

US3292365 (Prod: Clinical Trials of Texas, Inc)

Generated By: (b) (6)

Generated On: 26 Nov 2020 10:54:21

All time stamps listed in this document are displayed in GMT

US3292365

Form: Participant Creation

Generated On: 26 Nov 2020 10:54:21

[Participant ID](#)

US3292365

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

US3292365

Folder: Screening

Form: Visit Date

Generated On: 26 Nov 2020 10:54:21

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

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Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 10:54:21

Date of Birth (MMM yyyy)	(b) (6) 1962
Age	58
Age Units	YEARS
Age (Derived)	58
Sex	Female <input checked="" type="radio"/> Male <input type="radio"/>
Ethnicity	Hispanic or Latino <input type="radio"/> Not Hispanic or Latino <input checked="" type="radio"/> Not Reported <input type="radio"/> Unknown <input type="radio"/>
Race (Check All That Apply)	
White	True
Black	False
Asian	False
American Indian or Alaska Native	False
Native Hawaiian or other Pacific Islander	False
Other	False
If race is Other, specify _____	
Unknown	False
Not reported	False

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Folder: Screening

Form: Enrollment

Generated On: 26 Nov 2020 10:54:21

Date of Informed Consent (<i>dd MMM yyyy</i>)	29 AUG 2020
Month and Year of Informed Consent (derived)	AUG 2020
Year of Informed Consent (derived)	2020
Protocol Version	Amendment 1 <input type="radio"/>
	Amendment 2 <input type="radio"/>
	Amendment 3 <input checked="" type="radio"/>
	Amendment 4 <input type="radio"/>
	Amendment 5 <input type="radio"/>
Was participant enrolled in the study?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
If No, indicate reason for screen fail	Withdrew Consent <input type="radio"/>
	Inclusion/Exclusion <input type="radio"/>
	Cohort Full <input type="radio"/>
	Other <input type="radio"/>
If reason for screen fail is Other, specify	
Was this participant screened previously?	Yes <input type="radio"/>
	No <input checked="" type="radio"/>
If Yes, previous participant number	
Enrollment Trigger	1

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Folder: Screening

Form: Inclusion/Exclusion Criteria Summary

Generated On: 26 Nov 2020 10:54:21

Did the participant meet all eligibility criteria?

Yes ☒

No ☐

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Folder: Screening

Form: Medical History Summary

Generated On: 26 Nov 2020 10:54:21

Were any significant conditions reported?

Yes ☒

No ☐

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Folder: Screening

Form: Medical History (1)

Generated On: 26 Nov 2020 10:54:21

Condition	MOLD ALLERGY
Start date (dd MMM yyyy)	UN UNK 1984
Start date completely unknown	False
Condition ongoing at study entry	Yes <input checked="" type="radio"/> No <input type="radio"/>
If No, please specify the stop date (dd MMM yyyy) _____	
Stop date completely unknown	False
Start Month and Year (derived)	JAN 1984
Start Year (derived)	1984
Stop Month and Year (derived)	_____
Stop Year (derived)	_____

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Folder: Screening

Form: Medical History (2)

Generated On: 26 Nov 2020 10:54:21

Condition	OAK ALLERGY
Start date (dd MMM yyyy)	UN UNK 1984
Start date completely unknown	False
Condition ongoing at study entry	Yes <input checked="" type="radio"/> No <input type="radio"/>
If No, please specify the stop date (dd MMM yyyy)	
Stop date completely unknown	False
Start Month and Year (derived)	JAN 1984
Start Year (derived)	1984
Stop Month and Year (derived)	
Stop Year (derived)	

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Folder: Screening

Form: Medical History (3)

Generated On: 26 Nov 2020 10:54:21

Condition	BEE STING ALLERGY
Start date (dd MMM yyyy)	UN UNK 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)	JAN 1981
Start Year (derived)	1981
Stop Month and Year (derived)	_____
Stop Year (derived)	_____

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Folder: Screening

Form: Medical History (4)

Generated On: 26 Nov 2020 10:54:21

Condition	HYMENECTOMY
Start date (dd MMM yyyy)	UN UNK 1985
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 1985
Stop date completely unknown	False
Start Month and Year (derived)	JAN 1985
Start Year (derived)	1985
Stop Month and Year (derived)	JAN 1985
Stop Year (derived)	1985

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Folder: Screening

Form: Medical History (5)

Generated On: 26 Nov 2020 10:54:21

Condition	THICK/SEPTATE HYMEN
Start date (dd MMM yyyy)	UN UNK 1985
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 1985
Stop date completely unknown	False
Start Month and Year (derived)	JAN 1985
Start Year (derived)	1985
Stop Month and Year (derived)	JAN 1985
Stop Year (derived)	1985

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Folder: Screening

Form: Medical History (6)

Generated On: 26 Nov 2020 10:54:21

Condition	C-SECTION
Start date (dd MMM yyyy)	UN UNK 1989
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 1989
Stop date completely unknown	False
Start Month and Year (derived)	JAN 1989
Start Year (derived)	1989
Stop Month and Year (derived)	JAN 1989
Stop Year (derived)	1989

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Folder: Screening

Form: Medical History (7)

Generated On: 26 Nov 2020 10:54:21

Condition	LAPAROSCOPY FOR ENDOMETRIOSIS
Start date (dd MMM yyyy)	UN UNK 1997
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 1997
Stop date completely unknown	False
Start Month and Year (derived)	JAN 1997
Start Year (derived)	1997
Stop Month and Year (derived)	JAN 1997
Stop Year (derived)	1997

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Folder: Screening

Form: Medical History (8)

Generated On: 26 Nov 2020 10:54:21

Condition	ENDOMETRIOSIS
Start date (dd MMM yyyy)	UN UNK 1997
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 1997
Stop date completely unknown	False
Start Month and Year (derived)	JAN 1997
Start Year (derived)	1997
Stop Month and Year (derived)	JAN 1997
Stop Year (derived)	1997

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Folder: Screening

Form: Medical History (9)

Generated On: 26 Nov 2020 10:54:21

Condition	RIGHT EYE LASIK
Start date (dd MMM yyyy)	06 AUG 2020
Start date completely unknown	False
Condition ongoing at study entry	Yes <input type="radio"/> No <input checked="" type="radio"/>
If No, please specify the stop date (dd MMM yyyy)	06 AUG 2020
Stop date completely unknown	False
Start Month and Year (derived)	AUG 2020
Start Year (derived)	2020
Stop Month and Year (derived)	AUG 2020
Stop Year (derived)	2020

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Folder: Screening

Form: Medical History (10)

Generated On: 26 Nov 2020 10:54:21

Condition	COLONOSCOPY
Start date (dd MMM yyyy)	UN UNK 2015
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 2015
Stop date completely unknown	False
Start Month and Year (derived)	JAN 2015
Start Year (derived)	2015
Stop Month and Year (derived)	JAN 2015
Stop Year (derived)	2015

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Folder: Screening

Form: Medical History (11)

Generated On: 26 Nov 2020 10:54:21

Condition	POLYP REMOVAL
Start date (dd MMM yyyy)	UN UNK 2015
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 2015
Stop date completely unknown	False
Start Month and Year (derived)	JAN 2015
Start Year (derived)	2015
Stop Month and Year (derived)	JAN 2015
Stop Year (derived)	2015

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Folder: Screening

Form: Medical History (12)

Generated On: 26 Nov 2020 10:54:21

Condition	LEFT HAND SQUAMOUS CELL REMOVAL
Start date (dd MMM yyyy)	UN UNK 2009
Start date completely unknown	False
Condition ongoing at study entry	Yes <input type="checkbox"/> No <input checked="" type="checkbox"/>
If No, please specify the stop date (dd MMM yyyy)	UN UNK 2009
Stop date completely unknown	False
Start Month and Year (derived)	JAN 2009
Start Year (derived)	2009
Stop Month and Year (derived)	JAN 2009
Stop Year (derived)	2009

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Folder: Screening

Form: Medical History (13)

Generated On: 26 Nov 2020 10:54:21

Condition	LEFT HAND SQUAMOUS CELL CARCINOMA
Start date (dd MMM yyyy)	UN UNK 2009
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 2009
Stop date completely unknown	False
Start Month and Year (derived)	JAN 2009
Start Year (derived)	2009
Stop Month and Year (derived)	JAN 2009
Stop Year (derived)	2009

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Folder: Screening

Form: Medical History (14)

Generated On: 26 Nov 2020 10:54:21

Condition	LEFT HAND AND FOOT BASAL CELL REMOVAL
Start date (dd MMM yyyy)	UN UNK 2017
Start date completely unknown	False
Condition ongoing at study entry	Yes <input type="checkbox"/> No <input checked="" type="radio"/>
If No, please specify the stop date (dd MMM yyyy)	UN UNK 2017
Stop date completely unknown	False
Start Month and Year (derived)	JAN 2017
Start Year (derived)	2017
Stop Month and Year (derived)	JAN 2017
Stop Year (derived)	2017

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Folder: Screening

Form: Medical History (15)

Generated On: 26 Nov 2020 10:54:21

Condition	LEFT HAND AND FOOT BASAL CELL CARCINOMA
Start date (dd MMM yyyy)	UN UNK 2017
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 2017
Stop date completely unknown	False
Start Month and Year (derived)	JAN 2017
Start Year (derived)	2017
Stop Month and Year (derived)	JAN 2017
Stop Year (derived)	2017

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Folder: Screening

Form: Medical History (16)

Generated On: 26 Nov 2020 10:54:21

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

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Folder: Screening

Form: Medical History (17)

Generated On: 26 Nov 2020 10:54:21

Condition	CHRONIC COUGH
Start date (dd MMM yyyy)	UN UNK 1977
Start date completely unknown	False
Condition ongoing at study entry	Yes <input checked="" type="radio"/> No <input type="radio"/>
If No, please specify the stop date (dd MMM yyyy)	
Stop date completely unknown	False
Start Month and Year (derived)	JAN 1977
Start Year (derived)	1977
Stop Month and Year (derived)	
Stop Year (derived)	

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Folder: Screening

Form: Medical History (18)

Generated On: 26 Nov 2020 10:54:21

Condition	ASTHMA
Start date (dd MMM yyyy)	UN UNK 1998
Start date completely unknown	False
Condition ongoing at study entry	Yes <input checked="" type="radio"/> No <input type="radio"/>
If No, please specify the stop date (dd MMM yyyy) _____	
Stop date completely unknown	False
Start Month and Year (derived)	JAN 1998
Start Year (derived)	1998
Stop Month and Year (derived)	_____
Stop Year (derived)	_____

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Folder: Screening

Form: Medical History (19)

Generated On: 26 Nov 2020 10:54:21

Condition	COLON POLYP BENIGN
Start date (dd MMM yyyy)	UN UNK 2012
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 2015
Stop date completely unknown	False
Start Month and Year (derived)	JAN 2012
Start Year (derived)	2012
Stop Month and Year (derived)	JAN 2015
Stop Year (derived)	2015

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Folder: Screening

Form: Medical History (20)

Generated On: 26 Nov 2020 10:54:21

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

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Folder: Screening

Form: Medical History (21)

Generated On: 26 Nov 2020 10:54:21

Condition	MIGRAINES
Start date (dd MMM yyyy)	UN UNK 1993
Start date completely unknown	False
Condition ongoing at study entry	Yes <input checked="" type="radio"/> No <input type="radio"/>
If No, please specify the stop date (dd MMM yyyy) _____	
Stop date completely unknown	False
Start Month and Year (derived)	JAN 1993
Start Year (derived)	1993
Stop Month and Year (derived)	_____
Stop Year (derived)	_____

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Folder: Screening

Form: Medical History (22)

Generated On: 26 Nov 2020 10:54:21

Condition	ACNE
Start date (dd MMM yyyy)	UN UNK 1970
Start date completely unknown	False
Condition ongoing at study entry	Yes <input checked="" type="radio"/> No <input type="radio"/>
If No, please specify the stop date (dd MMM yyyy) _____	
Stop date completely unknown	False
Start Month and Year (derived)	JAN 1970
Start Year (derived)	1970
Stop Month and Year (derived)	_____
Stop Year (derived)	_____

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Folder: Screening

Form: Medical History (23)

Generated On: 26 Nov 2020 10:54:21

Condition	HOT FLASHES
Start date (dd MMM yyyy)	UN UNK 2008
Start date completely unknown	False
Condition ongoing at study entry	Yes <input checked="" type="radio"/> No <input type="radio"/>
If No, please specify the stop date (dd MMM yyyy)	
Stop date completely unknown	False
Start Month and Year (derived)	JAN 2008
Start Year (derived)	2008
Stop Month and Year (derived)	
Stop Year (derived)	

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Folder: Screening

Form: Medical History (24)

Generated On: 26 Nov 2020 10:54:21

Condition	BENIGN LEFT OVERIAN CYST
Start date (dd MMM yyyy)	UN UNK 2015
Start date completely unknown	False
Condition ongoing at study entry	Yes <input checked="" type="radio"/> No <input type="radio"/>
If No, please specify the stop date (dd MMM yyyy)	
Stop date completely unknown	False
Start Month and Year (derived)	JAN 2015
Start Year (derived)	2015
Stop Month and Year (derived)	
Stop Year (derived)	

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Folder: Screening

Form: Medical History (25)

Generated On: 26 Nov 2020 10:54:21

Condition	POST-MENOPAUSAL
Start date (dd MMM yyyy)	UN UNK 2014
Start date completely unknown	False
Condition ongoing at study entry	Yes <input checked="" type="radio"/> No <input type="radio"/>
If No, please specify the stop date (dd MMM yyyy) _____	
Stop date completely unknown	False
Start Month and Year (derived)	JAN 2014
Start Year (derived)	2014
Stop Month and Year (derived)	_____
Stop Year (derived)	_____

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Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 10:54:21

Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (<i>dd MMM yyyy</i>)	29 AUG 2020
Time of assessment (<i>00:00-23:59</i>)	10:11 (24 HR)
Vital Signs Date and Time (derived)	29 AUG 2020 10:11
Height (<i>xxx.x</i>)	179.4 cm
Weight (<i>xxx.x</i>)	92.0 kg
BMI (<i>xxx.x</i>)	28.58531 kg/m ²
BMI units	KG/M2
Temperature (<i>xxx.x</i>)	ND - Not Done
Route of measurement	Oral <input type="radio"/>
	Axillary <input type="radio"/>
	Other <input checked="" type="radio"/>
If Other, specify	ND - Not Done
Pulse (<i>xxx</i>)	ND - Not Done
Pulse units	BPM
Respiratory Rate (<i>xxx</i>)	ND - Not Done
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (<i>xxx</i>)	ND - Not Done
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (<i>xxx</i>)	ND - Not Done
Diastolic Blood Pressure units	MMHG
Height (derived)	
Weight (derived)	

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Folder: Screening

Form: Physical Examination

Generated On: 26 Nov 2020 10:54:21

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

29 AUG 2020

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

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Folder: Screening

Form: Childbearing Potential

Generated On: 26 Nov 2020 10:54:21

Date of assessment (<i>dd MMM yyyy</i>)	29 AUG 2020
Is the participant of childbearing potential?	Yes <input type="radio"/>
	No <input checked="" type="radio"/>
If No, what is the reason?	Surgically sterile <input type="radio"/>
	Post-menopausal <input checked="" type="radio"/>
	Partner medically sterile <input type="radio"/>
	Not reached age of Menarche <input type="radio"/>
	Other <input type="radio"/>
If Partner medically sterile or Other, specify _____	
If Surgically sterile, date of surgery (<i>dd MMM yyyy</i>) _____	
Date of surgery unknown	False
If Post-menopausal, date of last menstruation (<i>dd MMM yyyy</i>)	UN UNK 2014
Date of last menstruation unknown	False

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Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 10:54:21

Occupational Risk

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

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

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

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

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

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

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

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

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

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

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

Other Yes ☒ No ☐

Specify FREQUENT GROCERY STORE, GYMS WITH HIGH CUSTOMER VOLUME

Location and Living Circumstances Risk (check all that apply)

No Risk Identified False

Resides in Nursing Home or Assisted Living Facility False

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Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 10:54:21

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

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Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 26 Nov 2020 10:54:21

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	29 AUG 2020
Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>
Folder OID	VISIT1

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Folder: Visit 1 Day 1

Form: Randomization

Generated On: 26 Nov 2020 10:54:21

What was the date of randomization? (dd MMM yyyy) 29 AUG 2020

What was the participant's randomization number? 109997

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

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

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

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

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

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

Liver Disease Yes ☐ No ☒

Human Immunodeficiency Virus (HIV) infection Yes ☐ No ☐

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 26 Nov 2020 10:54:21

Height	ND - Not Done
Weight	ND - Not Done

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 10:54:21

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)	29 AUG 2020
Time of assessment (00:00-23:59)	11:21 (24 HR)
Vital Signs Date and Time (derived)	29 AUG 2020 11:21
Temperature (xxx.x)	36.7 C
Route of measurement	Oral <input checked="" type="radio"/> Axillary <input type="radio"/> Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	57 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	12 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	143 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	88 mmHg
Diastolic Blood Pressure units	MMHG

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 10:54:21

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)	29 AUG 2020
Time of assessment (00:00-23:59)	13:16 (24 HR)
Vital Signs Date and Time (derived)	29 AUG 2020 13:16
Temperature (xxx.x)	36.8 C
Route of measurement	Oral <input checked="" type="radio"/> Axillary <input type="radio"/> Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	61 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	140 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	89 mmHg
Diastolic Blood Pressure units	MMHG

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Folder: Visit 1 Day 1

Form: Physical Examination

Generated On: 26 Nov 2020 10:54:21

Was the physical examination performed?

Yes ☐
No ☒

Date of examination (dd MMM yyyy)

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

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Folder: Visit 1 Day 1

Form: Exposure

Generated On: 26 Nov 2020 10:54:21

Was study treatment given?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
If No, reason not given	Participant declined due to Adverse Event <input type="radio"/>
	Physician withheld dose due to Adverse Event <input type="radio"/>
	Death <input type="radio"/>
	Lost To Follow-Up <input type="radio"/>
	Physician Decision <input type="radio"/>
	Pregnancy <input type="radio"/>
	Protocol Deviation <input type="radio"/>
	Study Terminated by Sponsor <input type="radio"/>
	Withdrawal of Consent by Participant <input type="radio"/>
	Confirmed COVID-19 <input type="radio"/>
	Other <input type="radio"/>
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 AUG 2020
What was the treatment time? (00:00-23:59)	12:45 (24 HR)
Treatment Date and Time (derived)	29 AUG 2020 12:45
Which arm was used to give treatment?	Left Arm <input type="radio"/>
	Right Arm <input checked="" type="radio"/>
What was the frequency of the study treatment dosing?	ONCE
What was the route of administration for the study treatment?	INTRAMUSCULAR

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Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 26 Nov 2020 10:54:21

Was the sample collected?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Collection date (<i>dd MMM yyyy</i>)	29 AUG 2020
Collection time (<i>00:00-23:59</i>)	11:35 (24 HR)
Collection date and time (derived)	29 AUG 2020 11:35

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Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab

Generated On: 26 Nov 2020 10:54:21

Collection date (<i>dd MMM yyyy</i>)			29 AUG 2020
Lab Test	Was the sample collected?	Collection time (<i>00:00 - 23:59</i>)	Collection date and time (derived)
Nasopharyngeal Swab 1	Yes	11:50	29 AUG 2020 11:50
Nasopharyngeal Swab 2	No		

US3292365

Folder: Visit 1 Day 1

Form: Continuing

Generated On: 26 Nov 2020 10:54:21

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3292365

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 26 Nov 2020 10:54:21

TIMEPOINT

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

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

98.2 °F

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

Yes ☐

No ☒

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

PC Time Stamp

29 AUG 2020 13:22

PC Open Date & Time

29 AUG 2020 13:05

PC Close Date & Time

29 AUG 2020 15:35

US3292365

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 26 Nov 2020 10:54:21

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 97.2 °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	29 AUG 2020 20:55
PC Open Date & Time	29 AUG 2020 16:30
PC Close Date & Time	30 AUG 2020 11:59

US3292365

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 26 Nov 2020 10:54:21

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

30 AUG 2020 21:33

PC Open Date & Time

30 AUG 2020 12:00

PC Close Date & Time

31 AUG 2020 11:59

US3292365

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 26 Nov 2020 10:54:21

TIMEPOINT

DAY 3

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

96.5 °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

31 AUG 2020 21:07

PC Open Date & Time

31 AUG 2020 12:00

PC Close Date & Time

01 SEP 2020 11:59

US3292365

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 26 Nov 2020 10:54:21

TIMEPOINT

DAY 4

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.9 °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

01 SEP 2020 21:06

PC Open Date & Time

01 SEP 2020 12:00

PC Close Date & Time

02 SEP 2020 11:59

US3292365

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 26 Nov 2020 10:54:21

TIMEPOINT

DAY 5

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

96.9 °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

02 SEP 2020 21:48

PC Open Date & Time

02 SEP 2020 12:00

PC Close Date & Time

03 SEP 2020 11:59

US3292365

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 26 Nov 2020 10:54:21

TIMEPOINT

DAY 6

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.3 °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 21:04

PC Open Date & Time

03 SEP 2020 12:00

PC Close Date & Time

04 SEP 2020 11:59

US3292365

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 26 Nov 2020 10:54:21

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

97.3 °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 SEP 2020 22:41

PC Open Date & Time

04 SEP 2020 12:00

PC Close Date & Time

05 SEP 2020 11:59

US3292365

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 26 Nov 2020 10:54:21

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 AUG 2020 13:23

PC Open Date & Time

29 AUG 2020 13:05

PC Close Date & Time

29 AUG 2020 15:35

US3292365

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 26 Nov 2020 10:54:21

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 - **SWELLING/HARDNESS AT INJECTION SITE**
(in mm)

2

Measure the largest size across any injection site swelling/hardness
with the ruler provided.

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 AUG 2020 20:58

PC Open Date & Time

29 AUG 2020 16:30

PC Close Date & Time

30 AUG 2020 11:59

US3292365

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 26 Nov 2020 10:54:21

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 - **SWELLING/HARDNESS AT INJECTION SITE**
(in mm)

2

Measure the largest size across any injection site swelling/hardness
with the ruler provided.

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

30 AUG 2020 21:39

PC Open Date & Time

30 AUG 2020 12:00

PC Close Date & Time

31 AUG 2020 11:59

US3292365

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 26 Nov 2020 10:54:21

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

31 AUG 2020 21:07

PC Open Date & Time

31 AUG 2020 12:00

PC Close Date & Time

01 SEP 2020 11:59

US3292365

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 26 Nov 2020 10:54:21

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

01 SEP 2020 21:07

PC Open Date & Time

01 SEP 2020 12:00

PC Close Date & Time

02 SEP 2020 11:59

US3292365

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 26 Nov 2020 10:54:21

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

02 SEP 2020 21:49

PC Open Date & Time

02 SEP 2020 12:00

PC Close Date & Time

03 SEP 2020 11:59

US3292365

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 26 Nov 2020 10:54:21

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

03 SEP 2020 21:05

PC Open Date & Time

03 SEP 2020 12:00

PC Close Date & Time

04 SEP 2020 11:59

US3292365

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 26 Nov 2020 10:54:21

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

04 SEP 2020 22:41

PC Open Date & Time

04 SEP 2020 12:00

PC Close Date & Time

05 SEP 2020 11:59

US3292365

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 10:54:21

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 ☐

US3292365

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 10:54:21

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

No ☒

Yes ☐

PC Time stamp	29 AUG 2020 13:23
PC Open Date & Time	29 AUG 2020 13:05
PC Close Date & Time	29 AUG 2020 15:35

US3292365

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 10:54:21

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 ☐

US3292365

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 10:54:21

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

No ☒

Yes ☐

PC Time stamp	29 AUG 2020 20:58
PC Open Date & Time	29 AUG 2020 16:30
PC Close Date & Time	30 AUG 2020 11:59

US3292365

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 10:54:21

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 ☒

US3292365

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 10:54:21

Yes <input type="checkbox"/>	
PC Time stamp	30 AUG 2020 21:39
PC Open Date & Time	30 AUG 2020 12:00
PC Close Date & Time	31 AUG 2020 11:59

US3292365

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 10:54:21

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 ☒

US3292365

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 10:54:21

Yes <input type="checkbox"/>	
PC Time stamp	31 AUG 2020 21:07
PC Open Date & Time	31 AUG 2020 12:00
PC Close Date & Time	01 SEP 2020 11:59

US3292365

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 10:54:21

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 ☒

US3292365

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 10:54:21

Yes <input type="checkbox"/>	
PC Time stamp	01 SEP 2020 21:07
PC Open Date & Time	01 SEP 2020 12:00
PC Close Date & Time	02 SEP 2020 11:59

US3292365

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 10:54:21

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 ☒

US3292365

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 10:54:21

Yes <input type="checkbox"/>	
PC Time stamp	02 SEP 2020 21:49
PC Open Date & Time	02 SEP 2020 12:00
PC Close Date & Time	03 SEP 2020 11:59

US3292365

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 10:54:21

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 ☒

US3292365

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 10:54:21

Yes <input type="checkbox"/>	
PC Time stamp	03 SEP 2020 21:05
PC Open Date & Time	03 SEP 2020 12:00
PC Close Date & Time	04 SEP 2020 11:59

US3292365

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 10:54:21

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 ☒

US3292365

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 10:54:21

Yes <input type="checkbox"/>	
PC Time stamp	04 SEP 2020 22:42
PC Open Date & Time	04 SEP 2020 12:00
PC Close Date & Time	05 SEP 2020 11:59

US3292365

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 26 Nov 2020 10:54:21

Was Contact Attempted?

Yes ☒

No ☐

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

8 SEP 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3292365

Folder: Safety Call Day 8 (1)

Form: Continuing

Generated On: 26 Nov 2020 10:54:21

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3292365

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 26 Nov 2020 10:54:21

Was Contact Attempted?

Yes ☒

No ☐

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

15 SEP 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3292365

Folder: Safety Call Day 15 (1)

Form: Continuing

Generated On: 26 Nov 2020 10:54:21

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3292365

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 26 Nov 2020 10:54:21

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

US3292365

Folder: Safety Call Day 22 (1)

Form: Continuing

Generated On: 26 Nov 2020 10:54:21

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3292365

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 26 Nov 2020 10:54:21

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

US3292365

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 10:54:21

Timepoint	Pre-Dose <input checked="" type="radio"/>
	Post-Dose <input type="radio"/>
Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (dd MMM yyyy)	26 SEP 2020
Time of assessment (00:00-23:59)	08:45 (24 HR)
Vital Signs Date and Time (derived)	26 SEP 2020 08:45
Temperature (xxx.x)	36.5 C
Route of measurement	Oral <input checked="" type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	61 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	127 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	81 mmHg
Diastolic Blood Pressure units	MMHG

US3292365

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 10:54:21

Timepoint	Pre-Dose <input type="radio"/>
	Post-Dose <input checked="" type="radio"/>
Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (dd MMM yyyy)	26 SEP 2020
Time of assessment (00:00-23:59)	10:14 (24 HR)
Vital Signs Date and Time (derived)	26 SEP 2020 10:14
Temperature (xxx.x)	36.6 C
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)	138 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	87 mmHg
Diastolic Blood Pressure units	MMHG

US3292365

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Generated On: 26 Nov 2020 10:54:21

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

26 SEP 2020

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

US3292365

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 26 Nov 2020 10:54:21

Was study treatment given?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
If No, reason not given	Participant declined due to Adverse Event <input type="radio"/>
	Physician withheld dose due to Adverse Event <input type="radio"/>
	Death <input type="radio"/>
	Lost To Follow-Up <input type="radio"/>
	Physician Decision <input type="radio"/>
	Pregnancy <input type="radio"/>
	Protocol Deviation <input type="radio"/>
	Study Terminated by Sponsor <input type="radio"/>
	Withdrawal of Consent by Participant <input type="radio"/>
	Confirmed COVID-19 <input type="radio"/>
	Other <input type="radio"/>
If reason is Physician Decision, Withdrawal of Consent by Participant, Protocol Deviation, or Other, specify	
What was the study treatment?	MRNA-1273 OR PLACEBO
What was the treatment date? (dd MMM yyyy)	26 SEP 2020
What was the treatment time? (00:00-23:59)	09:42 (24 HR)
Treatment Date and Time (derived)	26 SEP 2020 09:42
Which arm was used to give treatment?	Left Arm <input type="radio"/>
	Right Arm <input checked="" type="radio"/>
What was the frequency of the study treatment dosing?	ONCE
What was the route of administration for the study treatment?	INTRAMUSCULAR

US3292365

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 26 Nov 2020 10:54:21

Was the sample collected?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Collection date (<i>dd MMM yyyy</i>)	26 SEP 2020
Collection time (<i>00:00-23:59</i>)	08:53 (24 HR)
Collection date and time (derived)	26 SEP 2020 08:53

US3292365

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab

Generated On: 26 Nov 2020 10:54:21

Collection date (<i>dd MMM yyyy</i>)			26 SEP 2020
Lab Test	Was the sample collected?	Collection time (<i>00:00 - 23:59</i>)	Collection date and time (derived)
Nasopharyngeal Swab 1	Yes	09:09	26 SEP 2020 09:09
Nasopharyngeal Swab 2	No		

US3292365

Folder: Visit 2 Day 29 (1)

Form: Continuing

Generated On: 26 Nov 2020 10:54:21

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3292365

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 26 Nov 2020 10:54:21

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

26 SEP 2020 10:17

PC Open Date & Time

26 SEP 2020 10:02

PC Close Date & Time

26 SEP 2020 12:32

US3292365

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 26 Nov 2020 10:54:21

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 96.4 °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	26 SEP 2020 21:31
PC Open Date & Time	26 SEP 2020 13:27
PC Close Date & Time	27 SEP 2020 11:59

US3292365

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 26 Nov 2020 10:54:21

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

100.5 °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

27 SEP 2020 21:03

PC Open Date & Time

27 SEP 2020 12:00

PC Close Date & Time

28 SEP 2020 11:59

US3292365

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 26 Nov 2020 10:54:21

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

97.5 °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

28 SEP 2020 20:56

PC Open Date & Time

28 SEP 2020 12:00

PC Close Date & Time

29 SEP 2020 11:59

US3292365

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 26 Nov 2020 10:54:21

TIMEPOINT

DAY 4

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.6 °F

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

Yes ☐

No ☒

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

PC Time Stamp

29 SEP 2020 22:31

PC Open Date & Time

29 SEP 2020 12:00

PC Close Date & Time

30 SEP 2020 11:59

US3292365

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 26 Nov 2020 10:54:21

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

97.1 °F

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

Yes ☐

No ☒

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

PC Time Stamp

30 SEP 2020 22:22

PC Open Date & Time

30 SEP 2020 12:00

PC Close Date & Time

01 OCT 2020 11:59

US3292365

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 26 Nov 2020 10:54:21

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

98.0 °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

01 OCT 2020 20:37

PC Open Date & Time

01 OCT 2020 12:00

PC Close Date & Time

02 OCT 2020 11:59

US3292365

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 26 Nov 2020 10:54:21

TIMEPOINT

DAY 7

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

96.5 °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

02 OCT 2020 23:27

PC Open Date & Time

02 OCT 2020 12:00

PC Close Date & Time

03 OCT 2020 11:59

US3292365

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 26 Nov 2020 10:54:21

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

26 SEP 2020 10:19

PC Open Date & Time

26 SEP 2020 10:02

PC Close Date & Time

26 SEP 2020 12:32

US3292365

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 26 Nov 2020 10:54:21

TIMEPOINT

DAY 1, AFTER VACCINATION
(AT HOME)

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

Please select one response below

None ☐

Does not interfere with activity ☒

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

Please select one response below

None ☒

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

26 SEP 2020 21:32

PC Open Date & Time

26 SEP 2020 13:27

PC Close Date & Time

27 SEP 2020 11:59

US3292365

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 26 Nov 2020 10:54:21

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 ☐

Please record - **REDNESS AT INJECTION SITE (in mm)**

4

Measure the largest size across any injection site redness with the
ruler provided.

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

Yes ☒

No ☐

Please record - **SWELLING/HARDNESS AT INJECTION SITE
(in mm)**

4

Measure the largest size across any injection site swelling/hardness
with the ruler provided.

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

27 SEP 2020 21:06

PC Open Date & Time

27 SEP 2020 12:00

PC Close Date & Time

28 SEP 2020 11:59

US3292365

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 26 Nov 2020 10:54:21

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 ☐

Please record - **REDNESS AT INJECTION SITE (in mm)**

6

Measure the largest size across any injection site redness with the
ruler provided.

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

28 SEP 2020 21:00

PC Open Date & Time

28 SEP 2020 12:00

PC Close Date & Time

29 SEP 2020 11:59

US3292365

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 26 Nov 2020 10:54:21

TIMEPOINT

DAY 4

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

None ☐

Please select one response below

Does not interfere with activity ☒

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

29 SEP 2020 22:32

PC Open Date & Time

29 SEP 2020 12:00

PC Close Date & Time

30 SEP 2020 11:59

US3292365

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 26 Nov 2020 10:54:21

TIMEPOINT

DAY 5

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

30 SEP 2020 22:20

PC Open Date & Time

30 SEP 2020 12:00

PC Close Date & Time

01 OCT 2020 11:59

US3292365

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 26 Nov 2020 10:54:21

TIMEPOINT

DAY 6

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

01 OCT 2020 20:38

PC Open Date & Time

01 OCT 2020 12:00

PC Close Date & Time

02 OCT 2020 11:59

US3292365

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 26 Nov 2020 10:54:21

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

02 OCT 2020 23:27

PC Open Date & Time

02 OCT 2020 12:00

PC Close Date & Time

03 OCT 2020 11:59

US3292365

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 10:54:21

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 ☐

US3292365

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 10:54:21

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

No ☒

Yes ☐

PC Time stamp	26 SEP 2020 10:19
PC Open Date & Time	26 SEP 2020 10:02
PC Close Date & Time	26 SEP 2020 12:32

US3292365

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 10:54:21

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 ☐

US3292365

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 10:54:21

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

No ☒

Yes ☐

PC Time stamp	26 SEP 2020 21:33
PC Open Date & Time	26 SEP 2020 13:27
PC Close Date & Time	27 SEP 2020 11:59

US3292365

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 10:54:21

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 ☒

US3292365

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 10:54:21

Yes <input type="checkbox"/>	
PC Time stamp	27 SEP 2020 21:07
PC Open Date & Time	27 SEP 2020 12:00
PC Close Date & Time	28 SEP 2020 11:59

US3292365

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 10:54:21

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 ☒

US3292365

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 10:54:21

Yes <input type="checkbox"/>	
PC Time stamp	28 SEP 2020 21:00
PC Open Date & Time	28 SEP 2020 12:00
PC Close Date & Time	29 SEP 2020 11:59

US3292365

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 10:54:21

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 ☒

US3292365

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 10:54:21

Yes <input type="checkbox"/>	
PC Time stamp	29 SEP 2020 22:32
PC Open Date & Time	29 SEP 2020 12:00
PC Close Date & Time	30 SEP 2020 11:59

US3292365

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 10:54:21

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 ☒

US3292365

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 10:54:21

Yes <input type="checkbox"/>	
PC Time stamp	30 SEP 2020 22:20
PC Open Date & Time	30 SEP 2020 12:00
PC Close Date & Time	01 OCT 2020 11:59

US3292365

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 10:54:21

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 ☒

US3292365

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 10:54:21

Yes <input type="checkbox"/>	
PC Time stamp	01 OCT 2020 20:38
PC Open Date & Time	01 OCT 2020 12:00
PC Close Date & Time	02 OCT 2020 11:59

US3292365

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 10:54:21

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 ☒

US3292365

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 10:54:21

Yes <input type="checkbox"/>	
PC Time stamp	02 OCT 2020 23:27
PC Open Date & Time	02 OCT 2020 12:00
PC Close Date & Time	03 OCT 2020 11:59

US3292365

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 26 Nov 2020 10:54:21

Was Contact Attempted?

Yes ☒

No ☐

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

4 OCT 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3292365

Folder: Safety Call Day 36 (1)

Form: Continuing

Generated On: 26 Nov 2020 10:54:21

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3292365

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 26 Nov 2020 10:54:21

Was Contact Attempted?

Yes ☒

No ☐

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

10 OCT 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3292365

Folder: Safety Call Day 43 (1)

Form: Continuing

Generated On: 26 Nov 2020 10:54:21

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3292365

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 26 Nov 2020 10:54:21

Was Contact Attempted?

Yes ☒

No ☐

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

17 OCT 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3292365

Folder: Safety Call Day 50 (1)

Form: Continuing

Generated On: 26 Nov 2020 10:54:21

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3292365

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 26 Nov 2020 10:54:21

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	27 OCT 2020
Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>
Folder OID	VISIT3

US3292365

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 10:54:21

Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (<i>dd MMM yyyy</i>)	27 OCT 2020
Time of assessment (<i>00:00-23:59</i>)	07:54 (24 HR)
Vital Signs Date and Time (derived)	27 OCT 2020 07:54
Temperature (<i>xxx.x</i>)	36.6 C
Route of measurement	Oral <input checked="" type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	
Pulse (<i>xxx</i>)	54 beats/min
Pulse units	BPM
Respiratory Rate (<i>xxx</i>)	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (<i>xxx</i>)	126 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (<i>xxx</i>)	88 mmHg
Diastolic Blood Pressure units	MMHG
Height (derived)	
Weight (derived)	

US3292365

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Generated On: 26 Nov 2020 10:54:21

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.

US3292365

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 26 Nov 2020 10:54:21

Was the sample collected?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Collection date (<i>dd MMM yyyy</i>)	27 OCT 2020
Collection time (<i>00:00-23:59</i>)	08:07 (24 HR)
Collection date and time (derived)	27 OCT 2020 08:07

US3292365

Folder: Visit 3 Day 57 (1)

Form: Continuing

Generated On: 26 Nov 2020 10:54:21

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3292365

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:54:21

TIMEPOINT

DAY 64

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

31 OCT 2020 13:54:44

Patient Cloud Open Date & Time

29 OCT 2020 00:01

Patient Cloud Close Date & Time

02 NOV 2020 23:59

US3292365

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:54:21

TIMEPOINT

DAY 71

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

07 NOV 2020 16:46:40

Patient Cloud Open Date & Time

05 NOV 2020 00:01

Patient Cloud Close Date & Time

09 NOV 2020 23:59

US3292365

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:54:21

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 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	14 NOV 2020 12:56:08
Patient Cloud Open Date & Time	12 NOV 2020 00:01
Patient Cloud Close Date & Time	16 NOV 2020 23:59

US3292365

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:54:21

TIMEPOINT	DAY 61
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"/>

US3292365

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:54:21

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
Patient Cloud Open Date & Time	26 OCT 2020 00:01
Patient Cloud Close Date & Time	30 OCT 2020 23:59

US3292365

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:54:21

TIMEPOINT	DAY 68
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"/>

US3292365

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:54:21

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

[Patient Cloud Open Date & Time](#)

02 NOV 2020 00:01

[Patient Cloud Close Date & Time](#)

06 NOV 2020 23:59

US3292365

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:54:21

TIMEPOINT	DAY 75
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="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"/>

US3292365

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:54:21

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

[Patient Cloud Close Date & Time](#)

13 NOV 2020 23:59

US3292365

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:54:21

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 ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

20 NOV 2020 19:07:04

Patient Cloud Open Date & Time

16 NOV 2020 00:01

Patient Cloud Close Date & Time

20 NOV 2020 23:59

US3292365

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:54:21

TIMEPOINT	DAY 89
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input 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"/>

US3292365

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:54:21

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

[Patient Cloud Open Date & Time](#)

23 NOV 2020 00:01

[Patient Cloud Close Date & Time](#)

27 NOV 2020 23:59

US3292365

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:54:21

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 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"/>

US3292365

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:54:21

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

[Patient Cloud Open Date & Time](#)

30 NOV 2020 00:01

[Patient Cloud Close Date & Time](#)

04 DEC 2020 23:59

US3292365

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:54:21

TIMEPOINT	DAY 103
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input 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"/>

US3292365

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:54:21

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

[Patient Cloud Open Date & Time](#)

07 DEC 2020 00:01

[Patient Cloud Close Date & Time](#)

11 DEC 2020 23:59

US3292365

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:54:21

TIMEPOINT	DAY 110
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

US3292365

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:54:21

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
Patient Cloud Open Date & Time	14 DEC 2020 00:01
Patient Cloud Close Date & Time	18 DEC 2020 23:59

US3292365

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:54:21

TIMEPOINT	DAY 117
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input 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"/>

US3292365

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:54:21

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
Patient Cloud Open Date & Time	21 DEC 2020 00:01
Patient Cloud Close Date & Time	25 DEC 2020 23:59

US3292365

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:54:21

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"/>

US3292365

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:54:21

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

[Patient Cloud Open Date & Time](#)

28 DEC 2020 00:01

[Patient Cloud Close Date & Time](#)

01 JAN 2021 23:59

US3292365

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:54:21

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 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"/>

US3292365

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:54:21

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

04 JAN 2021 00:01

[Patient Cloud Close Date & Time](#)

08 JAN 2021 23:59

US3292365

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:54:21

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

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

US3292365

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:54:21

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

[Patient Cloud Open Date & Time](#)

11 JAN 2021 00:01

[Patient Cloud Close Date & Time](#)

15 JAN 2021 23:59

US3292365

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:54:21

TIMEPOINT	DAY 145
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input 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"/>

US3292365

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:54:21

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

US3292365

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:54:21

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 <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"/>

US3292365

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:54:21

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

[Patient Cloud Open Date & Time](#)

25 JAN 2021 00:01

[Patient Cloud Close Date & Time](#)

29 JAN 2021 23:59

US3292365

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:54:21

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 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"/>

US3292365

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:54:21

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

[Patient Cloud Open Date & Time](#)

01 FEB 2021 00:01

[Patient Cloud Close Date & Time](#)

05 FEB 2021 23:59

US3292365

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:54:21

TIMEPOINT	DAY 166
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input 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"/>

US3292365

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:54:21

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
Patient Cloud Open Date & Time	08 FEB 2021 00:01
Patient Cloud Close Date & Time	12 FEB 2021 23:59

US3292365

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:54:21

TIMEPOINT	DAY 173
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="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"/>

US3292365

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:54:21

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

[Patient Cloud Open Date & Time](#)

15 FEB 2021 00:01

[Patient Cloud Close Date & Time](#)

19 FEB 2021 23:59

US3292365

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:54:21

TIMEPOINT	DAY 180
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input 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"/>

US3292365

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:54:21

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

[Patient Cloud Open Date & Time](#)

22 FEB 2021 00:01

[Patient Cloud Close Date & Time](#)

26 FEB 2021 23:59

US3292365

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:54:21

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="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"/>

US3292365

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:54:21

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

[Patient Cloud Open Date & Time](#)

01 MAR 2021 00:01

[Patient Cloud Close Date & Time](#)

05 MAR 2021 23:59

US3292365

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:54:21

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="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"/>

US3292365

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:54:21

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

[Patient Cloud Open Date & Time](#)

08 MAR 2021 00:01

[Patient Cloud Close Date & Time](#)

12 MAR 2021 23:59

US3292365

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:54:21

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 <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"/>

US3292365

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:54:21

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

US3292365

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:54:21

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

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

US3292365

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:54:21

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

[Patient Cloud Open Date & Time](#)

22 MAR 2021 00:01

[Patient Cloud Close Date & Time](#)

26 MAR 2021 23:59

US3292365

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:54:21

TIMEPOINT	DAY 215
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input 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"/>

US3292365

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:54:21

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

[Patient Cloud Open Date & Time](#)

29 MAR 2021 00:01

[Patient Cloud Close Date & Time](#)

02 APR 2021 23:59

US3292365

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:54:21

TIMEPOINT	DAY 222
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="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"/>

US3292365

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:54:21

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

[Patient Cloud Open Date & Time](#)

05 APR 2021 00:01

[Patient Cloud Close Date & Time](#)

09 APR 2021 23:59

US3292365

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:54:21

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="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"/>

US3292365

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:54:21

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

12 APR 2021 00:01

[Patient Cloud Close Date & Time](#)

16 APR 2021 23:59

US3292365

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:54:21

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="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"/>

US3292365

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:54:21

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

19 APR 2021 00:01

[Patient Cloud Close Date & Time](#)

23 APR 2021 23:59

US3292365

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:54:21

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

US3292365

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:54:21

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

US3292365

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:54:21

TIMEPOINT	DAY 250
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>

US3292365

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:54:21

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

[Patient Cloud Open Date & Time](#)

03 MAY 2021 00:01

[Patient Cloud Close Date & Time](#)

07 MAY 2021 23:59

US3292365

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:54:21

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 ☐

US3292365

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:54:21

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

[Patient Cloud Open Date & Time](#)

10 MAY 2021 00:01

[Patient Cloud Close Date & Time](#)

14 MAY 2021 23:59

US3292365

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:54:21

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"/>

US3292365

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:54:21

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

[Patient Cloud Open Date & Time](#)

17 MAY 2021 00:01

[Patient Cloud Close Date & Time](#)

21 MAY 2021 23:59

US3292365

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:54:21

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="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"/>

US3292365

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:54:21

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
Patient Cloud Open Date & Time	24 MAY 2021 00:01
Patient Cloud Close Date & Time	28 MAY 2021 23:59

US3292365

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:54:21

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="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"/>

US3292365

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:54:21

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

[Patient Cloud Open Date & Time](#)

31 MAY 2021 00:01

[Patient Cloud Close Date & Time](#)

04 JUN 2021 23:59

US3292365

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:54:21

TIMEPOINT	DAY 285
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="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"/>

US3292365

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:54:21

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

07 JUN 2021 00:01

[Patient Cloud Close Date & Time](#)

11 JUN 2021 23:59

US3292365

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:54:21

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 <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"/>

US3292365

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:54:21

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

[Patient Cloud Open Date & Time](#)

14 JUN 2021 00:01

[Patient Cloud Close Date & Time](#)

18 JUN 2021 23:59

US3292365

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:54:21

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"/>

US3292365

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:54:21

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

[Patient Cloud Open Date & Time](#)

21 JUN 2021 00:01

[Patient Cloud Close Date & Time](#)

25 JUN 2021 23:59

US3292365

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:54:21

TIMEPOINT

DAY 306

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

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

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

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

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

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

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

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

US3292365

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:54:21

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

[Patient Cloud Close Date & Time](#)

02 JUL 2021 23:59

US3292365

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:54:21

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"/>

US3292365

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:54:21

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

05 JUL 2021 00:01

[Patient Cloud Close Date & Time](#)

09 JUL 2021 23:59

US3292365

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:54:21

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

US3292365

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:54:21

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

US3292365

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:54:21

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"/>

US3292365

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:54:21

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

[Patient Cloud Open Date & Time](#)

19 JUL 2021 00:01

[Patient Cloud Close Date & Time](#)

23 JUL 2021 23:59

US3292365

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:54:21

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 ☐

US3292365

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:54:21

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

[Patient Cloud Open Date & Time](#)

26 JUL 2021 00:01

[Patient Cloud Close Date & Time](#)

30 JUL 2021 23:59

US3292365

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:54:21

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

US3292365

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:54:21

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm 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 AUG 2021 00:01
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Patient Cloud Close Date & Time	06 AUG 2021 23:59
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US3292365

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:54:21

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"/>

US3292365

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:54:21

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

[Patient Cloud Close Date & Time](#)

13 AUG 2021 23:59

US3292365

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:54:21

TIMEPOINT

DAY 355

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

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

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

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

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

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

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

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

US3292365

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:54:21

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

Patient Cloud Open Date & Time	16 AUG 2021 00:01
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Patient Cloud Close Date & Time	20 AUG 2021 23:59
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US3292365

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:54:21

TIMEPOINT

DAY 362

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

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

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

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

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

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

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

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

US3292365

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:54:21

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

Patient Cloud Open Date & Time	23 AUG 2021 00:01
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Patient Cloud Close Date & Time	27 AUG 2021 23:59
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US3292365

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:54:21

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 ☐

US3292365

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:54:21

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

30 AUG 2021 00:01

[Patient Cloud Close Date & Time](#)

03 SEP 2021 23:59

US3292365

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:54:21

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 ☐

US3292365

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:54:21

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

[Patient Cloud Open Date & Time](#)

06 SEP 2021 00:01

[Patient Cloud Close Date & Time](#)

10 SEP 2021 23:59

US3292365

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:54:21

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 ☐

US3292365

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:54:21

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

[Patient Cloud Open Date & Time](#)

13 SEP 2021 00:01

[Patient Cloud Close Date & Time](#)

17 SEP 2021 23:59

US3292365

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:54:21

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 <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"/>

US3292365

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:54:21

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

[Patient Cloud Open Date & Time](#)

20 SEP 2021 00:01

[Patient Cloud Close Date & Time](#)

24 SEP 2021 23:59

US3292365

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:54:21

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 ☐

US3292365

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:54:21

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

27 SEP 2021 00:01

[Patient Cloud Close Date & Time](#)

01 OCT 2021 23:59

US3292365

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:54:21

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"/>

US3292365

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:54:21

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

[Patient Cloud Open Date & Time](#)

04 OCT 2021 00:01

[Patient Cloud Close Date & Time](#)

08 OCT 2021 23:59

US3292365

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:54:21

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"/>

US3292365

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:54:21

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

[Patient Cloud Open Date & Time](#)

11 OCT 2021 00:01

[Patient Cloud Close Date & Time](#)

15 OCT 2021 23:59

US3292365

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:54:21

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 <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"/>

US3292365

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:54:21

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

US3292365

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:54:21

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 ☐

US3292365

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:54:21

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

Patient Cloud Open Date & Time	25 OCT 2021 00:01
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Patient Cloud Close Date & Time	29 OCT 2021 23:59
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US3292365

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:54:21

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="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"/>

US3292365

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:54:21

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

[Patient Cloud Open Date & Time](#)

01 NOV 2021 00:01

[Patient Cloud Close Date & Time](#)

05 NOV 2021 23:59

US3292365

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:54:21

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 ☐

US3292365

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:54:21

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

[Patient Cloud Close Date & Time](#)

12 NOV 2021 23:59

US3292365

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:54:21

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="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"/>

US3292365

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:54:21

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

US3292365

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:54:21

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 ☐

US3292365

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:54:21

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

[Patient Cloud Open Date & Time](#)

22 NOV 2021 00:01

[Patient Cloud Close Date & Time](#)

26 NOV 2021 23:59

US3292365

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:54:21

TIMEPOINT	DAY 460
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>

US3292365

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:54:21

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

[Patient Cloud Open Date & Time](#)

29 NOV 2021 00:01

[Patient Cloud Close Date & Time](#)

03 DEC 2021 23:59

US3292365

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:54:21

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 ☐

US3292365

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:54:21

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

[Patient Cloud Open Date & Time](#)

06 DEC 2021 00:01

[Patient Cloud Close Date & Time](#)

10 DEC 2021 23:59

US3292365

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:54:21

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 ☐

US3292365

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:54:21

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

US3292365

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:54:21

TIMEPOINT

DAY 481

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

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

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

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

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

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

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

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

US3292365

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:54:21

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
Patient Cloud Open Date & Time	20 DEC 2021 00:01
Patient Cloud Close Date & Time	24 DEC 2021 23:59

US3292365

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:54:21

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

US3292365

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:54:21

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

Patient Cloud Open Date & Time	27 DEC 2021 00:01
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Patient Cloud Close Date & Time	31 DEC 2021 23:59
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US3292365

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:54:21

TIMEPOINT	DAY 495
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>

US3292365

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:54:21

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

03 JAN 2022 00:01

[Patient Cloud Close Date & Time](#)

07 JAN 2022 23:59

US3292365

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:54:21

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 ☐

US3292365

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:54:21

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

[Patient Cloud Open Date & Time](#)

10 JAN 2022 00:01

[Patient Cloud Close Date & Time](#)

14 JAN 2022 23:59

US3292365

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:54:21

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 ☐

US3292365

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:54:21

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

[Patient Cloud Open Date & Time](#)

17 JAN 2022 00:01

[Patient Cloud Close Date & Time](#)

21 JAN 2022 23:59

US3292365

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:54:21

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="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"/>

US3292365

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:54:21

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

24 JAN 2022 00:01

[Patient Cloud Close Date & Time](#)

28 JAN 2022 23:59

US3292365

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:54:21

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 ☐

US3292365

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:54:21

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

[Patient Cloud Open Date & Time](#)

31 JAN 2022 00:01

[Patient Cloud Close Date & Time](#)

04 FEB 2022 23:59

US3292365

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:54:21

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

US3292365

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:54:21

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

[Patient Cloud Open Date & Time](#)

07 FEB 2022 00:01

[Patient Cloud Close Date & Time](#)

11 FEB 2022 23:59

US3292365

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:54:21

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 ☐

US3292365

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:54:21

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

[Patient Cloud Open Date & Time](#)

14 FEB 2022 00:01

[Patient Cloud Close Date & Time](#)

18 FEB 2022 23:59

US3292365

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:54:21

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 ☐

US3292365

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:54:21

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

[Patient Cloud Open Date & Time](#)

21 FEB 2022 00:01

[Patient Cloud Close Date & Time](#)

25 FEB 2022 23:59

US3292365

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:54:21

TIMEPOINT

DAY 551

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

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

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

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

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

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

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

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

US3292365

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:54:21

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

[Patient Cloud Open Date & Time](#)

28 FEB 2022 00:01

[Patient Cloud Close Date & Time](#)

04 MAR 2022 23:59

US3292365

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:54:21

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 ☐

US3292365

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:54:21

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

07 MAR 2022 00:01

[Patient Cloud Close Date & Time](#)

11 MAR 2022 23:59

US3292365

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:54:21

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 ☐

US3292365

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:54:21

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

14 MAR 2022 00:01

[Patient Cloud Close Date & Time](#)

18 MAR 2022 23:59

US3292365

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:54:21

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 ☐

US3292365

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:54:21

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

[Patient Cloud Open Date & Time](#)

21 MAR 2022 00:01

[Patient Cloud Close Date & Time](#)

25 MAR 2022 23:59

US3292365

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:54:21

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 ☐

US3292365

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:54:21

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

[Patient Cloud Open Date & Time](#)

28 MAR 2022 00:01

[Patient Cloud Close Date & Time](#)

01 APR 2022 23:59

US3292365

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:54:21

TIMEPOINT

DAY 586

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

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

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

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

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

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

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

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

US3292365

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:54:21

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

04 APR 2022 00:01

[Patient Cloud Close Date & Time](#)

08 APR 2022 23:59

US3292365

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:54:21

TIMEPOINT

DAY 593

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

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

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

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

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

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

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

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

US3292365

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:54:21

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
Patient Cloud Open Date & Time	11 APR 2022 00:01
Patient Cloud Close Date & Time	15 APR 2022 23:59

US3292365

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:54:21

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"/>

US3292365

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:54:21

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

18 APR 2022 00:01

[Patient Cloud Close Date & Time](#)

22 APR 2022 23:59

US3292365

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:54:21

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"/>

US3292365

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:54:21

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

25 APR 2022 00:01

[Patient Cloud Close Date & Time](#)

29 APR 2022 23:59

US3292365

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:54:21

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

US3292365

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:54:21

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

[Patient Cloud Open Date & Time](#)

02 MAY 2022 00:01

[Patient Cloud Close Date & Time](#)

06 MAY 2022 23:59

US3292365

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:54:21

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

US3292365

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:54:21

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

[Patient Cloud Close Date & Time](#)

13 MAY 2022 23:59

US3292365

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:54:21

TIMEPOINT	DAY 628
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="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"/>

US3292365

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:54:21

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

[Patient Cloud Open Date & Time](#)

16 MAY 2022 00:01

[Patient Cloud Close Date & Time](#)

20 MAY 2022 23:59

US3292365

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:54:21

TIMEPOINT	DAY 635
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>

US3292365

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:54:21

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

[Patient Cloud Close Date & Time](#)

27 MAY 2022 23:59

US3292365

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:54:21

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="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"/>

US3292365

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:54:21

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

[Patient Cloud Open Date & Time](#)

30 MAY 2022 00:01

[Patient Cloud Close Date & Time](#)

03 JUN 2022 23:59

US3292365

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:54:21

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

US3292365

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:54:21

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

[Patient Cloud Open Date & Time](#)

06 JUN 2022 00:01

[Patient Cloud Close Date & Time](#)

10 JUN 2022 23:59

US3292365

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:54:21

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 <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"/>

US3292365

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:54:21

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

[Patient Cloud Open Date & Time](#)

13 JUN 2022 00:01

[Patient Cloud Close Date & Time](#)

17 JUN 2022 23:59

US3292365

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:54:21

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 ☐

US3292365

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:54:21

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

[Patient Cloud Open Date & Time](#)

20 JUN 2022 00:01

[Patient Cloud Close Date & Time](#)

24 JUN 2022 23:59

US3292365

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:54:21

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

US3292365

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:54:21

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

[Patient Cloud Open Date & Time](#)

27 JUN 2022 00:01

[Patient Cloud Close Date & Time](#)

01 JUL 2022 23:59

US3292365

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:54:21

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 <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"/>

US3292365

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:54:21

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

[Patient Cloud Open Date & Time](#)

04 JUL 2022 00:01

[Patient Cloud Close Date & Time](#)

08 JUL 2022 23:59

US3292365

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:54:21

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="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"/>

US3292365

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:54:21

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

[Patient Cloud Open Date & Time](#)

11 JUL 2022 00:01

[Patient Cloud Close Date & Time](#)

15 JUL 2022 23:59

US3292365

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:54:21

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

US3292365

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:54:21

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

[Patient Cloud Open Date & Time](#)

18 JUL 2022 00:01

[Patient Cloud Close Date & Time](#)

22 JUL 2022 23:59

US3292365

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:54:21

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="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"/>

US3292365

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:54:21

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

25 JUL 2022 00:01

[Patient Cloud Close Date & Time](#)

29 JUL 2022 23:59

US3292365

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:54:21

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 ☐

US3292365

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:54:21

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

[Patient Cloud Open Date & Time](#)

01 AUG 2022 00:01

[Patient Cloud Close Date & Time](#)

05 AUG 2022 23:59

US3292365

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:54:21

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="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"/>

US3292365

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:54:21

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

08 AUG 2022 00:01

[Patient Cloud Close Date & Time](#)

12 AUG 2022 23:59

US3292365

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:54:21

TIMEPOINT	DAY 719
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<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"/>

US3292365

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:54:21

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

US3292365

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:54:21

TIMEPOINT

DAY 726

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

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

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

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

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

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

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

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

US3292365

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:54:21

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

[Patient Cloud Open Date & Time](#)

22 AUG 2022 00:01

[Patient Cloud Close Date & Time](#)

26 AUG 2022 23:59

US3292365

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:54:21

TIMEPOINT	DAY 733
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>

US3292365

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:54:21

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

29 AUG 2022 00:01

[Patient Cloud Close Date & Time](#)

02 SEP 2022 23:59

US3292365

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:54:21

TIMEPOINT	DAY 740
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>

US3292365

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:54:21

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

[Patient Cloud Open Date & Time](#)

05 SEP 2022 00:01

[Patient Cloud Close Date & Time](#)

09 SEP 2022 23:59

US3292365

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:54:21

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

US3292365

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:54:21

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

[Patient Cloud Open Date & Time](#)

12 SEP 2022 00:01

[Patient Cloud Close Date & Time](#)

16 SEP 2022 23:59

US3292365

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:54:21

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 ☐

US3292365

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:54:21

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

[Patient Cloud Open Date & Time](#)

19 SEP 2022 00:01

[Patient Cloud Close Date & Time](#)

23 SEP 2022 23:59

US3292365

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:54:21

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"/>

US3292365

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:54:21

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
Patient Cloud Open Date & Time	26 SEP 2022 00:01
Patient Cloud Close Date & Time	30 SEP 2022 23:59

US3292365

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:54:21

TIMEPOINT	DAY 768
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>

US3292365

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:54:21

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

[Patient Cloud Open Date & Time](#)

03 OCT 2022 00:01

[Patient Cloud Close Date & Time](#)

07 OCT 2022 23:59

US3292365

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:54:21

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 ☐

US3292365

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:54:21

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
Patient Cloud Open Date & Time	10 OCT 2022 00:01
Patient Cloud Close Date & Time	14 OCT 2022 23:59

US3292365

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:54:21

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 <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"/>

US3292365

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:54:21

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

[Patient Cloud Open Date & Time](#)

17 OCT 2022 00:01

[Patient Cloud Close Date & Time](#)

21 OCT 2022 23:59

US3292365

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:54:21

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 ☐

US3292365

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:54:21

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

Date and time of submission	
Patient Cloud Open Date & Time	24 OCT 2022 00:01
Patient Cloud Close Date & Time	28 OCT 2022 23:59

US3292365

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:54:21

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"/>

US3292365

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:54:21

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

31 OCT 2022 00:01

[Patient Cloud Close Date & Time](#)

04 NOV 2022 23:59

US3292365

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 26 Nov 2020 10:54:21

Was Contact Attempted?

Yes ☒

No ☐

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

20 NOV 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3292365

Folder: Safety Call Day 85 (1)

Form: Continuing

Generated On: 26 Nov 2020 10:54:21

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3292365

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 26 Nov 2020 10:54:21

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

US3292365

Folder: Safety Call Day 119 (1)

Form: Continuing

Generated On: 26 Nov 2020 10:54:21

Is the participant continuing to the next visit?

Yes ☐

No ☐

Continuing Flag

US3292365

Folder: Covid-19 Assessment (1)

Form: COVID-19 Contact

Generated On: 26 Nov 2020 10:54:21

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"/>

US3292365

Folder: Covid-19 Assessment (1)

Form: Generate Next COVID-19 Assessment

Generated On: 26 Nov 2020 10:54:21

Generate Next COVID-19 Assessment

Yes ☐

No ☐

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Folder: Adverse Events

Form: Adverse Events Summary

Generated On: 26 Nov 2020 10:54:21

Did the participant experience any adverse events?

Yes ☒

No ☐

If Yes, enter details on the Adverse Events form.

US3292365

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 10:54:21

AEID	USA-US072-2020-MRNA-1273-P30 1000010
Adverse event	INVASIVE LOBULAR BREAST CARCINOMA
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)	08 OCT 2020
Start time (00:00-23:59)	
AE start date and time (derived)	
Ongoing?	Yes <input checked="" type="radio"/> No <input type="radio"/>
If not Ongoing, end date (dd MMM yyyy)	
End time (00:00-23:59)	
AE End Date and Time (derived)	
Severity	Grade 1/Mild <input type="radio"/> Grade 2/Moderate <input type="radio"/> Grade 3/Severe <input checked="" type="radio"/> Grade 4 <input type="radio"/>
Is the adverse event serious?	Yes <input checked="" type="radio"/> No <input type="radio"/>
AE is serious due To (check all that apply)	
Death	False
Life threatening	False
Requires inpatient or prolongation of existing Hospitalization	False
Hospital Admission Date (dd MMM yyyy)	
Hospital Discharge Date (dd MMM yyyy)	
Admitted to ICU?	Yes <input type="radio"/> No <input type="radio"/> Unknown <input type="radio"/>
Number of Days in ICU	

v6.020 DTW (1102)

357 of 2018

US3292365

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 10:54:21

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

US3292365

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 10:54:21

PATIENT CONTACTED STUDY
STAFF THIS AFTERNOON
(09NOV2020) TO INFORM THE
STUDY TEAM THAT SHE HAD
RECEIVED THE RESULTS OF
HER ANNUAL MAMMOGRAM,
COMPLETED LAST WEEK. AS
PER THE PATIENT, SHE WAS
DIAGNOSED WITH A
GLANDULAR LOBULAR
CARCINOMA IN HER LEFT
BREAST. PATIENT STATES SHE
NEVER FELT A LUMP, NOR
DOES SHE FEEL ONE NOW. THE
CARCINOMA WAS
DISCOVERED VIA THE
MAMMOGRAM. AT THIS TIME,
PATIENT STATES THAT SHE
DOES NOT WANT TO PUT
HERSELF THROUGH
RADIATION OR
CHEMOTHERAPY AND PLANS
TO HAVE A TOTAL
MASTECTOMY DONE. PATIENT
HAS A FOLLOW-UP SURGERY
CONSULT SCHEDULED AND
WILL FOLLOW UP WITH STUDY
STAFF IN REGARDS TO HER
TREATMENT PLAN.

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)	
--	--

US3292365

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination Summary

Generated On: 26 Nov 2020 10:54:21

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

Yes ☒

No ☐

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

US3292365

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 10:54:21

Name of Medication	ASPIRIN
Prophylaxis	Yes <input checked="" type="radio"/> No <input type="radio"/>
Indication	PROPHYLAXIS FOR CARDIAC PREVENTATIVE
Dose per administration	81
Dose unit	mg <input checked="" type="radio"/> ug <input type="radio"/> mL <input type="radio"/> g <input type="radio"/> IU <input type="radio"/> tablet <input type="radio"/> capsule <input type="radio"/> puff <input type="radio"/> Other <input type="radio"/>
If dose unit is Other, specify _____	
Frequency	once daily <input checked="" type="radio"/> twice daily <input type="radio"/> three times daily <input type="radio"/> four times daily <input type="radio"/> every other day <input type="radio"/> every week <input type="radio"/> every month <input type="radio"/> as needed <input type="radio"/> once <input type="radio"/> unknown <input type="radio"/> other <input type="radio"/>
If frequency is Other, specify _____	
Route of administration	Oral <input checked="" type="radio"/> Topical <input type="radio"/> Subcutaneous <input type="radio"/> Transdermal <input type="radio"/> Intraocular <input type="radio"/>

US3292365

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 10:54:21

	Intramuscular	<input type="radio"/>
	Respiratory (Inhalation)	<input type="radio"/>
	Intralesional	<input type="radio"/>
	Intraperitoneal	<input type="radio"/>
	Nasal	<input type="radio"/>
	Vaginal	<input type="radio"/>
	Rectal	<input type="radio"/>
	Intravenous	<input type="radio"/>
	Intravenous Bolus	<input type="radio"/>
	Intravenous Drip	<input type="radio"/>
	Other	<input type="radio"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	UN	UNK 2010
Start date completely unknown	False	
Ongoing?	Yes <input type="radio"/>	No <input checked="" type="radio"/>
If not Ongoing, End date (dd MMM yyyy)		11 NOV 2020
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"/>	

US3292365

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 10:54:21

Name of Medication	VITAMIN C
Prophylaxis	Yes <input type="checkbox"/> No <input checked="" type="checkbox"/>
Indication	GENERAL HEALTH SUPPLEMENT
Dose per administration	1000
Dose unit	mg <input checked="" type="checkbox"/> ug <input type="checkbox"/> mL <input type="checkbox"/> g <input type="checkbox"/> IU <input type="checkbox"/> tablet <input type="checkbox"/> capsule <input type="checkbox"/> puff <input type="checkbox"/> Other <input type="checkbox"/>
If dose unit is Other, specify _____	
Frequency	once daily <input checked="" type="checkbox"/> twice daily <input type="checkbox"/> three times daily <input type="checkbox"/> four times daily <input type="checkbox"/> every other day <input type="checkbox"/> every week <input type="checkbox"/> every month <input type="checkbox"/> as needed <input type="checkbox"/> once <input type="checkbox"/> unknown <input type="checkbox"/> other <input type="checkbox"/>
If frequency is Other, specify _____	
Route of administration	Oral <input checked="" type="checkbox"/> Topical <input type="checkbox"/> Subcutaneous <input type="checkbox"/> Transdermal <input type="checkbox"/> Intraocular <input type="checkbox"/>

US3292365

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 10:54:21

	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"/>
<hr/>		
If route of administration is Other, specify <hr/>		
Start date (dd MMM yyyy)	UN AUG 2020	
Start date completely unknown	False	
Ongoing?	Yes	<input checked="" type="radio"/>
	No	<input type="radio"/>
<hr/>		
If not Ongoing, End date (dd MMM yyyy) <hr/>		
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"/>

US3292365

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 10:54:21

Name of Medication	ASPIRIN
Prophylaxis	Yes <input checked="" type="radio"/> No <input type="radio"/>
Indication	PROPHYLAXIS FOR PAIN
Dose per administration	500
Dose unit	mg <input checked="" type="radio"/> ug <input type="radio"/> mL <input type="radio"/> g <input type="radio"/> IU <input type="radio"/> tablet <input type="radio"/> capsule <input type="radio"/> puff <input type="radio"/> Other <input type="radio"/>
If dose unit is Other, specify _____	
Frequency	once daily <input type="radio"/> twice daily <input type="radio"/> three times daily <input type="radio"/> four times daily <input type="radio"/> every other day <input type="radio"/> every week <input type="radio"/> every month <input type="radio"/> as needed <input checked="" type="radio"/> once <input type="radio"/> unknown <input type="radio"/> other <input type="radio"/>
If frequency is Other, specify _____	
Route of administration	Oral <input checked="" type="radio"/> Topical <input type="radio"/> Subcutaneous <input type="radio"/> Transdermal <input type="radio"/> Intraocular <input type="radio"/> Intramuscular <input type="radio"/>

US3292365

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 10:54:21

	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)		UN AUG 2020
Start date completely unknown		False
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)		11 NOV 2020
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived) _____		
Interval Dosage Unit Number (derived) _____		
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input type="checkbox"/>

US3292365

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 10:54:21

Name of Medication	ZINC
Prophylaxis	Yes <input type="checkbox"/> No <input checked="" type="checkbox"/>
Indication	GENERAL HEALTH SUPPLIMENT
Dose per administration	1
Dose unit	mg <input type="checkbox"/> ug <input type="checkbox"/> mL <input type="checkbox"/> g <input type="checkbox"/> IU <input type="checkbox"/> tablet <input checked="" type="checkbox"/> capsule <input type="checkbox"/> puff <input type="checkbox"/> Other <input type="checkbox"/>
If dose unit is Other, specify _____	
Frequency	once daily <input type="checkbox"/> twice daily <input type="checkbox"/> three times daily <input type="checkbox"/> four times daily <input type="checkbox"/> every other day <input type="checkbox"/> every week <input type="checkbox"/> every month <input type="checkbox"/> as needed <input checked="" type="checkbox"/> once <input type="checkbox"/> unknown <input type="checkbox"/> other <input type="checkbox"/>
If frequency is Other, specify _____	
Route of administration	Oral <input checked="" type="checkbox"/> Topical <input type="checkbox"/> Subcutaneous <input type="checkbox"/> Transdermal <input type="checkbox"/> Intraocular <input type="checkbox"/>

US3292365

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 10:54:21

	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)		UN JUL 2020
Start date completely unknown		False
Ongoing?	Yes	<input checked="" type="radio"/>
	No	<input type="radio"/>
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived)		_____
Interval Dosage Unit Number (derived)		_____
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input type="radio"/>

US3292365

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 26 Nov 2020 10:54:21

Name of Medication	DULOXETINE HCL DR
Prophylaxis	Yes <input type="radio"/> No <input checked="" type="radio"/>
Indication	ANXIETY
Dose per administration	60
Dose unit	mg <input checked="" type="radio"/> ug <input type="radio"/> mL <input type="radio"/> g <input type="radio"/> IU <input type="radio"/> tablet <input type="radio"/> capsule <input type="radio"/> puff <input type="radio"/> Other <input type="radio"/>
If dose unit is Other, specify	
Frequency	once daily <input checked="" type="radio"/> twice daily <input type="radio"/> three times daily <input type="radio"/> four times daily <input type="radio"/> every other day <input type="radio"/> every week <input type="radio"/> every month <input type="radio"/> as needed <input type="radio"/> once <input type="radio"/> unknown <input type="radio"/> other <input type="radio"/>
If frequency is Other, specify	
Route of administration	Oral <input checked="" type="radio"/> Topical <input type="radio"/> Subcutaneous <input type="radio"/> Transdermal <input type="radio"/> Intraocular <input type="radio"/> Intramuscular <input type="radio"/>

US3292365

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 26 Nov 2020 10:54:21

	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	UN	UNK 2015
Start date completely unknown		False
Ongoing?	Yes	<input checked="" type="radio"/>
	No	<input type="radio"/>
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived)		1
Interval Dosage Unit Number (derived)		1
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input checked="" type="radio"/>

US3292365

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 26 Nov 2020 10:54:21

Name of Medication	MONTELUKAST SODIUM
Prophylaxis	Yes <input type="radio"/> No <input checked="" type="radio"/>
Indication	ASTHMA
Dose per administration	10
Dose unit	mg <input checked="" type="radio"/> ug <input type="radio"/> mL <input type="radio"/> g <input type="radio"/> IU <input type="radio"/> tablet <input type="radio"/> capsule <input type="radio"/> puff <input type="radio"/> Other <input type="radio"/>
If dose unit is Other, specify _____	
Frequency	once daily <input checked="" type="radio"/> twice daily <input type="radio"/> three times daily <input type="radio"/> four times daily <input type="radio"/> every other day <input type="radio"/> every week <input type="radio"/> every month <input type="radio"/> as needed <input type="radio"/> once <input type="radio"/> unknown <input type="radio"/> other <input type="radio"/>
If frequency is Other, specify _____	
Route of administration	Oral <input checked="" type="radio"/> Topical <input type="radio"/> Subcutaneous <input type="radio"/> Transdermal <input type="radio"/> Intraocular <input type="radio"/> Intramuscular <input type="radio"/>

US3292365

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 26 Nov 2020 10:54:21

	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	UN UNK 2005	
Start date completely unknown	False	
Ongoing?	Yes	<input checked="" type="radio"/>
	No	<input type="radio"/>
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived)	1	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input checked="" type="radio"/>

US3292365

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 26 Nov 2020 10:54:21

Name of Medication	PROAIR RESPICLICK
Prophylaxis	Yes <input type="radio"/> No <input checked="" type="radio"/>
Indication	ASTHMA
Dose per administration	90
Dose unit	mg <input type="radio"/> ug <input checked="" type="radio"/> mL <input type="radio"/> g <input type="radio"/> IU <input type="radio"/> tablet <input type="radio"/> capsule <input type="radio"/> puff <input type="radio"/> Other <input type="radio"/>
If dose unit is Other, specify	
Frequency	once daily <input type="radio"/> twice daily <input type="radio"/> three times daily <input type="radio"/> four times daily <input type="radio"/> every other day <input type="radio"/> every week <input type="radio"/> every month <input type="radio"/> as needed <input checked="" type="radio"/> once <input type="radio"/> unknown <input type="radio"/> other <input type="radio"/>
If frequency is Other, specify	
Route of administration	Oral <input type="radio"/> Topical <input type="radio"/> Subcutaneous <input type="radio"/> Transdermal <input type="radio"/> Intraocular <input type="radio"/> Intramuscular <input type="radio"/>

US3292365

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 26 Nov 2020 10:54:21

	Respiratory (Inhalation)	<input checked="" 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"/>
<hr/>		
If route of administration is Other, specify <hr/>		
Start date (dd MMM yyyy)	UN	UNK 2005
Start date completely unknown	False	
Ongoing?	Yes	<input checked="" type="radio"/>
	No	<input type="radio"/>
<hr/>		
If not Ongoing, End date (dd MMM yyyy) <hr/>		
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
<hr/>		
Separate Dosage Number (derived)	<hr/>	
Interval Dosage Unit Number (derived)	<hr/>	
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input type="radio"/>

US3292365

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 26 Nov 2020 10:54:21

Name of Medication	ARNUITY ELLIPTA
Prophylaxis	Yes <input type="radio"/> No <input checked="" type="radio"/>
Indication	ASTHMA
Dose per administration	100
Dose unit	mg <input type="radio"/> ug <input checked="" type="radio"/> mL <input type="radio"/> g <input type="radio"/> IU <input type="radio"/> tablet <input type="radio"/> capsule <input type="radio"/> puff <input type="radio"/> Other <input type="radio"/>
If dose unit is Other, specify	
Frequency	once daily <input checked="" type="radio"/> twice daily <input type="radio"/> three times daily <input type="radio"/> four times daily <input type="radio"/> every other day <input type="radio"/> every week <input type="radio"/> every month <input type="radio"/> as needed <input type="radio"/> once <input type="radio"/> unknown <input type="radio"/> other <input type="radio"/>
If frequency is Other, specify	
Route of administration	Oral <input type="radio"/> Topical <input type="radio"/> Subcutaneous <input type="radio"/> Transdermal <input type="radio"/> Intraocular <input type="radio"/> Intramuscular <input type="radio"/>

US3292365

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 26 Nov 2020 10:54:21

Respiratory (Inhalation)	<input checked="" type="radio"/>
Intralesional	<input type="radio"/>
Intraperitoneal	<input type="radio"/>
Nasal	<input type="radio"/>
Vaginal	<input type="radio"/>
Rectal	<input type="radio"/>
Intravenous	<input type="radio"/>
Intravenous Bolus	<input type="radio"/>
Intravenous Drip	<input type="radio"/>
Other	<input type="radio"/>
If route of administration is Other, specify _____	
Start date (dd MMM yyyy)	UN UNK 2015
Start date completely unknown	False
Ongoing?	Yes <input checked="" type="radio"/> No <input type="radio"/>
If not Ongoing, End date (dd MMM yyyy) _____	
Was this medication taken for solicited event?	Yes <input type="radio"/> No <input checked="" type="radio"/>
Separate Dosage Number (derived)	1
Interval Dosage Unit Number (derived)	1
Interval Dosage Definition (derived)	802 <input type="radio"/> 803 <input type="radio"/> 804 <input checked="" type="radio"/>

US3292365

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 26 Nov 2020 10:54:21

Name of Medication	SUMATRIPTAN SUCCINATE
Prophylaxis	Yes <input type="radio"/> No <input checked="" type="radio"/>
Indication	MIGRAINE
Dose per administration	100
Dose unit	mg <input checked="" type="radio"/> ug <input type="radio"/> mL <input type="radio"/> g <input type="radio"/> IU <input type="radio"/> tablet <input type="radio"/> capsule <input type="radio"/> puff <input type="radio"/> Other <input type="radio"/>
If dose unit is Other, specify	
Frequency	once daily <input type="radio"/> twice daily <input type="radio"/> three times daily <input type="radio"/> four times daily <input type="radio"/> every other day <input type="radio"/> every week <input type="radio"/> every month <input type="radio"/> as needed <input checked="" type="radio"/> once <input type="radio"/> unknown <input type="radio"/> other <input type="radio"/>
If frequency is Other, specify	
Route of administration	Oral <input checked="" type="radio"/> Topical <input type="radio"/> Subcutaneous <input type="radio"/> Transdermal <input type="radio"/> Intraocular <input type="radio"/> Intramuscular <input type="radio"/>

US3292365

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 26 Nov 2020 10:54:21

	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	UN UNK 2000	
Start date completely unknown	False	
Ongoing?	Yes	<input checked="" type="radio"/>
	No	<input type="radio"/>
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived) _____		
Interval Dosage Unit Number (derived) _____		
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input type="radio"/>

US3292365

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 26 Nov 2020 10:54:21

Name of Medication	PROGESTERONE
Prophylaxis	Yes <input type="radio"/> No <input checked="" type="radio"/>
Indication	HOT FLASHES
Dose per administration	200
Dose unit	mg <input checked="" type="radio"/> ug <input type="radio"/> mL <input type="radio"/> g <input type="radio"/> IU <input type="radio"/> tablet <input type="radio"/> capsule <input type="radio"/> puff <input type="radio"/> Other <input type="radio"/>
If dose unit is Other, specify _____	
Frequency	once daily <input checked="" type="radio"/> twice daily <input type="radio"/> three times daily <input type="radio"/> four times daily <input type="radio"/> every other day <input type="radio"/> every week <input type="radio"/> every month <input type="radio"/> as needed <input type="radio"/> once <input type="radio"/> unknown <input type="radio"/> other <input type="radio"/>
If frequency is Other, specify _____	
Route of administration	Oral <input checked="" type="radio"/> Topical <input type="radio"/> Subcutaneous <input type="radio"/> Transdermal <input type="radio"/> Intraocular <input type="radio"/> Intramuscular <input type="radio"/>

US3292365

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 26 Nov 2020 10:54:21

	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	UN	UNK 2014
Start date completely unknown	False	
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)	12 NOV 2020	
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"/>

US3292365

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 26 Nov 2020 10:54:21

Name of Medication	ESTRADIOL
Prophylaxis	Yes <input type="radio"/> No <input checked="" type="radio"/>
Indication	MENOPAUSE
Dose per administration	0.05
Dose unit	mg <input checked="" type="radio"/> ug <input type="radio"/> mL <input type="radio"/> g <input type="radio"/> IU <input type="radio"/> tablet <input type="radio"/> capsule <input type="radio"/> puff <input type="radio"/> Other <input type="radio"/>
If dose unit is Other, specify	
Frequency	once daily <input type="radio"/> twice daily <input type="radio"/> three times daily <input type="radio"/> four times daily <input type="radio"/> every other day <input type="radio"/> every week <input type="radio"/> every month <input type="radio"/> as needed <input type="radio"/> once <input type="radio"/> unknown <input type="radio"/> other <input checked="" type="radio"/>
If frequency is Other, specify	
Route of administration	Oral <input type="radio"/> Topical <input type="radio"/> Subcutaneous <input type="radio"/> Transdermal <input checked="" type="radio"/> Intraocular <input type="radio"/> Intramuscular <input type="radio"/>

US3292365

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 26 Nov 2020 10:54:21

	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	UN	UNK 2014
Start date completely unknown	False	
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)	12 NOV 2020	
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived)	_____	
Interval Dosage Unit Number (derived)	_____	
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input type="checkbox"/>

US3292365

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 26 Nov 2020 10:54:21

Name of Medication	TRETINOIN CREAM 0.05%
Prophylaxis	Yes <input type="radio"/> No <input checked="" type="radio"/>
Indication	ACNE
Dose per administration	1
Dose unit	mg <input type="radio"/> ug <input type="radio"/> mL <input type="radio"/> g <input type="radio"/> IU <input type="radio"/> tablet <input type="radio"/> capsule <input type="radio"/> puff <input type="radio"/> Other <input checked="" type="radio"/>
If dose unit is Other, specify	APPLICATION
Frequency	once daily <input checked="" type="radio"/> twice daily <input type="radio"/> three times daily <input type="radio"/> four times daily <input type="radio"/> every other day <input type="radio"/> every week <input type="radio"/> every month <input type="radio"/> as needed <input type="radio"/> once <input type="radio"/> unknown <input type="radio"/> other <input type="radio"/>
If frequency is Other, specify	
Route of administration	Oral <input type="radio"/> Topical <input checked="" type="radio"/> Subcutaneous <input type="radio"/> Transdermal <input type="radio"/> Intraocular <input type="radio"/> Intramuscular <input type="radio"/>

US3292365

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 26 Nov 2020 10:54:21

	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"/>
<hr/>		
If route of administration is Other, specify <input type="text"/>		
<hr/>		
Start date (dd MMM yyyy)	UN	UNK 1997
Start date completely unknown	False	
Ongoing?	Yes	<input checked="" type="radio"/>
	No	<input type="radio"/>
<hr/>		
If not Ongoing, End date (dd MMM yyyy) <input type="text"/>		
<hr/>		
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
<hr/>		
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"/>

US3292365

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures Summary

Generated On: 26 Nov 2020 10:54:21

Were any concomitant procedures performed?

Yes ☒

No ☐

If yes, please complete Concomitant Procedures form.

US3292365

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures

Generated On: 26 Nov 2020 10:54:21

Procedure/Surgery date (<i>dd MMM yyyy</i>)	Procedure/Surgery	Indication	If indication is Other, specify
8 OCT 2020	MAMMOGRAM	Other	PREVENTATIVE
29 OCT 2020	MAMMOGRAM	Diagnostic	
3 NOV 2020	LEFT BREAST BIOPSY	Diagnostic	

US3292365

Folder: End of Study (1)

Form: Dosing Discontinuation

Generated On: 26 Nov 2020 10:54:21

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

US3292365

Folder: End of Study (1)

Form: End of Study / Study Discontinuation

Generated On: 26 Nov 2020 10:54:21

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 ☐

US3292365

Folder: SAE USA-US072-2020-MRNA-1273-P301000010

Form: Safety Report Form

Generated On: 26 Nov 2020 10:54:21

SAEID	USA-US072-2020-MRNA-1273-P301000010
Serious	Yes <input checked="" type="radio"/> No <input type="radio"/>
Death	Yes <input type="radio"/> No <input checked="" type="radio"/>
Life threatening	Yes <input type="radio"/> No <input checked="" type="radio"/>
Requires inpatient or prolongation of existing Hospitalization	Yes <input type="radio"/> No <input checked="" type="radio"/>
Persistent or significant disability or incapacity	Yes <input type="radio"/> No <input checked="" type="radio"/>
Congenital anomaly or birth defect	Yes <input type="radio"/> No <input checked="" type="radio"/>
Other medically important event	Yes <input checked="" type="radio"/> No <input type="radio"/>
Investigator's First Name	DOUGLAS
Investigator's Last Name	DENHAM
Site Address: Street	7940 FLOYD CURL DRIVE
Site Address: City	SAN ANTONIO
Site Address: State	
Site Address: Postal Code	78229
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	2

US3292365

Folder: SAE USA-US072-2020-MRNA-1273-P301000010

Form: Safety Report Form (1)

Generated On: 26 Nov 2020 10:54:21

SAEID	USA-US072-2020-MRNA-1273-P301000010
Serious	Yes <input checked="" type="radio"/> No <input type="radio"/>
Death	Yes <input type="radio"/> No <input checked="" type="radio"/>
Life threatening	Yes <input type="radio"/> No <input checked="" type="radio"/>
Requires inpatient or prolongation of existing Hospitalization	Yes <input type="radio"/> No <input checked="" type="radio"/>
Persistent or significant disability or incapacity	Yes <input type="radio"/> No <input checked="" type="radio"/>
Congenital anomaly or birth defect	Yes <input type="radio"/> No <input checked="" type="radio"/>
Other medically important event	Yes <input checked="" type="radio"/> No <input type="radio"/>
Investigator's First Name	DOUGLAS
Investigator's Last Name	DENHAM
Site Address: Street	7940 FLOYD CURL DRIVE
Site Address: City	SAN ANTONIO
Site Address: State	
Site Address: Postal Code	78229
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	2
Date of submission (Pre-filled from custom function)	10/NOV/2020 18:41
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

US3292365

Folder: SAE USA-US072-2020-MRNA-1273-P301000010

Form: Safety Report Form (2)

Generated On: 26 Nov 2020 10:54:21

SAEID	USA-US072-2020-MRNA-1273-P301000010
Serious	Yes <input checked="" type="radio"/> No <input type="radio"/>
Death	Yes <input type="radio"/> No <input checked="" type="radio"/>
Life threatening	Yes <input type="radio"/> No <input checked="" type="radio"/>
Requires inpatient or prolongation of existing Hospitalization	Yes <input type="radio"/> No <input checked="" type="radio"/>
Persistent or significant disability or incapacity	Yes <input type="radio"/> No <input checked="" type="radio"/>
Congenital anomaly or birth defect	Yes <input type="radio"/> No <input checked="" type="radio"/>
Other medically important event	Yes <input checked="" type="radio"/> No <input type="radio"/>
Investigator's First Name	DOUGLAS
Investigator's Last Name	DENHAM
Site Address: Street	7940 FLOYD CURL DRIVE
Site Address: City	SAN ANTONIO
Site Address: State	
Site Address: Postal Code	78229
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	2
Date of submission (Pre-filled from custom function)	24/NOV/2020 12:32
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

US3292365 (Prod: Clinical Trials of Texas, Inc)

US3292365

Form: Participant Creation

Generated On: 26 Nov 2020 10:54:21

[Participant ID](#)

Audit	User	Time (GMT)
User entered 'US3292365'	RWS_ENDPOINT ENDPOINT (b) (4) <div></div>	29 Aug 2020 15:30:46

US3292365

Folder: Screening

Form: Visit Date

Generated On: 26 Nov 2020 10:54:21

[Was this visit performed?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	(b) (4), (b) (6)	01 Sep 2020 03:47:42

US3292365

Folder: Screening

Form: Visit Date

Generated On: 26 Nov 2020 10:54:21

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

Audit	User	Time (GMT)
User entered '29 AUG 2020'	RWS_ENDPOINT ENDPOINT (b) (4) <div></div>	29 Aug 2020 15:30:47

US3292365

Folder: Screening

Form: Visit Date

Generated On: 26 Nov 2020 10:54:21

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

Audit	User	Time (GMT)
User entered 'Clinic (Clinic)'	(b) (4), (b) (6)	01 Sep 2020 03:47:42

US3292365

Folder: Screening

Form: Visit Date

Generated On: 26 Nov 2020 10:54:21

[Folder OID](#)

Audit	User	Time (GMT)
User entered 'SCRN'	System	01 Sep 2020 03:47:42

US3292365

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 10:54:21

Date of Birth (MMM yyyy)

Audit	User	Time (GMT)
User entered (b) (6) 1962'	RWS_ENDPOINT ENDPOINT (b) (4) [REDACTED]	29 Aug 2020 15:30:48

US3292365

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 10:54:21

[Age](#)

Audit	User	Time (GMT)
User entered '58'	(b) (4), (b) (6)	01 Sep 2020 03:48:01

US3292365

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 10:54:21

[Age Units](#)

Audit	User	Time (GMT)
User entered 'YEARS'	System	01 Sep 2020 03:48:01

US3292365

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 10:54:21

[Age \(Derived\)](#)

Audit	User	Time (GMT)
User entered '58'	System	29 Aug 2020 18:20:56

US3292365

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 10:54:21

[Sex](#)

Audit	User	Time (GMT)
User entered 'Female (F)'	(b) (4), (b) (6)	01 Sep 2020 03:48:01

US3292365

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 10:54:21

[Ethnicity](#)

Audit	User	Time (GMT)
User entered 'Not Hispanic or Latino (NOT HISPANIC OR LATINO)'	(b) (4), (b) (6)	01 Sep 2020 03:48:01

US3292365

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 10:54:21

White

Audit	User	Time (GMT)
User entered '1'	(b) (4), (b) (6)	01 Sep 2020 03:48:01

US3292365

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 10:54:21

[Black](#)

Audit	User	Time (GMT)
User entered '0'	(b) (4), (b) (6)	01 Sep 2020 03:48:01

US3292365

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 10:54:21

[Asian](#)

Audit	User	Time (GMT)
User entered '0'	(b) (4), (b) (6)	01 Sep 2020 03:48:01

US3292365

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 10:54:21

[American Indian or Alaska Native](#)

Audit	User	Time (GMT)
User entered '0'	(b) (4), (b) (6)	01 Sep 2020 03:48:01

US3292365

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 10:54:21

[Native Hawaiian or other Pacific Islander](#)

Audit	User	Time (GMT)
User entered '0'	(b) (4), (b) (6)	01 Sep 2020 03:48:01

US3292365

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 10:54:21

[Other](#)

Audit	User	Time (GMT)
User entered '0'	(b) (4), (b) (6)	01 Sep 2020 03:48:01

US3292365

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 10:54:21

If race is Other, specify

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	01 Sep 2020 03:48:01

US3292365

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 10:54:21

Unknown

Audit	User	Time (GMT)
User entered '0'	(b) (4), (b) (6)	01 Sep 2020 03:48:01

US3292365

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 10:54:21

[Not reported](#)

Audit	User	Time (GMT)
User entered '0'	(b) (4), (b) (6)	01 Sep 2020 03:48:01

US3292365

Folder: Screening

Form: Enrollment

Generated On: 26 Nov 2020 10:54:21

Date of Informed Consent (*dd MMM yyyy*)

Audit	User	Time (GMT)
User entered '29 Aug 2020'	(b) (4), (b) (6)	29 Aug 2020 18:20:56

US3292365

Folder: Screening

Form: Enrollment

Generated On: 26 Nov 2020 10:54:21

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

Audit	User	Time (GMT)
User entered 'Aug 2020'	System	29 Aug 2020 18:20:56

US3292365

Folder: Screening

Form: Enrollment

Generated On: 26 Nov 2020 10:54:21

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

Audit	User	Time (GMT)
User entered '2020'	System	29 Aug 2020 18:20:56

US3292365

Folder: Screening

Form: Enrollment

Generated On: 26 Nov 2020 10:54:21

[Protocol Version](#)

Audit	User	Time (GMT)
User entered 'Amendment 3 (3)'	(b) (4), (b) (6)	29 Aug 2020 18:20:56

US3292365

Folder: Screening

Form: Enrollment

Generated On: 26 Nov 2020 10:54:21

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

Audit	User	Time (GMT)
User entered 'Yes (Y)'	(b) (4), (b) (6)	29 Aug 2020 18:20:56

US3292365

Folder: Screening

Form: Enrollment

Generated On: 26 Nov 2020 10:54:21

If No, indicate reason for screen fail

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	29 Aug 2020 18:20:56

US3292365

Folder: Screening

Form: Enrollment

Generated On: 26 Nov 2020 10:54:21

If reason for screen fail is Other, specify

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	29 Aug 2020 18:20:56

US3292365

Folder: Screening

Form: Enrollment

Generated On: 26 Nov 2020 10:54:21

[Was this participant screened previously?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	(b) (4), (b) (6)	29 Aug 2020 18:20:56

US3292365

Folder: Screening

Form: Enrollment

Generated On: 26 Nov 2020 10:54:21

[If Yes, previous participant number](#)

Audit	User	Time (GMT)
User entered empty.	RWS_ENDPOINT ENDPOINT (b) (4) [REDACTED]	29 Aug 2020 15:30:47

US3292365

Folder: Screening

Form: Enrollment

Generated On: 26 Nov 2020 10:54:21

[Enrollment Trigger](#)

Audit	User	Time (GMT)
User entered 'I'	System	29 Aug 2020 18:21:02

US3292365

Folder: Screening

Form: Inclusion/Exclusion Criteria Summary

Generated On: 26 Nov 2020 10:54:21

Did the participant meet all eligibility criteria?

Audit	User	Time (GMT)
User entered 'Yes (Y)'	(b) (4), (b) (6)	29 Aug 2020 18:21:02

US3292365

Folder: Screening

Form: Medical History Summary

Generated On: 26 Nov 2020 10:54:21

[Were any significant conditions reported?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	(b) (4), (b) (6)	01 Sep 2020 03:48:11

US3292365

Folder: Screening

Form: Medical History (1)

Generated On: 26 Nov 2020 10:54:21

Condition

Audit	User	Time (GMT)
User coded data point as SOC: Immune system disorders, HLGT: Allergic conditions, HLT: Allergic conditions NEC, PT: Mycotic allergy, LLT: Allergy to molds - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	01 Sep 2020 03:50:44
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 03:50:44
Data point term sent to Coder	System	01 Sep 2020 03:50:07
User entered 'Mold allergy'	(b) (4), (b) (6) (b) (4)	01 Sep 2020 03:49:11

US3292365

Folder: Screening

Form: Medical History (1)

Generated On: 26 Nov 2020 10:54:21

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

Audit	User	Time (GMT)
User entered 'un UNK 1984'	(b) (4), (b) (6)	01 Sep 2020 03:49:11

US3292365

Folder: Screening

Form: Medical History (1)

Generated On: 26 Nov 2020 10:54:21

[Start date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	(b) (4), (b) (6)	01 Sep 2020 03:49:11

US3292365

Folder: Screening

Form: Medical History (1)

Generated On: 26 Nov 2020 10:54:21

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	(b) (4), (b) (6)	01 Sep 2020 03:49:11

US3292365

Folder: Screening

Form: Medical History (1)

Generated On: 26 Nov 2020 10:54:21

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

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	01 Sep 2020 03:49:11

US3292365

Folder: Screening

Form: Medical History (1)

Generated On: 26 Nov 2020 10:54:21

[Stop date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	(b) (4), (b) (6)	01 Sep 2020 03:49:11

US3292365

Folder: Screening

Form: Medical History (1)

Generated On: 26 Nov 2020 10:54:21

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

Audit	User	Time (GMT)
User entered 'Jan 1984'	System	01 Sep 2020 03:49:11

US3292365

Folder: Screening

Form: Medical History (1)

Generated On: 26 Nov 2020 10:54:21

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

Audit	User	Time (GMT)
User entered '1984'	System	01 Sep 2020 03:49:11

US3292365

Folder: Screening

Form: Medical History (1)

Generated On: 26 Nov 2020 10:54:21

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

Audit	User	Time (GMT)
User entered empty.	System	01 Sep 2020 03:49:11

US3292365

Folder: Screening

Form: Medical History (1)

Generated On: 26 Nov 2020 10:54:21

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

Audit	User	Time (GMT)
User entered empty.	System	01 Sep 2020 03:49:11

US3292365

Folder: Screening

Form: Medical History (2)

Generated On: 26 Nov 2020 10:54:21

Condition

Audit	User	Time (GMT)
User coded data point as SOC: Immune system disorders, HLGT: Allergic conditions, HLT: Allergic conditions NEC, PT: Allergy to plants, LLT: Allergy to plants - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	24 Nov 2020 18:10:01
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	24 Nov 2020 18:10:01
Data point term sent to Coder	System	01 Sep 2020 03:50:07
User entered 'oak allergy'	(b) (4), (b) (6) (b) (4)	01 Sep 2020 03:49:26

US3292365

Folder: Screening

Form: Medical History (2)

Generated On: 26 Nov 2020 10:54:21

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

Audit	User	Time (GMT)
User entered 'un UNK 1984'	(b) (4), (b) (6)	01 Sep 2020 03:49:26

US3292365

Folder: Screening

Form: Medical History (2)

Generated On: 26 Nov 2020 10:54:21

[Start date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	(b) (4), (b) (6)	01 Sep 2020 03:49:26

US3292365

Folder: Screening

Form: Medical History (2)

Generated On: 26 Nov 2020 10:54:21

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	(b) (4), (b) (6)	01 Sep 2020 03:49:26

US3292365

Folder: Screening

Form: Medical History (2)

Generated On: 26 Nov 2020 10:54:21

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

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	01 Sep 2020 03:49:26

US3292365

Folder: Screening

Form: Medical History (2)

Generated On: 26 Nov 2020 10:54:21

[Stop date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	(b) (4), (b) (6)	01 Sep 2020 03:49:26

US3292365

Folder: Screening

Form: Medical History (2)

Generated On: 26 Nov 2020 10:54:21

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

Audit	User	Time (GMT)
User entered 'Jan 1984'	System	01 Sep 2020 03:49:26

US3292365

Folder: Screening

Form: Medical History (2)

Generated On: 26 Nov 2020 10:54:21

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

Audit	User	Time (GMT)
User entered '1984'	System	01 Sep 2020 03:49:26

US3292365

Folder: Screening

Form: Medical History (2)

Generated On: 26 Nov 2020 10:54:21

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

Audit	User	Time (GMT)
User entered empty.	System	01 Sep 2020 03:49:26

US3292365

Folder: Screening

Form: Medical History (2)

Generated On: 26 Nov 2020 10:54:21

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

Audit	User	Time (GMT)
User entered empty.	System	01 Sep 2020 03:49:26

US3292365

Folder: Screening

Form: Medical History (3)

Generated On: 26 Nov 2020 10:54:21

Condition

Audit	User	Time (GMT)
User coded data point as SOC: Immune system disorders, HLGT: Allergic conditions, HLT: Allergic conditions NEC, PT: Allergy to arthropod sting, LLT: Allergic reaction to bee sting - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	03 Sep 2020 19:25:13
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	03 Sep 2020 19:25:13
User coded data point as SOC: Immune system disorders, HLGT: Allergic conditions, HLT: Allergic conditions NEC, PT: Allergy to arthropod sting, LLT: Bee sting hypersensitivity - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	01 Sep 2020 03:51:45
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 03:51:45
Data point term sent to Coder	System	01 Sep 2020 03:51:08
User entered 'bee sting allergy'	(b) (4), (b) (6)	01 Sep 2020 03:50:32

US3292365

Folder: Screening

Form: Medical History (3)

Generated On: 26 Nov 2020 10:54:21

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

Audit	User	Time (GMT)
User entered 'un UNK 1981'	(b) (4), (b) (6)	01 Sep 2020 03:50:32

US3292365

Folder: Screening

Form: Medical History (3)

Generated On: 26 Nov 2020 10:54:21

[Start date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	(b) (4), (b) (6)	01 Sep 2020 03:50:32

US3292365

Folder: Screening

Form: Medical History (3)

Generated On: 26 Nov 2020 10:54:21

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	(b) (4), (b) (6)	01 Sep 2020 03:50:32

US3292365

Folder: Screening

Form: Medical History (3)

Generated On: 26 Nov 2020 10:54:21

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

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	01 Sep 2020 03:50:32

US3292365

Folder: Screening

Form: Medical History (3)

Generated On: 26 Nov 2020 10:54:21

[Stop date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	(b) (4), (b) (6)	01 Sep 2020 03:50:32

US3292365

Folder: Screening

Form: Medical History (3)

Generated On: 26 Nov 2020 10:54:21

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

Audit	User	Time (GMT)
User entered 'Jan 1981'	System	01 Sep 2020 03:50:32

US3292365

Folder: Screening

Form: Medical History (3)

Generated On: 26 Nov 2020 10:54:21

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

Audit	User	Time (GMT)
User entered '1981'	System	01 Sep 2020 03:50:32

US3292365

Folder: Screening

Form: Medical History (3)

Generated On: 26 Nov 2020 10:54:21

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

Audit	User	Time (GMT)
User entered empty.	System	01 Sep 2020 03:50:32

US3292365

Folder: Screening

Form: Medical History (3)

Generated On: 26 Nov 2020 10:54:21

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

Audit	User	Time (GMT)
User entered empty.	System	01 Sep 2020 03:50:32

US3292365

Folder: Screening

Form: Medical History (4)

Generated On: 26 Nov 2020 10:54:21

[Condition](#)

Audit	User	Time (GMT)
User coded data point as SOC: Surgical and medical procedures, HLGT: Obstetric and gynaecological therapeutic procedures, HLT: Vaginal therapeutic procedures, PT: Hymenectomy, LLT: Hymenectomy - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	01 Sep 2020 04:08:43
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 04:08:43
Data point term sent to Coder	System	01 Sep 2020 04:08:27
User entered 'hymenectomy'	(b) (4), (b) (6) (b) (4)	01 Sep 2020 04:08:24

US3292365

Folder: Screening

Form: Medical History (4)

Generated On: 26 Nov 2020 10:54:21

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

Audit	User	Time (GMT)
User entered 'un UNK 1985'	(b) (4), (b) (6)	01 Sep 2020 04:08:24

US3292365

Folder: Screening

Form: Medical History (4)

Generated On: 26 Nov 2020 10:54:21

[Start date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	(b) (4), (b) (6)	01 Sep 2020 04:08:24

US3292365

Folder: Screening

Form: Medical History (4)

Generated On: 26 Nov 2020 10:54:21

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
User entered 'No (N)'	(b) (4), (b) (6)	01 Sep 2020 04:08:24

US3292365

Folder: Screening

Form: Medical History (4)

Generated On: 26 Nov 2020 10:54:21

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

Audit	User	Time (GMT)
User entered 'un UNK 1985'	(b) (4), (b) (6)	01 Sep 2020 04:08:24

US3292365

Folder: Screening

Form: Medical History (4)

Generated On: 26 Nov 2020 10:54:21

[Stop date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	(b) (4), (b) (6)	01 Sep 2020 04:08:24

US3292365

Folder: Screening

Form: Medical History (4)

Generated On: 26 Nov 2020 10:54:21

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

Audit	User	Time (GMT)
User entered 'Jan 1985'	System	01 Sep 2020 04:08:24

US3292365

Folder: Screening

Form: Medical History (4)

Generated On: 26 Nov 2020 10:54:21

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

Audit	User	Time (GMT)
User entered '1985'	System	01 Sep 2020 04:08:24

US3292365

Folder: Screening

Form: Medical History (4)

Generated On: 26 Nov 2020 10:54:21

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

Audit	User	Time (GMT)
User entered 'Jan 1985'	System	01 Sep 2020 04:08:24

US3292365

Folder: Screening

Form: Medical History (4)

Generated On: 26 Nov 2020 10:54:21

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

Audit	User	Time (GMT)
User entered '1985'	System	01 Sep 2020 04:08:24

US3292365

Folder: Screening

Form: Medical History (5)

Generated On: 26 Nov 2020 10:54:21

Condition

Audit	User	Time (GMT)
User coded data point as SOC: Congenital, familial and genetic disorders, HLGT: Reproductive tract and breast disorders congenital, HLT: Female reproductive tract disorders congenital, PT: Septate hymen, LLT: Septate hymen - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	01 Sep 2020 08:41:49
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	01 Sep 2020 08:41:49
Data point term sent to Coder	System	01 Sep 2020 04:23:40
Coding entries removed.	(b) (4), (b) (6)	01 Sep 2020 04:23:25
User entered 'thick/SEPTATE HYMEN' reason for change: Data Entry Error	(b) (4), (b) (6)	01 Sep 2020 04:23:25
User coded data point as SOC: Congenital, familial and genetic disorders, HLGT: Reproductive tract and breast disorders congenital, HLT: Female reproductive tract disorders congenital, PT: Septate hymen, LLT: Septate hymen - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	01 Sep 2020 04:11:40
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 04:11:40
Data point term sent to Coder	System	01 Sep 2020 04:10:28
User entered 'septate hymen'	(b) (4), (b) (6)	01 Sep 2020 04:09:37

US3292365

Folder: Screening

Form: Medical History (5)

Generated On: 26 Nov 2020 10:54:21

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

Audit	User	Time (GMT)
User entered 'un UNK 1985'	(b) (4), (b) (6)	01 Sep 2020 04:09:37

US3292365

Folder: Screening

Form: Medical History (5)

Generated On: 26 Nov 2020 10:54:21

[Start date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	(b) (4), (b) (6)	01 Sep 2020 04:09:37

US3292365

Folder: Screening

Form: Medical History (5)

Generated On: 26 Nov 2020 10:54:21

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
User entered 'No (N)'	(b) (4), (b) (6)	01 Sep 2020 04:09:37

US3292365

Folder: Screening

Form: Medical History (5)

Generated On: 26 Nov 2020 10:54:21

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

Audit	User	Time (GMT)
User entered 'un UNK 1985'	(b) (4), (b) (6)	01 Sep 2020 04:09:37

US3292365

Folder: Screening

Form: Medical History (5)

Generated On: 26 Nov 2020 10:54:21

[Stop date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	(b) (4), (b) (6)	01 Sep 2020 04:09:37

US3292365

Folder: Screening

Form: Medical History (5)

Generated On: 26 Nov 2020 10:54:21

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

Audit	User	Time (GMT)
User entered 'Jan 1985'	System	01 Sep 2020 04:09:37

US3292365

Folder: Screening

Form: Medical History (5)

Generated On: 26 Nov 2020 10:54:21

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

Audit	User	Time (GMT)
User entered '1985'	System	01 Sep 2020 04:09:37

US3292365

Folder: Screening

Form: Medical History (5)

Generated On: 26 Nov 2020 10:54:21

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

Audit	User	Time (GMT)
User entered 'Jan 1985'	System	01 Sep 2020 04:09:37

US3292365

Folder: Screening

Form: Medical History (5)

Generated On: 26 Nov 2020 10:54:21

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

Audit	User	Time (GMT)
User entered '1985'	System	01 Sep 2020 04:09:37

US3292365

Folder: Screening

Form: Medical History (6)

Generated On: 26 Nov 2020 10:54:21

[Condition](#)

Audit	User	Time (GMT)
User coded data point as SOC: Surgical and medical procedures, HLGT: Obstetric and gynaecological therapeutic procedures, HLT: Obstetric therapeutic procedures, PT: Caesarean section, LLT: C-section - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	01 Sep 2020 04:13:42
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 04:13:42
Data point term sent to Coder	System	01 Sep 2020 04:12:28
User entered 'C-section'	(b) (4), (b) (6)	01 Sep 2020 04:11:29

US3292365

Folder: Screening

Form: Medical History (6)

Generated On: 26 Nov 2020 10:54:21

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

Audit	User	Time (GMT)
User entered 'un UNK 1989'	(b) (4), (b) (6)	01 Sep 2020 04:11:29

US3292365

Folder: Screening

Form: Medical History (6)

Generated On: 26 Nov 2020 10:54:21

[Start date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	(b) (4), (b) (6)	01 Sep 2020 04:11:29

US3292365

Folder: Screening

Form: Medical History (6)

Generated On: 26 Nov 2020 10:54:21

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
User entered 'No (N)'	(b) (4), (b) (6)	01 Sep 2020 04:11:29

US3292365

Folder: Screening

Form: Medical History (6)

Generated On: 26 Nov 2020 10:54:21

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

Audit	User	Time (GMT)
User entered 'un UNK 1989'	(b) (4), (b) (6)	01 Sep 2020 04:11:29

US3292365

Folder: Screening

Form: Medical History (6)

Generated On: 26 Nov 2020 10:54:21

[Stop date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	(b) (4), (b) (6)	01 Sep 2020 04:11:29

US3292365

Folder: Screening

Form: Medical History (6)

Generated On: 26 Nov 2020 10:54:21

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

Audit	User	Time (GMT)
User entered 'Jan 1989'	System	01 Sep 2020 04:11:29

US3292365

Folder: Screening

Form: Medical History (6)

Generated On: 26 Nov 2020 10:54:21

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

Audit	User	Time (GMT)
User entered '1989'	System	01 Sep 2020 04:11:29

US3292365

Folder: Screening

Form: Medical History (6)

Generated On: 26 Nov 2020 10:54:21

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

Audit	User	Time (GMT)
User entered 'Jan 1989'	System	01 Sep 2020 04:11:29

US3292365

Folder: Screening

Form: Medical History (6)

Generated On: 26 Nov 2020 10:54:21

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

Audit	User	Time (GMT)
User entered '1989'	System	01 Sep 2020 04:11:29

US3292365

Folder: Screening

Form: Medical History (7)

Generated On: 26 Nov 2020 10:54:21

Condition

Audit	User	Time (GMT)
User closed query 'Per DM CLR: Please specify the type of LAPROSCOPY (laparoscopic cholecystectomy, laparoscopic splenectomy, rtc.). Please ensure the associated condition which led to this procedure is also captured in the Med History eCRF. Please update to MHx is reconciled with any corresponding AE or ConMed entries, if applicable. ' (Site from DM).	(b) (4), (b) (6)	15 Oct 2020 23:21:37
User coded data point as SOC: Reproductive system and breast disorders, HLGT: Uterine, pelvic and broad ligament disorders, HLT: Uterine disorders NEC, PT: Endometriosis, LLT: Endometriosis - version MedDRA\23.0.	Coder Import (b) (4)	23 Sep 2020 14:39:39
User coded data point as Term Coded data point by User: Coder System - version MedDRA\23.0.	(b) (4)	23 Sep 2020 14:39:39
Data point term sent to Coder	System	23 Sep 2020 14:38:53
Query 'Per DM CLR: Please specify the type of LAPROSCOPY (laparoscopic cholecystectomy, laparoscopic splenectomy, rtc.). Please ensure the associated condition which led to this procedure is also captured in the Med History eCRF. Please update to MHx is reconciled with any corresponding AE or ConMed entries, if applicable. ' answered with 'updated' (Site from DM).	(b) (4), (b) (6)	23 Sep 2020 14:38:03
Coding entries removed.	(b) (4), (b) (6)	23 Sep 2020 14:37:55
User entered 'Laparoscopy for endometriosis' reason for change: Data Entry Error	(b) (4), (b) (6)	23 Sep 2020 14:37:55
User opened query 'Per DM CLR: Please specify the type of LAPROSCOPY (laparoscopic cholecystectomy, laparoscopic splenectomy, rtc.). Please ensure the associated condition which led to this procedure is also captured in the Med History eCRF. Please update to MHx is reconciled with any corresponding AE or ConMed entries, if applicable. ' (Site from DM).	(b) (4), (b) (6)	09 Sep 2020 21:24:52
User coded data point as SOC: Investigations, HLGT: Gastrointestinal investigations, HLT: Gastrointestinal and abdominal imaging procedures, PT: Laparoscopy, LLT: Laparoscopy - version MedDRA\23.0.	Coder Import (b) (4)	01 Sep 2020 04:13:41

US3292365

Folder: Screening

Form: Medical History (7)

Generated On: 26 Nov 2020 10:54:21

[Condition](#)

Audit	User	Time (GMT)
User coded data point as Term Coded data point by	Coder Import (b) (4)	01 Sep 2020 04:13:41
User: Coder System - version MedDRA\\23.0.	(b) (4)	
Data point term sent to Coder	System	01 Sep 2020 04:12:28
User entered 'laparoscopy'	(b) (4), (b) (6)	01 Sep 2020 04:12:15

US3292365

Folder: Screening

Form: Medical History (7)

Generated On: 26 Nov 2020 10:54:21

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

Audit	User	Time (GMT)
User entered 'un UNK 1997'	(b) (4), (b) (6)	01 Sep 2020 04:12:15

US3292365

Folder: Screening

Form: Medical History (7)

Generated On: 26 Nov 2020 10:54:21

[Start date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	(b) (4), (b) (6)	01 Sep 2020 04:12:15

US3292365

Folder: Screening

Form: Medical History (7)

Generated On: 26 Nov 2020 10:54:21

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
User entered 'No (N)'	(b) (4), (b) (6)	01 Sep 2020 04:12:15

US3292365

Folder: Screening

Form: Medical History (7)

Generated On: 26 Nov 2020 10:54:21

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

Audit	User	Time (GMT)
User entered 'un UNK 1997'	(b) (4), (b) (6)	01 Sep 2020 04:12:15

US3292365

Folder: Screening

Form: Medical History (7)

Generated On: 26 Nov 2020 10:54:21

[Stop date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	(b) (4), (b) (6)	01 Sep 2020 04:12:15

US3292365

Folder: Screening

Form: Medical History (7)

Generated On: 26 Nov 2020 10:54:21

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

Audit	User	Time (GMT)
User entered 'Jan 1997'	System	01 Sep 2020 04:12:15

US3292365

Folder: Screening

Form: Medical History (7)

Generated On: 26 Nov 2020 10:54:21

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

Audit	User	Time (GMT)
User entered '1997'	System	01 Sep 2020 04:12:15

US3292365

Folder: Screening

Form: Medical History (7)

Generated On: 26 Nov 2020 10:54:21

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

Audit	User	Time (GMT)
User entered 'Jan 1997'	System	01 Sep 2020 04:12:15

US3292365

Folder: Screening

Form: Medical History (7)

Generated On: 26 Nov 2020 10:54:21

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

Audit	User	Time (GMT)
User entered '1997'	System	01 Sep 2020 04:12:15

US3292365

Folder: Screening

Form: Medical History (8)

Generated On: 26 Nov 2020 10:54:21

[Condition](#)

Audit	User	Time (GMT)
User coded data point as SOC: Reproductive system and breast disorders, HLGT: Uterine, pelvic and broad ligament disorders, HLT: Uterine disorders NEC, PT: Endometriosis, LLT: Endometriosis - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	01 Sep 2020 04:14:43
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 04:14:43
Data point term sent to Coder	System	01 Sep 2020 04:13:29
User entered 'endometriosis'	(b) (4), (b) (6) (b) (4)	01 Sep 2020 04:13:10

US3292365

Folder: Screening

Form: Medical History (8)

Generated On: 26 Nov 2020 10:54:21

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

Audit	User	Time (GMT)
User entered 'un UNK 1997'	(b) (4), (b) (6)	01 Sep 2020 04:13:10

US3292365

Folder: Screening

Form: Medical History (8)

Generated On: 26 Nov 2020 10:54:21

[Start date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	(b) (4), (b) (6)	01 Sep 2020 04:13:10

US3292365

Folder: Screening

Form: Medical History (8)

Generated On: 26 Nov 2020 10:54:21

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
User entered 'No (N)'	(b) (4), (b) (6)	01 Sep 2020 04:13:10

US3292365

Folder: Screening

Form: Medical History (8)

Generated On: 26 Nov 2020 10:54:21

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

Audit	User	Time (GMT)
User entered 'un UNK 1997'	(b) (4), (b) (6)	01 Sep 2020 04:13:10

US3292365

Folder: Screening

Form: Medical History (8)

Generated On: 26 Nov 2020 10:54:21

[Stop date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	(b) (4), (b) (6)	01 Sep 2020 04:13:10

US3292365

Folder: Screening

Form: Medical History (8)

Generated On: 26 Nov 2020 10:54:21

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

Audit	User	Time (GMT)
User entered 'Jan 1997'	System	01 Sep 2020 04:13:10

US3292365

Folder: Screening

Form: Medical History (8)

Generated On: 26 Nov 2020 10:54:21

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

Audit	User	Time (GMT)
User entered '1997'	System	01 Sep 2020 04:13:10

US3292365

Folder: Screening

Form: Medical History (8)

Generated On: 26 Nov 2020 10:54:21

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

Audit	User	Time (GMT)
User entered 'Jan 1997'	System	01 Sep 2020 04:13:10

US3292365

Folder: Screening

Form: Medical History (8)

Generated On: 26 Nov 2020 10:54:21

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

Audit	User	Time (GMT)
User entered '1997'	System	01 Sep 2020 04:13:10

US3292365

Folder: Screening

Form: Medical History (9)

Generated On: 26 Nov 2020 10:54:21

[Condition](#)

Audit	User	Time (GMT)
User coded data point as SOC: Surgical and medical procedures, HLGT: Eye therapeutic procedures, HLT: Corneal and scleral therapeutic procedures, PT: Keratomileusis, LLT: LASIK eye surgery - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	01 Sep 2020 04:15:44
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 04:15:44
Data point term sent to Coder	System	01 Sep 2020 04:14:29
User entered 'right eye lasik'	(b) (4), (b) (6) (b) (4)	01 Sep 2020 04:13:42

US3292365

Folder: Screening

Form: Medical History (9)

Generated On: 26 Nov 2020 10:54:21

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

Audit	User	Time (GMT)
User entered '06 Aug 2020'	(b) (4), (b) (6)	01 Sep 2020 04:13:42

US3292365

Folder: Screening

Form: Medical History (9)

Generated On: 26 Nov 2020 10:54:21

[Start date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	(b) (4), (b) (6)	01 Sep 2020 04:13:42

US3292365

Folder: Screening

Form: Medical History (9)

Generated On: 26 Nov 2020 10:54:21

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
User entered 'No (N)'	(b) (4), (b) (6)	01 Sep 2020 04:13:42

US3292365

Folder: Screening

Form: Medical History (9)

Generated On: 26 Nov 2020 10:54:21

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

Audit	User	Time (GMT)
User entered '06 Aug 2020'	(b) (4), (b) (6)	01 Sep 2020 04:13:42

US3292365

Folder: Screening

Form: Medical History (9)

Generated On: 26 Nov 2020 10:54:21

[Stop date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	(b) (4), (b) (6)	01 Sep 2020 04:13:42

US3292365

Folder: Screening

Form: Medical History (9)

Generated On: 26 Nov 2020 10:54:21

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

Audit	User	Time (GMT)
User entered 'Aug 2020'	System	01 Sep 2020 04:13:42

US3292365

Folder: Screening

Form: Medical History (9)

Generated On: 26 Nov 2020 10:54:21

Start Year (derived)

Audit	User	Time (GMT)
User entered '2020'	System	01 Sep 2020 04:13:42

US3292365

Folder: Screening

Form: Medical History (9)

Generated On: 26 Nov 2020 10:54:21

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

Audit	User	Time (GMT)
User entered 'Aug 2020'	System	01 Sep 2020 04:13:42

US3292365

Folder: Screening

Form: Medical History (9)

Generated On: 26 Nov 2020 10:54:21

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

Audit	User	Time (GMT)
User entered '2020'	System	01 Sep 2020 04:13:42

US3292365

Folder: Screening

Form: Medical History (10)

Generated On: 26 Nov 2020 10:54:21

[Condition](#)

Audit	User	Time (GMT)
User coded data point as SOC: Investigations, HLGT: Gastrointestinal investigations, HLT: Gastrointestinal and abdominal imaging procedures, PT: Colonoscopy, LLT: Colonoscopy - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	01 Sep 2020 04:15:44
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 04:15:44
Data point term sent to Coder	System	01 Sep 2020 04:14:30
User entered 'colonoscopy'	(b) (4), (b) (6) (b) (4)	01 Sep 2020 04:14:22

US3292365

Folder: Screening

Form: Medical History (10)

Generated On: 26 Nov 2020 10:54:21

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

Audit	User	Time (GMT)
User entered 'un UNK 2015'	(b) (4), (b) (6)	01 Sep 2020 04:14:22

US3292365

Folder: Screening

Form: Medical History (10)

Generated On: 26 Nov 2020 10:54:21

[Start date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	(b) (4), (b) (6)	01 Sep 2020 04:14:22

US3292365

Folder: Screening

Form: Medical History (10)

Generated On: 26 Nov 2020 10:54:21

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
User entered 'No (N)'	(b) (4), (b) (6)	01 Sep 2020 04:14:22

US3292365

Folder: Screening

Form: Medical History (10)

Generated On: 26 Nov 2020 10:54:21

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

Audit	User	Time (GMT)
User entered 'un UNK 2015'	(b) (4), (b) (6)	01 Sep 2020 04:14:22

US3292365

Folder: Screening

Form: Medical History (10)

Generated On: 26 Nov 2020 10:54:21

[Stop date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	(b) (4), (b) (6)	01 Sep 2020 04:14:22

US3292365

Folder: Screening

Form: Medical History (10)

Generated On: 26 Nov 2020 10:54:21

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

Audit	User	Time (GMT)
User entered 'Jan 2015'	System	01 Sep 2020 04:14:22

US3292365

Folder: Screening

Form: Medical History (10)

Generated On: 26 Nov 2020 10:54:21

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

Audit	User	Time (GMT)
User entered '2015'	System	01 Sep 2020 04:14:22

US3292365

Folder: Screening

Form: Medical History (10)

Generated On: 26 Nov 2020 10:54:21

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

Audit	User	Time (GMT)
User entered 'Jan 2015'	System	01 Sep 2020 04:14:22

US3292365

Folder: Screening

Form: Medical History (10)

Generated On: 26 Nov 2020 10:54:21

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

Audit	User	Time (GMT)
User entered '2015'	System	01 Sep 2020 04:14:22

US3292365

Folder: Screening

Form: Medical History (11)

Generated On: 26 Nov 2020 10:54:21

Condition

Audit	User	Time (GMT)
User coded data point as SOC: Surgical and medical procedures, HLG: Therapeutic procedures and supportive care NEC, HLT: Therapeutic procedures NEC, PT: Polypectomy, LLT: Polyp removal - version MedDRA\\23.0.	Coder Import (b) (4)	01 Sep 2020 04:16:36
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	01 Sep 2020 04:16:36
Data point term sent to Coder	System	01 Sep 2020 04:15:30
User entered 'polyp removal'	(b) (4), (b) (6)	01 Sep 2020 04:14:47

US3292365

Folder: Screening

Form: Medical History (11)

Generated On: 26 Nov 2020 10:54:21

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

Audit	User	Time (GMT)
User entered 'un UNK 2015'	(b) (4), (b) (6)	01 Sep 2020 04:14:47

US3292365

Folder: Screening

Form: Medical History (11)

Generated On: 26 Nov 2020 10:54:21

[Start date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	(b) (4), (b) (6)	01 Sep 2020 04:14:47

US3292365

Folder: Screening

Form: Medical History (11)

Generated On: 26 Nov 2020 10:54:21

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
User entered 'No (N)'	(b) (4), (b) (6)	01 Sep 2020 04:14:47

US3292365

Folder: Screening

Form: Medical History (11)

Generated On: 26 Nov 2020 10:54:21

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

Audit	User	Time (GMT)
User entered 'un UNK 2015'	(b) (4), (b) (6)	01 Sep 2020 04:14:47

US3292365

Folder: Screening

Form: Medical History (11)

Generated On: 26 Nov 2020 10:54:21

[Stop date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	(b) (4), (b) (6)	01 Sep 2020 04:14:47

US3292365

Folder: Screening

Form: Medical History (11)

Generated On: 26 Nov 2020 10:54:21

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

Audit	User	Time (GMT)
User entered 'Jan 2015'	System	01 Sep 2020 04:14:47

US3292365

Folder: Screening

Form: Medical History (11)

Generated On: 26 Nov 2020 10:54:21

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

Audit	User	Time (GMT)
User entered '2015'	System	01 Sep 2020 04:14:47

US3292365

Folder: Screening

Form: Medical History (11)

Generated On: 26 Nov 2020 10:54:21

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

Audit	User	Time (GMT)
User entered 'Jan 2015'	System	01 Sep 2020 04:14:47

US3292365

Folder: Screening

Form: Medical History (11)

Generated On: 26 Nov 2020 10:54:21

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

Audit	User	Time (GMT)
User entered '2015'	System	01 Sep 2020 04:14:47

US3292365

Folder: Screening

Form: Medical History (12)

Generated On: 26 Nov 2020 10:54:21

Condition

Audit	User	Time (GMT)
User coded data point as SOC: Surgical and medical procedures, HLGT: Therapeutic procedures and supportive care NEC, HLT: Therapeutic procedures NEC, PT: Cancer surgery, LLT: Squamous cell carcinoma excision - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	01 Sep 2020 07:34:51
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	01 Sep 2020 07:34:51
Data point term sent to Coder	System	01 Sep 2020 04:16:32
User entered 'left hand squamous cell removal'	(b) (4), (b) (6) (b) (4)	01 Sep 2020 04:15:59

US3292365

Folder: Screening

Form: Medical History (12)

Generated On: 26 Nov 2020 10:54:21

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

Audit	User	Time (GMT)
User entered 'un UNK 2009'	(b) (4), (b) (6)	01 Sep 2020 04:15:59

US3292365

Folder: Screening

Form: Medical History (12)

Generated On: 26 Nov 2020 10:54:21

[Start date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	(b) (4), (b) (6)	01 Sep 2020 04:15:59

US3292365

Folder: Screening

Form: Medical History (12)

Generated On: 26 Nov 2020 10:54:21

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
User entered 'No (N)'	(b) (4), (b) (6)	01 Sep 2020 04:15:59

US3292365

Folder: Screening

Form: Medical History (12)

Generated On: 26 Nov 2020 10:54:21

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

Audit	User	Time (GMT)
User entered 'un UNK 2009'	(b) (4), (b) (6)	01 Sep 2020 04:15:59

US3292365

Folder: Screening

Form: Medical History (12)

Generated On: 26 Nov 2020 10:54:21

[Stop date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	(b) (4), (b) (6)	01 Sep 2020 04:15:59

US3292365

Folder: Screening

Form: Medical History (12)

Generated On: 26 Nov 2020 10:54:21

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

Audit	User	Time (GMT)
User entered 'Jan 2009'	System	01 Sep 2020 04:15:59

US3292365

Folder: Screening

Form: Medical History (12)

Generated On: 26 Nov 2020 10:54:21

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

Audit	User	Time (GMT)
User entered '2009'	System	01 Sep 2020 04:15:59

US3292365

Folder: Screening

Form: Medical History (12)

Generated On: 26 Nov 2020 10:54:21

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

Audit	User	Time (GMT)
User entered 'Jan 2009'	System	01 Sep 2020 04:15:59

US3292365

Folder: Screening

Form: Medical History (12)

Generated On: 26 Nov 2020 10:54:21

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

Audit	User	Time (GMT)
User entered '2009'	System	01 Sep 2020 04:15:59

US3292365

Folder: Screening

Form: Medical History (13)

Generated On: 26 Nov 2020 10:54:21

Condition

Audit	User	Time (GMT)
User coded data point as SOC: Neoplasms benign, malignant and unspecified (incl cysts and polyps), HLGT: Miscellaneous and site unspecified neoplasms malignant and unspecified, HLT: Neoplasms malignant site unspecified NEC, PT: Squamous cell carcinoma, LLT: Squamous cell carcinoma - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	01 Sep 2020 07:34:51
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	01 Sep 2020 07:34:51
Data point term sent to Coder	System	01 Sep 2020 04:16:31
User entered 'left hand squamous cell carcinoma'	(b) (4), (b) (6) (b) (4)	01 Sep 2020 04:16:17

US3292365

Folder: Screening

Form: Medical History (13)

Generated On: 26 Nov 2020 10:54:21

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

Audit	User	Time (GMT)
User entered 'un UNK 2009'	(b) (4), (b) (6)	01 Sep 2020 04:16:17

US3292365

Folder: Screening

Form: Medical History (13)

Generated On: 26 Nov 2020 10:54:21

[Start date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	(b) (4), (b) (6)	01 Sep 2020 04:16:17

US3292365

Folder: Screening

Form: Medical History (13)

Generated On: 26 Nov 2020 10:54:21

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
User entered 'No (N)'	(b) (4), (b) (6)	01 Sep 2020 04:16:17

US3292365

Folder: Screening

Form: Medical History (13)

Generated On: 26 Nov 2020 10:54:21

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

Audit	User	Time (GMT)
User entered 'un UNK 2009'	(b) (4), (b) (6)	01 Sep 2020 04:16:17

US3292365

Folder: Screening

Form: Medical History (13)

Generated On: 26 Nov 2020 10:54:21

[Stop date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	(b) (4), (b) (6)	01 Sep 2020 04:16:17

US3292365

Folder: Screening

Form: Medical History (13)

Generated On: 26 Nov 2020 10:54:21

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

Audit	User	Time (GMT)
User entered 'Jan 2009'	System	01 Sep 2020 04:16:17

US3292365

Folder: Screening

Form: Medical History (13)

Generated On: 26 Nov 2020 10:54:21

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

Audit	User	Time (GMT)
User entered '2009'	System	01 Sep 2020 04:16:17

US3292365

Folder: Screening

Form: Medical History (13)

Generated On: 26 Nov 2020 10:54:21

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

Audit	User	Time (GMT)
User entered 'Jan 2009'	System	01 Sep 2020 04:16:17

US3292365

Folder: Screening

Form: Medical History (13)

Generated On: 26 Nov 2020 10:54:21

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

Audit	User	Time (GMT)
User entered '2009'	System	01 Sep 2020 04:16:17

US3292365

Folder: Screening

Form: Medical History (14)

Generated On: 26 Nov 2020 10:54:21

[Condition](#)

Audit	User	Time (GMT)
User coded data point as SOC: Surgical and medical procedures, HLGT: Skin and subcutaneous tissue therapeutic procedures, HLT: Skin lesion excisions, PT: Skin neoplasm excision, LLT: Basal cell carcinoma excision - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	01 Sep 2020 07:41:37
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	01 Sep 2020 07:41:37
Data point term sent to Coder	System	01 Sep 2020 04:17:32
User entered 'left hand and foot basal cell removal'	(b) (4), (b) (6) (b) (4)	01 Sep 2020 04:17:13

US3292365

Folder: Screening

Form: Medical History (14)

Generated On: 26 Nov 2020 10:54:21

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

Audit	User	Time (GMT)
User entered 'un UNK 2017'	(b) (4), (b) (6)	01 Sep 2020 04:17:13

US3292365

Folder: Screening

Form: Medical History (14)

Generated On: 26 Nov 2020 10:54:21

[Start date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	(b) (4), (b) (6)	01 Sep 2020 04:17:13

US3292365

Folder: Screening

Form: Medical History (14)

Generated On: 26 Nov 2020 10:54:21

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
User entered 'No (N)'	(b) (4), (b) (6)	01 Sep 2020 04:17:13

US3292365

Folder: Screening

Form: Medical History (14)

Generated On: 26 Nov 2020 10:54:21

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

Audit	User	Time (GMT)
User entered 'un UNK 2017'	(b) (4), (b) (6)	01 Sep 2020 04:17:13

US3292365

Folder: Screening

Form: Medical History (14)

Generated On: 26 Nov 2020 10:54:21

[Stop date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	(b) (4), (b) (6)	01 Sep 2020 04:17:13

US3292365

Folder: Screening

Form: Medical History (14)

Generated On: 26 Nov 2020 10:54:21

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

Audit	User	Time (GMT)
User entered 'Jan 2017'	System	01 Sep 2020 04:17:13

US3292365

Folder: Screening

Form: Medical History (14)

Generated On: 26 Nov 2020 10:54:21

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

Audit	User	Time (GMT)
User entered '2017'	System	01 Sep 2020 04:17:13

US3292365

Folder: Screening

Form: Medical History (14)

Generated On: 26 Nov 2020 10:54:21

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

Audit	User	Time (GMT)
User entered 'Jan 2017'	System	01 Sep 2020 04:17:13

US3292365

Folder: Screening

Form: Medical History (14)

Generated On: 26 Nov 2020 10:54:21

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

Audit	User	Time (GMT)
User entered '2017'	System	01 Sep 2020 04:17:13

US3292365

Folder: Screening

Form: Medical History (15)

Generated On: 26 Nov 2020 10:54:21

[Condition](#)

Audit	User	Time (GMT)
User coded data point as SOC: Neoplasms benign, malignant and unspecified (incl cysts and polyps), HLGT: Skin neoplasms malignant and unspecified, HLT: Skin neoplasms malignant and unspecified (excl melanoma), PT: Basal cell carcinoma, LLT: Basal cell carcinoma - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	01 Sep 2020 07:36:44
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	01 Sep 2020 07:36:44
Data point term sent to Coder	System	01 Sep 2020 04:18:33
User entered 'left hand and foot basal cell carcinoma'	(b) (4), (b) (6) (b) (4)	01 Sep 2020 04:17:53

US3292365

Folder: Screening

Form: Medical History (15)

Generated On: 26 Nov 2020 10:54:21

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

Audit	User	Time (GMT)
User entered 'un UNK 2017'	(b) (4), (b) (6)	01 Sep 2020 04:17:53

US3292365

Folder: Screening

Form: Medical History (15)

Generated On: 26 Nov 2020 10:54:21

[Start date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	(b) (4), (b) (6)	01 Sep 2020 04:17:53

US3292365

Folder: Screening

Form: Medical History (15)

Generated On: 26 Nov 2020 10:54:21

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
User entered 'No (N)'	(b) (4), (b) (6)	01 Sep 2020 04:17:53

US3292365

Folder: Screening

Form: Medical History (15)

Generated On: 26 Nov 2020 10:54:21

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

Audit	User	Time (GMT)
User entered 'un UNK 2017'	(b) (4), (b) (6)	01 Sep 2020 04:17:53

US3292365

Folder: Screening

Form: Medical History (15)

Generated On: 26 Nov 2020 10:54:21

[Stop date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	(b) (4), (b) (6)	01 Sep 2020 04:17:53

US3292365

Folder: Screening

Form: Medical History (15)

Generated On: 26 Nov 2020 10:54:21

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

Audit	User	Time (GMT)
User entered 'Jan 2017'	System	01 Sep 2020 04:17:53

US3292365

Folder: Screening

Form: Medical History (15)

Generated On: 26 Nov 2020 10:54:21

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

Audit	User	Time (GMT)
User entered '2017'	System	01 Sep 2020 04:17:53

US3292365

Folder: Screening

Form: Medical History (15)

Generated On: 26 Nov 2020 10:54:21

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

Audit	User	Time (GMT)
User entered 'Jan 2017'	System	01 Sep 2020 04:17:53

US3292365

Folder: Screening

Form: Medical History (15)

Generated On: 26 Nov 2020 10:54:21

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

Audit	User	Time (GMT)
User entered '2017'	System	01 Sep 2020 04:17:53

US3292365

Folder: Screening

Form: Medical History (16)

Generated On: 26 Nov 2020 10:54:21

Condition

Audit	User	Time (GMT)
User closed query 'Per DM CLR: Please specify the location (bilateral, left, right) of DECREASED VISUAL ACUITY. Review and update medical history diagnosis as appropriate and ensure update to MHx is reconciled with any corresponding AE or ConMed entries, if applicable. ' (Site from DM).	(b) (4), (b) (6)	08 Oct 2020 16:19:47
User coded data point as SOC: Eye disorders, HLGT: Vision disorders, HLT: Visual impairment and blindness (excl colour blindness), PT: Visual acuity reduced, LLT: Visual acuity decreased - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	23 Sep 2020 14:43:38
User coded data point as Term Coded data point by User: Coder System - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	23 Sep 2020 14:43:38
Query 'Per DM CLR: Please specify the location (bilateral, left, right) of DECREASED VISUAL ACUITY. Review and update medical history diagnosis as appropriate and ensure update to MHx is reconciled with any corresponding AE or ConMed entries, if applicable. ' answered with 'updated' (Site from DM).	(b) (4), (b) (6)	23 Sep 2020 14:42:59
Data point term sent to Coder	System	23 Sep 2020 14:42:59
Coding entries removed.	(b) (4), (b) (6)	23 Sep 2020 14:42:50
User entered 'bilateral DECREASED VISUAL ACUITY' reason for change: Data Entry Error	(b) (4), (b) (6)	23 Sep 2020 14:42:50
User opened query 'Per DM CLR: Please specify the location (bilateral, left, right) of DECREASED VISUAL ACUITY. Review and update medical history diagnosis as appropriate and ensure update to MHx is reconciled with any corresponding AE or ConMed entries, if applicable. ' (Site from DM).	(b) (4), (b) (6)	09 Sep 2020 21:26:12
User coded data point as SOC: Eye disorders, HLGT: Vision disorders, HLT: Visual impairment and blindness (excl colour blindness), PT: Visual acuity reduced, LLT: Visual acuity decreased - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	01 Sep 2020 04:19:36
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 04:19:36
Data point term sent to Coder	System	01 Sep 2020 04:18:34

US3292365

Folder: Screening

Form: Medical History (16)

Generated On: 26 Nov 2020 10:54:21

[Condition](#)

Audit	User	Time (GMT)
User entered 'decreased visual acuity'	(b) (4), (b) (6)	01 Sep 2020 04:18:13

US3292365

Folder: Screening

Form: Medical History (16)

Generated On: 26 Nov 2020 10:54:21

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

Audit	User	Time (GMT)
User entered 'un UNK 2005'	(b) (4), (b) (6)	01 Sep 2020 04:18:13

US3292365

Folder: Screening

Form: Medical History (16)

Generated On: 26 Nov 2020 10:54:21

[Start date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	(b) (4), (b) (6)	01 Sep 2020 04:18:13

US3292365

Folder: Screening

Form: Medical History (16)

Generated On: 26 Nov 2020 10:54:21

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	(b) (4), (b) (6)	01 Sep 2020 04:18:13

US3292365

Folder: Screening

Form: Medical History (16)

Generated On: 26 Nov 2020 10:54:21

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

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	01 Sep 2020 04:18:13

US3292365

Folder: Screening

Form: Medical History (16)

Generated On: 26 Nov 2020 10:54:21

[Stop date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	(b) (4), (b) (6)	01 Sep 2020 04:18:13

US3292365

Folder: Screening

Form: Medical History (16)

Generated On: 26 Nov 2020 10:54:21

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

Audit	User	Time (GMT)
User entered 'Jan 2005'	System	01 Sep 2020 04:18:13

US3292365

Folder: Screening

Form: Medical History (16)

Generated On: 26 Nov 2020 10:54:21

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

Audit	User	Time (GMT)
User entered '2005'	System	01 Sep 2020 04:18:13

US3292365

Folder: Screening

Form: Medical History (16)

Generated On: 26 Nov 2020 10:54:21

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

Audit	User	Time (GMT)
User entered empty.	System	01 Sep 2020 04:18:13

US3292365

Folder: Screening

Form: Medical History (16)

Generated On: 26 Nov 2020 10:54:21

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

Audit	User	Time (GMT)
User entered empty.	System	01 Sep 2020 04:18:13

US3292365

Folder: Screening

Form: Medical History (17)

Generated On: 26 Nov 2020 10:54:21

[Condition](#)

Audit	User	Time (GMT)
User coded data point as SOC: Respiratory, thoracic and mediastinal disorders, HLGT: Respiratory disorders NEC, HLT: Coughing and associated symptoms, PT: Cough, LLT: Chronic cough - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	01 Sep 2020 04:19:36
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 04:19:36
Data point term sent to Coder	System	01 Sep 2020 04:18:33
User entered 'chronic cough'	(b) (4), (b) (6) (b) (4)	01 Sep 2020 04:18:32

US3292365

Folder: Screening

Form: Medical History (17)

Generated On: 26 Nov 2020 10:54:21

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

Audit	User	Time (GMT)
User entered 'un UNK 1977'	(b) (4), (b) (6)	01 Sep 2020 04:18:32

US3292365

Folder: Screening

Form: Medical History (17)

Generated On: 26 Nov 2020 10:54:21

[Start date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	(b) (4), (b) (6)	01 Sep 2020 04:18:32

US3292365

Folder: Screening

Form: Medical History (17)

Generated On: 26 Nov 2020 10:54:21

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	(b) (4), (b) (6)	01 Sep 2020 04:18:32

US3292365

Folder: Screening

Form: Medical History (17)

Generated On: 26 Nov 2020 10:54:21

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

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	01 Sep 2020 04:18:32

US3292365

Folder: Screening

Form: Medical History (17)

Generated On: 26 Nov 2020 10:54:21

[Stop date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	(b) (4), (b) (6)	01 Sep 2020 04:18:32

US3292365

Folder: Screening

Form: Medical History (17)

Generated On: 26 Nov 2020 10:54:21

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

Audit	User	Time (GMT)
User entered 'Jan 1977'	System	01 Sep 2020 04:18:32

US3292365

Folder: Screening

Form: Medical History (17)

Generated On: 26 Nov 2020 10:54:21

Start Year (derived)

Audit	User	Time (GMT)
User entered '1977'	System	01 Sep 2020 04:18:32

US3292365

Folder: Screening

Form: Medical History (17)

Generated On: 26 Nov 2020 10:54:21

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

Audit	User	Time (GMT)
User entered empty.	System	01 Sep 2020 04:18:32

US3292365

Folder: Screening

Form: Medical History (17)

Generated On: 26 Nov 2020 10:54:21

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

Audit	User	Time (GMT)
User entered empty.	System	01 Sep 2020 04:18:32

US3292365

Folder: Screening

Form: Medical History (18)

Generated On: 26 Nov 2020 10:54:21

[Condition](#)

Audit	User	Time (GMT)
User coded data point as SOC: Respiratory, thoracic and mediastinal disorders, HLGT: Bronchial disorders (excl neoplasms), HLT: Bronchospasm and obstruction, PT: Asthma, LLT: Asthma - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	01 Sep 2020 04:20:37
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 04:20:37
Data point term sent to Coder	System	01 Sep 2020 04:19:34
User entered 'asthma'	(b) (4), (b) (6) (b) (4)	01 Sep 2020 04:18:46

US3292365

Folder: Screening

Form: Medical History (18)

Generated On: 26 Nov 2020 10:54:21

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

Audit	User	Time (GMT)
User entered 'UN UNK 1998' reason for change:	Kevin Martinez (b) (4)	05 Nov 2020 19:17:00
Data Entry Error	(b) (4)	
User entered 'un UNK 2009'	(b) (4), (b) (6)	01 Sep 2020 04:18:46

US3292365

Folder: Screening

Form: Medical History (18)

Generated On: 26 Nov 2020 10:54:21

[Start date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	(b) (4), (b) (6)	01 Sep 2020 04:18:46

US3292365

Folder: Screening

Form: Medical History (18)

Generated On: 26 Nov 2020 10:54:21

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	(b) (4), (b) (6)	01 Sep 2020 04:18:46

US3292365

Folder: Screening

Form: Medical History (18)

Generated On: 26 Nov 2020 10:54:21

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

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	01 Sep 2020 04:18:46

US3292365

Folder: Screening

Form: Medical History (18)

Generated On: 26 Nov 2020 10:54:21

[Stop date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	(b) (4), (b) (6)	01 Sep 2020 04:18:46

US3292365

Folder: Screening

Form: Medical History (18)

Generated On: 26 Nov 2020 10:54:21

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

Audit	User	Time (GMT)
User entered 'Jan 1998'	System	05 Nov 2020 19:17:00
User entered 'Jan 2009'	System	01 Sep 2020 04:18:46

US3292365

Folder: Screening

Form: Medical History (18)

Generated On: 26 Nov 2020 10:54:21

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

Audit	User	Time (GMT)
User entered '1998'	System	05 Nov 2020 19:17:00
User entered '2009'	System	01 Sep 2020 04:18:46

US3292365

Folder: Screening

Form: Medical History (18)

Generated On: 26 Nov 2020 10:54:21

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

Audit	User	Time (GMT)
User entered empty.	System	01 Sep 2020 04:18:46

US3292365

Folder: Screening

Form: Medical History (18)

Generated On: 26 Nov 2020 10:54:21

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

Audit	User	Time (GMT)
User entered empty.	System	01 Sep 2020 04:18:46

US3292365

Folder: Screening

Form: Medical History (19)

Generated On: 26 Nov 2020 10:54:21

Condition

Audit	User	Time (GMT)
User closed query 'Per DM CLR: Please update the condition to confirm if the COLON POLYP was benign or cancerous. Review and update medical history diagnosis as appropriate and ensure update to MHx is reconciled with any corresponding AE or ConMed entries, if applicable. ' (Site from DM).	(b) (4), (b) (6)	08 Oct 2020 16:20:03
User coded data point as SOC: Gastrointestinal disorders, HLGT: Benign neoplasms gastrointestinal, HLT: Benign neoplasms gastrointestinal (excl oral cavity), PT: Large intestine polyp, LLT: Benign colonic polyp - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	23 Sep 2020 20:27:14
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	23 Sep 2020 20:27:14
Query 'Per DM CLR: Please update the condition to confirm if the COLON POLYP was benign or cancerous. Review and update medical history diagnosis as appropriate and ensure update to MHx is reconciled with any corresponding AE or ConMed entries, if applicable. ' answered with 'updated' (Site from DM).	(b) (4), (b) (6)	23 Sep 2020 14:42:08
Data point term sent to Coder	System	23 Sep 2020 14:41:58
Coding entries removed.	(b) (4), (b) (6)	23 Sep 2020 14:41:56
User entered 'COLON POLYP benign' reason for change: Data Entry Error	(b) (4), (b) (6)	23 Sep 2020 14:41:56
User opened query 'Per DM CLR: Please update the condition to confirm if the COLON POLYP was benign or cancerous. Review and update medical history diagnosis as appropriate and ensure update to MHx is reconciled with any corresponding AE or ConMed entries, if applicable. ' (Site from DM).	(b) (4), (b) (6)	09 Sep 2020 21:26:43
User coded data point as SOC: Gastrointestinal disorders, HLGT: Benign neoplasms gastrointestinal, HLT: Benign neoplasms gastrointestinal (excl oral cavity), PT: Large intestine polyp, LLT: Colonic polyp - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	01 Sep 2020 04:21:37
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 04:21:37
Data point term sent to Coder	System	01 Sep 2020 04:20:38

US3292365

Folder: Screening

Form: Medical History (19)

Generated On: 26 Nov 2020 10:54:21

[Condition](#)

Audit	User	Time (GMT)
User entered 'colon polyp'	(b) (4), (b) (6)	01 Sep 2020 04:20:07

US3292365

Folder: Screening

Form: Medical History (19)

Generated On: 26 Nov 2020 10:54:21

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

Audit	User	Time (GMT)
User entered 'un UNK 2012'	(b) (4), (b) (6)	01 Sep 2020 04:20:07

US3292365

Folder: Screening

Form: Medical History (19)

Generated On: 26 Nov 2020 10:54:21

[Start date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	(b) (4), (b) (6)	01 Sep 2020 04:20:07

US3292365

Folder: Screening

Form: Medical History (19)

Generated On: 26 Nov 2020 10:54:21

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
User entered 'No (N)'	(b) (4), (b) (6)	01 Sep 2020 04:20:07

US3292365

Folder: Screening

Form: Medical History (19)

Generated On: 26 Nov 2020 10:54:21

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

Audit	User	Time (GMT)
User entered 'un UNK 2015'	(b) (4), (b) (6)	01 Sep 2020 04:20:07

US3292365

Folder: Screening

Form: Medical History (19)

Generated On: 26 Nov 2020 10:54:21

[Stop date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	(b) (4), (b) (6)	01 Sep 2020 04:20:07

US3292365

Folder: Screening

Form: Medical History (19)

Generated On: 26 Nov 2020 10:54:21

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

Audit	User	Time (GMT)
User entered 'Jan 2012'	System	01 Sep 2020 04:20:07

US3292365

Folder: Screening

Form: Medical History (19)

Generated On: 26 Nov 2020 10:54:21

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

Audit	User	Time (GMT)
User entered '2012'	System	01 Sep 2020 04:20:07

US3292365

Folder: Screening

Form: Medical History (19)

Generated On: 26 Nov 2020 10:54:21

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

Audit	User	Time (GMT)
User entered 'Jan 2015'	System	01 Sep 2020 04:20:07

US3292365

Folder: Screening

Form: Medical History (19)

Generated On: 26 Nov 2020 10:54:21

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

Audit	User	Time (GMT)
User entered '2015'	System	01 Sep 2020 04:20:07

US3292365

Folder: Screening

Form: Medical History (20)

Generated On: 26 Nov 2020 10:54:21

[Condition](#)

Audit	User	Time (GMT)
User coded data point as SOC: Psychiatric disorders, HLGT: Anxiety disorders and symptoms, HLT: Anxiety symptoms, PT: Anxiety, LLT: Anxiety - version MedDRA\\23.0.	Coder Import (b) (4)	01 Sep 2020 04:22:38
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	01 Sep 2020 04:22:38
Data point term sent to Coder	System	01 Sep 2020 04:21:38
User entered 'anxiety'	(b) (4), (b) (6)	01 Sep 2020 04:20:45

US3292365

Folder: Screening

Form: Medical History (20)

Generated On: 26 Nov 2020 10:54:21

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

Audit	User	Time (GMT)
User entered 'un UNK 2010'	(b) (4), (b) (6)	01 Sep 2020 04:20:45

US3292365

Folder: Screening

Form: Medical History (20)

Generated On: 26 Nov 2020 10:54:21

[Start date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	(b) (4), (b) (6)	01 Sep 2020 04:20:45

US3292365

Folder: Screening

Form: Medical History (20)

Generated On: 26 Nov 2020 10:54:21

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	(b) (4), (b) (6)	01 Sep 2020 04:20:45

US3292365

Folder: Screening

Form: Medical History (20)

Generated On: 26 Nov 2020 10:54:21

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

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	01 Sep 2020 04:20:45

US3292365

Folder: Screening

Form: Medical History (20)

Generated On: 26 Nov 2020 10:54:21

[Stop date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	(b) (4), (b) (6)	01 Sep 2020 04:20:45

US3292365

Folder: Screening

Form: Medical History (20)

Generated On: 26 Nov 2020 10:54:21

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

Audit	User	Time (GMT)
User entered 'Jan 2010'	System	01 Sep 2020 04:20:45

US3292365

Folder: Screening

Form: Medical History (20)

Generated On: 26 Nov 2020 10:54:21

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

Audit	User	Time (GMT)
User entered '2010'	System	01 Sep 2020 04:20:45

US3292365

Folder: Screening

Form: Medical History (20)

Generated On: 26 Nov 2020 10:54:21

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

Audit	User	Time (GMT)
User entered empty.	System	01 Sep 2020 04:20:45

US3292365

Folder: Screening

Form: Medical History (20)

Generated On: 26 Nov 2020 10:54:21

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

Audit	User	Time (GMT)
User entered empty.	System	01 Sep 2020 04:20:45

US3292365

Folder: Screening

Form: Medical History (21)

Generated On: 26 Nov 2020 10:54:21

[Condition](#)

Audit	User	Time (GMT)
User coded data point as SOC: Nervous system disorders, HLGT: Headaches, HLT: Migraine headaches, PT: Migraine, LLT: Migraine - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	01 Sep 2020 04:22:39
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 04:22:39
Data point term sent to Coder	System	01 Sep 2020 04:21:39
User entered 'migraines'	(b) (4), (b) (6) (b) (4)	01 Sep 2020 04:21:04

US3292365

Folder: Screening

Form: Medical History (21)

Generated On: 26 Nov 2020 10:54:21

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

Audit	User	Time (GMT)
User entered 'un UNK 1993'	(b) (4), (b) (6)	01 Sep 2020 04:21:04

US3292365

Folder: Screening

Form: Medical History (21)

Generated On: 26 Nov 2020 10:54:21

[Start date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	(b) (4), (b) (6)	01 Sep 2020 04:21:04

US3292365

Folder: Screening

Form: Medical History (21)

Generated On: 26 Nov 2020 10:54:21

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	(b) (4), (b) (6)	01 Sep 2020 04:21:04

US3292365

Folder: Screening

Form: Medical History (21)

Generated On: 26 Nov 2020 10:54:21

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

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	01 Sep 2020 04:21:04

US3292365

Folder: Screening

Form: Medical History (21)

Generated On: 26 Nov 2020 10:54:21

[Stop date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	(b) (4), (b) (6)	01 Sep 2020 04:21:04

US3292365

Folder: Screening

Form: Medical History (21)

Generated On: 26 Nov 2020 10:54:21

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

Audit	User	Time (GMT)
User entered 'Jan 1993'	System	01 Sep 2020 04:21:04

US3292365

Folder: Screening

Form: Medical History (21)

Generated On: 26 Nov 2020 10:54:21

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

Audit	User	Time (GMT)
User entered '1993'	System	01 Sep 2020 04:21:04

US3292365

Folder: Screening

Form: Medical History (21)

Generated On: 26 Nov 2020 10:54:21

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

Audit	User	Time (GMT)
User entered empty.	System	01 Sep 2020 04:21:04

US3292365

Folder: Screening

Form: Medical History (21)

Generated On: 26 Nov 2020 10:54:21

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

Audit	User	Time (GMT)
User entered empty.	System	01 Sep 2020 04:21:04

US3292365

Folder: Screening

Form: Medical History (22)

Generated On: 26 Nov 2020 10:54:21

Condition

Audit	User	Time (GMT)
User closed query 'Per DM CLR: Please specify the location and/or type of ACNE. Review and update medical history diagnosis as appropriate and ensure update to MHx is reconciled with any corresponding AE or ConMed entries, if applicable. ' (Site from DM).	(b) (4), (b) (6)	15 Oct 2020 23:22:18
Query 'Per DM CLR: Please specify the location and/or type of ACNE. Review and update medical history diagnosis as appropriate and ensure update to MHx is reconciled with any corresponding AE or ConMed entries, if applicable. ' answered with 'unknown, attempted patient contact no answer' (Site from DM).	(b) (4), (b) (6)	23 Sep 2020 14:44:05
User opened query 'Per DM CLR: Please specify the location and/or type of ACNE. Review and update medical history diagnosis as appropriate and ensure update to MHx is reconciled with any corresponding AE or ConMed entries, if applicable. ' (Site from DM).	(b) (4), (b) (6)	09 Sep 2020 21:27:12
User coded data point as SOC: Skin and subcutaneous tissue disorders, HLT: Skin appendage conditions, HLT: Acnes, PT: Acne, LLT: Acne - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	01 Sep 2020 04:22:39
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 04:22:39
Data point term sent to Coder	System	01 Sep 2020 04:21:39
User entered 'acne'	(b) (4), (b) (6)	01 Sep 2020 04:21:17

US3292365

Folder: Screening

Form: Medical History (22)

Generated On: 26 Nov 2020 10:54:21

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

Audit	User	Time (GMT)
User entered 'un UNK 1970'	(b) (4), (b) (6)	01 Sep 2020 04:21:17

US3292365

Folder: Screening

Form: Medical History (22)

Generated On: 26 Nov 2020 10:54:21

[Start date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	(b) (4), (b) (6)	01 Sep 2020 04:21:17

US3292365

Folder: Screening

Form: Medical History (22)

Generated On: 26 Nov 2020 10:54:21

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	(b) (4), (b) (6)	01 Sep 2020 04:21:17

US3292365

Folder: Screening

Form: Medical History (22)

Generated On: 26 Nov 2020 10:54:21

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

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	01 Sep 2020 04:21:17

US3292365

Folder: Screening

Form: Medical History (22)

Generated On: 26 Nov 2020 10:54:21

[Stop date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	(b) (4), (b) (6)	01 Sep 2020 04:21:17

US3292365

Folder: Screening

Form: Medical History (22)

Generated On: 26 Nov 2020 10:54:21

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

Audit	User	Time (GMT)
User entered 'Jan 1970'	System	01 Sep 2020 04:21:17

US3292365

Folder: Screening

Form: Medical History (22)

Generated On: 26 Nov 2020 10:54:21

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

Audit	User	Time (GMT)
User entered '1970'	System	01 Sep 2020 04:21:17

US3292365

Folder: Screening

Form: Medical History (22)

Generated On: 26 Nov 2020 10:54:21

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

Audit	User	Time (GMT)
User entered empty.	System	01 Sep 2020 04:21:17

US3292365

Folder: Screening

Form: Medical History (22)

Generated On: 26 Nov 2020 10:54:21

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

Audit	User	Time (GMT)
User entered empty.	System	01 Sep 2020 04:21:17

US3292365

Folder: Screening

Form: Medical History (23)

Generated On: 26 Nov 2020 10:54:21

Condition

Audit	User	Time (GMT)
User coded data point as SOC: Vascular disorders, HLGT: Vascular disorders NEC, HLT: Peripheral vascular disorders NEC, PT: Hot flush, LLT: Hot flashes - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	01 Sep 2020 04:23:41
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 04:23:41
Data point term sent to Coder	System	01 Sep 2020 04:22:40
User entered 'hot flashes'	(b) (4), (b) (6) (b) (4)	01 Sep 2020 04:22:01

US3292365

Folder: Screening

Form: Medical History (23)

Generated On: 26 Nov 2020 10:54:21

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

Audit	User	Time (GMT)
User entered 'un UNK 2008'	(b) (4), (b) (6)	01 Sep 2020 04:22:01

US3292365

Folder: Screening

Form: Medical History (23)

Generated On: 26 Nov 2020 10:54:21

[Start date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	(b) (4), (b) (6)	01 Sep 2020 04:22:01

US3292365

Folder: Screening

Form: Medical History (23)

Generated On: 26 Nov 2020 10:54:21

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	(b) (4), (b) (6)	01 Sep 2020 04:22:01

US3292365

Folder: Screening

Form: Medical History (23)

Generated On: 26 Nov 2020 10:54:21

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

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	01 Sep 2020 04:22:01

US3292365

Folder: Screening

Form: Medical History (23)

Generated On: 26 Nov 2020 10:54:21

[Stop date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	(b) (4), (b) (6)	01 Sep 2020 04:22:01

US3292365

Folder: Screening

Form: Medical History (23)

Generated On: 26 Nov 2020 10:54:21

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

Audit	User	Time (GMT)
User entered 'Jan 2008'	System	01 Sep 2020 04:22:01

US3292365

Folder: Screening

Form: Medical History (23)

Generated On: 26 Nov 2020 10:54:21

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

Audit	User	Time (GMT)
User entered '2008'	System	01 Sep 2020 04:22:01

US3292365

Folder: Screening

Form: Medical History (23)

Generated On: 26 Nov 2020 10:54:21

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

Audit	User	Time (GMT)
User entered empty.	System	01 Sep 2020 04:22:01

US3292365

Folder: Screening

Form: Medical History (23)

Generated On: 26 Nov 2020 10:54:21

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

Audit	User	Time (GMT)
User entered empty.	System	01 Sep 2020 04:22:01

US3292365

Folder: Screening

Form: Medical History (24)

Generated On: 26 Nov 2020 10:54:21

Condition

Audit	User	Time (GMT)
User closed query 'Per DM CLR: Please update the condition to confirm if the LEFT OVARIAN CYST was benign or cancerous. Review and update medical history diagnosis as appropriate and ensure update to MHx is reconciled with any corresponding AE or ConMed entries, if applicable. ' (Site from DM).	(b) (4), (b) (6)	08 Oct 2020 16:20:29
User coded data point as SOC: Reproductive system and breast disorders, HLGT: Ovarian and fallopian tube disorders, HLT: Ovarian and fallopian tube cysts and neoplasms, PT: Ovarian cyst, LLT: Benign ovarian cyst - version MedDRA\\23.0.	Coder Import (b) (4)	23 Sep 2020 19:03:49
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4)	23 Sep 2020 19:03:49
Data point term sent to Coder	System	23 Sep 2020 14:45:11
Query 'Per DM CLR: Please update the condition to confirm if the LEFT OVARIAN CYST was benign or cancerous. Review and update medical history diagnosis as appropriate and ensure update to MHx is reconciled with any corresponding AE or ConMed entries, if applicable. ' answered with 'updated' (Site from DM).	(b) (4), (b) (6)	23 Sep 2020 14:44:36
Coding entries removed.	(b) (4), (b) (6)	23 Sep 2020 14:44:27
User entered 'benign LEFT OVARIAN CYST' reason for change: Data Entry Error	(b) (4), (b) (6)	23 Sep 2020 14:44:27
User opened query 'Per DM CLR: Please update the condition to confirm if the LEFT OVARIAN CYST was benign or cancerous. Review and update medical history diagnosis as appropriate and ensure update to MHx is reconciled with any corresponding AE or ConMed entries, if applicable. ' (Site from DM).	(b) (4), (b) (6)	09 Sep 2020 21:27:39
User coded data point as SOC: Reproductive system and breast disorders, HLGT: Ovarian and fallopian tube disorders, HLT: Ovarian and fallopian tube cysts and neoplasms, PT: Ovarian cyst, LLT: Ovarian cyst - version MedDRA\\23.0.	Coder Import (b) (4)	01 Sep 2020 07:36:44
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4)	01 Sep 2020 07:36:44
Data point term sent to Coder	System	01 Sep 2020 04:23:41

US3292365

Folder: Screening

Form: Medical History (24)

Generated On: 26 Nov 2020 10:54:21

[Condition](#)

Audit	User	Time (GMT)
User entered 'left ovarian cyst'	(b) (4), (b) (6)	01 Sep 2020 04:22:41

US3292365

Folder: Screening

Form: Medical History (24)

Generated On: 26 Nov 2020 10:54:21

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

Audit	User	Time (GMT)
User entered 'un UNK 2015'	(b) (4), (b) (6)	01 Sep 2020 04:22:41

US3292365

Folder: Screening

Form: Medical History (24)

Generated On: 26 Nov 2020 10:54:21

[Start date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	(b) (4), (b) (6)	01 Sep 2020 04:22:41

US3292365

Folder: Screening

Form: Medical History (24)

Generated On: 26 Nov 2020 10:54:21

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	(b) (4), (b) (6)	01 Sep 2020 04:22:41

US3292365

Folder: Screening

Form: Medical History (24)

Generated On: 26 Nov 2020 10:54:21

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

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	01 Sep 2020 04:22:41

US3292365

Folder: Screening

Form: Medical History (24)

Generated On: 26 Nov 2020 10:54:21

[Stop date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	(b) (4), (b) (6)	01 Sep 2020 04:22:41

US3292365

Folder: Screening

Form: Medical History (24)

Generated On: 26 Nov 2020 10:54:21

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

Audit	User	Time (GMT)
User entered 'Jan 2015'	System	01 Sep 2020 04:22:41

US3292365

Folder: Screening

Form: Medical History (24)

Generated On: 26 Nov 2020 10:54:21

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

Audit	User	Time (GMT)
User entered '2015'	System	01 Sep 2020 04:22:41

US3292365

Folder: Screening

Form: Medical History (24)

Generated On: 26 Nov 2020 10:54:21

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

Audit	User	Time (GMT)
User entered empty.	System	01 Sep 2020 04:22:41

US3292365

Folder: Screening

Form: Medical History (24)

Generated On: 26 Nov 2020 10:54:21

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

Audit	User	Time (GMT)
User entered empty.	System	01 Sep 2020 04:22:41

US3292365

Folder: Screening

Form: Medical History (25)

Generated On: 26 Nov 2020 10:54:21

Condition

Audit	User	Time (GMT)
User coded data point as SOC: Social circumstances, HLGT: Age related factors, HLT: Age related issues, PT: Postmenopause, LLT: Postmenopause - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	23 Sep 2020 14:49:35
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	23 Sep 2020 14:49:35
Data point term sent to Coder	System	23 Sep 2020 14:48:55
User entered 'Post-Menopausal'	(b) (4), (b) (6) (b) (4)	23 Sep 2020 14:48:29

US3292365

Folder: Screening

Form: Medical History (25)

Generated On: 26 Nov 2020 10:54:21

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

Audit	User	Time (GMT)
User entered 'UN UNK 2014'	(b) (4), (b) (6)	23 Sep 2020 14:48:29

US3292365

Folder: Screening

Form: Medical History (25)

Generated On: 26 Nov 2020 10:54:21

[Start date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	(b) (4), (b) (6)	23 Sep 2020 14:48:29

US3292365

Folder: Screening

Form: Medical History (25)

Generated On: 26 Nov 2020 10:54:21

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	(b) (4), (b) (6)	23 Sep 2020 14:48:29

US3292365

Folder: Screening

Form: Medical History (25)

Generated On: 26 Nov 2020 10:54:21

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

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	23 Sep 2020 14:48:29

US3292365

Folder: Screening

Form: Medical History (25)

Generated On: 26 Nov 2020 10:54:21

[Stop date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	(b) (4), (b) (6)	23 Sep 2020 14:48:29

US3292365

Folder: Screening

Form: Medical History (25)

Generated On: 26 Nov 2020 10:54:21

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

Audit	User	Time (GMT)
User entered 'Jan 2014'	System	23 Sep 2020 14:48:29

US3292365

Folder: Screening

Form: Medical History (25)

Generated On: 26 Nov 2020 10:54:21

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

Audit	User	Time (GMT)
User entered '2014'	System	23 Sep 2020 14:48:29

US3292365

Folder: Screening

Form: Medical History (25)

Generated On: 26 Nov 2020 10:54:21

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

Audit	User	Time (GMT)
User entered empty.	System	23 Sep 2020 14:48:29

US3292365

Folder: Screening

Form: Medical History (25)

Generated On: 26 Nov 2020 10:54:21

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

Audit	User	Time (GMT)
User entered empty.	System	23 Sep 2020 14:48:29

US3292365

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 10:54:21

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	(b) (4), (b) (6)	01 Sep 2020 04:26:16

US3292365

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 10:54:21

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
User entered '29 Aug 2020'	(b) (4), (b) (6)	01 Sep 2020 04:26:16

US3292365

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 10:54:21

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

Audit	User	Time (GMT)
User entered '10:11'	(b) (4), (b) (6)	01 Sep 2020 04:26:16

US3292365

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 10:54:21

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

Audit	User	Time (GMT)
User entered '29 Aug 2020 10:11'	System	01 Sep 2020 04:26:16

US3292365

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 10:54:21

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

Audit	User	Time (GMT)
User entered '179.4' cm	(b) (4), (b) (6)	01 Sep 2020 04:26:16
DataPoint set to visible.	System	29 Aug 2020 18:21:02

US3292365

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 10:54:21

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

Audit	User	Time (GMT)
User entered '92.0' kg	(b) (4), (b) (6)	01 Sep 2020 04:26:16
DataPoint set to visible.	System	29 Aug 2020 18:21:02

US3292365

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 10:54:21

BMI (xxx.x)

Audit	User	Time (GMT)
User entered '28.58531'	System	01 Sep 2020 04:26:16
DataPoint set to visible.	System	29 Aug 2020 18:21:02

US3292365

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 10:54:21

[BMI units](#)

Audit	User	Time (GMT)
User entered 'kg/m2'	System	01 Sep 2020 04:26:16
DataPoint set to visible.	System	29 Aug 2020 18:21:02

US3292365

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 10:54:21

Temperature (xxx.x)

Audit	User	Time (GMT)
User entered missing code ND - Not Done.	(b) (4), (b) (6)	01 Sep 2020 04:26:16

US3292365

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 10:54:21

[Route of measurement](#)

Audit	User	Time (GMT)
User entered 'Other (Other)'	(b) (4), (b) (6)	01 Sep 2020 04:26:16

US3292365

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 10:54:21

[If Other, specify](#)

Audit	User	Time (GMT)
User entered missing code ND - Not Done.	(b) (4), (b) (6)	01 Sep 2020 04:26:16

US3292365

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 10:54:21

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
User entered missing code ND - Not Done.	(b) (4), (b) (6)	01 Sep 2020 04:26:16

US3292365

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 10:54:21

[Pulse units](#)

Audit	User	Time (GMT)
User entered 'bpm'	System	01 Sep 2020 04:26:16

US3292365

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 10:54:21

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

Audit	User	Time (GMT)
User entered missing code ND - Not Done.	(b) (4), (b) (6)	01 Sep 2020 04:26:16

US3292365

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 10:54:21

[Respiratory Rate units](#)

Audit	User	Time (GMT)
User entered 'breaths/min'	System	01 Sep 2020 04:26:16

US3292365

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 10:54:21

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
User entered missing code ND - Not Done.	(b) (4), (b) (6)	01 Sep 2020 04:26:16

US3292365

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 10:54:21

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered 'mmHg'	System	01 Sep 2020 04:26:16

US3292365

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 10:54:21

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
User entered missing code ND - Not Done.	(b) (4), (b) (6)	01 Sep 2020 04:26:16

US3292365

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 10:54:21

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered 'mmHg'	System	01 Sep 2020 04:26:16

US3292365

Folder: Screening

Form: Physical Examination

Generated On: 26 Nov 2020 10:54:21

Was the physical examination performed?

Audit	User	Time (GMT)
User entered 'Yes (Y)'	(b) (4), (b) (6)	01 Sep 2020 04:24:29

US3292365

Folder: Screening

Form: Physical Examination

Generated On: 26 Nov 2020 10:54:21

Date of examination (*dd MMM yyyy*)

Audit	User	Time (GMT)
User entered '29 Aug 2020'	(b) (4), (b) (6)	01 Sep 2020 04:24:29

US3292365

Folder: Screening

Form: Childbearing Potential

Generated On: 26 Nov 2020 10:54:21

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
User entered '29 Aug 2020'	(b) (4), (b) (6)	01 Sep 2020 04:24:16

US3292365

Folder: Screening

Form: Childbearing Potential

Generated On: 26 Nov 2020 10:54:21

Is the participant of childbearing potential?

Audit	User	Time (GMT)
User entered 'No (N)'	(b) (4), (b) (6)	01 Sep 2020 04:24:16

US3292365

Folder: Screening

Form: Childbearing Potential

Generated On: 26 Nov 2020 10:54:21

[If No, what is the reason?](#)

Audit	User	Time (GMT)
User entered 'Post-menopausal (POST-MENOPAUSAL)'	(b) (4), (b) (6)	01 Sep 2020 04:24:16

US3292365

Folder: Screening

Form: Childbearing Potential

Generated On: 26 Nov 2020 10:54:21

If Partner medically sterile or Other, specify

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	01 Sep 2020 04:24:16

US3292365

Folder: Screening

Form: Childbearing Potential

Generated On: 26 Nov 2020 10:54:21

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

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	01 Sep 2020 04:24:16

US3292365

Folder: Screening

Form: Childbearing Potential

Generated On: 26 Nov 2020 10:54:21

[Date of surgery unknown](#)

Audit	User	Time (GMT)
User entered '0'	(b) (4), (b) (6)	01 Sep 2020 04:24:16

US3292365

Folder: Screening

Form: Childbearing Potential

Generated On: 26 Nov 2020 10:54:21

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

Audit	User	Time (GMT)
User entered 'un UNK 2014'	(b) (4), (b) (6)	01 Sep 2020 04:24:16

US3292365

Folder: Screening

Form: Childbearing Potential

Generated On: 26 Nov 2020 10:54:21

[Date of last menstruation unknown](#)

Audit	User	Time (GMT)
User entered '0'	(b) (4), (b) (6)	01 Sep 2020 04:24:16

US3292365

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 10:54:21

Healthcare workers (e.g., doctors, nurses, dentists, hospital support staff, morgue/mortuary workers)

Audit	User	Time (GMT)
User entered 'No (N)'	(b) (4), (b) (6)	01 Sep 2020 04:27:40

US3292365

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 10:54:21

Emergency Response (e.g., Law enforcement officers, Firefighters, emergency medical service workers)

Audit	User	Time (GMT)
User entered 'No (N)'	(b) (4), (b) (6)	01 Sep 2020 04:27:40

US3292365

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 10:54:21

Retail or Restaurant Operations, particularly those in critical and/high-customer volume (e.g., grocery, convenience, hardware, big-box stores)

Audit	User	Time (GMT)
User entered 'No (N)'	(b) (4), (b) (6)	01 Sep 2020 04:27:40

US3292365

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 10:54:21

Manufacturing & Production Operations with inherent overcrowding (e.g., factory workers, meat/food processing plants)

Audit	User	Time (GMT)
User entered 'No (N)'	(b) (4), (b) (6)	01 Sep 2020 04:27:40

US3292365

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 10:54:21

[Warehouse shipping and fulfillment centers and jobs \(e.g., Amazon facilities\)](#)

Audit	User	Time (GMT)
User entered 'No (N)'	(b) (4), (b) (6)	01 Sep 2020 04:27:40

US3292365

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 10:54:21

Transportation and delivery services (e.g., airlines, public transit, taxi/UBER, fed ex/UPS, postal workers)

Audit	User	Time (GMT)
User entered 'No (N)'	(b) (4), (b) (6)	01 Sep 2020 04:27:40

US3292365

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 10:54:21

Border Protection and Military Personnel (e.g., TSA, custom and border protection agents, military personnel not social distancing)

Audit	User	Time (GMT)
User entered 'No (N)'	(b) (4), (b) (6)	01 Sep 2020 04:27:40

US3292365

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 10:54:21

Personal Care and in-home services (e.g., barber/salon/spa, in-home repair services, electricians, plumbers, janitorial services)

Audit	User	Time (GMT)
User entered 'No (N)'	(b) (4), (b) (6)	01 Sep 2020 04:27:40

US3292365

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 10:54:21

Hospitality and Tourism Workers (e.g., hotel, casino, amusement/theme park, entertainment, ski resorts)

Audit	User	Time (GMT)
User entered 'No (N)'	(b) (4), (b) (6)	01 Sep 2020 04:27:40

US3292365

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 10:54:21

Pastoral, Social or Public Health Workers requiring frequent contact with community members (e.g., social workers, volunteers, religious clergy)

Audit	User	Time (GMT)
User entered 'No (N)'	(b) (4), (b) (6)	01 Sep 2020 04:27:40

US3292365

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 10:54:21

Educators and Students (e.g., teachers, administrators, support staff, and students interacting in face-to-face school setting)

Audit	User	Time (GMT)
User entered 'No (N)'	(b) (4), (b) (6)	01 Sep 2020 04:27:40

US3292365

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 10:54:21

[Other](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	(b) (4), (b) (6)	01 Sep 2020 04:27:40

US3292365

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 10:54:21

[Specify](#)

Audit	User	Time (GMT)
User entered 'frequent grocery store, gyms with high customer volume'	(b) (4), (b) (6)	01 Sep 2020 04:27:40

US3292365

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 10:54:21

No Risk Identified

Audit	User	Time (GMT)
User entered '0'	(b) (4), (b) (6)	01 Sep 2020 04:27:40

US3292365

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 10:54:21

Resides in Nursing Home or Assisted Living Facility

Audit	User	Time (GMT)
User entered '0'	(b) (4), (b) (6)	01 Sep 2020 04:27:40

US3292365

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 10:54:21

Resides in Multi-family dwelling (e.g., cohabitation in dwelling with > 5 people, includes grandparents living with children < 18yrs)

Audit	User	Time (GMT)
User entered '0'	(b) (4), (b) (6)	01 Sep 2020 04:27:40

US3292365

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 10:54:21

Resides in high density housing (e.g., high rise apartments with shared entrances or elevators)

Audit	User	Time (GMT)
User entered '0'	(b) (4), (b) (6)	01 Sep 2020 04:27:40

US3292365

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 10:54:21

Resides in low density, multi-family setting without (e.g., apartments complex without shared entrances or elevators, duplexes)

Audit	User	Time (GMT)
User entered '0'	(b) (4), (b) (6)	01 Sep 2020 04:27:40

US3292365

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 10:54:21

[Resides in a single family home](#) (i.e., detached housing)

Audit	User	Time (GMT)
User entered 'I'	(b) (4), (b) (6)	01 Sep 2020 04:27:40

US3292365

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 10:54:21

[Other](#)

Audit	User	Time (GMT)
User entered '0'	(b) (4), (b) (6)	01 Sep 2020 04:27:40

US3292365

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 10:54:21

[Specify](#)

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	01 Sep 2020 04:27:40

US3292365

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 26 Nov 2020 10:54:21

[Was this visit performed?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	(b) (4), (b) (6)	01 Sep 2020 04:25:28

US3292365

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 26 Nov 2020 10:54:21

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

Audit	User	Time (GMT)
User entered '29 Aug 2020'	(b) (4), (b) (6)	01 Sep 2020 04:25:28

US3292365

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 26 Nov 2020 10:54:21

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

Audit	User	Time (GMT)
User entered 'Clinic (Clinic)'	(b) (4), (b) (6)	01 Sep 2020 04:25:28

US3292365

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 26 Nov 2020 10:54:21

[Folder OID](#)

Audit	User	Time (GMT)
User entered 'VISIT1'	System	01 Sep 2020 04:25:28

US3292365

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 26 Nov 2020 10:54:21

What was the date of randomization? (*dd MMM yyyy*)

Audit	User	Time (GMT)
User entered '29 AUG 2020'	RWS_ENDPOINT ENDPOINT (b) (4) <div></div>	29 Aug 2020 17:40:36

US3292365

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 26 Nov 2020 10:54:21

What was the participant's randomization number?

Audit	User	Time (GMT)
User entered '109997'	RWS_ENDPOINT ENDPOINT (b) (4) <div></div>	29 Aug 2020 17:40:36

US3292365

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 26 Nov 2020 10:54:21

[In what Cohort was the participant enrolled?](#)

Audit	User	Time (GMT)
User entered '>=18 and <65 years and not at risk (1)'	RWS_ENDPOINT ENDPOINT (b) (4) <div></div>	29 Aug 2020 17:40:36

US3292365

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 26 Nov 2020 10:54:21

Chronic lung disease (eg, emphysema and chronic bronchitis, idiopathic pulmonary fibrosis and cystic fibrosis, or moderate to severe asthma)

Audit	User	Time (GMT)
User entered 'No (N)'	(b) (4), (b) (6)	01 Sep 2020 04:25:18

US3292365

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 26 Nov 2020 10:54:21

Significant cardiac disease (eg, heart failure, coronary artery disease, congenital heart disease, cardiomyopathies, and pulmonary hypertension)

Audit	User	Time (GMT)
User entered 'No (N)'	(b) (4), (b) (6)	01 Sep 2020 04:25:18

US3292365

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 26 Nov 2020 10:54:21

Severe obesity (body mass index > or = 40kg/m2

Audit	User	Time (GMT)
User entered 'No (N)'	(b) (4), (b) (6)	01 Sep 2020 04:25:18

US3292365

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 26 Nov 2020 10:54:21

Diabetes (Type I, Type 2, or gestational)

Audit	User	Time (GMT)
User entered 'No (N)'	(b) (4), (b) (6)	01 Sep 2020 04:25:18

US3292365

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 26 Nov 2020 10:54:21

[Liver Disease](#)

Audit	User	Time (GMT)
User entered 'No (N)'	(b) (4), (b) (6)	01 Sep 2020 04:25:18

US3292365

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 26 Nov 2020 10:54:21

[Human Immunodeficiency Virus \(HIV\) infection](#)

Audit	User	Time (GMT)
Amendment Manager: DataPoint set to visible.	System	19 Sep 2020 08:36:52
Amendment Manager inserted this DataPoint.	System	19 Sep 2020 08:36:51

US3292365

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 26 Nov 2020 10:54:21

[Height](#)

Audit	User	Time (GMT)
User entered missing code ND - Not Done.	(b) (4), (b) (6)	01 Sep 2020 04:30:44

US3292365

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 26 Nov 2020 10:54:21

Weight

Audit	User	Time (GMT)
User entered missing code ND - Not Done.	(b) (4), (b) (6)	01 Sep 2020 04:30:44

US3292365

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 26 Nov 2020 10:54:21

[Height](#)

Audit	User	Time (GMT)
User entered missing code ND - Not Done.	(b) (4), (b) (6)	01 Sep 2020 04:30:44

US3292365

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 26 Nov 2020 10:54:21

[Weight](#)

Audit	User	Time (GMT)
User entered missing code ND - Not Done.	(b) (4), (b) (6)	01 Sep 2020 04:30:44

US3292365

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 10:54:21

[Timepoint](#)

Audit	User	Time (GMT)
User accepted default value 'Pre-Dose (PREDOSE)'	(b) (4), (b) (6)	01 Sep 2020 04:30:44

US3292365

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 10:54:21

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	(b) (4), (b) (6)	01 Sep 2020 04:30:44

US3292365

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 10:54:21

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
User entered '29 Aug 2020'	(b) (4), (b) (6)	01 Sep 2020 04:30:44

US3292365

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 10:54:21

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

Audit	User	Time (GMT)
User entered '11:21'	(b) (4), (b) (6)	01 Sep 2020 04:30:44

US3292365

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 10:54:21

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

Audit	User	Time (GMT)
User entered '29 Aug 2020 11:21'	System	01 Sep 2020 04:30:44

US3292365

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 10:54:21

Temperature (xxx.x)

Audit	User	Time (GMT)
User entered '36.7' C	(b) (4), (b) (6)	01 Sep 2020 04:30:44

US3292365

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 10:54:21

[Route of measurement](#)

Audit	User	Time (GMT)
User entered 'Oral (Oral)'	(b) (4), (b) (6)	01 Sep 2020 04:30:44

US3292365

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 10:54:21

[If Other, specify](#)

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	01 Sep 2020 04:30:44

US3292365

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 10:54:21

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
User entered '57'	(b) (4), (b) (6)	01 Sep 2020 04:30:44

US3292365

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 10:54:21

[Pulse units](#)

Audit	User	Time (GMT)
User entered 'bpm'	System	01 Sep 2020 04:30:44

US3292365

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 10:54:21

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

Audit	User	Time (GMT)
User entered '12'	(b) (4), (b) (6)	01 Sep 2020 04:30:44

US3292365

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 10:54:21

[Respiratory Rate units](#)

Audit	User	Time (GMT)
User entered 'breaths/min'	System	01 Sep 2020 04:30:44

US3292365

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 10:54:21

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
User entered '143'	(b) (4), (b) (6)	01 Sep 2020 04:30:44

US3292365

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 10:54:21

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered 'mmHg'	System	01 Sep 2020 04:30:44

US3292365

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 10:54:21

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
User entered '88'	(b) (4), (b) (6)	01 Sep 2020 04:30:44

US3292365

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 10:54:21

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered 'mmHg'	System	01 Sep 2020 04:30:44

US3292365

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 26 Nov 2020 10:54:21

[Height](#)

Audit	User	Time (GMT)
User entered missing code ND - Not Done.	(b) (4), (b) (6)	01 Sep 2020 04:30:44

US3292365

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 26 Nov 2020 10:54:21

Weight

Audit	User	Time (GMT)
User entered missing code ND - Not Done.	(b) (4), (b) (6)	01 Sep 2020 04:30:44

US3292365

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 10:54:21

[Timepoint](#)

Audit	User	Time (GMT)
User accepted default value 'Post-Dose (POSTDOSE)'	(b) (4), (b) (6)	01 Sep 2020 04:30:44

US3292365

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 10:54:21

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	(b) (4), (b) (6)	01 Sep 2020 04:30:44

US3292365

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 10:54:21

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
User entered '29 Aug 2020'	(b) (4), (b) (6)	01 Sep 2020 04:30:44

US3292365

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 10:54:21

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

Audit	User	Time (GMT)
User entered '13:16'	(b) (4), (b) (6)	01 Sep 2020 04:30:44

US3292365

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 10:54:21

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

Audit	User	Time (GMT)
User entered '29 Aug 2020 13:16'	System	01 Sep 2020 04:30:44

US3292365

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 10:54:21

Temperature (xxx.x)

Audit	User	Time (GMT)
User entered '36.8' C	(b) (4), (b) (6)	01 Sep 2020 04:30:44

US3292365

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 10:54:21

[Route of measurement](#)

Audit	User	Time (GMT)
User entered 'Oral (Oral)'	(b) (4), (b) (6)	01 Sep 2020 04:30:44

US3292365

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 10:54:21

[If Other, specify](#)

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	01 Sep 2020 04:30:44

US3292365

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 10:54:21

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
User entered '61'	(b) (4), (b) (6)	01 Sep 2020 04:30:44

US3292365

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 10:54:21

[Pulse units](#)

Audit	User	Time (GMT)
User entered 'bpm'	System	01 Sep 2020 04:30:44

US3292365

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 10:54:21

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

Audit	User	Time (GMT)
User entered '16'	(b) (4), (b) (6)	01 Sep 2020 04:30:44

US3292365

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 10:54:21

[Respiratory Rate units](#)

Audit	User	Time (GMT)
User entered 'breaths/min'	System	01 Sep 2020 04:30:44

US3292365

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 10:54:21

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
User entered '140'	(b) (4), (b) (6)	01 Sep 2020 04:30:44

US3292365

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 10:54:21

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered 'mmHg'	System	01 Sep 2020 04:30:44

US3292365

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 10:54:21

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
User entered '89'	(b) (4), (b) (6)	01 Sep 2020 04:30:44

US3292365

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 10:54:21

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered 'mmHg'	System	01 Sep 2020 04:30:44

US3292365

Folder: Visit 1 Day 1

Form: Physical Examination

Generated On: 26 Nov 2020 10:54:21

Was the physical examination performed?

Audit	User	Time (GMT)
User entered 'No (N)'	(b) (4), (b) (6)	01 Sep 2020 04:28:44

US3292365

Folder: Visit 1 Day 1

Form: Physical Examination

Generated On: 26 Nov 2020 10:54:21

Date of examination (*dd MMM yyyy*)

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	01 Sep 2020 04:28:44

US3292365

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 26 Nov 2020 10:54:21

[Was study treatment given?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	(b) (4), (b) (6)	29 Aug 2020 18:21:38

US3292365

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 26 Nov 2020 10:54:21

If No, reason not given

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	29 Aug 2020 18:21:38

US3292365

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 26 Nov 2020 10:54:21

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

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	29 Aug 2020 18:21:38

US3292365

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 26 Nov 2020 10:54:21

[What was the study treatment?](#)

Audit	User	Time (GMT)
User entered 'MRNA-1273 OR PLACEBO'	System	29 Aug 2020 18:21:38

US3292365

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 26 Nov 2020 10:54:21

What was the treatment date? (dd MMM yyyy)

Audit	User	Time (GMT)
User entered '29 Aug 2020'	(b) (4), (b) (6)	29 Aug 2020 18:21:38

US3292365

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 26 Nov 2020 10:54:21

[What was the treatment time? \(00:00-23:59\)](#)

Audit	User	Time (GMT)
User entered '12:45'	(b) (4), (b) (6)	29 Aug 2020 18:21:38

US3292365

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 26 Nov 2020 10:54:21

[Treatment Date and Time \(derived\)](#)

Audit	User	Time (GMT)
User entered '29 Aug 2020 12:45'	System	29 Aug 2020 18:21:38

US3292365

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 26 Nov 2020 10:54:21

[Which arm was used to give treatment?](#)

Audit	User	Time (GMT)
User entered 'Right Arm (RIGHT ARM)'	(b) (4), (b) (6)	29 Aug 2020 18:21:38

US3292365

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 26 Nov 2020 10:54:21

[What was the frequency of the study treatment dosing?](#)

Audit	User	Time (GMT)
User entered 'ONCE'	System	29 Aug 2020 18:21:38

US3292365

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 26 Nov 2020 10:54:21

What was the route of administration for the study treatment?

Audit	User	Time (GMT)
User entered 'INTRAMUSCULAR'	System	29 Aug 2020 18:21:38

US3292365

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 26 Nov 2020 10:54:21

[Was the sample collected?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	(b) (4), (b) (6)	01 Sep 2020 04:28:09

US3292365

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 26 Nov 2020 10:54:21

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User entered '29 Aug 2020'	(b) (4), (b) (6)	01 Sep 2020 04:28:09

US3292365

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 26 Nov 2020 10:54:21

Collection time (00:00-23:59)

Audit	User	Time (GMT)
User entered '11:35'	(b) (4), (b) (6)	01 Sep 2020 04:28:09

US3292365

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 26 Nov 2020 10:54:21

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
User entered '29 Aug 2020 11:35'	System	01 Sep 2020 04:28:09

US3292365

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab

Generated On: 26 Nov 2020 10:54:21

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User entered '29 Aug 2020'	(b) (4), (b) (6)	01 Sep 2020 04:28:30

US3292365

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 26 Nov 2020 10:54:21

[Lab Test](#)

Audit	User	Time (GMT)
User accepted default value 'Nasopharyngeal Swab 1 (NASAL1)'	(b) (4), (b) (6)	01 Sep 2020 04:28:30

US3292365

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 26 Nov 2020 10:54:21

[Was the sample collected?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	(b) (4), (b) (6)	01 Sep 2020 04:28:30

US3292365

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 26 Nov 2020 10:54:21

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
User entered '11:50'	(b) (4), (b) (6)	01 Sep 2020 04:28:30

US3292365

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 26 Nov 2020 10:54:21

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
User entered '29 Aug 2020 11:50'	System	01 Sep 2020 04:28:30

US3292365

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 26 Nov 2020 10:54:21

[Lab Test](#)

Audit	User	Time (GMT)
User accepted default value 'Nasopharyngeal Swab 2 (NASAL2)'	(b) (4), (b) (6)	01 Sep 2020 04:28:30

US3292365

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 26 Nov 2020 10:54:21

[Was the sample collected?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	(b) (4), (b) (6)	01 Sep 2020 04:28:30

US3292365

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 26 Nov 2020 10:54:21

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	01 Sep 2020 04:28:30

US3292365

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 26 Nov 2020 10:54:21

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	01 Sep 2020 04:28:30

US3292365

Folder: Visit 1 Day 1

Form: Continuing

Generated On: 26 Nov 2020 10:54:21

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	(b) (4), (b) (6)	01 Sep 2020 04:28:36

US3292365

Folder: Visit 1 Day 1

Form: Continuing

Generated On: 26 Nov 2020 10:54:21

[Continuing Flag](#)

Audit	User	Time (GMT)
User entered '1'	System	01 Sep 2020 04:28:36

US3292365

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 26 Nov 2020 10:54:21

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	29 Aug 2020 18:21:38
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	29 Aug 2020 18:21:38

US3292365

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 26 Nov 2020 10:54:21

Was TEMPERATURE taken?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5d3a9a116dfc2943)', Time: '2020-08-29T13:22:16', User OID: 'PatientReportedOutcome (US3292365)', ODM File OID: '5a75ecee-62cf-4058-ba2a-f244ddab5562'	System	29 Aug 2020 18:22:53
User entered 'Yes (Y)'	System	29 Aug 2020 18:22:53

US3292365

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 26 Nov 2020 10:54:21

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5d3a9a116dfc2943)', Time: '2020-08-29T13:22:33', User OID: 'PatientReportedOutcome (US3292365)', ODM File OID: '5a75ecee-62cf-4058-ba2a-f244ddab5562'	System	29 Aug 2020 18:22:53
User entered '98.2'	System	29 Aug 2020 18:22:53

US3292365

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 26 Nov 2020 10:54:21

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5d3a9a116dfc2943)', Time: '2020-08-29T13:22:43', User OID: 'PatientReportedOutcome (US3292365)', ODM File OID: '5a75ecee-62cf-4058-ba2a-f244ddab5562'	System	29 Aug 2020 18:22:53
User entered 'No (N)'	System	29 Aug 2020 18:22:53

US3292365

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 26 Nov 2020 10:54:21

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5d3a9a116dfc2943)', Time: '2020-08-29T13:22:50', User OID: 'PatientReportedOutcome (US3292365)', ODM File OID: '5a75ecee-62cf-4058-ba2a-f244ddab5562'	System	29 Aug 2020 18:22:53
User entered '29 Aug 2020 13:22'	System	29 Aug 2020 18:22:53

US3292365

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 26 Nov 2020 10:54:21

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '29 Aug 2020 13:05'	System	29 Aug 2020 18:21:38

US3292365

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 26 Nov 2020 10:54:21

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '29 Aug 2020 15:35'	System	29 Aug 2020 18:21:38

US3292365

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 26 Nov 2020 10:54:21

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	29 Aug 2020 18:21:38
User entered 'Day 1, after vaccination (at home)'	System	29 Aug 2020 18:21:38

US3292365

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 26 Nov 2020 10:54:21

Was TEMPERATURE taken?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5d3a9a116dfc2943)', Time: '2020-08-29T20:54:33', User OID: 'PatientReportedOutcome (US3292365)', ODM File OID: 'b9a76140-cabe-4bad-ba85-a80d1c5ef452'	System	30 Aug 2020 01:55:52
User entered 'Yes (Y)'	System	30 Aug 2020 01:55:52

US3292365

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 26 Nov 2020 10:54:21

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5d3a9a116dfc2943)', Time: '2020-08-29T20:55:31', User OID: 'PatientReportedOutcome (US3292365)', ODM File OID: 'b9a76140-cabe-4bad-ba85-a80d1c5ef452'	System	30 Aug 2020 01:55:52
User entered '97.2'	System	30 Aug 2020 01:55:52

US3292365

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 26 Nov 2020 10:54:21

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5d3a9a116dfc2943)', Time: '2020-08-29T20:55:35', User OID: 'PatientReportedOutcome (US3292365)', ODM File OID: 'b9a76140-cabe-4bad-ba85-a80d1c5ef452'	System	30 Aug 2020 01:55:52
User entered 'No (N)'	System	30 Aug 2020 01:55:52

US3292365

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 26 Nov 2020 10:54:21

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5d3a9a116dfc2943)', Time: '2020-08-29T20:55:50', User OID: 'PatientReportedOutcome (US3292365)', ODM File OID: 'b9a76140-cabe-4bad-ba85-a80d1c5ef452'	System	30 Aug 2020 01:55:52
User entered '29 Aug 2020 20:55'	System	30 Aug 2020 01:55:52

US3292365

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 26 Nov 2020 10:54:21

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '29 Aug 2020 16:30'	System	29 Aug 2020 18:21:38

US3292365

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 26 Nov 2020 10:54:21

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '30 Aug 2020 11:59'	System	29 Aug 2020 18:21:38

US3292365

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 26 Nov 2020 10:54:21

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	29 Aug 2020 18:21:38
User entered 'Day 2'	System	29 Aug 2020 18:21:38

US3292365

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 26 Nov 2020 10:54:21

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5d3a9a116dfc2943)', Time: '2020-08-30T21:32:53', User OID: 'PatientReportedOutcome (US3292365)', ODM File OID: '62c31202-31d8-42f4-8b61-38f2b8ec30e8'	System	31 Aug 2020 02:33:09
User entered 'Yes (Y)'	System	31 Aug 2020 02:33:09

US3292365

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 26 Nov 2020 10:54:21

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5d3a9a116dfc2943)', Time: '2020-08-30T21:32:59', User OID: 'PatientReportedOutcome (US3292365)', ODM File OID: '62c31202-31d8-42f4-8b61-38f2b8ec30e8'	System	31 Aug 2020 02:33:09
User entered '97.8'	System	31 Aug 2020 02:33:09

US3292365

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 26 Nov 2020 10:54:21

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5d3a9a116dfc2943)', Time: '2020-08-30T21:33:01', User OID: 'PatientReportedOutcome (US3292365)', ODM File OID: '62c31202-31d8-42f4-8b61-38f2b8ec30e8'	System	31 Aug 2020 02:33:09
User entered 'No (N)'	System	31 Aug 2020 02:33:09

US3292365

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 26 Nov 2020 10:54:21

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5d3a9a116dfc2943)', Time: '2020-08-30T21:33:06', User OID: 'PatientReportedOutcome (US3292365)', ODM File OID: '62c31202-31d8-42f4-8b61-38f2b8ec30e8'	System	31 Aug 2020 02:33:09
User entered '30 Aug 2020 21:33'	System	31 Aug 2020 02:33:09

US3292365

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 26 Nov 2020 10:54:21

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '30 Aug 2020 12:00'	System	29 Aug 2020 18:21:38

US3292365

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 26 Nov 2020 10:54:21

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '31 Aug 2020 11:59'	System	29 Aug 2020 18:21:38

US3292365

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 26 Nov 2020 10:54:21

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	29 Aug 2020 18:21:38
User entered 'Day 3'	System	29 Aug 2020 18:21:38

US3292365

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 26 Nov 2020 10:54:21

Was TEMPERATURE taken?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5d3a9a116dfc2943)', Time: '2020-08-31T21:06:51', User OID: 'PatientReportedOutcome (US3292365)', ODM File OID: 'd246e6ed-06c0-424e-948a-5697a8a6996b'	System	01 Sep 2020 02:07:08
User entered 'Yes (Y)'	System	01 Sep 2020 02:07:08

US3292365

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 26 Nov 2020 10:54:21

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5d3a9a116dfc2943)', Time: '2020-08-31T21:06:58', User OID: 'PatientReportedOutcome (US3292365)', ODM File OID: 'd246e6ed-06c0-424e-948a-5697a8a6996b'	System	01 Sep 2020 02:07:08
User entered '96.5'	System	01 Sep 2020 02:07:08

US3292365

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 26 Nov 2020 10:54:21

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5d3a9a116dfc2943)', Time: '2020-08-31T21:07:01', User OID: 'PatientReportedOutcome (US3292365)', ODM File OID: 'd246e6ed-06c0-424e-948a-5697a8a6996b'	System	01 Sep 2020 02:07:08
User entered 'No (N)'	System	01 Sep 2020 02:07:08

US3292365

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 26 Nov 2020 10:54:21

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5d3a9a116dfc2943)', Time: '2020-08-31T21:07:05', User OID: 'PatientReportedOutcome (US3292365)', ODM File OID: 'd246e6ed-06c0-424e-948a-5697a8a6996b'	System	01 Sep 2020 02:07:08
User entered '31 Aug 2020 21:07'	System	01 Sep 2020 02:07:08

US3292365

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 26 Nov 2020 10:54:21

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '31 Aug 2020 12:00'	System	29 Aug 2020 18:21:38

US3292365

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 26 Nov 2020 10:54:21

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '01 Sep 2020 11:59'	System	29 Aug 2020 18:21:38

US3292365

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 26 Nov 2020 10:54:21

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	29 Aug 2020 18:21:38
User entered 'Day 4'	System	29 Aug 2020 18:21:38

US3292365

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 26 Nov 2020 10:54:21

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5d3a9a116dfc2943)', Time: '2020-09-01T21:04:50', User OID: 'PatientReportedOutcome (US3292365)', ODM File OID: 'ccd45752-0fa3-4db4-9235-900125d0d548'	System	02 Sep 2020 02:06:50
User entered 'Yes (Y)'	System	02 Sep 2020 02:06:50

US3292365

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 26 Nov 2020 10:54:21

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5d3a9a116dfc2943)', Time: '2020-09-01T21:06:39', User OID: 'PatientReportedOutcome (US3292365)', ODM File OID: 'ccd45752-0fa3-4db4-9235-900125d0d548'	System	02 Sep 2020 02:06:50
User entered '97.9'	System	02 Sep 2020 02:06:50

US3292365

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 26 Nov 2020 10:54:21

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5d3a9a116dfc2943)', Time: '2020-09-01T21:06:43', User OID: 'PatientReportedOutcome (US3292365)', ODM File OID: 'ccd45752-0fa3-4db4-9235-900125d0d548'	System	02 Sep 2020 02:06:50
User entered 'No (N)'	System	02 Sep 2020 02:06:50

US3292365

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 26 Nov 2020 10:54:21

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5d3a9a116dfc2943)', Time: '2020-09-01T21:06:47', User OID: 'PatientReportedOutcome (US3292365)', ODM File OID: 'ccd45752-0fa3-4db4-9235-900125d0d548'	System	02 Sep 2020 02:06:50
User entered '01 Sep 2020 21:06'	System	02 Sep 2020 02:06:50

US3292365

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 26 Nov 2020 10:54:21

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '01 Sep 2020 12:00'	System	29 Aug 2020 18:21:38

US3292365

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 26 Nov 2020 10:54:21

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '02 Sep 2020 11:59'	System	29 Aug 2020 18:21:38

US3292365

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 26 Nov 2020 10:54:21

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	29 Aug 2020 18:21:38
User entered 'Day 5'	System	29 Aug 2020 18:21:38

US3292365

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 26 Nov 2020 10:54:21

Was TEMPERATURE taken?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5d3a9a116dfc2943)', Time: '2020-09-02T21:48:19', User OID: 'PatientReportedOutcome (US3292365)', ODM File OID: '002038dd-10b6-4634-aa99-e4479cc63153'	System	03 Sep 2020 02:48:44
User entered 'Yes (Y)'	System	03 Sep 2020 02:48:44

US3292365

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 26 Nov 2020 10:54:21

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5d3a9a116dfc2943)', Time: '2020-09-02T21:48:28', User OID: 'PatientReportedOutcome (US3292365)', ODM File OID: '002038dd-10b6-4634-aa99-e4479cc63153'	System	03 Sep 2020 02:48:44
User entered '96.9'	System	03 Sep 2020 02:48:44

US3292365

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 26 Nov 2020 10:54:21

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5d3a9a116dfc2943)', Time: '2020-09-02T21:48:33', User OID: 'PatientReportedOutcome (US3292365)', ODM File OID: '002038dd-10b6-4634-aa99-e4479cc63153'	System	03 Sep 2020 02:48:44
User entered 'No (N)'	System	03 Sep 2020 02:48:44

US3292365

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 26 Nov 2020 10:54:21

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5d3a9a116dfc2943)', Time: '2020-09-02T21:48:41', User OID: 'PatientReportedOutcome (US3292365)', ODM File OID: '002038dd-10b6-4634-aa99-e4479cc63153'	System	03 Sep 2020 02:48:44
User entered '02 Sep 2020 21:48'	System	03 Sep 2020 02:48:44

US3292365

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 26 Nov 2020 10:54:21

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '02 Sep 2020 12:00'	System	29 Aug 2020 18:21:38

US3292365

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 26 Nov 2020 10:54:21

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '03 Sep 2020 11:59'	System	29 Aug 2020 18:21:38

US3292365

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 26 Nov 2020 10:54:21

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	29 Aug 2020 18:21:38
User entered 'Day 6'	System	29 Aug 2020 18:21:38

US3292365

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 26 Nov 2020 10:54:21

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5d3a9a116dfc2943)', Time: '2020-09-03T21:04:32', User OID: 'PatientReportedOutcome (US3292365)', ODM File OID: '0f488190-ad3e-4c01-a282-5e3c066aa1c6'	System	04 Sep 2020 02:04:50
User entered 'Yes (Y)'	System	04 Sep 2020 02:04:50

US3292365

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 26 Nov 2020 10:54:21

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5d3a9a116dfc2943)', Time: '2020-09-03T21:04:40', User OID: 'PatientReportedOutcome (US3292365)', ODM File OID: '0f488190-ad3e-4c01-a282-5e3c066aa1c6'	System	04 Sep 2020 02:04:50
User entered '97.3'	System	04 Sep 2020 02:04:50

US3292365

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 26 Nov 2020 10:54:21

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5d3a9a116dfc2943)', Time: '2020-09-03T21:04:43', User OID: 'PatientReportedOutcome (US3292365)', ODM File OID: '0f488190-ad3e-4c01-a282-5e3c066aa1c6'	System	04 Sep 2020 02:04:50
User entered 'No (N)'	System	04 Sep 2020 02:04:50

US3292365

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 26 Nov 2020 10:54:21

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5d3a9a116dfc2943)', Time: '2020-09-03T21:04:46', User OID: 'PatientReportedOutcome (US3292365)', ODM File OID: '0f488190-ad3e-4c01-a282-5e3c066aa1c6'	System	04 Sep 2020 02:04:50
User entered '03 Sep 2020 21:04'	System	04 Sep 2020 02:04:50

US3292365

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 26 Nov 2020 10:54:21

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '03 Sep 2020 12:00'	System	29 Aug 2020 18:21:38

US3292365

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 26 Nov 2020 10:54:21

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '04 Sep 2020 11:59'	System	29 Aug 2020 18:21:38

US3292365

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 26 Nov 2020 10:54:21

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	29 Aug 2020 18:21:38
User entered 'Day 7'	System	29 Aug 2020 18:21:38

US3292365

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 26 Nov 2020 10:54:21

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5d3a9a116dfc2943)', Time: '2020-09-04T22:41:15', User OID: 'PatientReportedOutcome (US3292365)', ODM File OID: '0de0f01a-3164-44ee-a9bb-80b3d027844b'	System	05 Sep 2020 03:41:37
User entered 'Yes (Y)'	System	05 Sep 2020 03:41:37

US3292365

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 26 Nov 2020 10:54:21

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5d3a9a116dfc2943)', Time: '2020-09-04T22:41:24', User OID: 'PatientReportedOutcome (US3292365)', ODM File OID: '0de0f01a-3164-44ee-a9bb-80b3d027844b'	System	05 Sep 2020 03:41:37
User entered '97.3'	System	05 Sep 2020 03:41:37

US3292365

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 26 Nov 2020 10:54:21

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5d3a9a116dfc2943)', Time: '2020-09-04T22:41:28', User OID: 'PatientReportedOutcome (US3292365)', ODM File OID: '0de0f01a-3164-44ee-a9bb-80b3d027844b'	System	05 Sep 2020 03:41:37
User entered 'No (N)'	System	05 Sep 2020 03:41:37

US3292365

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 26 Nov 2020 10:54:21

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5d3a9a116dfc2943)', Time: '2020-09-04T22:41:32', User OID: 'PatientReportedOutcome (US3292365)', ODM File OID: '0de0f01a-3164-44ee-a9bb-80b3d027844b'	System	05 Sep 2020 03:41:37
User entered '04 Sep 2020 22:41'	System	05 Sep 2020 03:41:37

US3292365

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 26 Nov 2020 10:54:21

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '04 Sep 2020 12:00'	System	29 Aug 2020 18:21:38

US3292365

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 26 Nov 2020 10:54:21

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '05 Sep 2020 11:59'	System	29 Aug 2020 18:21:38

US3292365

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 26 Nov 2020 10:54:21

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	29 Aug 2020 18:21:38
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	29 Aug 2020 18:21:38

US3292365

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 26 Nov 2020 10:54:21

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

Please select one response below

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5d3a9a116dfc2943)', Time: '2020-08-29T13:23:03', User OID: 'PatientReportedOutcome (US3292365)', ODM File OID: '14aab5de-b82d-48a8-8b8b-ddc7725b5a11'	System	29 Aug 2020 18:23:34
User entered 'None (1)'	System	29 Aug 2020 18:23:34

US3292365

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 26 Nov 2020 10:54:21

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5d3a9a116dfc2943)', Time: '2020-08-29T13:23:13', User OID: 'PatientReportedOutcome (US3292365)', ODM File OID: '14aab5de-b82d-48a8-8b8b-ddc7725b5a11'	System	29 Aug 2020 18:23:34
User entered 'No (N)'	System	29 Aug 2020 18:23:34

US3292365

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 26 Nov 2020 10:54:21

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5d3a9a116dfc2943)', Time: '2020-08-29T13:23:20', User OID: 'PatientReportedOutcome (US3292365)', ODM File OID: '14aab5de-b82d-48a8-8b8b-ddc7725b5a11'	System	29 Aug 2020 18:23:34
User entered 'No (N)'	System	29 Aug 2020 18:23:34

US3292365

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 26 Nov 2020 10:54:21

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

Please select one response below

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5d3a9a116dfc2943)', Time: '2020-08-29T13:23:23', User OID: 'PatientReportedOutcome (US3292365)', ODM File OID: '14aab5de-b82d-48a8-8b8b-ddc7725b5a11'	System	29 Aug 2020 18:23:34
User entered 'None (1)'	System	29 Aug 2020 18:23:34

US3292365

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 26 Nov 2020 10:54:21

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5d3a9a116dfc2943)', Time: '2020-08-29T13:23:28', User OID: 'PatientReportedOutcome (US3292365)', ODM File OID: '14aab5de-b82d-48a8-8b8b-ddc7725b5a11'	System	29 Aug 2020 18:23:34
User entered '29 Aug 2020 13:23'	System	29 Aug 2020 18:23:34

US3292365

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 26 Nov 2020 10:54:21

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '29 Aug 2020 13:05'	System	29 Aug 2020 18:21:38

US3292365

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 26 Nov 2020 10:54:21

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '29 Aug 2020 15:35'	System	29 Aug 2020 18:21:38

US3292365

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 26 Nov 2020 10:54:21

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	29 Aug 2020 18:21:38
User entered 'Day 1, after vaccination (at home)'	System	29 Aug 2020 18:21:38

US3292365

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 26 Nov 2020 10:54:21

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

Please select one response below

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5d3a9a116dfc2943)', Time: '2020-08-29T20:56:08', User OID: 'PatientReportedOutcome (US3292365)', ODM File OID: 'b0e0ffe0-08b9-4ec2-a745-ce261b8d1bbe'	System	30 Aug 2020 01:58:30
User entered 'Does not interfere with activity (2)'	System	30 Aug 2020 01:58:30

US3292365

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 26 Nov 2020 10:54:21

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5d3a9a116dfc2943)', Time: '2020-08-29T20:56:18', User OID: 'PatientReportedOutcome (US3292365)', ODM File OID: 'b0e0ffe0-08b9-4ec2-a745-ce261b8d1bbe'	System	30 Aug 2020 01:58:30
User entered 'No (N)'	System	30 Aug 2020 01:58:30

US3292365

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 26 Nov 2020 10:54:21

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5d3a9a116dfc2943)', Time: '2020-08-29T20:56:21', User OID: 'PatientReportedOutcome (US3292365)', ODM File OID: 'b0e0ffe0-08b9-4ec2-a745-ce261b8d1bbe'	System	30 Aug 2020 01:58:30
User entered 'Yes (Y)'	System	30 Aug 2020 01:58:30

US3292365

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 26 Nov 2020 10:54:21

Please record - **SWELLING/HARDNESS AT INJECTION SITE (in mm)**

Measure the largest size across any injection site swelling/hardness with the ruler provided.

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5d3a9a116dfc2943)', Time: '2020-08-29T20:58:11', User OID: 'PatientReportedOutcome (US3292365)', ODM File OID: 'b0e0ffe0-08b9-4ec2-a745-ce261b8d1bbe' User entered '2'	System	30 Aug 2020 01:58:30

US3292365

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 26 Nov 2020 10:54:21

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

Please select one response below

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5d3a9a116dfc2943)', Time: '2020-08-29T20:58:16', User OID: 'PatientReportedOutcome (US3292365)', ODM File OID: 'b0e0ffe0-08b9-4ec2-a745-ce261b8d1bbe'	System	30 Aug 2020 01:58:30
User entered 'None (1)'	System	30 Aug 2020 01:58:30

US3292365

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 26 Nov 2020 10:54:21

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5d3a9a116dfc2943)', Time: '2020-08-29T20:58:29', User OID: 'PatientReportedOutcome (US3292365)', ODM File OID: 'b0e0ffe0-08b9-4ec2-a745-ce261b8d1bbe'	System	30 Aug 2020 01:58:30
User entered '29 Aug 2020 20:58'	System	30 Aug 2020 01:58:30

US3292365

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 26 Nov 2020 10:54:21

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '29 Aug 2020 16:30'	System	29 Aug 2020 18:21:38

US3292365

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 26 Nov 2020 10:54:21

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '30 Aug 2020 11:59'	System	29 Aug 2020 18:21:38

US3292365

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 26 Nov 2020 10:54:21

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	29 Aug 2020 18:21:38
User entered 'Day 2'	System	29 Aug 2020 18:21:38

US3292365

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 26 Nov 2020 10:54:21

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

Please select one response below

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5d3a9a116dfc2943)', Time: '2020-08-30T21:33:34', User OID: 'PatientReportedOutcome (US3292365)', ODM File OID: '32a35f4e-ef34-41bc-b308-ad1de1260617'	System	31 Aug 2020 02:39:05
User entered 'Does not interfere with activity (2)'	System	31 Aug 2020 02:39:05

US3292365

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 26 Nov 2020 10:54:21

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5d3a9a116dfc2943)', Time: '2020-08-30T21:33:38', User OID: 'PatientReportedOutcome (US3292365)', ODM File OID: '32a35f4e-ef34-41bc-b308-ad1de1260617'	System	31 Aug 2020 02:39:05
User entered 'No (N)'	System	31 Aug 2020 02:39:05

US3292365

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 26 Nov 2020 10:54:21

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5d3a9a116dfc2943)', Time: '2020-08-30T21:33:55', User OID: 'PatientReportedOutcome (US3292365)', ODM File OID: '32a35f4e-ef34-41bc-b308-ad1de1260617'	System	31 Aug 2020 02:39:05
User entered 'Yes (Y)'	System	31 Aug 2020 02:39:05

US3292365

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 26 Nov 2020 10:54:21

Please record - **SWELLING/HARDNESS AT INJECTION SITE (in mm)**

Measure the largest size across any injection site swelling/hardness with the ruler provided.

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5d3a9a116dfc2943)', Time: '2020-08-30T21:38:39', User OID: 'PatientReportedOutcome (US3292365)', ODM File OID: '32a35f4e-ef34-41bc-b308-ad1de1260617'	System	31 Aug 2020 02:39:05
User entered '2'	System	31 Aug 2020 02:39:05

US3292365

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 26 Nov 2020 10:54:21

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

Please select one response below

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5d3a9a116dfc2943)', Time: '2020-08-30T21:38:51', User OID: 'PatientReportedOutcome (US3292365)', ODM File OID: '32a35f4e-ef34-41bc-b308-ad1de1260617'	System	31 Aug 2020 02:39:05
User entered 'None (1)'	System	31 Aug 2020 02:39:05

US3292365

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 26 Nov 2020 10:54:21

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5d3a9a116dfc2943)', Time: '2020-08-30T21:39:02', User OID: 'PatientReportedOutcome (US3292365)', ODM File OID: '32a35f4e-ef34-41bc-b308-ad1de1260617'	System	31 Aug 2020 02:39:05
User entered '30 Aug 2020 21:39'	System	31 Aug 2020 02:39:05

US3292365

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 26 Nov 2020 10:54:21

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '30 Aug 2020 12:00'	System	29 Aug 2020 18:21:38

US3292365

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 26 Nov 2020 10:54:21

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '31 Aug 2020 11:59'	System	29 Aug 2020 18:21:38

US3292365

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 26 Nov 2020 10:54:21

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	29 Aug 2020 18:21:38
User entered 'Day 3'	System	29 Aug 2020 18:21:38

US3292365

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 26 Nov 2020 10:54:21

[Please record - PAIN AT INJECTION SITE.](#)

[Please select one response below](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5d3a9a116dfc2943)', Time: '2020-08-31T21:07:12', User OID: 'PatientReportedOutcome (US3292365)', ODM File OID: 'd5bff098-092a-4eb2-b6e6-18b03e1537d0'	System	01 Sep 2020 02:07:28
User entered 'None (1)'	System	01 Sep 2020 02:07:28

US3292365

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 26 Nov 2020 10:54:21

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5d3a9a116dfc2943)', Time: '2020-08-31T21:07:15', User OID: 'PatientReportedOutcome (US3292365)', ODM File OID: 'd5bff098-092a-4eb2-b6e6-18b03e1537d0'	System	01 Sep 2020 02:07:28
User entered 'No (N)'	System	01 Sep 2020 02:07:28

US3292365

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 26 Nov 2020 10:54:21

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5d3a9a116dfc2943)', Time: '2020-08-31T21:07:18', User OID: 'PatientReportedOutcome (US3292365)', ODM File OID: 'd5bff098-092a-4eb2-b6e6-18b03e1537d0'	System	01 Sep 2020 02:07:28
User entered 'No (N)'	System	01 Sep 2020 02:07:28

US3292365

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 26 Nov 2020 10:54:21

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

Please select one response below

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5d3a9a116dfc2943)', Time: '2020-08-31T21:07:21', User OID: 'PatientReportedOutcome (US3292365)', ODM File OID: 'd5bff098-092a-4eb2-b6e6-18b03e1537d0'	System	01 Sep 2020 02:07:28
User entered 'None (1)'	System	01 Sep 2020 02:07:28

US3292365

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 26 Nov 2020 10:54:21

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5d3a9a116dfc2943)', Time: '2020-08-31T21:07:26', User OID: 'PatientReportedOutcome (US3292365)', ODM File OID: 'd5bff098-092a-4eb2-b6e6-18b03e1537d0'	System	01 Sep 2020 02:07:28
User entered '31 Aug 2020 21:07'	System	01 Sep 2020 02:07:28

US3292365

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 26 Nov 2020 10:54:21

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '31 Aug 2020 12:00'	System	29 Aug 2020 18:21:38

US3292365

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 26 Nov 2020 10:54:21

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '01 Sep 2020 11:59'	System	29 Aug 2020 18:21:38

US3292365

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 26 Nov 2020 10:54:21

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	29 Aug 2020 18:21:38
User entered 'Day 4'	System	29 Aug 2020 18:21:38

US3292365

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 26 Nov 2020 10:54:21

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

Please select one response below

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5d3a9a116dfc2943)', Time: '2020-09-01T21:06:53', User OID: 'PatientReportedOutcome (US3292365)', ODM File OID: '038ed6c5-5807-4957-9918-a39e229d728c'	System	02 Sep 2020 02:07:08
User entered 'None (1)'	System	02 Sep 2020 02:07:08

US3292365

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 26 Nov 2020 10:54:21

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5d3a9a116dfc2943)', Time: '2020-09-01T21:06:56', User OID: 'PatientReportedOutcome (US3292365)', ODM File OID: '038ed6c5-5807-4957-9918-a39e229d728c'	System	02 Sep 2020 02:07:08
User entered 'No (N)'	System	02 Sep 2020 02:07:08

US3292365

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 26 Nov 2020 10:54:21

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5d3a9a116dfc2943)', Time: '2020-09-01T21:06:58', User OID: 'PatientReportedOutcome (US3292365)', ODM File OID: '038ed6c5-5807-4957-9918-a39e229d728c'	System	02 Sep 2020 02:07:08
User entered 'No (N)'	System	02 Sep 2020 02:07:08

US3292365

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 26 Nov 2020 10:54:21

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

Please select one response below

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5d3a9a116dfc2943)', Time: '2020-09-01T21:07:01', User OID: 'PatientReportedOutcome (US3292365)', ODM File OID: '038ed6c5-5807-4957-9918-a39e229d728c'	System	02 Sep 2020 02:07:08
User entered 'None (1)'	System	02 Sep 2020 02:07:08

US3292365

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 26 Nov 2020 10:54:21

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5d3a9a116dfc2943)', Time: '2020-09-01T21:07:05', User OID: 'PatientReportedOutcome (US3292365)', ODM File OID: '038ed6c5-5807-4957-9918-a39e229d728c'	System	02 Sep 2020 02:07:08
User entered '01 Sep 2020 21:07'	System	02 Sep 2020 02:07:08

US3292365

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 26 Nov 2020 10:54:21

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '01 Sep 2020 12:00'	System	29 Aug 2020 18:21:38

US3292365

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 26 Nov 2020 10:54:21

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '02 Sep 2020 11:59'	System	29 Aug 2020 18:21:38

US3292365

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 26 Nov 2020 10:54:21

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	29 Aug 2020 18:21:38
User entered 'Day 5'	System	29 Aug 2020 18:21:38

US3292365

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 26 Nov 2020 10:54:21

[Please record - PAIN AT INJECTION SITE.](#)

[Please select one response below](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5d3a9a116dfc2943)', Time: '2020-09-02T21:48:46', User OID: 'PatientReportedOutcome (US3292365)', ODM File OID: '85b8dadd-c791-425f-bb1c-15b0736e7867'	System	03 Sep 2020 02:49:04
User entered 'None (1)'	System	03 Sep 2020 02:49:04

US3292365

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 26 Nov 2020 10:54:21

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5d3a9a116dfc2943)', Time: '2020-09-02T21:48:49', User OID: 'PatientReportedOutcome (US3292365)', ODM File OID: '85b8dadd-c791-425f-bb1c-15b0736e7867'	System	03 Sep 2020 02:49:04
User entered 'No (N)'	System	03 Sep 2020 02:49:04

US3292365

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 26 Nov 2020 10:54:21

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5d3a9a116dfc2943)', Time: '2020-09-02T21:48:51', User OID: 'PatientReportedOutcome (US3292365)', ODM File OID: '85b8dadd-c791-425f-bb1c-15b0736e7867'	System	03 Sep 2020 02:49:04
User entered 'No (N)'	System	03 Sep 2020 02:49:04

US3292365

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 26 Nov 2020 10:54:21

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

Please select one response below

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5d3a9a116dfc2943)', Time: '2020-09-02T21:48:54', User OID: 'PatientReportedOutcome (US3292365)', ODM File OID: '85b8dadd-c791-425f-bb1c-15b0736e7867'	System	03 Sep 2020 02:49:04
User entered 'None (1)'	System	03 Sep 2020 02:49:04

US3292365

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 26 Nov 2020 10:54:21

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5d3a9a116dfc2943)', Time: '2020-09-02T21:49:03', User OID: 'PatientReportedOutcome (US3292365)', ODM File OID: '85b8dadd-c791-425f-bb1c-15b0736e7867'	System	03 Sep 2020 02:49:04
User entered '02 Sep 2020 21:49'	System	03 Sep 2020 02:49:04

US3292365

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 26 Nov 2020 10:54:21

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '02 Sep 2020 12:00'	System	29 Aug 2020 18:21:38

US3292365

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 26 Nov 2020 10:54:21

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '03 Sep 2020 11:59'	System	29 Aug 2020 18:21:38

US3292365

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 26 Nov 2020 10:54:21

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	29 Aug 2020 18:21:38
User entered 'Day 6'	System	29 Aug 2020 18:21:38

US3292365

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 26 Nov 2020 10:54:21

[Please record - PAIN AT INJECTION SITE.](#)

[Please select one response below](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5d3a9a116dfc2943)', Time: '2020-09-03T21:04:51', User OID: 'PatientReportedOutcome (US3292365)', ODM File OID: '535272ef-95b0-416b-a8d2-181caba263a6'	System	04 Sep 2020 02:05:11
User entered 'None (1)'	System	04 Sep 2020 02:05:11

US3292365

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 26 Nov 2020 10:54:21

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5d3a9a116dfc2943)', Time: '2020-09-03T21:04:54', User OID: 'PatientReportedOutcome (US3292365)', ODM File OID: '535272ef-95b0-416b-a8d2-181caba263a6'	System	04 Sep 2020 02:05:11
User entered 'No (N)'	System	04 Sep 2020 02:05:11

US3292365

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 26 Nov 2020 10:54:21

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5d3a9a116dfc2943)', Time: '2020-09-03T21:04:57', User OID: 'PatientReportedOutcome (US3292365)', ODM File OID: '535272ef-95b0-416b-a8d2-181caba263a6'	System	04 Sep 2020 02:05:11
User entered 'No (N)'	System	04 Sep 2020 02:05:11

US3292365

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 26 Nov 2020 10:54:21

[Please record](#) - **UNDERARM GLAND SWELLING OR TENDERNESS.**

[Please select one response below](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5d3a9a116dfc2943)', Time: '2020-09-03T21:05:00', User OID: 'PatientReportedOutcome (US3292365)', ODM File OID: '535272ef-95b0-416b-a8d2-181caba263a6'	System	04 Sep 2020 02:05:11
User entered 'None (1)'	System	04 Sep 2020 02:05:11

US3292365

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 26 Nov 2020 10:54:21

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5d3a9a116dfc2943)', Time: '2020-09-03T21:05:07', User OID: 'PatientReportedOutcome (US3292365)', ODM File OID: '535272ef-95b0-416b-a8d2-181caba263a6'	System	04 Sep 2020 02:05:11
User entered '03 Sep 2020 21:05'	System	04 Sep 2020 02:05:11

US3292365

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 26 Nov 2020 10:54:21

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '03 Sep 2020 12:00'	System	29 Aug 2020 18:21:38

US3292365

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 26 Nov 2020 10:54:21

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '04 Sep 2020 11:59'	System	29 Aug 2020 18:21:38

US3292365

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 26 Nov 2020 10:54:21

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	29 Aug 2020 18:21:38
User entered 'Day 7'	System	29 Aug 2020 18:21:38

US3292365

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 26 Nov 2020 10:54:21

[Please record - PAIN AT INJECTION SITE.](#)

[Please select one response below](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5d3a9a116dfc2943)', Time: '2020-09-04T22:41:44', User OID: 'PatientReportedOutcome (US3292365)', ODM File OID: '46c4fb11-78f9-4a61-bd6a-f2ff9b92af06'	System	05 Sep 2020 03:42:01
User entered 'None (1)'	System	05 Sep 2020 03:42:01

US3292365

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 26 Nov 2020 10:54:21

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5d3a9a116dfc2943)', Time: '2020-09-04T22:41:42', User OID: 'PatientReportedOutcome (US3292365)', ODM File OID: '46c4fb11-78f9-4a61-bd6a-f2ff9b92af06'	System	05 Sep 2020 03:42:01
User entered 'No (N)'	System	05 Sep 2020 03:42:01

US3292365

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 26 Nov 2020 10:54:21

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5d3a9a116dfc2943)', Time: '2020-09-04T22:41:47', User OID: 'PatientReportedOutcome (US3292365)', ODM File OID: '46c4fb11-78f9-4a61-bd6a-f2ff9b92af06'	System	05 Sep 2020 03:42:01
User entered 'No (N)'	System	05 Sep 2020 03:42:01

US3292365

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 26 Nov 2020 10:54:21

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

Please select one response below

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5d3a9a116dfc2943)', Time: '2020-09-04T22:41:51', User OID: 'PatientReportedOutcome (US3292365)', ODM File OID: '46c4fb11-78f9-4a61-bd6a-f2ff9b92af06'	System	05 Sep 2020 03:42:01
User entered 'None (1)'	System	05 Sep 2020 03:42:01

US3292365

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 26 Nov 2020 10:54:21

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5d3a9a116dfc2943)', Time: '2020-09-04T22:41:57', User OID: 'PatientReportedOutcome (US3292365)', ODM File OID: '46c4fb11-78f9-4a61-bd6a-f2ff9b92af06'	System	05 Sep 2020 03:42:01
User entered '04 Sep 2020 22:41'	System	05 Sep 2020 03:42:01

US3292365

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 26 Nov 2020 10:54:21

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '04 Sep 2020 12:00'	System	29 Aug 2020 18:21:38

US3292365

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 26 Nov 2020 10:54:21

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '05 Sep 2020 11:59'	System	29 Aug 2020 18:21:38

US3292365

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 10:54:21

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	29 Aug 2020 18:21:38
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	29 Aug 2020 18:21:38

US3292365

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 10:54:21

HEADACHE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5d3a9a116dfc2943)', Time: '2020-08-29T13:23:33', User OID: 'PatientReportedOutcome (US3292365)', ODM File OID: 'e0d99ad8-4a4b-4800-b8f4-750055dc4bde'	System	29 Aug 2020 18:23:55
User entered 'None (0)'	System	29 Aug 2020 18:23:55

US3292365

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 10:54:21

FATIGUE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5d3a9a116dfc2943)', Time: '2020-08-29T13:23:35', User OID: 'PatientReportedOutcome (US3292365)', ODM File OID: 'e0d99ad8-4a4b-4800-b8f4-750055dc4bde'	System	29 Aug 2020 18:23:55
User entered 'None (0)'	System	29 Aug 2020 18:23:55

US3292365

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 10:54:21

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5d3a9a116dfc2943)', Time: '2020-08-29T13:23:38', User OID: 'PatientReportedOutcome (US3292365)', ODM File OID: 'e0d99ad8-4a4b-4800-b8f4-750055dc4bde'	System	29 Aug 2020 18:23:55
User entered 'None (0)'	System	29 Aug 2020 18:23:55

US3292365

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 10:54:21

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5d3a9a116dfc2943)', Time: '2020-08-29T13:23:40', User OID: 'PatientReportedOutcome (US3292365)', ODM File OID: 'e0d99ad8-4a4b-4800-b8f4-750055dc4bde'	System	29 Aug 2020 18:23:55
User entered 'None (0)'	System	29 Aug 2020 18:23:55

US3292365

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 10:54:21

NAUSEA/VOMITING

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5d3a9a116dfc2943)', Time: '2020-08-29T13:23:42', User OID: 'PatientReportedOutcome (US3292365)', ODM File OID: 'e0d99ad8-4a4b-4800-b8f4-750055dc4bde'	System	29 Aug 2020 18:23:55
User entered 'None (0)'	System	29 Aug 2020 18:23:55

US3292365

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 10:54:21

CHILLS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5d3a9a116dfc2943)', Time: '2020-08-29T13:23:44', User OID: 'PatientReportedOutcome (US3292365)', ODM File OID: 'e0d99ad8-4a4b-4800-b8f4-750055dc4bde'	System	29 Aug 2020 18:23:55
User entered 'None (0)'	System	29 Aug 2020 18:23:55

US3292365

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 10:54:21

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5d3a9a116dfc2943)', Time: '2020-08-29T13:23:49', User OID: 'PatientReportedOutcome (US3292365)', ODM File OID: 'e0d99ad8-4a4b-4800-b8f4-750055dc4bde'	System	29 Aug 2020 18:23:55
User entered 'No (N)'	System	29 Aug 2020 18:23:55

US3292365

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 10:54:21

[PC Time stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5d3a9a116dfc2943)', Time: '2020-08-29T13:23:52', User OID: 'PatientReportedOutcome (US3292365)', ODM File OID: 'e0d99ad8-4a4b-4800-b8f4-750055dc4bde'	System	29 Aug 2020 18:23:55
User entered '29 Aug 2020 13:23'	System	29 Aug 2020 18:23:55

US3292365

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 10:54:21

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '29 Aug 2020 13:05'	System	29 Aug 2020 18:21:38

US3292365

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 10:54:21

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '29 Aug 2020 15:35'	System	29 Aug 2020 18:21:38

US3292365

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 10:54:21

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	29 Aug 2020 18:21:38
User entered 'Day 1, after vaccination (at home)'	System	29 Aug 2020 18:21:38

US3292365

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 10:54:21

HEADACHE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5d3a9a116dfc2943)', Time: '2020-08-29T20:58:34', User OID: 'PatientReportedOutcome (US3292365)', ODM File OID: '24086eb7-170a-4bfd-87c2-3fde52ca9d5a'	System	30 Aug 2020 01:59:01
User entered 'None (0)'	System	30 Aug 2020 01:59:01

US3292365

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 10:54:21

FATIGUE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5d3a9a116dfc2943)', Time: '2020-08-29T20:58:37', User OID: 'PatientReportedOutcome (US3292365)', ODM File OID: '24086eb7-170a-4bfd-87c2-3fde52ca9d5a'	System	30 Aug 2020 01:59:01
User entered 'None (0)'	System	30 Aug 2020 01:59:01

US3292365

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 10:54:21

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5d3a9a116dfc2943)', Time: '2020-08-29T20:58:40', User OID: 'PatientReportedOutcome (US3292365)', ODM File OID: '24086eb7-170a-4bfd-87c2-3fde52ca9d5a'	System	30 Aug 2020 01:59:01
User entered 'None (0)'	System	30 Aug 2020 01:59:01

US3292365

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 10:54:21

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5d3a9a116dfc2943)', Time: '2020-08-29T20:58:42', User OID: 'PatientReportedOutcome (US3292365)', ODM File OID: '24086eb7-170a-4bfd-87c2-3fde52ca9d5a'	System	30 Aug 2020 01:59:01
User entered 'None (0)'	System	30 Aug 2020 01:59:01

US3292365

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 10:54:21

NAUSEA/VOMITING

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5d3a9a116dfc2943)', Time: '2020-08-29T20:58:44', User OID: 'PatientReportedOutcome (US3292365)', ODM File OID: '24086eb7-170a-4bfd-87c2-3fde52ca9d5a'	System	30 Aug 2020 01:59:01
User entered 'None (0)'	System	30 Aug 2020 01:59:01

US3292365

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 10:54:21

CHILLS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5d3a9a116dfc2943)', Time: '2020-08-29T20:58:46', User OID: 'PatientReportedOutcome (US3292365)', ODM File OID: '24086eb7-170a-4bfd-87c2-3fde52ca9d5a'	System	30 Aug 2020 01:59:01
User entered 'None (0)'	System	30 Aug 2020 01:59:01

US3292365

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 10:54:21

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5d3a9a116dfc2943)', Time: '2020-08-29T20:58:51', User OID: 'PatientReportedOutcome (US3292365)', ODM File OID: '24086eb7-170a-4bfd-87c2-3fde52ca9d5a'	System	30 Aug 2020 01:59:01
User entered 'No (N)'	System	30 Aug 2020 01:59:01

US3292365

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 10:54:21

[PC Time stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5d3a9a116dfc2943)', Time: '2020-08-29T20:58:56', User OID: 'PatientReportedOutcome (US3292365)', ODM File OID: '24086eb7-170a-4bfd-87c2-3fde52ca9d5a'	System	30 Aug 2020 01:59:01
User entered '29 Aug 2020 20:58'	System	30 Aug 2020 01:59:01

US3292365

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 10:54:21

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '29 Aug 2020 16:30'	System	29 Aug 2020 18:21:38

US3292365

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 10:54:21

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '30 Aug 2020 11:59'	System	29 Aug 2020 18:21:38

US3292365

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 10:54:21

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	29 Aug 2020 18:21:38
User entered 'Day 2'	System	29 Aug 2020 18:21:38

US3292365

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 10:54:21

HEADACHE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5d3a9a116dfc2943)', Time: '2020-08-30T21:39:09', User OID: 'PatientReportedOutcome (US3292365)', ODM File OID: '2ec36d36-4324-482a-a0e5-2e73a0e3719b'	System	31 Aug 2020 02:39:35
User entered 'None (0)'	System	31 Aug 2020 02:39:35

US3292365

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 10:54:21

FATIGUE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5d3a9a116dfc2943)', Time: '2020-08-30T21:39:12', User OID: 'PatientReportedOutcome (US3292365)', ODM File OID: '2ec36d36-4324-482a-a0e5-2e73a0e3719b'	System	31 Aug 2020 02:39:35
User entered 'None (0)'	System	31 Aug 2020 02:39:35

US3292365

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 10:54:21

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5d3a9a116dfc2943)', Time: '2020-08-30T21:39:14', User OID: 'PatientReportedOutcome (US3292365)', ODM File OID: '2ec36d36-4324-482a-a0e5-2e73a0e3719b'	System	31 Aug 2020 02:39:35
User entered 'None (0)'	System	31 Aug 2020 02:39:35

US3292365

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 10:54:21

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5d3a9a116dfc2943)', Time: '2020-08-30T21:39:16', User OID: 'PatientReportedOutcome (US3292365)', ODM File OID: '2ec36d36-4324-482a-a0e5-2e73a0e3719b'	System	31 Aug 2020 02:39:35
User entered 'None (0)'	System	31 Aug 2020 02:39:35

US3292365

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 10:54:21

NAUSEA/VOMITING

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5d3a9a116dfc2943)', Time: '2020-08-30T21:39:18', User OID: 'PatientReportedOutcome (US3292365)', ODM File OID: '2ec36d36-4324-482a-a0e5-2e73a0e3719b'	System	31 Aug 2020 02:39:35
User entered 'None (0)'	System	31 Aug 2020 02:39:35

US3292365

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 10:54:21

CHILLS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5d3a9a116dfc2943)', Time: '2020-08-30T21:39:21', User OID: 'PatientReportedOutcome (US3292365)', ODM File OID: '2ec36d36-4324-482a-a0e5-2e73a0e3719b'	System	31 Aug 2020 02:39:35
User entered 'None (0)'	System	31 Aug 2020 02:39:35

US3292365

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 10:54:21

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5d3a9a116dfc2943)', Time: '2020-08-30T21:39:25', User OID: 'PatientReportedOutcome (US3292365)', ODM File OID: '2ec36d36-4324-482a-a0e5-2e73a0e3719b'	System	31 Aug 2020 02:39:35
User entered 'No (N)'	System	31 Aug 2020 02:39:35

US3292365

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 10:54:21

[PC Time stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5d3a9a116dfc2943)', Time: '2020-08-30T21:39:32', User OID: 'PatientReportedOutcome (US3292365)', ODM File OID: '2ec36d36-4324-482a-a0e5-2e73a0e3719b'	System	31 Aug 2020 02:39:35
User entered '30 Aug 2020 21:39'	System	31 Aug 2020 02:39:35

US3292365

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 10:54:21

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '30 Aug 2020 12:00'	System	29 Aug 2020 18:21:38

US3292365

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 10:54:21

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '31 Aug 2020 11:59'	System	29 Aug 2020 18:21:38

US3292365

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 10:54:21

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	29 Aug 2020 18:21:38
User entered 'Day 3'	System	29 Aug 2020 18:21:38

US3292365

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 10:54:21

HEADACHE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5d3a9a116dfc2943)', Time: '2020-08-31T21:07:32', User OID: 'PatientReportedOutcome (US3292365)', ODM File OID: '409d7d8d-4ea6-4e19-810d-6c6a666c551e'	System	01 Sep 2020 02:07:53
User entered 'None (0)'	System	01 Sep 2020 02:07:53

US3292365

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 10:54:21

FATIGUE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5d3a9a116dfc2943)', Time: '2020-08-31T21:07:35', User OID: 'PatientReportedOutcome (US3292365)', ODM File OID: '409d7d8d-4ea6-4e19-810d-6c6a666c551e'	System	01 Sep 2020 02:07:53
User entered 'None (0)'	System	01 Sep 2020 02:07:53

US3292365

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 10:54:21

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5d3a9a116dfc2943)', Time: '2020-08-31T21:07:38', User OID: 'PatientReportedOutcome (US3292365)', ODM File OID: '409d7d8d-4ea6-4e19-810d-6c6a666c551e'	System	01 Sep 2020 02:07:53
User entered 'None (0)'	System	01 Sep 2020 02:07:53

US3292365

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 10:54:21

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5d3a9a116dfc2943)', Time: '2020-08-31T21:07:40', User OID: 'PatientReportedOutcome (US3292365)', ODM File OID: '409d7d8d-4ea6-4e19-810d-6c6a666c551e'	System	01 Sep 2020 02:07:53
User entered 'None (0)'	System	01 Sep 2020 02:07:53

US3292365

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 10:54:21

NAUSEA/VOMITING

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5d3a9a116dfc2943)', Time: '2020-08-31T21:07:42', User OID: 'PatientReportedOutcome (US3292365)', ODM File OID: '409d7d8d-4ea6-4e19-810d-6c6a666c551e'	System	01 Sep 2020 02:07:53
User entered 'None (0)'	System	01 Sep 2020 02:07:53

US3292365

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 10:54:21

CHILLS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5d3a9a116dfc2943)', Time: '2020-08-31T21:07:44', User OID: 'PatientReportedOutcome (US3292365)', ODM File OID: '409d7d8d-4ea6-4e19-810d-6c6a666c551e'	System	01 Sep 2020 02:07:53
User entered 'None (0)'	System	01 Sep 2020 02:07:53

US3292365

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 10:54:21

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5d3a9a116dfc2943)', Time: '2020-08-31T21:07:47', User OID: 'PatientReportedOutcome (US3292365)', ODM File OID: '409d7d8d-4ea6-4e19-810d-6c6a666c551e'	System	01 Sep 2020 02:07:53
User entered 'No (N)'	System	01 Sep 2020 02:07:53

US3292365

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 10:54:21

[PC Time stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5d3a9a116dfc2943)', Time: '2020-08-31T21:07:50', User OID: 'PatientReportedOutcome (US3292365)', ODM File OID: '409d7d8d-4ea6-4e19-810d-6c6a666c551e'	System	01 Sep 2020 02:07:53
User entered '31 Aug 2020 21:07'	System	01 Sep 2020 02:07:53

US3292365

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 10:54:21

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '31 Aug 2020 12:00'	System	29 Aug 2020 18:21:38

US3292365

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 10:54:21

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '01 Sep 2020 11:59'	System	29 Aug 2020 18:21:38

US3292365

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 10:54:21

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	29 Aug 2020 18:21:38
User entered 'Day 4'	System	29 Aug 2020 18:21:38

US3292365

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 10:54:21

HEADACHE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5d3a9a116dfc2943)', Time: '2020-09-01T21:07:09', User OID: 'PatientReportedOutcome (US3292365)', ODM File OID: '463e8178-0dce-44f6-92e8-214eb8317ab3'	System	02 Sep 2020 02:07:28
User entered 'None (0)'	System	02 Sep 2020 02:07:28

US3292365

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 10:54:21

FATIGUE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5d3a9a116dfc2943)', Time: '2020-09-01T21:07:11', User OID: 'PatientReportedOutcome (US3292365)', ODM File OID: '463e8178-0dce-44f6-92e8-214eb8317ab3'	System	02 Sep 2020 02:07:28
User entered 'None (0)'	System	02 Sep 2020 02:07:28

US3292365

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 10:54:21

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5d3a9a116dfc2943)', Time: '2020-09-01T21:07:13', User OID: 'PatientReportedOutcome (US3292365)', ODM File OID: '463e8178-0dce-44f6-92e8-214eb8317ab3'	System	02 Sep 2020 02:07:28
User entered 'None (0)'	System	02 Sep 2020 02:07:28

US3292365

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 10:54:21

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5d3a9a116dfc2943)', Time: '2020-09-01T21:07:15', User OID: 'PatientReportedOutcome (US3292365)', ODM File OID: '463e8178-0dce-44f6-92e8-214eb8317ab3'	System	02 Sep 2020 02:07:28
User entered 'None (0)'	System	02 Sep 2020 02:07:28

US3292365

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 10:54:21

NAUSEA/VOMITING

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5d3a9a116dfc2943)', Time: '2020-09-01T21:07:17', User OID: 'PatientReportedOutcome (US3292365)', ODM File OID: '463e8178-0dce-44f6-92e8-214eb8317ab3'	System	02 Sep 2020 02:07:28
User entered 'None (0)'	System	02 Sep 2020 02:07:28

US3292365

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 10:54:21

CHILLS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5d3a9a116dfc2943)', Time: '2020-09-01T21:07:18', User OID: 'PatientReportedOutcome (US3292365)', ODM File OID: '463e8178-0dce-44f6-92e8-214eb8317ab3'	System	02 Sep 2020 02:07:28
User entered 'None (0)'	System	02 Sep 2020 02:07:28

US3292365

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 10:54:21

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5d3a9a116dfc2943)', Time: '2020-09-01T21:07:21', User OID: 'PatientReportedOutcome (US3292365)', ODM File OID: '463e8178-0dce-44f6-92e8-214eb8317ab3'	System	02 Sep 2020 02:07:28
User entered 'No (N)'	System	02 Sep 2020 02:07:28

US3292365

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 10:54:21

[PC Time stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5d3a9a116dfc2943)', Time: '2020-09-01T21:07:25', User OID: 'PatientReportedOutcome (US3292365)', ODM File OID: '463e8178-0dce-44f6-92e8-214eb8317ab3'	System	02 Sep 2020 02:07:28
User entered '01 Sep 2020 21:07'	System	02 Sep 2020 02:07:28

US3292365

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 10:54:21

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '01 Sep 2020 12:00'	System	29 Aug 2020 18:21:38

US3292365

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 10:54:21

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '02 Sep 2020 11:59'	System	29 Aug 2020 18:21:38

US3292365

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 10:54:21

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	29 Aug 2020 18:21:38
User entered 'Day 5'	System	29 Aug 2020 18:21:38

US3292365

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 10:54:21

HEADACHE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5d3a9a116dfc2943)', Time: '2020-09-02T21:49:08', User OID: 'PatientReportedOutcome (US3292365)', ODM File OID: '720c6602-41d1-46f4-bab5-adf0d0c410e9'	System	03 Sep 2020 02:49:28
User entered 'None (0)'	System	03 Sep 2020 02:49:28

US3292365

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 10:54:21

FATIGUE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5d3a9a116dfc2943)', Time: '2020-09-02T21:49:11', User OID: 'PatientReportedOutcome (US3292365)', ODM File OID: '720c6602-41d1-46f4-bab5-adf0d0c410e9'	System	03 Sep 2020 02:49:28
User entered 'None (0)'	System	03 Sep 2020 02:49:28

US3292365

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 10:54:21

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5d3a9a116dfc2943)', Time: '2020-09-02T21:49:13', User OID: 'PatientReportedOutcome (US3292365)', ODM File OID: '720c6602-41d1-46f4-bab5-adf0d0c410e9'	System	03 Sep 2020 02:49:28
User entered 'None (0)'	System	03 Sep 2020 02:49:28

US3292365

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 10:54:21

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5d3a9a116dfc2943)', Time: '2020-09-02T21:49:17', User OID: 'PatientReportedOutcome (US3292365)', ODM File OID: '720c6602-41d1-46f4-bab5-adf0d0c410e9'	System	03 Sep 2020 02:49:28
User entered 'None (0)'	System	03 Sep 2020 02:49:28

US3292365

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 10:54:21

NAUSEA/VOMITING

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5d3a9a116dfc2943)', Time: '2020-09-02T21:49:19', User OID: 'PatientReportedOutcome (US3292365)', ODM File OID: '720c6602-41d1-46f4-bab5-adf0d0c410e9'	System	03 Sep 2020 02:49:28
User entered 'None (0)'	System	03 Sep 2020 02:49:28

US3292365

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 10:54:21

CHILLS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5d3a9a116dfc2943)', Time: '2020-09-02T21:49:21', User OID: 'PatientReportedOutcome (US3292365)', ODM File OID: '720c6602-41d1-46f4-bab5-adf0d0c410e9'	System	03 Sep 2020 02:49:28
User entered 'None (0)'	System	03 Sep 2020 02:49:28

US3292365

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 10:54:21

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5d3a9a116dfc2943)', Time: '2020-09-02T21:49:24', User OID: 'PatientReportedOutcome (US3292365)', ODM File OID: '720c6602-41d1-46f4-bab5-adf0d0c410e9'	System	03 Sep 2020 02:49:28
User entered 'No (N)'	System	03 Sep 2020 02:49:28

US3292365

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 10:54:21

[PC Time stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5d3a9a116dfc2943)', Time: '2020-09-02T21:49:27', User OID: 'PatientReportedOutcome (US3292365)', ODM File OID: '720c6602-41d1-46f4-bab5-adf0d0c410e9'	System	03 Sep 2020 02:49:28
User entered '02 Sep 2020 21:49'	System	03 Sep 2020 02:49:28

US3292365

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 10:54:21

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '02 Sep 2020 12:00'	System	29 Aug 2020 18:21:38

US3292365

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 10:54:21

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '03 Sep 2020 11:59'	System	29 Aug 2020 18:21:38

US3292365

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 10:54:21

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	29 Aug 2020 18:21:38
User entered 'Day 6'	System	29 Aug 2020 18:21:38

US3292365

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 10:54:21

HEADACHE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5d3a9a116dfc2943)', Time: '2020-09-03T21:05:13', User OID: 'PatientReportedOutcome (US3292365)', ODM File OID: 'fc9c62e0-da92-4dc1-ac5c-b463649e334c'	System	04 Sep 2020 02:05:36
User entered 'None (0)'	System	04 Sep 2020 02:05:36

US3292365

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 10:54:21

FATIGUE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5d3a9a116dfc2943)', Time: '2020-09-03T21:05:16', User OID: 'PatientReportedOutcome (US3292365)', ODM File OID: 'fc9c62e0-da92-4dc1-ac5c-b463649e334c'	System	04 Sep 2020 02:05:36
User entered 'None (0)'	System	04 Sep 2020 02:05:36

US3292365

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 10:54:21

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5d3a9a116dfc2943)', Time: '2020-09-03T21:05:18', User OID: 'PatientReportedOutcome (US3292365)', ODM File OID: 'fc9c62e0-da92-4dc1-ac5c-b463649e334c'	System	04 Sep 2020 02:05:36
User entered 'None (0)'	System	04 Sep 2020 02:05:36

US3292365

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 10:54:21

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5d3a9a116dfc2943)', Time: '2020-09-03T21:05:20', User OID: 'PatientReportedOutcome (US3292365)', ODM File OID: 'fc9c62e0-da92-4dc1-ac5c-b463649e334c'	System	04 Sep 2020 02:05:36
User entered 'None (0)'	System	04 Sep 2020 02:05:36

US3292365

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 10:54:21

NAUSEA/VOMITING

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5d3a9a116dfc2943)', Time: '2020-09-03T21:05:23', User OID: 'PatientReportedOutcome (US3292365)', ODM File OID: 'fc9c62e0-da92-4dc1-ac5c-b463649e334c'	System	04 Sep 2020 02:05:36
User entered 'None (0)'	System	04 Sep 2020 02:05:36

US3292365

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 10:54:21

CHILLS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5d3a9a116dfc2943)', Time: '2020-09-03T21:05:25', User OID: 'PatientReportedOutcome (US3292365)', ODM File OID: 'fc9c62e0-da92-4dc1-ac5c-b463649e334c'	System	04 Sep 2020 02:05:36
User entered 'None (0)'	System	04 Sep 2020 02:05:36

US3292365

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 10:54:21

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5d3a9a116dfc2943)', Time: '2020-09-03T21:05:30', User OID: 'PatientReportedOutcome (US3292365)', ODM File OID: 'fc9c62e0-da92-4dc1-ac5c-b463649e334c'	System	04 Sep 2020 02:05:36
User entered 'No (N)'	System	04 Sep 2020 02:05:36

US3292365

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 10:54:21

[PC Time stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5d3a9a116dfc2943)', Time: '2020-09-03T21:05:34', User OID: 'PatientReportedOutcome (US3292365)', ODM File OID: 'fc9c62e0-da92-4dc1-ac5c-b463649e334c'	System	04 Sep 2020 02:05:36
User entered '03 Sep 2020 21:05'	System	04 Sep 2020 02:05:36

US3292365

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 10:54:21

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '03 Sep 2020 12:00'	System	29 Aug 2020 18:21:38

US3292365

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 10:54:21

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '04 Sep 2020 11:59'	System	29 Aug 2020 18:21:38

US3292365

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 10:54:21

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	29 Aug 2020 18:21:38
User entered 'Day 7'	System	29 Aug 2020 18:21:38

US3292365

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 10:54:21

HEADACHE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5d3a9a116dfc2943)', Time: '2020-09-04T22:42:03', User OID: 'PatientReportedOutcome (US3292365)', ODM File OID: 'af8a7b9a-0593-4d05-9e8d-05ed126d431b'	System	05 Sep 2020 03:42:22
User entered 'None (0)'	System	05 Sep 2020 03:42:22

US3292365

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 10:54:21

FATIGUE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5d3a9a116dfc2943)', Time: '2020-09-04T22:42:05', User OID: 'PatientReportedOutcome (US3292365)', ODM File OID: 'af8a7b9a-0593-4d05-9e8d-05ed126d431b'	System	05 Sep 2020 03:42:22
User entered 'None (0)'	System	05 Sep 2020 03:42:22

US3292365

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 10:54:21

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5d3a9a116dfc2943)', Time: '2020-09-04T22:42:07', User OID: 'PatientReportedOutcome (US3292365)', ODM File OID: 'af8a7b9a-0593-4d05-9e8d-05ed126d431b'	System	05 Sep 2020 03:42:22
User entered 'None (0)'	System	05 Sep 2020 03:42:22

US3292365

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 10:54:21

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5d3a9a116dfc2943)', Time: '2020-09-04T22:42:09', User OID: 'PatientReportedOutcome (US3292365)', ODM File OID: 'af8a7b9a-0593-4d05-9e8d-05ed126d431b'	System	05 Sep 2020 03:42:22
User entered 'None (0)'	System	05 Sep 2020 03:42:22

US3292365

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 10:54:21

NAUSEA/VOMITING

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5d3a9a116dfc2943)', Time: '2020-09-04T22:42:11', User OID: 'PatientReportedOutcome (US3292365)', ODM File OID: 'af8a7b9a-0593-4d05-9e8d-05ed126d431b'	System	05 Sep 2020 03:42:22
User entered 'None (0)'	System	05 Sep 2020 03:42:22

US3292365

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 10:54:21

CHILLS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5d3a9a116dfc2943)', Time: '2020-09-04T22:42:13', User OID: 'PatientReportedOutcome (US3292365)', ODM File OID: 'af8a7b9a-0593-4d05-9e8d-05ed126d431b'	System	05 Sep 2020 03:42:22
User entered 'None (0)'	System	05 Sep 2020 03:42:22

US3292365

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 10:54:21

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5d3a9a116dfc2943)', Time: '2020-09-04T22:42:17', User OID: 'PatientReportedOutcome (US3292365)', ODM File OID: 'af8a7b9a-0593-4d05-9e8d-05ed126d431b'	System	05 Sep 2020 03:42:22
User entered 'No (N)'	System	05 Sep 2020 03:42:22

US3292365

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 10:54:21

[PC Time stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5d3a9a116dfc2943)', Time: '2020-09-04T22:42:19', User OID: 'PatientReportedOutcome (US3292365)', ODM File OID: 'af8a7b9a-0593-4d05-9e8d-05ed126d431b'	System	05 Sep 2020 03:42:22
User entered '04 Sep 2020 22:42'	System	05 Sep 2020 03:42:22

US3292365

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 10:54:21

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '04 Sep 2020 12:00'	System	29 Aug 2020 18:21:38

US3292365

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 10:54:21

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '05 Sep 2020 11:59'	System	29 Aug 2020 18:21:38

US3292365

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 26 Nov 2020 10:54:21

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Kristy Trevino (b) (4) (b) (4)	08 Sep 2020 20:47:41

US3292365

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 26 Nov 2020 10:54:21

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

Audit	User	Time (GMT)
User entered '8 Sep 2020'	Kristy Trevino (b) (4) (b) (4)	08 Sep 2020 20:47:41

US3292365

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 26 Nov 2020 10:54:21

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
User entered 'Contact Made (CONTACT MADE)'	Kristy Trevino (b) (4) (b) (4)	08 Sep 2020 20:47:41

US3292365

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 26 Nov 2020 10:54:21

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
User entered empty.	Kristy Trevino (b) (4) (b) (4)	08 Sep 2020 20:47:41

US3292365

Folder: Safety Call Day 8 (1)

Form: Continuing

Generated On: 26 Nov 2020 10:54:21

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Kristy Trevino (b) (4) (b) (4)	08 Sep 2020 20:47:46

US3292365

Folder: Safety Call Day 8 (1)

Form: Continuing

Generated On: 26 Nov 2020 10:54:21

[Continuing Flag](#)

Audit	User	Time (GMT)
User entered 'I'	System	08 Sep 2020 20:47:46

US3292365

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 26 Nov 2020 10:54:21

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Kristy Trevino (b) (4) (b) (4)	15 Sep 2020 18:23:24

US3292365

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 26 Nov 2020 10:54:21

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

Audit	User	Time (GMT)
User entered '15 Sep 2020'	Kristy Trevino (b) (4) (b) (4)	15 Sep 2020 18:23:24

US3292365

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 26 Nov 2020 10:54:21

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
User entered 'Contact Made (CONTACT MADE)'	Kristy Trevino (b) (4) (b) (4)	15 Sep 2020 18:23:24

US3292365

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 26 Nov 2020 10:54:21

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
User entered empty.	Kristy Trevino (b) (4) (b) (4)	15 Sep 2020 18:23:24

US3292365

Folder: Safety Call Day 15 (1)

Form: Continuing

Generated On: 26 Nov 2020 10:54:21

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Kristy Trevino (b) (4) (b) (4)	15 Sep 2020 18:23:56

US3292365

Folder: Safety Call Day 15 (1)

Form: Continuing

Generated On: 26 Nov 2020 10:54:21

[Continuing Flag](#)

Audit	User	Time (GMT)
User entered 'I'	System	15 Sep 2020 18:23:56

US3292365

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 26 Nov 2020 10:54:21

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	(b) (4), (b) (6)	22 Sep 2020 20:02:12

US3292365

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 26 Nov 2020 10:54:21

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

Audit	User	Time (GMT)
User entered '22 Sep 2020'	(b) (4), (b) (6)	22 Sep 2020 20:02:12

US3292365

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 26 Nov 2020 10:54:21

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
User entered 'Contact Made (CONTACT MADE)'	(b) (4), (b) (6)	22 Sep 2020 20:02:12

US3292365

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 26 Nov 2020 10:54:21

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	22 Sep 2020 20:02:12

US3292365

Folder: Safety Call Day 22 (1)

Form: Continuing

Generated On: 26 Nov 2020 10:54:21

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	(b) (4), (b) (6)	22 Sep 2020 20:02:16

US3292365

Folder: Safety Call Day 22 (1)

Form: Continuing

Generated On: 26 Nov 2020 10:54:21

[Continuing Flag](#)

Audit	User	Time (GMT)
User entered 'I'	System	22 Sep 2020 20:02:16

US3292365

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 26 Nov 2020 10:54:21

[Was this visit performed?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	(b) (4), (b) (6)	26 Sep 2020 17:00:42

US3292365

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 26 Nov 2020 10:54:21

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

Audit	User	Time (GMT)
User entered '26 Sep 2020'	(b) (4), (b) (6)	26 Sep 2020 17:00:42

US3292365

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 26 Nov 2020 10:54:21

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

Audit	User	Time (GMT)
User entered 'Clinic (Clinic)'	(b) (4), (b) (6)	26 Sep 2020 17:00:42

US3292365

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 26 Nov 2020 10:54:21

[Folder OID](#)

Audit	User	Time (GMT)
User entered 'VISIT2'	System	26 Sep 2020 17:00:42

US3292365

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 10:54:21

[Timepoint](#)

Audit	User	Time (GMT)
User accepted default value 'Pre-Dose (PREDOSE)'	(b) (4), (b) (6)	26 Sep 2020 17:02:03

US3292365

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 10:54:21

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	(b) (4), (b) (6)	26 Sep 2020 17:02:03

US3292365

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 10:54:21

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
User entered '26 Sep 2020'	(b) (4), (b) (6)	26 Sep 2020 17:02:03

US3292365

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 10:54:21

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

Audit	User	Time (GMT)
User entered '08:45'	(b) (4), (b) (6)	26 Sep 2020 17:02:03

US3292365

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 10:54:21

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

Audit	User	Time (GMT)
User entered '26 Sep 2020 08:45'	System	26 Sep 2020 17:02:03

US3292365

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 10:54:21

Temperature (xxx.x)

Audit	User	Time (GMT)
User entered '36.5' C	(b) (4), (b) (6)	26 Sep 2020 17:02:03

US3292365

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 10:54:21

[Route of measurement](#)

Audit	User	Time (GMT)
User entered 'Oral (Oral)'	(b) (4), (b) (6)	26 Sep 2020 17:02:03

US3292365

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 10:54:21

[If Other, specify](#)

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	26 Sep 2020 17:02:03

US3292365

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 10:54:21

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
User entered '61'	(b) (4), (b) (6)	26 Sep 2020 17:02:03

US3292365

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 10:54:21

[Pulse units](#)

Audit	User	Time (GMT)
User entered 'bpm'	System	26 Sep 2020 17:02:03

US3292365

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 10:54:21

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

Audit	User	Time (GMT)
User entered '16'	(b) (4), (b) (6)	26 Sep 2020 17:02:03

US3292365

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 10:54:21

[Respiratory Rate units](#)

Audit	User	Time (GMT)
User entered 'breaths/min'	System	26 Sep 2020 17:02:03

US3292365

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 10:54:21

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
User entered '127'	(b) (4), (b) (6)	26 Sep 2020 17:02:03

US3292365

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 10:54:21

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered 'mmHg'	System	26 Sep 2020 17:02:03

US3292365

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 10:54:21

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
User entered '81'	(b) (4), (b) (6)	26 Sep 2020 17:02:03

US3292365

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 10:54:21

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered 'mmHg'	System	26 Sep 2020 17:02:03

US3292365

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 10:54:21

[Timepoint](#)

Audit	User	Time (GMT)
User accepted default value 'Post-Dose (POSTDOSE)'	(b) (4), (b) (6)	26 Sep 2020 17:02:49

US3292365

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 10:54:21

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	(b) (4), (b) (6)	26 Sep 2020 17:02:49

US3292365

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 10:54:21

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
User entered '26 Sep 2020'	(b) (4), (b) (6)	26 Sep 2020 17:02:49

US3292365

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 10:54:21

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

Audit	User	Time (GMT)
User entered '10:14'	(b) (4), (b) (6)	26 Sep 2020 17:02:49

US3292365

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 10:54:21

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

Audit	User	Time (GMT)
User entered '26 Sep 2020 10:14'	System	26 Sep 2020 17:02:49

US3292365

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 10:54:21

Temperature (xxx.x)

Audit	User	Time (GMT)
User entered '36.6' C	(b) (4), (b) (6)	26 Sep 2020 17:02:49

US3292365

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 10:54:21

[Route of measurement](#)

Audit	User	Time (GMT)
User entered 'Oral (Oral)'	(b) (4), (b) (6)	26 Sep 2020 17:02:49

US3292365

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 10:54:21

[If Other, specify](#)

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	26 Sep 2020 17:02:49

US3292365

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 10:54:21

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
User entered '56'	(b) (4), (b) (6)	26 Sep 2020 17:02:49

US3292365

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 10:54:21

[Pulse units](#)

Audit	User	Time (GMT)
User entered 'bpm'	System	26 Sep 2020 17:02:49

US3292365

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 10:54:21

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

Audit	User	Time (GMT)
User entered '16'	(b) (4), (b) (6)	26 Sep 2020 17:02:49

US3292365

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 10:54:21

[Respiratory Rate units](#)

Audit	User	Time (GMT)
User entered 'breaths/min'	System	26 Sep 2020 17:02:49

US3292365

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 10:54:21

[Systolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
User entered '138'	(b) (4), (b) (6)	26 Sep 2020 17:02:49

US3292365

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 10:54:21

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered 'mmHg'	System	26 Sep 2020 17:02:49

US3292365

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 10:54:21

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
User entered '87'	(b) (4), (b) (6)	26 Sep 2020 17:02:49

US3292365

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 10:54:21

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered 'mmHg'	System	26 Sep 2020 17:02:49

US3292365

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Generated On: 26 Nov 2020 10:54:21

Was the physical examination performed?

Audit	User	Time (GMT)
User entered 'Yes (Y)'	(b) (4), (b) (6)	26 Sep 2020 17:00:49

US3292365

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Generated On: 26 Nov 2020 10:54:21

Date of examination (*dd MMM yyyy*)

Audit	User	Time (GMT)
User entered '26 Sep 2020'	(b) (4), (b) (6)	26 Sep 2020 17:00:49

US3292365

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 26 Nov 2020 10:54:21

[Was study treatment given?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Nathan Cortez (b) (4) [REDACTED]	26 Sep 2020 15:15:38

US3292365

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 26 Nov 2020 10:54:21

If No, reason not given

Audit	User	Time (GMT)
User entered empty.	Nathan Cortez (b) (4) [REDACTED]	26 Sep 2020 15:15:38

US3292365

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 26 Nov 2020 10:54:21

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

Audit	User	Time (GMT)
User entered empty.	Nathan Cortez (b) (4) [REDACTED]	26 Sep 2020 15:15:38

US3292365

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 26 Nov 2020 10:54:21

[What was the study treatment?](#)

Audit	User	Time (GMT)
User entered 'MRNA-1273 OR PLACEBO'	System	26 Sep 2020 15:15:38

US3292365

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 26 Nov 2020 10:54:21

What was the treatment date? (dd MMM yyyy)

Audit	User	Time (GMT)
User entered '26 Sep 2020'	Nathan Cortez (b) (4) [REDACTED]	26 Sep 2020 15:15:38

US3292365

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 26 Nov 2020 10:54:21

[What was the treatment time? \(00:00-23:59\)](#)

Audit	User	Time (GMT)
User entered '09:42'	Nathan Cortez (b) (4) [REDACTED]	26 Sep 2020 15:15:38

US3292365

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 26 Nov 2020 10:54:21

[Treatment Date and Time \(derived\)](#)

Audit	User	Time (GMT)
User entered '26 Sep 2020 09:42'	System	26 Sep 2020 15:15:38

US3292365

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 26 Nov 2020 10:54:21

Which arm was used to give treatment?

Audit	User	Time (GMT)
User entered 'Right Arm (RIGHT ARM)'	Nathan Cortez (b) (4)	26 Sep 2020 15:15:38

US3292365

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 26 Nov 2020 10:54:21

[What was the frequency of the study treatment dosing?](#)

Audit	User	Time (GMT)
User entered 'ONCE'	System	26 Sep 2020 15:15:38

US3292365

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 26 Nov 2020 10:54:21

What was the route of administration for the study treatment?

Audit	User	Time (GMT)
User entered 'INTRAMUSCULAR'	System	26 Sep 2020 15:15:38

US3292365

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 26 Nov 2020 10:54:21

[Was the sample collected?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	(b) (4), (b) (6)	26 Sep 2020 17:01:04

US3292365

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 26 Nov 2020 10:54:21

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User entered '26 Sep 2020'	(b) (4), (b) (6)	26 Sep 2020 17:01:04

US3292365

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 26 Nov 2020 10:54:21

Collection time (00:00-23:59)

Audit	User	Time (GMT)
User entered '08:53'	(b) (4), (b) (6)	26 Sep 2020 17:01:04

US3292365

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 26 Nov 2020 10:54:21

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
User entered '26 Sep 2020 08:53'	System	26 Sep 2020 17:01:04

US3292365

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab

Generated On: 26 Nov 2020 10:54:21

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User entered '26 Sep 2020'	(b) (4), (b) (6)	26 Sep 2020 17:01:23

US3292365

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 26 Nov 2020 10:54:21

[Lab Test](#)

Audit	User	Time (GMT)
User accepted default value 'Nasopharyngeal Swab 1 (NASAL1)'	(b) (4), (b) (6)	26 Sep 2020 17:01:23

US3292365

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 26 Nov 2020 10:54:21

[Was the sample collected?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	(b) (4), (b) (6)	26 Sep 2020 17:01:23

US3292365

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 26 Nov 2020 10:54:21

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
User entered '09:09'	(b) (4), (b) (6)	26 Sep 2020 17:01:23

US3292365

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 26 Nov 2020 10:54:21

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
User entered '26 Sep 2020 09:09'	System	26 Sep 2020 17:01:23

US3292365

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 26 Nov 2020 10:54:21

[Lab Test](#)

Audit	User	Time (GMT)
User accepted default value 'Nasopharyngeal Swab 2 (NASAL2)'	(b) (4), (b) (6)	26 Sep 2020 17:01:23

US3292365

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 26 Nov 2020 10:54:21

[Was the sample collected?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	(b) (4), (b) (6)	26 Sep 2020 17:01:23

US3292365

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 26 Nov 2020 10:54:21

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	26 Sep 2020 17:01:23

US3292365

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 26 Nov 2020 10:54:21

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	26 Sep 2020 17:01:23

US3292365

Folder: Visit 2 Day 29 (1)

Form: Continuing

Generated On: 26 Nov 2020 10:54:21

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	(b) (4), (b) (6)	26 Sep 2020 17:01:27

US3292365

Folder: Visit 2 Day 29 (1)

Form: Continuing

Generated On: 26 Nov 2020 10:54:21

[Continuing Flag](#)

Audit	User	Time (GMT)
User entered '1'	System	26 Sep 2020 17:01:27

US3292365

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 26 Nov 2020 10:54:21

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	26 Sep 2020 15:15:38
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	26 Sep 2020 15:15:38

US3292365

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 26 Nov 2020 10:54:21

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5d3a9a116dfc2943)', Time: '2020-09-26T10:17:33', User OID: 'PatientReportedOutcome (US3292365)', ODM File OID: 'f45b8eaf-17cb-4e04-97cf-5ba9178c9942'	System	26 Sep 2020 15:17:59
User entered 'Yes (Y)'	System	26 Sep 2020 15:17:59

US3292365

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 26 Nov 2020 10:54:21

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5d3a9a116dfc2943)', Time: '2020-09-26T10:17:39', User OID: 'PatientReportedOutcome (US3292365)', ODM File OID: 'f45b8eaf-17cb-4e04-97cf-5ba9178c9942'	System	26 Sep 2020 15:17:59
User entered '97.8'	System	26 Sep 2020 15:17:59

US3292365

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 26 Nov 2020 10:54:21

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5d3a9a116dfc2943)', Time: '2020-09-26T10:17:49', User OID: 'PatientReportedOutcome (US3292365)', ODM File OID: 'f45b8eaf-17cb-4e04-97cf-5ba9178c9942'	System	26 Sep 2020 15:17:59
User entered 'No (N)'	System	26 Sep 2020 15:17:59

US3292365

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 26 Nov 2020 10:54:21

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5d3a9a116dfc2943)', Time: '2020-09-26T10:17:57', User OID: 'PatientReportedOutcome (US3292365)', ODM File OID: 'f45b8eaf-17cb-4e04-97cf-5ba9178c9942'	System	26 Sep 2020 15:17:59
User entered '26 Sep 2020 10:17'	System	26 Sep 2020 15:17:59

US3292365

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 26 Nov 2020 10:54:21

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '26 Sep 2020 10:02'	System	26 Sep 2020 15:15:38

US3292365

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 26 Nov 2020 10:54:21

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '26 Sep 2020 12:32'	System	26 Sep 2020 15:15:38

US3292365

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 26 Nov 2020 10:54:21

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	26 Sep 2020 15:15:38
User entered 'Day 1, after vaccination (at home)'	System	26 Sep 2020 15:15:38

US3292365

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 26 Nov 2020 10:54:21

Was TEMPERATURE taken?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5d3a9a116dfc2943)', Time: '2020-09-26T21:30:57', User OID: 'PatientReportedOutcome (US3292365)', ODM File OID: 'dbbfcfb2-effb-4f5b-9dad-1a78d30ca278'	System	27 Sep 2020 02:32:01
User entered 'Yes (Y)'	System	27 Sep 2020 02:32:01

US3292365

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 26 Nov 2020 10:54:21

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5d3a9a116dfc2943)', Time: '2020-09-26T21:31:46', User OID: 'PatientReportedOutcome (US3292365)', ODM File OID: 'dbbfcfb2-effb-4f5b-9dad-1a78d30ca278'	System	27 Sep 2020 02:32:01
User entered '96.4'	System	27 Sep 2020 02:32:01

US3292365

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 26 Nov 2020 10:54:21

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5d3a9a116dfc2943)', Time: '2020-09-26T21:31:48', User OID: 'PatientReportedOutcome (US3292365)', ODM File OID: 'dbbfcfb2-effb-4f5b-9dad-1a78d30ca278'	System	27 Sep 2020 02:32:01
User entered 'No (N)'	System	27 Sep 2020 02:32:01

US3292365

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 26 Nov 2020 10:54:21

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5d3a9a116dfc2943)', Time: '2020-09-26T21:31:58', User OID: 'PatientReportedOutcome (US3292365)', ODM File OID: 'dbbfcfb2-effb-4f5b-9dad-1a78d30ca278'	System	27 Sep 2020 02:32:01
User entered '26 Sep 2020 21:31'	System	27 Sep 2020 02:32:01

US3292365

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 26 Nov 2020 10:54:21

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '26 Sep 2020 13:27'	System	26 Sep 2020 15:15:38

US3292365

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 26 Nov 2020 10:54:21

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '27 Sep 2020 11:59'	System	26 Sep 2020 15:15:38

US3292365

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 26 Nov 2020 10:54:21

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	26 Sep 2020 15:15:38
User entered 'Day 2'	System	26 Sep 2020 15:15:38

US3292365

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 26 Nov 2020 10:54:21

Was TEMPERATURE taken?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5d3a9a116dfc2943)', Time: '2020-09-27T21:03:00', User OID: 'PatientReportedOutcome (US3292365)', ODM File OID: '45453b71-5042-4295-b816-d53432b925dc'	System	28 Sep 2020 02:03:23
User entered 'Yes (Y)'	System	28 Sep 2020 02:03:23

US3292365

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 26 Nov 2020 10:54:21

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5d3a9a116dfc2943)', Time: '2020-09-27T21:03:06', User OID: 'PatientReportedOutcome (US3292365)', ODM File OID: '45453b71-5042-4295-b816-d53432b925dc'	System	28 Sep 2020 02:03:23
User entered '100.5'	System	28 Sep 2020 02:03:23

US3292365

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 26 Nov 2020 10:54:21

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5d3a9a116dfc2943)', Time: '2020-09-27T21:03:11', User OID: 'PatientReportedOutcome (US3292365)', ODM File OID: '45453b71-5042-4295-b816-d53432b925dc'	System	28 Sep 2020 02:03:23
User entered 'No (N)'	System	28 Sep 2020 02:03:23

US3292365

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 26 Nov 2020 10:54:21

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5d3a9a116dfc2943)', Time: '2020-09-27T21:03:22', User OID: 'PatientReportedOutcome (US3292365)', ODM File OID: '45453b71-5042-4295-b816-d53432b925dc'	System	28 Sep 2020 02:03:23
User entered '27 Sep 2020 21:03'	System	28 Sep 2020 02:03:23

US3292365

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 26 Nov 2020 10:54:21

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '27 Sep 2020 12:00'	System	26 Sep 2020 15:15:38

US3292365

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 26 Nov 2020 10:54:21

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '28 Sep 2020 11:59'	System	26 Sep 2020 15:15:38

US3292365

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 26 Nov 2020 10:54:21

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	26 Sep 2020 15:15:38
User entered 'Day 3'	System	26 Sep 2020 15:15:38

US3292365

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 26 Nov 2020 10:54:21

Was TEMPERATURE taken?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5d3a9a116dfc2943)', Time: '2020-09-28T20:56:39', User OID: 'PatientReportedOutcome (US3292365)', ODM File OID: 'f64c688f-e17d-462b-b810-25e8dc6aebcb'	System	29 Sep 2020 01:56:57
User entered 'Yes (Y)'	System	29 Sep 2020 01:56:57

US3292365

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 26 Nov 2020 10:54:21

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5d3a9a116dfc2943)', Time: '2020-09-28T20:56:46', User OID: 'PatientReportedOutcome (US3292365)', ODM File OID: 'f64c688f-e17d-462b-b810-25e8dc6aebcb'	System	29 Sep 2020 01:56:57
User entered '97.5'	System	29 Sep 2020 01:56:57

US3292365

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 26 Nov 2020 10:54:21

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5d3a9a116dfc2943)', Time: '2020-09-28T20:56:49', User OID: 'PatientReportedOutcome (US3292365)', ODM File OID: 'f64c688f-e17d-462b-b810-25e8dc6aebcb'	System	29 Sep 2020 01:56:57
User entered 'No (N)'	System	29 Sep 2020 01:56:57

US3292365

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 26 Nov 2020 10:54:21

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5d3a9a116dfc2943)', Time: '2020-09-28T20:56:54', User OID: 'PatientReportedOutcome (US3292365)', ODM File OID: 'f64c688f-e17d-462b-b810-25e8dc6aebcb'	System	29 Sep 2020 01:56:57
User entered '28 Sep 2020 20:56'	System	29 Sep 2020 01:56:57

US3292365

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 26 Nov 2020 10:54:21

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '28 Sep 2020 12:00'	System	26 Sep 2020 15:15:38

US3292365

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 26 Nov 2020 10:54:21

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '29 Sep 2020 11:59'	System	26 Sep 2020 15:15:38

US3292365

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 26 Nov 2020 10:54:21

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	26 Sep 2020 15:15:38
User entered 'Day 4'	System	26 Sep 2020 15:15:38

US3292365

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 26 Nov 2020 10:54:21

Was TEMPERATURE taken?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5d3a9a116dfc2943)', Time: '2020-09-29T22:31:35', User OID: 'PatientReportedOutcome (US3292365)', ODM File OID: '17ba10dd-5fd7-4bdf-bcfa-a5d12673d4f3'	System	30 Sep 2020 03:31:53
User entered 'Yes (Y)'	System	30 Sep 2020 03:31:53

US3292365

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 26 Nov 2020 10:54:21

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5d3a9a116dfc2943)', Time: '2020-09-29T22:31:41', User OID: 'PatientReportedOutcome (US3292365)', ODM File OID: '17ba10dd-5fd7-4bdf-bcfa-a5d12673d4f3'	System	30 Sep 2020 03:31:53
User entered '97.6'	System	30 Sep 2020 03:31:53

US3292365

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 26 Nov 2020 10:54:21

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5d3a9a116dfc2943)', Time: '2020-09-29T22:31:44', User OID: 'PatientReportedOutcome (US3292365)', ODM File OID: '17ba10dd-5fd7-4bdf-bcfa-a5d12673d4f3'	System	30 Sep 2020 03:31:53
User entered 'No (N)'	System	30 Sep 2020 03:31:53

US3292365

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 26 Nov 2020 10:54:21

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5d3a9a116dfc2943)', Time: '2020-09-29T22:31:50', User OID: 'PatientReportedOutcome (US3292365)', ODM File OID: '17ba10dd-5fd7-4bdf-bcfa-a5d12673d4f3'	System	30 Sep 2020 03:31:53
User entered '29 Sep 2020 22:31'	System	30 Sep 2020 03:31:53

US3292365

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 26 Nov 2020 10:54:21

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '29 Sep 2020 12:00'	System	26 Sep 2020 15:15:38

US3292365

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 26 Nov 2020 10:54:21

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '30 Sep 2020 11:59'	System	26 Sep 2020 15:15:38

US3292365

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 26 Nov 2020 10:54:21

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	26 Sep 2020 15:15:38
User entered 'Day 5'	System	26 Sep 2020 15:15:38

US3292365

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 26 Nov 2020 10:54:21

Was TEMPERATURE taken?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5d3a9a116dfc2943)', Time: '2020-09-30T22:21:09', User OID: 'PatientReportedOutcome (US3292365)', ODM File OID: '43ebe4ba-7cad-40a8-b80c-266a81f67674'	System	01 Oct 2020 03:22:55
User entered 'Yes (Y)'	System	01 Oct 2020 03:22:55

US3292365

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 26 Nov 2020 10:54:21

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5d3a9a116dfc2943)', Time: '2020-09-30T22:22:46', User OID: 'PatientReportedOutcome (US3292365)', ODM File OID: '43ebe4ba-7cad-40a8-b80c-266a81f67674'	System	01 Oct 2020 03:22:55
User entered '97.1'	System	01 Oct 2020 03:22:55

US3292365

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 26 Nov 2020 10:54:21

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5d3a9a116dfc2943)', Time: '2020-09-30T22:22:49', User OID: 'PatientReportedOutcome (US3292365)', ODM File OID: '43ebe4ba-7cad-40a8-b80c-266a81f67674'	System	01 Oct 2020 03:22:55
User entered 'No (N)'	System	01 Oct 2020 03:22:55

US3292365

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 26 Nov 2020 10:54:21

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5d3a9a116dfc2943)', Time: '2020-09-30T22:22:53', User OID: 'PatientReportedOutcome (US3292365)', ODM File OID: '43ebe4ba-7cad-40a8-b80c-266a81f67674'	System	01 Oct 2020 03:22:55
User entered '30 Sep 2020 22:22'	System	01 Oct 2020 03:22:55

US3292365

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 26 Nov 2020 10:54:21

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '30 Sep 2020 12:00'	System	26 Sep 2020 15:15:38

US3292365

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 26 Nov 2020 10:54:21

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '01 Oct 2020 11:59'	System	26 Sep 2020 15:15:38

US3292365

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 26 Nov 2020 10:54:21

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	26 Sep 2020 15:15:38
User entered 'Day 6'	System	26 Sep 2020 15:15:38

US3292365

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 26 Nov 2020 10:54:21

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5d3a9a116dfc2943)', Time: '2020-10-01T20:37:23', User OID: 'PatientReportedOutcome (US3292365)', ODM File OID: 'cba51f93-33b1-4705-ab79-544520d3f4f3'	System	02 Oct 2020 01:37:50
User entered 'Yes (Y)'	System	02 Oct 2020 01:37:50

US3292365

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 26 Nov 2020 10:54:21

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5d3a9a116dfc2943)', Time: '2020-10-01T20:37:30', User OID: 'PatientReportedOutcome (US3292365)', ODM File OID: 'cba51f93-33b1-4705-ab79-544520d3f4f3'	System	02 Oct 2020 01:37:50
User entered '98.0'	System	02 Oct 2020 01:37:50

US3292365

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 26 Nov 2020 10:54:21

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5d3a9a116dfc2943)', Time: '2020-10-01T20:37:35', User OID: 'PatientReportedOutcome (US3292365)', ODM File OID: 'cba51f93-33b1-4705-ab79-544520d3f4f3'	System	02 Oct 2020 01:37:50
User entered 'No (N)'	System	02 Oct 2020 01:37:50

US3292365

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 26 Nov 2020 10:54:21

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5d3a9a116dfc2943)', Time: '2020-10-01T20:37:45', User OID: 'PatientReportedOutcome (US3292365)', ODM File OID: 'cba51f93-33b1-4705-ab79-544520d3f4f3'	System	02 Oct 2020 01:37:50
User entered '01 Oct 2020 20:37'	System	02 Oct 2020 01:37:50

US3292365

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 26 Nov 2020 10:54:21

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '01 Oct 2020 12:00'	System	26 Sep 2020 15:15:38

US3292365

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 26 Nov 2020 10:54:21

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '02 Oct 2020 11:59'	System	26 Sep 2020 15:15:38

US3292365

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 26 Nov 2020 10:54:21

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	26 Sep 2020 15:15:38
User entered 'Day 7'	System	26 Sep 2020 15:15:38

US3292365

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 26 Nov 2020 10:54:21

Was TEMPERATURE taken?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5d3a9a116dfc2943)', Time: '2020-10-02T23:26:48', User OID: 'PatientReportedOutcome (US3292365)', ODM File OID: '66bf52bf-db90-4f33-81dc-44fa954c75d6'	System	03 Oct 2020 04:27:09
User entered 'Yes (Y)'	System	03 Oct 2020 04:27:09

US3292365

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 26 Nov 2020 10:54:21

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5d3a9a116dfc2943)', Time: '2020-10-02T23:26:55', User OID: 'PatientReportedOutcome (US3292365)', ODM File OID: '66bf52bf-db90-4f33-81dc-44fa954c75d6'	System	03 Oct 2020 04:27:09
User entered '96.5'	System	03 Oct 2020 04:27:09

US3292365

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 26 Nov 2020 10:54:21

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5d3a9a116dfc2943)', Time: '2020-10-02T23:27:02', User OID: 'PatientReportedOutcome (US3292365)', ODM File OID: '66bf52bf-db90-4f33-81dc-44fa954c75d6'	System	03 Oct 2020 04:27:09
User entered 'No (N)'	System	03 Oct 2020 04:27:09

US3292365

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 26 Nov 2020 10:54:21

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5d3a9a116dfc2943)', Time: '2020-10-02T23:27:05', User OID: 'PatientReportedOutcome (US3292365)', ODM File OID: '66bf52bf-db90-4f33-81dc-44fa954c75d6'	System	03 Oct 2020 04:27:09
User entered '02 Oct 2020 23:27'	System	03 Oct 2020 04:27:09

US3292365

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 26 Nov 2020 10:54:21

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '02 Oct 2020 12:00'	System	26 Sep 2020 15:15:38

US3292365

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 26 Nov 2020 10:54:21

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '03 Oct 2020 11:59'	System	26 Sep 2020 15:15:38

US3292365

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 26 Nov 2020 10:54:21

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	26 Sep 2020 15:15:38
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	26 Sep 2020 15:15:38

US3292365

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 26 Nov 2020 10:54:21

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

Please select one response below

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5d3a9a116dfc2943)', Time: '2020-09-26T10:18:12', User OID: 'PatientReportedOutcome (US3292365)', ODM File OID: '87bc2331-ef5f-4b32-9220-43ae11324efd'	System	26 Sep 2020 15:19:22
User entered 'None (1)'	System	26 Sep 2020 15:19:22

US3292365

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 26 Nov 2020 10:54:21

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5d3a9a116dfc2943)', Time: '2020-09-26T10:18:18', User OID: 'PatientReportedOutcome (US3292365)', ODM File OID: '87bc2331-ef5f-4b32-9220-43ae11324efd'	System	26 Sep 2020 15:19:22
User entered 'No (N)'	System	26 Sep 2020 15:19:22

US3292365

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 26 Nov 2020 10:54:21

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5d3a9a116dfc2943)', Time: '2020-09-26T10:19:12', User OID: 'PatientReportedOutcome (US3292365)', ODM File OID: '87bc2331-ef5f-4b32-9220-43ae11324efd'	System	26 Sep 2020 15:19:22
User entered 'No (N)'	System	26 Sep 2020 15:19:22

US3292365

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 26 Nov 2020 10:54:21

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

Please select one response below

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5d3a9a116dfc2943)', Time: '2020-09-26T10:19:15', User OID: 'PatientReportedOutcome (US3292365)', ODM File OID: '87bc2331-ef5f-4b32-9220-43ae11324efd'	System	26 Sep 2020 15:19:22
User entered 'None (1)'	System	26 Sep 2020 15:19:22

US3292365

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 26 Nov 2020 10:54:21

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5d3a9a116dfc2943)', Time: '2020-09-26T10:19:20', User OID: 'PatientReportedOutcome (US3292365)', ODM File OID: '87bc2331-ef5f-4b32-9220-43ae11324efd'	System	26 Sep 2020 15:19:22
User entered '26 Sep 2020 10:19'	System	26 Sep 2020 15:19:22

US3292365

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 26 Nov 2020 10:54:21

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '26 Sep 2020 10:02'	System	26 Sep 2020 15:15:38

US3292365

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 26 Nov 2020 10:54:21

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '26 Sep 2020 12:32'	System	26 Sep 2020 15:15:38

US3292365

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 26 Nov 2020 10:54:21

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	26 Sep 2020 15:15:38
User entered 'Day 1, after vaccination (at home)'	System	26 Sep 2020 15:15:38

US3292365

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 26 Nov 2020 10:54:21

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

Please select one response below

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5d3a9a116dfc2943)', Time: '2020-09-26T21:32:06', User OID: 'PatientReportedOutcome (US3292365)', ODM File OID: '7231c723-9ff3-418e-9d30-8308a9b620f2'	System	27 Sep 2020 02:33:01
User entered 'Does not interfere with activity (2)'	System	27 Sep 2020 02:33:01

US3292365

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 26 Nov 2020 10:54:21

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5d3a9a116dfc2943)', Time: '2020-09-26T21:32:30', User OID: 'PatientReportedOutcome (US3292365)', ODM File OID: '7231c723-9ff3-418e-9d30-8308a9b620f2'	System	27 Sep 2020 02:33:01
User entered 'No (N)'	System	27 Sep 2020 02:33:01

US3292365

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 26 Nov 2020 10:54:21

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5d3a9a116dfc2943)', Time: '2020-09-26T21:32:50', User OID: 'PatientReportedOutcome (US3292365)', ODM File OID: '7231c723-9ff3-418e-9d30-8308a9b620f2'	System	27 Sep 2020 02:33:01
User entered 'No (N)'	System	27 Sep 2020 02:33:01

US3292365

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 26 Nov 2020 10:54:21

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

Please select one response below

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5d3a9a116dfc2943)', Time: '2020-09-26T21:32:53', User OID: 'PatientReportedOutcome (US3292365)', ODM File OID: '7231c723-9ff3-418e-9d30-8308a9b620f2'	System	27 Sep 2020 02:33:01
User entered 'None (1)'	System	27 Sep 2020 02:33:01

US3292365

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 26 Nov 2020 10:54:21

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5d3a9a116dfc2943)', Time: '2020-09-26T21:32:56', User OID: 'PatientReportedOutcome (US3292365)', ODM File OID: '7231c723-9ff3-418e-9d30-8308a9b620f2'	System	27 Sep 2020 02:33:01
User entered '26 Sep 2020 21:32'	System	27 Sep 2020 02:33:01

US3292365

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 26 Nov 2020 10:54:21

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '26 Sep 2020 13:27'	System	26 Sep 2020 15:15:38

US3292365

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 26 Nov 2020 10:54:21

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '27 Sep 2020 11:59'	System	26 Sep 2020 15:15:38

US3292365

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 26 Nov 2020 10:54:21

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	26 Sep 2020 15:15:38
User entered 'Day 2'	System	26 Sep 2020 15:15:38

US3292365

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 26 Nov 2020 10:54:21

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

Please select one response below

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5d3a9a116dfc2943)', Time: '2020-09-27T21:03:32', User OID: 'PatientReportedOutcome (US3292365)', ODM File OID: 'f4623788-2c00-4d87-bae3-42ae606a9fac'	System	28 Sep 2020 02:06:19
User entered 'Does not interfere with activity (2)'	System	28 Sep 2020 02:06:19

US3292365

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 26 Nov 2020 10:54:21

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5d3a9a116dfc2943)', Time: '2020-09-27T21:05:32', User OID: 'PatientReportedOutcome (US3292365)', ODM File OID: 'f4623788-2c00-4d87-bae3-42ae606a9fac'	System	28 Sep 2020 02:06:19
User entered 'Yes (Y)'	System	28 Sep 2020 02:06:19

US3292365

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 26 Nov 2020 10:54:21

Please record - **REDNESS AT INJECTION SITE (in mm)**

Measure the largest size across any injection site redness with the ruler provided.

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5d3a9a116dfc2943)', Time: '2020-09-27T21:05:46', User OID: 'PatientReportedOutcome (US3292365)', ODM File OID: 'f4623788-2c00-4d87-bae3-42ae606a9fac' User entered '4'	System	28 Sep 2020 02:06:19

US3292365

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 26 Nov 2020 10:54:21

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5d3a9a116dfc2943)', Time: '2020-09-27T21:05:49', User OID: 'PatientReportedOutcome (US3292365)', ODM File OID: 'f4623788-2c00-4d87-bae3-42ae606a9fac'	System	28 Sep 2020 02:06:19
User entered 'Yes (Y)'	System	28 Sep 2020 02:06:19

US3292365

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 26 Nov 2020 10:54:21

Please record - **SWELLING/HARDNESS AT INJECTION SITE (in mm)**

Measure the largest size across any injection site swelling/hardness with the ruler provided.

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5d3a9a116dfc2943)', Time: '2020-09-27T21:05:54', User OID: 'PatientReportedOutcome (US3292365)', ODM File OID: 'f4623788-2c00-4d87-bae3-42ae606a9fac'	System	28 Sep 2020 02:06:19
User entered '4'	System	28 Sep 2020 02:06:19

US3292365

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 26 Nov 2020 10:54:21

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

Please select one response below

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5d3a9a116dfc2943)', Time: '2020-09-27T21:06:04', User OID: 'PatientReportedOutcome (US3292365)', ODM File OID: 'f4623788-2c00-4d87-bae3-42ae606a9fac'	System	28 Sep 2020 02:06:19
User entered 'None (1)'	System	28 Sep 2020 02:06:19

US3292365

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 26 Nov 2020 10:54:21

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5d3a9a116dfc2943)', Time: '2020-09-27T21:06:17', User OID: 'PatientReportedOutcome (US3292365)', ODM File OID: 'f4623788-2c00-4d87-bae3-42ae606a9fac'	System	28 Sep 2020 02:06:19
User entered '27 Sep 2020 21:06'	System	28 Sep 2020 02:06:19

US3292365

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 26 Nov 2020 10:54:21

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '27 Sep 2020 12:00'	System	26 Sep 2020 15:15:38

US3292365

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 26 Nov 2020 10:54:21

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '28 Sep 2020 11:59'	System	26 Sep 2020 15:15:38

US3292365

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 26 Nov 2020 10:54:21

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	26 Sep 2020 15:15:38
User entered 'Day 3'	System	26 Sep 2020 15:15:38

US3292365

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 26 Nov 2020 10:54:21

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

Please select one response below

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5d3a9a116dfc2943)', Time: '2020-09-28T20:57:06', User OID: 'PatientReportedOutcome (US3292365)', ODM File OID: '255e8603-ca93-489d-8988-9cf12ae7e5ca'	System	29 Sep 2020 02:00:16
User entered 'Does not interfere with activity (2)'	System	29 Sep 2020 02:00:16

US3292365

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 26 Nov 2020 10:54:21

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5d3a9a116dfc2943)', Time: '2020-09-28T20:57:30', User OID: 'PatientReportedOutcome (US3292365)', ODM File OID: '255e8603-ca93-489d-8988-9cf12ae7e5ca'	System	29 Sep 2020 02:00:16
User entered 'Yes (Y)'	System	29 Sep 2020 02:00:16

US3292365

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 26 Nov 2020 10:54:21

Please record - **REDNESS AT INJECTION SITE (in mm)**

Measure the largest size across any injection site redness with the ruler provided.

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5d3a9a116dfc2943)', Time: '2020-09-28T20:58:50', User OID: 'PatientReportedOutcome (US3292365)', ODM File OID: '255e8603-ca93-489d-8988-9cf12ae7e5ca' User entered '6'	System	29 Sep 2020 02:00:16

US3292365

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 26 Nov 2020 10:54:21

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5d3a9a116dfc2943)', Time: '2020-09-28T20:59:50', User OID: 'PatientReportedOutcome (US3292365)', ODM File OID: '255e8603-ca93-489d-8988-9cf12ae7e5ca'	System	29 Sep 2020 02:00:16
User entered 'No (N)'	System	29 Sep 2020 02:00:16

US3292365

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 26 Nov 2020 10:54:21

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

Please select one response below

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5d3a9a116dfc2943)', Time: '2020-09-28T20:59:57', User OID: 'PatientReportedOutcome (US3292365)', ODM File OID: '255e8603-ca93-489d-8988-9cf12ae7e5ca'	System	29 Sep 2020 02:00:16
User entered 'None (1)'	System	29 Sep 2020 02:00:16

US3292365

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 26 Nov 2020 10:54:21

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5d3a9a116dfc2943)', Time: '2020-09-28T21:00:14', User OID: 'PatientReportedOutcome (US3292365)', ODM File OID: '255e8603-ca93-489d-8988-9cf12ae7e5ca'	System	29 Sep 2020 02:00:16
User entered '28 Sep 2020 21:00'	System	29 Sep 2020 02:00:16

US3292365

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 26 Nov 2020 10:54:21

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '28 Sep 2020 12:00'	System	26 Sep 2020 15:15:38

US3292365

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 26 Nov 2020 10:54:21

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '29 Sep 2020 11:59'	System	26 Sep 2020 15:15:38

US3292365

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 26 Nov 2020 10:54:21

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	26 Sep 2020 15:15:38
User entered 'Day 4'	System	26 Sep 2020 15:15:38

US3292365

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 26 Nov 2020 10:54:21

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

Please select one response below

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5d3a9a116dfc2943)', Time: '2020-09-29T22:31:55', User OID: 'PatientReportedOutcome (US3292365)', ODM File OID: '72e4a4ac-3ccd-4647-8958-7f86165ea30e'	System	30 Sep 2020 03:32:13
User entered 'Does not interfere with activity (2)'	System	30 Sep 2020 03:32:13

US3292365

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 26 Nov 2020 10:54:21

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5d3a9a116dfc2943)', Time: '2020-09-29T22:31:57', User OID: 'PatientReportedOutcome (US3292365)', ODM File OID: '72e4a4ac-3ccd-4647-8958-7f86165ea30e'	System	30 Sep 2020 03:32:13
User entered 'No (N)'	System	30 Sep 2020 03:32:13

US3292365

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 26 Nov 2020 10:54:21

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5d3a9a116dfc2943)', Time: '2020-09-29T22:32:00', User OID: 'PatientReportedOutcome (US3292365)', ODM File OID: '72e4a4ac-3ccd-4647-8958-7f86165ea30e'	System	30 Sep 2020 03:32:13
User entered 'No (N)'	System	30 Sep 2020 03:32:13

US3292365

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 26 Nov 2020 10:54:21

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

Please select one response below

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5d3a9a116dfc2943)', Time: '2020-09-29T22:32:02', User OID: 'PatientReportedOutcome (US3292365)', ODM File OID: '72e4a4ac-3ccd-4647-8958-7f86165ea30e'	System	30 Sep 2020 03:32:13
User entered 'None (1)'	System	30 Sep 2020 03:32:13

US3292365

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 26 Nov 2020 10:54:21

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5d3a9a116dfc2943)', Time: '2020-09-29T22:32:07', User OID: 'PatientReportedOutcome (US3292365)', ODM File OID: '72e4a4ac-3ccd-4647-8958-7f86165ea30e'	System	30 Sep 2020 03:32:13
User entered '29 Sep 2020 22:32'	System	30 Sep 2020 03:32:13

US3292365

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 26 Nov 2020 10:54:21

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '29 Sep 2020 12:00'	System	26 Sep 2020 15:15:38

US3292365

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 26 Nov 2020 10:54:21

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '30 Sep 2020 11:59'	System	26 Sep 2020 15:15:38

US3292365

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 26 Nov 2020 10:54:21

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	26 Sep 2020 15:15:38
User entered 'Day 5'	System	26 Sep 2020 15:15:38

US3292365

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 26 Nov 2020 10:54:21

[Please record - PAIN AT INJECTION SITE.](#)

[Please select one response below](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5d3a9a116dfc2943)', Time: '2020-09-30T22:20:05', User OID: 'PatientReportedOutcome (US3292365)', ODM File OID: '727b4fea-0dc4-403d-85d6-4fd487498cb9'	System	01 Oct 2020 03:20:22
User entered 'None (1)'	System	01 Oct 2020 03:20:22

US3292365

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 26 Nov 2020 10:54:21

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5d3a9a116dfc2943)', Time: '2020-09-30T22:20:08', User OID: 'PatientReportedOutcome (US3292365)', ODM File OID: '727b4fea-0dc4-403d-85d6-4fd487498cb9'	System	01 Oct 2020 03:20:22
User entered 'No (N)'	System	01 Oct 2020 03:20:22

US3292365

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 26 Nov 2020 10:54:21

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5d3a9a116dfc2943)', Time: '2020-09-30T22:20:13', User OID: 'PatientReportedOutcome (US3292365)', ODM File OID: '727b4fea-0dc4-403d-85d6-4fd487498cb9'	System	01 Oct 2020 03:20:22
User entered 'No (N)'	System	01 Oct 2020 03:20:22

US3292365

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 26 Nov 2020 10:54:21

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

Please select one response below

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5d3a9a116dfc2943)', Time: '2020-09-30T22:20:16', User OID: 'PatientReportedOutcome (US3292365)', ODM File OID: '727b4fea-0dc4-403d-85d6-4fd487498cb9'	System	01 Oct 2020 03:20:22
User entered 'None (1)'	System	01 Oct 2020 03:20:22

US3292365

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 26 Nov 2020 10:54:21

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5d3a9a116dfc2943)', Time: '2020-09-30T22:20:19', User OID: 'PatientReportedOutcome (US3292365)', ODM File OID: '727b4fea-0dc4-403d-85d6-4fd487498cb9' User entered '30 Sep 2020 22:20'	System	01 Oct 2020 03:20:22
	System	01 Oct 2020 03:20:22

US3292365

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 26 Nov 2020 10:54:21

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '30 Sep 2020 12:00'	System	26 Sep 2020 15:15:38

US3292365

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 26 Nov 2020 10:54:21

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '01 Oct 2020 11:59'	System	26 Sep 2020 15:15:38

US3292365

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 26 Nov 2020 10:54:21

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	26 Sep 2020 15:15:38
User entered 'Day 6'	System	26 Sep 2020 15:15:38

US3292365

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 26 Nov 2020 10:54:21

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

Please select one response below

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5d3a9a116dfc2943)', Time: '2020-10-01T20:37:52', User OID: 'PatientReportedOutcome (US3292365)', ODM File OID: '1d37fc7e-15ca-49a2-91d0-59937076df1a'	System	02 Oct 2020 01:38:07
User entered 'None (1)'	System	02 Oct 2020 01:38:07

US3292365

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 26 Nov 2020 10:54:21

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5d3a9a116dfc2943)', Time: '2020-10-01T20:37:55', User OID: 'PatientReportedOutcome (US3292365)', ODM File OID: '1d37fc7e-15ca-49a2-91d0-59937076df1a'	System	02 Oct 2020 01:38:07
User entered 'No (N)'	System	02 Oct 2020 01:38:07

US3292365

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 26 Nov 2020 10:54:21

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5d3a9a116dfc2943)', Time: '2020-10-01T20:37:57', User OID: 'PatientReportedOutcome (US3292365)', ODM File OID: '1d37fc7e-15ca-49a2-91d0-59937076df1a'	System	02 Oct 2020 01:38:07
User entered 'No (N)'	System	02 Oct 2020 01:38:07

US3292365

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 26 Nov 2020 10:54:21

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

Please select one response below

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5d3a9a116dfc2943)', Time: '2020-10-01T20:38:00', User OID: 'PatientReportedOutcome (US3292365)', ODM File OID: '1d37fc7e-15ca-49a2-91d0-59937076df1a'	System	02 Oct 2020 01:38:07
User entered 'None (1)'	System	02 Oct 2020 01:38:07

US3292365

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 26 Nov 2020 10:54:21

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5d3a9a116dfc2943)', Time: '2020-10-01T20:38:04', User OID: 'PatientReportedOutcome (US3292365)', ODM File OID: '1d37fc7e-15ca-49a2-91d0-59937076df1a'	System	02 Oct 2020 01:38:07
User entered '01 Oct 2020 20:38'	System	02 Oct 2020 01:38:07

US3292365

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 26 Nov 2020 10:54:21

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '01 Oct 2020 12:00'	System	26 Sep 2020 15:15:38

US3292365

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 26 Nov 2020 10:54:21

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '02 Oct 2020 11:59'	System	26 Sep 2020 15:15:38

US3292365

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 26 Nov 2020 10:54:21

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	26 Sep 2020 15:15:38
User entered 'Day 7'	System	26 Sep 2020 15:15:38

US3292365

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 26 Nov 2020 10:54:21

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

Please select one response below

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5d3a9a116dfc2943)', Time: '2020-10-02T23:27:11', User OID: 'PatientReportedOutcome (US3292365)', ODM File OID: '61d1b0d9-327a-49de-b400-b07c713178d5'	System	03 Oct 2020 04:27:28
User entered 'None (1)'	System	03 Oct 2020 04:27:28

US3292365

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 26 Nov 2020 10:54:21

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5d3a9a116dfc2943)', Time: '2020-10-02T23:27:13', User OID: 'PatientReportedOutcome (US3292365)', ODM File OID: '61d1b0d9-327a-49de-b400-b07c713178d5'	System	03 Oct 2020 04:27:28
User entered 'No (N)'	System	03 Oct 2020 04:27:28

US3292365

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 26 Nov 2020 10:54:21

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5d3a9a116dfc2943)', Time: '2020-10-02T23:27:16', User OID: 'PatientReportedOutcome (US3292365)', ODM File OID: '61d1b0d9-327a-49de-b400-b07c713178d5'	System	03 Oct 2020 04:27:28
User entered 'No (N)'	System	03 Oct 2020 04:27:28

US3292365

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 26 Nov 2020 10:54:21

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

Please select one response below

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5d3a9a116dfc2943)', Time: '2020-10-02T23:27:19', User OID: 'PatientReportedOutcome (US3292365)', ODM File OID: '61d1b0d9-327a-49de-b400-b07c713178d5'	System	03 Oct 2020 04:27:28
User entered 'None (1)'	System	03 Oct 2020 04:27:28

US3292365

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 26 Nov 2020 10:54:21

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5d3a9a116dfc2943)', Time: '2020-10-02T23:27:26', User OID: 'PatientReportedOutcome (US3292365)', ODM File OID: '61d1b0d9-327a-49de-b400-b07c713178d5'	System	03 Oct 2020 04:27:28
User entered '02 Oct 2020 23:27'	System	03 Oct 2020 04:27:28

US3292365

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 26 Nov 2020 10:54:21

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '02 Oct 2020 12:00'	System	26 Sep 2020 15:15:38

US3292365

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 26 Nov 2020 10:54:21

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '03 Oct 2020 11:59'	System	26 Sep 2020 15:15:38

US3292365

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 10:54:21

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	26 Sep 2020 15:15:38
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	26 Sep 2020 15:15:38

US3292365

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 10:54:21

HEADACHE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5d3a9a116dfc2943)', Time: '2020-09-26T10:19:24', User OID: 'PatientReportedOutcome (US3292365)', ODM File OID: '0b989698-7fba-41e6-88d8-011a1c52dcb8'	System	26 Sep 2020 15:19:45
User entered 'None (0)'	System	26 Sep 2020 15:19:45

US3292365

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 10:54:21

FATIGUE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5d3a9a116dfc2943)', Time: '2020-09-26T10:19:26', User OID: 'PatientReportedOutcome (US3292365)', ODM File OID: '0b989698-7fba-41e6-88d8-011a1c52dcb8'	System	26 Sep 2020 15:19:45
User entered 'None (0)'	System	26 Sep 2020 15:19:45

US3292365

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 10:54:21

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5d3a9a116dfc2943)', Time: '2020-09-26T10:19:27', User OID: 'PatientReportedOutcome (US3292365)', ODM File OID: '0b989698-7fba-41e6-88d8-011a1c52dcb8'	System	26 Sep 2020 15:19:45
User entered 'None (0)'	System	26 Sep 2020 15:19:45

US3292365

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 10:54:21

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5d3a9a116dfc2943)', Time: '2020-09-26T10:19:29', User OID: 'PatientReportedOutcome (US3292365)', ODM File OID: '0b989698-7fba-41e6-88d8-011a1c52dcb8'	System	26 Sep 2020 15:19:45
User entered 'None (0)'	System	26 Sep 2020 15:19:45

US3292365

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 10:54:21

NAUSEA/VOMITING

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5d3a9a116dfc2943)', Time: '2020-09-26T10:19:31', User OID: 'PatientReportedOutcome (US3292365)', ODM File OID: '0b989698-7fba-41e6-88d8-011a1c52dcb8'	System	26 Sep 2020 15:19:45
User entered 'None (0)'	System	26 Sep 2020 15:19:45

US3292365

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 10:54:21

CHILLS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5d3a9a116dfc2943)', Time: '2020-09-26T10:19:32', User OID: 'PatientReportedOutcome (US3292365)', ODM File OID: '0b989698-7fba-41e6-88d8-011a1c52dcb8'	System	26 Sep 2020 15:19:45
User entered 'None (0)'	System	26 Sep 2020 15:19:45

US3292365

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 10:54:21

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5d3a9a116dfc2943)', Time: '2020-09-26T10:19:36', User OID: 'PatientReportedOutcome (US3292365)', ODM File OID: '0b989698-7fba-41e6-88d8-011a1c52dcb8'	System	26 Sep 2020 15:19:45
User entered 'No (N)'	System	26 Sep 2020 15:19:45

US3292365

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 10:54:21

[PC Time stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5d3a9a116dfc2943)', Time: '2020-09-26T10:19:40', User OID: 'PatientReportedOutcome (US3292365)', ODM File OID: '0b989698-7fba-41e6-88d8-011a1c52dcb8'	System	26 Sep 2020 15:19:45
User entered '26 Sep 2020 10:19'	System	26 Sep 2020 15:19:45

US3292365

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 10:54:21

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '26 Sep 2020 10:02'	System	26 Sep 2020 15:15:38

US3292365

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 10:54:21

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '26 Sep 2020 12:32'	System	26 Sep 2020 15:15:38

US3292365

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 10:54:21

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	26 Sep 2020 15:15:38
User entered 'Day 1, after vaccination (at home)'	System	26 Sep 2020 15:15:38

US3292365

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 10:54:21

HEADACHE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5d3a9a116dfc2943)', Time: '2020-09-26T21:33:00', User OID: 'PatientReportedOutcome (US3292365)', ODM File OID: 'f1f8296e-b326-476d-b3e7-4a73b1a640d8'	System	27 Sep 2020 02:33:24
User entered 'None (0)'	System	27 Sep 2020 02:33:24

US3292365

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 10:54:21

FATIGUE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5d3a9a116dfc2943)', Time: '2020-09-26T21:33:02', User OID: 'PatientReportedOutcome (US3292365)', ODM File OID: 'f1f8296e-b326-476d-b3e7-4a73b1a640d8'	System	27 Sep 2020 02:33:24
User entered 'None (0)'	System	27 Sep 2020 02:33:24

US3292365

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 10:54:21

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5d3a9a116dfc2943)', Time: '2020-09-26T21:33:04', User OID: 'PatientReportedOutcome (US3292365)', ODM File OID: 'f1f8296e-b326-476d-b3e7-4a73b1a640d8'	System	27 Sep 2020 02:33:24
User entered 'None (0)'	System	27 Sep 2020 02:33:24

US3292365

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 10:54:21

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5d3a9a116dfc2943)', Time: '2020-09-26T21:33:06', User OID: 'PatientReportedOutcome (US3292365)', ODM File OID: 'f1f8296e-b326-476d-b3e7-4a73b1a640d8'	System	27 Sep 2020 02:33:24
User entered 'None (0)'	System	27 Sep 2020 02:33:24

US3292365

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 10:54:21

NAUSEA/VOMITING

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5d3a9a116dfc2943)', Time: '2020-09-26T21:33:08', User OID: 'PatientReportedOutcome (US3292365)', ODM File OID: 'f1f8296e-b326-476d-b3e7-4a73b1a640d8'	System	27 Sep 2020 02:33:24
User entered 'None (0)'	System	27 Sep 2020 02:33:24

US3292365

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 10:54:21

CHILLS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5d3a9a116dfc2943)', Time: '2020-09-26T21:33:10', User OID: 'PatientReportedOutcome (US3292365)', ODM File OID: 'f1f8296e-b326-476d-b3e7-4a73b1a640d8'	System	27 Sep 2020 02:33:24
User entered 'None (0)'	System	27 Sep 2020 02:33:24

US3292365

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 10:54:21

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5d3a9a116dfc2943)', Time: '2020-09-26T21:33:14', User OID: 'PatientReportedOutcome (US3292365)', ODM File OID: 'f1f8296e-b326-476d-b3e7-4a73b1a640d8'	System	27 Sep 2020 02:33:24
User entered 'No (N)'	System	27 Sep 2020 02:33:24

US3292365

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 10:54:21

[PC Time stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5d3a9a116dfc2943)', Time: '2020-09-26T21:33:18', User OID: 'PatientReportedOutcome (US3292365)', ODM File OID: 'f1f8296e-b326-476d-b3e7-4a73b1a640d8'	System	27 Sep 2020 02:33:24
User entered '26 Sep 2020 21:33'	System	27 Sep 2020 02:33:24

US3292365

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 10:54:21

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '26 Sep 2020 13:27'	System	26 Sep 2020 15:15:38

US3292365

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 10:54:21

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '27 Sep 2020 11:59'	System	26 Sep 2020 15:15:38

US3292365

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 10:54:21

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	26 Sep 2020 15:15:38
User entered 'Day 2'	System	26 Sep 2020 15:15:38

US3292365

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 10:54:21

HEADACHE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5d3a9a116dfc2943)', Time: '2020-09-27T21:06:25', User OID: 'PatientReportedOutcome (US3292365)', ODM File OID: '6589c7bb-d701-49f9-ab8e-05482bea70b5'	System	28 Sep 2020 02:07:49
User entered 'No interference with activity (1)'	System	28 Sep 2020 02:07:49

US3292365

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 10:54:21

FATIGUE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5d3a9a116dfc2943)', Time: '2020-09-27T21:06:38', User OID: 'PatientReportedOutcome (US3292365)', ODM File OID: '6589c7bb-d701-49f9-ab8e-05482bea70b5'	System	28 Sep 2020 02:07:49
User entered 'Some interference with activity (2)'	System	28 Sep 2020 02:07:49

US3292365

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 10:54:21

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5d3a9a116dfc2943)', Time: '2020-09-27T21:06:45', User OID: 'PatientReportedOutcome (US3292365)', ODM File OID: '6589c7bb-d701-49f9-ab8e-05482bea70b5'	System	28 Sep 2020 02:07:49
User entered 'Some interference with activity (2)'	System	28 Sep 2020 02:07:49

US3292365

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 10:54:21

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5d3a9a116dfc2943)', Time: '2020-09-27T21:06:50', User OID: 'PatientReportedOutcome (US3292365)', ODM File OID: '6589c7bb-d701-49f9-ab8e-05482bea70b5'	System	28 Sep 2020 02:07:49
User entered 'None (0)'	System	28 Sep 2020 02:07:49

US3292365

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 10:54:21

NAUSEA/VOMITING

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5d3a9a116dfc2943)', Time: '2020-09-27T21:07:20', User OID: 'PatientReportedOutcome (US3292365)', ODM File OID: '6589c7bb-d701-49f9-ab8e-05482bea70b5'	System	28 Sep 2020 02:07:49
User entered 'No interference with activity or 1-2 episodes/24 hours (1)'	System	28 Sep 2020 02:07:49

US3292365

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 10:54:21

CHILLS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5d3a9a116dfc2943)', Time: '2020-09-27T21:07:23', User OID: 'PatientReportedOutcome (US3292365)', ODM File OID: '6589c7bb-d701-49f9-ab8e-05482bea70b5'	System	28 Sep 2020 02:07:49
User entered 'None (0)'	System	28 Sep 2020 02:07:49

US3292365

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 10:54:21

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5d3a9a116dfc2943)', Time: '2020-09-27T21:07:28', User OID: 'PatientReportedOutcome (US3292365)', ODM File OID: '6589c7bb-d701-49f9-ab8e-05482bea70b5'	System	28 Sep 2020 02:07:49
User entered 'No (N)'	System	28 Sep 2020 02:07:49

US3292365

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 10:54:21

[PC Time stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5d3a9a116dfc2943)', Time: '2020-09-27T21:07:43', User OID: 'PatientReportedOutcome (US3292365)', ODM File OID: '6589c7bb-d701-49f9-ab8e-05482bea70b5'	System	28 Sep 2020 02:07:49
User entered '27 Sep 2020 21:07'	System	28 Sep 2020 02:07:49

US3292365

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 10:54:21

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '27 Sep 2020 12:00'	System	26 Sep 2020 15:15:38

US3292365

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 10:54:21

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '28 Sep 2020 11:59'	System	26 Sep 2020 15:15:38

US3292365

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 10:54:21

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	26 Sep 2020 15:15:38
User entered 'Day 3'	System	26 Sep 2020 15:15:38

US3292365

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 10:54:21

HEADACHE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5d3a9a116dfc2943)', Time: '2020-09-28T21:00:20', User OID: 'PatientReportedOutcome (US3292365)', ODM File OID: '8575d4f6-e2b2-4106-b841-ea02d034dc5d'	System	29 Sep 2020 02:00:45
User entered 'None (0)'	System	29 Sep 2020 02:00:45

US3292365

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 10:54:21

FATIGUE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5d3a9a116dfc2943)', Time: '2020-09-28T21:00:25', User OID: 'PatientReportedOutcome (US3292365)', ODM File OID: '8575d4f6-e2b2-4106-b841-ea02d034dc5d'	System	29 Sep 2020 02:00:45
User entered 'No interference with activity (1)'	System	29 Sep 2020 02:00:45

US3292365

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 10:54:21

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5d3a9a116dfc2943)', Time: '2020-09-28T21:00:27', User OID: 'PatientReportedOutcome (US3292365)', ODM File OID: '8575d4f6-e2b2-4106-b841-ea02d034dc5d'	System	29 Sep 2020 02:00:45
User entered 'None (0)'	System	29 Sep 2020 02:00:45

US3292365

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 10:54:21

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5d3a9a116dfc2943)', Time: '2020-09-28T21:00:29', User OID: 'PatientReportedOutcome (US3292365)', ODM File OID: '8575d4f6-e2b2-4106-b841-ea02d034dc5d'	System	29 Sep 2020 02:00:45
User entered 'None (0)'	System	29 Sep 2020 02:00:45

US3292365

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 10:54:21

NAUSEA/VOMITING

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5d3a9a116dfc2943)', Time: '2020-09-28T21:00:31', User OID: 'PatientReportedOutcome (US3292365)', ODM File OID: '8575d4f6-e2b2-4106-b841-ea02d034dc5d'	System	29 Sep 2020 02:00:45
User entered 'None (0)'	System	29 Sep 2020 02:00:45

US3292365

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 10:54:21

CHILLS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5d3a9a116dfc2943)', Time: '2020-09-28T21:00:33', User OID: 'PatientReportedOutcome (US3292365)', ODM File OID: '8575d4f6-e2b2-4106-b841-ea02d034dc5d'	System	29 Sep 2020 02:00:45
User entered 'None (0)'	System	29 Sep 2020 02:00:45

US3292365

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 10:54:21

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5d3a9a116dfc2943)', Time: '2020-09-28T21:00:37', User OID: 'PatientReportedOutcome (US3292365)', ODM File OID: '8575d4f6-e2b2-4106-b841-ea02d034dc5d'	System	29 Sep 2020 02:00:45
User entered 'No (N)'	System	29 Sep 2020 02:00:45

US3292365

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 10:54:21

[PC Time stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5d3a9a116dfc2943)', Time: '2020-09-28T21:00:43', User OID: 'PatientReportedOutcome (US3292365)', ODM File OID: '8575d4f6-e2b2-4106-b841-ea02d034dc5d'	System	29 Sep 2020 02:00:45
User entered '28 Sep 2020 21:00'	System	29 Sep 2020 02:00:45

US3292365

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 10:54:21

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '28 Sep 2020 12:00'	System	26 Sep 2020 15:15:38

US3292365

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 10:54:21

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '29 Sep 2020 11:59'	System	26 Sep 2020 15:15:38

US3292365

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 10:54:21

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	26 Sep 2020 15:15:38
User entered 'Day 4'	System	26 Sep 2020 15:15:38

US3292365

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 10:54:21

HEADACHE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5d3a9a116dfc2943)', Time: '2020-09-29T22:32:11', User OID: 'PatientReportedOutcome (US3292365)', ODM File OID: '7b335c6c-e451-4bf1-940d-676ccb4fded2'	System	30 Sep 2020 03:32:27
User entered 'None (0)'	System	30 Sep 2020 03:32:27

US3292365

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 10:54:21

FATIGUE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5d3a9a116dfc2943)', Time: '2020-09-29T22:32:13', User OID: 'PatientReportedOutcome (US3292365)', ODM File OID: '7b335c6c-e451-4bf1-940d-676ccb4fded2'	System	30 Sep 2020 03:32:27
User entered 'None (0)'	System	30 Sep 2020 03:32:27

US3292365

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 10:54:21

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5d3a9a116dfc2943)', Time: '2020-09-29T22:32:15', User OID: 'PatientReportedOutcome (US3292365)', ODM File OID: '7b335c6c-e451-4bf1-940d-676ccb4fded2'	System	30 Sep 2020 03:32:27
User entered 'None (0)'	System	30 Sep 2020 03:32:27

US3292365

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 10:54:21

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5d3a9a116dfc2943)', Time: '2020-09-29T22:32:17', User OID: 'PatientReportedOutcome (US3292365)', ODM File OID: '7b335c6c-e451-4bf1-940d-676ccb4fded2'	System	30 Sep 2020 03:32:27
User entered 'None (0)'	System	30 Sep 2020 03:32:27

US3292365

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 10:54:21

NAUSEA/VOMITING

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5d3a9a116dfc2943)', Time: '2020-09-29T22:32:19', User OID: 'PatientReportedOutcome (US3292365)', ODM File OID: '7b335c6c-e451-4bf1-940d-676ccb4fded2'	System	30 Sep 2020 03:32:27
User entered 'None (0)'	System	30 Sep 2020 03:32:27

US3292365

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 10:54:21

CHILLS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5d3a9a116dfc2943)', Time: '2020-09-29T22:32:20', User OID: 'PatientReportedOutcome (US3292365)', ODM File OID: '7b335c6c-e451-4bf1-940d-676ccb4fded2'	System	30 Sep 2020 03:32:27
User entered 'None (0)'	System	30 Sep 2020 03:32:27

US3292365

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 10:54:21

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5d3a9a116dfc2943)', Time: '2020-09-29T22:32:22', User OID: 'PatientReportedOutcome (US3292365)', ODM File OID: '7b335c6c-e451-4bf1-940d-676ccb4fded2'	System	30 Sep 2020 03:32:27
User entered 'No (N)'	System	30 Sep 2020 03:32:27

US3292365

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 10:54:21

[PC Time stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5d3a9a116dfc2943)', Time: '2020-09-29T22:32:25', User OID: 'PatientReportedOutcome (US3292365)', ODM File OID: '7b335c6c-e451-4bf1-940d-676ccb4fded2'	System	30 Sep 2020 03:32:27
User entered '29 Sep 2020 22:32'	System	30 Sep 2020 03:32:27

US3292365

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 10:54:21

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '29 Sep 2020 12:00'	System	26 Sep 2020 15:15:38

US3292365

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 10:54:21

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '30 Sep 2020 11:59'	System	26 Sep 2020 15:15:38

US3292365

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 10:54:21

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	26 Sep 2020 15:15:38
User entered 'Day 5'	System	26 Sep 2020 15:15:38

US3292365

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 10:54:21

HEADACHE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5d3a9a116dfc2943)', Time: '2020-09-30T22:19:46', User OID: 'PatientReportedOutcome (US3292365)', ODM File OID: 'd1820b2f-8a7b-4b0b-bd2a-d672326a4e4e'	System	01 Oct 2020 03:20:05
User entered 'None (0)'	System	01 Oct 2020 03:20:05

US3292365

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 10:54:21

FATIGUE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5d3a9a116dfc2943)', Time: '2020-09-30T22:19:48', User OID: 'PatientReportedOutcome (US3292365)', ODM File OID: 'd1820b2f-8a7b-4b0b-bd2a-d672326a4e4e'	System	01 Oct 2020 03:20:05
User entered 'None (0)'	System	01 Oct 2020 03:20:05

US3292365

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 10:54:21

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5d3a9a116dfc2943)', Time: '2020-09-30T22:19:50', User OID: 'PatientReportedOutcome (US3292365)', ODM File OID: 'd1820b2f-8a7b-4b0b-bd2a-d672326a4e4e'	System	01 Oct 2020 03:20:05
User entered 'None (0)'	System	01 Oct 2020 03:20:05

US3292365

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 10:54:21

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5d3a9a116dfc2943)', Time: '2020-09-30T22:19:52', User OID: 'PatientReportedOutcome (US3292365)', ODM File OID: 'd1820b2f-8a7b-4b0b-bd2a-d672326a4e4e'	System	01 Oct 2020 03:20:05
User entered 'None (0)'	System	01 Oct 2020 03:20:05

US3292365

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 10:54:21

NAUSEA/VOMITING

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5d3a9a116dfc2943)', Time: '2020-09-30T22:19:53', User OID: 'PatientReportedOutcome (US3292365)', ODM File OID: 'd1820b2f-8a7b-4b0b-bd2a-d672326a4e4e'	System	01 Oct 2020 03:20:05
User entered 'None (0)'	System	01 Oct 2020 03:20:05

US3292365

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 10:54:21

CHILLS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5d3a9a116dfc2943)', Time: '2020-09-30T22:19:55', User OID: 'PatientReportedOutcome (US3292365)', ODM File OID: 'd1820b2f-8a7b-4b0b-bd2a-d672326a4e4e'	System	01 Oct 2020 03:20:05
User entered 'None (0)'	System	01 Oct 2020 03:20:05

US3292365

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 10:54:21

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5d3a9a116dfc2943)', Time: '2020-09-30T22:19:57', User OID: 'PatientReportedOutcome (US3292365)', ODM File OID: 'd1820b2f-8a7b-4b0b-bd2a-d672326a4e4e'	System	01 Oct 2020 03:20:05
User entered 'No (N)'	System	01 Oct 2020 03:20:05

US3292365

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 10:54:21

[PC Time stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5d3a9a116dfc2943)', Time: '2020-09-30T22:20:00', User OID: 'PatientReportedOutcome (US3292365)', ODM File OID: 'd1820b2f-8a7b-4b0b-bd2a-d672326a4e4e'	System	01 Oct 2020 03:20:05
User entered '30 Sep 2020 22:20'	System	01 Oct 2020 03:20:05

US3292365

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 10:54:21

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '30 Sep 2020 12:00'	System	26 Sep 2020 15:15:38

US3292365

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 10:54:21

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '01 Oct 2020 11:59'	System	26 Sep 2020 15:15:38

US3292365

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 10:54:21

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	26 Sep 2020 15:15:38
User entered 'Day 6'	System	26 Sep 2020 15:15:38

US3292365

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 10:54:21

HEADACHE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5d3a9a116dfc2943)', Time: '2020-10-01T20:38:09', User OID: 'PatientReportedOutcome (US3292365)', ODM File OID: '2dc4ff1-8f3f-4b8b-aa4d-d9d5ab206754'	System	02 Oct 2020 01:38:36
User entered 'None (0)'	System	02 Oct 2020 01:38:36

US3292365

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 10:54:21

FATIGUE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5d3a9a116dfc2943)', Time: '2020-10-01T20:38:12', User OID: 'PatientReportedOutcome (US3292365)', ODM File OID: '2dc4ff1-8f3f-4b8b-aa4d-d9d5ab206754'	System	02 Oct 2020 01:38:36
User entered 'None (0)'	System	02 Oct 2020 01:38:36

US3292365

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 10:54:21

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5d3a9a116dfc2943)', Time: '2020-10-01T20:38:14', User OID: 'PatientReportedOutcome (US3292365)', ODM File OID: '2dc4ff1-8f3f-4b8b-aa4d-d9d5ab206754'	System	02 Oct 2020 01:38:36
User entered 'None (0)'	System	02 Oct 2020 01:38:36

US3292365

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 10:54:21

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5d3a9a116dfc2943)', Time: '2020-10-01T20:38:17', User OID: 'PatientReportedOutcome (US3292365)', ODM File OID: '2dcb4ff1-8f3f-4b8b-aa4d-d9d5ab206754'	System	02 Oct 2020 01:38:36
User entered 'None (0)'	System	02 Oct 2020 01:38:36

US3292365

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 10:54:21

NAUSEA/VOMITING

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5d3a9a116dfc2943)', Time: '2020-10-01T20:38:19', User OID: 'PatientReportedOutcome (US3292365)', ODM File OID: '2dcb4ff1-8f3f-4b8b-aa4d-d9d5ab206754'	System	02 Oct 2020 01:38:36
User entered 'None (0)'	System	02 Oct 2020 01:38:36

US3292365

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 10:54:21

CHILLS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5d3a9a116dfc2943)', Time: '2020-10-01T20:38:21', User OID: 'PatientReportedOutcome (US3292365)', ODM File OID: '2dcb4ff1-8f3f-4b8b-aa4d-d9d5ab206754'	System	02 Oct 2020 01:38:36
User entered 'None (0)'	System	02 Oct 2020 01:38:36

US3292365

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 10:54:21

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5d3a9a116dfc2943)', Time: '2020-10-01T20:38:26', User OID: 'PatientReportedOutcome (US3292365)', ODM File OID: '2dcb4ff1-8f3f-4b8b-aa4d-d9d5ab206754'	System	02 Oct 2020 01:38:36
User entered 'No (N)'	System	02 Oct 2020 01:38:36

US3292365

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 10:54:21

[PC Time stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5d3a9a116dfc2943)', Time: '2020-10-01T20:38:33', User OID: 'PatientReportedOutcome (US3292365)', ODM File OID: '2dcb4ff1-8f3f-4b8b-aa4d-d9d5ab206754'	System	02 Oct 2020 01:38:36
User entered '01 Oct 2020 20:38'	System	02 Oct 2020 01:38:36

US3292365

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 10:54:21

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '01 Oct 2020 12:00'	System	26 Sep 2020 15:15:38

US3292365

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 10:54:21

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '02 Oct 2020 11:59'	System	26 Sep 2020 15:15:38

US3292365

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 10:54:21

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	26 Sep 2020 15:15:38
User entered 'Day 7'	System	26 Sep 2020 15:15:38

US3292365

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 10:54:21

HEADACHE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5d3a9a116dfc2943)', Time: '2020-10-02T23:27:30', User OID: 'PatientReportedOutcome (US3292365)', ODM File OID: '45274eb2-df34-4e0e-a4c6-dac429de6f9a'	System	03 Oct 2020 04:27:51
User entered 'None (0)'	System	03 Oct 2020 04:27:51

US3292365

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 10:54:21

FATIGUE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5d3a9a116dfc2943)', Time: '2020-10-02T23:27:32', User OID: 'PatientReportedOutcome (US3292365)', ODM File OID: '45274eb2-df34-4e0e-a4c6-dac429de6f9a'	System	03 Oct 2020 04:27:51
User entered 'None (0)'	System	03 Oct 2020 04:27:51

US3292365

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 10:54:21

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5d3a9a116dfc2943)', Time: '2020-10-02T23:27:34', User OID: 'PatientReportedOutcome (US3292365)', ODM File OID: '45274eb2-df34-4e0e-a4c6-dac429de6f9a'	System	03 Oct 2020 04:27:51
User entered 'None (0)'	System	03 Oct 2020 04:27:51

US3292365

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 10:54:21

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5d3a9a116dfc2943)', Time: '2020-10-02T23:27:36', User OID: 'PatientReportedOutcome (US3292365)', ODM File OID: '45274eb2-df34-4e0e-a4c6-dac429de6f9a'	System	03 Oct 2020 04:27:51
User entered 'None (0)'	System	03 Oct 2020 04:27:51

US3292365

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 10:54:21

NAUSEA/VOMITING

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5d3a9a116dfc2943)', Time: '2020-10-02T23:27:38', User OID: 'PatientReportedOutcome (US3292365)', ODM File OID: '45274eb2-df34-4e0e-a4c6-dac429de6f9a'	System	03 Oct 2020 04:27:51
User entered 'None (0)'	System	03 Oct 2020 04:27:51

US3292365

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 10:54:21

CHILLS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5d3a9a116dfc2943)', Time: '2020-10-02T23:27:40', User OID: 'PatientReportedOutcome (US3292365)', ODM File OID: '45274eb2-df34-4e0e-a4c6-dac429de6f9a'	System	03 Oct 2020 04:27:51
User entered 'None (0)'	System	03 Oct 2020 04:27:51

US3292365

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 10:54:21

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5d3a9a116dfc2943)', Time: '2020-10-02T23:27:43', User OID: 'PatientReportedOutcome (US3292365)', ODM File OID: '45274eb2-df34-4e0e-a4c6-dac429de6f9a'	System	03 Oct 2020 04:27:51
User entered 'No (N)'	System	03 Oct 2020 04:27:51

US3292365

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 10:54:21

[PC Time stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5d3a9a116dfc2943)', Time: '2020-10-02T23:27:50', User OID: 'PatientReportedOutcome (US3292365)', ODM File OID: '45274eb2-df34-4e0e-a4c6-dac429de6f9a'	System	03 Oct 2020 04:27:51
User entered '02 Oct 2020 23:27'	System	03 Oct 2020 04:27:51

US3292365

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 10:54:21

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '02 Oct 2020 12:00'	System	26 Sep 2020 15:15:38

US3292365

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 10:54:21

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '03 Oct 2020 11:59'	System	26 Sep 2020 15:15:38

US3292365

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 26 Nov 2020 10:54:21

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Kristy Trevino (b) (4) (b) (4)	04 Oct 2020 20:03:31

US3292365

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 26 Nov 2020 10:54:21

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

Audit	User	Time (GMT)
User entered '4 Oct 2020'	Kristy Trevino (b) (4) (b) (4)	04 Oct 2020 20:03:31

US3292365

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 26 Nov 2020 10:54:21

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
User entered 'Contact Made (CONTACT MADE)'	Kristy Trevino (b) (4) (b) (4)	04 Oct 2020 20:03:31

US3292365

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 26 Nov 2020 10:54:21

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
User entered empty.	Kristy Trevino (b) (4) (b) (4)	04 Oct 2020 20:03:31

US3292365

Folder: Safety Call Day 36 (1)

Form: Continuing

Generated On: 26 Nov 2020 10:54:21

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Kristy Trevino (b) (4) (b) (4)	04 Oct 2020 20:03:35

US3292365

Folder: Safety Call Day 36 (1)

Form: Continuing

Generated On: 26 Nov 2020 10:54:21

[Continuing Flag](#)

Audit	User	Time (GMT)
User entered 'I'	System	04 Oct 2020 20:03:35

US3292365

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 26 Nov 2020 10:54:21

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	(b) (4), (b) (6)	10 Oct 2020 15:36:40

US3292365

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 26 Nov 2020 10:54:21

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

Audit	User	Time (GMT)
User entered '10 Oct 2020'	(b) (4), (b) (6)	10 Oct 2020 15:36:40

US3292365

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 26 Nov 2020 10:54:21

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
User entered 'Contact Made (CONTACT MADE)'	(b) (4), (b) (6)	10 Oct 2020 15:36:40

US3292365

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 26 Nov 2020 10:54:21

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	10 Oct 2020 15:36:40

US3292365

Folder: Safety Call Day 43 (1)

Form: Continuing

Generated On: 26 Nov 2020 10:54:21

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	(b) (4), (b) (6)	10 Oct 2020 15:36:46

US3292365

Folder: Safety Call Day 43 (1)

Form: Continuing

Generated On: 26 Nov 2020 10:54:21

[Continuing Flag](#)

Audit	User	Time (GMT)
User entered 'I'	System	10 Oct 2020 15:36:46

US3292365

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 26 Nov 2020 10:54:21

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Kristy Trevino (b) (4) (b) (4)	17 Oct 2020 15:31:31

US3292365

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 26 Nov 2020 10:54:21

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

Audit	User	Time (GMT)
User entered '17 Oct 2020'	Kristy Trevino (b) (4) (b) (4)	17 Oct 2020 15:31:31

US3292365

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 26 Nov 2020 10:54:21

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
User entered 'Contact Made (CONTACT MADE)'	Kristy Trevino (b) (4) (b) (4)	17 Oct 2020 15:31:31

US3292365

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 26 Nov 2020 10:54:21

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
User entered empty.	Kristy Trevino (b) (4) (b) (4)	17 Oct 2020 15:31:31

US3292365

Folder: Safety Call Day 50 (1)

Form: Continuing

Generated On: 26 Nov 2020 10:54:21

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Kristy Trevino (b) (4) (b) (4)	17 Oct 2020 15:31:42

US3292365

Folder: Safety Call Day 50 (1)

Form: Continuing

Generated On: 26 Nov 2020 10:54:21

[Continuing Flag](#)

Audit	User	Time (GMT)
User entered 'I'	System	17 Oct 2020 15:31:42

US3292365

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 26 Nov 2020 10:54:21

[Was this visit performed?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	(b) (4), (b) (6)	27 Oct 2020 14:05:29

US3292365

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 26 Nov 2020 10:54:21

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

Audit	User	Time (GMT)
User entered '27 Oct 2020'	(b) (4), (b) (6)	27 Oct 2020 14:05:29

US3292365

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 26 Nov 2020 10:54:21

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

Audit	User	Time (GMT)
User entered 'Clinic (Clinic)'	(b) (4), (b) (6)	27 Oct 2020 14:05:29

US3292365

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 26 Nov 2020 10:54:21

[Folder OID](#)

Audit	User	Time (GMT)
User entered 'VISIT3'	System	27 Oct 2020 14:05:29

US3292365

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 10:54:21

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	(b) (4), (b) (6)	27 Oct 2020 14:06:18

US3292365

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 10:54:21

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
User entered '27 Oct 2020'	(b) (4), (b) (6)	27 Oct 2020 14:06:18

US3292365

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 10:54:21

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

Audit	User	Time (GMT)
User entered '07:54'	(b) (4), (b) (6)	27 Oct 2020 14:06:18

US3292365

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 10:54:21

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

Audit	User	Time (GMT)
User entered '27 Oct 2020 07:54'	System	27 Oct 2020 14:06:18

US3292365

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 10:54:21

Temperature (xxx.x)

Audit	User	Time (GMT)
User entered '36.6' C	(b) (4), (b) (6)	27 Oct 2020 14:06:18

US3292365

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 10:54:21

[Route of measurement](#)

Audit	User	Time (GMT)
User entered 'Oral (Oral)'	(b) (4), (b) (6)	27 Oct 2020 14:06:18

US3292365

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 10:54:21

[If Other, specify](#)

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	27 Oct 2020 14:06:18

US3292365

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 10:54:21

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
User entered '54'	(b) (4), (b) (6)	27 Oct 2020 14:06:18

US3292365

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 10:54:21

[Pulse units](#)

Audit	User	Time (GMT)
User entered 'bpm'	System	27 Oct 2020 14:06:18

US3292365

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 10:54:21

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

Audit	User	Time (GMT)
User entered '16'	(b) (4), (b) (6)	27 Oct 2020 14:06:18

US3292365

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 10:54:21

[Respiratory Rate units](#)

Audit	User	Time (GMT)
User entered 'breaths/min'	System	27 Oct 2020 14:06:18

US3292365

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 10:54:21

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
User entered '126'	(b) (4), (b) (6)	27 Oct 2020 14:06:18

US3292365

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 10:54:21

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered 'mmHg'	System	27 Oct 2020 14:06:18

US3292365

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 10:54:21

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
User entered '88'	(b) (4), (b) (6)	27 Oct 2020 14:06:18

US3292365

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 10:54:21

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered 'mmHg'	System	27 Oct 2020 14:06:18

US3292365

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Generated On: 26 Nov 2020 10:54:21

Was the physical examination performed?

Audit	User	Time (GMT)
User entered 'No (N)'	(b) (4), (b) (6)	27 Oct 2020 14:06:23

US3292365

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Generated On: 26 Nov 2020 10:54:21

Date of examination (*dd MMM yyyy*)

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	27 Oct 2020 14:06:23

US3292365

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 26 Nov 2020 10:54:21

[Was the sample collected?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	(b) (4), (b) (6)	27 Oct 2020 14:06:56

US3292365

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 26 Nov 2020 10:54:21

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User entered '27 Oct 2020'	(b) (4), (b) (6)	27 Oct 2020 14:06:56

US3292365

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 26 Nov 2020 10:54:21

[Collection time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
User entered '08:07'	(b) (4), (b) (6)	27 Oct 2020 14:06:56

US3292365

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 26 Nov 2020 10:54:21

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
User entered '27 Oct 2020 08:07'	System	27 Oct 2020 14:06:56

US3292365

Folder: Visit 3 Day 57 (1)

Form: Continuing

Generated On: 26 Nov 2020 10:54:21

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	(b) (4), (b) (6)	27 Oct 2020 14:07:01

US3292365

Folder: Visit 3 Day 57 (1)

Form: Continuing

Generated On: 26 Nov 2020 10:54:21

[Continuing Flag](#)

Audit	User	Time (GMT)
User entered 'I'	System	27 Oct 2020 14:07:01

US3292365

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:54:21

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	29 Aug 2020 18:21:38
User entered 'Day 64'	System	29 Aug 2020 18:21:38

US3292365

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:54:21

[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 (5d3a9a116dfc2943)', Time: '2020-10-31T13:54:30', User OID: 'PatientReportedOutcome (US3292365)', ODM File OID: 'a5fc3085-a248-4069-b43e-1216bd360f81'	System	31 Oct 2020 18:54:47
User entered 'No (N)'	System	31 Oct 2020 18:54:47

US3292365

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:54:21

Have you been exposed to someone with 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 (5d3a9a116dfc2943)', Time: '2020-10-31T13:54:35', User OID: 'PatientReportedOutcome (US3292365)', ODM File OID: 'a5fc3085-a248-4069-b43e-1216bd360f81'	System	31 Oct 2020 18:54:47
User entered 'No (N)'	System	31 Oct 2020 18:54:47

US3292365

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:54:21

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5d3a9a116dfc2943)', Time: '2020-10-31T13:54:44', User OID: 'PatientReportedOutcome (US3292365)', ODM File OID: 'a5fc3085-a248-4069-b43e-1216bd360f81'	System	31 Oct 2020 18:54:47
User entered '31 Oct 2020 13:54:44'	System	31 Oct 2020 18:54:47

US3292365

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:54:21

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data entry locked.	System	29 Aug 2020 18:21:38
User entered '29 Oct 2020 00:01'	System	29 Aug 2020 18:21:38

US3292365

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:54:21

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data entry locked.	System	29 Aug 2020 18:21:38
User entered '02 Nov 2020 23:59'	System	29 Aug 2020 18:21:38

US3292365

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:54:21

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	29 Aug 2020 18:21:38
User entered 'Day 71'	System	29 Aug 2020 18:21:38

US3292365

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:54:21

[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 (5d3a9a116dfc2943)', Time: '2020-11-07T16:46:24', User OID: 'PatientReportedOutcome (US3292365)', ODM File OID: '09067362-821f-44d5-8842-67e0f7fa6c72'	System	07 Nov 2020 22:46:42
User entered 'No (N)'	System	07 Nov 2020 22:46:42

US3292365

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:54:21

Have you been exposed to someone with 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 (5d3a9a116dfc2943)', Time: '2020-11-07T16:46:34', User OID: 'PatientReportedOutcome (US3292365)', ODM File OID: '09067362-821f-44d5-8842-67e0f7fa6c72'	System	07 Nov 2020 22:46:42
User entered 'No (N)'	System	07 Nov 2020 22:46:42

US3292365

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:54:21

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5d3a9a116dfc2943)', Time: '2020-11-07T16:46:40', User OID: 'PatientReportedOutcome (US3292365)', ODM File OID: '09067362-821f-44d5-8842-67e0f7fa6c72'	System	07 Nov 2020 22:46:42
User entered '07 Nov 2020 16:46:40'	System	07 Nov 2020 22:46:42

US3292365

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:54:21

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data entry locked.	System	29 Aug 2020 18:21:38
User entered '05 Nov 2020 00:01'	System	29 Aug 2020 18:21:38

US3292365

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:54:21

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data entry locked.	System	29 Aug 2020 18:21:38
User entered '09 Nov 2020 23:59'	System	29 Aug 2020 18:21:38

US3292365

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:54:21

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	29 Aug 2020 18:21:38
User entered 'Day 78'	System	29 Aug 2020 18:21:38

US3292365

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:54:21

[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 (5d3a9a116dfc2943)', Time: '2020-11-14T12:55:10', User OID: 'PatientReportedOutcome (US3292365)', ODM File OID: 'a3f87f2c-8ecd-47f7-8b3c-58ec30b5a589'	System	14 Nov 2020 18:56:20
User entered 'Yes (Y)'	System	14 Nov 2020 18:56:20

US3292365

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:54:21

Have you been exposed to someone with 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 (5d3a9a116dfc2943)', Time: '2020-11-14T12:55:16', User OID: 'PatientReportedOutcome (US3292365)', ODM File OID: 'a3f87f2c-8ecd-47f7-8b3c-58ec30b5a589'	System	14 Nov 2020 18:56:20
User entered 'No (N)'	System	14 Nov 2020 18:56:20

US3292365

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:54:21

[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 (5d3a9a116dfc2943)', Time: '2020-11-14T12:55:22', User OID: 'PatientReportedOutcome (US3292365)', ODM File OID: 'a3f87f2c-8ecd-47f7-8b3c-58ec30b5a589'	System	14 Nov 2020 18:56:20
User entered 'No (N)'	System	14 Nov 2020 18:56:20

US3292365

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:54:21

[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 (5d3a9a116dfc2943)', Time: '2020-11-14T12:55:32', User OID: 'PatientReportedOutcome (US3292365)', ODM File OID: 'a3f87f2c-8ecd-47f7-8b3c-58ec30b5a589'	System	14 Nov 2020 18:56:20
User entered 'Yes (Y)'	System	14 Nov 2020 18:56:20

US3292365

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:54:21

[Please 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 (5d3a9a116dfc2943)', Time: '2020-11-14T12:55:48', User OID: 'PatientReportedOutcome (US3292365)', ODM File OID: 'a3f87f2c-8ecd-47f7-8b3c-58ec30b5a589'	System	14 Nov 2020 18:56:20
User entered 'I confirm I have read this message and will call the study clinic immediately (9)'	System	14 Nov 2020 18:56:20

US3292365

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:54:21

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5d3a9a116dfc2943)', Time: '2020-11-14T12:56:08', User OID: 'PatientReportedOutcome (US3292365)', ODM File OID: 'a3f87f2c-8ecd-47f7-8b3c-58ec30b5a589'	System	14 Nov 2020 18:56:20
User entered '14 Nov 2020 12:56:08'	System	14 Nov 2020 18:56:20

US3292365

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:54:21

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data entry locked.	System	29 Aug 2020 18:21:38
User entered '12 Nov 2020 00:01'	System	29 Aug 2020 18:21:38

US3292365

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:54:21

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data entry locked.	System	29 Aug 2020 18:21:38
User entered '16 Nov 2020 23:59'	System	29 Aug 2020 18:21:38

US3292365

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:54:21

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:31:43
Amendment Manager: User entered 'Day 61'	System	19 Nov 2020 20:31:43

US3292365

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:54:21

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:31:43
Amendment Manager: User entered '26 Oct 2020 00:01'	System	19 Nov 2020 20:31:43

US3292365

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:54:21

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:31:43
Amendment Manager: User entered '30 Oct 2020 23:59'	System	19 Nov 2020 20:31:43

US3292365

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:54:21

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:31:43
Amendment Manager: User entered 'Day 68'	System	19 Nov 2020 20:31:43

US3292365

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:54:21

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:31:43
Amendment Manager: User entered '02 Nov 2020 00:01'	System	19 Nov 2020 20:31:43

US3292365

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:54:21

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:31:43
Amendment Manager: User entered '06 Nov 2020 23:59'	System	19 Nov 2020 20:31:43

US3292365

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:54:21

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:31:43
Amendment Manager: User entered 'Day 75'	System	19 Nov 2020 20:31:43

US3292365

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:54:21

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:31:43
Amendment Manager: User entered '09 Nov 2020 00:01'	System	19 Nov 2020 20:31:43

US3292365

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:54:21

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:31:43
Amendment Manager: User entered '13 Nov 2020 23:59'	System	19 Nov 2020 20:31:43

US3292365

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:54:21

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:31:43
Amendment Manager: User entered 'Day 82'	System	19 Nov 2020 20:31:43

US3292365

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:54:21

[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 (5d3a9a116dfc2943)', Time: '2020-11-20T19:06:50', User OID: 'PatientReportedOutcome (US3292365)', ODM File OID: 'f0aa5784-3679-4ce2-b561-5be4fa2e9c83'	System	21 Nov 2020 01:07:09
User entered 'No (N)'	System	21 Nov 2020 01:07:09

US3292365

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:54:21

[Have you been exposed to someone with 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 (5d3a9a116dfc2943)', Time: '2020-11-20T19:06:56', User OID: 'PatientReportedOutcome (US3292365)', ODM File OID: 'f0aa5784-3679-4ce2-b561-5be4fa2e9c83'	System	21 Nov 2020 01:07:09
User entered 'No (N)'	System	21 Nov 2020 01:07:09

US3292365

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:54:21

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5d3a9a116dfc2943)', Time: '2020-11-20T19:07:04', User OID: 'PatientReportedOutcome (US3292365)', ODM File OID: 'f0aa5784-3679-4ce2-b561-5be4fa2e9c83'	System	21 Nov 2020 01:07:09
User entered '20 Nov 2020 19:07:04'	System	21 Nov 2020 01:07:09

US3292365

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:54:21

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:31:43
Amendment Manager: User entered '16 Nov 2020 00:01'	System	19 Nov 2020 20:31:43

US3292365

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:54:21

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:31:43
Amendment Manager: User entered '20 Nov 2020 23:59'	System	19 Nov 2020 20:31:43

US3292365

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:54:21

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:31:43
Amendment Manager: User entered 'Day 89'	System	19 Nov 2020 20:31:43

US3292365

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:54:21

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:31:43
Amendment Manager: User entered '23 Nov 2020 00:01'	System	19 Nov 2020 20:31:43

US3292365

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:54:21

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:31:43
Amendment Manager: User entered '27 Nov 2020 23:59'	System	19 Nov 2020 20:31:43

US3292365

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:54:21

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:31:43
Amendment Manager: User entered 'Day 96'	System	19 Nov 2020 20:31:43

US3292365

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:54:21

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:31:43
Amendment Manager: User entered '30 Nov 2020 00:01'	System	19 Nov 2020 20:31:43

US3292365

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:54:21

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:31:43
Amendment Manager: User entered '04 Dec 2020 23:59'	System	19 Nov 2020 20:31:43

US3292365

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:54:21

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:31:43
Amendment Manager: User entered 'Day 103'	System	19 Nov 2020 20:31:43

US3292365

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:54:21

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:31:43
Amendment Manager: User entered '07 Dec 2020 00:01'	System	19 Nov 2020 20:31:43

US3292365

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:54:21

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:31:43
Amendment Manager: User entered '11 Dec 2020 23:59'	System	19 Nov 2020 20:31:43

US3292365

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:54:21

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:31:43
Amendment Manager: User entered 'Day 110'	System	19 Nov 2020 20:31:43

US3292365

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:54:21

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:31:43
Amendment Manager: User entered '14 Dec 2020 00:01'	System	19 Nov 2020 20:31:43

US3292365

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:54:21

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:31:43
Amendment Manager: User entered '18 Dec 2020 23:59'	System	19 Nov 2020 20:31:43

US3292365

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:54:21

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:31:43
Amendment Manager: User entered 'Day 117'	System	19 Nov 2020 20:31:43

US3292365

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:54:21

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:31:43
Amendment Manager: User entered '21 Dec 2020 00:01'	System	19 Nov 2020 20:31:43

US3292365

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:54:21

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:31:43
Amendment Manager: User entered '25 Dec 2020 23:59'	System	19 Nov 2020 20:31:43

US3292365

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:54:21

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:31:43
Amendment Manager: User entered 'Day 124'	System	19 Nov 2020 20:31:43

US3292365

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:54:21

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:31:43
Amendment Manager: User entered '28 Dec 2020 00:01'	System	19 Nov 2020 20:31:43

US3292365

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:54:21

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:31:43
Amendment Manager: User entered '01 Jan 2021 23:59'	System	19 Nov 2020 20:31:43

US3292365

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:54:21

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:31:43
Amendment Manager: User entered 'Day 131'	System	19 Nov 2020 20:31:43

US3292365

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:54:21

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:31:43
Amendment Manager: User entered '04 Jan 2021 00:01'	System	19 Nov 2020 20:31:43

US3292365

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:54:21

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:31:43
Amendment Manager: User entered '08 Jan 2021 23:59'	System	19 Nov 2020 20:31:43

US3292365

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:54:21

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:31:43
Amendment Manager: User entered 'Day 138'	System	19 Nov 2020 20:31:43

US3292365

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:54:21

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:31:43
Amendment Manager: User entered '11 Jan 2021 00:01'	System	19 Nov 2020 20:31:43

US3292365

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:54:21

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:31:43
Amendment Manager: User entered '15 Jan 2021 23:59'	System	19 Nov 2020 20:31:43

US3292365

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:54:21

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:31:43
Amendment Manager: User entered 'Day 145'	System	19 Nov 2020 20:31:43

US3292365

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:54:21

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:31:43
Amendment Manager: User entered '18 Jan 2021 00:01'	System	19 Nov 2020 20:31:43

US3292365

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:54:21

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:31:43
Amendment Manager: User entered '22 Jan 2021 23:59'	System	19 Nov 2020 20:31:43

US3292365

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:54:21

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:31:43
Amendment Manager: User entered 'Day 152'	System	19 Nov 2020 20:31:43

US3292365

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:54:21

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:31:43
Amendment Manager: User entered '25 Jan 2021 00:01'	System	19 Nov 2020 20:31:43

US3292365

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:54:21

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:31:43
Amendment Manager: User entered '29 Jan 2021 23:59'	System	19 Nov 2020 20:31:43

US3292365

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:54:21

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:31:43
Amendment Manager: User entered 'Day 159'	System	19 Nov 2020 20:31:43

US3292365

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:54:21

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:31:43
Amendment Manager: User entered '01 Feb 2021 00:01'	System	19 Nov 2020 20:31:43

US3292365

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:54:21

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:31:43
Amendment Manager: User entered '05 Feb 2021 23:59'	System	19 Nov 2020 20:31:43

US3292365

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:54:21

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:31:43
Amendment Manager: User entered 'Day 166'	System	19 Nov 2020 20:31:43

US3292365

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:54:21

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:31:43
Amendment Manager: User entered '08 Feb 2021 00:01'	System	19 Nov 2020 20:31:43

US3292365

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:54:21

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:31:43
Amendment Manager: User entered '12 Feb 2021 23:59'	System	19 Nov 2020 20:31:43

US3292365

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:54:21

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:31:43
Amendment Manager: User entered 'Day 173'	System	19 Nov 2020 20:31:43

US3292365

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:54:21

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:31:43
Amendment Manager: User entered '15 Feb 2021 00:01'	System	19 Nov 2020 20:31:43

US3292365

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:54:21

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:31:43
Amendment Manager: User entered '19 Feb 2021 23:59'	System	19 Nov 2020 20:31:43

US3292365

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:54:21

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:31:43
Amendment Manager: User entered 'Day 180'	System	19 Nov 2020 20:31:43

US3292365

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:54:21

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:31:43
Amendment Manager: User entered '22 Feb 2021 00:01'	System	19 Nov 2020 20:31:43

US3292365

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:54:21

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:31:43
Amendment Manager: User entered '26 Feb 2021 23:59'	System	19 Nov 2020 20:31:43

US3292365

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:54:21

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:31:43
Amendment Manager: User entered 'Day 187'	System	19 Nov 2020 20:31:43

US3292365

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:54:21

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:31:43
Amendment Manager: User entered '01 Mar 2021 00:01'	System	19 Nov 2020 20:31:43

US3292365

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:54:21

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:31:43
Amendment Manager: User entered '05 Mar 2021 23:59'	System	19 Nov 2020 20:31:43

US3292365

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:54:21

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:31:43
Amendment Manager: User entered 'Day 194'	System	19 Nov 2020 20:31:43

US3292365

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:54:21

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:31:43
Amendment Manager: User entered '08 Mar 2021 00:01'	System	19 Nov 2020 20:31:43

US3292365

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:54:21

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:31:43
Amendment Manager: User entered '12 Mar 2021 23:59'	System	19 Nov 2020 20:31:43

US3292365

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:54:21

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:31:43
Amendment Manager: User entered 'Day 201'	System	19 Nov 2020 20:31:43

US3292365

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:54:21

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:31:43
Amendment Manager: User entered '15 Mar 2021 00:01'	System	19 Nov 2020 20:31:43

US3292365

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:54:21

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:31:43
Amendment Manager: User entered '19 Mar 2021 23:59'	System	19 Nov 2020 20:31:43

US3292365

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:54:21

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:31:43
Amendment Manager: User entered 'Day 208'	System	19 Nov 2020 20:31:43

US3292365

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:54:21

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:31:43
Amendment Manager: User entered '22 Mar 2021 00:01'	System	19 Nov 2020 20:31:43

US3292365

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:54:21

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:31:43
Amendment Manager: User entered '26 Mar 2021 23:59'	System	19 Nov 2020 20:31:43

US3292365

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:54:21

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:31:43
Amendment Manager: User entered 'Day 215'	System	19 Nov 2020 20:31:43

US3292365

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:54:21

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:31:43
Amendment Manager: User entered '29 Mar 2021 00:01'	System	19 Nov 2020 20:31:43

US3292365

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:54:21

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:31:43
Amendment Manager: User entered '02 Apr 2021 23:59'	System	19 Nov 2020 20:31:43

US3292365

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:54:21

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:31:43
Amendment Manager: User entered 'Day 222'	System	19 Nov 2020 20:31:43

US3292365

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:54:21

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:31:43
Amendment Manager: User entered '05 Apr 2021 00:01'	System	19 Nov 2020 20:31:43

US3292365

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:54:21

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:31:43
Amendment Manager: User entered '09 Apr 2021 23:59'	System	19 Nov 2020 20:31:43

US3292365

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:54:21

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:31:43
Amendment Manager: User entered 'Day 229'	System	19 Nov 2020 20:31:43

US3292365

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:54:21

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:31:43
Amendment Manager: User entered '12 Apr 2021 00:01'	System	19 Nov 2020 20:31:43

US3292365

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:54:21

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:31:43
Amendment Manager: User entered '16 Apr 2021 23:59'	System	19 Nov 2020 20:31:43

US3292365

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:54:21

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:31:43
Amendment Manager: User entered 'Day 236'	System	19 Nov 2020 20:31:43

US3292365

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:54:21

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:31:43
Amendment Manager: User entered '19 Apr 2021 00:01'	System	19 Nov 2020 20:31:43

US3292365

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:54:21

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:31:43
Amendment Manager: User entered '23 Apr 2021 23:59'	System	19 Nov 2020 20:31:43

US3292365

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:54:21

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:31:43
Amendment Manager: User entered 'Day 243'	System	19 Nov 2020 20:31:43

US3292365

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:54:21

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:31:43
Amendment Manager: User entered '26 Apr 2021 00:01'	System	19 Nov 2020 20:31:43

US3292365

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:54:21

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:31:43
Amendment Manager: User entered '30 Apr 2021 23:59'	System	19 Nov 2020 20:31:43

US3292365

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:54:21

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:31:43
Amendment Manager: User entered 'Day 250'	System	19 Nov 2020 20:31:43

US3292365

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:54:21

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:31:43
Amendment Manager: User entered '03 May 2021 00:01'	System	19 Nov 2020 20:31:43

US3292365

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:54:21

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:31:43
Amendment Manager: User entered '07 May 2021 23:59'	System	19 Nov 2020 20:31:43

US3292365

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:54:21

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:31:43
Amendment Manager: User entered 'Day 257'	System	19 Nov 2020 20:31:43

US3292365

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:54:21

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:31:43
Amendment Manager: User entered '10 May 2021 00:01'	System	19 Nov 2020 20:31:43

US3292365

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:54:21

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:31:43
Amendment Manager: User entered '14 May 2021 23:59'	System	19 Nov 2020 20:31:43

US3292365

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:54:21

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:31:43
Amendment Manager: User entered 'Day 264'	System	19 Nov 2020 20:31:43

US3292365

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:54:21

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:31:43
Amendment Manager: User entered '17 May 2021 00:01'	System	19 Nov 2020 20:31:43

US3292365

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:54:21

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:31:43
Amendment Manager: User entered '21 May 2021 23:59'	System	19 Nov 2020 20:31:43

US3292365

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:54:21

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:31:43
Amendment Manager: User entered 'Day 271'	System	19 Nov 2020 20:31:43

US3292365

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:54:21

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:31:43
Amendment Manager: User entered '24 May 2021 00:01'	System	19 Nov 2020 20:31:43

US3292365

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:54:21

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:31:43
Amendment Manager: User entered '28 May 2021 23:59'	System	19 Nov 2020 20:31:43

US3292365

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:54:21

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:31:43
Amendment Manager: User entered 'Day 278'	System	19 Nov 2020 20:31:43

US3292365

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:54:21

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:31:43
Amendment Manager: User entered '31 May 2021 00:01'	System	19 Nov 2020 20:31:43

US3292365

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:54:21

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:31:43
Amendment Manager: User entered '04 Jun 2021 23:59'	System	19 Nov 2020 20:31:43

US3292365

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:54:21

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:31:43
Amendment Manager: User entered 'Day 285'	System	19 Nov 2020 20:31:43

US3292365

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:54:21

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:31:43
Amendment Manager: User entered '07 Jun 2021 00:01'	System	19 Nov 2020 20:31:43

US3292365

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:54:21

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:31:43
Amendment Manager: User entered '11 Jun 2021 23:59'	System	19 Nov 2020 20:31:43

US3292365

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:54:21

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:31:43
Amendment Manager: User entered 'Day 292'	System	19 Nov 2020 20:31:43

US3292365

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:54:21

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:31:43
Amendment Manager: User entered '14 Jun 2021 00:01'	System	19 Nov 2020 20:31:43

US3292365

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:54:21

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:31:43
Amendment Manager: User entered '18 Jun 2021 23:59'	System	19 Nov 2020 20:31:43

US3292365

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:54:21

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:31:43
Amendment Manager: User entered 'Day 299'	System	19 Nov 2020 20:31:43

US3292365

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:54:21

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:31:43
Amendment Manager: User entered '21 Jun 2021 00:01'	System	19 Nov 2020 20:31:43

US3292365

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:54:21

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:31:43
Amendment Manager: User entered '25 Jun 2021 23:59'	System	19 Nov 2020 20:31:43

US3292365

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:54:21

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:31:43
Amendment Manager: User entered 'Day 306'	System	19 Nov 2020 20:31:43

US3292365

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:54:21

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:31:43
Amendment Manager: User entered '28 Jun 2021 00:01'	System	19 Nov 2020 20:31:43

US3292365

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:54:21

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:31:43
Amendment Manager: User entered '02 Jul 2021 23:59'	System	19 Nov 2020 20:31:43

US3292365

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:54:21

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:31:43
Amendment Manager: User entered 'Day 313'	System	19 Nov 2020 20:31:43

US3292365

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:54:21

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:31:43
Amendment Manager: User entered '05 Jul 2021 00:01'	System	19 Nov 2020 20:31:43

US3292365

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:54:21

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:31:43
Amendment Manager: User entered '09 Jul 2021 23:59'	System	19 Nov 2020 20:31:43

US3292365

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:54:21

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:31:43
Amendment Manager: User entered 'Day 320'	System	19 Nov 2020 20:31:43

US3292365

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:54:21

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:31:43
Amendment Manager: User entered '12 Jul 2021 00:01'	System	19 Nov 2020 20:31:43

US3292365

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:54:21

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:31:43
Amendment Manager: User entered '16 Jul 2021 23:59'	System	19 Nov 2020 20:31:43

US3292365

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:54:21

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:31:43
Amendment Manager: User entered 'Day 327'	System	19 Nov 2020 20:31:43

US3292365

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:54:21

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:31:43
Amendment Manager: User entered '19 Jul 2021 00:01'	System	19 Nov 2020 20:31:43

US3292365

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:54:21

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:31:43
Amendment Manager: User entered '23 Jul 2021 23:59'	System	19 Nov 2020 20:31:43

US3292365

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:54:21

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:31:43
Amendment Manager: User entered 'Day 334'	System	19 Nov 2020 20:31:43

US3292365

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:54:21

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:31:43
Amendment Manager: User entered '26 Jul 2021 00:01'	System	19 Nov 2020 20:31:43

US3292365

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:54:21

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:31:43
Amendment Manager: User entered '30 Jul 2021 23:59'	System	19 Nov 2020 20:31:43

US3292365

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:54:21

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:31:43
Amendment Manager: User entered 'Day 341'	System	19 Nov 2020 20:31:43

US3292365

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:54:21

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:31:43
Amendment Manager: User entered '02 Aug 2021 00:01'	System	19 Nov 2020 20:31:43

US3292365

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:54:21

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:31:43
Amendment Manager: User entered '06 Aug 2021 23:59'	System	19 Nov 2020 20:31:43

US3292365

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:54:21

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:31:43
Amendment Manager: User entered 'Day 348'	System	19 Nov 2020 20:31:43

US3292365

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:54:21

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:31:43
Amendment Manager: User entered '09 Aug 2021 00:01'	System	19 Nov 2020 20:31:43

US3292365

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:54:21

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:31:43
Amendment Manager: User entered '13 Aug 2021 23:59'	System	19 Nov 2020 20:31:43

US3292365

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:54:21

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:31:43
Amendment Manager: User entered 'Day 355'	System	19 Nov 2020 20:31:43

US3292365

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:54:21

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:31:43
Amendment Manager: User entered '16 Aug 2021 00:01'	System	19 Nov 2020 20:31:43

US3292365

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:54:21

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:31:43
Amendment Manager: User entered '20 Aug 2021 23:59'	System	19 Nov 2020 20:31:43

US3292365

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:54:21

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:31:43
Amendment Manager: User entered 'Day 362'	System	19 Nov 2020 20:31:43

US3292365

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:54:21

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:31:43
Amendment Manager: User entered '23 Aug 2021 00:01'	System	19 Nov 2020 20:31:43

US3292365

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:54:21

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:31:43
Amendment Manager: User entered '27 Aug 2021 23:59'	System	19 Nov 2020 20:31:43

US3292365

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:54:21

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:31:43
Amendment Manager: User entered 'Day 369'	System	19 Nov 2020 20:31:43

US3292365

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:54:21

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:31:43
Amendment Manager: User entered '30 Aug 2021 00:01'	System	19 Nov 2020 20:31:43

US3292365

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:54:21

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:31:43
Amendment Manager: User entered '03 Sep 2021 23:59'	System	19 Nov 2020 20:31:43

US3292365

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:54:21

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:31:43
Amendment Manager: User entered 'Day 376'	System	19 Nov 2020 20:31:43

US3292365

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:54:21

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:31:43
Amendment Manager: User entered '06 Sep 2021 00:01'	System	19 Nov 2020 20:31:43

US3292365

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:54:21

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:31:43
Amendment Manager: User entered '10 Sep 2021 23:59'	System	19 Nov 2020 20:31:43

US3292365

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:54:21

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:31:43
Amendment Manager: User entered 'Day 383'	System	19 Nov 2020 20:31:43

US3292365

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:54:21

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:31:43
Amendment Manager: User entered '13 Sep 2021 00:01'	System	19 Nov 2020 20:31:43

US3292365

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:54:21

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:31:43
Amendment Manager: User entered '17 Sep 2021 23:59'	System	19 Nov 2020 20:31:43

US3292365

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:54:21

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:31:43
Amendment Manager: User entered 'Day 390'	System	19 Nov 2020 20:31:43

US3292365

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:54:21

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:31:43
Amendment Manager: User entered '20 Sep 2021 00:01'	System	19 Nov 2020 20:31:43

US3292365

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:54:21

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:31:43
Amendment Manager: User entered '24 Sep 2021 23:59'	System	19 Nov 2020 20:31:43

US3292365

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:54:21

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:31:43
Amendment Manager: User entered 'Day 397'	System	19 Nov 2020 20:31:43

US3292365

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:54:21

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:31:43
Amendment Manager: User entered '27 Sep 2021 00:01'	System	19 Nov 2020 20:31:43

US3292365

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:54:21

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:31:43
Amendment Manager: User entered '01 Oct 2021 23:59'	System	19 Nov 2020 20:31:43

US3292365

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:54:21

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:31:43
Amendment Manager: User entered 'Day 404'	System	19 Nov 2020 20:31:43

US3292365

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:54:21

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:31:43
Amendment Manager: User entered '04 Oct 2021 00:01'	System	19 Nov 2020 20:31:43

US3292365

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:54:21

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:31:43
Amendment Manager: User entered '08 Oct 2021 23:59'	System	19 Nov 2020 20:31:43

US3292365

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:54:21

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:31:43
Amendment Manager: User entered 'Day 411'	System	19 Nov 2020 20:31:43

US3292365

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:54:21

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:31:43
Amendment Manager: User entered '11 Oct 2021 00:01'	System	19 Nov 2020 20:31:43

US3292365

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:54:21

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:31:43
Amendment Manager: User entered '15 Oct 2021 23:59'	System	19 Nov 2020 20:31:43

US3292365

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:54:21

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:31:43
Amendment Manager: User entered 'Day 418'	System	19 Nov 2020 20:31:43

US3292365

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:54:21

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:31:43
Amendment Manager: User entered '18 Oct 2021 00:01'	System	19 Nov 2020 20:31:43

US3292365

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:54:21

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:31:43
Amendment Manager: User entered '22 Oct 2021 23:59'	System	19 Nov 2020 20:31:43

US3292365

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:54:21

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:31:43
Amendment Manager: User entered 'Day 425'	System	19 Nov 2020 20:31:43

US3292365

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:54:21

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:31:43
Amendment Manager: User entered '25 Oct 2021 00:01'	System	19 Nov 2020 20:31:43

US3292365

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:54:21

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:31:43
Amendment Manager: User entered '29 Oct 2021 23:59'	System	19 Nov 2020 20:31:43

US3292365

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:54:21

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:31:43
Amendment Manager: User entered 'Day 432'	System	19 Nov 2020 20:31:43

US3292365

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:54:21

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:31:43
Amendment Manager: User entered '01 Nov 2021 00:01'	System	19 Nov 2020 20:31:43

US3292365

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:54:21

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:31:43
Amendment Manager: User entered '05 Nov 2021 23:59'	System	19 Nov 2020 20:31:43

US3292365

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:54:21

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:31:43
Amendment Manager: User entered 'Day 439'	System	19 Nov 2020 20:31:43

US3292365

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:54:21

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:31:43
Amendment Manager: User entered '08 Nov 2021 00:01'	System	19 Nov 2020 20:31:43

US3292365

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:54:21

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:31:43
Amendment Manager: User entered '12 Nov 2021 23:59'	System	19 Nov 2020 20:31:43

US3292365

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:54:21

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:31:43
Amendment Manager: User entered 'Day 446'	System	19 Nov 2020 20:31:43

US3292365

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:54:21

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:31:43
Amendment Manager: User entered '15 Nov 2021 00:01'	System	19 Nov 2020 20:31:43

US3292365

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:54:21

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:31:43
Amendment Manager: User entered '19 Nov 2021 23:59'	System	19 Nov 2020 20:31:43

US3292365

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:54:21

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:31:43
Amendment Manager: User entered 'Day 453'	System	19 Nov 2020 20:31:43

US3292365

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:54:21

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:31:43
Amendment Manager: User entered '22 Nov 2021 00:01'	System	19 Nov 2020 20:31:43

US3292365

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:54:21

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:31:43
Amendment Manager: User entered '26 Nov 2021 23:59'	System	19 Nov 2020 20:31:43

US3292365

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:54:21

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:31:43
Amendment Manager: User entered 'Day 460'	System	19 Nov 2020 20:31:43

US3292365

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:54:21

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:31:43
Amendment Manager: User entered '29 Nov 2021 00:01'	System	19 Nov 2020 20:31:43

US3292365

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:54:21

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:31:43
Amendment Manager: User entered '03 Dec 2021 23:59'	System	19 Nov 2020 20:31:43

US3292365

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:54:21

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:31:43
Amendment Manager: User entered 'Day 467'	System	19 Nov 2020 20:31:43

US3292365

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:54:21

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:31:43
Amendment Manager: User entered '06 Dec 2021 00:01'	System	19 Nov 2020 20:31:43

US3292365

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:54:21

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:31:43
Amendment Manager: User entered '10 Dec 2021 23:59'	System	19 Nov 2020 20:31:43

US3292365

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:54:21

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:31:43
Amendment Manager: User entered 'Day 474'	System	19 Nov 2020 20:31:43

US3292365

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:54:21

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:31:43
Amendment Manager: User entered '13 Dec 2021 00:01'	System	19 Nov 2020 20:31:43

US3292365

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:54:21

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:31:43
Amendment Manager: User entered '17 Dec 2021 23:59'	System	19 Nov 2020 20:31:43

US3292365

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:54:21

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:31:43
Amendment Manager: User entered 'Day 481'	System	19 Nov 2020 20:31:43

US3292365

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:54:21

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:31:43
Amendment Manager: User entered '20 Dec 2021 00:01'	System	19 Nov 2020 20:31:43

US3292365

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:54:21

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:31:43
Amendment Manager: User entered '24 Dec 2021 23:59'	System	19 Nov 2020 20:31:43

US3292365

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:54:21

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:31:43
Amendment Manager: User entered 'Day 488'	System	19 Nov 2020 20:31:43

US3292365

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:54:21

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:31:43
Amendment Manager: User entered '27 Dec 2021 00:01'	System	19 Nov 2020 20:31:43

US3292365

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:54:21

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:31:43
Amendment Manager: User entered '31 Dec 2021 23:59'	System	19 Nov 2020 20:31:43

US3292365

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:54:21

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:31:43
Amendment Manager: User entered 'Day 495'	System	19 Nov 2020 20:31:43

US3292365

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:54:21

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:31:43
Amendment Manager: User entered '03 Jan 2022 00:01'	System	19 Nov 2020 20:31:43

US3292365

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:54:21

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:31:43
Amendment Manager: User entered '07 Jan 2022 23:59'	System	19 Nov 2020 20:31:43

US3292365

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:54:21

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:31:43
Amendment Manager: User entered 'Day 502'	System	19 Nov 2020 20:31:43

US3292365

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:54:21

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:31:43
Amendment Manager: User entered '10 Jan 2022 00:01'	System	19 Nov 2020 20:31:43

US3292365

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:54:21

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:31:43
Amendment Manager: User entered '14 Jan 2022 23:59'	System	19 Nov 2020 20:31:43

US3292365

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:54:21

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:31:43
Amendment Manager: User entered 'Day 509'	System	19 Nov 2020 20:31:43

US3292365

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:54:21

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:31:43
Amendment Manager: User entered '17 Jan 2022 00:01'	System	19 Nov 2020 20:31:43

US3292365

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:54:21

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:31:43
Amendment Manager: User entered '21 Jan 2022 23:59'	System	19 Nov 2020 20:31:43

US3292365

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:54:21

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:31:43
Amendment Manager: User entered 'Day 516'	System	19 Nov 2020 20:31:43

US3292365

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:54:21

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:31:43
Amendment Manager: User entered '24 Jan 2022 00:01'	System	19 Nov 2020 20:31:43

US3292365

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:54:21

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:31:43
Amendment Manager: User entered '28 Jan 2022 23:59'	System	19 Nov 2020 20:31:43

US3292365

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:54:21

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:31:43
Amendment Manager: User entered 'Day 523'	System	19 Nov 2020 20:31:43

US3292365

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:54:21

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:31:43
Amendment Manager: User entered '31 Jan 2022 00:01'	System	19 Nov 2020 20:31:43

US3292365

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:54:21

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:31:43
Amendment Manager: User entered '04 Feb 2022 23:59'	System	19 Nov 2020 20:31:43

US3292365

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:54:21

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:31:43
Amendment Manager: User entered 'Day 530'	System	19 Nov 2020 20:31:43

US3292365

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:54:21

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:31:43
Amendment Manager: User entered '07 Feb 2022 00:01'	System	19 Nov 2020 20:31:43

US3292365

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:54:21

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:31:43
Amendment Manager: User entered '11 Feb 2022 23:59'	System	19 Nov 2020 20:31:43

US3292365

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:54:21

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:31:43
Amendment Manager: User entered 'Day 537'	System	19 Nov 2020 20:31:43

US3292365

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:54:21

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:31:43
Amendment Manager: User entered '14 Feb 2022 00:01'	System	19 Nov 2020 20:31:43

US3292365

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:54:21

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:31:43
Amendment Manager: User entered '18 Feb 2022 23:59'	System	19 Nov 2020 20:31:43

US3292365

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:54:21

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:31:43
Amendment Manager: User entered 'Day 544'	System	19 Nov 2020 20:31:43

US3292365

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:54:21

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:31:43
Amendment Manager: User entered '21 Feb 2022 00:01'	System	19 Nov 2020 20:31:43

US3292365

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:54:21

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:31:43
Amendment Manager: User entered '25 Feb 2022 23:59'	System	19 Nov 2020 20:31:43

US3292365

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:54:21

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:31:43
Amendment Manager: User entered 'Day 551'	System	19 Nov 2020 20:31:43

US3292365

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:54:21

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:31:43
Amendment Manager: User entered '28 Feb 2022 00:01'	System	19 Nov 2020 20:31:43

US3292365

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:54:21

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:31:43
Amendment Manager: User entered '04 Mar 2022 23:59'	System	19 Nov 2020 20:31:43

US3292365

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:54:21

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:31:43
Amendment Manager: User entered 'Day 558'	System	19 Nov 2020 20:31:43

US3292365

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:54:21

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:31:43
Amendment Manager: User entered '07 Mar 2022 00:01'	System	19 Nov 2020 20:31:43

US3292365

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:54:21

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:31:43
Amendment Manager: User entered '11 Mar 2022 23:59'	System	19 Nov 2020 20:31:43

US3292365

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:54:21

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:31:43
Amendment Manager: User entered 'Day 565'	System	19 Nov 2020 20:31:43

US3292365

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:54:21

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:31:43
Amendment Manager: User entered '14 Mar 2022 00:01'	System	19 Nov 2020 20:31:43

US3292365

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:54:21

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:31:43
Amendment Manager: User entered '18 Mar 2022 23:59'	System	19 Nov 2020 20:31:43

US3292365

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:54:21

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:31:43
Amendment Manager: User entered 'Day 572'	System	19 Nov 2020 20:31:43

US3292365

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:54:21

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:31:43
Amendment Manager: User entered '21 Mar 2022 00:01'	System	19 Nov 2020 20:31:43

US3292365

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:54:21

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:31:43
Amendment Manager: User entered '25 Mar 2022 23:59'	System	19 Nov 2020 20:31:43

US3292365

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:54:21

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:31:43
Amendment Manager: User entered 'Day 579'	System	19 Nov 2020 20:31:43

US3292365

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:54:21

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:31:43
Amendment Manager: User entered '28 Mar 2022 00:01'	System	19 Nov 2020 20:31:43

US3292365

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:54:21

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:31:43
Amendment Manager: User entered '01 Apr 2022 23:59'	System	19 Nov 2020 20:31:43

US3292365

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:54:21

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:31:43
Amendment Manager: User entered 'Day 586'	System	19 Nov 2020 20:31:43

US3292365

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:54:21

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:31:43
Amendment Manager: User entered '04 Apr 2022 00:01'	System	19 Nov 2020 20:31:43

US3292365

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:54:21

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:31:43
Amendment Manager: User entered '08 Apr 2022 23:59'	System	19 Nov 2020 20:31:43

US3292365

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:54:21

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:31:43
Amendment Manager: User entered 'Day 593'	System	19 Nov 2020 20:31:43

US3292365

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:54:21

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:31:43
Amendment Manager: User entered '11 Apr 2022 00:01'	System	19 Nov 2020 20:31:43

US3292365

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:54:21

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:31:43
Amendment Manager: User entered '15 Apr 2022 23:59'	System	19 Nov 2020 20:31:43

US3292365

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:54:21

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:31:43
Amendment Manager: User entered 'Day 600'	System	19 Nov 2020 20:31:43

US3292365

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:54:21

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:31:43
Amendment Manager: User entered '18 Apr 2022 00:01'	System	19 Nov 2020 20:31:43

US3292365

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:54:21

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:31:43
Amendment Manager: User entered '22 Apr 2022 23:59'	System	19 Nov 2020 20:31:43

US3292365

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:54:21

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:31:43
Amendment Manager: User entered 'Day 607'	System	19 Nov 2020 20:31:43

US3292365

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:54:21

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:31:43
Amendment Manager: User entered '25 Apr 2022 00:01'	System	19 Nov 2020 20:31:43

US3292365

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:54:21

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:31:43
Amendment Manager: User entered '29 Apr 2022 23:59'	System	19 Nov 2020 20:31:43

US3292365

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:54:21

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:31:43
Amendment Manager: User entered 'Day 614'	System	19 Nov 2020 20:31:43

US3292365

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:54:21

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:31:43
Amendment Manager: User entered '02 May 2022 00:01'	System	19 Nov 2020 20:31:43

US3292365

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:54:21

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:31:43
Amendment Manager: User entered '06 May 2022 23:59'	System	19 Nov 2020 20:31:43

US3292365

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:54:21

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:31:43
Amendment Manager: User entered 'Day 621'	System	19 Nov 2020 20:31:43

US3292365

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:54:21

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:31:43
Amendment Manager: User entered '09 May 2022 00:01'	System	19 Nov 2020 20:31:43

US3292365

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:54:21

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:31:43
Amendment Manager: User entered '13 May 2022 23:59'	System	19 Nov 2020 20:31:43

US3292365

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:54:21

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:31:43
Amendment Manager: User entered 'Day 628'	System	19 Nov 2020 20:31:43

US3292365

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:54:21

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:31:43
Amendment Manager: User entered '16 May 2022 00:01'	System	19 Nov 2020 20:31:43

US3292365

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:54:21

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:31:43
Amendment Manager: User entered '20 May 2022 23:59'	System	19 Nov 2020 20:31:43

US3292365

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:54:21

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:31:43
Amendment Manager: User entered 'Day 635'	System	19 Nov 2020 20:31:43

US3292365

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:54:21

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:31:43
Amendment Manager: User entered '23 May 2022 00:01'	System	19 Nov 2020 20:31:43

US3292365

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:54:21

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:31:43
Amendment Manager: User entered '27 May 2022 23:59'	System	19 Nov 2020 20:31:43

US3292365

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:54:21

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:31:43
Amendment Manager: User entered 'Day 642'	System	19 Nov 2020 20:31:43

US3292365

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:54:21

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:31:43
Amendment Manager: User entered '30 May 2022 00:01'	System	19 Nov 2020 20:31:43

US3292365

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:54:21

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:31:43
Amendment Manager: User entered '03 Jun 2022 23:59'	System	19 Nov 2020 20:31:43

US3292365

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:54:21

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:31:43
Amendment Manager: User entered 'Day 649'	System	19 Nov 2020 20:31:43

US3292365

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:54:21

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:31:43
Amendment Manager: User entered '06 Jun 2022 00:01'	System	19 Nov 2020 20:31:43

US3292365

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:54:21

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:31:43
Amendment Manager: User entered '10 Jun 2022 23:59'	System	19 Nov 2020 20:31:43

US3292365

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:54:21

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:31:43
Amendment Manager: User entered 'Day 656'	System	19 Nov 2020 20:31:43

US3292365

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:54:21

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:31:43
Amendment Manager: User entered '13 Jun 2022 00:01'	System	19 Nov 2020 20:31:43

US3292365

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:54:21

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:31:43
Amendment Manager: User entered '17 Jun 2022 23:59'	System	19 Nov 2020 20:31:43

US3292365

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:54:21

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:31:43
Amendment Manager: User entered 'Day 663'	System	19 Nov 2020 20:31:43

US3292365

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:54:21

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:31:43
Amendment Manager: User entered '20 Jun 2022 00:01'	System	19 Nov 2020 20:31:43

US3292365

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:54:21

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:31:43
Amendment Manager: User entered '24 Jun 2022 23:59'	System	19 Nov 2020 20:31:43

US3292365

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:54:21

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:31:43
Amendment Manager: User entered 'Day 670'	System	19 Nov 2020 20:31:43

US3292365

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:54:21

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:31:43
Amendment Manager: User entered '27 Jun 2022 00:01'	System	19 Nov 2020 20:31:43

US3292365

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:54:21

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:31:43
Amendment Manager: User entered '01 Jul 2022 23:59'	System	19 Nov 2020 20:31:43

US3292365

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:54:21

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:31:43
Amendment Manager: User entered 'Day 677'	System	19 Nov 2020 20:31:43

US3292365

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:54:21

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:31:43
Amendment Manager: User entered '04 Jul 2022 00:01'	System	19 Nov 2020 20:31:43

US3292365

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:54:21

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:31:43
Amendment Manager: User entered '08 Jul 2022 23:59'	System	19 Nov 2020 20:31:43

US3292365

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:54:21

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:31:43
Amendment Manager: User entered 'Day 684'	System	19 Nov 2020 20:31:43

US3292365

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:54:21

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:31:43
Amendment Manager: User entered '11 Jul 2022 00:01'	System	19 Nov 2020 20:31:43

US3292365

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:54:21

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:31:43
Amendment Manager: User entered '15 Jul 2022 23:59'	System	19 Nov 2020 20:31:43

US3292365

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:54:21

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:31:43
Amendment Manager: User entered 'Day 691'	System	19 Nov 2020 20:31:43

US3292365

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:54:21

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:31:43
Amendment Manager: User entered '18 Jul 2022 00:01'	System	19 Nov 2020 20:31:43

US3292365

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:54:21

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:31:43
Amendment Manager: User entered '22 Jul 2022 23:59'	System	19 Nov 2020 20:31:43

US3292365

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:54:21

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:31:43
Amendment Manager: User entered 'Day 698'	System	19 Nov 2020 20:31:43

US3292365

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:54:21

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:31:43
Amendment Manager: User entered '25 Jul 2022 00:01'	System	19 Nov 2020 20:31:43

US3292365

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:54:21

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:31:43
Amendment Manager: User entered '29 Jul 2022 23:59'	System	19 Nov 2020 20:31:43

US3292365

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:54:21

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:31:43
Amendment Manager: User entered 'Day 705'	System	19 Nov 2020 20:31:43

US3292365

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:54:21

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:31:43
Amendment Manager: User entered '01 Aug 2022 00:01'	System	19 Nov 2020 20:31:43

US3292365

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:54:21

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:31:43
Amendment Manager: User entered '05 Aug 2022 23:59'	System	19 Nov 2020 20:31:43

US3292365

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:54:21

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:31:43
Amendment Manager: User entered 'Day 712'	System	19 Nov 2020 20:31:43

US3292365

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:54:21

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:31:43
Amendment Manager: User entered '08 Aug 2022 00:01'	System	19 Nov 2020 20:31:43

US3292365

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:54:21

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:31:43
Amendment Manager: User entered '12 Aug 2022 23:59'	System	19 Nov 2020 20:31:43

US3292365

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:54:21

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:31:43
Amendment Manager: User entered 'Day 719'	System	19 Nov 2020 20:31:43

US3292365

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:54:21

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:31:43
Amendment Manager: User entered '15 Aug 2022 00:01'	System	19 Nov 2020 20:31:43

US3292365

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:54:21

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:31:43
Amendment Manager: User entered '19 Aug 2022 23:59'	System	19 Nov 2020 20:31:43

US3292365

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:54:21

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:31:43
Amendment Manager: User entered 'Day 726'	System	19 Nov 2020 20:31:43

US3292365

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:54:21

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:31:43
Amendment Manager: User entered '22 Aug 2022 00:01'	System	19 Nov 2020 20:31:43

US3292365

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:54:21

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:31:43
Amendment Manager: User entered '26 Aug 2022 23:59'	System	19 Nov 2020 20:31:43

US3292365

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:54:21

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:31:43
Amendment Manager: User entered 'Day 733'	System	19 Nov 2020 20:31:43

US3292365

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:54:21

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:31:43
Amendment Manager: User entered '29 Aug 2022 00:01'	System	19 Nov 2020 20:31:43

US3292365

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:54:21

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:31:43
Amendment Manager: User entered '02 Sep 2022 23:59'	System	19 Nov 2020 20:31:43

US3292365

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:54:21

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:31:43
Amendment Manager: User entered 'Day 740'	System	19 Nov 2020 20:31:43

US3292365

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:54:21

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:31:43
Amendment Manager: User entered '05 Sep 2022 00:01'	System	19 Nov 2020 20:31:43

US3292365

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:54:21

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:31:43
Amendment Manager: User entered '09 Sep 2022 23:59'	System	19 Nov 2020 20:31:43

US3292365

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:54:21

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:31:43
Amendment Manager: User entered 'Day 747'	System	19 Nov 2020 20:31:43

US3292365

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:54:21

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:31:43
Amendment Manager: User entered '12 Sep 2022 00:01'	System	19 Nov 2020 20:31:43

US3292365

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:54:21

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:31:43
Amendment Manager: User entered '16 Sep 2022 23:59'	System	19 Nov 2020 20:31:43

US3292365

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:54:21

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:31:43
Amendment Manager: User entered 'Day 754'	System	19 Nov 2020 20:31:43

US3292365

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:54:21

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:31:43
Amendment Manager: User entered '19 Sep 2022 00:01'	System	19 Nov 2020 20:31:43

US3292365

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:54:21

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:31:43
Amendment Manager: User entered '23 Sep 2022 23:59'	System	19 Nov 2020 20:31:43

US3292365

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:54:21

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:31:43
Amendment Manager: User entered 'Day 761'	System	19 Nov 2020 20:31:43

US3292365

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:54:21

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:31:43
Amendment Manager: User entered '26 Sep 2022 00:01'	System	19 Nov 2020 20:31:43

US3292365

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:54:21

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:31:43
Amendment Manager: User entered '30 Sep 2022 23:59'	System	19 Nov 2020 20:31:43

US3292365

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:54:21

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:31:43
Amendment Manager: User entered 'Day 768'	System	19 Nov 2020 20:31:43

US3292365

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:54:21

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:31:43
Amendment Manager: User entered '03 Oct 2022 00:01'	System	19 Nov 2020 20:31:43

US3292365

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:54:21

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:31:43
Amendment Manager: User entered '07 Oct 2022 23:59'	System	19 Nov 2020 20:31:43

US3292365

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:54:21

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:31:43
Amendment Manager: User entered 'Day 775'	System	19 Nov 2020 20:31:43

US3292365

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:54:21

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:31:43
Amendment Manager: User entered '10 Oct 2022 00:01'	System	19 Nov 2020 20:31:43

US3292365

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:54:21

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:31:43
Amendment Manager: User entered '14 Oct 2022 23:59'	System	19 Nov 2020 20:31:43

US3292365

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:54:21

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:31:43
Amendment Manager: User entered 'Day 782'	System	19 Nov 2020 20:31:43

US3292365

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:54:21

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:31:43
Amendment Manager: User entered '17 Oct 2022 00:01'	System	19 Nov 2020 20:31:43

US3292365

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:54:21

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:31:43
Amendment Manager: User entered '21 Oct 2022 23:59'	System	19 Nov 2020 20:31:43

US3292365

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:54:21

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:31:43
Amendment Manager: User entered 'Day 789'	System	19 Nov 2020 20:31:43

US3292365

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:54:21

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:31:43
Amendment Manager: User entered '24 Oct 2022 00:01'	System	19 Nov 2020 20:31:43

US3292365

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:54:21

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:31:43
Amendment Manager: User entered '28 Oct 2022 23:59'	System	19 Nov 2020 20:31:43

US3292365

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:54:21

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:31:43
Amendment Manager: User entered 'Day 796'	System	19 Nov 2020 20:31:43

US3292365

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:54:21

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:31:43
Amendment Manager: User entered '31 Oct 2022 00:01'	System	19 Nov 2020 20:31:43

US3292365

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:54:21

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:31:43
Amendment Manager: User entered '04 Nov 2022 23:59'	System	19 Nov 2020 20:31:43

US3292365

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 26 Nov 2020 10:54:21

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Gerardo Pena (b) (4) (b) (4)	23 Nov 2020 22:30:23

US3292365

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 26 Nov 2020 10:54:21

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

Audit	User	Time (GMT)
User entered '20 Nov 2020'	Gerardo Pena (b) (4) (b) (4)	23 Nov 2020 22:30:23

US3292365

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 26 Nov 2020 10:54:21

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
User entered 'Contact Made (CONTACT MADE)'	Gerardo Pena (b) (4) (b) (4)	23 Nov 2020 22:30:23

US3292365

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 26 Nov 2020 10:54:21

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
User entered empty.	Gerardo Pena (b) (4) (b) (4)	23 Nov 2020 22:30:23

US3292365

Folder: Safety Call Day 85 (1)

Form: Continuing

Generated On: 26 Nov 2020 10:54:21

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Gerardo Pena (b) (4) (b) (4)	23 Nov 2020 22:30:28

US3292365

Folder: Safety Call Day 85 (1)

Form: Continuing

Generated On: 26 Nov 2020 10:54:21

[Continuing Flag](#)

Audit	User	Time (GMT)
User entered 'I'	System	23 Nov 2020 22:30:28

US3292365

Folder: Adverse Events

Form: Adverse Events Summary

Generated On: 26 Nov 2020 10:54:21

[Did the participant experience any adverse events?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Antonio Gutierrez (b) (4)	09 Nov 2020 20:08:38

US3292365

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 10:54:21

[AEID](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Nov 2020 18:42:35
Reviewed for Safety.	(b) (4), (b) (6)	10 Nov 2020 23:39:52
User entered 'USA-US072-2020-mRNA-1273-P301000010'	System	10 Nov 2020 23:39:46
User entered 'New'	(b) (4), (b) (6)	10 Nov 2020 23:39:46

US3292365

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 10:54:21

[Adverse event](#)

Audit	User	Time (GMT)
User coded data point as SOC: Neoplasms benign, malignant and unspecified (incl cysts and polyps), HLGT: Breast neoplasms malignant and unspecified (incl nipple), HLT: Breast and nipple neoplasms malignant, PT: Invasive lobular breast carcinoma, LLT: Invasive lobular breast carcinoma - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	23 Nov 2020 20:12:20
User coded data point as Term Coded data point by User: Coder System - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	23 Nov 2020 20:12:20
Data point term sent to Coder	System	23 Nov 2020 19:40:38
User closed query 'CDM Coding: Please update the term if it means 'Invasive lobular breast carcinoma', else please clarify.' (Site from System).	System	23 Nov 2020 19:40:24
Query 'CDM Coding: Please update the term if it means 'Invasive lobular breast carcinoma', else please clarify.' answered with 'updated' (Site from System).	Antonio Gutierrez (b) (4)	23 Nov 2020 19:40:24
DataPoint Un-verified.	Antonio Gutierrez (b) (4)	23 Nov 2020 19:40:16
User entered 'INVASIVE LOBULAR BREAST CARCINOMA' reason for change: Per Query Resolution	Antonio Gutierrez (b) (4)	23 Nov 2020 19:40:16
DataPoint Verified.	(b) (4), (b) (6)	23 Nov 2020 18:44:22
User opened query 'CDM Coding: Please update the term if it means 'Invasive lobular breast carcinoma', else please clarify.' (Site from System).	Coder Import (b) (4) (b) (4)	12 Nov 2020 03:43:40
Data point term sent to Coder	System	09 Nov 2020 21:53:39
User entered 'Invasive LOBULAR CARCINOMA' reason for change: New Information	Antonio Gutierrez (b) (4)	09 Nov 2020 21:53:37
Data point term sent to Coder	System	09 Nov 2020 20:48:39
User entered 'Gladular Lobular Carcinoma'	Antonio Gutierrez (b) (4)	09 Nov 2020 20:48:20

US3292365

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 10:54:21

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Nov 2020 18:43:30
User entered 'Yes (Y)'	Antonio Gutierrez (b) (4)	09 Nov 2020 20:48:20

US3292365

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 10:54:21

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Nov 2020 18:43:31
User entered 'No (N)'	Antonio Gutierrez (b) (4)	09 Nov 2020 20:48:20

US3292365

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 10:54:21

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Nov 2020 18:43:32
User entered 'No (N)'	Antonio Gutierrez (b) (4)	09 Nov 2020 20:48:20

US3292365

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 10:54:21

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Un-verified.	Antonio Gutierrez (b) (4)	24 Nov 2020 22:56:39
User entered '08 Oct 2020' reason for change: Per Query Resolution	Antonio Gutierrez (b) (4)	24 Nov 2020 22:56:39
DataPoint Verified.	(b) (4), (b) (6)	23 Nov 2020 18:43:34
User entered '9 Nov 2020'	Antonio Gutierrez (b) (4)	09 Nov 2020 20:48:20

US3292365

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 10:54:21

[Start time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Nov 2020 18:43:35
User entered empty.	Antonio Gutierrez (b) (4)	09 Nov 2020 20:48:20

US3292365

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 10:54:21

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	09 Nov 2020 20:48:20

US3292365

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 10:54:21

[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Nov 2020 18:43:36
User entered 'Yes (Y)'	Antonio Gutierrez (b) (4)	09 Nov 2020 20:48:20

US3292365

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 10:54:21

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
Query 'PV Query: Please provide the event end date (recovered, returned to baseline, or, in the investigator's opinion, a new baseline has been achieved), when available.' answered with 'Event ongoing. Double mastectomy scheduled for 14DEC2020.' (Site from Safety). DataPoint Verified.	Antonio Gutierrez (b) (4)	24 Nov 2020 22:59:36
	(b) (4), (b) (6)	23 Nov 2020 18:43:38
User opened query 'PV Query: Please provide the event end date (recovered, returned to baseline, or, in the investigator's opinion, a new baseline has been achieved), when available.' (Site from Safety). User entered empty.	(b) (4), (b) (6)	19 Nov 2020 18:13:27
	Antonio Gutierrez (b) (4)	09 Nov 2020 20:48:20

US3292365

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 10:54:21

End time (00:00-23:59)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Nov 2020 18:43:39
User entered empty.	Antonio Gutierrez (b) (4)	09 Nov 2020 20:48:20

US3292365

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 10:54:21

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	09 Nov 2020 20:48:20

US3292365

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 10:54:21

[Severity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Nov 2020 18:43:41
User entered 'Grade 3/Severe (Grade 3/Severe)'	Antonio Gutierrez (b) (4)	09 Nov 2020 20:48:20

US3292365

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 10:54:21

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Nov 2020 18:43:42
User entered 'Yes (Y)'	Antonio Gutierrez (b) (4)	09 Nov 2020 20:48:20

US3292365

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 10:54:21

[Death](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Nov 2020 18:43:46
User entered '0'	Antonio Gutierrez (b) (4)	09 Nov 2020 20:48:20

US3292365

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 10:54:21

[Life threatening](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Nov 2020 18:43:47
User entered '0'	Antonio Gutierrez (b) (4)	09 Nov 2020 20:48:20

US3292365

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 10:54:21

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Nov 2020 18:43:49
User entered '0'	Antonio Gutierrez (b) (4)	09 Nov 2020 20:48:20

US3292365

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 10:54:21

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Nov 2020 18:43:50
User entered empty.	Antonio Gutierrez (b) (4)	09 Nov 2020 20:48:20

US3292365

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 10:54:21

Hospital Discharge Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Nov 2020 18:43:51
User entered empty.	Antonio Gutierrez (b) (4)	09 Nov 2020 20:48:20

US3292365

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 10:54:21

[Admitted to ICU?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Nov 2020 18:43:53
User entered empty.	Antonio Gutierrez (b) (4)	09 Nov 2020 20:48:20

US3292365

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 10:54:21

[Number of Days in ICU](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Nov 2020 18:43:54
User entered empty.	Antonio Gutierrez (b) (4)	09 Nov 2020 20:48:20

US3292365

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 10:54:21

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Nov 2020 18:43:57
User entered '0'	Antonio Gutierrez (b) (4)	09 Nov 2020 20:48:20

US3292365

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 10:54:21

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Nov 2020 18:43:56
User entered '0'	Antonio Gutierrez (b) (4)	09 Nov 2020 20:48:20

US3292365

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 10:54:21

[Other medically important event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Nov 2020 18:43:59
User entered 'I'	Antonio Gutierrez (b) (4)	09 Nov 2020 20:48:20

US3292365

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 10:54:21

[Relationship to investigational product](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Nov 2020 18:44:00
User entered 'Not Related (NOT RELATED)'	Antonio Gutierrez (b) (4)	09 Nov 2020 20:48:20

US3292365

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 10:54:21

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Nov 2020 18:44:02
User entered 'Not Related (NOT RELATED)'	Antonio Gutierrez (b) (4)	09 Nov 2020 20:48:20

US3292365

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 10:54:21

[Action taken with investigational product](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Nov 2020 18:44:05
User entered 'Not Applicable (NOT APPLICABLE)'	Antonio Gutierrez (b) (4)	09 Nov 2020 20:48:20

US3292365

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 10:54:21

None

Audit	User	Time (GMT)
DataPoint Un-verified.	Antonio Gutierrez (b) (4)	24 Nov 2020 22:37:48
User entered '1' reason for change: Per Query Resolution	Antonio Gutierrez (b) (4)	24 Nov 2020 22:37:48
DataPoint Verified.	(b) (4), (b) (6)	23 Nov 2020 18:44:06
User entered '0' reason for change: New Information	Antonio Gutierrez (b) (4)	09 Nov 2020 21:53:37
User entered '1'	Antonio Gutierrez (b) (4)	09 Nov 2020 20:48:20

US3292365

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 10:54:21

[Concomitant Medication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Nov 2020 18:44:08
User entered '0'	Antonio Gutierrez (b) (4)	09 Nov 2020 20:48:20

US3292365

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 10:54:21

[Concomitant Procedure](#)

Audit	User	Time (GMT)
Query 'Per DM CLR: Other Action Taken = Con Proc, however the recorded Concomitant Procedure is a Diagnostic procedure and not a Medical Treatment Procedure. Please review and record a Medical Treatment Procedure as appropriate or update action taken.' answered with 'updated' (Site from DM).	Antonio Gutierrez (b) (4)	24 Nov 2020 22:39:40
DataPoint Un-verified.	Antonio Gutierrez (b) (4)	24 Nov 2020 22:37:48
User entered '0' reason for change: Per Query Resolution	Antonio Gutierrez (b) (4)	24 Nov 2020 22:37:48
User opened query 'Per DM CLR: Other Action Taken = Con Proc, however the recorded Concomitant Procedure is a Diagnostic procedure and not a Medical Treatment Procedure. Please review and record a Medical Treatment Procedure as appropriate or update action taken.' (Site from DM).	(b) (4), (b) (6)	24 Nov 2020 00:01:59
DataPoint Verified.	(b) (4), (b) (6)	23 Nov 2020 18:44:09
User entered '1' reason for change: New Information	Antonio Gutierrez (b) (4)	09 Nov 2020 21:53:37
User entered '0'	Antonio Gutierrez (b) (4)	09 Nov 2020 20:48:20

US3292365

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 10:54:21

[Outcome](#)

Audit	User	Time (GMT)
Query 'PV Query: Please provide the final event outcome, when available. If not expected to resolve, please confirm in your response. If resolution is expected, please keep query open until achieved.' answered with 'Event ongoing. Double mastectomy scheduled for 14DEC2020.' (Site from Safety). DataPoint Verified.	Antonio Gutierrez (b) (4)	24 Nov 2020 23:00:03
	(b) (4), (b) (6)	23 Nov 2020 18:44:12
User opened query 'PV Query: Please provide the final event outcome, when available. If not expected to resolve, please confirm in your response. If resolution is expected, please keep query open until achieved.' (Site from Safety).	(b) (4), (b) (6)	19 Nov 2020 18:13:44
User entered 'Not Recovered/Not Resolved (NOT RECOVERED/NOT RESOLVED)'	Antonio Gutierrez (b) (4)	09 Nov 2020 20:48:20

US3292365

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 10:54:21

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Nov 2020 18:44:13
User entered empty.	Antonio Gutierrez (b) (4)	09 Nov 2020 20:48:20

US3292365

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 10:54:21

[Narrative](#)

Audit	User	Time (GMT)
Query 'PV Query: Please provide any relevant laboratory and diagnostic test results (i.e. additional scans). Please include units and reference ranges if applicable' answered with 'Medical records to be requested. No new information available at this time.' (Site from Safety).	Antonio Gutierrez (b) (4)	24 Nov 2020 23:00:45
Query 'PV Query: Please provide treatment given for the event including medical intervention and/or surgical treatments. Please add any treatment medications to the concomitant medication eCRF (including dates of administration, dose, units, frequency, route and indication). If no treatment was provided, please state so.' answered with 'Double mastectomy scheduled for 14DEC2020.' (Site from Safety).	Antonio Gutierrez (b) (4)	24 Nov 2020 23:00:21
Query 'Per DM CLR: SAE Narrative = PATIENT CONTACTED STUDY STAFF THIS AFTERNOON (09NOV2020) TO INFORM THE STUDY TEAM THAT SHE HAD RECEIVED THE RESULTS OF HER ANNUAL MAMMOGRAM, COMPLETED LAST WEEK. Please review and determine if the start date of this AE should be reconciled as it mentioned that on 09NOV2020, the site was informed that the MAMMOGRAM was completed "LAST WEEK". Verify and update as appropriate. Otherwise, clarify. ' answered with 'dates updated' (Site from DM).	Antonio Gutierrez (b) (4)	24 Nov 2020 22:58:56
Query 'PV Query: Please report if the patient has any family history or risk factors for development of breast cancer.' answered with 'Patient states (b) (6) and (b) (6) both had breast cancer. Additionally, (b) (6) had breast cancer as well. ' (Site from Safety).	Antonio Gutierrez (b) (4)	24 Nov 2020 22:58:43
Query 'PV Query: Has the subject seen an oncologist or have plans to see one? If so, please provide oncology consultation notes with patient identifiers redacted and subject ID added to Safety_Moderna@iqvia.com or fax to 866.599.1342.' answered with 'Patient has not seen oncologist. Plans to have double mastectomy first' (Site from Safety).	Antonio Gutierrez (b) (4)	24 Nov 2020 22:57:27

US3292365

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 10:54:21

[Narrative](#)

Audit	User	Time (GMT)
Query 'PV Query: Please consider updating start date to date of mammogram.' answered with 'updated' (Site from Safety).	Antonio Gutierrez (b) (4)	24 Nov 2020 22:56:58
Query 'PV Query: Please provide the date the subject underwent mammogram.' answered with 'First mammogram 08OCT2020. Confirmatory mammogram on 29OCT2020.' (Site from Safety).	Antonio Gutierrez (b) (4)	24 Nov 2020 22:55:58
User opened query 'Per DM CLR: SAE Narrative = PATIENT CONTACTED STUDY STAFF THIS AFTERNOON (09NOV2020) TO INFORM THE STUDY TEAM THAT SHE HAD RECEIVED THE RESULTS OF HER ANNUAL MAMMOGRAM, COMPLETED LAST WEEK. Please review and determine if the start date of this AE should be reconciled as it mentioned that on 09NOV2020, the site was informed that the MAMMOGRAM was completed "LAST WEEK". Verify and update as appropriate. Otherwise, clarify. (Site from DM).	(b) (4), (b) (6)	24 Nov 2020 00:02:33
DataPoint Verified.	(b) (4), (b) (6)	23 Nov 2020 18:44:15
User opened query 'PV Query: Please report if the patient has any family history or risk factors for development of breast cancer.' (Site from Safety).	(b) (4), (b) (6)	19 Nov 2020 18:16:58
User opened query 'PV Query: Has the subject seen an oncologist or have plans to see one? If so, please provide oncology consultation notes with patient identifiers redacted and subject ID added to Safety_Moderna@iqvia.com or fax to 866.599.1342.' (Site from Safety).	(b) (4), (b) (6)	19 Nov 2020 18:16:38
User opened query 'PV Query: Please consider updating start date to date of mammogram.' (Site from Safety).	(b) (4), (b) (6)	19 Nov 2020 18:16:26
User opened query 'PV Query: Please provide the date the subject underwent mammogram.' (Site from Safety).	(b) (4), (b) (6)	19 Nov 2020 18:14:39
User opened query 'PV Query: Please provide any relevant laboratory and diagnostic test results (i.e. additional scans). Please include units and reference ranges if applicable' (Site from Safety).	(b) (4), (b) (6)	19 Nov 2020 18:14:25

US3292365

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 10:54:21

[Narrative](#)

Audit	User	Time (GMT)
User opened query 'PV Query: Please provide treatment given for the event including medical intervention and/or surgical treatments. Please add any treatment medications to the concomitant medication eCRF (including dates of administration, dose, units, frequency, route and indication). If no treatment was provided, please state so.' (Site from Safety).	(b) (4), (b) (6)	19 Nov 2020 18:14:12
User entered 'PATIENT CONTACTED STUDY STAFF THIS AFTERNOON (09NOV2020) TO INFORM THE STUDY TEAM THAT SHE HAD RECEIVED THE RESULTS OF HER ANNUAL MAMMOGRAM, COMPLETED LAST WEEK. AS PER THE PATIENT, SHE WAS DIAGNOSED WITH A GLANDULAR LOBULAR CARCINOMA IN HER LEFT BREAST. PATIENT STATES SHE NEVER FELT A LUMP, NOR DOES SHE FEEL ONE NOW. THE CARCINOMA WAS DISCOVERED VIA THE MAMMOGRAM. AT THIS TIME, PATIENT STATES THAT SHE DOES NOT WANT TO PUT HERSELF THROUGH RADIATION OR CHEMOTHERAPY AND PLANS TO HAVE A TOTAL MASTECTOMY DONE. PATIENT HAS A FOLLOW-UP SURGERY CONSULT SCHEDULED AND WILL FOLLOW UP WITH STUDY STAFF IN REGARDS TO HER TREATMENT PLAN.' reason for change: Data Entry Error	Antonio Gutierrez (b) (4)	09 Nov 2020 20:50:17
User entered 'Patient contacted study staff this afternoon (09NOV2020) to inform the study team that she had received the results of her annual mammogram, completed last week. As per the patient, she was diagnosed with a glandular lobular carcinoma in her left breast. Patient states she never felt a lump, nor does she feel one now. The carcinoma was discovered via the mammogram. At this time, patient states that she does not want to put herself through radiation or chemotherapy and plants to have a total mastectomy done. Patient has a follow-up surgery consult scheduled and will follow up with study staff in regards to her treatment plan.'	Antonio Gutierrez (b) (4)	09 Nov 2020 20:48:20

US3292365

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 10:54:21

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered 'I'	System	09 Nov 2020 20:48:20

US3292365

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 10:54:21

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered 'I'	System	09 Nov 2020 20:48:20

US3292365

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination Summary

Generated On: 26 Nov 2020 10:54:21

[Were any prior/concomitant medications and/or vaccinations taken?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	(b) (4), (b) (6)	01 Sep 2020 03:50:39

US3292365

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 10:54:21

[Name of Medication](#)

Audit	User	Time (GMT)
User coded data point as ATC: BLOOD AND BLOOD FORMING ORGANS, ATC: ANTITHROMBOTIC AGENTS, ATC: ANTITHROMBOTIC AGENTS, ATC: PLATELET AGGREGATION INHIBITORS EXCL. HEPARIN, PRODUCT: ACETYLSALICYLIC ACID, PRODUCTSYNONYM: ASPIRIN [ACETYLSALICYLIC ACID] - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	01 Sep 2020 03:58:46
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 03:58:46
Data point term sent to Coder	System	01 Sep 2020 03:52:10
User entered 'aspirin'	(b) (4), (b) (6) (b) (4)	01 Sep 2020 03:51:37

US3292365

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 10:54:21

[Prophylaxis](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	(b) (4), (b) (6)	01 Sep 2020 03:51:37

US3292365

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 10:54:21

[Indication](#)

Audit	User	Time (GMT)
User entered 'Prophylaxis for cardiac preventative'	(b) (4), (b) (6)	01 Sep 2020 03:51:37

US3292365

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 10:54:21

[Dose per administration](#)

Audit	User	Time (GMT)
User entered '81'	(b) (4), (b) (6)	01 Sep 2020 03:51:37

US3292365

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 10:54:21

[Dose unit](#)

Audit	User	Time (GMT)
User entered 'mg (mg)'	(b) (4), (b) (6)	01 Sep 2020 03:51:37

US3292365

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 10:54:21

If dose unit is Other, specify

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	01 Sep 2020 03:51:37

US3292365

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 10:54:21

[Frequency](#)

Audit	User	Time (GMT)
User entered 'once daily (QD)'	(b) (4), (b) (6)	01 Sep 2020 03:51:37

US3292365

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 10:54:21

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	01 Sep 2020 03:51:37

US3292365

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 10:54:21

[Route of administration](#)

Audit	User	Time (GMT)
User entered 'Oral (ORAL)'	(b) (4), (b) (6)	01 Sep 2020 03:51:37

US3292365

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 10:54:21

If route of administration is Other, specify

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	01 Sep 2020 03:51:37

US3292365

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 10:54:21

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

Audit	User	Time (GMT)
User entered 'un UNK 2010'	(b) (4), (b) (6)	01 Sep 2020 03:51:37

US3292365

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 10:54:21

[Start date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	(b) (4), (b) (6)	01 Sep 2020 03:51:37

US3292365

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 10:54:21

[Ongoing?](#)

Audit	User	Time (GMT)
User entered 'No (N)' reason for change: New Information	Gerardo Pena (b) (4) (b) (4)	17 Nov 2020 22:46:18
User entered 'Yes (Y)'	(b) (4), (b) (6) (b) (4), (b) (6)	01 Sep 2020 03:51:37

US3292365

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 10:54:21

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
User entered '11 Nov 2020' reason for change: New Information	Gerardo Pena (b) (4)	17 Nov 2020 22:46:18
User entered empty.	(b) (4), (b) (6)	01 Sep 2020 03:51:37

US3292365

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 10:54:21

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	(b) (4), (b) (6)	01 Sep 2020 03:51:37

US3292365

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 10:54:21

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	01 Sep 2020 03:51:37

US3292365

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 10:54:21

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	01 Sep 2020 03:51:37

US3292365

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 10:54:21

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	01 Sep 2020 03:51:37

US3292365

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 10:54:21

[Name of Medication](#)

Audit	User	Time (GMT)
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: VITAMINS, ATC: ASCORBIC ACID (VITAMIN C), INCL. COMBINATIONS, ATC: ASCORBIC ACID (VITAMIN C), PLAIN, PRODUCT: ASCORBIC ACID, PRODUCTSYNONYM: VITAMIN C [ASCORBIC ACID] - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	01 Sep 2020 08:50:43
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	01 Sep 2020 08:50:43
Data point term sent to Coder	System	01 Sep 2020 03:53:11
User entered 'Vitamin C'	(b) (4), (b) (6)	01 Sep 2020 03:52:25

US3292365

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 10:54:21

[Prophylaxis](#)

Audit	User	Time (GMT)
User opened query 'Per CDM: Response is recorded as No; however, indication is recorded as health promotion measure. Please clarify if this was given as a prophylactic or preventative measure. If yes, please update accordingly' (Site from DM).	(b) (4), (b) (6)	11 Nov 2020 15:01:54
User entered 'No (N)'	(b) (4), (b) (6)	01 Sep 2020 03:52:25

US3292365

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 10:54:21

[Indication](#)

Audit	User	Time (GMT)
User entered 'general health suppliment'	(b) (4), (b) (6)	01 Sep 2020 03:52:25

US3292365

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 10:54:21

[Dose per administration](#)

Audit	User	Time (GMT)
User entered '1000'	(b) (4), (b) (6)	01 Sep 2020 03:52:25

US3292365

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 10:54:21

[Dose unit](#)

Audit	User	Time (GMT)
User entered 'mg (mg)'	(b) (4), (b) (6)	01 Sep 2020 03:52:25

US3292365

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 10:54:21

If dose unit is Other, specify

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	01 Sep 2020 03:52:25

US3292365

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 10:54:21

[Frequency](#)

Audit	User	Time (GMT)
User entered 'once daily (QD)'	(b) (4), (b) (6)	01 Sep 2020 03:52:25

US3292365

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 10:54:21

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	01 Sep 2020 03:52:25

US3292365

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 10:54:21

[Route of administration](#)

Audit	User	Time (GMT)
User entered 'Oral (ORAL)'	(b) (4), (b) (6)	01 Sep 2020 03:52:25

US3292365

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 10:54:21

If route of administration is Other, specify

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	01 Sep 2020 03:52:25

US3292365

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 10:54:21

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

Audit	User	Time (GMT)
User entered 'un Aug 2020'	(b) (4), (b) (6)	01 Sep 2020 03:52:25

US3292365

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 10:54:21

[Start date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	(b) (4), (b) (6)	01 Sep 2020 03:52:25

US3292365

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 10:54:21

[Ongoing?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	(b) (4), (b) (6)	01 Sep 2020 03:52:25

US3292365

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 10:54:21

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	01 Sep 2020 03:52:25

US3292365

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 10:54:21

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	(b) (4), (b) (6)	01 Sep 2020 03:52:25

US3292365

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 10:54:21

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	01 Sep 2020 03:52:25

US3292365

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 10:54:21

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	01 Sep 2020 03:52:25

US3292365

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 10:54:21

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	01 Sep 2020 03:52:25

US3292365

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 10:54:21

[Name of Medication](#)

Audit	User	Time (GMT)
User coded data point as ATC: NERVOUS SYSTEM, ATC: ANALGESICS, ATC: OTHER ANALGESICS AND ANTIPYRETICS, ATC: SALICYLIC ACID AND DERIVATIVES, PRODUCT: ACETYLSALICYLIC ACID, PRODUCTSYNONYM: ASPIRIN [ACETYLSALICYLIC ACID] - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	01 Sep 2020 03:59:47
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 03:59:47
Data point term sent to Coder	System	01 Sep 2020 03:55:13
User entered 'aspirin'	(b) (4), (b) (6) (b) (4)	01 Sep 2020 03:54:24

US3292365

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 10:54:21

[Prophylaxis](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	(b) (4), (b) (6)	01 Sep 2020 03:54:24

US3292365

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 10:54:21

[Indication](#)

Audit	User	Time (GMT)
User entered 'Prophylaxis for pain'	(b) (4), (b) (6)	01 Sep 2020 03:54:24

US3292365

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 10:54:21

[Dose per administration](#)

Audit	User	Time (GMT)
User entered '500'	(b) (4), (b) (6)	01 Sep 2020 03:54:24

US3292365

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 10:54:21

[Dose unit](#)

Audit	User	Time (GMT)
User entered 'mg (mg)'	(b) (4), (b) (6)	01 Sep 2020 03:54:24

US3292365

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 10:54:21

If dose unit is Other, specify

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	01 Sep 2020 03:54:24

US3292365

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 10:54:21

[Frequency](#)

Audit	User	Time (GMT)
User entered 'as needed (PRN)'	(b) (4), (b) (6)	01 Sep 2020 03:54:24

US3292365

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 10:54:21

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	01 Sep 2020 03:54:24

US3292365

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 10:54:21

[Route of administration](#)

Audit	User	Time (GMT)
User entered 'Oral (ORAL)'	(b) (4), (b) (6)	01 Sep 2020 03:54:24

US3292365

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 10:54:21

If route of administration is Other, specify

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	01 Sep 2020 03:54:24

US3292365

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 10:54:21

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

Audit	User	Time (GMT)
User entered 'un Aug 2020'	(b) (4), (b) (6)	01 Sep 2020 03:54:24

US3292365

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 10:54:21

[Start date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	(b) (4), (b) (6)	01 Sep 2020 03:54:24

US3292365

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 10:54:21

[Ongoing?](#)

Audit	User	Time (GMT)
User entered 'No (N)' reason for change: New Information	Gerardo Pena (b) (4) (b) (4)	17 Nov 2020 22:45:48
User entered 'Yes (Y)'	(b) (4), (b) (6) (b) (4), (b) (6)	01 Sep 2020 03:54:24

US3292365

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 10:54:21

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
User entered '11 Nov 2020' reason for change: Data Entry Error	Gerardo Pena (b) (4)	17 Nov 2020 22:45:48
User entered empty.	(b) (4), (b) (6)	01 Sep 2020 03:54:24

US3292365

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 10:54:21

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	(b) (4), (b) (6)	01 Sep 2020 03:54:24

US3292365

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 10:54:21

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	01 Sep 2020 03:54:24

US3292365

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 10:54:21

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	01 Sep 2020 03:54:24

US3292365

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 10:54:21

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	01 Sep 2020 03:54:24

US3292365

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 10:54:21

[Name of Medication](#)

Audit	User	Time (GMT)
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: MINERAL SUPPLEMENTS, ATC: OTHER MINERAL SUPPLEMENTS, ATC: ZINC, PRODUCT: ZINC - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	01 Sep 2020 08:53:48
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	01 Sep 2020 08:53:48
Data point term sent to Coder	System	01 Sep 2020 03:55:15
User entered 'zinc'	(b) (4), (b) (6)	01 Sep 2020 03:55:07

US3292365

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 10:54:21

[Prophylaxis](#)

Audit	User	Time (GMT)
User opened query 'Per CDM: Response is recorded as No; however, indication is recorded as health promotion measure. Please clarify if this was given as a prophylactic or preventative measure. If yes, please update accordingly' (Site from DM).	(b) (4), (b) (6)	11 Nov 2020 15:01:08
User entered 'No (N)'	(b) (4), (b) (6)	01 Sep 2020 03:55:07

US3292365

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 10:54:21

[Indication](#)

Audit	User	Time (GMT)
User entered 'general health suppliment'	(b) (4), (b) (6)	01 Sep 2020 03:55:07

US3292365

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 10:54:21

[Dose per administration](#)

Audit	User	Time (GMT)
User closed query 'Per DM CLR: Please provide the actual dose for this medication instead of number of tablets as there are other dosage options for this drug. Update Con Med eCRF as appropriate. ' (Site from DM).	(b) (4), (b) (6)	11 Nov 2020 15:01:12
Query 'Per DM CLR: Please provide the actual dose for this medication instead of number of tablets as there are other dosage options for this drug. Update Con Med eCRF as appropriate. ' answered with 'unknown per patient' (Site from DM).	(b) (4), (b) (6)	23 Sep 2020 14:45:29
User opened query 'Per DM CLR: Please provide the actual dose for this medication instead of number of tablets as there are other dosage options for this drug. Update Con Med eCRF as appropriate. ' (Site from DM).	(b) (4), (b) (6)	23 Sep 2020 04:37:14
User entered 'I'	(b) (4), (b) (6)	01 Sep 2020 03:55:07

US3292365

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 10:54:21

[Dose unit](#)

Audit	User	Time (GMT)
User entered 'tablet (TABLET)'	(b) (4), (b) (6)	01 Sep 2020 03:55:07

US3292365

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 10:54:21

If dose unit is Other, specify

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	01 Sep 2020 03:55:07

US3292365

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 10:54:21

[Frequency](#)

Audit	User	Time (GMT)
User entered 'as needed (PRN)'	(b) (4), (b) (6)	01 Sep 2020 03:55:07

US3292365

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 10:54:21

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	01 Sep 2020 03:55:07

US3292365

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 10:54:21

[Route of administration](#)

Audit	User	Time (GMT)
User entered 'Oral (ORAL)'	(b) (4), (b) (6)	01 Sep 2020 03:55:07

US3292365

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 10:54:21

If route of administration is Other, specify

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	01 Sep 2020 03:55:07

US3292365

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 10:54:21

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

Audit	User	Time (GMT)
User entered 'un Jul 2020'	(b) (4), (b) (6)	01 Sep 2020 03:55:07

US3292365

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 10:54:21

[Start date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	(b) (4), (b) (6)	01 Sep 2020 03:55:07

US3292365

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 10:54:21

[Ongoing?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	(b) (4), (b) (6)	01 Sep 2020 03:55:07

US3292365

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 10:54:21

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	01 Sep 2020 03:55:07

US3292365

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 10:54:21

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	(b) (4), (b) (6)	01 Sep 2020 03:55:07

US3292365

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 10:54:21

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	01 Sep 2020 03:55:07

US3292365

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 10:54:21

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	01 Sep 2020 03:55:07

US3292365

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 10:54:21

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	01 Sep 2020 03:55:07

US3292365

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 26 Nov 2020 10:54:21

[Name of Medication](#)

Audit	User	Time (GMT)
User coded data point as ATC: NERVOUS SYSTEM, ATC: PSYCHOLEPTICS, ATC: ANXIOLYTICS, ATC: OTHER ANXIOLYTICS, PRODUCT: DULOXETINE HYDROCHLORIDE, PRODUCTSYNONYM: DULOXETINE HCL - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	01 Sep 2020 05:53:47
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 05:53:47
Data point term sent to Coder	System	01 Sep 2020 03:57:16
User entered 'duloxetine hcl dr'	(b) (4), (b) (6) (b) (4)	01 Sep 2020 03:56:18

US3292365

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 26 Nov 2020 10:54:21

[Prophylaxis](#)

Audit	User	Time (GMT)
User entered 'No (N)'	(b) (4), (b) (6)	01 Sep 2020 03:56:18

US3292365

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 26 Nov 2020 10:54:21

[Indication](#)

Audit	User	Time (GMT)
User entered 'anxiety'	(b) (4), (b) (6)	01 Sep 2020 03:56:18

US3292365

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 26 Nov 2020 10:54:21

[Dose per administration](#)

Audit	User	Time (GMT)
User entered '60'	(b) (4), (b) (6)	01 Sep 2020 03:56:18

US3292365

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 26 Nov 2020 10:54:21

[Dose unit](#)

Audit	User	Time (GMT)
User entered 'mg (mg)'	(b) (4), (b) (6)	01 Sep 2020 03:56:18

US3292365

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 26 Nov 2020 10:54:21

If dose unit is Other, specify

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	01 Sep 2020 03:56:18

US3292365

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 26 Nov 2020 10:54:21

[Frequency](#)

Audit	User	Time (GMT)
User entered 'once daily (QD)'	(b) (4), (b) (6)	01 Sep 2020 03:56:18

US3292365

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 26 Nov 2020 10:54:21

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	01 Sep 2020 03:56:18

US3292365

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 26 Nov 2020 10:54:21

[Route of administration](#)

Audit	User	Time (GMT)
User entered 'Oral (ORAL)'	(b) (4), (b) (6)	01 Sep 2020 03:56:18

US3292365

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 26 Nov 2020 10:54:21

If route of administration is Other, specify

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	01 Sep 2020 03:56:18

US3292365

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 26 Nov 2020 10:54:21

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

Audit	User	Time (GMT)
User entered 'un UNK 2015'	(b) (4), (b) (6)	01 Sep 2020 03:56:18

US3292365

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 26 Nov 2020 10:54:21

[Start date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	(b) (4), (b) (6)	01 Sep 2020 03:56:18

US3292365

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 26 Nov 2020 10:54:21

[Ongoing?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	(b) (4), (b) (6)	01 Sep 2020 03:56:18

US3292365

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 26 Nov 2020 10:54:21

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	01 Sep 2020 03:56:18

US3292365

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 26 Nov 2020 10:54:21

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	(b) (4), (b) (6)	01 Sep 2020 03:56:18

US3292365

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 26 Nov 2020 10:54:21

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	01 Sep 2020 03:56:18

US3292365

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 26 Nov 2020 10:54:21

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	01 Sep 2020 03:56:18

US3292365

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 26 Nov 2020 10:54:21

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	01 Sep 2020 03:56:18

US3292365

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 26 Nov 2020 10:54:21

[Name of Medication](#)

Audit	User	Time (GMT)
User coded data point as ATC: RESPIRATORY SYSTEM, ATC: DRUGS FOR OBSTRUCTIVE AIRWAY DISEASES, ATC: OTHER SYSTEMIC DRUGS FOR OBSTRUCTIVE AIRWAY DISEASES, ATC: LEUKOTRIENE RECEPTOR ANTAGONISTS, PRODUCT: MONTELUKAST SODIUM - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	01 Sep 2020 03:58:46
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	01 Sep 2020 03:58:46
Data point term sent to Coder	System	01 Sep 2020 03:58:17
User entered 'montelukast sodium'	(b) (4), (b) (6) (b) (4)	01 Sep 2020 03:57:24

US3292365

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 26 Nov 2020 10:54:21

[Prophylaxis](#)

Audit	User	Time (GMT)
User entered 'No (N)'	(b) (4), (b) (6)	01 Sep 2020 03:57:24

US3292365

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 26 Nov 2020 10:54:21

[Indication](#)

Audit	User	Time (GMT)
User entered 'asthma'	(b) (4), (b) (6)	01 Sep 2020 03:57:24

US3292365

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 26 Nov 2020 10:54:21

[Dose per administration](#)

Audit	User	Time (GMT)
User entered '10'	(b) (4), (b) (6)	01 Sep 2020 03:57:24

US3292365

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 26 Nov 2020 10:54:21

[Dose unit](#)

Audit	User	Time (GMT)
User entered 'mg (mg)'	(b) (4), (b) (6)	01 Sep 2020 03:57:24

US3292365

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 26 Nov 2020 10:54:21

If dose unit is Other, specify

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	01 Sep 2020 03:57:24

US3292365

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 26 Nov 2020 10:54:21

[Frequency](#)

Audit	User	Time (GMT)
User entered 'once daily (QD)'	(b) (4), (b) (6)	01 Sep 2020 03:57:24

US3292365

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 26 Nov 2020 10:54:21

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	01 Sep 2020 03:57:24

US3292365

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 26 Nov 2020 10:54:21

[Route of administration](#)

Audit	User	Time (GMT)
User entered 'Oral (ORAL)'	(b) (4), (b) (6)	01 Sep 2020 03:57:24

US3292365

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 26 Nov 2020 10:54:21

If route of administration is Other, specify

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	01 Sep 2020 03:57:24

US3292365

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 26 Nov 2020 10:54:21

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User closed query 'Per DM CLR: Con Med start date is prior to the start date of the corresponding MH condition. Please review and reconcile Con Med and MH start dates as appropriate.' (Site from DM).	(b) (4), (b) (6)	11 Nov 2020 15:04:08
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 'unable to clarify, patient did not answer' (Site from DM).	(b) (4), (b) (6)	23 Sep 2020 14:46:48
User opened query 'Per DM CLR: Con Med start date is prior to the start date of the corresponding MH condition. Please review and reconcile Con Med and MH start dates as appropriate.' (Site from DM).	(b) (4), (b) (6)	23 Sep 2020 03:59:37
User entered 'un UNK 2005'	(b) (4), (b) (6)	01 Sep 2020 03:57:24

US3292365

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 26 Nov 2020 10:54:21

[Start date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	(b) (4), (b) (6)	01 Sep 2020 03:57:24

US3292365

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 26 Nov 2020 10:54:21

[Ongoing?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	(b) (4), (b) (6)	01 Sep 2020 03:57:24

US3292365

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 26 Nov 2020 10:54:21

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	01 Sep 2020 03:57:24

US3292365

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 26 Nov 2020 10:54:21

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	(b) (4), (b) (6)	01 Sep 2020 03:57:24

US3292365

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 26 Nov 2020 10:54:21

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	01 Sep 2020 03:57:24

US3292365

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 26 Nov 2020 10:54:21

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	01 Sep 2020 03:57:24

US3292365

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 26 Nov 2020 10:54:21

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	01 Sep 2020 03:57:24

US3292365

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 26 Nov 2020 10:54:21

[Name of Medication](#)

Audit	User	Time (GMT)
User coded data point as ATC: RESPIRATORY SYSTEM, ATC: DRUGS FOR OBSTRUCTIVE AIRWAY DISEASES, ATC: ADRENERGICS, INHALANTS, ATC: SELECTIVE BETA-2-ADRENORECEPTOR AGONISTS, PRODUCT: SALBUTAMOL SULFATE, PRODUCTSYNONYM: PROAIR RESPICLICK - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	24 Sep 2020 11:30:53
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	24 Sep 2020 11:30:53
Data point term sent to Coder	System	23 Sep 2020 14:47:44
Coding entries removed.	(b) (4), (b) (6)	23 Sep 2020 14:47:03
User coded data point as ATC: RESPIRATORY SYSTEM, ATC: DRUGS FOR OBSTRUCTIVE AIRWAY DISEASES, ATC: ADRENERGICS, INHALANTS, ATC: SELECTIVE BETA-2-ADRENORECEPTOR AGONISTS, PRODUCT: SALBUTAMOL SULFATE, PRODUCTSYNONYM: PROAIR RESPICLICK - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	08 Sep 2020 08:33:52
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	08 Sep 2020 08:33:52
Data point term sent to Coder	System	01 Sep 2020 04:00:19
User entered 'proair respiclick'	(b) (4), (b) (6)	01 Sep 2020 03:59:56

US3292365

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 26 Nov 2020 10:54:21

[Prophylaxis](#)

Audit	User	Time (GMT)
User entered 'No (N)'	(b) (4), (b) (6)	01 Sep 2020 03:59:56

US3292365

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 26 Nov 2020 10:54:21

[Indication](#)

Audit	User	Time (GMT)
User closed query 'Per DM CLR: Please update the indication to reflect the underlying medical condition that this medication is being used to prevent/treat instead of the DRUG ACTION/CLASS. Please reconcile with AE or Med History eCRF so there is an appropriate match.' (Site from DM).	(b) (4), (b) (6)	07 Oct 2020 15:06:06
Query 'Per DM CLR: Please update the indication to reflect the underlying medical condition that this medication is being used to prevent/treat instead of the DRUG ACTION/CLASS. Please reconcile with AE or Med History eCRF so there is an appropriate match.' answered with 'updated' (Site from DM).	(b) (4), (b) (6)	23 Sep 2020 14:47:13
User entered 'asthma' reason for change: Data Entry Error	(b) (4), (b) (6)	23 Sep 2020 14:47:03
User opened query 'Per DM CLR: Please update the indication to reflect the underlying medical condition that this medication is being used to prevent/treat instead of the DRUG ACTION/CLASS. Please reconcile with AE or Med History eCRF so there is an appropriate match.' (Site from DM).	(b) (4), (b) (6)	23 Sep 2020 04:14:13
User entered 'rescue inhaler'	(b) (4), (b) (6)	01 Sep 2020 03:59:56

US3292365

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 26 Nov 2020 10:54:21

[Dose per administration](#)

Audit	User	Time (GMT)
User entered '90'	(b) (4), (b) (6)	01 Sep 2020 03:59:56

US3292365

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 26 Nov 2020 10:54:21

[Dose unit](#)

Audit	User	Time (GMT)
User entered 'ug (ug)'	(b) (4), (b) (6)	01 Sep 2020 03:59:56

US3292365

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 26 Nov 2020 10:54:21

If dose unit is Other, specify

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	01 Sep 2020 03:59:56

US3292365

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 26 Nov 2020 10:54:21

[Frequency](#)

Audit	User	Time (GMT)
User entered 'as needed (PRN)'	(b) (4), (b) (6)	01 Sep 2020 03:59:56

US3292365

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 26 Nov 2020 10:54:21

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	01 Sep 2020 03:59:56

US3292365

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 26 Nov 2020 10:54:21

[Route of administration](#)

Audit	User	Time (GMT)
User entered 'Respiratory (Inhalation) (RESPIRATORY (INHALATION))'	(b) (4), (b) (6)	01 Sep 2020 03:59:56

US3292365

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 26 Nov 2020 10:54:21

If route of administration is Other, specify

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	01 Sep 2020 03:59:56

US3292365

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 26 Nov 2020 10:54:21

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User closed query 'Per DM CLR: Con Med start date is prior to the start date of the corresponding MH condition. Please review and reconcile Con Med and MH start dates as appropriate.' (Site from DM).	(b) (4), (b) (6)	11 Nov 2020 15:04:18
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 'asthma data corrected and updated' (Site from DM).	Kevin Martinez (b) (4)	05 Nov 2020 19:16:25
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)	22 Oct 2020 03:53:13
User entered 'un UNK 2005'	(b) (4), (b) (6)	01 Sep 2020 03:59:56

US3292365

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 26 Nov 2020 10:54:21

[Start date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	(b) (4), (b) (6)	01 Sep 2020 03:59:56

US3292365

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 26 Nov 2020 10:54:21

[Ongoing?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	(b) (4), (b) (6)	01 Sep 2020 03:59:56

US3292365

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 26 Nov 2020 10:54:21

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	01 Sep 2020 03:59:56

US3292365

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 26 Nov 2020 10:54:21

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	(b) (4), (b) (6)	01 Sep 2020 03:59:56

US3292365

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 26 Nov 2020 10:54:21

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	01 Sep 2020 03:59:56

US3292365

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 26 Nov 2020 10:54:21

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	01 Sep 2020 03:59:56

US3292365

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 26 Nov 2020 10:54:21

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	01 Sep 2020 03:59:56

US3292365

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 26 Nov 2020 10:54:21

[Name of Medication](#)

Audit	User	Time (GMT)
User coded data point as ATC: RESPIRATORY SYSTEM, ATC: DRUGS FOR OBSTRUCTIVE AIRWAY DISEASES, ATC: OTHER DRUGS FOR OBSTRUCTIVE AIRWAY DISEASES, INHALANTS, ATC: GLUCOCORTICOIDS, PRODUCT: FLUTICASONE FUROATE, PRODUCTSYNONYM: ARNUITY ELLIPTA - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	01 Sep 2020 04:02:38
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	01 Sep 2020 04:02:38
Data point term sent to Coder	System	01 Sep 2020 04:02:20
User entered 'arnuity ellipta'	(b) (4), (b) (6)	01 Sep 2020 04:01:24

US3292365

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 26 Nov 2020 10:54:21

[Prophylaxis](#)

Audit	User	Time (GMT)
User entered 'No (N)'	(b) (4), (b) (6)	01 Sep 2020 04:01:24

US3292365

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 26 Nov 2020 10:54:21

[Indication](#)

Audit	User	Time (GMT)
User entered 'asthma'	(b) (4), (b) (6)	01 Sep 2020 04:01:24

US3292365

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 26 Nov 2020 10:54:21

[Dose per administration](#)

Audit	User	Time (GMT)
User entered '100'	(b) (4), (b) (6)	01 Sep 2020 04:01:24

US3292365

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 26 Nov 2020 10:54:21

[Dose unit](#)

Audit	User	Time (GMT)
User entered 'ug (ug)'	(b) (4), (b) (6)	01 Sep 2020 04:01:24

US3292365

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 26 Nov 2020 10:54:21

If dose unit is Other, specify

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	01 Sep 2020 04:01:24

US3292365

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 26 Nov 2020 10:54:21

[Frequency](#)

Audit	User	Time (GMT)
User entered 'once daily (QD)'	(b) (4), (b) (6)	01 Sep 2020 04:01:24

US3292365

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 26 Nov 2020 10:54:21

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	01 Sep 2020 04:01:24

US3292365

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 26 Nov 2020 10:54:21

[Route of administration](#)

Audit	User	Time (GMT)
User entered 'Respiratory (Inhalation) (RESPIRATORY (INHALATION))'	(b) (4), (b) (6)	01 Sep 2020 04:01:24

US3292365

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 26 Nov 2020 10:54:21

If route of administration is Other, specify

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	01 Sep 2020 04:01:24

US3292365

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 26 Nov 2020 10:54:21

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

Audit	User	Time (GMT)
User entered 'un UNK 2015'	(b) (4), (b) (6)	01 Sep 2020 04:01:24

US3292365

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 26 Nov 2020 10:54:21

[Start date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	(b) (4), (b) (6)	01 Sep 2020 04:01:24

US3292365

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 26 Nov 2020 10:54:21

[Ongoing?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	(b) (4), (b) (6)	01 Sep 2020 04:01:24

US3292365

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 26 Nov 2020 10:54:21

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	01 Sep 2020 04:01:24

US3292365

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 26 Nov 2020 10:54:21

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	(b) (4), (b) (6)	01 Sep 2020 04:01:24

US3292365

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 26 Nov 2020 10:54:21

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	01 Sep 2020 04:01:24

US3292365

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 26 Nov 2020 10:54:21

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	01 Sep 2020 04:01:24

US3292365

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 26 Nov 2020 10:54:21

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	01 Sep 2020 04:01:24

US3292365

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 26 Nov 2020 10:54:21

[Name of Medication](#)

Audit	User	Time (GMT)
User coded data point as ATC: NERVOUS SYSTEM, ATC: ANALGESICS, ATC: ANTIMIGRAINE PREPARATIONS, ATC: SELECTIVE SEROTONIN (5HT1) AGONISTS, PRODUCT: SUMATRIPTAN SUCCINATE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	01 Sep 2020 06:39:45
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 06:39:45
Data point term sent to Coder	System	01 Sep 2020 04:02:22
User entered 'sumatriptan succinate'	(b) (4), (b) (6) (b) (4)	01 Sep 2020 04:02:18

US3292365

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 26 Nov 2020 10:54:21

[Prophylaxis](#)

Audit	User	Time (GMT)
User entered 'No (N)'	(b) (4), (b) (6)	01 Sep 2020 04:02:18

US3292365

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 26 Nov 2020 10:54:21

[Indication](#)

Audit	User	Time (GMT)
User entered 'migraine'	(b) (4), (b) (6)	01 Sep 2020 04:02:18

US3292365

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 26 Nov 2020 10:54:21

[Dose per administration](#)

Audit	User	Time (GMT)
User entered '100'	(b) (4), (b) (6)	01 Sep 2020 04:02:18

US3292365

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 26 Nov 2020 10:54:21

[Dose unit](#)

Audit	User	Time (GMT)
User entered 'mg (mg)'	(b) (4), (b) (6)	01 Sep 2020 04:02:18

US3292365

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 26 Nov 2020 10:54:21

If dose unit is Other, specify

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	01 Sep 2020 04:02:18

US3292365

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 26 Nov 2020 10:54:21

[Frequency](#)

Audit	User	Time (GMT)
User entered 'as needed (PRN)'	(b) (4), (b) (6)	01 Sep 2020 04:02:18

US3292365

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 26 Nov 2020 10:54:21

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	01 Sep 2020 04:02:18

US3292365

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 26 Nov 2020 10:54:21

[Route of administration](#)

Audit	User	Time (GMT)
User entered 'Oral (ORAL)'	(b) (4), (b) (6)	01 Sep 2020 04:02:18

US3292365

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 26 Nov 2020 10:54:21

If route of administration is Other, specify

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	01 Sep 2020 04:02:18

US3292365

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 26 Nov 2020 10:54:21

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

Audit	User	Time (GMT)
User entered 'un UNK 2000'	(b) (4), (b) (6)	01 Sep 2020 04:02:18

US3292365

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 26 Nov 2020 10:54:21

[Start date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	(b) (4), (b) (6)	01 Sep 2020 04:02:18

US3292365

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 26 Nov 2020 10:54:21

[Ongoing?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	(b) (4), (b) (6)	01 Sep 2020 04:02:18

US3292365

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 26 Nov 2020 10:54:21

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	01 Sep 2020 04:02:18

US3292365

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 26 Nov 2020 10:54:21

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	(b) (4), (b) (6)	01 Sep 2020 04:02:18

US3292365

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 26 Nov 2020 10:54:21

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	01 Sep 2020 04:02:18

US3292365

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 26 Nov 2020 10:54:21

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	01 Sep 2020 04:02:18

US3292365

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 26 Nov 2020 10:54:21

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	01 Sep 2020 04:02:18

US3292365

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 26 Nov 2020 10:54:21

[Name of Medication](#)

Audit	User	Time (GMT)
User coded data point as ATC: GENITO URINARY SYSTEM AND SEX HORMONES, ATC: SEX HORMONES AND MODULATORS OF THE GENITAL SYSTEM, ATC: PROGESTOGENS, ATC: PREGNEN (4) DERIVATIVES, PRODUCT: PROGESTERONE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	01 Sep 2020 04:03:40
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	01 Sep 2020 04:03:40
Data point term sent to Coder	System	01 Sep 2020 04:03:23
User entered 'progesterone'	(b) (4), (b) (6)	01 Sep 2020 04:02:54

US3292365

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 26 Nov 2020 10:54:21

[Prophylaxis](#)

Audit	User	Time (GMT)
User entered 'No (N)'	(b) (4), (b) (6)	01 Sep 2020 04:02:54

US3292365

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 26 Nov 2020 10:54:21

[Indication](#)

Audit	User	Time (GMT)
User entered 'hot flashes'	(b) (4), (b) (6)	01 Sep 2020 04:02:54

US3292365

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 26 Nov 2020 10:54:21

[Dose per administration](#)

Audit	User	Time (GMT)
User entered '200'	(b) (4), (b) (6)	01 Sep 2020 04:02:54

US3292365

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 26 Nov 2020 10:54:21

[Dose unit](#)

Audit	User	Time (GMT)
User entered 'mg (mg)'	(b) (4), (b) (6)	01 Sep 2020 04:02:54

US3292365

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 26 Nov 2020 10:54:21

If dose unit is Other, specify

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	01 Sep 2020 04:02:54

US3292365

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 26 Nov 2020 10:54:21

[Frequency](#)

Audit	User	Time (GMT)
User entered 'once daily (QD)'	(b) (4), (b) (6)	01 Sep 2020 04:02:54

US3292365

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 26 Nov 2020 10:54:21

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	01 Sep 2020 04:02:54

US3292365

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 26 Nov 2020 10:54:21

[Route of administration](#)

Audit	User	Time (GMT)
User entered 'Oral (ORAL)'	(b) (4), (b) (6)	01 Sep 2020 04:02:54

US3292365

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 26 Nov 2020 10:54:21

If route of administration is Other, specify

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	01 Sep 2020 04:02:54

US3292365

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 26 Nov 2020 10:54:21

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

Audit	User	Time (GMT)
User entered 'un UNK 2014'	(b) (4), (b) (6)	01 Sep 2020 04:02:54

US3292365

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 26 Nov 2020 10:54:21

[Start date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	(b) (4), (b) (6)	01 Sep 2020 04:02:54

US3292365

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 26 Nov 2020 10:54:21

[Ongoing?](#)

Audit	User	Time (GMT)
User entered 'No (N)' reason for change: New Information	Gerardo Pena (b) (4) (b) (4)	17 Nov 2020 22:47:22
User entered 'Yes (Y)'	(b) (4), (b) (6) (b) (4), (b) (6)	01 Sep 2020 04:02:54

US3292365

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 26 Nov 2020 10:54:21

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
User entered '12 Nov 2020' reason for change: Data Entry Error	Gerardo Pena (b) (4)	17 Nov 2020 22:47:22
User entered empty.	(b) (4), (b) (6)	01 Sep 2020 04:02:54

US3292365

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 26 Nov 2020 10:54:21

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	(b) (4), (b) (6)	01 Sep 2020 04:02:54

US3292365

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 26 Nov 2020 10:54:21

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	01 Sep 2020 04:02:54

US3292365

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 26 Nov 2020 10:54:21

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	01 Sep 2020 04:02:54

US3292365

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 26 Nov 2020 10:54:21

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	01 Sep 2020 04:02:54

US3292365

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 26 Nov 2020 10:54:21

[Name of Medication](#)

Audit	User	Time (GMT)
User coded data point as ATC: GENITO URINARY SYSTEM AND SEX HORMONES, ATC: SEX HORMONES AND MODULATORS OF THE GENITAL SYSTEM, ATC: ESTROGENS, ATC: NATURAL AND SEMISYNTHETIC ESTROGENS, PLAIN, PRODUCT: ESTRADIOL - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	01 Sep 2020 04:05:42
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	01 Sep 2020 04:05:42
Data point term sent to Coder	System	01 Sep 2020 04:04:23
User entered 'estradiol'	(b) (4), (b) (6)	01 Sep 2020 04:04:16

US3292365

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 26 Nov 2020 10:54:21

[Prophylaxis](#)

Audit	User	Time (GMT)
User entered 'No (N)'	(b) (4), (b) (6)	01 Sep 2020 04:04:16

US3292365

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 26 Nov 2020 10:54:21

[Indication](#)

Audit	User	Time (GMT)
User closed query 'Per DM CLR: Please note that this condition is not recorded on the MH eCRF. Please review Con Med use and add a medical condition and all applicable details to the appropriate MH eCRF.' (Site from DM).	(b) (4), (b) (6)	07 Oct 2020 15:06:38
Query 'Per DM CLR: Please note that this condition is not recorded on the MH eCRF. Please review Con Med use and add a medical condition and all applicable details to the appropriate MH eCRF.' answered with 'added to med Hx' (Site from DM).	(b) (4), (b) (6)	23 Sep 2020 14:48:59
User opened query 'Per DM CLR: Please note that this condition is not recorded on the MH eCRF. Please review Con Med use and add a medical condition and all applicable details to the appropriate MH eCRF.' (Site from DM).	(b) (4), (b) (6)	22 Sep 2020 12:04:03
User entered 'menopause'	(b) (4), (b) (6)	01 Sep 2020 04:04:16

US3292365

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 26 Nov 2020 10:54:21

[Dose per administration](#)

Audit	User	Time (GMT)
User entered '0.05'	(b) (4), (b) (6)	01 Sep 2020 04:04:16

US3292365

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 26 Nov 2020 10:54:21

[Dose unit](#)

Audit	User	Time (GMT)
User entered 'mg (mg)'	(b) (4), (b) (6)	01 Sep 2020 04:04:16

US3292365

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 26 Nov 2020 10:54:21

If dose unit is Other, specify

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	01 Sep 2020 04:04:16

US3292365

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 26 Nov 2020 10:54:21

[Frequency](#)

Audit	User	Time (GMT)
User entered 'other (OTHER)'	(b) (4), (b) (6)	01 Sep 2020 04:04:16

US3292365

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 26 Nov 2020 10:54:21

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User entered 'biweekly'	(b) (4), (b) (6)	01 Sep 2020 04:04:16

US3292365

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 26 Nov 2020 10:54:21

[Route of administration](#)

Audit	User	Time (GMT)
User entered 'Transdermal (TRANSDERMAL)'	(b) (4), (b) (6)	01 Sep 2020 04:04:16

US3292365

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 26 Nov 2020 10:54:21

If route of administration is Other, specify

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	01 Sep 2020 04:04:16

US3292365

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 26 Nov 2020 10:54:21

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

Audit	User	Time (GMT)
User entered 'un UNK 2014'	(b) (4), (b) (6)	01 Sep 2020 04:04:16

US3292365

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 26 Nov 2020 10:54:21

[Start date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	(b) (4), (b) (6)	01 Sep 2020 04:04:16

US3292365

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 26 Nov 2020 10:54:21

[Ongoing?](#)

Audit	User	Time (GMT)
User entered 'No (N)' reason for change: New Information	Gerardo Pena (b) (4)	17 Nov 2020 22:46:45
User entered 'Yes (Y)'	(b) (4), (b) (6)	01 Sep 2020 04:04:16

US3292365

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 26 Nov 2020 10:54:21

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
User entered '12 Nov 2020' reason for change: New Information	Gerardo Pena (b) (4)	17 Nov 2020 22:46:45
User entered empty.	(b) (4), (b) (6)	01 Sep 2020 04:04:16

US3292365

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 26 Nov 2020 10:54:21

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	(b) (4), (b) (6)	01 Sep 2020 04:04:16

US3292365

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 26 Nov 2020 10:54:21

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	01 Sep 2020 04:04:16

US3292365

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 26 Nov 2020 10:54:21

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	01 Sep 2020 04:04:16

US3292365

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 26 Nov 2020 10:54:21

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	01 Sep 2020 04:04:16

US3292365

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 26 Nov 2020 10:54:21

Name of Medication

Audit	User	Time (GMT)
User coded data point as ATC: DERMATOLOGICALS, ATC: ANTI-ACNE PREPARATIONS, ATC: ANTI-ACNE PREPARATIONS FOR TOPICAL USE, ATC: RETINOIDS FOR TOPICAL USE IN ACNE, PRODUCT: TRETINOIN - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	24 Sep 2020 10:44:55
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	24 Sep 2020 10:44:55
Data point term sent to Coder	System	23 Sep 2020 14:51:01
Data point term sent to Coder	System	23 Sep 2020 14:49:56
Coding entries removed.	(b) (4), (b) (6)	23 Sep 2020 14:49:35
User entered 'TRETINOIN CREAM 0.05%' reason for change: Data Entry Error	(b) (4), (b) (6)	23 Sep 2020 14:49:35
User coded data point as ATC: DERMATOLOGICALS, ATC: ANTI-ACNE PREPARATIONS, ATC: ANTI-ACNE PREPARATIONS FOR TOPICAL USE, ATC: RETINOIDS FOR TOPICAL USE IN ACNE, PRODUCT: TRETINOIN - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	01 Sep 2020 06:37:48
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	01 Sep 2020 06:37:48
Data point term sent to Coder	System	01 Sep 2020 04:06:24
User entered 'tretinoin cream'	(b) (4), (b) (6)	01 Sep 2020 04:05:47

US3292365

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 26 Nov 2020 10:54:21

[Prophylaxis](#)

Audit	User	Time (GMT)
User entered 'No (N)'	(b) (4), (b) (6)	01 Sep 2020 04:05:47

US3292365

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 26 Nov 2020 10:54:21

[Indication](#)

Audit	User	Time (GMT)
User entered 'acne'	(b) (4), (b) (6)	01 Sep 2020 04:05:47

US3292365

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 26 Nov 2020 10:54:21

[Dose per administration](#)

Audit	User	Time (GMT)
User closed query 'Per DM CLR: Please provide the strength of this topical medication in the medication name, and consider recording the number of applications instead (e.g. Dose = 1; Other Unit, Specify = Application). Review and amend as appropriate. ' (Site from DM).	(b) (4), (b) (6)	07 Oct 2020 15:06:57
Query 'Per DM CLR: Please provide the strength of this topical medication in the medication name, and consider recording the number of applications instead (e.g. Dose = 1; Other Unit, Specify = Application). Review and amend as appropriate. ' answered with 'updated' (Site from DM).	(b) (4), (b) (6)	23 Sep 2020 14:51:17
User entered '1' reason for change: Data Entry Error	(b) (4), (b) (6)	23 Sep 2020 14:50:12
User opened query 'Per DM CLR: Please provide the strength of this topical medication in the medication name, and consider recording the number of applications instead (e.g. Dose = 1; Other Unit, Specify = Application). Review and amend as appropriate. ' (Site from DM).	(b) (4), (b) (6)	23 Sep 2020 04:19:41
User entered '0.05'	(b) (4), (b) (6)	01 Sep 2020 04:05:47

US3292365

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 26 Nov 2020 10:54:21

[Dose unit](#)

Audit	User	Time (GMT)
User closed query 'Per DM CLR: Please review the Route as this medication is not typically administered as indicated. Please review and confirm if (Topical) is the more appropriate route for this medication. Update Con Med eCRF if applicable.' (Site from DM).	(b) (4), (b) (6)	11 Nov 2020 15:05:06
Query 'Per DM CLR: Please review the Route as this medication is not typically administered as indicated. Please review and confirm if (Topical) is the more appropriate route for this medication. Update Con Med eCRF if applicable.' answered with 'updated' (Site from DM).	(b) (4), (b) (6)	23 Sep 2020 14:51:22
User opened query 'Per DM CLR: Please review the Route as this medication is not typically administered as indicated. Please review and confirm if (Topical) is the more appropriate route for this medication. Update Con Med eCRF if applicable.' (Site from DM).	(b) (4), (b) (6)	23 Sep 2020 04:19:51
User entered 'Other (OTHER)'	(b) (4), (b) (6)	01 Sep 2020 04:05:47

US3292365

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 26 Nov 2020 10:54:21

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
User entered 'application' reason for change: Data Entry Error	(b) (4), (b) (6)	23 Sep 2020 14:50:12
User entered '%'	(b) (4), (b) (6)	01 Sep 2020 04:05:47

US3292365

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 26 Nov 2020 10:54:21

[Frequency](#)

Audit	User	Time (GMT)
User entered 'once daily (QD)'	(b) (4), (b) (6)	01 Sep 2020 04:05:47

US3292365

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 26 Nov 2020 10:54:21

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	01 Sep 2020 04:05:47

US3292365

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 26 Nov 2020 10:54:21

[Route of administration](#)

Audit	User	Time (GMT)
User entered 'Topical (TOPICAL)' reason for change: Data Entry Error	(b) (4), (b) (6)	23 Sep 2020 14:50:12
User entered 'Other (OTHER)'	(b) (4), (b) (6)	01 Sep 2020 04:05:47

US3292365

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 26 Nov 2020 10:54:21

If route of administration is Other, specify

Audit	User	Time (GMT)
User entered empty; reason for change Data Entry Error	(b) (4), (b) (6)	23 Sep 2020 14:50:12
User entered 'application'	(b) (4), (b) (6)	01 Sep 2020 04:05:47

US3292365

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 26 Nov 2020 10:54:21

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

Audit	User	Time (GMT)
User entered 'un UNK 1997'	(b) (4), (b) (6)	01 Sep 2020 04:05:47

US3292365

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 26 Nov 2020 10:54:21

[Start date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	(b) (4), (b) (6)	01 Sep 2020 04:05:47

US3292365

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 26 Nov 2020 10:54:21

[Ongoing?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	(b) (4), (b) (6)	01 Sep 2020 04:05:47

US3292365

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 26 Nov 2020 10:54:21

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	01 Sep 2020 04:05:47

US3292365

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 26 Nov 2020 10:54:21

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	(b) (4), (b) (6)	01 Sep 2020 04:05:47

US3292365

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 26 Nov 2020 10:54:21

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	01 Sep 2020 04:05:47

US3292365

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 26 Nov 2020 10:54:21

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	01 Sep 2020 04:05:47

US3292365

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 26 Nov 2020 10:54:21

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	01 Sep 2020 04:05:47

US3292365

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures Summary

Generated On: 26 Nov 2020 10:54:21

[Were any concomitant procedures performed?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Antonio Gutierrez (b) (4)	09 Nov 2020 21:57:59

US3292365

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (1)

Generated On: 26 Nov 2020 10:54:21

Procedure/Surgery date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User entered '8 Oct 2020'	Antonio Gutierrez (b) (4)	09 Nov 2020 21:58:34

US3292365

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (1)

Generated On: 26 Nov 2020 10:54:21

[Procedure/Surgery](#)

Audit	User	Time (GMT)
User entered 'Mammogram'	Antonio Gutierrez (b) (4)	09 Nov 2020 21:58:34

US3292365

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (1)

Generated On: 26 Nov 2020 10:54:21

[Indication](#)

Audit	User	Time (GMT)
User entered 'Other (OTHER)'	Antonio Gutierrez (b) (4)	09 Nov 2020 21:58:34

US3292365

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (1)

Generated On: 26 Nov 2020 10:54:21

[If indication is Other, specify](#)

Audit	User	Time (GMT)
User entered 'Preventative'	Antonio Gutierrez (b) (4)	09 Nov 2020 21:58:34

US3292365

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (2)

Generated On: 26 Nov 2020 10:54:21

Procedure/Surgery date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User entered '29 Oct 2020'	Antonio Gutierrez (b) (4)	09 Nov 2020 21:59:11

US3292365

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (2)

Generated On: 26 Nov 2020 10:54:21

[Procedure/Surgery](#)

Audit	User	Time (GMT)
User entered 'Mammogram'	Antonio Gutierrez (b) (4)	09 Nov 2020 21:59:11

US3292365

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (2)

Generated On: 26 Nov 2020 10:54:21

[Indication](#)

Audit	User	Time (GMT)
User entered 'Diagnostic (DIAGNOSTIC)' reason for change: Per Query Resolution	Antonio Gutierrez (b) (4)	24 Nov 2020 22:40:15
User entered 'Adverse Event (AE)'	Antonio Gutierrez (b) (4)	09 Nov 2020 21:59:11

US3292365

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (2)

Generated On: 26 Nov 2020 10:54:21

[If indication is Other, specify](#)

Audit	User	Time (GMT)
User entered empty.	Antonio Gutierrez (b) (4)	09 Nov 2020 21:59:11

US3292365

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (3)

Generated On: 26 Nov 2020 10:54:21

Procedure/Surgery date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User entered '3 Nov 2020'	Antonio Gutierrez (b) (4)	09 Nov 2020 21:59:37

US3292365

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (3)

Generated On: 26 Nov 2020 10:54:21

[Procedure/Surgery](#)

Audit	User	Time (GMT)
User entered 'Left Breast Biopsy'	Antonio Gutierrez (b) (4)	09 Nov 2020 21:59:37

US3292365

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (3)

Generated On: 26 Nov 2020 10:54:21

[Indication](#)

Audit	User	Time (GMT)
User entered 'Diagnostic (DIAGNOSTIC)' reason for change: Per Query Resolution	Antonio Gutierrez (b) (4)	24 Nov 2020 22:40:29
User entered 'Adverse Event (AE)'	Antonio Gutierrez (b) (4)	09 Nov 2020 21:59:37

US3292365

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (3)

Generated On: 26 Nov 2020 10:54:21

[If indication is Other, specify](#)

Audit	User	Time (GMT)
User entered empty.	Antonio Gutierrez (b) (4)	09 Nov 2020 21:59:37

US3292365

Folder: SAE USA-US072-2020-MRNA-1273-P301000010

Form: Safety Report Form

Generated On: 26 Nov 2020 10:54:21

[SAEID](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Nov 2020 19:47:26
Reviewed for Safety.	(b) (4), (b) (6)	10 Nov 2020 23:40:15
User entered 'USA-US072-2020-MRNA-1273-P301000010'	System	10 Nov 2020 23:39:46

US3292365

Folder: SAE USA-US072-2020-MRNA-1273-P301000010

Form: Safety Report Form

Generated On: 26 Nov 2020 10:54:21

Serious

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Nov 2020 19:47:26
Reviewed for Safety.	(b) (4), (b) (6)	10 Nov 2020 23:40:15
User entered 'Yes (Y)'	System	10 Nov 2020 23:39:46

US3292365

Folder: SAE USA-US072-2020-MRNA-1273-P301000010

Form: Safety Report Form

Generated On: 26 Nov 2020 10:54:21

[Death](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Nov 2020 19:47:26
Reviewed for Safety.	(b) (4), (b) (6)	10 Nov 2020 23:40:15
User entered 'No (N)'	System	10 Nov 2020 23:39:46

US3292365

Folder: SAE USA-US072-2020-MRNA-1273-P301000010

Form: Safety Report Form

Generated On: 26 Nov 2020 10:54:21

[Life threatening](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Nov 2020 19:47:26
Reviewed for Safety.	(b) (4), (b) (6)	10 Nov 2020 23:40:15
User entered 'No (N)'	System	10 Nov 2020 23:39:46

US3292365

Folder: SAE USA-US072-2020-MRNA-1273-P301000010

Form: Safety Report Form

Generated On: 26 Nov 2020 10:54:21

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Nov 2020 19:47:26
Reviewed for Safety.	(b) (4), (b) (6)	10 Nov 2020 23:40:15
User entered 'No (N)'	System	10 Nov 2020 23:39:46

US3292365

Folder: SAE USA-US072-2020-MRNA-1273-P301000010

Form: Safety Report Form

Generated On: 26 Nov 2020 10:54:21

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Nov 2020 19:47:26
Reviewed for Safety.	(b) (4), (b) (6)	10 Nov 2020 23:40:15
User entered 'No (N)'	System	10 Nov 2020 23:39:46

US3292365

Folder: SAE USA-US072-2020-MRNA-1273-P301000010

Form: Safety Report Form

Generated On: 26 Nov 2020 10:54:21

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Nov 2020 19:47:26
Reviewed for Safety.	(b) (4), (b) (6)	10 Nov 2020 23:40:15
User entered 'No (N)'	System	10 Nov 2020 23:39:46

US3292365

Folder: SAE USA-US072-2020-MRNA-1273-P301000010

Form: Safety Report Form

Generated On: 26 Nov 2020 10:54:21

[Other medically important event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Nov 2020 19:47:26
Reviewed for Safety.	(b) (4), (b) (6)	10 Nov 2020 23:40:15
User entered 'Yes (Y)'	System	10 Nov 2020 23:39:46

US3292365

Folder: SAE USA-US072-2020-MRNA-1273-P301000010

Form: Safety Report Form

Generated On: 26 Nov 2020 10:54:21

[Investigator's First Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Nov 2020 19:47:26
Reviewed for Safety.	(b) (4), (b) (6)	10 Nov 2020 23:40:15
User entered 'Douglas'	System	10 Nov 2020 23:39:46

US3292365

Folder: SAE USA-US072-2020-MRNA-1273-P301000010

Form: Safety Report Form

Generated On: 26 Nov 2020 10:54:21

[Investigator's Last Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Nov 2020 19:47:26
Reviewed for Safety.	(b) (4), (b) (6)	10 Nov 2020 23:40:15
User entered 'Denham'	System	10 Nov 2020 23:39:46

US3292365

Folder: SAE USA-US072-2020-MRNA-1273-P301000010

Form: Safety Report Form

Generated On: 26 Nov 2020 10:54:21

[Site Address: Street](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Nov 2020 19:47:26
Reviewed for Safety.	(b) (4), (b) (6)	10 Nov 2020 23:40:15
User entered '7940 Floyd Curl Drive'	System	10 Nov 2020 23:39:46

US3292365

Folder: SAE USA-US072-2020-MRNA-1273-P301000010

Form: Safety Report Form

Generated On: 26 Nov 2020 10:54:21

[Site Address: City](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Nov 2020 19:47:26
Reviewed for Safety.	(b) (4), (b) (6)	10 Nov 2020 23:40:15
User entered 'San Antonio'	System	10 Nov 2020 23:39:46

US3292365

Folder: SAE USA-US072-2020-MRNA-1273-P301000010

Form: Safety Report Form

Generated On: 26 Nov 2020 10:54:21

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Nov 2020 19:47:26
Reviewed for Safety.	(b) (4), (b) (6)	10 Nov 2020 23:40:15
User entered '78229'	System	10 Nov 2020 23:39:46

US3292365

Folder: SAE USA-US072-2020-MRNA-1273-P301000010

Form: Safety Report Form

Generated On: 26 Nov 2020 10:54:21

[Investigator Country](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	24 Nov 2020 17:32:25
DataPoint Verified.	(b) (4), (b) (6)	23 Nov 2020 19:47:26
User entered 'US'	System	10 Nov 2020 23:41:55

US3292365

Folder: SAE USA-US072-2020-MRNA-1273-P301000010

Form: Safety Report Form

Generated On: 26 Nov 2020 10:54:21

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '2'	System	24 Nov 2020 17:32:43
User entered '1'	System	10 Nov 2020 23:41:55

US3292365

Folder: SAE USA-US072-2020-MRNA-1273-P301000010

Form: Safety Report Form

Generated On: 26 Nov 2020 10:54:21

[SAEID](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Nov 2020 19:47:26
Reviewed for Safety.	(b) (4), (b) (6)	10 Nov 2020 23:40:15
User entered 'USA-US072-2020-MRNA-1273-P301000010'	System	10 Nov 2020 23:39:46

US3292365

Folder: SAE USA-US072-2020-MRNA-1273-P301000010

Form: Safety Report Form

Generated On: 26 Nov 2020 10:54:21

Serious

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Nov 2020 19:47:26
Reviewed for Safety.	(b) (4), (b) (6)	10 Nov 2020 23:40:15
User entered 'Yes (Y)'	System	10 Nov 2020 23:39:46

US3292365

Folder: SAE USA-US072-2020-MRNA-1273-P301000010

Form: Safety Report Form

Generated On: 26 Nov 2020 10:54:21

[Death](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Nov 2020 19:47:26
Reviewed for Safety.	(b) (4), (b) (6)	10 Nov 2020 23:40:15
User entered 'No (N)'	System	10 Nov 2020 23:39:46

US3292365

Folder: SAE USA-US072-2020-MRNA-1273-P301000010

Form: Safety Report Form

Generated On: 26 Nov 2020 10:54:21

[Life threatening](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Nov 2020 19:47:26
Reviewed for Safety.	(b) (4), (b) (6)	10 Nov 2020 23:40:15
User entered 'No (N)'	System	10 Nov 2020 23:39:46

US3292365

Folder: SAE USA-US072-2020-MRNA-1273-P301000010

Form: Safety Report Form

Generated On: 26 Nov 2020 10:54:21

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Nov 2020 19:47:26
Reviewed for Safety.	(b) (4), (b) (6)	10 Nov 2020 23:40:15
User entered 'No (N)'	System	10 Nov 2020 23:39:46

US3292365

Folder: SAE USA-US072-2020-MRNA-1273-P301000010

Form: Safety Report Form

Generated On: 26 Nov 2020 10:54:21

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Nov 2020 19:47:26
Reviewed for Safety.	(b) (4), (b) (6)	10 Nov 2020 23:40:15
User entered 'No (N)'	System	10 Nov 2020 23:39:46

US3292365

Folder: SAE USA-US072-2020-MRNA-1273-P301000010

Form: Safety Report Form

Generated On: 26 Nov 2020 10:54:21

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Nov 2020 19:47:26
Reviewed for Safety.	(b) (4), (b) (6)	10 Nov 2020 23:40:15
User entered 'No (N)'	System	10 Nov 2020 23:39:46

US3292365

Folder: SAE USA-US072-2020-MRNA-1273-P301000010

Form: Safety Report Form

Generated On: 26 Nov 2020 10:54:21

[Other medically important event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Nov 2020 19:47:26
Reviewed for Safety.	(b) (4), (b) (6)	10 Nov 2020 23:40:15
User entered 'Yes (Y)'	System	10 Nov 2020 23:39:46

US3292365

Folder: SAE USA-US072-2020-MRNA-1273-P301000010

Form: Safety Report Form

Generated On: 26 Nov 2020 10:54:21

[Investigator's First Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Nov 2020 19:47:26
Reviewed for Safety.	(b) (4), (b) (6)	10 Nov 2020 23:40:15
User entered 'Douglas'	System	10 Nov 2020 23:39:46

US3292365

Folder: SAE USA-US072-2020-MRNA-1273-P301000010

Form: Safety Report Form

Generated On: 26 Nov 2020 10:54:21

[Investigator's Last Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Nov 2020 19:47:26
Reviewed for Safety.	(b) (4), (b) (6)	10 Nov 2020 23:40:15
User entered 'Denham'	System	10 Nov 2020 23:39:46

US3292365

Folder: SAE USA-US072-2020-MRNA-1273-P301000010

Form: Safety Report Form

Generated On: 26 Nov 2020 10:54:21

[Site Address: Street](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Nov 2020 19:47:26
Reviewed for Safety.	(b) (4), (b) (6)	10 Nov 2020 23:40:15
User entered '7940 Floyd Curl Drive'	System	10 Nov 2020 23:39:46

US3292365

Folder: SAE USA-US072-2020-MRNA-1273-P301000010

Form: Safety Report Form

Generated On: 26 Nov 2020 10:54:21

[Site Address: City](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Nov 2020 19:47:26
Reviewed for Safety.	(b) (4), (b) (6)	10 Nov 2020 23:40:15
User entered 'San Antonio'	System	10 Nov 2020 23:39:46

US3292365

Folder: SAE USA-US072-2020-MRNA-1273-P301000010

Form: Safety Report Form

Generated On: 26 Nov 2020 10:54:21

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Nov 2020 19:47:26
Reviewed for Safety.	(b) (4), (b) (6)	10 Nov 2020 23:40:15
User entered '78229'	System	10 Nov 2020 23:39:46

US3292365

Folder: SAE USA-US072-2020-MRNA-1273-P301000010

Form: Safety Report Form

Generated On: 26 Nov 2020 10:54:21

[Investigator Country](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	24 Nov 2020 17:32:25
DataPoint Verified.	(b) (4), (b) (6)	23 Nov 2020 19:47:26
User entered 'US'	System	10 Nov 2020 23:41:55

US3292365

Folder: SAE USA-US072-2020-MRNA-1273-P301000010

Form: Safety Report Form

Generated On: 26 Nov 2020 10:54:21

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '2'	System	24 Nov 2020 17:32:43
User entered '1'	System	10 Nov 2020 23:41:55

US3292365

Folder: SAE USA-US072-2020-MRNA-1273-P301000010

Form: Safety Report Form (1)

Generated On: 26 Nov 2020 10:54:21

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Nov 2020 19:47:26
User entered '10/Nov/2020 18:41'	System	10 Nov 2020 23:41:55

US3292365

Folder: SAE USA-US072-2020-MRNA-1273-P301000010

Form: Safety Report Form (1)

Generated On: 26 Nov 2020 10:54:21

Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	24 Nov 2020 17:32:25
DataPoint Verified.	(b) (4), (b) (6)	23 Nov 2020 19:47:26
User entered 'I'	(b) (4), (b) (6)	10 Nov 2020 23:41:55

US3292365

Folder: SAE USA-US072-2020-MRNA-1273-P301000010

Form: Safety Report Form

Generated On: 26 Nov 2020 10:54:21

[SAEID](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Nov 2020 19:47:26
Reviewed for Safety.	(b) (4), (b) (6)	10 Nov 2020 23:40:15
User entered 'USA-US072-2020-MRNA-1273-P301000010'	System	10 Nov 2020 23:39:46

US3292365

Folder: SAE USA-US072-2020-MRNA-1273-P301000010

Form: Safety Report Form

Generated On: 26 Nov 2020 10:54:21

Serious

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Nov 2020 19:47:26
Reviewed for Safety.	(b) (4), (b) (6)	10 Nov 2020 23:40:15
User entered 'Yes (Y)'	System	10 Nov 2020 23:39:46

US3292365

Folder: SAE USA-US072-2020-MRNA-1273-P301000010

Form: Safety Report Form

Generated On: 26 Nov 2020 10:54:21

[Death](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Nov 2020 19:47:26
Reviewed for Safety.	(b) (4), (b) (6)	10 Nov 2020 23:40:15
User entered 'No (N)'	System	10 Nov 2020 23:39:46

US3292365

Folder: SAE USA-US072-2020-MRNA-1273-P301000010

Form: Safety Report Form

Generated On: 26 Nov 2020 10:54:21

[Life threatening](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Nov 2020 19:47:26
Reviewed for Safety.	(b) (4), (b) (6)	10 Nov 2020 23:40:15
User entered 'No (N)'	System	10 Nov 2020 23:39:46

US3292365

Folder: SAE USA-US072-2020-MRNA-1273-P301000010

Form: Safety Report Form

Generated On: 26 Nov 2020 10:54:21

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Nov 2020 19:47:26
Reviewed for Safety.	(b) (4), (b) (6)	10 Nov 2020 23:40:15
User entered 'No (N)'	System	10 Nov 2020 23:39:46

US3292365

Folder: SAE USA-US072-2020-MRNA-1273-P301000010

Form: Safety Report Form

Generated On: 26 Nov 2020 10:54:21

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Nov 2020 19:47:26
Reviewed for Safety.	(b) (4), (b) (6)	10 Nov 2020 23:40:15
User entered 'No (N)'	System	10 Nov 2020 23:39:46

US3292365

Folder: SAE USA-US072-2020-MRNA-1273-P301000010

Form: Safety Report Form

Generated On: 26 Nov 2020 10:54:21

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Nov 2020 19:47:26
Reviewed for Safety.	(b) (4), (b) (6)	10 Nov 2020 23:40:15
User entered 'No (N)'	System	10 Nov 2020 23:39:46

US3292365

Folder: SAE USA-US072-2020-MRNA-1273-P301000010

Form: Safety Report Form

Generated On: 26 Nov 2020 10:54:21

[Other medically important event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Nov 2020 19:47:26
Reviewed for Safety.	(b) (4), (b) (6)	10 Nov 2020 23:40:15
User entered 'Yes (Y)'	System	10 Nov 2020 23:39:46

US3292365

Folder: SAE USA-US072-2020-MRNA-1273-P301000010

Form: Safety Report Form

Generated On: 26 Nov 2020 10:54:21

[Investigator's First Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Nov 2020 19:47:26
Reviewed for Safety.	(b) (4), (b) (6)	10 Nov 2020 23:40:15
User entered 'Douglas'	System	10 Nov 2020 23:39:46

US3292365

Folder: SAE USA-US072-2020-MRNA-1273-P301000010

Form: Safety Report Form

Generated On: 26 Nov 2020 10:54:21

[Investigator's Last Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Nov 2020 19:47:26
Reviewed for Safety.	(b) (4), (b) (6)	10 Nov 2020 23:40:15
User entered 'Denham'	System	10 Nov 2020 23:39:46

US3292365

Folder: SAE USA-US072-2020-MRNA-1273-P301000010

Form: Safety Report Form

Generated On: 26 Nov 2020 10:54:21

[Site Address: Street](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Nov 2020 19:47:26
Reviewed for Safety.	(b) (4), (b) (6)	10 Nov 2020 23:40:15
User entered '7940 Floyd Curl Drive'	System	10 Nov 2020 23:39:46

US3292365

Folder: SAE USA-US072-2020-MRNA-1273-P301000010

Form: Safety Report Form

Generated On: 26 Nov 2020 10:54:21

[Site Address: City](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Nov 2020 19:47:26
Reviewed for Safety.	(b) (4), (b) (6)	10 Nov 2020 23:40:15
User entered 'San Antonio'	System	10 Nov 2020 23:39:46

US3292365

Folder: SAE USA-US072-2020-MRNA-1273-P301000010

Form: Safety Report Form

Generated On: 26 Nov 2020 10:54:21

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Nov 2020 19:47:26
Reviewed for Safety.	(b) (4), (b) (6)	10 Nov 2020 23:40:15
User entered '78229'	System	10 Nov 2020 23:39:46

US3292365

Folder: SAE USA-US072-2020-MRNA-1273-P301000010

Form: Safety Report Form

Generated On: 26 Nov 2020 10:54:21

[Investigator Country](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	24 Nov 2020 17:32:25
DataPoint Verified.	(b) (4), (b) (6)	23 Nov 2020 19:47:26
User entered 'US'	System	10 Nov 2020 23:41:55

US3292365

Folder: SAE USA-US072-2020-MRNA-1273-P301000010

Form: Safety Report Form

Generated On: 26 Nov 2020 10:54:21

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '2'	System	24 Nov 2020 17:32:43
User entered '1'	System	10 Nov 2020 23:41:55

US3292365

Folder: SAE USA-US072-2020-MRNA-1273-P301000010

Form: Safety Report Form (2)

Generated On: 26 Nov 2020 10:54:21

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
User entered '24/Nov/2020 12:32'	System	24 Nov 2020 17:32:43

US3292365

Folder: SAE USA-US072-2020-MRNA-1273-P301000010

Form: Safety Report Form (2)

Generated On: 26 Nov 2020 10:54:21

Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.

Audit	User	Time (GMT)
Un-reviewed for Safety.	(b) (4), (b) (6)	24 Nov 2020 17:32:43
DataPoint Un-verified.	(b) (4), (b) (6)	24 Nov 2020 17:32:43
User entered '1' reason for change: Data Entry Error	(b) (4), (b) (6)	24 Nov 2020 17:32:43
Reviewed for Safety.	(b) (4), (b) (6)	24 Nov 2020 17:32:25
DataPoint Verified.	(b) (4), (b) (6)	23 Nov 2020 19:47:26
User entered '0'	(b) (4), (b) (6)	10 Nov 2020 23:41:55