signature succeeded.	Richard Rupp (b) (4)	22 Apr 2021 15:29:49
Reviewed for Safety.	(b) (4)	21 Apr 2021 15:26:31
User entered 'Yes (Y)'	System	21 Apr 2021 15:26:12

**US3612005**

**Folder: SAE USA-US129-2021-MRNA-1273-P301000006**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:15:23**

[Death](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 16:22:14
User signature succeeded.	Richard Rupp (b) (4)	22 Apr 2021 15:29:49
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	21 Apr 2021 15:26:31
User entered 'No (N)'	System	21 Apr 2021 15:26:12

**US3612005**

**Folder: SAE USA-US129-2021-MRNA-1273-P301000006**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:15:23**

[Life threatening](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 16:22:14
User signature succeeded.	Richard Rupp (b) (4)	22 Apr 2021 15:29:49
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	21 Apr 2021 15:26:31
User entered 'Yes (Y)'	System	21 Apr 2021 15:26:12

**US3612005**

**Folder: SAE USA-US129-2021-MRNA-1273-P301000006**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:15:23**

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 16:22:14
User signature succeeded.	Richard Rupp (b) (4)	22 Apr 2021 15:29:49
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	21 Apr 2021 15:26:31
User entered 'Yes (Y)'	System	21 Apr 2021 15:26:12

**US3612005**

**Folder: SAE USA-US129-2021-MRNA-1273-P301000006**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:15:23**

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 16:22:14
User signature succeeded.	Richard Rupp (b) (4)	22 Apr 2021 15:29:49
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	21 Apr 2021 15:26:31
User entered 'No (N)'	System	21 Apr 2021 15:26:12

**US3612005**

**Folder: SAE USA-US129-2021-MRNA-1273-P301000006**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:15:23**

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 16:22:14
User signature succeeded.	Richard Rupp (b) (4)	22 Apr 2021 15:29:49
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	21 Apr 2021 15:26:31
User entered 'No (N)'	System	21 Apr 2021 15:26:12

**US3612005**

**Folder: SAE USA-US129-2021-MRNA-1273-P301000006**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:15:23**

[Other medically important event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 16:22:14
User signature succeeded.	Richard Rupp (b) (4)	22 Apr 2021 15:29:49
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	21 Apr 2021 15:26:31
User entered 'No (N)'	System	21 Apr 2021 15:26:12

**US3612005**

**Folder: SAE USA-US129-2021-MRNA-1273-P301000006**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:15:23**

[Investigator's First Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 16:22:14
User signature succeeded.	Richard Rupp (b) (4)	22 Apr 2021 15:29:49
Reviewed for Safety.	(b) (4)	
	(b) (4), (b) (6)	21 Apr 2021 15:26:31
User entered 'Richard'	System	21 Apr 2021 15:26:12

**US3612005**

**Folder: SAE USA-US129-2021-MRNA-1273-P301000006**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:15:23**

[Investigator's Last Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 16:22:14
User signature succeeded.	Richard Rupp (b) (4)	22 Apr 2021 15:29:49
Reviewed for Safety.	(b) (4)	21 Apr 2021 15:26:31
User entered 'Rupp'	System	21 Apr 2021 15:26:12

**US3612005**

**Folder: SAE USA-US129-2021-MRNA-1273-P301000006**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:15:23**

[Site Address: Street](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 16:22:14
User signature succeeded.	Richard Rupp (b) (4)	22 Apr 2021 15:29:49
Reviewed for Safety.	(b) (4)	21 Apr 2021 15:26:31
User entered '301 University Blvd'	System	21 Apr 2021 15:26:12

**US3612005**

**Folder: SAE USA-US129-2021-MRNA-1273-P301000006**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:15:23**

[Site Address: City](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 16:22:14
User signature succeeded.	Richard Rupp (b) (4)	22 Apr 2021 15:29:49
Reviewed for Safety.	(b) (4)	21 Apr 2021 15:26:31
User entered 'Galveston'	System	21 Apr 2021 15:26:12

**US3612005**

**Folder: SAE USA-US129-2021-MRNA-1273-P301000006**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:15:23**

[Site Address: State](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 16:22:14
User signature succeeded.	Richard Rupp (b) (4)	22 Apr 2021 15:29:49
Reviewed for Safety.	(b) (4)	21 Apr 2021 15:26:31
User entered 'TX'	System	21 Apr 2021 15:26:12

**US3612005**

**Folder: SAE USA-US129-2021-MRNA-1273-P301000006**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:15:23**

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 16:22:14
User signature succeeded.	Richard Rupp (b) (4)	22 Apr 2021 15:29:49
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	21 Apr 2021 15:26:31
User entered '77555'	System	21 Apr 2021 15:26:12

**US3612005**

**Folder: SAE USA-US129-2021-MRNA-1273-P301000006**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:15:23**

[Investigator Country](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 16:22:14
User signature succeeded.	Richard Rupp (b) (4)	22 Apr 2021 15:29:49
User entered 'US'	(b) (4) System	21 Apr 2021 15:26:42

**US3612005**

**Folder: SAE USA-US129-2021-MRNA-1273-P301000006**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:15:23**

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '3'	System	03 May 2021 14:24:31
User entered '2'	System	23 Apr 2021 19:24:05
User entered '1'	System	21 Apr 2021 15:26:42

**US3612005**

**Folder: SAE USA-US129-2021-MRNA-1273-P301000006**

**Form: Safety Report Form (3)**

**Generated On: 10 Jun 2021 09:15:23**

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
User entered '03/May/2021 10:24'	System	03 May 2021 14:24:31

US3612005

Folder: SAE USA-US129-2021-MRNA-1273-P301000006

Form: Safety Report Form (3)

Generated On: 10 Jun 2021 09:15:23

**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 entered 'I'	(b) (4), (b) (6)	03 May 2021 14:24:31