

v6.020 DTW - MASTER

Generated By: (b) (6)

Generated On: 26 Nov 2020 14:07:14

All time stamps listed in this document are displayed in GMT

v6.020 DTW: MASTER

Folder: Screening

Form: Visit Date

Generated On: 26 Nov 2020 14:07:14

Was this visit performed?	Yes <input type="checkbox"/>	1
	No <input type="checkbox"/>	
Visit date (dd MMM yyyy)		2
Was visit performed at the participant's home or at the clinic?	Home <input type="checkbox"/>	3
	Clinic <input type="checkbox"/>	
Folder OID		4

v6.020 DTW: MASTER**Folder: Screening****Form: Visit Date****Generated On: 26 Nov 2020 14:07:14**

	Field Name	Data Type	Field Label	Values	Include Field OID
①	VISITYN	\$1	Was this visit performed?	Y = Yes N = No	VISITYN
②	VISITDAT	dd MMM yyyy	Visit date (dd MMM yyyy)		VISITDAT
③	VISTYPE	\$6	Was visit performed at the participant's home or at the clinic?	Home = Home Clinic = Clinic	VISTYPE
④	FOLDER_OID	\$15	Folder OID		FOLDER_OID

v6.020 DTW: MASTER

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 14:07:14

Date of Birth (MMM yyyy)		1
Age		2
Age Units		3
Age (Derived)		4
Sex	Female <input type="checkbox"/> Male <input type="checkbox"/>	5
Ethnicity	Hispanic or Latino <input type="checkbox"/> Not Hispanic or Latino <input type="checkbox"/> Not Reported <input type="checkbox"/> Unknown <input type="checkbox"/>	6
Race (Check All That Apply)		
White		8
Black		9
Asian		10
American Indian or Alaska Native		11
Native Hawaiian or other Pacific Islander		12
Other		13
If race is Other, specify		14
Unknown		15
Not reported		16

v6.020 DTW: MASTER

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 14:07:14

	Field Name	Data Type	Field Label	Values	Include Field OID
1	BRTHDAT	MMM- yyyy	Date of Birth (MMM yyyy)		BRTHDAT
2	AGE	3	Age		AGE
3	AGEU	\$5	Age Units		AGEU
4	AGE_DER	3	Age (Derived)		AGE_DER
5	SEX	\$1	Sex	F = Female M = Male	SEX
6	ETHNIC	\$25	Ethnicity	HISPANIC OR LATINO = Hispanic or Latino NOT HISPANIC OR LATINO = Not Hispanic or Latino NOT REPORTED = Not Reported UNKNOWN = Unknown	ETHNIC
8	RACE1	1	White		RACE1
9	RACE2	1	Black		RACE2
10	RACE3	1	Asian		RACE3
11	RACE4	1	American Indian or Alaska Native		RACE4
12	RACE5	1	Native Hawaiian or other Pacific Islander		RACE5
13	RACE6	1	Other		RACE6
14	RACEOTH	\$200	If race is Other, specify		RACEOTH
15	RACE7	1	Unknown		RACE7
16	RACE8	1	Not reported		RACE8

v6.020 DTW: MASTER

Folder: Screening

Form: Enrollment

Generated On: 26 Nov 2020 14:07:14

Date of Informed Consent (<i>dd MMM yyyy</i>)		1
Month and Year of Informed Consent (derived)		2
Year of Informed Consent (derived)		3
Protocol Version	Amendment 1 <input type="checkbox"/>	4
	Amendment 2 <input type="checkbox"/>	
	Amendment 3 <input type="checkbox"/>	
	Amendment 4 <input type="checkbox"/>	
	Amendment 5 <input type="checkbox"/>	
Was participant enrolled in the study?	Yes <input type="checkbox"/>	5
	No <input type="checkbox"/>	
If No, indicate reason for screen fail	Withdrew Consent <input type="checkbox"/>	6
	Inclusion/Exclusion <input type="checkbox"/>	
	Cohort Full <input type="checkbox"/>	
	Other <input type="checkbox"/>	
If reason for screen fail is Other, specify		7
Was this participant screened previously?	Yes <input type="checkbox"/>	8
	No <input type="checkbox"/>	
If Yes, previous participant number		9
Enrollment Trigger		10

v6.020 DTW: MASTER

Folder: Screening

Form: Enrollment

Generated On: 26 Nov 2020 14:07:14

	Field Name	Data Type	Field Label	Values	Include Field OID
1	ICDAT	dd MMM yyyy	Date of Informed Consent (<i>dd MMM yyyy</i>)		ICDAT
2	ICMONYR	MMM yyyy	Month and Year of Informed Consent (derived)		ICMONYR
3	ICYR	yyyy	Year of Informed Consent (derived)		ICYR
4	PROTOCOL	1	Protocol Version	1 = Amendment 1 2 = Amendment 2 3 = Amendment 3 4 = Amendment 4 5 = Amendment 5	PROTOCOL
5	ENROLLYN	\$1	Was participant enrolled in the study?	Y = Yes N = No	ENROLLYN
6	SFREAS	\$20	If No, indicate reason for screen fail	WITHDREW CONSENT = Withdrew Consent INCLUSION/ EXCLUSION = Inclusion/Excl usion COHORT FULL = Cohort Full	SFREAS

v6.020 DTW: MASTER**Folder: Screening****Form: Enrollment****Generated On: 26 Nov 2020 14:07:14**

Field Name	Data Type	Field Label	Values	Include Field OID
			OTHER = Other	
7 SFREASSP	\$200	If reason for screen fail is Other, specify		SFREASSP
8 PREVYN	\$1	Was this participant screened previously?	Y = Yes N = No	PREVYN
9 PREVNUM	\$9	If Yes, previous participant number		PREVNUM
10 ENRFLAG	1	Enrollment Trigger		ENRFLAG

v6.020 DTW: MASTER

Folder: Screening

Form: Inclusion/Exclusion Criteria Summary

Generated On: 26 Nov 2020 14:07:14

Did the participant meet all eligibility criteria?

Yes ☒ 1
No ☐

v6.020 DTW: MASTER

Folder: Screening

Form: Inclusion/Exclusion Criteria Summary

Generated On: 26 Nov 2020 14:07:14

Field Name	Data Type	Field Label	Values	Include Field OID
1 IEYN	\$1	Did the participant meet all eligibility criteria?	Y = Yes N = No	IEYN

v6.020 DTW: MASTER

Folder: Screening

Form: Inclusion/Exclusion Criteria

Generated On: 26 Nov 2020 14:07:14

Select inclusion criteria not met and/or exclusion criteria met

Criterion Type	Inclusion	Exclusion
Criterion Identifier	1	2
	2	3
	3	
	4	
	5	
	6	
	7	
	8	
	9	
	10	
	11	
	12	
	13	
	14	
	15	
	16	
	17	
	18	
	19	
	20	
	21	
	22	
	23	
	24	
	25	
	26	
	27	
	28	
	29	
	30	

v6.020 DTW: MASTER

Folder: Screening

Form: Inclusion/Exclusion Criteria

Generated On: 26 Nov 2020 14:07:14

Field Name	Data Type	Field Label	Values	Include Field OID
2 IECAT	\$9	Criterion Type	INCLUSION = Inclusion EXCLUSION = Exclusion	IECAT
3 IETESTCD	2	Criterion Identifier	1 = 1 2 = 2 3 = 3 4 = 4 5 = 5 6 = 6 7 = 7 8 = 8 9 = 9 10 = 10 11 = 11 12 = 12 13 = 13 14 = 14 15 = 15 16 = 16 17 = 17 18 = 18 19 = 19 20 = 20 21 = 21 22 = 22 23 = 23 24 = 24 25 = 25 26 = 26 27 = 27 28 = 28 29 = 29 30 = 30	IETESTCD

v6.020 DTW: MASTER

Folder: Screening

Form: Medical History Summary

Generated On: 26 Nov 2020 14:07:14

Were any significant conditions reported?

Yes ☒

No ☐

v6.020 DTW: MASTER

Folder: Screening

Form: Medical History Summary

Generated On: 26 Nov 2020 14:07:14

Field Name	Data Type	Field Label	Values	Include Field OID
① MHYN	\$1	Were any significant conditions reported?	Y = Yes N = No	MHYN

v6.020 DTW: MASTER

Folder: Screening

Form: Medical History

Generated On: 26 Nov 2020 14:07:14

Condition		1
Start date (dd MMM yyyy)		2
Start date completely unknown		3
Condition ongoing at study entry	Yes <input type="checkbox"/> No <input type="checkbox"/>	4
If No, please specify the stop date (dd MMM yyyy)		5
Stop date completely unknown		6
Start Month and Year (derived)		7
Start Year (derived)		8
Stop Month and Year (derived)		9
Stop Year (derived)		10

v6.020 DTW: MASTER**Folder: Screening****Form: Medical History****Generated On: 26 Nov 2020 14:07:14**

	Field Name	Data Type	Field Label	Values	Include Field OID
1	MHTERM	\$200	Condition		MHTERM
2	MHSTDAT	dd- MMM- yyyy	Start date (dd MMM yyyy)		MHSTDAT
3	MHSTUNK	1	Start date completely unknown		MHSTUNK
4	MHONGO	\$1	Condition ongoing at study entry	Y = Yes N = No	MHONGO
5	MHENDAT	dd- MMM- yyyy	If No, please specify the stop date (dd MMM yyyy)		MHENDAT
6	MHENUNK	1	Stop date completely unknown		MHENUNK
7	MHSTMONEY R	MMM- yyyy	Start Month and Year (derived)		MHSTMONEY R
8	MHSTYR	yyyy	Start Year (derived)		MHSTYR
9	MHENMONEY R	MMM- yyyy	Stop Month and Year (derived)		MHENMONEY R
10	MHENYR	yyyy	Stop Year (derived)		MHENYR

v6.020 DTW: MASTER

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 14:07:14

Were vital signs assessed?	Yes <input type="checkbox"/>	1
	No <input type="checkbox"/>	
Date of assessment (<i>dd MMM yyyy</i>)		2
Time of assessment (<i>00:00-23:59</i>)	Fixed Unit: (24 HR)	3
Vital Signs Date and Time (derived)		4
Height (<i>xxx.x</i>)	cm <input type="checkbox"/>	5
	in <input type="checkbox"/>	
Weight (<i>xxx.x</i>)	kg <input type="checkbox"/>	6
	lb <input type="checkbox"/>	
BMI (<i>xxx.x</i>)	Fixed Unit: kg/m ²	7
BMI units		8
Temperature (<i>xxx.x</i>)	C <input type="checkbox"/>	9
	F <input type="checkbox"/>	
Route of measurement	Oral <input type="checkbox"/>	10
	Axillary <input type="checkbox"/>	
	Other <input type="checkbox"/>	
If Other, specify		11
Pulse (<i>xxx</i>)	Fixed Unit: beats/min	12
Pulse units		13
Respiratory Rate (<i>xxx</i>)	Fixed Unit: breaths/min	14
Respiratory Rate units		15
Systolic Blood Pressure (<i>xxx</i>)	Fixed Unit: mmHg	16
Systolic Blood Pressure units		17
Diastolic Blood Pressure (<i>xxx</i>)	Fixed Unit: mmHg	18
Diastolic Blood Pressure units		19
Height (derived)	Fixed Unit: cm	20

v6.020 DTW: MASTER

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 14:07:14

Weight (derived)

Fixed Unit: kg

21

v6.020 DTW: MASTER

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 14:07:14

	Field Name	Data Type	Field Label	Values	Include Field OID
1	VSPERF	\$1	Were vital signs assessed?	Y = Yes N = No	VSPERF
2	VSDAT	dd MMM yyyy	Date of assessment (<i>dd MMM yyyy</i>)		VSDAT
3	VSTIM	HH:nn	Time of assessment (<i>00:00-23:59</i>)		VSTIM
4	VSDTTIM	dd MMM yyyy HH:nn	Vital Signs Date and Time (derived)		VSDTTIM
5	HEIGHT_VS ORRES	20.5	Height (<i>xxx.x</i>)		HEIGHT_VS ORRES
6	WEIGHT_VS ORRES	20.5	Weight (<i>xxx.x</i>)		WEIGHT_VS ORRES
7	VSBMI	20.5	BMI (<i>xxx.x</i>)		VSBMI
8	VSBIU	\$10	BMI units		VSBIU
9	TEMP_VSOR RES	20.5	Temperature (<i>xxx.x</i>)		TEMP_VSOR RES
10	VSROUTE	\$8	Route of measurement	Oral = Oral Axillary = Axillary Other = Other	VSROUTE
11	VSROUTESP	\$200	If Other, specify		VSROUTESP
12	HR_VSORRE S	3	Pulse (<i>xxx</i>)		HR_VSORRE S
13	HR_VSORRE SU	\$9	Pulse units		HR_VSORRE SU
14	RR_VSORRE S	3	Respiratory Rate (<i>xxx</i>)		RR_VSORRE S
15	RR_VSORRE SU	\$11	Respiratory Rate units		RR_VSORRE SU
16	SYSBP_VSO RRES	3	Systolic Blood Pressure (<i>xxx</i>)		SYSBP_VSO RRES

v6.020 DTW: MASTER**Folder: Screening****Form: Vital Signs****Generated On: 26 Nov 2020 14:07:14**

	Field Name	Data Type	Field Label	Values	Include Field OID
17	SYSBP_VSO RRESU	\$4	Systolic Blood Pressure units		SYSBP_VSO RRESU
18	DIABP_VSO RRES	3	Diastolic Blood Pressure (<i>xxx</i>)		DIABP_VSO RRES
19	DIABP_VSO RRESU	\$4	Diastolic Blood Pressure units		DIABP_VSO RRESU
20	HEIGHT_D	3	Height (derived)		HEIGHT_D
21	WEIGHT_D	4.1	Weight (derived)		WEIGHT_D

v6.020 DTW: MASTER

Folder: Screening

Form: Physical Examination

Generated On: 26 Nov 2020 14:07:14

Was the physical examination performed?

Yes ☐ **1**

No ☐

Date of examination (dd MMM yyyy)

2

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

v6.020 DTW: MASTER

Folder: Screening

Form: Physical Examination

Generated On: 26 Nov 2020 14:07:14

	Field Name	Data Type	Field Label	Values	Include Field OID
1	PEYN	\$1	Was the physical examination performed?	Y = Yes N = No	PEYN
2	PEDAT	dd MMM yyyy	Date of examination (<i>dd MMM yyyy</i>)		PEDAT

v6.020 DTW: MASTER

Folder: Screening

Form: Childbearing Potential

Generated On: 26 Nov 2020 14:07:14

Date of assessment (<i>dd MMM yyyy</i>)		1
Is the participant of childbearing potential?	Yes <input type="checkbox"/>	2
	No <input type="checkbox"/>	
If No, what is the reason?	Surgically sterile <input type="checkbox"/>	3
	Post-menopausal <input type="checkbox"/>	
	Partner medically sterile <input type="checkbox"/>	
	Not reached age of Menarche <input type="checkbox"/>	
	Other <input type="checkbox"/>	
If Partner medically sterile or Other, specify		4
If Surgically sterile, date of surgery (<i>dd MMM yyyy</i>)		5
Date of surgery unknown		6
If Post-menopausal, date of last menstruation (<i>dd MMM yyyy</i>)		7
Date of last menstruation unknown		8

v6.020 DTW: MASTER

Folder: Screening

Form: Childbearing Potential

Generated On: 26 Nov 2020 14:07:14

	Field Name	Data Type	Field Label	Values	Include Field OID
1	CBDAT	dd MMM yyyy	Date of assessment (<i>dd MMM yyyy</i>)		CBDAT
2	CBYN	\$1	Is the participant of childbearing potential?	Y = Yes N = No	CBYN
3	CBRSN	\$25	If No, what is the reason?	SURGICALL Y STERILE = Surgically sterile POST-MENO PAUSAL = Post-menopau sal PARTNER STERILE = Partner medically sterile AGE = Not reached age of Menarche OTHER = Other	CBRSN
4	CBSP	\$200	If Partner medically sterile or Other, specify		CBSP
5	CBSDAT	dd- MMM- yyyy	If Surgically sterile, date of surgery (<i>dd MMM yyyy</i>)		CBSDAT
6	CBSDAUNK 1		Date of surgery unknown		CBSDAUNK

v6.020 DTW: MASTER

Folder: Screening

Form: Childbearing Potential

Generated On: 26 Nov 2020 14:07:14

	Field Name	Data Type	Field Label	Values	Include Field OID
7	CBMENDAT	dd- MMM- yyyy	If Post-menopau sal, date of last menstruation (<i>dd MMM</i> <i>yyyy</i>)		CBMENDAT
8	CBMENDAT 1 UNK		Date of last menstruation unknown		CBMENDAT UNK

v6.020 DTW: MASTER

Folder: Screening

Form: Pregnancy Test

Generated On: 26 Nov 2020 14:07:14

Was the pregnancy test performed?	Yes <input type="checkbox"/>	1
	No <input type="checkbox"/>	
Date of test (<i>dd MMM yyyy</i>)		2
Test performed	Urine <input type="checkbox"/>	3
	Serum <input type="checkbox"/>	
Result	Positive <input type="checkbox"/>	4
	Negative <input type="checkbox"/>	
Was FSH sample collected?	Yes <input type="checkbox"/>	5
	No <input type="checkbox"/>	
Collection date		6
Collection time		7
Collection date and time (derived)		8

v6.020 DTW: MASTER

Folder: Screening

Form: Pregnancy Test

Generated On: 26 Nov 2020 14:07:14

	Field Name	Data Type	Field Label	Values	Include Field OID
①	PTPERF	\$1	Was the pregnancy test performed?	Y = Yes N = No	PTPERF
②	PTDAT	dd MMM yyyy	Date of test (<i>dd MMM yyyy</i>)		PTDAT
③	PTSTYP	\$5	Test performed	URINE = Urine SERUM = Serum	PTSTYP
④	PTORRES	\$25	Result	POSITIVE = Positive NEGATIVE = Negative	PTORRES
⑤	LBPERF	\$1	Was FSH sample collected?	Y = Yes N = No	LBPERF
⑥	LBDAT5	dd MMM yyyy	Collection date		LBDAT5
⑦	LBTIM5	HH:nn	Collection time		LBTIM5
⑧	LBDTTM	dd MMM yyyy HH:nn	Collection date and time (derived)		LBDTTM

v6.020 DTW: MASTER**Folder: Screening****Form: Risk of Exposure****Generated On: 26 Nov 2020 14:07:14****Occupational Risk**

Healthcare workers (e.g., doctors, nurses, dentists, hospital support staff, morgue/mortuary workers) Yes ☐ **2**
No ☐

Emergency Response (e.g., Law enforcement officers, Firefighters, emergency medical service workers) Yes ☐ **3**
No ☐

Retail or Restaurant Operations, particularly those in critical and/high-customer volume (e.g., grocery, convenience, hardware, big-box stores) Yes ☐ **4**
No ☐

Manufacturing & Production Operations with inherent overcrowding (e.g., factory workers, meat/food processing plants) Yes ☐ **5**
No ☐

Warehouse shipping and fulfillment centers and jobs (e.g., Amazon facilities) Yes ☐ **6**
No ☐

Transportation and delivery services (e.g., airlines, public transit, taxi/UBER, fed ex/UPS, postal workers) Yes ☐ **7**
No ☐

Border Protection and Military Personnel (e.g., TSA, custom and border protection agents, military personnel not social distancing) Yes ☐ **8**
No ☐

Personal Care and in-home services (e.g., barber/salon/spa, in-home repair services, electricians, plumbers, janitorial services) Yes ☐ **9**
No ☐

Hospitality and Tourism Workers (e.g., hotel, casino, amusement/theme park, entertainment, ski resorts) Yes ☐ **10**
No ☐

Pastoral, Social or Public Health Workers requiring frequent contact with community members (e.g., social workers, volunteers, religious clergy) Yes ☐ **11**
No ☐

Educators and Students (e.g., teachers, administrators, support staff, and students interacting in face-to-face school setting) Yes ☐ **12**
No ☐

Other Yes ☐ **13**
No ☐

Specify _____ **14**

Location and Living Circumstances Risk (check all that apply)

No Risk Identified _____ **16**

Resides in Nursing Home or Assisted Living Facility _____ **17**

Resides in Multi-family dwelling (e.g., cohabitation in dwelling with > 5 people, includes grandparents living with children < 18yrs) _____ **18**

v6.020 DTW: MASTER

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 14:07:14

Resides in high density housing (e.g., high rise apartments with shared entrances or elevators)	19
Resides in low density, multi-family setting without (e.g., apartments complex without shared entrances or elevators, duplexes)	20
Resides in a single family home (i.e., detached housing)	21
Other	22
Specify	23

v6.020 DTW: MASTER

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 14:07:14

	Field Name	Data Type	Field Label	Values	Include Field OID
2	OCCRISK1	\$1	Healthcare workers (e.g., N = No doctors, nurses, dentists, hospital support staff, morgue/mortu ary workers)	Y = Yes N = No	OCCRISK1
3	OCCRISK2	\$1	Emergency Response (e.g., Law enforcement officers, Firefighters, emergency medical service workers)	Y = Yes N = No	OCCRISK2
4	OCCRISK3	\$1	Retail or Restaurant Operations, particularly those in critical and/high-custo mer volume (e.g., grocery, convenience, hardware, big-box stores)	Y = Yes N = No	OCCRISK3

v6.020 DTW: MASTER

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 14:07:14

	Field Name	Data Type	Field Label	Values	Include Field OID
5	OCCRISK4	\$1	Manufacturing & Production Operations with inherent overcrowding (e.g., factory workers, meat/food processing plants)	Y = Yes N = No	OCCRISK4
6	OCCRISK5	\$1	Warehouse shipping and fulfillment centers and jobs (e.g., Amazon facilities)	Y = Yes N = No	OCCRISK5
7	OCCRISK6	\$1	Transportation and delivery services (e.g., airlines, public transit, taxi/UBER, fed ex/UPS, postal workers)	Y = Yes N = No	OCCRISK6
8	OCCRISK7	\$1	Border Protection and Military Personnel (e.g., TSA, custom and border protection agents, military personnel not social distancing)	Y = Yes N = No	OCCRISK7

v6.020 DTW: MASTER

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 14:07:14

	Field Name	Data Type	Field Label	Values	Include Field OID
9	OCCRISK8	\$1	Personal Care and in-home services (e.g., barber/salon/s pa, in-home repair services, electricians, plumbers, janitorial services)	Y = Yes N = No	OCCRISK8
10	OCCRISK9	\$1	Hospitality and Tourism Workers (e.g., hotel, casino, amusement/th eme park, entertainment, ski resorts)	Y = Yes N = No	OCCRISK9
11	OCCRISK10	\$1	Pastoral, Social or Public Health Workers requiring frequent contact with community members (e.g., social workers, volunteers, religious clergy)	Y = Yes N = No	OCCRISK10

v6.020 DTW: MASTER

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 14:07:14

	Field Name	Data Type	Field Label	Values	Include Field OID
12	OCCRISK11	\$1	Educators and Students (e.g., teachers, administrators, support staff, and students interacting in face-to-face school setting)	Y = Yes N = No	OCCRISK11
13	OCCRISK12	\$1	Other	Y = Yes N = No	OCCRISK12
14	OCCOTH	\$200	Specify		OCCOTH
16	LLNORISK	1	No Risk Identified		LLNORISK
17	LLRISK1	1	Resides in Nursing Home or Assisted Living Facility		LLRISK1
18	LLRISK2	1	Resides in Multi-family dwelling (e.g., cohabitation in dwelling with > 5 people, includes grandparents living with children < 18yrs)		LLRISK2
19	LLRISK3	1	Resides in high density housing (e.g., high rise apartments with shared entrances or elevators)		LLRISK3

v6.020 DTW: MASTER

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 14:07:14

	Field Name	Data Type	Field Label	Values	Include Field OID
20	LLRISK4	1	Resides in low density, multi-family setting without (e.g., apartments complex without shared entrances or elevators, duplexes)		LLRISK4
21	LLRISK5	1	Resides in a single family home (i.e., detached housing)		LLRISK5
22	LLRISK6	1	Other		LLRISK6
23	LLOTH	\$200	Specify		LLOTH

v6.020 DTW: MASTER

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 26 Nov 2020 14:07:14

Was this visit performed?	Yes <input type="checkbox"/>	1
	No <input type="checkbox"/>	
Visit date (dd MMM yyyy)		2
Was visit performed at the participant's home or at the clinic?	Home <input type="checkbox"/>	3
	Clinic <input type="checkbox"/>	
Folder OID		4

v6.020 DTW: MASTER**Folder: Visit 1 Day 1****Form: Visit Date****Generated On: 26 Nov 2020 14:07:14**

	Field Name	Data Type	Field Label	Values	Include Field OID
1	VISITYN	\$1	Was this visit performed?	Y = Yes N = No	VISITYN
2	VISITDAT	dd MMM yyyy	Visit date (dd MMM yyyy)		VISITDAT
3	VISTYPE	\$6	Was visit performed at the participant's home or at the clinic?	Home = Home Clinic = Clinic	VISTYPE
4	FOLDER_OID	\$15	Folder OID		FOLDER_OID

v6.020 DTW: MASTER

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 26 Nov 2020 14:07:14

What was the date of randomization? (<i>dd MMM yyyy</i>)	<input type="text"/>	1
What was the participant's randomization number?	<input type="text"/>	2
In what Cohort was the participant enrolled?	<input type="checkbox"/> ≥ 18 and < 65 years and not at risk <input type="checkbox"/> ≥ 18 and < 65 years and at risk <input type="checkbox"/> ≥ 65 years	3
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 <input type="checkbox"/> No <input type="checkbox"/>	5
Significant cardiac disease (eg, heart failure, coronary artery disease, congenital heart disease, cardiomyopathies, and pulmonary hypertension)	Yes <input type="checkbox"/> No <input type="checkbox"/>	6
Severe obesity (body mass index ≥ 40 kg/m ²)	Yes <input type="checkbox"/> No <input type="checkbox"/>	7
Diabetes (Type I, Type 2, or gestational)	Yes <input type="checkbox"/> No <input type="checkbox"/>	8
Liver Disease	Yes <input type="checkbox"/> No <input type="checkbox"/>	9
Human Immunodeficiency Virus (HIV) infection	Yes <input type="checkbox"/> No <input type="checkbox"/>	10

v6.020 DTW: MASTER

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 26 Nov 2020 14:07:14

	Field Name	Data Type	Field Label	Values	Include Field OID
1	RANDDAT	dd MMM yyyy	What was the date of randomization ? (dd MMM yyyy)		RANDDAT
2	RANDNUM	10	What was the participant's randomization number?		RANDNUM
3	COHORT	1	In what Cohort was the participant enrolled?	1 = >=18 and <65 years and not at risk 2 = >=18 and <65 years and at risk 3 = >=65 years	COHORT
5	RANDLUNG	\$1	Chronic lung disease (eg, emphysema and chronic bronchitis, idiopathic pulmonary fibrosis and cystic fibrosis, or moderate to severe asthma)	Y = Yes N = No	RANDLUNG
6	RANDCARD	\$1	Significant cardiac disease (eg, heart failure, coronary artery disease, congenital heart disease, cardiomyopath ies, and pulmonary hypertension)	Y = Yes N = No	RANDCARD

v6.020 DTW: MASTER**Folder: Visit 1 Day 1****Form: Randomization****Generated On: 26 Nov 2020 14:07:14**

	Field Name	Data Type	Field Label	Values	Include Field OID
7	RANDOBES	\$1	Severe obesity (body mass index > or = 40kg/m2)	Y = Yes N = No	RANDOBES
8	RANDDIAB	\$1	Diabetes (Type I, Type 2, or gestational)	Y = Yes N = No	RANDDIAB
9	RANDLIV	\$1	Liver Disease	Y = Yes N = No	RANDLIV
10	RANDHIV	\$1	Human Immunodefici ency Virus (HIV) infection	Y = Yes N = No	RANDHIV

v6.020 DTW: MASTER

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 26 Nov 2020 14:07:14

Height	cm <input type="checkbox"/>	1
	in <input type="checkbox"/>	
Weight	kg <input type="checkbox"/>	2
	lb <input type="checkbox"/>	
Timepoint	Pre-Dose <input checked="" type="checkbox"/>	3
	Post-Dose <input type="checkbox"/>	
Were vital signs assessed?	Yes <input type="checkbox"/>	4
	No <input type="checkbox"/>	
Date of assessment (<i>dd MMM yyyy</i>)		5
Time of assessment (<i>00:00-23:59</i>)	Fixed Unit: (24 HR)	6
Vital Signs Date and Time (derived)		7
Temperature (<i>xxx.x</i>)	C <input type="checkbox"/>	8
	F <input type="checkbox"/>	
Route of measurement	Oral <input type="checkbox"/>	9
	Axillary <input type="checkbox"/>	
	Other <input type="checkbox"/>	
If Other, specify		10
Pulse (<i>xxx</i>)	Fixed Unit: beats/min	11
Pulse units		12
Respiratory Rate (<i>xxx</i>)	Fixed Unit: breaths/min	13
Respiratory Rate units		14
Systolic Blood Pressure (<i>xxx</i>)	Fixed Unit: mmHg	15
Systolic Blood Pressure units		16
Diastolic Blood Pressure (<i>xxx</i>)	Fixed Unit: mmHg	17
Diastolic Blood Pressure units		18
Timepoint	Pre-Dose <input type="checkbox"/>	3
	Post-Dose <input checked="" type="checkbox"/>	
v6.020 DTW (1102)		39 of 300

v6.020 DTW: MASTER

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 26 Nov 2020 14:07:14

Were vital signs assessed?	Yes <input type="checkbox"/>	4
	No <input type="checkbox"/>	
Date of assessment (<i>dd MMM yyyy</i>)		5
Time of assessment (<i>00:00-23:59</i>)	Fixed Unit: (24 HR)	6
Vital Signs Date and Time (derived)		7
Temperature (<i>xxx.x</i>)	C <input type="checkbox"/>	8
	F <input type="checkbox"/>	
Route of measurement	Oral <input type="checkbox"/>	9
	Axillary <input type="checkbox"/>	
	Other <input type="checkbox"/>	
If Other, specify		10
Pulse (<i>xxx</i>)	Fixed Unit: beats/min	11
Pulse units		12
Respiratory Rate (<i>xxx</i>)	Fixed Unit: breaths/min	13
Respiratory Rate units		14
Systolic Blood Pressure (<i>xxx</i>)	Fixed Unit: mmHg	15
Systolic Blood Pressure units		16
Diastolic Blood Pressure (<i>xxx</i>)	Fixed Unit: mmHg	17
Diastolic Blood Pressure units		18

v6.020 DTW: MASTER

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 26 Nov 2020 14:07:14

	Field Name	Data Type	Field Label	Values	Include Field OID
1	HEIGHT_VS ORRES	20.5	Height		HEIGHT_VS ORRES
2	WEIGHT_VS ORRES	20.5	Weight		WEIGHT_VS ORRES
3	VSTPT	\$15	Timepoint	PREDOSE = Pre-Dose POSTDOSE = Post-Dose	VSTPT
4	VSPERF	\$1	Were vital signs assessed?	Y = Yes N = No	VSPERF
5	VSDAT	dd MMM yyyy	Date of assessment (dd MMM yyyy)		VSDAT
6	VSTIM	HH:nn	Time of assessment (00:00-23:59)		VSTIM
7	VSDTTIM	dd MMM yyyy HH:nn	Vital Signs Date and Time (derived)		VSDTTIM
8	TEMP_VSOR RES	20.5	Temperature (xxx.x)		TEMP_VSOR RES
9	VSROUTE	\$8	Route of measurement	Oral = Oral Axillary = Axillary Other = Other	VSROUTE
10	VSROUTESP	\$200	If Other, specify		VSROUTESP
11	HR_VSORRE S	3	Pulse (xxx)		HR_VSORRE S
12	HR_VSORRE SU	\$9	Pulse units		HR_VSORRE SU
13	RR_VSORRE S	3	Respiratory Rate (xxx)		RR_VSORRE S
14	RR_VSORRE SU	\$11	Respiratory Rate units		RR_VSORRE SU
15	SYSBP_VSO RRES	3	Systolic Blood Pressure (xxx)		SYSBP_VSO RRES

v6.020 DTW: MASTER

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 26 Nov 2020 14:07:14

	Field Name	Data Type	Field Label	Values	Include Field OID
16	SYSBP_VSO RRESU	\$4	Systolic Blood Pressure units		SYSBP_VSO RRESU
17	DIABP_VSO RRES	3	Diastolic Blood Pressure (xxx)		DIABP_VSO RRES
18	DIABP_VSO RRESU	\$4	Diastolic Blood Pressure units		DIABP_VSO RRESU

v6.020 DTW: MASTER

Folder: Visit 1 Day 1

Form: Physical Examination

Generated On: 26 Nov 2020 14:07:14

Was the physical examination performed?

Yes ☐ **1**

No ☐

Date of examination (dd MMM yyyy)

2

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

v6.020 DTW: MASTER

Folder: Visit 1 Day 1

Form: Physical Examination

Generated On: 26 Nov 2020 14:07:14

	Field Name	Data Type	Field Label	Values	Include Field OID
1	PEYN	\$1	Was the physical examination performed?	Y = Yes N = No	PEYN
2	PEDAT	dd MMM yyyy	Date of examination (<i>dd MMM yyyy</i>)		PEDAT

v6.020 DTW: MASTER

Folder: Visit 1 Day 1

Form: Pregnancy Test

Generated On: 26 Nov 2020 14:07:14

Was the pregnancy test performed?	Yes <input type="checkbox"/>	1
	No <input type="checkbox"/>	
Date of test (<i>dd MMM yyyy</i>)		2
Test performed	Urine <input type="checkbox"/>	3
	Serum <input type="checkbox"/>	
Result	Positive <input type="checkbox"/>	4
	Negative <input type="checkbox"/>	
Was FSH sample collected?	Yes <input type="checkbox"/>	5
	No <input type="checkbox"/>	
Collection date		6
Collection time		7
Collection date and time (derived)		8

v6.020 DTW: MASTER

Folder: Visit 1 Day 1

Form: Pregnancy Test

Generated On: 26 Nov 2020 14:07:14

	Field Name	Data Type	Field Label	Values	Include Field OID
1	PTPERF	\$1	Was the pregnancy test performed?	Y = Yes N = No	PTPERF
2	PTDAT	dd MMM yyyy	Date of test (dd MMM yyyy)		PTDAT
3	PTSTYP	\$5	Test performed	URINE = Urine SERUM = Serum	PTSTYP
4	PTORRES	\$25	Result	POSITIVE = Positive NEGATIVE = Negative	PTORRES
5	LBPERF	\$1	Was FSH sample collected?	Y = Yes N = No	LBPERF
6	LBDAT5	dd MMM yyyy	Collection date		LBDAT5
7	LBTIM5	HH:nn	Collection time		LBTIM5
8	LBDTTM	dd MMM yyyy HH:nn	Collection date and time (derived)		LBDTTM

v6.020 DTW: MASTER

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 26 Nov 2020 14:07:14

Was study treatment given?	Yes <input type="checkbox"/>	1
	No <input type="checkbox"/>	
If No, reason not given	Participant declined due to Adverse Event <input type="checkbox"/>	2
	Physician withheld dose due to Adverse Event <input type="checkbox"/>	
	Death <input type="checkbox"/>	
	Lost To Follow-Up <input type="checkbox"/>	
	Physician Decision <input type="checkbox"/>	
	Pregnancy <input type="checkbox"/>	
	Protocol Deviation <input type="checkbox"/>	
	Study Terminated by Sponsor <input type="checkbox"/>	
	Withdrawal of Consent by Participant <input type="checkbox"/>	
	Confirmed COVID-19 <input type="checkbox"/>	
	Other <input type="checkbox"/>	
If reason is Physician Decision, Withdrawal of Consent by Participant, Protocol Deviation, or Other, specify		3
What was the study treatment?		4
What was the treatment date? (dd MMM yyyy)		5
What was the treatment time? (00:00-23:59)	Fixed Unit: (24 HR)	6
Treatment Date and Time (derived)		7
Which arm was used to give treatment?	Left Arm <input type="checkbox"/>	8
	Right Arm <input type="checkbox"/>	
What was the frequency of the study treatment dosing?		9
What was the route of administration for the study treatment?		10

v6.020 DTW: MASTER**Folder: Visit 1 Day 1****Form: Exposure****Generated On: 26 Nov 2020 14:07:14**

	Field Name	Data Type	Field Label	Values	Include Field OID
1	EXYN	\$1	Was study treatment given?	Y = Yes N = No	EXYN
2	EXREAS	\$50	If No, reason not given	ADVERSE EVENT = Participant declined due to Adverse Event PHYSICIAN AE = Physician withheld dose due to Adverse Event DEATH = Death LOST TO FOLLOW-UP = Lost To Follow-Up PHYSICIAN DECISION = Physician Decision PREGNANC Y = Pregnancy PROTOCOL DEVIATION = Protocol Deviation TERMINATE D BY SPONSOR = Study Terminated by Sponsor	EXREAS

v6.020 DTW: MASTER

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 26 Nov 2020 14:07:14

Field Name	Data Type	Field Label	Values	Include Field OID
			WITHDRAW AL OF CONSENT = Withdrawal of Consent by Participant COVID = Confirmed COVID-19 OTHER = Other	
3 EXREASSP	\$200	If reason is Physician Decision, Withdrawal of Consent by Participant, Protocol Deviation, or Other, specify		EXREASSP
4 EXTRT	\$50	What was the study treatment?		EXTRT
5 EXSTDAT	dd MMM yyyy	What was the treatment date? (<i>dd MMM yyyy</i>)		EXSTDAT
6 EXSTTIM	HH:nn	What was the treatment time? (<i>00:00-23:59</i>)		EXSTTIM
7 EXSTDTTIM	dd MMM yyyy HH:nn	Treatment Date and Time (derived)		EXSTDTTIM
8 EXARM	\$10	Which arm was used to give treatment?	LEFT ARM = EXARM Left Arm RIGHT ARM = Right Arm	

v6.020 DTW: MASTER

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 26 Nov 2020 14:07:14

	Field Name	Data Type	Field Label	Values	Include Field OID
9	EXFRQ	\$5	What was the frequency of the study treatment dosing?		EXFRQ
10	EXROUTE	\$13	What was the route of administration for the study treatment?		EXROUTE

v6.020 DTW: MASTER

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 26 Nov 2020 14:07:14

Was the sample collected?	Yes <input type="checkbox"/>	1
	No <input type="checkbox"/>	
Collection date (<i>dd MMM yyyy</i>)		2
Collection time (<i>00:00-23:59</i>)	Fixed Unit: (24 HR)	3
Collection date and time (derived)		4

v6.020 DTW: MASTER

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 26 Nov 2020 14:07:14

	Field Name	Data Type	Field Label	Values	Include Field OID
①	LBPERF	\$1	Was the sample collected?	Y = Yes N = No	LBPERF
②	LBDAT	dd MMM yyyy	Collection date (<i>dd MMM yyyy</i>)		LBDAT
③	LBTIM	HH:nn	Collection time (<i>00:00-23:59</i>)		LBTIM
④	LBDTTM	dd MMM yyyy HH:nn	Collection date and time (derived)		LBDTTM

v6.020 DTW: MASTER

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab

Generated On: 26 Nov 2020 14:07:14

Collection date (<i>dd MMM yyyy</i>)		1
Lab Test	Nasopharyngeal Swab 1	2
	Nasopharyngeal Swab 2	
	Blood Collection for exposure to SARS-CoV-2	
Was the sample collected?	Yes	3
	No	
Collection time (<i>00:00 - 23:59</i>)		4
Collection date and time (derived)		5
Lab Test	Nasopharyngeal Swab 1	2
	Nasopharyngeal Swab 2	
	Blood Collection for exposure to SARS-CoV-2	
Was the sample collected?	Yes	3
	No	
Collection time (<i>00:00 - 23:59</i>)		4
Collection date and time (derived)		5

v6.020 DTW: MASTER

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab

Generated On: 26 Nov 2020 14:07:14

	Field Name	Data Type	Field Label	Values	Include Field OID
1	LBDAT	dd MMM yyyy	Collection date (<i>dd MMM yyyy</i>)		LBDAT
2	LBPANEL3	\$6	Lab Test	NASAL1 = Nasopharyngeal Swab 1 NASAL2 = Nasopharyngeal Swab 2 SARS = Blood Collection for exposure to SARS-CoV-2	LBPANEL3
3	LBPERF	\$1	Was the sample collected?	Y = Yes N = No	LBPERF
4	LBTIM	HH:nn	Collection time (<i>00:00 - 23:59</i>)		LBTIM
5	LBDTTM	dd MMM yyyy HH:nn	Collection date and time (derived)		LBDTTM

v6.020 DTW: MASTER

Folder: Visit 1 Day 1

Form: Continuing

Generated On: 26 Nov 2020 14:07:14

Is the participant continuing to the next visit?	Yes <input type="checkbox"/>	1
	No <input type="checkbox"/>	
Continuing Flag		2

v6.020 DTW: MASTER

Folder: Visit 1 Day 1

Form: Continuing

Generated On: 26 Nov 2020 14:07:14

	Field Name	Data Type	Field Label	Values	Include Field OID
①	CONTYN	\$1	Is the participant continuing to the next visit?	Y = Yes N = No	CONTYN
②	CONTFLAG	1	Continuing Flag		CONTFLAG

v6.020 DTW: MASTER

Folder: Safety Call Day 8

Form: Safety Call

Generated On: 26 Nov 2020 14:07:14

Was Contact Attempted? Yes ☐ **1**
No ☐

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

Please select one status for the follow-up contact
Contact Made ☐ **3**
Contact Not Made ☐

Comments _____ **4**

If Contact Not Made, please provide Comments _____

v6.020 DTW: MASTER**Folder: Safety Call Day 8****Form: Safety Call****Generated On: 26 Nov 2020 14:07:14**

	Field Name	Data Type	Field Label	Values	Include Field OID
①	SCCONATT	\$1	Was Contact Attempted?	Y = Yes N = No	SCCONATT
②	SCCONDAT	dd MMM yyyy	Date of Contact or Contact Attempt (<i>dd MMM yyyy</i>)		SCCONDAT
③	SCSTATUS	\$16	Please select one status for the follow-up contact	CONTACT MADE = Contact Made CONTACT NOT MADE = Contact Not Made	SCSTATUS
④	SCREAS	\$200	Comments <i>If Contact Not Made, please provide Comments</i>		SCREAS

v6.020 DTW: MASTER

Folder: Safety Call Day 8

Form: Continuing

Generated On: 26 Nov 2020 14:07:14

Is the participant continuing to the next visit?

Yes ☐ **1**

No ☐

Continuing Flag

2

v6.020 DTW: MASTER

Folder: Safety Call Day 8

Form: Continuing

Generated On: 26 Nov 2020 14:07:14

	Field Name	Data Type	Field Label	Values	Include Field OID
①	CONTYN	\$1	Is the participant continuing to the next visit?	Y = Yes N = No	CONTYN
②	CONTFLAG	1	Continuing Flag		CONTFLAG

v6.020 DTW: MASTER

Folder: Safety Call Day 15

Form: Safety Call

Generated On: 26 Nov 2020 14:07:14

Was Contact Attempted? Yes ☐ **1**
No ☐

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

Please select one status for the follow-up contact
Contact Made ☐ **3**
Contact Not Made ☐

Comments _____ **4**

If Contact Not Made, please provide Comments _____

v6.020 DTW: MASTER**Folder: Safety Call Day 15****Form: Safety Call****Generated On: 26 Nov 2020 14:07:14**

	Field Name	Data Type	Field Label	Values	Include Field OID
①	SCCONATT	\$1	Was Contact Attempted?	Y = Yes N = No	SCCONATT
②	SCCONDAT	dd MMM yyyy	Date of Contact or Contact Attempt (<i>dd MMM yyyy</i>)		SCCONDAT
③	SCSTATUS	\$16	Please select one status for the follow-up contact	CONTACT MADE = Contact Made CONTACT NOT MADE = Contact Not Made	SCSTATUS
④	SCREAS	\$200	Comments <i>If Contact Not Made, please provide Comments</i>		SCREAS

v6.020 DTW: MASTER

Folder: Safety Call Day 15

Form: Continuing

Generated On: 26 Nov 2020 14:07:14

Is the participant continuing to the next visit?

Yes ☐ **1**

No ☐

Continuing Flag

2

v6.020 DTW: MASTER

Folder: Safety Call Day 15

Form: Continuing

Generated On: 26 Nov 2020 14:07:14

	Field Name	Data Type	Field Label	Values	Include Field OID
①	CONTYN	\$1	Is the participant continuing to the next visit?	Y = Yes N = No	CONTYN
②	CONTFLAG	1	Continuing Flag		CONTFLAG

v6.020 DTW: MASTER

Folder: Safety Call Day 22

Form: Safety Call

Generated On: 26 Nov 2020 14:07:14

Was Contact Attempted? Yes ☐ **1**
No ☐

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

Please select one status for the follow-up contact
Contact Made ☐ **3**
Contact Not Made ☐

Comments **4**

If Contact Not Made, please provide Comments

v6.020 DTW: MASTER**Folder: Safety Call Day 22****Form: Safety Call****Generated On: 26 Nov 2020 14:07:14**

	Field Name	Data Type	Field Label	Values	Include Field OID
①	SCCONATT	\$1	Was Contact Attempted?	Y = Yes N = No	SCCONATT
②	SCCONDAT	dd MMM yyyy	Date of Contact or Contact Attempt (<i>dd MMM yyyy</i>)		SCCONDAT
③	SCSTATUS	\$16	Please select one status for the follow-up contact	CONTACT MADE = Contact Made CONTACT NOT MADE = Contact Not Made	SCSTATUS
④	SCREAS	\$200	Comments <i>If Contact Not Made, please provide Comments</i>		SCREAS

v6.020 DTW: MASTER

Folder: Safety Call Day 22

Form: Continuing

Generated On: 26 Nov 2020 14:07:14

Is the participant continuing to the next visit?

Yes ☐ **1**

No ☐

Continuing Flag

2

v6.020 DTW: MASTER

Folder: Safety Call Day 22

Form: Continuing

Generated On: 26 Nov 2020 14:07:14

	Field Name	Data Type	Field Label	Values	Include Field OID
①	CONTYN	\$1	Is the participant continuing to the next visit?	Y = Yes N = No	CONTYN
②	CONTFLAG	1	Continuing Flag		CONTFLAG

v6.020 DTW: MASTER

Folder: Visit 2 Day 29

Form: Visit Date

Generated On: 26 Nov 2020 14:07:14

Was this visit performed?	Yes <input type="checkbox"/>	1
	No <input type="checkbox"/>	
Visit date (dd MMM yyyy)		2
Was visit performed at the participant's home or at the clinic?	Home <input type="checkbox"/>	3
	Clinic <input type="checkbox"/>	
Folder OID		4

v6.020 DTW: MASTER**Folder: Visit 2 Day 29****Form: Visit Date****Generated On: 26 Nov 2020 14:07:14**

	Field Name	Data Type	Field Label	Values	Include Field OID
1	VISITYN	\$1	Was this visit performed?	Y = Yes N = No	VISITYN
2	VISITDAT	dd MMM yyyy	Visit date (dd MMM yyyy)		VISITDAT
3	VISTYPE	\$6	Was visit performed at the participant's home or at the clinic?	Home = Home Clinic = Clinic	VISTYPE
4	FOLDER_OID	\$15	Folder OID		FOLDER_OID

v6.020 DTW: MASTER

Folder: Visit 2 Day 29

Form: Vital Signs - Dosing

Generated On: 26 Nov 2020 14:07:14

Height	cm <input type="checkbox"/>	1
	in <input type="checkbox"/>	
Weight	kg <input type="checkbox"/>	2
	lb <input type="checkbox"/>	
Timepoint	Pre-Dose <input checked="" type="checkbox"/>	3
	Post-Dose <input type="checkbox"/>	
Were vital signs assessed?	Yes <input type="checkbox"/>	4
	No <input type="checkbox"/>	
Date of assessment (<i>dd MMM yyyy</i>)		5
Time of assessment (<i>00:00-23:59</i>)	Fixed Unit: (24 HR)	6
Vital Signs Date and Time (derived)		7
Temperature (<i>xxx.x</i>)	C <input type="checkbox"/>	8
	F <input type="checkbox"/>	
Route of measurement	Oral <input type="checkbox"/>	9
	Axillary <input type="checkbox"/>	
	Other <input type="checkbox"/>	
If Other, specify		10
Pulse (<i>xxx</i>)	Fixed Unit: beats/min	11
Pulse units		12
Respiratory Rate (<i>xxx</i>)	Fixed Unit: breaths/min	13
Respiratory Rate units		14
Systolic Blood Pressure (<i>xxx</i>)	Fixed Unit: mmHg	15
Systolic Blood Pressure units		16
Diastolic Blood Pressure (<i>xxx</i>)	Fixed Unit: mmHg	17
Diastolic Blood Pressure units		18
Timepoint	Pre-Dose <input type="checkbox"/>	3
	Post-Dose <input checked="" type="checkbox"/>	
v6.020 DTW (1102)		71 of 300

v6.020 DTW: MASTER

Folder: Visit 2 Day 29

Form: Vital Signs - Dosing

Generated On: 26 Nov 2020 14:07:14

Were vital signs assessed?	Yes <input type="checkbox"/>	4
	No <input type="checkbox"/>	
Date of assessment (<i>dd MMM yyyy</i>)		5
Time of assessment (<i>00:00-23:59</i>)	Fixed Unit: (24 HR)	6
Vital Signs Date and Time (derived)		7
Temperature (<i>xxx.x</i>)	C <input type="checkbox"/>	8
	F <input type="checkbox"/>	
Route of measurement	Oral <input type="checkbox"/>	9
	Axillary <input type="checkbox"/>	
	Other <input type="checkbox"/>	
If Other, specify		10
Pulse (<i>xxx</i>)	Fixed Unit: beats/min	11
Pulse units		12
Respiratory Rate (<i>xxx</i>)	Fixed Unit: breaths/min	13
Respiratory Rate units		14
Systolic Blood Pressure (<i>xxx</i>)	Fixed Unit: mmHg	15
Systolic Blood Pressure units		16
Diastolic Blood Pressure (<i>xxx</i>)	Fixed Unit: mmHg	17
Diastolic Blood Pressure units		18

v6.020 DTW: MASTER

Folder: Visit 2 Day 29

Form: Vital Signs - Dosing

Generated On: 26 Nov 2020 14:07:14

	Field Name	Data Type	Field Label	Values	Include Field OID
1	HEIGHT_VS ORRES	20.5	Height		HEIGHT_VS ORRES
2	WEIGHT_VS ORRES	20.5	Weight		WEIGHT_VS ORRES
3	VSTPT	\$15	Timepoint	PREDOSE = Pre-Dose POSTDOSE = Post-Dose	VSTPT
4	VSPERF	\$1	Were vital signs assessed?	Y = Yes N = No	VSPERF
5	VSDAT	dd MMM yyyy	Date of assessment (dd MMM yyyy)		VSDAT
6	VSTIM	HH:nn	Time of assessment (00:00-23:59)		VSTIM
7	VSDTTIM	dd MMM yyyy HH:nn	Vital Signs Date and Time (derived)		VSDTTIM
8	TEMP_VSOR RES	20.5	Temperature (xxx.x)		TEMP_VSOR RES
9	VSROUTE	\$8	Route of measurement	Oral = Oral Axillary = Axillary Other = Other	VSROUTE
10	VSROUTESP	\$200	If Other, specify		VSROUTESP
11	HR_VSORRE S	3	Pulse (xxx)		HR_VSORRE S
12	HR_VSORRE SU	\$9	Pulse units		HR_VSORRE SU
13	RR_VSORRE S	3	Respiratory Rate (xxx)		RR_VSORRE S
14	RR_VSORRE SU	\$11	Respiratory Rate units		RR_VSORRE SU
15	SYSBP_VSO RRES	3	Systolic Blood Pressure (xxx)		SYSBP_VSO RRES

v6.020 DTW: MASTER

Folder: Visit 2 Day 29

Form: Vital Signs - Dosing

Generated On: 26 Nov 2020 14:07:14

	Field Name	Data Type	Field Label	Values	Include Field OID
16	SYSBP_VSO \$4 RRESU		Systolic Blood Pressure units		SYSBP_VSO RRESU
17	DIABP_VSO 3 RRES		Diastolic Blood Pressure (xxx)		DIABP_VSO RRES
18	DIABP_VSO \$4 RRESU		Diastolic Blood Pressure units		DIABP_VSO RRESU

v6.020 DTW: MASTER

Folder: Visit 2 Day 29

Form: Physical Examination

Generated On: 26 Nov 2020 14:07:14

Was the physical examination performed?

Yes ☐ **1**

No ☐

Date of examination (dd MMM yyyy)

2

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

v6.020 DTW: MASTER

Folder: Visit 2 Day 29

Form: Physical Examination

Generated On: 26 Nov 2020 14:07:14

	Field Name	Data Type	Field Label	Values	Include Field OID
1	PEYN	\$1	Was the physical examination performed?	Y = Yes N = No	PEYN
2	PEDAT	dd MMM yyyy	Date of examination (<i>dd MMM yyyy</i>)		PEDAT

v6.020 DTW: MASTER

Folder: Visit 2 Day 29

Form: Pregnancy Test

Generated On: 26 Nov 2020 14:07:14

Was the pregnancy test performed?	Yes <input type="checkbox"/>	1
	No <input type="checkbox"/>	
Date of test (<i>dd MMM yyyy</i>)		2
Test performed	Urine <input type="checkbox"/>	3
	Serum <input type="checkbox"/>	
Result	Positive <input type="checkbox"/>	4
	Negative <input type="checkbox"/>	
Was FSH sample collected?	Yes <input type="checkbox"/>	5
	No <input type="checkbox"/>	
Collection date		6
Collection time		7
Collection date and time (derived)		8

v6.020 DTW: MASTER**Folder: Visit 2 Day 29****Form: Pregnancy Test****Generated On: 26 Nov 2020 14:07:14**

	Field Name	Data Type	Field Label	Values	Include Field OID
①	PTPERF	\$1	Was the pregnancy test performed?	Y = Yes N = No	PTPERF
②	PTDAT	dd MMM yyyy	Date of test (<i>dd MMM yyyy</i>)		PTDAT
③	PTSTYP	\$5	Test performed	URINE = Urine SERUM = Serum	PTSTYP
④	PTORRES	\$25	Result	POSITIVE = Positive NEGATIVE = Negative	PTORRES
⑤	LBPERF	\$1	Was FSH sample collected?	Y = Yes N = No	LBPERF
⑥	LBDAT5	dd MMM yyyy	Collection date		LBDAT5
⑦	LBTIM5	HH:nn	Collection time		LBTIM5
⑧	LBDTTM	dd MMM yyyy HH:nn	Collection date and time (derived)		LBDTTM

v6.020 DTW: MASTER

Folder: Visit 2 Day 29

Form: Exposure

Generated On: 26 Nov 2020 14:07:14

Was study treatment given?		Yes <input type="checkbox"/>	1
		No <input type="checkbox"/>	
If No, reason not given	Participant declined due to Adverse Event	<input type="checkbox"/>	2
	Physician withheld dose due to Adverse Event	<input type="checkbox"/>	
	Death	<input type="checkbox"/>	
	Lost To Follow-Up	<input type="checkbox"/>	
	Physician Decision	<input type="checkbox"/>	
	Pregnancy	<input type="checkbox"/>	
	Protocol Deviation	<input type="checkbox"/>	
	Study Terminated by Sponsor	<input type="checkbox"/>	
	Withdrawal of Consent by Participant	<input type="checkbox"/>	
	Confirmed COVID-19	<input type="checkbox"/>	
	Other	<input type="checkbox"/>	
If reason is Physician Decision, Withdrawal of Consent by Participant, Protocol Deviation, or Other, specify			3
What was the study treatment?			4
What was the treatment date? (dd MMM yyyy)			5
What was the treatment time? (00:00-23:59)		Fixed Unit: (24 HR)	6
Treatment Date and Time (derived)			7
Which arm was used to give treatment?		Left Arm <input type="checkbox"/>	8
		Right Arm <input type="checkbox"/>	
What was the frequency of the study treatment dosing?			9
What was the route of administration for the study treatment?			10

v6.020 DTW: MASTER**Folder: Visit 2 Day 29****Form: Exposure****Generated On: 26 Nov 2020 14:07:14**

	Field Name	Data Type	Field Label	Values	Include Field OID
1	EXYN	\$1	Was study treatment given?	Y = Yes N = No	EXYN
2	EXREAS	\$50	If No, reason not given	ADVERSE EVENT = Participant declined due to Adverse Event PHYSICIAN AE = Physician withheld dose due to Adverse Event DEATH = Death LOST TO FOLLOW-UP = Lost To Follow-Up PHYSICIAN DECISION = Physician Decision PREGNANC Y = Pregnancy PROTOCOL DEVIATION = Protocol Deviation TERMINATE D BY SPONSOR = Study Terminated by Sponsor	EXREAS

v6.020 DTW: MASTER

Folder: Visit 2 Day 29

Form: Exposure

Generated On: 26 Nov 2020 14:07:14

Field Name	Data Type	Field Label	Values	Include Field OID
			WITHDRAW AL OF CONSENT = Withdrawal of Consent by Participant COVID = Confirmed COVID-19 OTHER = Other	
3 EXREASSP	\$200	If reason is Physician Decision, Withdrawal of Consent by Participant, Protocol Deviation, or Other, specify		EXREASSP
4 EXTRT	\$50	What was the study treatment?		EXTRT
5 EXSTDAT	dd MMM yyyy	What was the treatment date? (<i>dd MMM yyyy</i>)		EXSTDAT
6 EXSTTIM	HH:nn	What was the treatment time? (<i>00:00-23:59</i>)		EXSTTIM
7 EXSTDTTIM	dd MMM yyyy HH:nn	Treatment Date and Time (derived)		EXSTDTTIM
8 EXARM	\$10	Which arm was used to give treatment?	LEFT ARM = EXARM Left Arm RIGHT ARM = Right Arm	

v6.020 DTW: MASTER

Folder: Visit 2 Day 29

Form: Exposure

Generated On: 26 Nov 2020 14:07:14

	Field Name	Data Type	Field Label	Values	Include Field OID
9	EXFRQ	\$5	What was the frequency of the study treatment dosing?		EXFRQ
10	EXROUTE	\$13	What was the route of administration for the study treatment?		EXROUTE

v6.020 DTW: MASTER

Folder: Visit 2 Day 29

Form: Immunogenicity Assessment

Generated On: 26 Nov 2020 14:07:14

Was the sample collected?	Yes <input type="checkbox"/>	1
	No <input type="checkbox"/>	
Collection date (<i>dd MMM yyyy</i>)		2
Collection time (<i>00:00-23:59</i>)	Fixed Unit: (24 HR)	3
Collection date and time (derived)		4

v6.020 DTW: MASTER

Folder: Visit 2 Day 29

Form: Immunogenicity Assessment

Generated On: 26 Nov 2020 14:07:14

	Field Name	Data Type	Field Label	Values	Include Field OID
①	LBPERF	\$1	Was the sample collected?	Y = Yes N = No	LBPERF
②	LBDAT	dd MMM yyyy	Collection date (<i>dd MMM yyyy</i>)		LBDAT
③	LBTIM	HH:nn	Collection time (<i>00:00-23:59</i>)		LBTIM
④	LBDTTM	dd MMM yyyy HH:nn	Collection date and time (derived)		LBDTTM

v6.020 DTW: MASTER

Folder: Visit 2 Day 29

Form: Central Laboratory - Nasopharyngeal Swab

Generated On: 26 Nov 2020 14:07:14

Collection date (dd MMM yyyy)		1
Lab Test	Nasopharyngeal Swab 1	2
	Nasopharyngeal Swab 2	
	Blood Collection for exposure to SARS-CoV-2	
Was the sample collected?	Yes	3
	No	
Collection time (00:00 - 23:59)		4
Collection date and time (derived)		5
Lab Test	Nasopharyngeal Swab 1	2
	Nasopharyngeal Swab 2	
	Blood Collection for exposure to SARS-CoV-2	
Was the sample collected?	Yes	3
	No	
Collection time (00:00 - 23:59)		4
Collection date and time (derived)		5

v6.020 DTW: MASTER

Folder: Visit 2 Day 29

Form: Central Laboratory - Nasopharyngeal Swab

Generated On: 26 Nov 2020 14:07:14

	Field Name	Data Type	Field Label	Values	Include Field OID
1	LBDAT	dd MMM yyyy	Collection date (<i>dd MMM yyyy</i>)		LBDAT
2	LBPANEL3	\$6	Lab Test	NASAL1 = Nasopharyngeal Swab 1 NASAL2 = Nasopharyngeal Swab 2 SARS = Blood Collection for exposure to SARS-CoV-2	LBPANEL3
3	LBPERF	\$1	Was the sample collected?	Y = Yes N = No	LBPERF
4	LBTIM	HH:nn	Collection time (<i>00:00 - 23:59</i>)		LBTIM
5	LBDTTM	dd MMM yyyy HH:nn	Collection date and time (derived)		LBDTTM

v6.020 DTW: MASTER

Folder: Visit 2 Day 29

Form: Continuing

Generated On: 26 Nov 2020 14:07:14

Is the participant continuing to the next visit?

Yes ☐ **1**

No ☐

Continuing Flag

2

v6.020 DTW: MASTER

Folder: Visit 2 Day 29

Form: Continuing

Generated On: 26 Nov 2020 14:07:14

	Field Name	Data Type	Field Label	Values	Include Field OID
①	CONTYN	\$1	Is the participant continuing to the next visit?	Y = Yes N = No	CONTYN
②	CONTFLAG	1	Continuing Flag		CONTFLAG

v6.020 DTW: MASTER

Folder: Safety Call Day 36

Form: Safety Call

Generated On: 26 Nov 2020 14:07:14

Was Contact Attempted? Yes ☐ **1**
No ☐

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

Please select one status for the follow-up contact
Contact Made ☐ **3**
Contact Not Made ☐

Comments **4**

If Contact Not Made, please provide Comments

v6.020 DTW: MASTER**Folder: Safety Call Day 36****Form: Safety Call****Generated On: 26 Nov 2020 14:07:14**

	Field Name	Data Type	Field Label	Values	Include Field OID
①	SCCONATT	\$1	Was Contact Attempted?	Y = Yes N = No	SCCONATT
②	SCCONDAT	dd MMM yyyy	Date of Contact or Contact Attempt (<i>dd MMM yyyy</i>)		SCCONDAT
③	SCSTATUS	\$16	Please select one status for the follow-up contact	CONTACT MADE = Contact Made CONTACT NOT MADE = Contact Not Made	SCSTATUS
④	SCREAS	\$200	Comments <i>If Contact Not Made, please provide Comments</i>		SCREAS

v6.020 DTW: MASTER

Folder: Safety Call Day 36

Form: Continuing

Generated On: 26 Nov 2020 14:07:14

Is the participant continuing to the next visit?

Yes ☐ **1**

No ☐

Continuing Flag

2

v6.020 DTW: MASTER

Folder: Safety Call Day 36

Form: Continuing

Generated On: 26 Nov 2020 14:07:14

	Field Name	Data Type	Field Label	Values	Include Field OID
1	CONTYN	\$1	Is the participant continuing to the next visit?	Y = Yes N = No	CONTYN
2	CONTFLAG	1	Continuing Flag		CONTFLAG

v6.020 DTW: MASTER

Folder: Safety Call Day 43

Form: Safety Call

Generated On: 26 Nov 2020 14:07:14

Was Contact Attempted? Yes ☐ **1**
No ☐

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

Please select one status for the follow-up contact
Contact Made ☐ **3**
Contact Not Made ☐

Comments **4**

If Contact Not Made, please provide Comments

v6.020 DTW: MASTER

Folder: Safety Call Day 43

Form: Safety Call

Generated On: 26 Nov 2020 14:07:14

	Field Name	Data Type	Field Label	Values	Include Field OID
①	SCCONATT	\$1	Was Contact Attempted?	Y = Yes N = No	SCCONATT
②	SCCONDAT	dd MMM yyyy	Date of Contact or Contact Attempt (<i>dd MMM yyyy</i>)		SCCONDAT
③	SCSTATUS	\$16	Please select one status for the follow-up contact	CONTACT MADE = Contact Made CONTACT NOT MADE = Contact Not Made	SCSTATUS
④	SCREAS	\$200	Comments <i>If Contact Not Made, please provide Comments</i>		SCREAS

v6.020 DTW: MASTER

Folder: Safety Call Day 43

Form: Continuing

Generated On: 26 Nov 2020 14:07:14

Is the participant continuing to the next visit?

Yes ☐ **1**

No ☐

Continuing Flag

2

v6.020 DTW: MASTER

Folder: Safety Call Day 43

Form: Continuing

Generated On: 26 Nov 2020 14:07:14

	Field Name	Data Type	Field Label	Values	Include Field OID
①	CONTYN	\$1	Is the participant continuing to the next visit?	Y = Yes N = No	CONTYN
②	CONTFLAG	1	Continuing Flag		CONTFLAG

v6.020 DTW: MASTER

Folder: Safety Call Day 50

Form: Safety Call

Generated On: 26 Nov 2020 14:07:14

Was Contact Attempted? Yes ☐ **1**
No ☐

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

Please select one status for the follow-up contact
Contact Made ☐ **3**
Contact Not Made ☐

Comments _____ **4**

If Contact Not Made, please provide Comments _____

v6.020 DTW: MASTER**Folder: Safety Call Day 50****Form: Safety Call****Generated On: 26 Nov 2020 14:07:14**

	Field Name	Data Type	Field Label	Values	Include Field OID
①	SCCONATT	\$1	Was Contact Attempted?	Y = Yes N = No	SCCONATT
②	SCCONDAT	dd MMM yyyy	Date of Contact or Contact Attempt (<i>dd MMM yyyy</i>)		SCCONDAT
③	SCSTATUS	\$16	Please select one status for the follow-up contact	CONTACT MADE = Contact Made CONTACT NOT MADE = Contact Not Made	SCSTATUS
④	SCREAS	\$200	Comments <i>If Contact Not Made, please provide Comments</i>		SCREAS

v6.020 DTW: MASTER

Folder: Safety Call Day 50

Form: Continuing

Generated On: 26 Nov 2020 14:07:14

Is the participant continuing to the next visit?

Yes ☐ **1**

No ☐

Continuing Flag

2

v6.020 DTW: MASTER

Folder: Safety Call Day 50

Form: Continuing

Generated On: 26 Nov 2020 14:07:14

	Field Name	Data Type	Field Label	Values	Include Field OID
①	CONTYN	\$1	Is the participant continuing to the next visit?	Y = Yes N = No	CONTYN
②	CONTFLAG	1	Continuing Flag		CONTFLAG

v6.020 DTW: MASTER

Folder: Visit 3 Day 57

Form: Visit Date

Generated On: 26 Nov 2020 14:07:14

Was this visit performed?	Yes <input type="checkbox"/>	1
	No <input type="checkbox"/>	
Visit date (dd MMM yyyy)		2
Was visit performed at the participant's home or at the clinic?	Home <input type="checkbox"/>	3
	Clinic <input type="checkbox"/>	
Folder OID		4

v6.020 DTW: MASTER**Folder: Visit 3 Day 57****Form: Visit Date****Generated On: 26 Nov 2020 14:07:14**

	Field Name	Data Type	Field Label	Values	Include Field OID
1	VISITYN	\$1	Was this visit performed?	Y = Yes N = No	VISITYN
2	VISITDAT	dd MMM yyyy	Visit date (dd MMM yyyy)		VISITDAT
3	VISTYPE	\$6	Was visit performed at the participant's home or at the clinic?	Home = Home Clinic = Clinic	VISTYPE
4	FOLDER_OID	\$15	Folder OID		FOLDER_OID

v6.020 DTW: MASTER

Folder: Visit 3 Day 57

Form: Vital Signs

Generated On: 26 Nov 2020 14:07:14

Were vital signs assessed?	Yes <input type="checkbox"/>	1
	No <input type="checkbox"/>	
Date of assessment (<i>dd MMM yyyy</i>)		2
Time of assessment (<i>00:00-23:59</i>)	Fixed Unit: (24 HR)	3
Vital Signs Date and Time (derived)		4
Height (<i>xxx.x</i>)	cm <input type="checkbox"/>	5
	in <input type="checkbox"/>	
Weight (<i>xxx.x</i>)	kg <input type="checkbox"/>	6
	lb <input type="checkbox"/>	
BMI (<i>xxx.x</i>)	Fixed Unit: kg/m ²	7
BMI units		8
Temperature (<i>xxx.x</i>)	C <input type="checkbox"/>	9
	F <input type="checkbox"/>	
Route of measurement	Oral <input type="checkbox"/>	10
	Axillary <input type="checkbox"/>	
	Other <input type="checkbox"/>	
If Other, specify		11
Pulse (<i>xxx</i>)	Fixed Unit: beats/min	12
Pulse units		13
Respiratory Rate (<i>xxx</i>)	Fixed Unit: breaths/min	14
Respiratory Rate units		15
Systolic Blood Pressure (<i>xxx</i>)	Fixed Unit: mmHg	16
Systolic Blood Pressure units		17
Diastolic Blood Pressure (<i>xxx</i>)	Fixed Unit: mmHg	18
Diastolic Blood Pressure units		19
Height (derived)	Fixed Unit: cm	20

v6.020 DTW: MASTER

Folder: Visit 3 Day 57

Form: Vital Signs

Generated On: 26 Nov 2020 14:07:14

Weight (derived)

Fixed Unit: kg

21

v6.020 DTW: MASTER

Folder: Visit 3 Day 57

Form: Vital Signs

Generated On: 26 Nov 2020 14:07:14

	Field Name	Data Type	Field Label	Values	Include Field OID
1	VSPERF	\$1	Were vital signs assessed?	Y = Yes N = No	VSPERF
2	VSDAT	dd MMM yyyy	Date of assessment (dd MMM yyyy)		VSDAT
3	VSTIM	HH:nn	Time of assessment (00:00-23:59)		VSTIM
4	VSDTTIM	dd MMM yyyy HH:nn	Vital Signs Date and Time (derived)		VSDTTIM
5	HEIGHT_VS ORRES	20.5	Height (xxx.x)		HEIGHT_VS ORRES
6	WEIGHT_VS ORRES	20.5	Weight (xxx.x)		WEIGHT_VS ORRES
7	VSBMI	20.5	BMI (xxx.x)		VSBMI
8	VSBMUI	\$10	BMI units		VSBMUI
9	TEMP_VSOR RES	20.5	Temperature (xxx.x)		TEMP_VSOR RES
10	VSROUTE	\$8	Route of measurement	Oral = Oral Axillary = Axillary Other = Other	VSROUTE
11	VSROUTESP	\$200	If Other, specify		VSROUTESP
12	HR_VSORRE S	3	Pulse (xxx)		HR_VSORRE S
13	HR_VSORRE SU	\$9	Pulse units		HR_VSORRE SU
14	RR_VSORRE S	3	Respiratory Rate (xxx)		RR_VSORRE S
15	RR_VSORRE SU	\$11	Respiratory Rate units		RR_VSORRE SU
16	SYSBP_VSO RRES	3	Systolic Blood Pressure (xxx)		SYSBP_VSO RRES

v6.020 DTW: MASTER**Folder: Visit 3 Day 57****Form: Vital Signs****Generated On: 26 Nov 2020 14:07:14**

	Field Name	Data Type	Field Label	Values	Include Field OID
17	SYSBP_VSO RRESU	\$4	Systolic Blood Pressure units		SYSBP_VSO RRESU
18	DIABP_VSO RRES	3	Diastolic Blood Pressure (xxx)		DIABP_VSO RRES
19	DIABP_VSO RRESU	\$4	Diastolic Blood Pressure units		DIABP_VSO RRESU
20	HEIGHT_D	3	Height (derived)		HEIGHT_D
21	WEIGHT_D	4.1	Weight (derived)		WEIGHT_D

v6.020 DTW: MASTER

Folder: Visit 3 Day 57

Form: Physical Examination

Generated On: 26 Nov 2020 14:07:14

Was the physical examination performed?

Yes ☐ **1**

No ☐

Date of examination (dd MMM yyyy)

2

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

v6.020 DTW: MASTER

Folder: Visit 3 Day 57

Form: Physical Examination

Generated On: 26 Nov 2020 14:07:14

	Field Name	Data Type	Field Label	Values	Include Field OID
1	PEYN	\$1	Was the physical examination performed?	Y = Yes N = No	PEYN
2	PEDAT	dd MMM yyyy	Date of examination (<i>dd MMM yyyy</i>)		PEDAT

v6.020 DTW: MASTER

Folder: Visit 3 Day 57

Form: Immunogenicity Assessment

Generated On: 26 Nov 2020 14:07:14

Was the sample collected?	Yes <input type="checkbox"/>	1
	No <input type="checkbox"/>	
Collection date (<i>dd MMM yyyy</i>)		2
Collection time (<i>00:00-23:59</i>)	Fixed Unit: (24 HR)	3
Collection date and time (derived)		4

v6.020 DTW: MASTER

Folder: Visit 3 Day 57

Form: Immunogenicity Assessment

Generated On: 26 Nov 2020 14:07:14

	Field Name	Data Type	Field Label	Values	Include Field OID
①	LBPERF	\$1	Was the sample collected?	Y = Yes N = No	LBPERF
②	LBDAT	dd MMM yyyy	Collection date (<i>dd MMM yyyy</i>)		LBDAT
③	LBTIM	HH:nn	Collection time (<i>00:00-23:59</i>)		LBTIM
④	LBDTTM	dd MMM yyyy HH:nn	Collection date and time (derived)		LBDTTM

v6.020 DTW: MASTER

Folder: Visit 3 Day 57

Form: Continuing

Generated On: 26 Nov 2020 14:07:14

Is the participant continuing to the next visit?

Yes ☐ **1**

No ☐

Continuing Flag

2

v6.020 DTW: MASTER

Folder: Visit 3 Day 57

Form: Continuing

Generated On: 26 Nov 2020 14:07:14

	Field Name	Data Type	Field Label	Values	Include Field OID
1	CONTYN	\$1	Is the participant continuing to the next visit?	Y = Yes N = No	CONTYN
2	CONTFLAG	1	Continuing Flag		CONTFLAG

v6.020 DTW: MASTER

Folder: Safety Call Day 85

Form: Safety Call

Generated On: 26 Nov 2020 14:07:14

Was Contact Attempted? Yes ☐ **1**
No ☐

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

Please select one status for the follow-up contact
Contact Made ☐ **3**
Contact Not Made ☐

Comments **4**

If Contact Not Made, please provide Comments

v6.020 DTW: MASTER

Folder: Safety Call Day 85

Form: Safety Call

Generated On: 26 Nov 2020 14:07:14

	Field Name	Data Type	Field Label	Values	Include Field OID
①	SCCONATT	\$1	Was Contact Attempted?	Y = Yes N = No	SCCONATT
②	SCCONDAT	dd MMM yyyy	Date of Contact or Contact Attempt (<i>dd MMM yyyy</i>)		SCCONDAT
③	SCSTATUS	\$16	Please select one status for the follow-up contact	CONTACT MADE = Contact Made CONTACT NOT MADE = Contact Not Made	SCSTATUS
④	SCREAS	\$200	Comments <i>If Contact Not Made, please provide Comments</i>		SCREAS

v6.020 DTW: MASTER

Folder: Safety Call Day 85

Form: Continuing

Generated On: 26 Nov 2020 14:07:14

Is the participant continuing to the next visit?

Yes ☐ **1**

No ☐

Continuing Flag

2

v6.020 DTW: MASTER

Folder: Safety Call Day 85

Form: Continuing

Generated On: 26 Nov 2020 14:07:14

	Field Name	Data Type	Field Label	Values	Include Field OID
①	CONTYN	\$1	Is the participant continuing to the next visit?	Y = Yes N = No	CONTYN
②	CONTFLAG	1	Continuing Flag		CONTFLAG

v6.020 DTW: MASTER

Folder: Safety Call Day 119

Form: Safety Call

Generated On: 26 Nov 2020 14:07:14

Was Contact Attempted? Yes ☐ **1**
No ☐

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

Please select one status for the follow-up contact
Contact Made ☐ **3**
Contact Not Made ☐

Comments **4**

If Contact Not Made, please provide Comments

v6.020 DTW: MASTER

Folder: Safety Call Day 119

Form: Safety Call

Generated On: 26 Nov 2020 14:07:14

	Field Name	Data Type	Field Label	Values	Include Field OID
①	SCCONATT	\$1	Was Contact Attempted?	Y = Yes N = No	SCCONATT
②	SCCONDAT	dd MMM yyyy	Date of Contact or Contact Attempt (<i>dd MMM yyyy</i>)		SCCONDAT
③	SCSTATUS	\$16	Please select one status for the follow-up contact	CONTACT MADE = Contact Made CONTACT NOT MADE = Contact Not Made	SCSTATUS
④	SCREAS	\$200	Comments <i>If Contact Not Made, please provide Comments</i>		SCREAS

v6.020 DTW: MASTER

Folder: Safety Call Day 119

Form: Continuing

Generated On: 26 Nov 2020 14:07:14

Is the participant continuing to the next visit?

Yes ☐ **1**

No ☐

Continuing Flag

2

v6.020 DTW: MASTER

Folder: Safety Call Day 119

Form: Continuing

Generated On: 26 Nov 2020 14:07:14

	Field Name	Data Type	Field Label	Values	Include Field OID
①	CONTYN	\$1	Is the participant continuing to the next visit?	Y = Yes N = No	CONTYN
②	CONTFLAG	1	Continuing Flag		CONTFLAG

v6.020 DTW: MASTER

Folder: Safety Call Day 149

Form: Safety Call

Generated On: 26 Nov 2020 14:07:14

Was Contact Attempted? Yes ☐ **1**
No ☐

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

Please select one status for the follow-up contact Contact Made ☐ **3**
Contact Not Made ☐

Comments **4**

If Contact Not Made, please provide Comments

v6.020 DTW: MASTER**Folder: Safety Call Day 149****Form: Safety Call****Generated On: 26 Nov 2020 14:07:14**

	Field Name	Data Type	Field Label	Values	Include Field OID
①	SCCONATT	\$1	Was Contact Attempted?	Y = Yes N = No	SCCONATT
②	SCCONDAT	dd MMM yyyy	Date of Contact or Contact Attempt (<i>dd MMM yyyy</i>)		SCCONDAT
③	SCSTATUS	\$16	Please select one status for the follow-up contact	CONTACT MADE = Contact Made CONTACT NOT MADE = Contact Not Made	SCSTATUS
④	SCREAS	\$200	Comments <i>If Contact Not Made, please provide Comments</i>		SCREAS

v6.020 DTW: MASTER

Folder: Safety Call Day 149

Form: Continuing

Generated On: 26 Nov 2020 14:07:14

Is the participant continuing to the next visit?

Yes ☐ **1**

No ☐

Continuing Flag

2

v6.020 DTW: MASTER

Folder: Safety Call Day 149

Form: Continuing

Generated On: 26 Nov 2020 14:07:14

	Field Name	Data Type	Field Label	Values	Include Field OID
①	CONTYN	\$1	Is the participant continuing to the next visit?	Y = Yes N = No	CONTYN
②	CONTFLAG	1	Continuing Flag		CONTFLAG

v6.020 DTW: MASTER

Folder: Safety Call Day 179

Form: Safety Call

Generated On: 26 Nov 2020 14:07:14

Was Contact Attempted? Yes ☐ **1**
No ☐

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

Please select one status for the follow-up contact
Contact Made ☐ **3**
Contact Not Made ☐

Comments **4**

If Contact Not Made, please provide Comments

v6.020 DTW: MASTER

Folder: Safety Call Day 179

Form: Safety Call

Generated On: 26 Nov 2020 14:07:14

	Field Name	Data Type	Field Label	Values	Include Field OID
①	SCCONATT	\$1	Was Contact Attempted?	Y = Yes N = No	SCCONATT
②	SCCONDAT	dd MMM yyyy	Date of Contact or Contact Attempt (<i>dd MMM yyyy</i>)		SCCONDAT
③	SCSTATUS	\$16	Please select one status for the follow-up contact	CONTACT MADE = Contact Made CONTACT NOT MADE = Contact Not Made	SCSTATUS
④	SCREAS	\$200	Comments <i>If Contact Not Made, please provide Comments</i>		SCREAS

v6.020 DTW: MASTER

Folder: Safety Call Day 179

Form: Continuing

Generated On: 26 Nov 2020 14:07:14

Is the participant continuing to the next visit?

Yes ☐ **1**

No ☐

Continuing Flag

2

v6.020 DTW: MASTER

Folder: Safety Call Day 179

Form: Continuing

Generated On: 26 Nov 2020 14:07:14

	Field Name	Data Type	Field Label	Values	Include Field OID
①	CONTYN	\$1	Is the participant continuing to the next visit?	Y = Yes N = No	CONTYN
②	CONTFLAG	1	Continuing Flag		CONTFLAG

v6.020 DTW: MASTER

Folder: Visit 4 Day 209

Form: Visit Date

Generated On: 26 Nov 2020 14:07:14

Was this visit performed?	Yes <input type="checkbox"/>	1
	No <input type="checkbox"/>	
Visit date (dd MMM yyyy)		2
Was visit performed at the participant's home or at the clinic?	Home <input type="checkbox"/>	3
	Clinic <input type="checkbox"/>	
Folder OID		4

v6.020 DTW: MASTER**Folder: Visit 4 Day 209****Form: Visit Date****Generated On: 26 Nov 2020 14:07:14**

	Field Name	Data Type	Field Label	Values	Include Field OID
1	VISITYN	\$1	Was this visit performed?	Y = Yes N = No	VISITYN
2	VISITDAT	dd MMM yyyy	Visit date (dd MMM yyyy)		VISITDAT
3	VISTYPE	\$6	Was visit performed at the participant's home or at the clinic?	Home = Home Clinic = Clinic	VISTYPE
4	FOLDER_OID	\$15	Folder OID		FOLDER_OID

v6.020 DTW: MASTER

Folder: Visit 4 Day 209

Form: Physical Examination

Generated On: 26 Nov 2020 14:07:14

Was the physical examination performed?

Yes ☐ **1**

No ☐

Date of examination (dd MMM yyyy)

2

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

v6.020 DTW: MASTER

Folder: Visit 4 Day 209

Form: Physical Examination

Generated On: 26 Nov 2020 14:07:14

	Field Name	Data Type	Field Label	Values	Include Field OID
1	PEYN	\$1	Was the physical examination performed?	Y = Yes N = No	PEYN
2	PEDAT	dd MMM yyyy	Date of examination (<i>dd MMM yyyy</i>)		PEDAT

v6.020 DTW: MASTER

Folder: Visit 4 Day 209

Form: Continuing

Generated On: 26 Nov 2020 14:07:14

Is the participant continuing to the next visit?

Yes ☐ **1**

No ☐

Continuing Flag

2

v6.020 DTW: MASTER

Folder: Visit 4 Day 209

Form: Continuing

Generated On: 26 Nov 2020 14:07:14

	Field Name	Data Type	Field Label	Values	Include Field OID
①	CONTYN	\$1	Is the participant continuing to the next visit?	Y = Yes N = No	CONTYN
②	CONTFLAG	1	Continuing Flag		CONTFLAG

v6.020 DTW: MASTER

Folder: Safety Call Day 239

Form: Safety Call

Generated On: 26 Nov 2020 14:07:14

Was Contact Attempted? Yes ☐ **1**
No ☐

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

Please select one status for the follow-up contact
Contact Made ☐ **3**
Contact Not Made ☐

Comments **4**

If Contact Not Made, please provide Comments

v6.020 DTW: MASTER**Folder: Safety Call Day 239****Form: Safety Call****Generated On: 26 Nov 2020 14:07:14**

	Field Name	Data Type	Field Label	Values	Include Field OID
①	SCCONATT	\$1	Was Contact Attempted?	Y = Yes N = No	SCCONATT
②	SCCONDAT	dd MMM yyyy	Date of Contact or Contact Attempt (<i>dd MMM yyyy</i>)		SCCONDAT
③	SCSTATUS	\$16	Please select one status for the follow-up contact	CONTACT MADE = Contact Made CONTACT NOT MADE = Contact Not Made	SCSTATUS
④	SCREAS	\$200	Comments <i>If Contact Not Made, please provide Comments</i>		SCREAS

v6.020 DTW: MASTER

Folder: Safety Call Day 239

Form: Continuing

Generated On: 26 Nov 2020 14:07:14

Is the participant continuing to the next visit?

Yes ☐ **1**

No ☐

Continuing Flag

2

v6.020 DTW: MASTER

Folder: Safety Call Day 239

Form: Continuing

Generated On: 26 Nov 2020 14:07:14

	Field Name	Data Type	Field Label	Values	Include Field OID
①	CONTYN	\$1	Is the participant continuing to the next visit?	Y = Yes N = No	CONTYN
②	CONTFLAG	1	Continuing Flag		CONTFLAG

v6.020 DTW: MASTER

Folder: Safety Call Day 269

Form: Safety Call

Generated On: 26 Nov 2020 14:07:14

Was Contact Attempted? Yes ☐ **1**
No ☐

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

Please select one status for the follow-up contact
Contact Made ☐ **3**
Contact Not Made ☐

Comments _____ **4**

If Contact Not Made, please provide Comments _____

v6.020 DTW: MASTER

Folder: Safety Call Day 269

Form: Safety Call

Generated On: 26 Nov 2020 14:07:14

	Field Name	Data Type	Field Label	Values	Include Field OID
①	SCCONATT	\$1	Was Contact Attempted?	Y = Yes N = No	SCCONATT
②	SCCONDAT	dd MMM yyyy	Date of Contact or Contact Attempt (<i>dd MMM yyyy</i>)		SCCONDAT
③	SCSTATUS	\$16	Please select one status for the follow-up contact	CONTACT MADE = Contact Made CONTACT NOT MADE = Contact Not Made	SCSTATUS
④	SCREAS	\$200	Comments <i>If Contact Not Made, please provide Comments</i>		SCREAS

v6.020 DTW: MASTER

Folder: Safety Call Day 269

Form: Continuing

Generated On: 26 Nov 2020 14:07:14

Is the participant continuing to the next visit?

Yes ☐ **1**

No ☐

Continuing Flag

2

v6.020 DTW: MASTER

Folder: Safety Call Day 269

Form: Continuing

Generated On: 26 Nov 2020 14:07:14

	Field Name	Data Type	Field Label	Values	Include Field OID
①	CONTYN	\$1	Is the participant continuing to the next visit?	Y = Yes N = No	CONTYN
②	CONTFLAG	1	Continuing Flag		CONTFLAG

v6.020 DTW: MASTER

Folder: Safety Call Day 299

Form: Safety Call

Generated On: 26 Nov 2020 14:07:14

Was Contact Attempted? Yes ☐ **1**
No ☐

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

Please select one status for the follow-up contact
Contact Made ☐ **3**
Contact Not Made ☐

Comments _____ **4**

If Contact Not Made, please provide Comments _____

v6.020 DTW: MASTER

Folder: Safety Call Day 299

Form: Safety Call

Generated On: 26 Nov 2020 14:07:14

	Field Name	Data Type	Field Label	Values	Include Field OID
①	SCCONATT	\$1	Was Contact Attempted?	Y = Yes N = No	SCCONATT
②	SCCONDAT	dd MMM yyyy	Date of Contact or Contact Attempt (<i>dd MMM yyyy</i>)		SCCONDAT
③	SCSTATUS	\$16	Please select one status for the follow-up contact	CONTACT MADE = Contact Made CONTACT NOT MADE = Contact Not Made	SCSTATUS
④	SCREAS	\$200	Comments <i>If Contact Not Made, please provide Comments</i>		SCREAS

v6.020 DTW: MASTER

Folder: Safety Call Day 299

Form: Continuing

Generated On: 26 Nov 2020 14:07:14

Is the participant continuing to the next visit?

Yes ☐ **1**

No ☐

Continuing Flag

2

v6.020 DTW: MASTER

Folder: Safety Call Day 299

Form: Continuing

Generated On: 26 Nov 2020 14:07:14

	Field Name	Data Type	Field Label	Values	Include Field OID
①	CONTYN	\$1	Is the participant continuing to the next visit?	Y = Yes N = No	CONTYN
②	CONTFLAG	1	Continuing Flag		CONTFLAG

v6.020 DTW: MASTER

Folder: Safety Call Day 329

Form: Safety Call

Generated On: 26 Nov 2020 14:07:14

Was Contact Attempted? Yes ☐ **1**
No ☐

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

Please select one status for the follow-up contact
Contact Made ☐ **3**
Contact Not Made ☐

Comments **4**

If Contact Not Made, please provide Comments

v6.020 DTW: MASTER**Folder: Safety Call Day 329****Form: Safety Call****Generated On: 26 Nov 2020 14:07:14**

	Field Name	Data Type	Field Label	Values	Include Field OID
①	SCCONATT	\$1	Was Contact Attempted?	Y = Yes N = No	SCCONATT
②	SCCONDAT	dd MMM yyyy	Date of Contact or Contact Attempt (<i>dd MMM yyyy</i>)		SCCONDAT
③	SCSTATUS	\$16	Please select one status for the follow-up contact	CONTACT MADE = Contact Made CONTACT NOT MADE = Contact Not Made	SCSTATUS
④	SCREAS	\$200	Comments <i>If Contact Not Made, please provide Comments</i>		SCREAS

v6.020 DTW: MASTER

Folder: Safety Call Day 329

Form: Continuing

Generated On: 26 Nov 2020 14:07:14

Is the participant continuing to the next visit?

Yes ☐ **1**

No ☐

Continuing Flag

2

v6.020 DTW: MASTER

Folder: Safety Call Day 329

Form: Continuing

Generated On: 26 Nov 2020 14:07:14

	Field Name	Data Type	Field Label	Values	Include Field OID
①	CONTYN	\$1	Is the participant continuing to the next visit?	Y = Yes N = No	CONTYN
②	CONTFLAG	1	Continuing Flag		CONTFLAG

v6.020 DTW: MASTER

Folder: Safety Call Day 359

Form: Safety Call

Generated On: 26 Nov 2020 14:07:14

Was Contact Attempted? Yes ☐ **1**
No ☐

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

Please select one status for the follow-up contact
Contact Made ☐ **3**
Contact Not Made ☐

Comments **4**

If Contact Not Made, please provide Comments

v6.020 DTW: MASTER**Folder: Safety Call Day 359****Form: Safety Call****Generated On: 26 Nov 2020 14:07:14**

	Field Name	Data Type	Field Label	Values	Include Field OID
①	SCCONATT	\$1	Was Contact Attempted?	Y = Yes N = No	SCCONATT
②	SCCONDAT	dd MMM yyyy	Date of Contact or Contact Attempt (<i>dd MMM yyyy</i>)		SCCONDAT
③	SCSTATUS	\$16	Please select one status for the follow-up contact	CONTACT MADE = Contact Made CONTACT NOT MADE = Contact Not Made	SCSTATUS
④	SCREAS	\$200	Comments <i>If Contact Not Made, please provide Comments</i>		SCREAS

v6.020 DTW: MASTER

Folder: Safety Call Day 359

Form: Continuing

Generated On: 26 Nov 2020 14:07:14

Is the participant continuing to the next visit?

Yes ☐ **1**

No ☐

Continuing Flag

2

v6.020 DTW: MASTER

Folder: Safety Call Day 359

Form: Continuing

Generated On: 26 Nov 2020 14:07:14

	Field Name	Data Type	Field Label	Values	Include Field OID
①	CONTYN	\$1	Is the participant continuing to the next visit?	Y = Yes N = No	CONTYN
②	CONTFLAG	1	Continuing Flag		CONTFLAG

v6.020 DTW: MASTER

Folder: Visit 5 Day 394

Form: Visit Date

Generated On: 26 Nov 2020 14:07:14

Was this visit performed?	Yes <input type="checkbox"/>	1
	No <input type="checkbox"/>	
Visit date (dd MMM yyyy)		2
Was visit performed at the participant's home or at the clinic?	Home <input type="checkbox"/>	3
	Clinic <input type="checkbox"/>	
Folder OID		4

v6.020 DTW: MASTER**Folder: Visit 5 Day 394****Form: Visit Date****Generated On: 26 Nov 2020 14:07:14**

	Field Name	Data Type	Field Label	Values	Include Field OID
1	VISITYN	\$1	Was this visit performed?	Y = Yes N = No	VISITYN
2	VISITDAT	dd MMM yyyy	Visit date (dd MMM yyyy)		VISITDAT
3	VISTYPE	\$6	Was visit performed at the participant's home or at the clinic?	Home = Home Clinic = Clinic	VISTYPE
4	FOLDER_OID	\$15	Folder OID		FOLDER_OID

v6.020 DTW: MASTER

Folder: Visit 5 Day 394

Form: Physical Examination

Generated On: 26 Nov 2020 14:07:14

Was the physical examination performed?

Yes ☐ **1**

No ☐

Date of examination (dd MMM yyyy)

2

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

v6.020 DTW: MASTER

Folder: Visit 5 Day 394

Form: Physical Examination

Generated On: 26 Nov 2020 14:07:14

	Field Name	Data Type	Field Label	Values	Include Field OID
1	PEYN	\$1	Was the physical examination performed?	Y = Yes N = No	PEYN
2	PEDAT	dd MMM yyyy	Date of examination (<i>dd MMM yyyy</i>)		PEDAT

v6.020 DTW: MASTER

Folder: Visit 5 Day 394

Form: Immunogenicity Assessment

Generated On: 26 Nov 2020 14:07:14

Was the sample collected?	Yes <input type="checkbox"/>	1
	No <input type="checkbox"/>	
Collection date (<i>dd MMM yyyy</i>)		2
Collection time (<i>00:00-23:59</i>)	Fixed Unit: (24 HR)	3
Collection date and time (derived)		4

v6.020 DTW: MASTER**Folder: Visit 5 Day 394****Form: Immunogenicity Assessment****Generated On: 26 Nov 2020 14:07:14**

	Field Name	Data Type	Field Label	Values	Include Field OID
①	LBPERF	\$1	Was the sample collected?	Y = Yes N = No	LBPERF
②	LBDAT	dd MMM yyyy	Collection date (<i>dd MMM yyyy</i>)		LBDAT
③	LBTIM	HH:nn	Collection time (<i>00:00-23:59</i>)		LBTIM
④	LBDTTM	dd MMM yyyy HH:nn	Collection date and time (derived)		LBDTTM

v6.020 DTW: MASTER

Folder: Visit 5 Day 394

Form: Continuing

Generated On: 26 Nov 2020 14:07:14

Is the participant continuing to the next visit?

Yes ☐ **1**

No ☐

Continuing Flag

2

v6.020 DTW: MASTER

Folder: Visit 5 Day 394

Form: Continuing

Generated On: 26 Nov 2020 14:07:14

	Field Name	Data Type	Field Label	Values	Include Field OID
①	CONTYN	\$1	Is the participant continuing to the next visit?	Y = Yes N = No	CONTYN
②	CONTFLAG	1	Continuing Flag		CONTFLAG

v6.020 DTW: MASTER

Folder: Safety Call Day 424

Form: Safety Call

Generated On: 26 Nov 2020 14:07:14

Was Contact Attempted? Yes ☐ **1**
No ☐

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

Please select one status for the follow-up contact
Contact Made ☐ **3**
Contact Not Made ☐

Comments _____ **4**

If Contact Not Made, please provide Comments _____

v6.020 DTW: MASTER**Folder: Safety Call Day 424****Form: Safety Call****Generated On: 26 Nov 2020 14:07:14**

	Field Name	Data Type	Field Label	Values	Include Field OID
①	SCCONATT	\$1	Was Contact Attempted?	Y = Yes N = No	SCCONATT
②	SCCONDAT	dd MMM yyyy	Date of Contact or Contact Attempt (<i>dd MMM yyyy</i>)		SCCONDAT
③	SCSTATUS	\$16	Please select one status for the follow-up contact	CONTACT MADE = Contact Made CONTACT NOT MADE = Contact Not Made	SCSTATUS
④	SCREAS	\$200	Comments <i>If Contact Not Made, please provide Comments</i>		SCREAS

v6.020 DTW: MASTER

Folder: Safety Call Day 424

Form: Continuing

Generated On: 26 Nov 2020 14:07:14

Is the participant continuing to the next visit?

Yes ☐ **1**

No ☐

Continuing Flag

2

v6.020 DTW: MASTER

Folder: Safety Call Day 424

Form: Continuing

Generated On: 26 Nov 2020 14:07:14

	Field Name	Data Type	Field Label	Values	Include Field OID
①	CONTYN	\$1	Is the participant continuing to the next visit?	Y = Yes N = No	CONTYN
②	CONTFLAG	1	Continuing Flag		CONTFLAG

v6.020 DTW: MASTER

Folder: Safety Call Day 454

Form: Safety Call

Generated On: 26 Nov 2020 14:07:14

Was Contact Attempted? Yes ☐ **1**
No ☐

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

Please select one status for the follow-up contact
Contact Made ☐ **3**
Contact Not Made ☐

Comments **4**

If Contact Not Made, please provide Comments

v6.020 DTW: MASTER**Folder: Safety Call Day 454****Form: Safety Call****Generated On: 26 Nov 2020 14:07:14**

	Field Name	Data Type	Field Label	Values	Include Field OID
①	SCCONATT	\$1	Was Contact Attempted?	Y = Yes N = No	SCCONATT
②	SCCONDAT	dd MMM yyyy	Date of Contact or Contact Attempt (<i>dd MMM yyyy</i>)		SCCONDAT
③	SCSTATUS	\$16	Please select one status for the follow-up contact	CONTACT MADE = Contact Made CONTACT NOT MADE = Contact Not Made	SCSTATUS
④	SCREAS	\$200	Comments <i>If Contact Not Made, please provide Comments</i>		SCREAS

v6.020 DTW: MASTER

Folder: Safety Call Day 454

Form: Continuing

Generated On: 26 Nov 2020 14:07:14

Is the participant continuing to the next visit?

Yes ☐ **1**

No ☐

Continuing Flag

2

v6.020 DTW: MASTER

Folder: Safety Call Day 454

Form: Continuing

Generated On: 26 Nov 2020 14:07:14

	Field Name	Data Type	Field Label	Values	Include Field OID
①	CONTYN	\$1	Is the participant continuing to the next visit?	Y = Yes N = No	CONTYN
②	CONTFLAG	1	Continuing Flag		CONTFLAG

v6.020 DTW: MASTER

Folder: Safety Call Day 484

Form: Safety Call

Generated On: 26 Nov 2020 14:07:14

Was Contact Attempted? Yes ☐ **1**
No ☐

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

Please select one status for the follow-up contact
Contact Made ☐ **3**
Contact Not Made ☐

Comments **4**

If Contact Not Made, please provide Comments

v6.020 DTW: MASTER

Folder: Safety Call Day 484

Form: Safety Call

Generated On: 26 Nov 2020 14:07:14

	Field Name	Data Type	Field Label	Values	Include Field OID
①	SCCONATT	\$1	Was Contact Attempted?	Y = Yes N = No	SCCONATT
②	SCCONDAT	dd MMM yyyy	Date of Contact or Contact Attempt (dd MMM yyyy)		SCCONDAT
③	SCSTATUS	\$16	Please select one status for the follow-up contact	CONTACT MADE = Contact Made CONTACT NOT MADE = Contact Not Made	SCSTATUS
④	SCREAS	\$200	Comments <i>If Contact Not Made, please provide Comments</i>		SCREAS

v6.020 DTW: MASTER

Folder: Safety Call Day 484

Form: Continuing

Generated On: 26 Nov 2020 14:07:14

Is the participant continuing to the next visit?

Yes ☐ **1**

No ☐

Continuing Flag

2

v6.020 DTW: MASTER

Folder: Safety Call Day 484

Form: Continuing

Generated On: 26 Nov 2020 14:07:14

	Field Name	Data Type	Field Label	Values	Include Field OID
①	CONTYN	\$1	Is the participant continuing to the next visit?	Y = Yes N = No	CONTYN
②	CONTFLAG	1	Continuing Flag		CONTFLAG

v6.020 DTW: MASTER

Folder: Safety Call Day 514

Form: Safety Call

Generated On: 26 Nov 2020 14:07:14

Was Contact Attempted? Yes ☐ **1**
No ☐

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

Please select one status for the follow-up contact
Contact Made ☐ **3**
Contact Not Made ☐

Comments **4**

If Contact Not Made, please provide Comments

v6.020 DTW: MASTER

Folder: Safety Call Day 514

Form: Safety Call

Generated On: 26 Nov 2020 14:07:14

	Field Name	Data Type	Field Label	Values	Include Field OID
①	SCCONATT	\$1	Was Contact Attempted?	Y = Yes N = No	SCCONATT
②	SCCONDAT	dd MMM yyyy	Date of Contact or Contact Attempt (<i>dd MMM yyyy</i>)		SCCONDAT
③	SCSTATUS	\$16	Please select one status for the follow-up contact	CONTACT MADE = Contact Made CONTACT NOT MADE = Contact Not Made	SCSTATUS
④	SCREAS	\$200	Comments <i>If Contact Not Made, please provide Comments</i>		SCREAS

v6.020 DTW: MASTER

Folder: Safety Call Day 514

Form: Continuing

Generated On: 26 Nov 2020 14:07:14

Is the participant continuing to the next visit?

Yes ☐ **1**

No ☐

Continuing Flag

2

v6.020 DTW: MASTER

Folder: Safety Call Day 514

Form: Continuing

Generated On: 26 Nov 2020 14:07:14

	Field Name	Data Type	Field Label	Values	Include Field OID
①	CONTYN	\$1	Is the participant continuing to the next visit?	Y = Yes N = No	CONTYN
②	CONTFLAG	1	Continuing Flag		CONTFLAG

v6.020 DTW: MASTER

Folder: Safety Call Day 544

Form: Safety Call

Generated On: 26 Nov 2020 14:07:14

Was Contact Attempted? Yes ☐ **1**
No ☐

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

Please select one status for the follow-up contact
Contact Made ☐ **3**
Contact Not Made ☐

Comments **4**

If Contact Not Made, please provide Comments

v6.020 DTW: MASTER

Folder: Safety Call Day 544

Form: Safety Call

Generated On: 26 Nov 2020 14:07:14

	Field Name	Data Type	Field Label	Values	Include Field OID
①	SCCONATT	\$1	Was Contact Attempted?	Y = Yes N = No	SCCONATT
②	SCCONDAT	dd MMM yyyy	Date of Contact or Contact Attempt (<i>dd MMM yyyy</i>)		SCCONDAT
③	SCSTATUS	\$16	Please select one status for the follow-up contact	CONTACT MADE = Contact Made CONTACT NOT MADE = Contact Not Made	SCSTATUS
④	SCREAS	\$200	Comments <i>If Contact Not Made, please provide Comments</i>		SCREAS

v6.020 DTW: MASTER

Folder: Safety Call Day 544

Form: Continuing

Generated On: 26 Nov 2020 14:07:14

Is the participant continuing to the next visit?

Yes ☐ **1**

No ☐

Continuing Flag

2

v6.020 DTW: MASTER

Folder: Safety Call Day 544

Form: Continuing

Generated On: 26 Nov 2020 14:07:14

	Field Name	Data Type	Field Label	Values	Include Field OID
①	CONTYN	\$1	Is the participant continuing to the next visit?	Y = Yes N = No	CONTYN
②	CONTFLAG	1	Continuing Flag		CONTFLAG

v6.020 DTW: MASTER

Folder: Safety Call Day 604

Form: Safety Call

Generated On: 26 Nov 2020 14:07:14

Was Contact Attempted? Yes ☐ **1**
No ☐

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

Please select one status for the follow-up contact
Contact Made ☐ **3**
Contact Not Made ☐

Comments **4**

If Contact Not Made, please provide Comments

v6.020 DTW: MASTER

Folder: Safety Call Day 604

Form: Safety Call

Generated On: 26 Nov 2020 14:07:14

	Field Name	Data Type	Field Label	Values	Include Field OID
①	SCCONATT	\$1	Was Contact Attempted?	Y = Yes N = No	SCCONATT
②	SCCONDAT	dd MMM yyyy	Date of Contact or Contact Attempt (<i>dd MMM yyyy</i>)		SCCONDAT
③	SCSTATUS	\$16	Please select one status for the follow-up contact	CONTACT MADE = Contact Made CONTACT NOT MADE = Contact Not Made	SCSTATUS
④	SCREAS	\$200	Comments <i>If Contact Not Made, please provide Comments</i>		SCREAS

v6.020 DTW: MASTER

Folder: Safety Call Day 604

Form: Continuing

Generated On: 26 Nov 2020 14:07:14

Is the participant continuing to the next visit?

Yes ☐ **1**

No ☐

Continuing Flag

2

v6.020 DTW: MASTER

Folder: Safety Call Day 604

Form: Continuing

Generated On: 26 Nov 2020 14:07:14

	Field Name	Data Type	Field Label	Values	Include Field OID
①	CONTYN	\$1	Is the participant continuing to the next visit?	Y = Yes N = No	CONTYN
②	CONTFLAG	1	Continuing Flag		CONTFLAG

v6.020 DTW: MASTER

Folder: Safety Call Day 634

Form: Safety Call

Generated On: 26 Nov 2020 14:07:14

Was Contact Attempted? Yes ☐ **1**
No ☐

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

Please select one status for the follow-up contact
Contact Made ☐ **3**
Contact Not Made ☐

Comments **4**

If Contact Not Made, please provide Comments

v6.020 DTW: MASTER

Folder: Safety Call Day 634

Form: Safety Call

Generated On: 26 Nov 2020 14:07:14

	Field Name	Data Type	Field Label	Values	Include Field OID
①	SCCONATT	\$1	Was Contact Attempted?	Y = Yes N = No	SCCONATT
②	SCCONDAT	dd MMM yyyy	Date of Contact or Contact Attempt (<i>dd MMM yyyy</i>)		SCCONDAT
③	SCSTATUS	\$16	Please select one status for the follow-up contact	CONTACT MADE = Contact Made CONTACT NOT MADE = Contact Not Made	SCSTATUS
④	SCREAS	\$200	Comments <i>If Contact Not Made, please provide Comments</i>		SCREAS

v6.020 DTW: MASTER

Folder: Safety Call Day 634

Form: Continuing

Generated On: 26 Nov 2020 14:07:14

Is the participant continuing to the next visit?

Yes

☐

1

No

☐

Continuing Flag

2

v6.020 DTW: MASTER

Folder: Safety Call Day 634

Form: Continuing

Generated On: 26 Nov 2020 14:07:14

	Field Name	Data Type	Field Label	Values	Include Field OID
①	CONTYN	\$1	Is the participant continuing to the next visit?	Y = Yes N = No	CONTYN
②	CONTFLAG	1	Continuing Flag		CONTFLAG

v6.020 DTW: MASTER

Folder: Safety Call Day 664

Form: Safety Call

Generated On: 26 Nov 2020 14:07:14

Was Contact Attempted? Yes ☐ **1**
No ☐

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

Please select one status for the follow-up contact
Contact Made ☐ **3**
Contact Not Made ☐

Comments **4**

If Contact Not Made, please provide Comments

v6.020 DTW: MASTER**Folder: Safety Call Day 664****Form: Safety Call****Generated On: 26 Nov 2020 14:07:14**

	Field Name	Data Type	Field Label	Values	Include Field OID
①	SCCONATT	\$1	Was Contact Attempted?	Y = Yes N = No	SCCONATT
②	SCCONDAT	dd MMM yyyy	Date of Contact or Contact Attempt (<i>dd MMM yyyy</i>)		SCCONDAT
③	SCSTATUS	\$16	Please select one status for the follow-up contact	CONTACT MADE = Contact Made CONTACT NOT MADE = Contact Not Made	SCSTATUS
④	SCREAS	\$200	Comments <i>If Contact Not Made, please provide Comments</i>		SCREAS

v6.020 DTW: MASTER

Folder: Safety Call Day 664

Form: Continuing

Generated On: 26 Nov 2020 14:07:14

Is the participant continuing to the next visit?

Yes ☐ **1**

No ☐

Continuing Flag

2

v6.020 DTW: MASTER

Folder: Safety Call Day 664

Form: Continuing

Generated On: 26 Nov 2020 14:07:14

	Field Name	Data Type	Field Label	Values	Include Field OID
①	CONTYN	\$1	Is the participant continuing to the next visit?	Y = Yes N = No	CONTYN
②	CONTFLAG	1	Continuing Flag		CONTFLAG

v6.020 DTW: MASTER

Folder: Safety Call Day 694

Form: Safety Call

Generated On: 26 Nov 2020 14:07:14

Was Contact Attempted? Yes ☐ **1**
No ☐

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

Please select one status for the follow-up contact
Contact Made ☐ **3**
Contact Not Made ☐

Comments **4**

If Contact Not Made, please provide Comments

v6.020 DTW: MASTER

Folder: Safety Call Day 694

Form: Safety Call

Generated On: 26 Nov 2020 14:07:14

	Field Name	Data Type	Field Label	Values	Include Field OID
①	SCCONATT	\$1	Was Contact Attempted?	Y = Yes N = No	SCCONATT
②	SCCONDAT	dd MMM yyyy	Date of Contact or Contact Attempt (<i>dd MMM yyyy</i>)		SCCONDAT
③	SCSTATUS	\$16	Please select one status for the follow-up contact	CONTACT MADE = Contact Made CONTACT NOT MADE = Contact Not Made	SCSTATUS
④	SCREAS	\$200	Comments <i>If Contact Not Made, please provide Comments</i>		SCREAS

v6.020 DTW: MASTER

Folder: Safety Call Day 694

Form: Continuing

Generated On: 26 Nov 2020 14:07:14

Is the participant continuing to the next visit?

Yes ☐ **1**

No ☐

Continuing Flag

2

v6.020 DTW: MASTER

Folder: Safety Call Day 694

Form: Continuing

Generated On: 26 Nov 2020 14:07:14

	Field Name	Data Type	Field Label	Values	Include Field OID
①	CONTYN	\$1	Is the participant continuing to the next visit?	Y = Yes N = No	CONTYN
②	CONTFLAG	1	Continuing Flag		CONTFLAG

v6.020 DTW: MASTER

Folder: Safety Call Day 724

Form: Safety Call

Generated On: 26 Nov 2020 14:07:14

Was Contact Attempted? Yes ☐ **1**
No ☐

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

Please select one status for the follow-up contact
Contact Made ☐ **3**
Contact Not Made ☐

Comments **4**

If Contact Not Made, please provide Comments

v6.020 DTW: MASTER**Folder: Safety Call Day 724****Form: Safety Call****Generated On: 26 Nov 2020 14:07:14**

	Field Name	Data Type	Field Label	Values	Include Field OID
①	SCCONATT	\$1	Was Contact Attempted?	Y = Yes N = No	SCCONATT
②	SCCONDAT	dd MMM yyyy	Date of Contact or Contact Attempt (<i>dd MMM yyyy</i>)		SCCONDAT
③	SCSTATUS	\$16	Please select one status for the follow-up contact	CONTACT MADE = Contact Made CONTACT NOT MADE = Contact Not Made	SCSTATUS
④	SCREAS	\$200	Comments <i>If Contact Not Made, please provide Comments</i>		SCREAS

v6.020 DTW: MASTER

Folder: Safety Call Day 724

Form: Continuing

Generated On: 26 Nov 2020 14:07:14

Is the participant continuing to the next visit?

Yes ☐ **1**

No ☐

Continuing Flag

2

v6.020 DTW: MASTER

Folder: Safety Call Day 724

Form: Continuing

Generated On: 26 Nov 2020 14:07:14

	Field Name	Data Type	Field Label	Values	Include Field OID
①	CONTYN	\$1	Is the participant continuing to the next visit?	Y = Yes N = No	CONTYN
②	CONTFLAG	1	Continuing Flag		CONTFLAG

v6.020 DTW: MASTER

Folder: Visit 6 Day 759

Form: Visit Date

Generated On: 26 Nov 2020 14:07:14

Was this visit performed?	Yes <input type="checkbox"/>	1
	No <input type="checkbox"/>	
Visit date (dd MMM yyyy)		2
Was visit performed at the participant's home or at the clinic?	Home <input type="checkbox"/>	3
	Clinic <input type="checkbox"/>	
Folder OID		4

v6.020 DTW: MASTER**Folder: Visit 6 Day 759****Form: Visit Date****Generated On: 26 Nov 2020 14:07:14**

	Field Name	Data Type	Field Label	Values	Include Field OID
1	VISITYN	\$1	Was this visit performed?	Y = Yes N = No	VISITYN
2	VISITDAT	dd MMM yyyy	Visit date (dd MMM yyyy)		VISITDAT
3	VISTYPE	\$6	Was visit performed at the participant's home or at the clinic?	Home = Home Clinic = Clinic	VISTYPE
4	FOLDER_OID	\$15	Folder OID		FOLDER_OID

v6.020 DTW: MASTER

Folder: Visit 6 Day 759

Form: Physical Examination

Generated On: 26 Nov 2020 14:07:14

Was the physical examination performed?

Yes ☐ **1**

No ☐

Date of examination (dd MMM yyyy)

2

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

v6.020 DTW: MASTER

Folder: Visit 6 Day 759

Form: Physical Examination

Generated On: 26 Nov 2020 14:07:14

	Field Name	Data Type	Field Label	Values	Include Field OID
1	PEYN	\$1	Was the physical examination performed?	Y = Yes N = No	PEYN
2	PEDAT	dd MMM yyyy	Date of examination (<i>dd MMM yyyy</i>)		PEDAT

v6.020 DTW: MASTER

Folder: Visit 6 Day 759

Form: Immunogenicity Assessment

Generated On: 26 Nov 2020 14:07:14

Was the sample collected?	Yes <input type="checkbox"/>	1
	No <input type="checkbox"/>	
Collection date (<i>dd MMM yyyy</i>)		2
Collection time (<i>00:00-23:59</i>)	Fixed Unit: (24 HR)	3
Collection date and time (derived)		4

v6.020 DTW: MASTER**Folder: Visit 6 Day 759****Form: Immunogenicity Assessment****Generated On: 26 Nov 2020 14:07:14**

	Field Name	Data Type	Field Label	Values	Include Field OID
①	LBPERF	\$1	Was the sample collected?	Y = Yes N = No	LBPERF
②	LBDAT	dd MMM yyyy	Collection date (<i>dd MMM yyyy</i>)		LBDAT
③	LBTIM	HH:nn	Collection time (<i>00:00-23:59</i>)		LBTIM
④	LBDTTM	dd MMM yyyy HH:nn	Collection date and time (derived)		LBDTTM

v6.020 DTW: MASTER

Folder: Covid-19 Assessment

Form: COVID-19 Contact

Generated On: 26 Nov 2020 14:07:14

Date of Contact		1
Time of Contact		2
Date and Time of Contact (derived)		3
Type of Contact	Clinic Visit - Scheduled	4
	Clinical Visit - Unscheduled	
	Safety Call	
	Convalescent Tele-visit	
Has the subject reported symptoms of SARS-COV-2?	Yes	5
	No	

v6.020 DTW: MASTER**Folder: Covid-19 Assessment****Form: COVID-19 Contact****Generated On: 26 Nov 2020 14:07:14**

	Field Name	Data Type	Field Label	Values	Include Field OID
①	SICKDT	dd MMM yyyy	Date of Contact		SICKDT
②	SICKTIM	HH:nn	Time of Contact		SICKTIM
③	SICKDTTM	dd MMM yyyy HH:nn	Date and Time of Contact (derived)		SICKDTTM
④	SICKTYP	\$30	Type of Contact	Clinic Visit - Scheduled = Clinic Visit - Scheduled Clinical Visit - Unscheduled = Clinical Visit - Unscheduled Safety Call = Safety Call Convalescent Tele-visit = Convalescent Tele-visit	SICKTYP
⑤	SICKSYMP	\$1	Has the subject reported symptoms of SARS-COV-2 ?	Y = Yes N = No	SICKSYMP

v6.020 DTW: MASTER

Folder: Covid-19 Assessment

Form: Symptom Log

Generated On: 26 Nov 2020 14:07:14

Symptom Day

Day 1	<input checked="" type="checkbox"/>
Day 2	<input type="checkbox"/>
Day 3	<input type="checkbox"/>
Day 4	<input type="checkbox"/>
Day 5	<input type="checkbox"/>
Day 6	<input type="checkbox"/>
Day 7	<input type="checkbox"/>
Day 8	<input type="checkbox"/>
Day 9	<input type="checkbox"/>
Day 10	<input type="checkbox"/>
Day 11	<input type="checkbox"/>
Day 12	<input type="checkbox"/>
Day 13	<input type="checkbox"/>
Day 14	<input type="checkbox"/>
Day 15	<input type="checkbox"/>
Day 16	<input type="checkbox"/>
Day 17	<input type="checkbox"/>
Day 18	<input type="checkbox"/>
Day 19	<input type="checkbox"/>
Day 20	<input type="checkbox"/>
Day 21	<input type="checkbox"/>
Day 22	<input type="checkbox"/>
Day 23	<input type="checkbox"/>
Day 24	<input type="checkbox"/>
Day 25	<input type="checkbox"/>
Day 26	<input type="checkbox"/>
Day 27	<input type="checkbox"/>
Day 28	<input type="checkbox"/>
Day 29	<input type="checkbox"/>
Day 30	<input type="checkbox"/>
Day 31	<input type="checkbox"/>
Day 32	<input type="checkbox"/>
Day 33	<input type="checkbox"/>

v6.020 DTW: MASTER

Folder: Covid-19 Assessment

Form: Symptom Log

Generated On: 26 Nov 2020 14:07:14

	Day 34	<input type="checkbox"/>
	Day 35	<input type="checkbox"/>
	Day 36	<input type="checkbox"/>
	Day 37	<input type="checkbox"/>
	Day 38	<input type="checkbox"/>
	Day 39	<input type="checkbox"/>
	Day 40	<input type="checkbox"/>
Date		<input type="checkbox"/> 2
Assessment Not Done		<input type="checkbox"/> 3
O2 Saturation	Fixed Unit: %	<input type="checkbox"/> 4
O2 Saturation Units		<input type="checkbox"/> 5
Temperature	C <input type="checkbox"/>	<input type="checkbox"/> 6
	F <input type="checkbox"/>	
Chills	None <input type="checkbox"/>	<input type="checkbox"/> 7
	Mild <input type="checkbox"/>	
	Moderate <input type="checkbox"/>	
	Severe <input type="checkbox"/>	
	Not Done <input type="checkbox"/>	
Cough	None <input type="checkbox"/>	<input type="checkbox"/> 8
	Mild <input type="checkbox"/>	
	Moderate <input type="checkbox"/>	
	Severe <input type="checkbox"/>	
	Not Done <input type="checkbox"/>	
Shortness of Breath	None <input type="checkbox"/>	<input type="checkbox"/> 9
	Mild <input type="checkbox"/>	
	Moderate <input type="checkbox"/>	
	Severe <input type="checkbox"/>	
	Not Done <input type="checkbox"/>	
Difficulty Breathing	None <input type="checkbox"/>	<input type="checkbox"/> 10
	Mild <input type="checkbox"/>	
	Moderate <input type="checkbox"/>	

v6.020 DTW: MASTER

Folder: Covid-19 Assessment

Form: Symptom Log

Generated On: 26 Nov 2020 14:07:14

	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
Fatigue	None	<input checked="" type="checkbox"/> 11
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
Muscle Aches (Myalgia)	None	<input checked="" type="checkbox"/> 12
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
Body Aches	None	<input checked="" type="checkbox"/> 13
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
Headache	None	<input checked="" type="checkbox"/> 14
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
New Loss of Taste	None	<input checked="" type="checkbox"/> 15
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
New Loss of Smell	None	<input checked="" type="checkbox"/> 16
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>

v6.020 DTW: MASTER

Folder: Covid-19 Assessment

Form: Symptom Log

Generated On: 26 Nov 2020 14:07:14

Nasal Congestion	None	<input type="checkbox"/>	17
	Mild	<input type="checkbox"/>	
	Moderate	<input type="checkbox"/>	
	Severe	<input type="checkbox"/>	
	Not Done	<input type="checkbox"/>	
Runny Nose (Rhinorrhea)	None	<input type="checkbox"/>	18
	Mild	<input type="checkbox"/>	
	Moderate	<input type="checkbox"/>	
	Severe	<input type="checkbox"/>	
	Not Done	<input type="checkbox"/>	
Nausea	None	<input type="checkbox"/>	19
	Mild	<input type="checkbox"/>	
	Moderate	<input type="checkbox"/>	
	Severe	<input type="checkbox"/>	
	Not Done	<input type="checkbox"/>	
Vomiting	None	<input type="checkbox"/>	20
	Mild	<input type="checkbox"/>	
	Moderate	<input type="checkbox"/>	
	Severe	<input type="checkbox"/>	
	Not Done	<input type="checkbox"/>	
Diarrhea	None	<input type="checkbox"/>	21
	Mild	<input type="checkbox"/>	
	Moderate	<input type="checkbox"/>	
	Severe	<input type="checkbox"/>	
	Not Done	<input type="checkbox"/>	
Sore Throat	None	<input type="checkbox"/>	22
	Mild	<input type="checkbox"/>	
	Moderate	<input type="checkbox"/>	
	Severe	<input type="checkbox"/>	
	Not Done	<input type="checkbox"/>	

v6.020 DTW: MASTER

Folder: Covid-19 Assessment

Form: Symptom Log

Generated On: 26 Nov 2020 14:07:14

Field Name	Data Type	Field Label	Values	Include Field OID
1 DAY	\$6	Symptom Day	Day 1 = Day 1 Day 2 = Day 2 Day 3 = Day 3 Day 4 = Day 4 Day 5 = Day 5 Day 6 = Day 6 Day 7 = Day 7 Day 8 = Day 8 Day 9 = Day 9 Day 10 = Day 10 Day 11 = Day 11 Day 12 = Day 12 Day 13 = Day 13 Day 14 = Day 14 Day 15 = Day 15 Day 16 = Day 16 Day 17 = Day 17 Day 18 = Day 18 Day 19 = Day 19 Day 20 = Day 20 Day 21 = Day 21 Day 22 = Day 22 Day 23 = Day 23 Day 24 = Day 24 Day 25 = Day 25	1 DAY

v6.020 DTW: MASTER

Folder: Covid-19 Assessment

Form: Symptom Log

Generated On: 26 Nov 2020 14:07:14

Field Name	Data Type	Field Label	Values	Include Field OID
			Day 26 = Day 26 Day 27 = Day 27 Day 28 = Day 28 Day 29 = Day 29 Day 30 = Day 30 Day 31 = Day 31 Day 32 = Day 32 Day 33 = Day 33 Day 34 = Day 34 Day 35 = Day 35 Day 36 = Day 36 Day 37 = Day 37 Day 38 = Day 38 Day 39 = Day 39 Day 40 = Day 40	
2 SYMPDAT	dd MMM yyyy	Date		SYMPDAT
3 SYMPND	1	Assessment Not Done		SYMPND
4 SYMPO2	3	O2 Saturation		SYMPO2
5 SYMPO2U	\$1	O2 Saturation Units		SYMPO2U
6 SYMPTEMP	4.1	Temperature		SYMPTEMP
7 SYMPCHILL	\$10	Chills	None = None Mild = Mild	SYMPCHILL

v6.020 DTW: MASTER

Folder: Covid-19 Assessment

Form: Symptom Log

Generated On: 26 Nov 2020 14:07:14

Field Name	Data Type	Field Label	Values	Include Field OID
			Moderate = Moderate Severe = Severe Not Done = Not Done	
8 SYMPCOUG H	\$10	Cough	None = None Mild = Mild Moderate = Moderate Severe = Severe Not Done = Not Done	SYMPCOUG H
9 SYMPBREA	\$10	Shortness of Breath	None = None Mild = Mild Moderate = Moderate Severe = Severe Not Done = Not Done	SYMPBREA
10 SYMPDFF	\$10	Difficulty Breathing	None = None Mild = Mild Moderate = Moderate Severe = Severe Not Done = Not Done	SYMPDFF
11 SYMPFATG	\$10	Fatigue	None = None Mild = Mild Moderate = Moderate Severe = Severe Not Done = Not Done	SYMPFATG
12 SYMPMUSC L	\$10	Muscle Aches (Myalgia)	None = None Mild = Mild	SYMPMUSC L

v6.020 DTW: MASTER

Folder: Covid-19 Assessment

Form: Symptom Log

Generated On: 26 Nov 2020 14:07:14

Field Name	Data Type	Field Label	Values	Include Field OID
			Moderate = Moderate Severe = Severe Not Done = Not Done	
13 SYMPBODY	\$10	Body Aches	None = None Mild = Mild Moderate = Moderate Severe = Severe Not Done = Not Done	SYMPBODY
14 SYMPHEAD	\$10	Headache	None = None Mild = Mild Moderate = Moderate Severe = Severe Not Done = Not Done	SYMPHEAD
15 SYMPTAST	\$10	New Loss of Taste	None = None Mild = Mild Moderate = Moderate Severe = Severe Not Done = Not Done	SYMPTAST
16 SYMPSMLL	\$10	New Loss of Smell	None = None Mild = Mild Moderate = Moderate Severe = Severe Not Done = Not Done	SYMPSMLL
17 SYMPCNGS	\$10	Nasal Congestion	None = None Mild = Mild	SYMPCNGS

v6.020 DTW: MASTER

Folder: Covid-19 Assessment

Form: Symptom Log

Generated On: 26 Nov 2020 14:07:14

Field Name	Data Type	Field Label	Values	Include Field OID
			Moderate = Moderate Severe = Severe Not Done = Not Done	
18 SYMPNOSE	\$10	Runny Nose (Rhinorrhea)	None = None Mild = Mild Moderate = Moderate Severe = Severe Not Done = Not Done	SYMPNOSE
19 SYMPNAUS	\$10	Nausea	None = None Mild = Mild Moderate = Moderate Severe = Severe Not Done = Not Done	SYMPNAUS
20 SYMPVOMT	\$10	Vomiting	None = None Mild = Mild Moderate = Moderate Severe = Severe Not Done = Not Done	SYMPVOMT
21 SYMPDRRH	\$10	Diarrhea	None = None Mild = Mild Moderate = Moderate Severe = Severe Not Done = Not Done	SYMPDRRH
22 SYMPHRT	\$10	Sore Throat	None = None Mild = Mild	SYMPHRT

v6.020 DTW: MASTER

Folder: Covid-19 Assessment

Form: Symptom Log

Generated On: 26 Nov 2020 14:07:14

Field Name	Data Type	Field Label	Values	Include Field OID
			Moderate = Moderate Severe = Severe Not Done = Not Done	

v6.020 DTW: MASTER

Folder: Covid-19 Assessment

Form: COVID Diagnostic Test

Generated On: 26 Nov 2020 14:07:14

Date of Visit	_____	1
Was the Subject Tested For SARS-CoV-2 by RT-PCR?	Yes <input type="checkbox"/> No <input type="checkbox"/>	2
Did Subject Test Positive For SARS-CoV-2 by RT-PCR?	Yes <input type="checkbox"/> No <input type="checkbox"/>	3
Date of Test	_____	4
Type of Test Performed	Nasopharyngeal Swab <input type="checkbox"/> Nasal Swab <input type="checkbox"/> Saliva Test <input type="checkbox"/> Other <input type="checkbox"/>	5
Other, specify	_____	6
Was this diagnostic test performed at a lab other than the Study Central Lab?	Yes <input type="checkbox"/> No <input type="checkbox"/>	7
If yes, provide lab information below		
Lab/ Institution Test Performed	_____	9
CLIA Certified?	Yes <input type="checkbox"/> No <input type="checkbox"/>	10
COVID-19 Positive (CSA Programming Field Only)	_____	11

v6.020 DTW: MASTER

Folder: Covid-19 Assessment

Form: COVID Diagnostic Test

Generated On: 26 Nov 2020 14:07:14

	Field Name	Data Type	Field Label	Values	Include Field OID
1	LDTVISDT	dd MMM yyyy	Date of Visit		LDTVISDT
2	LDTCOV1	\$1	Was the Subject Tested For SARS-CoV-2 by RT-PCR?	Y = Yes N = No	LDTCOV1
3	LDTCOV2	\$1	Did Subject Test Positive For SARS-CoV-2 by RT-PCR?	Y = Yes N = No	LDTCOV2
4	LDTDAT	dd MMM yyyy	Date of Test		LDTDAT
5	LDTTEST	\$20	Type of Test Performed	Nasopharyngeal Swab = Nasopharyngeal Swab Nasal Swab = Nasal Swab Saliva Test = Saliva Test Other = Other	LDTTEST
6	LDTTESTO	\$200	Other, specify		LDTTESTO
7	LDTPERF	\$1	Was this diagnostic test performed at a lab other than the Study Central Lab?	Y = Yes N = No	LDTPERF
9	LDTLAB	\$200	Lab/ Institution Test Performed		LDTLAB
10	LDTCLIA	\$1	CLIA Certified?	Y = Yes N = No	LDTCLIA
11	LDTCOV2_D 1		COVID-19 Positive (CSA Programming Field Only)		LDTCOV2_D

v6.020 DTW: MASTER

Folder: Covid-19 Assessment

Form: Covid-19 Severity Assessment

Generated On: 26 Nov 2020 14:07:14

Did the subject have Respiratory Rates ≥ 30 per Minute? Yes ☐ **1**
No ☐

If Yes, provide:

Start Date _____ **3**

End Date _____ **4**

Respiratory Rate _____ Fixed Unit: /minute **5**

Did the subject have Heart Rate ≥ 125 beats per minute? Yes ☐ **6**
No ☐

If Yes, provide:

Start Date _____ **8**

End Date _____ **9**

Heart Rate _____ Fixed Unit: BPM **10**

Did the subject have Oxygen Saturation of SpO₂ $\leq 93\%$ on room air at sea level? Yes ☐ **11**
No ☐

If Yes, provide:

Start Date _____ **13**

End Date _____ **14**

Oxygen Saturation _____ Fixed Unit: % **15**

Did the subject have PaO₂/FIO₂ Ratio < 300 mm Hg? Yes ☐ **16**
No ☐

If Yes, provide:

Start Date _____ **18**

End Date _____ **19**

PaO₂ _____ Fixed Unit: mmHg **20**

Did the subject have Respiratory failure? Yes ☐ **22**
No ☐

Start Date _____ **23**

v6.020 DTW: MASTER

Folder: Covid-19 Assessment

Form: Covid-19 Severity Assessment

Generated On: 26 Nov 2020 14:07:14

Did the subject have Acute Respiratory Distress Syndrome (ARDS)? Yes ☐ **24**
No ☐

Start Date _____ **25**

If Yes to either Did subject require any of the following:

Ventilator Support:

High-Flow Oxygen? Yes ☐ **28**
No ☐

Start Date _____ **29**

End Date _____ **30**

Non-Invasive Ventilation? Yes ☐ **31**
No ☐

Start Date _____ **32**

End Date _____ **33**

Mechanical Ventilation? Yes ☐ **34**
No ☐

Start Date _____ **35**

End Date _____ **36**

ECMO? Yes ☐ **37**
No ☐

Start Date _____ **38**

End Date _____ **39**

Evidence of Shock:

Systolic Blood Pressure < 90 mmHg, Diastolic Blood Pressure < 60 mmHg Yes ☐ **41**
No ☐

Start Date _____ **42**

End Date _____ **43**

Evidence of Shock Requires Vasopressors Yes ☐ **44**
No ☐

Start Date _____ **45**

End Date _____ **46**

Acute Renal Dysfunction? Yes ☐ **47**
No ☐

v6.020 DTW: MASTER

Folder: Covid-19 Assessment

Form: Covid-19 Severity Assessment

Generated On: 26 Nov 2020 14:07:14

Start Date		48
Hepatic Dysfunction?	Yes <input type="checkbox"/>	49
	No <input type="checkbox"/>	
Start Date		50
Neurologic Dysfunction?	Yes <input type="checkbox"/>	51
	No <input type="checkbox"/>	
Start Date		52
Evidence of Pneumonia:		
Clinical Evidence	Yes <input type="checkbox"/>	54
	No <input type="checkbox"/>	
Date of Assessment		55
Radiographical Evidence	Yes <input type="checkbox"/>	56
	No <input type="checkbox"/>	
Date of Assessment		57
Admission to an intensive care unit due to SARS-CoV-2	Yes <input type="checkbox"/>	59
	No <input type="checkbox"/>	
Start Date		60
End Date		61

v6.020 DTW: MASTER

Folder: Covid-19 Assessment

Form: Covid-19 Severity Assessment

Generated On: 26 Nov 2020 14:07:14

	Field Name	Data Type	Field Label	Values	Include Field OID
1	RESPYN	\$1	Did the subject have Respiratory Rates ≥ 30 per Minute?	Y = Yes N = No	RESPYN
3	RSPSTDAT	dd MMM yyyy	Start Date		RSPSTDAT
4	RSPENDAT	dd MMM yyyy	End Date		RSPENDAT
5	RESP	3	Respiratory Rate		RESP
6	HRYN	\$1	Did the subject have Heart Rate ≥ 125 beats per minute	Y = Yes N = No	HRYN
8	HRSTDAT	dd MMM yyyy	Start Date		HRSTDAT
9	HRENDAT	dd MMM yyyy	End Date		HRENDAT
10	HR	3	Heart Rate		HR
11	SPO2YN	\$1	Did the subject have Oxygen Saturation of SpO2 $\leq 93\%$ on room air at sea level?	Y = Yes N = No	SPO2YN
13	SPO2STDAT	dd MMM yyyy	Start Date		SPO2STDAT
14	SPO2ENDAT	dd MMM yyyy	End Date		SPO2ENDAT
15	SPO2	3	Oxygen Saturation		SPO2
16	PAO2YN	\$1	Did the subject have PaO2/FIO2 Ratio < 300 mm Hg?	Y = Yes N = No	PAO2YN

v6.020 DTW: MASTER

Folder: Covid-19 Assessment

Form: Covid-19 Severity Assessment

Generated On: 26 Nov 2020 14:07:14

	Field Name	Data Type	Field Label	Values	Include Field OID
18	PAO2STDAT	dd MMM yyyy	Start Date		PAO2STDAT
19	PAO2ENDAT	dd MMM yyyy	End Date		PAO2ENDAT
20	PAO2	3	PaO2		PAO2
22	RESPFAIL	\$1	Did the subject have Respiratory failure?	Y = Yes N = No	RESPFAIL
23	RESPSTD	dd MMM yyyy	Start Date		RESPSTD
24	ARDS	\$1	Did the subject have Acute Respiratory Distress Syndrome (ARDS)?	Y = Yes N = No	ARDS
25	ARDSSTD	dd MMM yyyy	Start Date		ARDSSTD
28	HIGHOX	\$1	High-Flow Oxygen?	Y = Yes N = No	HIGHOX
29	OXSTD	dd MMM yyyy	Start Date		OXSTD
30	OXENDT	dd MMM yyyy	End Date		OXENDT
31	NONINVS	\$1	Non-Invasive Ventilation?	Y = Yes N = No	NONINVS
32	NINVSTD	dd MMM yyyy	Start Date		NINVSTD
33	NINVENDT	dd MMM yyyy	End Date		NINVENDT
34	MECHVENT	\$1	Mechanical Ventilation?	Y = Yes N = No	MECHVENT
35	MECHSTD	dd MMM yyyy	Start Date		MECHSTD
36	MECHENDT	dd MMM yyyy	End Date		MECHENDT

v6.020 DTW: MASTER

Folder: Covid-19 Assessment

Form: Covid-19 Severity Assessment

Generated On: 26 Nov 2020 14:07:14

	Field Name	Data Type	Field Label	Values	Include Field OID
37	ECMO	\$1	ECMO?	Y = Yes N = No	ECMO
38	ECMOSTDT	dd MMM yyyy	Start Date		ECMOSTDT
39	ECMOENDT	dd MMM yyyy	End Date		ECMOENDT
41	MMHG	\$1	Systolic Blood Pressure < 90 mmHg, Diastolic Blood Pressure < 60 mmHg	Y = Yes N = No	MMHG
42	MMHGSTDT	dd MMM yyyy	Start Date		MMHGSTDT
43	MMHGENDT	dd MMM yyyy	End Date		MMHGENDT
44	VASO	\$1	Evidence of Shock Requires Vasopressors	Y = Yes N = No	VASO
45	VASOSTDT	dd MMM yyyy	Start Date		VASOSTDT
46	VASOENDT	dd MMM yyyy	End Date		VASOENDT
47	RENAL	\$1	Acute Renal Dysfunction?	Y = Yes N = No	RENAL
48	RENSTDT	dd MMM yyyy	Start Date		RENSTDT
49	HEPDYS	\$1	Hepatic Dysfunction?	Y = Yes N = No	HEPDYS
50	HEPSTDT	dd MMM yyyy	Start Date		HEPSTDT
51	NEUR	\$1	Neurologic Dysfunction?	Y = Yes N = No	NEUR
52	NEURSTDT	dd MMM yyyy	Start Date		NEURSTDT

v6.020 DTW: MASTER**Folder: Covid-19 Assessment****Form: Covid-19 Severity Assessment****Generated On: 26 Nov 2020 14:07:14**

	Field Name	Data Type	Field Label	Values	Include Field OID
54	CLINEVD	\$1	Clinical Evidence	Y = Yes N = No	CLINEVD
55	CLINSTDT	dd MMM yyyy	Date of Assessment		CLINSTDT
56	RADIO	\$1	Radiographica l Evidence	Y = Yes N = No	RADIO
57	RADSTDT	dd MMM yyyy	Date of Assessment		RADSTDT
59	ICU	\$1	Admission to an intensive care unit due to SARS-CoV-2	Y = Yes N = No	ICU
60	ICUSTDT	dd MMM yyyy	Start Date		ICUSTDT
61	ICUENDT	dd MMM yyyy	End Date		ICUENDT

v6.020 DTW: MASTER

Folder: Illness Visit

Form: Saliva Collection

Generated On: 26 Nov 2020 14:07:14

Visit	Day 3	<input checked="" type="checkbox"/>	1
	Day 5	<input type="checkbox"/>	
	Day 7	<input type="checkbox"/>	
	Day 9	<input type="checkbox"/>	
	Day 14	<input type="checkbox"/>	
	Day 21	<input type="checkbox"/>	
	Day 28	<input type="checkbox"/>	

Was Saliva Collected?	Yes	<input checked="" type="checkbox"/>	2
	No	<input type="checkbox"/>	
	NA (COVID-19 Negative)	<input type="checkbox"/>	

Date of Collection			3
--------------------	--	--	---

Visit	Day 3	<input checked="" type="checkbox"/>	1
	Day 5	<input type="checkbox"/>	
	Day 7	<input type="checkbox"/>	
	Day 9	<input type="checkbox"/>	
	Day 14	<input type="checkbox"/>	
	Day 21	<input type="checkbox"/>	
	Day 28	<input type="checkbox"/>	

Was Saliva Collected?	Yes	<input checked="" type="checkbox"/>	2
	No	<input type="checkbox"/>	
	NA (COVID-19 Negative)	<input type="checkbox"/>	

Date of Collection			3
--------------------	--	--	---

Visit	Day 3	<input checked="" type="checkbox"/>	1
	Day 5	<input type="checkbox"/>	
	Day 7	<input type="checkbox"/>	
	Day 9	<input type="checkbox"/>	
	Day 14	<input type="checkbox"/>	
	Day 21	<input type="checkbox"/>	
	Day 28	<input type="checkbox"/>	

Was Saliva Collected?	Yes	<input checked="" type="checkbox"/>	2
	No	<input type="checkbox"/>	
	NA (COVID-19 Negative)	<input type="checkbox"/>	

v6.020 DTW: MASTER

Folder: Illness Visit

Form: Saliva Collection

Generated On: 26 Nov 2020 14:07:14

Date of Collection		3
Visit	Day 3	1
	Day 5	
	Day 7	
	Day 9	
	Day 14	
	Day 21	
	Day 28	
Was Saliva Collected?	Yes	2
	No	
	NA (COVID-19 Negative)	

Date of Collection		3
Visit	Day 3	1
	Day 5	
	Day 7	
	Day 9	
	Day 14	
	Day 21	
	Day 28	
Was Saliva Collected?	Yes	2
	No	
	NA (COVID-19 Negative)	

Date of Collection		3
Visit	Day 3	1
	Day 5	
	Day 7	
	Day 9	
	Day 14	
	Day 21	
	Day 28	
Was Saliva Collected?	Yes	2
	No	

v6.020 DTW: MASTER

Folder: Illness Visit

Form: Saliva Collection

Generated On: 26 Nov 2020 14:07:14

NA (COVID-19 Negative)		<input type="checkbox"/>
Date of Collection		<input type="checkbox"/> 3
Visit	Day 3	<input type="checkbox"/> 1
	Day 5	<input type="checkbox"/>
	Day 7	<input type="checkbox"/>
	Day 9	<input type="checkbox"/>
	Day 14	<input type="checkbox"/>
	Day 21	<input type="checkbox"/>
	Day 28	<input checked="" type="checkbox"/>
Was Saliva Collected?	Yes	<input type="checkbox"/> 2
	No	<input type="checkbox"/>
NA (COVID-19 Negative)		<input type="checkbox"/>
Date of Collection		<input type="checkbox"/> 3

v6.020 DTW: MASTER**Folder: Illness Visit****Form: Saliva Collection****Generated On: 26 Nov 2020 14:07:14**

Field Name	Data Type	Field Label	Values	Include Field OID
1 SALVISIT	\$6	Visit	Day 3 = Day 3 Day 5 = Day 5 Day 7 = Day 7 Day 9 = Day 9 Day 14 = Day 14 Day 21 = Day 21 Day 28 = Day 28	SALVISIT
2 SALIVAYN	\$2	Was Saliva Collected?	Y = Yes N = No NA = NA (COVID-19 Negative)	SALIVAYN
3 SALIVADT	dd MMM yyyy	Date of Collection		SALIVADT

v6.020 DTW: MASTER

Folder: Illness Visit Day 1

Form: Visit Date

Generated On: 26 Nov 2020 14:07:14

Was this visit performed?	Yes <input type="checkbox"/>	1
	No <input type="checkbox"/>	
Visit date (dd MMM yyyy)		2
Was visit performed at the participant's home or at the clinic?	Home <input type="checkbox"/>	3
	Clinic <input type="checkbox"/>	
Folder OID		4

v6.020 DTW: MASTER**Folder: Illness Visit Day 1****Form: Visit Date****Generated On: 26 Nov 2020 14:07:14**

	Field Name	Data Type	Field Label	Values	Include Field OID
1	VISITYN	\$1	Was this visit performed?	Y = Yes N = No	VISITYN
2	VISITDAT	dd MMM yyyy	Visit date (dd MMM yyyy)		VISITDAT
3	VISTYPE	\$6	Was visit performed at the participant's home or at the clinic?	Home = Home Clinic = Clinic	VISTYPE
4	FOLDER_OID	\$15	Folder OID		FOLDER_OID

v6.020 DTW: MASTER

Folder: Illness Visit Day 1

Form: Vital Signs

Generated On: 26 Nov 2020 14:07:14

Were vital signs assessed?	Yes <input type="checkbox"/>	1
	No <input type="checkbox"/>	
Date of assessment (<i>dd MMM yyyy</i>)		2
Time of assessment (<i>00:00-23:59</i>)	Fixed Unit: (24 HR)	3
Vital Signs Date and Time (derived)		4
Height (<i>xxx.x</i>)	cm <input type="checkbox"/>	5
	in <input type="checkbox"/>	
Weight (<i>xxx.x</i>)	kg <input type="checkbox"/>	6
	lb <input type="checkbox"/>	
BMI (<i>xxx.x</i>)	Fixed Unit: kg/m ²	7
BMI units		8
Temperature (<i>xxx.x</i>)	C <input type="checkbox"/>	9
	F <input type="checkbox"/>	
Route of measurement	Oral <input type="checkbox"/>	10
	Axillary <input type="checkbox"/>	
	Other <input type="checkbox"/>	
If Other, specify		11
Pulse (<i>xxx</i>)	Fixed Unit: beats/min	12
Pulse units		13
Respiratory Rate (<i>xxx</i>)	Fixed Unit: breaths/min	14
Respiratory Rate units		15
Systolic Blood Pressure (<i>xxx</i>)	Fixed Unit: mmHg	16
Systolic Blood Pressure units		17
Diastolic Blood Pressure (<i>xxx</i>)	Fixed Unit: mmHg	18
Diastolic Blood Pressure units		19
Height (derived)	Fixed Unit: cm	20

v6.020 DTW: MASTER

Folder: Illness Visit Day 1

Form: Vital Signs

Generated On: 26 Nov 2020 14:07:14

Weight (derived)

Fixed Unit: kg

21

v6.020 DTW: MASTER

Folder: Illness Visit Day 1

Form: Vital Signs

Generated On: 26 Nov 2020 14:07:14

	Field Name	Data Type	Field Label	Values	Include Field OID
1	VSPERF	\$1	Were vital signs assessed?	Y = Yes N = No	VSPERF
2	VSDAT	dd MMM yyyy	Date of assessment (<i>dd MMM yyyy</i>)		VSDAT
3	VSTIM	HH:nn	Time of assessment (<i>00:00-23:59</i>)		VSTIM
4	VSDTTIM	dd MMM yyyy HH:nn	Vital Signs Date and Time (derived)		VSDTTIM
5	HEIGHT_VS ORRES	20.5	Height (<i>xxx.x</i>)		HEIGHT_VS ORRES
6	WEIGHT_VS ORRES	20.5	Weight (<i>xxx.x</i>)		WEIGHT_VS ORRES
7	VSBMI	20.5	BMI (<i>xxx.x</i>)		VSBMI
8	VSBMUI	\$10	BMI units		VSBMUI
9	TEMP_VSOR RES	20.5	Temperature (<i>xxx.x</i>)		TEMP_VSOR RES
10	VSROUTE	\$8	Route of measurement	Oral = Oral Axillary = Axillary Other = Other	VSROUTE
11	VSROUTESP	\$200	If Other, specify		VSROUTESP
12	HR_VSORRE S	3	Pulse (<i>xxx</i>)		HR_VSORRE S
13	HR_VSORRE SU	\$9	Pulse units		HR_VSORRE SU
14	RR_VSORRE S	3	Respiratory Rate (<i>xxx</i>)		RR_VSORRE S
15	RR_VSORRE SU	\$11	Respiratory Rate units		RR_VSORRE SU
16	SYSBP_VSO RRES	3	Systolic Blood Pressure (<i>xxx</i>)		SYSBP_VSO RRES

v6.020 DTW: MASTER**Folder: Illness Visit Day 1****Form: Vital Signs****Generated On: 26 Nov 2020 14:07:14**

	Field Name	Data Type	Field Label	Values	Include Field OID
17	SYSBP_VSO RRESU	\$4	Systolic Blood Pressure units		SYSBP_VSO RRESU
18	DIABP_VSO RRES	3	Diastolic Blood Pressure (xxx)		DIABP_VSO RRES
19	DIABP_VSO RRESU	\$4	Diastolic Blood Pressure units		DIABP_VSO RRESU
20	HEIGHT_D	3	Height (derived)		HEIGHT_D
21	WEIGHT_D	4.1	Weight (derived)		WEIGHT_D

v6.020 DTW: MASTER

Folder: Illness Visit Day 1

Form: Physical Examination

Generated On: 26 Nov 2020 14:07:14

Was the physical examination performed?

Yes ☐ **1**

No ☐

Date of examination (*dd MMM yyyy*)

2

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

v6.020 DTW: MASTER

Folder: Illness Visit Day 1

Form: Physical Examination

Generated On: 26 Nov 2020 14:07:14

	Field Name	Data Type	Field Label	Values	Include Field OID
1	PEYN	\$1	Was the physical examination performed?	Y = Yes N = No	PEYN
2	PEDAT	dd MMM yyyy	Date of examination (<i>dd MMM yyyy</i>)		PEDAT

v6.020 DTW: MASTER

Folder: Illness Visit Day 1

Form: Blood Sample Collection for Immunologic Assessment of SARS-CoV-2 Infection

Generated On: 26 Nov 2020 14:07:14

Was Blood Sample Taken for Immunologic Assessment of SARS_COV-2 Infection?	Yes <input type="checkbox"/>	1
	No <input type="checkbox"/>	
	NA (COVID-19 Negative) <input type="checkbox"/>	
Date of Collection		2

v6.020 DTW: MASTER

Folder: Illness Visit Day 1

Form: Blood Sample Collection for Immunologic Assessment of SARS-CoV-2 Infection

Generated On: 26 Nov 2020 14:07:14

Field Name	Data Type	Field Label	Values	Include Field OID
① IMPPERF	\$2	Was Blood Sample Taken for Immunologic Assessment of SARS_COV-2 Infection?	Y = Yes N = No NA = NA (COVID-19 Negative)	IMMPERF
② IMMDT	dd MMM yyyy	Date of Collection		IMMDT

v6.020 DTW: MASTER

Folder: Convalescence Visit Day 28

Form: Visit Date

Generated On: 26 Nov 2020 14:07:14

Was this visit performed?	Yes <input type="checkbox"/>	1
	No <input type="checkbox"/>	
Visit date (dd MMM yyyy)		2
Was visit performed at the participant's home or at the clinic?	Home <input type="checkbox"/>	3
	Clinic <input type="checkbox"/>	
Folder OID		4

v6.020 DTW: MASTER**Folder: Convalescence Visit Day 28****Form: Visit Date****Generated On: 26 Nov 2020 14:07:14**

	Field Name	Data Type	Field Label	Values	Include Field OID
1	VISITYN	\$1	Was this visit performed?	Y = Yes N = No	VISITYN
2	VISITDAT	dd MMM yyyy	Visit date (dd MMM yyyy)		VISITDAT
3	VISTYPE	\$6	Was visit performed at the participant's home or at the clinic?	Home = Home Clinic = Clinic	VISTYPE
4	FOLDER_OID	\$15	Folder OID		FOLDER_OID

v6.020 DTW: MASTER

Folder: Convalescence Visit Day 28

Form: Vital Signs

Generated On: 26 Nov 2020 14:07:14

Were vital signs assessed?	Yes <input type="checkbox"/>	1
	No <input type="checkbox"/>	
Date of assessment (<i>dd MMM yyyy</i>)		2
Time of assessment (<i>00:00-23:59</i>)	Fixed Unit: (24 HR)	3
Vital Signs Date and Time (derived)		4
Height (<i>xxx.x</i>)	cm <input type="checkbox"/>	5
	in <input type="checkbox"/>	
Weight (<i>xxx.x</i>)	kg <input type="checkbox"/>	6
	lb <input type="checkbox"/>	
BMI (<i>xxx.x</i>)	Fixed Unit: kg/m ²	7
BMI units		8
Temperature (<i>xxx.x</i>)	C <input type="checkbox"/>	9
	F <input type="checkbox"/>	
Route of measurement	Oral <input type="checkbox"/>	10
	Axillary <input type="checkbox"/>	
	Other <input type="checkbox"/>	
If Other, specify		11
Pulse (<i>xxx</i>)	Fixed Unit: beats/min	12
Pulse units		13
Respiratory Rate (<i>xxx</i>)	Fixed Unit: breaths/min	14
Respiratory Rate units		15
Systolic Blood Pressure (<i>xxx</i>)	Fixed Unit: mmHg	16
Systolic Blood Pressure units		17
Diastolic Blood Pressure (<i>xxx</i>)	Fixed Unit: mmHg	18
Diastolic Blood Pressure units		19
Height (derived)	Fixed Unit: cm	20

v6.020 DTW: MASTER

Folder: Convalescence Visit Day 28

Form: Vital Signs

Generated On: 26 Nov 2020 14:07:14

Weight (derived)

Fixed Unit: kg **21**

v6.020 DTW: MASTER

Folder: Convalescence Visit Day 28

Form: Vital Signs

Generated On: 26 Nov 2020 14:07:14

	Field Name	Data Type	Field Label	Values	Include Field OID
1	VSPERF	\$1	Were vital signs assessed?	Y = Yes N = No	VSPERF
2	VSDAT	dd MMM yyyy	Date of assessment (<i>dd MMM yyyy</i>)		VSDAT
3	VSTIM	HH:nn	Time of assessment (<i>00:00-23:59</i>)		VSTIM
4	VSDTTIM	dd MMM yyyy HH:nn	Vital Signs Date and Time (derived)		VSDTTIM
5	HEIGHT_VS ORRES	20.5	Height (<i>xxx.x</i>)		HEIGHT_VS ORRES
6	WEIGHT_VS ORRES	20.5	Weight (<i>xxx.x</i>)		WEIGHT_VS ORRES
7	VSBMI	20.5	BMI (<i>xxx.x</i>)		VSBMI
8	VSBMUI	\$10	BMI units		VSBMUI
9	TEMP_VSOR RES	20.5	Temperature (<i>xxx.x</i>)		TEMP_VSOR RES
10	VSROUTE	\$8	Route of measurement	Oral = Oral Axillary = Axillary Other = Other	VSROUTE
11	VSROUTESP	\$200	If Other, specify		VSROUTESP
12	HR_VSORRE S	3	Pulse (<i>xxx</i>)		HR_VSORRE S
13	HR_VSORRE SU	\$9	Pulse units		HR_VSORRE SU
14	RR_VSORRE S	3	Respiratory Rate (<i>xxx</i>)		RR_VSORRE S
15	RR_VSORRE SU	\$11	Respiratory Rate units		RR_VSORRE SU
16	SYSBP_VSO RRES	3	Systolic Blood Pressure (<i>xxx</i>)		SYSBP_VSO RRES

v6.020 DTW: MASTER**Folder: Convalescence Visit Day 28****Form: Vital Signs****Generated On: 26 Nov 2020 14:07:14**

	Field Name	Data Type	Field Label	Values	Include Field OID
17	SYSBP_VSO RRESU	\$4	Systolic Blood Pressure units		SYSBP_VSO RRESU
18	DIABP_VSO RRES	3	Diastolic Blood Pressure (<i>xxx</i>)		DIABP_VSO RRES
19	DIABP_VSO RRESU	\$4	Diastolic Blood Pressure units		DIABP_VSO RRESU
20	HEIGHT_D	3	Height (derived)		HEIGHT_D
21	WEIGHT_D	4.1	Weight (derived)		WEIGHT_D

v6.020 DTW: MASTER

Folder: Convalescence Visit Day 28

Form: Physical Examination

Generated On: 26 Nov 2020 14:07:14

Was the physical examination performed?

Yes ☐ **1**

No ☐

Date of examination (dd MMM yyyy)

2

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

v6.020 DTW: MASTER

Folder: Convalescence Visit Day 28

Form: Physical Examination

Generated On: 26 Nov 2020 14:07:14

	Field Name	Data Type	Field Label	Values	Include Field OID
1	PEYN	\$1	Was the physical examination performed?	Y = Yes N = No	PEYN
2	PEDAT	dd MMM yyyy	Date of examination (<i>dd MMM yyyy</i>)		PEDAT

v6.020 DTW: MASTER

Folder: Convalescence Visit Day 28

Form: Blood Sample Collection for Immunologic Assessment of SARS-CoV-2 Infection

Generated On: 26 Nov 2020 14:07:14

Was Blood Sample Taken for Immunologic Assessment of SARS_COV-2 Infection?	Yes <input type="checkbox"/>	1
	No <input type="checkbox"/>	
	NA (COVID-19 Negative) <input type="checkbox"/>	
Date of Collection		2

v6.020 DTW: MASTER

Folder: Convalescence Visit Day 28

Form: Blood Sample Collection for Immunologic Assessment of SARS-CoV-2 Infection

Generated On: 26 Nov 2020 14:07:14

Field Name	Data Type	Field Label	Values	Include Field OID
① IMPPERF	\$2	Was Blood Sample Taken for Immunologic Assessment of SARS_COV-2 Infection?	Y = Yes N = No NA = NA (COVID-19 Negative)	IMMPERF
② IMMDT	dd MMM yyyy	Date of Collection		IMMDT

v6.020 DTW: MASTER

Folder: Unscheduled

Form: Unscheduled Visit Assessment

Generated On: 26 Nov 2020 14:07:14

Visit Date		1
Please check all assessments that apply for this visit		
Physical Exam		3
Vital Signs		4
Immunogenicity Assessment		5
Pregnancy Test		6

v6.020 DTW: MASTER

Folder: Unscheduled

Form: Unscheduled Visit Assessment

Generated On: 26 Nov 2020 14:07:14

	Field Name	Data Type	Field Label	Values	Include Field OID
1	VISITDAT	dd MMM yyyy	Visit Date		VISITDAT
3	UNSPE	1	Physical Exam		UNSPE
4	UNSVS	1	Vital Signs		UNSVS
5	UNCLABIM	1	Immunogenici ty Assessment		UNCLABIM
6	UNSPT	1	Pregnancy Test		UNSPT

v6.020 DTW: MASTER

Folder: Unscheduled

Form: Vital Signs

Generated On: 26 Nov 2020 14:07:14

Were vital signs assessed?	Yes <input type="checkbox"/>	1
	No <input type="checkbox"/>	
Date of assessment (<i>dd MMM yyyy</i>)		2
Time of assessment (<i>00:00-23:59</i>)	Fixed Unit: (24 HR)	3
Vital Signs Date and Time (derived)		4
Height (<i>xxx.x</i>)	cm <input type="checkbox"/>	5
	in <input type="checkbox"/>	
Weight (<i>xxx.x</i>)	kg <input type="checkbox"/>	6
	lb <input type="checkbox"/>	
BMI (<i>xxx.x</i>)	Fixed Unit: kg/m ²	7
BMI units		8
Temperature (<i>xxx.x</i>)	C <input type="checkbox"/>	9
	F <input type="checkbox"/>	
Route of measurement	Oral <input type="checkbox"/>	10
	Axillary <input type="checkbox"/>	
	Other <input type="checkbox"/>	
If Other, specify		11
Pulse (<i>xxx</i>)	Fixed Unit: beats/min	12
Pulse units		13
Respiratory Rate (<i>xxx</i>)	Fixed Unit: breaths/min	14
Respiratory Rate units		15
Systolic Blood Pressure (<i>xxx</i>)	Fixed Unit: mmHg	16
Systolic Blood Pressure units		17
Diastolic Blood Pressure (<i>xxx</i>)	Fixed Unit: mmHg	18
Diastolic Blood Pressure units		19
Height (derived)	Fixed Unit: cm	20

v6.020 DTW: MASTER

Folder: Unscheduled

Form: Vital Signs

Generated On: 26 Nov 2020 14:07:14

Weight (derived)

Fixed Unit: kg **21**

v6.020 DTW: MASTER

Folder: Unscheduled

Form: Vital Signs

Generated On: 26 Nov 2020 14:07:14

	Field Name	Data Type	Field Label	Values	Include Field OID
1	VSPERF	\$1	Were vital signs assessed?	Y = Yes N = No	VSPERF
2	VSDAT	dd MMM yyyy	Date of assessment (<i>dd MMM yyyy</i>)		VSDAT
3	VSTIM	HH:nn	Time of assessment (<i>00:00-23:59</i>)		VSTIM
4	VSDTTIM	dd MMM yyyy HH:nn	Vital Signs Date and Time (derived)		VSDTTIM
5	HEIGHT_VS ORRES	20.5	Height (<i>xxx.x</i>)		HEIGHT_VS ORRES
6	WEIGHT_VS ORRES	20.5	Weight (<i>xxx.x</i>)		WEIGHT_VS ORRES
7	VSBMI	20.5	BMI (<i>xxx.x</i>)		VSBMI
8	VSBMUI	\$10	BMI units		VSBMUI
9	TEMP_VSOR RES	20.5	Temperature (<i>xxx.x</i>)		TEMP_VSOR RES
10	VSROUTE	\$8	Route of measurement	Oral = Oral Axillary = Axillary Other = Other	VSROUTE
11	VSROUTESP	\$200	If Other, specify		VSROUTESP
12	HR_VSORRE S	3	Pulse (<i>xxx</i>)		HR_VSORRE S
13	HR_VSORRE SU	\$9	Pulse units		HR_VSORRE SU
14	RR_VSORRE S	3	Respiratory Rate (<i>xxx</i>)		RR_VSORRE S
15	RR_VSORRE SU	\$11	Respiratory Rate units		RR_VSORRE SU
16	SYSBP_VSO RRES	3	Systolic Blood Pressure (<i>xxx</i>)		SYSBP_VSO RRES

v6.020 DTW: MASTER**Folder: Unscheduled****Form: Vital Signs****Generated On: 26 Nov 2020 14:07:14**

	Field Name	Data Type	Field Label	Values	Include Field OID
17	SYSBP_VSO RRESU	\$4	Systolic Blood Pressure units		SYSBP_VSO RRESU
18	DIABP_VSO RRES	3	Diastolic Blood Pressure (xxx)		DIABP_VSO RRES
19	DIABP_VSO RRESU	\$4	Diastolic Blood Pressure units		DIABP_VSO RRESU
20	HEIGHT_D	3	Height (derived)		HEIGHT_D
21	WEIGHT_D	4.1	Weight (derived)		WEIGHT_D

v6.020 DTW: MASTER

Folder: Unscheduled

Form: Physical Examination

Generated On: 26 Nov 2020 14:07:14

Was the physical examination performed?

Yes ☐ **1**

No ☐

Date of examination (dd MMM yyyy)

2

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

v6.020 DTW: MASTER

Folder: Unscheduled

Form: Physical Examination

Generated On: 26 Nov 2020 14:07:14

	Field Name	Data Type	Field Label	Values	Include Field OID
1	PEYN	\$1	Was the physical examination performed?	Y = Yes N = No	PEYN
2	PEDAT	dd MMM yyyy	Date of examination (<i>dd MMM yyyy</i>)		PEDAT

v6.020 DTW: MASTER

Folder: Unscheduled

Form: Pregnancy Test

Generated On: 26 Nov 2020 14:07:14

Was the pregnancy test performed?	Yes <input type="checkbox"/>	1
	No <input type="checkbox"/>	
Date of test (<i>dd MMM yyyy</i>)		2
Test performed	Urine <input type="checkbox"/>	3
	Serum <input type="checkbox"/>	
Result	Positive <input type="checkbox"/>	4
	Negative <input type="checkbox"/>	
Was FSH sample collected?	Yes <input type="checkbox"/>	5
	No <input type="checkbox"/>	
Collection date		6
Collection time		7
Collection date and time (derived)		8

v6.020 DTW: MASTER**Folder: Unscheduled****Form: Pregnancy Test****Generated On: 26 Nov 2020 14:07:14**

	Field Name	Data Type	Field Label	Values	Include Field OID
1	PTPERF	\$1	Was the pregnancy test performed?	Y = Yes N = No	PTPERF
2	PTDAT	dd MMM yyyy	Date of test (dd MMM yyyy)		PTDAT
3	PTSTYP	\$5	Test performed	URINE = Urine SERUM = Serum	PTSTYP
4	PTORRES	\$25	Result	POSITIVE = Positive NEGATIVE = Negative	PTORRES
5	LBPERF	\$1	Was FSH sample collected?	Y = Yes N = No	LBPERF
6	LBDAT5	dd MMM yyyy	Collection date		LBDAT5
7	LBTIM5	HH:nn	Collection time		LBTIM5
8	LBDTTM	dd MMM yyyy HH:nn	Collection date and time (derived)		LBDTTM

v6.020 DTW: MASTER

Folder: Unscheduled

Form: Immunogenicity Assessment

Generated On: 26 Nov 2020 14:07:14

Was the sample collected?	Yes <input type="checkbox"/>	1
	No <input type="checkbox"/>	
Collection date (<i>dd MMM yyyy</i>)		2
Collection time (<i>00:00-23:59</i>)	Fixed Unit: (24 HR)	3
Collection date and time (derived)		4

v6.020 DTW: MASTER**Folder: Unscheduled****Form: Immunogenicity Assessment****Generated On: 26 Nov 2020 14:07:14**

	Field Name	Data Type	Field Label	Values	Include Field OID
①	LBPERF	\$1	Was the sample collected?	Y = Yes N = No	LBPERF
②	LBDAT	dd MMM yyyy	Collection date (<i>dd MMM yyyy</i>)		LBDAT
③	LBTIM	HH:nn	Collection time (<i>00:00-23:59</i>)		LBTIM
④	LBDTTM	dd MMM yyyy HH:nn	Collection date and time (derived)		LBDTTM

v6.020 DTW: MASTER

Folder: Adverse Events

Form: Adverse Events Summary

Generated On: 26 Nov 2020 14:07:14

Did the participant experience any adverse events?

Yes ☐ 1
No ☐

If Yes, enter details on the Adverse Events form.

v6.020 DTW: MASTER

Folder: Adverse Events

Form: Adverse Events Summary

Generated On: 26 Nov 2020 14:07:14

Field Name	Data Type	Field Label	Values	Include Field OID
1 AEYN	\$1	Did the participant experience any adverse events?	Y = Yes N = No	AEYN

v6.020 DTW: MASTER

Folder: Adverse Events

Form: Adverse Events

Generated On: 26 Nov 2020 14:07:14

AEID			1
Adverse event			2
Was this a medically-attended AE?	Yes <input type="checkbox"/>		3
	No <input type="checkbox"/>		
Was this a Solicited Adverse Reaction?	Yes <input type="checkbox"/>		4
	No <input type="checkbox"/>		
Is this event a confirmed diagnosis of Symptomatic Covid-19?	Yes <input type="checkbox"/>		5
	No <input type="checkbox"/>		
Start date (dd MMM yyyy)			6
Start time (00:00-23:59)		Fixed Unit: (24 HR)	7
AE start date and time (derived)			8
Ongoing?	Yes <input type="checkbox"/>		9
	No <input type="checkbox"/>		
If not Ongoing, end date (dd MMM yyyy)			10
End time (00:00-23:59)		Fixed Unit: (24 HR)	11
AE End Date and Time (derived)			12
Severity	Grade 1/Mild <input type="checkbox"/>		13
	Grade 2/Moderate <input type="checkbox"/>		
	Grade 3/Severe <input type="checkbox"/>		
	Grade 4 <input type="checkbox"/>		
Is the adverse event serious?	Yes <input type="checkbox"/>		14
	No <input type="checkbox"/>		
AE is serious due To (check all that apply)			
Death			16
Life threatening			17
Requires inpatient or prolongation of existing Hospitalization			18
Hospital Admission Date (dd MMM yyyy)			19
Hospital Discharge Date (dd MMM yyyy)			20
Admitted to ICU?	Yes <input type="checkbox"/>		21
	No <input type="checkbox"/>		
	Unknown <input type="checkbox"/>		

v6.020 DTW: MASTER**Folder: Adverse Events****Form: Adverse Events****Generated On: 26 Nov 2020 14:07:14**

Number of Days in ICU		22
Persistent or significant disability or incapacity		23
Congenital anomaly or birth defect		24
Other medically important event		25
Relationship to investigational product	Not Related <input type="checkbox"/>	26
	Related <input type="checkbox"/>	
	Not Applicable <input type="checkbox"/>	
Relationship to Study Procedure	Not Related <input type="checkbox"/>	27
	Related <input type="checkbox"/>	
	Not Applicable <input type="checkbox"/>	
Action taken with investigational product	None <input type="checkbox"/>	28
	Dose Delayed <input type="checkbox"/>	
	Investigational Product <input type="checkbox"/>	
	Withdrawn <input type="checkbox"/>	
	Not Applicable <input type="checkbox"/>	
Other action taken (check all that apply)		
None		30
Concomitant Medication		31
Concomitant Procedure		32
Outcome	Fatal <input type="checkbox"/>	33
	Not Recovered/Not Resolved <input type="checkbox"/>	
	Recovered/Resolved <input type="checkbox"/>	
	Recovered/Resolved with Sequelae <input type="checkbox"/>	
	Recovering/Resolving <input type="checkbox"/>	
	Unknown <input type="checkbox"/>	
If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:		34
Narrative		35
Serious Adverse Event Derived (CSA Programming Field Only)		36
Medically Attended AE Derived (CSA Programming Field Only)		37
Admitted to ICU Derived (CSA Programming Field Only)		38

v6.020 DTW: MASTER

Folder: Adverse Events

Form: Adverse Events

Generated On: 26 Nov 2020 14:07:14

	Field Name	Data Type	Field Label	Values	Include Field OID
1	AEID	\$80	AEID		AEID
2	AETERM	\$200	Adverse event		AETERM
3	AEMED	\$1	Was this a medically-attended AE?	Y = Yes N = No	AEMED
4	AESAR	\$1	Was this a Solicited Adverse Reaction?	Y = Yes N = No	AESAR
5	AECVDIAG	\$1	Is this event a confirmed diagnosis of Symptomatic Covid-19?	Y = Yes N = No	AECVDIAG
6	AESTDAT	dd MMM yyyy	Start date (dd MMM yyyy)		AESTDAT
7	AESTTIM	HH:nn	Start time (00:00-23:59)		AESTTIM
8	AESTDTTM	dd MMM yyyy HH:nn	AE start date and time (derived)		AESTDTTM
9	AEONGO	\$1	Ongoing?	Y = Yes N = No	AEONGO
10	AEENDAT	dd MMM yyyy	If not Ongoing, end date (dd MMM yyyy)		AEENDAT
11	AEENTIM	HH:nn	End time (00:00-23:59)		AEENTIM
12	AEENDTTM	dd MMM yyyy HH:nn	AE End Date and Time (derived)		AEENDTTM
13	AESEV	\$20	Severity	Grade 1/Mild = Grade 1/Mild Grade 2/Moderate = Grade 2/Moderate	AESEV

v6.020 DTW: MASTER

Folder: Adverse Events

Form: Adverse Events

Generated On: 26 Nov 2020 14:07:14

Field Name	Data Type	Field Label	Values	Include Field OID
			Grade 3/Severe = Grade 3/Severe Grade 4 = Grade 4	
14 AESER	\$1	Is the adverse event serious?	Y = Yes N = No	AESER
16 AESDTH	1	Death		AESDTH
17 AESLIFE	1	Life threatening		AESLIFE
18 AESHOSP	1	Requires inpatient or prolongation of existing Hospitalization		AESHOSP
19 AEHOSPDAT	dd MMM yyyy	Hospital Admission Date (dd MMM yyyy)		AEHOSPDAT
20 AEHOSPDCGDAT	dd MMM yyyy	Hospital Discharge Date (dd MMM yyyy)		AEHOSPDCGDAT
21 AEICU	\$3	Admitted to ICU?	Y = Yes N = No UNK = Unknown	AEICU
22 AEICUNUM	3	Number of Days in ICU		AEICUNUM
23 AESDISAB	1	Persistent or significant disability or incapacity		AESDISAB
24 AESCONG	1	Congenital anomaly or birth defect		AESCONG

v6.020 DTW: MASTER

Folder: Adverse Events

Form: Adverse Events

Generated On: 26 Nov 2020 14:07:14

	Field Name	Data Type	Field Label	Values	Include Field OID
25	AESMIE	1	Other medically important event		AESMIE
26	AEREL	\$20	Relationship to investigational product	NOT RELATED = Not Related RELATED = Related NOT APPLICABL E = Not Applicable	AEREL
27	AERELP	\$20	Relationship to Study Procedure	NOT RELATED = Not Related RELATED = Related NOT APPLICABL E = Not Applicable	AERELP
28	AEACN	\$20	Action taken with investigational product	NONE = None DOSE DELAYED = Dose Delayed WITHDRAW N = Investigational Product Withdrawn NOT APPLICABL E = Not Applicable	AEACN
30	AEACNOTH1		None		AEACNOTH1
31	AEACNOTH2		Concomitant Medication		AEACNOTH2
32	AEACNOTH3		Concomitant Procedure		AEACNOTH3

v6.020 DTW: MASTER

Folder: Adverse Events

Form: Adverse Events

Generated On: 26 Nov 2020 14:07:14

Field Name	Data Type	Field Label	Values	Include Field OID
33 AEOUT	\$35	Outcome	FATAL = Fatal NOT RECOVERE D/NOT RESOLVED = Not Recovered/No t Resolved RECOVERE D/RESOLVE D = Recovered/Re solved RECOVERE D/RESOLVE D WITH SEQUELAE = Recovered/Re solved with Sequelae RECOVERIN G/RESOLVIN G = Recovering/Re solving UNKNOWN = Unknown	AEOUT
34 AEOUTSP	\$200	If outcome is Recovered/Re solved with Sequelae, please specify the sequelae:		AEOUTSP
35 AESAEDSCR	\$1999	Narrative		AESAEDSCR
36 AESER_D	1	Serious Adverse Event Derived (CSA Programming Field Ony)		AESER_D

v6.020 DTW: MASTER

Folder: Adverse Events

Form: Adverse Events

Generated On: 26 Nov 2020 14:07:14

	Field Name	Data Type	Field Label	Values	Include Field OID
37	AEMED_D	1	Medically Attended AE Derived (CSA Programming Field Only)		AEMED_D
38	AEICU_D	1	Admitted to ICU Derived (CSA Programming Field Only)		AEICU_D

v6.020 DTW: MASTER

Folder: Concomitant Medication and Vaccination

Form: Prior/Concomitant Medication and Vaccination Summary

Generated On: 26 Nov 2020 14:07:14

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

Yes ☐ **1**
No ☐

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

v6.020 DTW: MASTER

Folder: Concomitant Medication and Vaccination

Form: Prior/Concomitant Medication and Vaccination Summary

Generated On: 26 Nov 2020 14:07:14

Field Name	Data Type	Field Label	Values	Include Field OID
1 CMYN	\$1	Were any prior/concomitant medications and/or vaccinations taken?	Y = Yes N = No	CMYN

v6.020 DTW: MASTER

Folder: Concomitant Medication and Vaccination

Form: Prior/Concomitant Medication and Vaccination

Generated On: 26 Nov 2020 14:07:14

Name of Medication		<div>1</div>
Prophylaxis	Yes <input type="checkbox"/>	<div>2</div>
	No <input type="checkbox"/>	
Indication		<div>3</div>
Dose per administration		<div>4</div>
Dose unit	mg <input type="checkbox"/>	<div>5</div>
	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		<div>6</div>
Frequency	once daily <input type="checkbox"/>	<div>7</div>
	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		<div>8</div>
Route of administration	Oral <input type="checkbox"/>	<div>9</div>
	Topical <input type="checkbox"/>	
	Subcutaneous <input type="checkbox"/>	
	Transdermal <input type="checkbox"/>	
	Intraocular <input type="checkbox"/>	
	Intramuscular <input type="checkbox"/>	

v6.020 DTW: MASTER

Folder: Concomitant Medication and Vaccination

Form: Prior/Concomitant Medication and Vaccination

Generated On: 26 Nov 2020 14:07:14

	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			10
Start date (dd MMM yyyy)			11
Start date completely unknown			12
Ongoing?	Yes	<input type="checkbox"/>	13
	No	<input type="checkbox"/>	
If not Ongoing, End date (dd MMM yyyy)			14
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>	15
	No	<input type="checkbox"/>	
Separate Dosage Number (derived)			16
Interval Dosage Unit Number (derived)			17
Interval Dosage Definition (derived)	802	<input type="checkbox"/>	18
	803	<input type="checkbox"/>	
	804	<input type="checkbox"/>	

v6.020 DTW: MASTER

Folder: Concomitant Medication and Vaccination

Form: Prior/Concomitant Medication and Vaccination

Generated On: 26 Nov 2020 14:07:14

	Field Name	Data Type	Field Label	Values	Include Field OID
1	CMTRT	\$200	Name of Medication		CMTRT
2	CMPLX	\$1	Prophylaxis	Y = Yes N = No	CMPLX
3	CMINDC	\$200	Indication		CMINDC
4	CMDOSE	\$25	Dose per administration		CMDOSE
5	CMDOSU	\$30	Dose unit	mg = mg ug = ug mL = mL g = g IU = IU TABLET = tablet CAPSULE = capsule PUFF = puff OTHER = Other	CMDOSU
6	CMDOSUOT H	\$200	If dose unit is Other, specify		CMDOSUOT H
7	CMDOSFRQ	\$25	Frequency	QD = once daily BID = twice daily TID = three times daily QID = four times daily QOD = every other day QS = every week QM = every month PRN = as needed ONCE = once UNKNOWN = unknown	CMDOSFRQ

v6.020 DTW: MASTER

Folder: Concomitant Medication and Vaccination

Form: Prior/Concomitant Medication and Vaccination

Generated On: 26 Nov 2020 14:07:14

Field Name	Data Type	Field Label	Values	Include Field OID
OTHER = other				
8 CMDOSFRQ OTH	\$200	If frequency is Other, specify		CMDOSFRQ OTH
9 CMROUTE	\$30	Route of administration	ORAL = Oral TOPICAL = Topical SUBCUTAN EOUS = Subcutaneous TRANSDER MAL = Transdermal INTRAOCUL AR = Intraocular INTRAMUSC ULAR = Intramuscular RESPIRATO RY (INHALATIO N) = Respiratory (Inhalation) INTRALESIO NAL = Intralesional INTRAPERIT EONEAL = Intraperitone al NASAL = Nasal VAGINAL = Vaginal RECTAL = Rectal INTRAVENO US = Intravenous	CMROUTE

v6.020 DTW: MASTER

Folder: Concomitant Medication and Vaccination

Form: Prior/Concomitant Medication and Vaccination

Generated On: 26 Nov 2020 14:07:14

Field Name	Data Type	Field Label	Values	Include Field OID
			INTRAVENO US BOLUS = Intravenous Bolus INTRAVENO US DRIP = Intravenous Drip OTHER = Other	
10 CMROUTE TH	\$200	If route of administration is Other, specify		CMROUTE TH
11 CMSTDAT	dd- MMM- yyyy	Start date (<i>dd MMM yyyy</i>)		CMSTDAT
12 CMSTDATU NK	1	Start date completely unknown		CMSTDATU NK
13 CMONGO	\$1	Ongoing?	Y = Yes N = No	CMONGO
14 CMENDAT	dd- MMM- yyyy	If not Ongoing, End date (<i>dd MMM yyyy</i>)		CMENDAT
15 CMEVENT	\$1	Was this medication taken for solicited event?	Y = Yes N = No	CMEVENT
16 CMDOSFRQ 1	1	Separate Dosage Number (derived)		CMDOSFRQ 1
17 CMDOSFRQ 2	1	Interval Dosage Unit Number (derived)		CMDOSFRQ 2

v6.020 DTW: MASTER

Folder: Concomitant Medication and Vaccination

Form: Prior/Concomitant Medication and Vaccination

Generated On: 26 Nov 2020 14:07:14

Field Name	Data Type	Field Label	Values	Include Field OID
18 CMDOSFRQ 3	3	Interval	802 = 802	CMDOSFRQ
		Dosage	803 = 803	3
		Definition	804 = 804	
		(derived)		

v6.020 DTW: MASTER

Folder: Concomitant Procedures

Form: Concomitant Procedures Summary

Generated On: 26 Nov 2020 14:07:14

Were any concomitant procedures performed?

Yes ☒ 1
No ☐

If yes, please complete Concomitant Procedures form.

v6.020 DTW: MASTER

Folder: Concomitant Procedures

Form: Concomitant Procedures Summary

Generated On: 26 Nov 2020 14:07:14

Field Name	Data Type	Field Label	Values	Include Field OID
① CPYN	\$1	Were any concomitant procedures performed?	Y = Yes N = No	CPYN

v6.020 DTW: MASTER

Folder: Concomitant Procedures

Form: Concomitant Procedures

Generated On: 26 Nov 2020 14:07:14

Procedure/Surgery date (<i>dd MMM yyyy</i>)		1
Procedure/Surgery		2
Indication	Adverse Event <input type="checkbox"/>	3
	Medical History <input type="checkbox"/>	
	Diagnostic <input type="checkbox"/>	
	Other <input type="checkbox"/>	
If indication is Other, specify		4

v6.020 DTW: MASTER**Folder: Concomitant Procedures****Form: Concomitant Procedures****Generated On: 26 Nov 2020 14:07:14**

	Field Name	Data Type	Field Label	Values	Include Field OID
①	CPDAT	dd MMM yyyy	Procedure/Sur gery date (<i>dd MMM yyyy</i>)		CPDAT
②	CPTRT	\$200	Procedure/Sur gery		CPTRT
③	CPIND	\$10	Indication	AE = Adverse CPIND Event MH = Medical History DIAGNOSTI C = Diagnostic OTHER = Other	
④	CPINDOTH	\$200	If indication is Other, specify		CPINDOTH

v6.020 DTW: MASTER

Folder: COVID-19 Impact

Form: COVID-19 Impact

Generated On: 26 Nov 2020 14:07:14

Visit	Screening	<input type="checkbox"/>	1
	Visit 1 Day 1	<input type="checkbox"/>	
	Visit 2 Day 29	<input type="checkbox"/>	
	Visit 3 Day 57	<input type="checkbox"/>	
	Visit 4 Day 209	<input type="checkbox"/>	
	Visit 5 Day 394	<input type="checkbox"/>	
	Visit 6 Day 759	<input type="checkbox"/>	

Case Report Form

Visit Date		3
Demographics		4
Enrollment		5
Inclusion/Exclusion Criteria Summary		6
Inclusion/Exclusion Criteria		7
Medical History Summary		8
Medical History		9
Vital Signs		10
Vital Signs - Dosing		11
Physical Examination		12
Central Laboratory - Nasopharyngeal Swab		13
Childbearing Potential		14
Pregnancy Test		15
Randomization		16
Exposure		17
Immunogenicity Assessment		18
Saliva Collection		19
COVID Diagnostic Test		20
Symptom Log		21
Blood Sample Collection for Immunologic Assessment of SARS-CoV-2 Infection		22
COVID-19 Severity Assessment		23
COVID-19 Contact		24
Risk of Exposure		25
Safety Call		26
Dosing Discontinuation		27
End of Study / Study Discontinuation		28

v6.020 DTW: MASTER

Folder: COVID-19 Impact

Form: COVID-19 Impact

Generated On: 26 Nov 2020 14:07:14

All	29
Date of missed or out of window visit or assessment	31
Category	
Inclusion criteria not met/Exclusion criteria met	33
Study Treatment not given	34
Missed Visit	35
Missed Assessment	36
Visit performed out of window	37
Assessment performed out of window	38
Scheduled clinical visit performed as home visit	39
Other	40
Other, specify	41
Description of Relationship to COVID-19	
Clinical site closed	43
Travel restrictions	44
Quarantine due to COVID-19	45
Possible exposure to COVID-19	46
Exposure to COVID-19	47
Presumption / confirmed COVID-19	48
Symptoms of COVID-19	49
Sponsor hold due to COVID-19	50
Participant decision	51

v6.020 DTW: MASTER

Folder: COVID-19 Impact

Form: COVID-19 Impact

Generated On: 26 Nov 2020 14:07:14

	Field Name	Data Type	Field Label	Values	Include Field OID
1	COVVISIT	\$25	Visit	SCRN = Screening VISIT1 = Visit 1 Day 1 VISIT2 = Visit 2 Day 29 VISIT3 = Visit 3 Day 57 VISIT4 = Visit 4 Day 209 VISIT5 = Visit 5 Day 394 VISIT6 = Visit 6 Day 759	COVVISIT
3	COVISDT	1	Visit Date		COVISDT
4	COVDM	1	Demographics		COVDM
5	COVENROL L	1	Enrollment		COVENROL L
6	COVIEYN	1	Inclusion/Excl usion Criteria Summary		COVIEYN
7	COVIE	1	Inclusion/Excl usion Criteria		COVIE
8	COVMHYN	1	Medical History Summary		COVMHYN
9	COVMH	1	Medical History		COVMH
10	COVVS	1	Vital Signs		COVVS
11	COVSDOSE	1	Vital Signs - Dosing		COVSDOSE
12	COVPE	1	Physical Examination		COVPE

v6.020 DTW: MASTER**Folder: COVID-19 Impact****Form: COVID-19 Impact****Generated On: 26 Nov 2020 14:07:14**

	Field Name	Data Type	Field Label	Values	Include Field OID
13	COVNASAL_1 SARS		Central Laboratory - Nasopharyngeal Swab		COVNASAL_ SARS
14	COVCB	1	Childbearing Potential		COVCB
15	COVPT	1	Pregnancy Test		COVPT
16	COVRAND	1	Randomization		COVRAND
17	COVEX	1	Exposure		COVEX
18	COVCLABI M	1	Immunogenicity Assessment		COVCLABI M
19	COVSALIVA	1	Saliva Collection		COVSALIVA
20	COVLDT	1	COVID Diagnostic Test		COVLDT
21	COVSYMP	1	Symptom Log		COVSYMP
22	COVBLOOD	1	Blood Sample Collection for Immunologic Assessment of SARS-CoV-2 Infection		COVBLOOD
23	COVSEV	1	COVID-19 Severity Assessment		COVSEV
24	COVCNTC	1	COVID-19 Contact		COVCNTC
25	COVRISK	1	Risk of Exposure		COVRISK
26	COVSC	1	Safety Call		COVSC
27	COVEOT	1	Dosing Discontinuation		COVEOT

v6.020 DTW: MASTER**Folder: COVID-19 Impact****Form: COVID-19 Impact****Generated On: 26 Nov 2020 14:07:14**

	Field Name	Data Type	Field Label	Values	Include Field OID
28	COVDS	1	End of Study / Study Discontinuation		COVDS
29	COVALL	1	All		COVALL
31	COVSTDAT	dd MMM yyyy	Date of missed or out of window visit or assessment		COVSTDAT
33	COVDECOD 1	1	Inclusion criteria not met/Exclusion criteria met		COVDECOD 1
34	COVDECOD 2	1	Study Treatment not given		COVDECOD 2
35	COVDECOD 3	1	Missed Visit		COVDECOD 3
36	COVDECOD 4	1	Missed Assessment		COVDECOD 4
37	COVDECOD 5	1	Visit performed out of window		COVDECOD 5
38	COVDECOD 6	1	Assessment performed out of window		COVDECOD 6
39	COVDECOD 7	1	Scheduled clinical visit performed as home visit		COVDECOD 7
40	COVDECOD 8	1	Other		COVDECOD 8
41	COVOTH	\$200	Other, specify		COVOTH
43	COVDESC1	1	Clinical site closed		COVDESC1
44	COVDESC2	1	Travel restrictions		COVDESC2

v6.020 DTW: MASTER**Folder: COVID-19 Impact****Form: COVID-19 Impact****Generated On: 26 Nov 2020 14:07:14**

	Field Name	Data Type	Field Label	Values	Include Field OID
45	COVDESC3	1	Quarantine due to COVID-19		COVDESC3
46	COVDESC4	1	Possible exposure to COVID-19		COVDESC4
47	COVDESC5	1	Exposure to COVID-19		COVDESC5
48	COVDESC6	1	Presumption / confirmed COVID-19		COVDESC6
49	COVDESC7	1	Symptoms of COVID-19		COVDESC7
50	COVDESC8	1	Sponsor hold due to COVID-19		COVDESC8
51	COVDESC9	1	Participant decision		COVDESC9

v6.020 DTW: MASTER

Folder: End of Study

Form: Dosing Discontinuation

Generated On: 26 Nov 2020 14:07:14

Date of dosing discontinuation (dd MMM yyyy)	<input type="text"/>	1
Primary reason for dosing discontinuation	<div><div>AE (specify) <input type="checkbox"/></div><div>SAE (specify) <input type="checkbox"/></div><div>Death <input type="checkbox"/></div><div>Lost To Follow-up <input type="checkbox"/></div><div>Physician decision (specify) <input type="checkbox"/></div><div>Pregnancy <input type="checkbox"/></div><div>Protocol deviation (specify) <input type="checkbox"/></div><div>Study Terminated By Sponsor <input type="checkbox"/></div><div>Withdrawal of consent by participant (specify) <input type="checkbox"/></div><div>Due to SARS-COV-2 <input type="checkbox"/></div><div>Other <input type="checkbox"/></div></div>	2
If reason is AE, SAE, Physician Decision, Withdrawal of consent by participant, Protocol deviation, or Other, specify	<input type="text"/>	3

v6.020 DTW: MASTER

Folder: End of Study

Form: Dosing Discontinuation

Generated On: 26 Nov 2020 14:07:14

	Field Name	Data Type	Field Label	Values	Include Field OID
①	DSSTDAT	dd MMM yyyy	Date of dosing discontinuation (dd MMM yyyy)		DSSTDAT
②	DSTERM	\$30	Primary reason for dosing discontinuation	ADVERSE EVENT = AE (specify) SAE = SAE (specify) DEATH = Death LOST TO FOLLOW-UP = Lost To Follow-up PHYSICIAN DECISION = Physician decision (specify) PREGNANCY Y = Pregnancy PROTOCOL DEVIATION = Protocol deviation (specify) STUDY TERMINATE D BY SPONSOR = Study Terminated By Sponsor WITHDRAWAL OF CONSENT = Withdrawal of consent by participant (specify)	DSTERM

v6.020 DTW: MASTER

Folder: End of Study

Form: Dosing Discontinuation

Generated On: 26 Nov 2020 14:07:14

Field Name	Data Type	Field Label	Values	Include Field OID
			COVID = Due to SARS-COV-2 OTHER = Other	
3 DSTERMSP	\$200	If reason is AE, SAE, Physician Decision, Withdrawal of consent by participant, Protocol deviation, or Other, specify		DSTERMSP

v6.020 DTW: MASTER

Folder: End of Study

Form: End of Study / Study Discontinuation

Generated On: 26 Nov 2020 14:07:14

Date of study discontinuation/completion (<i>dd MMM yyyy</i>)		1
Reason for discontinuation	AE (specify) <input type="checkbox"/>	2
	SAE (specify) <input type="checkbox"/>	
	Complete <input type="checkbox"/>	
	Death <input type="checkbox"/>	
	Lost To Follow-up <input type="checkbox"/>	
	Physician decision (specify) <input type="checkbox"/>	
	Pregnancy <input type="checkbox"/>	
	Protocol deviation (specify) <input type="checkbox"/>	
	Study Terminated By Sponsor <input type="checkbox"/>	
	Withdrawal of consent by participant (specify) <input type="checkbox"/>	
	Other <input type="checkbox"/>	
If reason is AE, SAE, Physician Decision, Withdrawal of consent by participant, Protocol deviation, or Other, specify		3
If reason for discontinuation is Death, main cause of death	Adverse event <input type="checkbox"/>	4
	Unknown <input type="checkbox"/>	
	Other <input type="checkbox"/>	
If main cause of death is Other, specify		5
Date of death (<i>dd MMM yyyy</i>)		6
Was autopsy performed?	Yes <input type="checkbox"/>	7
	No <input type="checkbox"/>	
	Unknown <input type="checkbox"/>	

v6.020 DTW: MASTER

Folder: End of Study

Form: End of Study / Study Discontinuation

Generated On: 26 Nov 2020 14:07:14

	Field Name	Data Type	Field Label	Values	Include Field OID
①	DSSTDAT	dd MMM yyyy	Date of study discontinuation/completion (dd MMM yyyy)		DSSTDAT
②	DSTERM	\$30	Reason for discontinuation	ADVERSE EVENT = AE (specify) SAE = SAE (specify) COMPLETE = Complete DEATH = Death LOST TO FOLLOW-UP = Lost To Follow-up PHYSICIAN DECISION = Physician decision (specify) PREGNANCY Y = Pregnancy PROTOCOL DEVIATION = Protocol deviation (specify) STUDY TERMINATE D BY SPONSOR = Study Terminated By Sponsor	DSTERM

v6.020 DTW: MASTER

Folder: End of Study

Form: End of Study / Study Discontinuation

Generated On: 26 Nov 2020 14:07:14

Field Name	Data Type	Field Label	Values	Include Field OID
			WITHDRAW AL OF CONSENT = Withdrawal of consent by participant (specify) OTHER = Other	
3 DSTERMSP	\$200	If reason is AE, SAE, Physician Decision, Withdrawal of consent by participant, Protocol deviation, or Other, specify		DSTERMSP
4 DSTERMSP2	\$20	If reason for discontinuation is Death, main cause of death	ADVERSE EVENT = Adverse event UNKNOWN = Unknown OTHER = Other	DSTERMSP2
5 DSDTHSP	\$200	If main cause of death is Other, specify		DSDTHSP
6 DTHDAT	dd MMM yyyy	Date of death (<i>dd MMM yyyy</i>)		DTHDAT
7 DTHAUTO	\$3	Was autopsy performed?	Y = Yes N = No UNK = Unknown	DTHAUTO

Participant ID	<div>1</div>
mRNA-1273-P301 Completion Guidelines	<div>2</div>

v6.020 DTW: MASTER

Form: Participant Creation

Generated On: 26 Nov 2020 14:07:14

	Field Name	Data Type	Field Label	Values	Include Field OID
1	SUBJID	\$9	Participant ID		SUBJID
2	CCGLINK	1	mRNA-1273-P301 Completion Guidelines		CCGLINK