

Annotated Study Book for Study Design: COLCORONA

Study Design Version: 3.2

Sponsor: MHICC

Protocol: MHIPS-2020-001

COL-CORONA

Generated by Central Designer™

August 13, 2020 9:38AM

COLCORONA: System Screening (Screen) [fm_Screening]		
System Screening [fm_Screening]		
1.	Subject's initials [Subject's initials]	[tx_PatientInit] <input type="text"/> NOT SUBMITTED
2.	Select Yes to continue [Select Yes to continue]	[rb_Continue] [N:1] <input type="radio"/> Yes NOT SUBMITTED

COLCORONA: System Enrollment (Enroll) [fm_Enroll]		
System Enrollment [fm_Enroll]		
This form must be completed immediately after the system SCREEN form in order to create a subject casebook		
1.	System date [System date]	[dt_Enrolldate] <input type="text"/> / <input type="text"/> / <input type="text"/> <input type="text"/> NOT SUBMITTED
2.	Select Yes to continue [Select Yes to continue]	[rb_Continue] [N:1] <input type="radio"/> Yes NOT SUBMITTED

SV=Subject Visit

COLCORONA: SUBJECT VISITS (DOV) [fm_DOV]	
SUBJECT VISITS [fm_DOV]	
1. Date of visit [Date of visit]	[dt_DOV] <input type="button" value="v"/> / <input type="button" value="v"/> / <input type="button" value="v"/> SVSTDTC

DM=Demographics

VS=Vital Signs

LB=Laboratory

RP=Reproductive System Findings

DS=Disposition

COLCORONA: Demographics (Demog) [fm_Dem]

Demographics [fm_Dem]

1.	Subject's initials [Subject's initials]	[tx_SubjectInit] <input type="text"/> NOT SUBMITTED
2.	In what country is the subject treated? [Country]	[rb_country] [N:1] <input type="radio"/> Canada [N:2] <input type="radio"/> United States [N:3] <input type="radio"/> Spain [N:5] <input type="radio"/> South Africa COUNTRY [N:6] <input type="radio"/> UK [N:7] <input type="radio"/> France [N:4] <input type="radio"/> [tx_OtherCountry] Other, specify <input type="text"/>

Personal Data [sc_PersonalData]

3.	What is the subject's date of birth? [Date of birth]	[dt_DOB] <input type="text"/> / <input type="text"/> / <input type="text"/> BRTHDTC
4.	What is the sex of the subject? [Sex] SEX	[rb_Sex] [N:1] <input type="radio"/> Male RPTSTCD = "Childbearing Potential" [N:2] <input type="radio"/> Female RPTSTCD = "CHILDPOT" [N:1] <input type="radio"/> [rb_ChildBearing] Child Bearing Potential RPORRES = "CONTRACEPTIVE METHOD" OR "WITHOUT CONTRACEPTIVE METHOD" [N:1] <input type="radio"/> With contraceptive protection (please record on concomitant medication form) [N:2] <input type="radio"/> Without contraceptive protection [N:2] <input type="radio"/> Postmenopausal RPTSTCD = "POSTMENO" RPTST = "Postmenopausal" RPORRES = "Y" [N:3] <input type="radio"/> Surgically sterilized RPTSTCD = "SURGSTER" RPTST = "Surgically Sterilized" RPORRES = "Y" [N:4] <input type="radio"/> [tx_OtherRP] RPTSTCD = "OTHERRP" RPTST = "Other Reproductive System" Other, specify: <input type="text"/> RPORRES
5.	What is the ethnicity of the subject? [What is the ethnicity of the subject?]	[rb_ethnic] ETHNIC [N:1] <input type="radio"/> Hispanic or Latino [N:2] <input type="radio"/> Not Hispanic or Latino [N:3] <input type="radio"/> Not Reported [N:4] <input type="radio"/> Unknown
6.	What is the race of the subject? [Ethnic origin]	[rb_Race] RACE [N:1] <input type="checkbox"/> American Indian or Alaska Native [N:2] <input type="checkbox"/> Asian [N:3] <input type="checkbox"/> Black [N:4] <input type="checkbox"/> Native Hawaiian or Other Pacific Islander [N:5] <input type="checkbox"/> White RACE = "MULTIPLE" when more than one box is checked. SUPPDM.QVAL when QNAM = "RACE1", "RACE2", "RACE3", "RACE4", "RACE5"
7.	Informed Consent date [Informed Consent date]	[dt_IC] RFICDTC DSSTDTC DSCAT = "PROTOCOL MILESTONE" <input type="text"/> / <input type="text"/> / <input type="text"/> DSTERM = "INFORM CONTENT OBTAINED"
8.	Are you interested in participating in Pharmacogenomic Sub-study? [PGX Sub-Study]	[rb_PGXSubStudy] [N:1] <input type="radio"/> Yes [N:0] <input type="radio"/> No SUPPDM.QVAL when QNAM = "PGXSSTUD"
9.	Pharmacogenomics informed consent date [Pharmacogenomics informed consent date (Autofilled, editable)]	[rb_PharmacoConsent] NOT SUBMITTED [N:1] <input type="radio"/> [dt_PGC] Yes, specify date: <input type="text"/> / <input type="text"/> / <input type="text"/> [N:0] <input type="radio"/> No

Physical Data [sc_PhysicalData]

10.	Height [Height]	[fl_Height] <input type="text"/> <input type="radio"/> cm <input type="radio"/> in VSTESTCD = "HEIGHT" VSTEST = "Height" VSORRES VSORRESU
11.	Weight [Weight]	[fl_Weight] <input type="text"/> <input type="radio"/> kg <input type="radio"/> lb VSTESTCD = "WEIGHT" VSTEST = "Weight" VSORRES VSORRESU
12.	Serum Creatinine [Serum Creatinine]	[tx_SerumCreatinine] LBCAT = "CHEMISTRY" LBORRES umol/L LBORRESU LBTESTCD = "CREAT" LBTEST = "Creatinine"
13.	eGFR calculation (Autocalculated) [eGFR calculation]	[fl_eGFR] LBORRES mL/min/1.73m2 LBORRESU LBTESTCD = "GFR" LBTEST = "Glomerular Filtration Rate"
14.	Serum Creatinine Numeric	[fl_CreatNum]

[Serum Creatinine Numeric]		LBSTRESN	LBTESTCD = "CREAT"	LBTEST = "Creatinine"	LBSTRESU = "umol/L"
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SU = Substance Use

MH=Medical History

COLCORONA: Medical and Surgical History (Med/Surg Hist) [fm_CVH]		
Medical and Surgical History [fm_CVH]		
1. Did the subject ever smoke cigarettes/cigars? [Did the subject ever smoke cigarettes/cigars?]	<p>[rb_Smoker]</p> <p>[N:1] <input type="radio"/> Non-smoker</p> <p>[N:2] <input type="radio"/> [dt_SmokerQuit] Previous smoker, specify when did the subject quit: <input type="text"/> SUENDTC</p> <p>[N:3] <input type="radio"/> Smoker (≥ 1 cigarette per day), SUOCCUR = "Y", SUENRPT = "ONGOING"</p>	<p>SUTRT = "CIGARETTES"</p> <p>SUOCCUR = "N"</p> <p>SUOCCUR = "Y"</p>
2. History of diabetes [History of diabetes]	<p>[rb_Diabetes]</p> <p>[N:1] <input type="radio"/> [rb_DiabetesType] Yes, type:</p> <p>[N:1] <input type="radio"/> Type 1 SUPPMH.QVAL when QNAM = "DIATYPE"</p> <p>[N:2] <input type="radio"/> Type 2</p> <p>[N:0] <input type="radio"/> No</p>	<p>MHTERM MHOCCUR</p>
3. History of hypertension [History of hypertension]	<p>[rb_Hypertension]</p> <p>[N:1] <input type="radio"/> Yes</p> <p>[N:0] <input type="radio"/> No</p>	<p>MHTERM MHOCCUR</p>
4. History of respiratory disease [History of respiratory disease]	<p>[rb_RespYN]</p> <p>[N:1] <input type="radio"/> [cb_RD] Yes, specify:</p> <p>[N:1] <input type="checkbox"/> Asthma</p> <p>[N:2] <input type="checkbox"/> Chronic Obstructive Pulmonary Disease (COPD) MHTERM</p> <p>[N:3] <input type="checkbox"/> Pneumonia</p> <p>[N:4] <input type="checkbox"/> Bronchiectasis</p> <p>[N:5] <input type="checkbox"/> Pulmonary fibrosis</p> <p>[N:6] <input type="checkbox"/> [tx_OtherRD] Other: <input type="text"/></p> <p>[N:0] <input type="radio"/> No</p>	<p>MHOCCUR</p> <p>MHTERM MHSCAT = "OTHER RESPIRATORY DISEASE"</p>
5. Prior Myocardial Infarction (MI) [MI]	<p>[rb_MI]</p> <p>[N:1] <input type="radio"/> Yes MHTERM MHOCCUR</p> <p>[N:0] <input type="radio"/> No</p>	
6. Prior Percutaneous Coronary Intervention (PCI) [PCI]	<p>[rb_PCI]</p> <p>[N:1] <input type="radio"/> Yes MHTERM MHOCCUR</p> <p>[N:0] <input type="radio"/> No</p>	
7. Prior Coronary Artery Bypass Graft (CABG) [CABG]	<p>[rb_CABG]</p> <p>[N:1] <input type="radio"/> Yes MHTERM MHOCCUR</p> <p>[N:0] <input type="radio"/> No</p>	
8. Prior Stroke/Transient Ischemic Attack (TIA) [TIA]	<p>[rb_TIA]</p> <p>[N:1] <input type="radio"/> Yes MHTERM MHOCCUR</p> <p>[N:0] <input type="radio"/> No</p>	
9. Prior Heart Failure [HF]	<p>[rb_HF]</p> <p>[N:1] <input type="radio"/> Yes MHTERM MHOCCUR</p> <p>[N:0] <input type="radio"/> No</p>	
10. Date of first symptoms associated to potential COVID-19 infection [COVID-19 First Symptom Date]	<p>[dt_FSCOV19]</p> <p><input type="text"/> / <input type="text"/> / <input type="text"/></p>	<p>MHSTDTC</p>
11. Medical History Term to Code [Medical History Term to Code]	<p>[tx_MHTerm]</p> <p>NOT SUBMITTED</p>	
12. Verbatim Comparison [Verbatim Comparison]	<p>[tx_VERBCOMP]</p> <p>NOT SUBMITTED</p>	
13. Coder's Name [Coder's Name]	<p>[tx_CoderName]</p> <p>NOT SUBMITTED</p>	

14.	Dictionary Version [Dictionary Version]	[tx_DictionaryVersion] NOT SUBMITTED
15.	SOC Term [SOC Term]	[tx_MHSOCTerm] MHBODSYS
16.	SOC Code [SOC Code]	[tx_MHSOCCode] NOT SUBMITTED
17.	HLGT Term [HLGT Term]	[tx_MHHLGTTerm] NOT SUBMITTED
18.	HLGT Code [HLGT Code]	[tx_MHHLGTCode] NOT SUBMITTED
19.	HLT Term [HLT Term]	[tx_MHHLTTerm] NOT SUBMITTED
20.	HLT Code [HLT Code]	[tx_MHHLTCode] NOT SUBMITTED
21.	PT Term [PT Term]	[tx_MHPTTerm] MHDECOD
22.	PT Code [PT Code]	[tx_MHPTCode] NOT SUBMITTED
23.	LLT Term [LLT Term]	[tx_MHLLTTerm] NOT SUBMITTED
24.	LLT Code	[tx_MHLLTCode]

[LLT Code]	NOT SUBMITTED
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IE=Inclusion/Exclusion Criteria Not Met

COLCORONA: Inclusion/Exclusion criteria not met (IE) [fm_IE]

Inclusion/Exclusion criteria not met [fm_IE]

1. Did the subject meet all eligibility criteria? [Meet Criteria] **[rb_MeetCriteria]** **NOT SUBMITTED**
 [N:0] No, please specify below
 [N:1] Yes

Inclusion/Exclusion

2. ✓

Criterion not met Entry [sc_IE]

2.1 What is the identifier of the criterion the subject did not meet? [Inclusion/Exclusion] **[rb_IE]** **IETEST * List of Inclusion/Exclusion in DefineXML**
 [N:1] **[rb_Inclusion]** Inclusion **IECAT="INCLUSION" IERORRES when "No" only**
[cl_Inclusion] **IETESTCD="INCL01- INCL06"**
 [N:2] **[rb_Exclusion]** Exclusion **IECAT="EXCLUSION" IERORRES when "Yes" only**
[cl_Exclusion] **IETESTCD="EXCL01- EXCL11"**

Codelist Values Tables: Inclusion/Exclusion criteria not met

Codelist RefName	Codelist Data Type	Label	Code	Codelist Item RefName	Data Variable RefName
cl_Inclusion	Integer	INC01	1	ci_Inc1	rb_Inclusion
		INC02	2	ci_Inc2	
		INC03	3	ci_Inc3	
		INC04	4	ci_Inc4	
		INC05	5	ci_Inc5	
		INC06	6	ci_Inc6	
cl_Exclusion	Integer	EXC01	1	ci_Exc1	rb_Exclusion
		EXC02	2	ci_Exc2	
		EXC03	3	ci_Exc3	
		EXC04	4	ci_Exc4	
		EXC05	5	ci_Exc5	
		EXC06	6	ci_Exc6	
		EXC07	7	ci_Exc7	
		EXC08	8	ci_Exc8	
		EXC09	9	ci_Exc9	
		EXC10	10	ci_Exc10	
		EXC11	11	ci_Exc11	

DM=Demographics

DS=Disposition

SS=Subject Status

MH=Medical History

COLCORONA: Randomization (Rando) [fm_Rando]

Randomization [fm_Rando]

<p>1. Was the subject randomized? [Randomization]</p>	<p>[rb_Randomization] [N:1] <input type="radio"/> [dt_Rando] Yes, specify date of Randomization: / / [N:0] <input type="radio"/> No</p> <p>DSCAT = "PROTOCOL MILESTONE" DSTERM = "RANDOMIZED"</p> <p>SSDTC DSSTDTC RFSTDTC</p>
<p>2. Randomization number [Randomization number]</p>	<p>[tx_RandoNumber] R- <input type="text"/> NOT SUBMITTED</p>
<p>3. Date of positive diagnosis for COVID-19 [Date of randomization]</p>	<p>[dt_Diagnosis] / / </p> <p>MHSTDTC MHTERM="COVID-19"</p>
<p>4. How was the Covid-19 diagnostic established? [Covid-19 Diagnostic]</p>	<p>[rb_DiagnostisType] [N:1] <input type="radio"/> Covid 19 screening test [N:2] <input type="radio"/> Epidemiologic link [N:3] <input type="radio"/> Clinical diagnostic</p> <p>SUPPMH.QVAL when QNAM = "C19DTEST"</p>
<p>5. Does the patient take any medications at randomization? [Any Meds at Rando]</p>	<p>[rb_AnyMedRando] [N:1] <input type="radio"/> Yes [N:0] <input type="radio"/> No</p> <p>SSTESTCD = "ANYMEDRD" SSTEST = "Any Medications at Randomization"</p> <p>SSORRES</p>

LB=Laboratory

COLCORONA: Pregnancy test (Preg Test) [fm_PregTest]		LBCAT = "CHEMISTRY"
Pregnancy test [fm_PregTest]		LBTEST = "Choriogonadotropine Beta" LBTESTCD = "HCG"
1. What was the date of pregnancy test [Date of pregnancy test]	[dt_PregTest] <input type="text"/> / <input type="text"/> / <input type="text"/> LBDTC	
2. What was the result of the pregnancy test? [Result of the pregnancy test]	[rb_PregTestResult] [N:1] <input type="radio"/> Negative LBORRES [N:2] <input type="radio"/> Positive (Subject is NOT eligible if the result is positive)	

COLCORONA: Biomarkers (BIO) [fm_Biomarkers]	
Biomarkers [fm_Biomarkers]	
1. Was sample collected? [Biomarkers Sample Collected]	<div style="text-align: right; border: 1px solid black; padding: 2px; color: orange; font-weight: bold;">NOT SUBMITTED</div> <p>[rb_Sample]</p> <p>[N:1] <input type="radio"/> Yes</p> <p>[N:2] <input type="radio"/> [tx_ReasonNoSample]</p> <p>No, specify reason:</p> <div style="border: 1px solid black; height: 40px; width: 100%;"></div> <p>[N:3] <input type="radio"/> Not Applicable</p>
2. Yes, specify sample collection date: [Biomarkers Sample collection date]	<div style="text-align: right; border: 1px solid black; padding: 2px; color: orange; font-weight: bold;">NOT SUBMITTED</div> <p>[dt_Sample]</p> <p> <input type="text" value=""/> / <input type="text" value=""/> / <input type="text" value=""/> </p>

COLCORONA: Pharmacogenomics (PGX) [fm_PGX]	
Pharmacogenomics [fm_PGX]	
1. Was sample collected? [Biomarkers Sample Collected]	[rb_Sample] [N:1] <input type="radio"/> Yes NOT SUBMITTED [N:2] <input type="radio"/> [tx_ReasonNoSample] No, specify reason: <div style="border: 1px solid black; height: 40px; width: 100%;"></div> [N:3] <input type="radio"/> Not Applicable
2. Yes, specify sample collection date: [Biomarkers Sample collection date]	[dt_Sample] <input type="text"/> / <input type="text"/> / <input type="text"/> NOT SUBMITTED

DA=Drug Accountability

SV=Subject Visit

SS=Subject Status

COLCORONA: Visit Information (Phone Contact) [fm_PhoneContact]	
Visit Information [fm_PhoneContact]	
1. Date of visit [Visit Done] <div style="border: 1px solid black; padding: 2px; margin-top: 5px;">SSORRES</div> <div style="border: 1px solid black; padding: 2px; margin-top: 5px;">SSTEST = "Visit Done"</div> <div style="border: 1px solid black; padding: 2px; margin-top: 5px;">SSTESTCD = "VISDONE"</div>	[rb_visitDone] <div style="border: 1px solid black; padding: 2px; margin-top: 5px;">SVSTDTC</div> <div style="border: 1px solid black; padding: 2px; margin-top: 5px;">SSDTC</div> [N:1] <input type="radio"/> [dt_DOVPC] Date of visit <input type="text"/> / <input type="text"/> / <input type="text"/> [N:0] <input type="radio"/> [tx_ReasonVND] Not done, specify: <div style="border: 1px solid black; padding: 2px; margin-top: 5px;">SSSTAT</div> <div style="border: 1px solid black; padding: 2px; margin-top: 5px;">SSREASND</div>
2. How was the visit conducted? [Visit Type]	[rb_VisitType] <div style="border: 1px solid black; padding: 2px; margin-top: 5px;">SSORRES</div> [N:1] <input type="radio"/> Phone or video Contact (direct contact with subject) <div style="border: 1px solid black; padding: 2px; margin-top: 5px;">SSTEST = "How Visit Conducted"</div> [N:2] <input type="radio"/> Phone or video Contact (not direct contact with subject) <div style="border: 1px solid black; padding: 2px; margin-top: 5px;">SSTESTCD = "VISCOND"</div> [N:3] <input type="radio"/> Not done
3. Were any new adverse events experienced? (If yes, please complete the AE Form) [Any AEs]	[rb_AnySAE] <div style="border: 1px solid black; padding: 2px; margin-top: 5px;">SSORRES</div> [N:1] <input type="radio"/> Yes <div style="border: 1px solid black; padding: 2px; margin-top: 5px;">SSTESTCD = "ANYAE"</div> [N:0] <input type="radio"/> No <div style="border: 1px solid black; padding: 2px; margin-top: 5px;">SSTEST = "Any Adverse Events"</div> [N:2] <input type="radio"/> Unknown
4. Were any new medications taken? (If yes, please complete the CM Form) [Any Med]	[rb_AnyMed] <div style="border: 1px solid black; padding: 2px; margin-top: 5px;">SSORRES</div> [N:1] <input type="radio"/> Yes <div style="border: 1px solid black; padding: 2px; margin-top: 5px;">SSTESTCD = "ANYNWMED"</div> [N:0] <input type="radio"/> No <div style="border: 1px solid black; padding: 2px; margin-top: 5px;">SSTEST = "Any New Medications"</div> [N:2] <input type="radio"/> Unknown
5. Did the subject take the IP every day since the last visit? [Compliant] <div style="border: 1px solid black; padding: 2px; margin-top: 5px;">SUPPDA.QVAL when QNAM = "D15COMPL" or QNAM = "EOSCOMPL"</div>	[rb_Comp] [N:1] <input type="radio"/> Yes <div style="border: 1px solid black; padding: 2px; margin-top: 5px;">SUPPDA.QVAL when QNAM = "D15MISSD" or QNAM = "EOSMISSD"</div> [N:2] <input type="radio"/> [in_AnyMissDose] No, please specify how many days the study medication has been missed since last visit: <input type="text"/> [N:3] <input type="radio"/> Not applicable (Subject never took any study medication since the last visit)

FA=Findings about

HO=Healthcare Encounters

COLCORONA: Subject Status D15 (Subject Status D15) [fm_SSD15]

Subject Status D15 [fm_SSD15]

1.	Are you symptom-free? [Symptom-free] FACAT = "LAST COVID-19 SYMPTOM" FAOBJ = "Symptom-free" FATESTCD= "OCCUR" FATEST= "Occurence"	[rb_Symptomfree] FAORRES [N:1] <input type="radio"/> [dt_LastSymptomFree] Yes, date of last known symptoms <input type="text"/> / <input type="text"/> / <input type="text"/> FADTC [N:0] <input type="radio"/> No [N:2] <input type="radio"/> Unknown
2.	Since your last visit have you been diagnosed with pneumonia? [Pneumonia Diagnosis] FACAT = "PNEUMONIA" FAOBJ = "New Diagnosis" FATESTCD = "OCCUR" FATEST= "Occurence"	[rb_PneumoniaDiagnosis] [N:1] <input type="radio"/> [rb_Hospitalization] Yes, required hospitalization? [N:1] <input type="radio"/> Yes (Please complete AE form) [N:0] <input type="radio"/> No [N:0] <input type="radio"/> No [N:2] <input type="radio"/> Unknown

HOCAT= "HOSPITALIZATION #" * See page 22

HOSCAT= "PNEUMONIA"

HOTERM = "HOSPITAL"

HOCCUR * If Yes, information will be reported in AE form. See page 22

FA=Findings about

HO=Healthcare Encounters

COLCORONA: Subject Status EOS (Subject Status EOS) [fm_SSOES]	
Subject Status EOS [fm_SSOES]	
1. Are you symptom-free? [Symptom-free] FACAT = "LAST COVID-19 SYMPTOM" FAOBJ = "SYMPTOM-FREE" FATESTCD = "OCCUR" FATEST = "Occurence"	[rb_Symptomfree] FAORRES [N:1] <input type="radio"/> [rb_LastSymptomFree] FASCAT = "SAME DATE OF LAST KNOWN SYMPTOM AS REPORTE AT DAY 15" Yes [N:1] <input type="radio"/> Same date of last known symptoms as reported on day 15 [N:2] <input type="radio"/> [dt_LastSymptomFree] After Day 15 date of last known symptoms <input type="text"/> / <input type="text"/> / <input type="text"/> FADTC [N:0] <input type="radio"/> No [N:2] <input type="radio"/> Unknown
2. Since your last visit have you been diagnosed with pneumonia? [Pneumonia Diagnosis] FACAT = "NEW DIAGNOSIS" FAOBJ = "PNEUMONIA" FATESTCD = "OCCUR" FATEST = "Occurence"	[rb_PneumoniaDiagnosis] FAORRES [N:1] <input type="radio"/> [rb_Hospitalization] HOCAT = "HOSPITALIZATION #" * See page 22 Yes, required hospitalization? [N:1] <input type="radio"/> Yes (Please complete AE form) HOSCAT = "PNEUMONIA" [N:0] <input type="radio"/> No HOTERM = "HOSPITAL" [N:0] <input type="radio"/> No [N:2] <input type="radio"/> Unknown HOOCCUR * If Yes, information will be reported in AE form. See page 22

DA=Drug Accountability

COLCORONA: Compliance (Compliance) [fm_Compliance]			
Compliance [fm_Compliance]		DACAT= "STUDY MEDICATION"	
1.	How many pills are left in the bottle [Pills Return]	[in_PillsReturn] <input type="text"/>	DATESTCD = "RETAMT"
	DAORRES		DATEST = "Returned Amount"

DA=Drug Accountability

EC = Exposure as Collected

DM=Demographics

COLCORONA: Study Drug Dispensed (Study Drug) [fm_StudyDrug]

Study Drug Dispensed [fm_StudyDrug]		DACAT= "STUDY MEDICATION"	DATESTCD = "DISPAMT"	DATEST = "Dispensed Amount"
1. Bottle number provided by subject [Bottle number dispensed]	DASCAT= "ONE BOTTLE"	[in_BND] <input type="text"/>	DAREFID	ECREFID
2. Additional dispensation (if applicable) [Additional dispensation]		[in_AddBD] <input type="text"/>	DASCAT= "TWO BOTTLES" * DAREFID = Concatenation of in_BND and in_AddBND if additional dispensation	
3. IP delivery date: [IP delivery date]		[dt_Delivery] <input type="text"/> / <input type="text"/> / <input type="text"/> <input type="text"/> : <input type="text"/> 24-hour clock	DADTC	
4. Date of first dose of study medication [First Dose Study Drug]		[dt_FirstDose_1] <input type="text"/> / <input type="text"/> / <input type="text"/> <input type="text"/> : <input type="text"/> 24-hour clock	ECCAT = "TREATMENT" ECSTDTC RFXSTDTC	

DS=Disposition

EC = Exposure as Collected

DA=Drug Accountability

DM=Demographics

COLCORONA: STUDY COMPLETION (SC) [fm_SC]

STUDY COMPLETION [fm_SC]

<p>1. What was the date of Completion/Discontinuation? [What was the date of Completion/Discontinuation?]</p>	<p>[dt_sc] / /</p> <p>DSSTDTC DADTC * When DATEST = "Returned Amount"</p> <p>RFENDTC</p>
<p>2. Date of first dose of study medication [First Dose Study Drug]</p>	<p>[dt_FistDose] / /</p> <p>: : 24-hour clock</p> <p>NOT SUBMITTED *Collected at page 19</p>
<p>3. Date of last dose of study medication [Last Dose Study Drug]</p>	<p>[dt_LastDose] / /</p> <p>ECENDTC RFXENDTC</p>
<p>4. What was the subject's status? [What was the subject's status?]</p>	<p>[rb_sc] DSDECOD DSCAT = "DISPOSITION EVENT"</p> <p>[N:1] <input type="radio"/> Completed</p> <p>[N:2] <input type="radio"/> Discontinued due to Death</p> <p>[N:3] <input type="radio"/> [tx_SpeInvDecision] Discontinued due to Investigator decision, specify:</p> <p>DSTERM</p> <p>[N:4] <input type="radio"/> Discontinued due to Lost To Follow-up</p> <p>[N:5] <input type="radio"/> Discontinued due to Site Terminated by Sponsor</p> <p>[N:6] <input type="radio"/> Discontinued due to Withdrawal of Consent by Subject</p> <p>[N:7] <input type="radio"/> [tx_scoth] Other specify:</p> <p>DSTERM</p>

DV=Protocol Deviations

COLCORONA: PROTOCOL DEVIATIONS (Prot Dev) [fm_PV]	
PROTOCOL DEVIATIONS [fm_PV]	
1. Were there any protocol deviations? [Any Deviations?]	<p>[rb_AnyPD] [N:0] <input type="radio"/> No NOT SUBMITTED [N:1] <input type="radio"/> Yes</p>
2. What was the protocol deviation? [What was the protocol deviation?]	<p>[cb_PD] [N:1] <input type="checkbox"/> Selection criteria not met NOT SUBMITTED * See section 4.1 below [N:2] <input type="checkbox"/> [rb_PDIC] Informed consent [N:1] <input type="radio"/> Failure to obtain informed consent. [N:2] <input type="radio"/> Informed consent form was not properly completed (copy was not given to patient, a page is missing or illegible, subject did not initial a page) [N:3] <input type="radio"/> Informed consent obtained after subject has started study procedures [N:3] <input type="checkbox"/> [tx_ProhMed] Prohibited concomitant medication, specify <div style="border: 1px solid black; height: 40px; width: 100%;"></div> [N:4] <input type="checkbox"/> Subject was prematurely unblinded in error [N:5] <input type="checkbox"/> Incorrect dose or wrong study product kit administered to subject [N:6] <input type="checkbox"/> Subject received another investigational agent [N:7] <input type="checkbox"/> [tx_PDReason] Other, specify: <div style="border: 1px solid black; height: 40px; width: 100%;"></div></p>
3. What was the date of the protocol deviation? [What was the date of the protocol deviation?]	<p>[dt_PD] <div style="display: flex; align-items: center; gap: 10px;"> <div style="border: 1px solid black; padding: 2px;">▼</div> / <div style="border: 1px solid black; padding: 2px;">▼</div> / <div style="border: 1px solid black; padding: 2px;">▼</div> </div> </p>
<p>What was the protocol deviation? What was the date of the protocol deviation?</p>	
4. ✓	
Add Protocol Deviation Entry [sc_ProtocolDeviation]	
4.1 What was the protocol deviation? [What was the protocol deviation?]	<p>[cb_PD_1] DVDECOD [N:1] <input type="checkbox"/> Selection criteria not met [N:2] <input type="checkbox"/> [rb_PDIC_1] Informed consent DVTERM [N:1] <input type="radio"/> Failure to obtain informed consent. [N:2] <input type="radio"/> Informed consent form was not properly completed (copy was not given to patient, a page is missing or illegible, subject did not initial a page) [N:3] <input type="radio"/> Informed consent obtained after subject has started study procedures [N:3] <input type="checkbox"/> [tx_ProhMed_1] Prohibited concomitant medication, specify <div style="border: 1px solid black; padding: 5px; text-align: center;">DVTERM</div> [N:4] <input type="checkbox"/> Subject was prematurely unblinded in error [N:5] <input type="checkbox"/> Incorrect dose or wrong study product kit administered to subject [N:6] <input type="checkbox"/> Subject received another investigational agent [N:7] <input type="checkbox"/> [tx_PDReason_1] Other deviation <div style="border: 1px solid black; padding: 5px; text-align: center;">DVTERM</div></p>
4.2 What was the date of the protocol deviation? [What was the date of the protocol deviation?]	<p>[dt_PD_1] <div style="display: flex; align-items: center; gap: 10px;"> <div style="border: 1px solid black; padding: 2px;">▼</div> / <div style="border: 1px solid black; padding: 2px;">▼</div> / <div style="border: 1px solid black; padding: 2px;">▼</div> </div> DVSTDTC </p>

AE=Adverse Events

PR=Procedures

CO=Comments

EC = Exposure as Collected

HO=Healthcare Encounters

DD=Death Details

COLCORONA: Adverse Event (AE) - Repeating Form [fm_AE]													
#	AE number	Any AE	Date of onset	AE started point	Is the adverse event serious?	Subject hospitalised	Procedure/Treatment Perform	Severity	Is this event related to study treatment?	What action was taken with study treatment?	What was the outcome of this adverse event?	AE comment	AE Term
1													
Adverse Event [fm_AE]													
Please enter one adverse event per line for each event that occurred after the study treatment administration.													
1.	AE Identifier [autofilled, read only] [AE number]					[in_AESeq] <input type="text"/> AESPID							
2.	Adverse Event term <i>Do not use abbreviations</i> [Any AE]					[rb_AE] [N:1] <input type="radio"/> [tx_AECovid19] AECAT = "HOSPITALIZATION DUE TO COVID-19 COMPLICATION" Hospitalization due to covid19 complication, specify: NOT SUBMITTED * Derived in item no. 13 [N:2] <input type="radio"/> [tx_OtherAE] Other, specify: AECAT = "OTHER ADVERSE EVENT" NOT SUBMITTED * Derived in item no. 13							
3.	What is the date the adverse event started? [Date of onset]					[dt_AEOnset] <input type="text"/> / <input type="text"/> / <input type="text"/> AESTDTC							
4.	If the AE started the same day as delivery date, did the AE start prior delivery of IP? [AE started point]					[rb_AEstartedpoint] [N:1] <input type="radio"/> Yes SUPPAE.QVAL when QNAM = "PRIORDIP" [N:0] <input type="radio"/> No							
5.	Which category is it? [Is the adverse event serious?]					[cb_AECat] [N:1] <input type="checkbox"/> [rb_Death] AESER Serious adverse event, specify: [N:0] <input type="radio"/> No [N:1] <input type="radio"/> Yes, Fatal or immediately life-threatening AESLIFE AESDTH *If outcome is "Death" [rb_LifeT] [N:0] <input type="radio"/> No [N:1] <input type="radio"/> Yes, Results in persistent or significant disability/incapacity AESDISAB [rb_hosp] [N:0] <input type="radio"/> No [N:1] <input type="radio"/> Yes, Requires or prolongs inpatient hospitalization AESHOSP [rb_cong] [N:0] <input type="radio"/> No [N:1] <input type="radio"/> Yes, A congenital anomaly/birth defect in the offspring of the patient AESCONG [rb_cancer] [N:0] <input type="radio"/> No [N:1] <input type="radio"/> Yes, Cancer AESCAN [rb_Overdose] [N:0] <input type="radio"/> No [N:1] <input type="radio"/> Yes, Overdose (intentional or accidental) AESOD [rb_otherm] [N:0] <input type="radio"/> No [N:1] <input type="radio"/> Yes, Other Medically important event AESMIE [N:2] <input type="checkbox"/> Gastrointestinal AE [N:3] <input type="checkbox"/> Adverse Event related to study drug as per Principal Investigator judgment [N:4] <input type="checkbox"/> Laboratory abnormality (judged clinically significant)							
AESCAT *Concatenate all checks separate by " "													
6.	If subject hospitalised: [Subject hospitalised]					[cp_Subjecthospitalised] HOSTDTC [dt_HospAdmin] Admission date: <input type="text"/> / <input type="text"/> / <input type="text"/> HOTERM = "HOSPITAL" HOCCUR = "Y" [cp_Discharge] [dt_HospDis] HOENDTC [cb_Discharge] Discharge date: <input type="text"/> / <input type="text"/> / <input type="text"/> [N:1] <input type="radio"/> Not discharge at study completion HOENRTPT = "ONGOING"							
7.	Was mechanical ventilation performed or treatment given for this event? [Procedure/Treatment Perform]					[rb_PTYN] [N:1] <input type="radio"/> Yes PROCCUR [N:1] <input type="checkbox"/> [dt_MVSTR] Mechanical ventilation, Start date: <input type="text"/> / <input type="text"/> / <input type="text"/> PRSTDTC [dt_MVSTP] Stop date: <input type="text"/> / <input type="text"/> / <input type="text"/> PRENDTC [N:2] <input type="checkbox"/> Treatment [N:0] <input type="radio"/> No SUPPAE.QVAL when QNAM = "TRTGIVEN"							
8.	What was the Intensity of the adverse event?					[rb_AESev] [N:1] <input type="radio"/> Mild (discomfort noticed but no disruption of normal daily activity) AESEV							

	<p>[Severity]</p> <p>[N:2] <input type="radio"/> Moderate (discomfort sufficient to reduce or affect daily activity) [N:3] <input type="radio"/> Severe (inability to work or perform normal daily activity)</p>
<p>9. Is this event related to study treatment? [Is this event related to study treatment?]</p>	<p>[rb_AERel] AEREL</p> <p>[N:1] <input type="radio"/> Not related [N:2] <input type="radio"/> Possibly related [N:3] <input type="radio"/> Probably related</p>
<p>10. What action was taken with study treatment? [What action was taken with study treatment?]</p>	<p>[rb_action] AEACN</p> <p>[N:1] <input type="radio"/> Dose not changed [N:2] <input type="radio"/> Dose reduced [N:3] <input type="radio"/> [dt_DrugEnd] Drug interrupted, Interruption date [dt_DrugEnd] / / [ECENDTC] ECCAT = "INTERRUPTION" [dt_DrugRestart] Restart date [dt_DrugRestart] / / [ECSTDTC]</p> <p>[N:4] <input type="radio"/> Drug withdrawn [N:5] <input type="radio"/> Not applicable [N:6] <input type="radio"/> Unknown</p>
<p>11. What was the outcome of this adverse event? [What was the outcome of this adverse event?]</p>	<p>[rb_AEOUT] AEOUT</p> <p>[N:1] <input type="radio"/> [dt_Death] Death Related to Adverse Event, specify date of death: [dt_Death] / / [AEENDTC]</p> <p>[rb_Causeofdeath] Cause of death: DDTESTCD = "Cause of Death" DDTESTCD = "CDTH" DDORRES</p> <p>[N:1] <input type="radio"/> Respiratory [N:2] <input type="radio"/> Non-Respiratory [N:3] <input type="radio"/> Undetermined</p> <p>[N:2] <input type="radio"/> Not Recovered/Not resolved [N:3] <input type="radio"/> [dt_AEEnd1] Recovered/Resolved, specify end date [dt_AEEnd1] / / [AEENDTC]</p> <p>[N:4] <input type="radio"/> [dt_AEEnd2] Resolved with sequelae, specify end date [dt_AEEnd2] / / [AEENDTC]</p> <p>[N:5] <input type="radio"/> Recovering/Resolving [N:6] <input type="radio"/> Unknown</p>
<p>12. Event description [AE comment]</p>	<p>[tx_AEcom] GOVAL SUPPAE.QVAL when QNAM = "AESMIE"</p>
<p>13. AE Term [AE Term]</p>	<p>[tx_AETerm] AETERM</p>
<p>14. Coder's Name [Coder's Name]</p>	<p>[tx_CoderName] NOT SUBMITTED</p>
<p>15. Dictionary Version [Dictionary Version]</p>	<p>[tx_DictionaryVersion] NOT SUBMITTED</p>
<p>16. SOC Term [SOC Term]</p>	<p>[tx_SOCTerm] AEBODSYS</p>
<p>17. SOC Code [SOC Code]</p>	<p>[tx_SOCCode] AEBDSYCD</p>

18.	HLGT Term [HLGT Term]	[tx_HLGTterm] AEHLGT
19.	Flag for Serious AE [Flag for Serious AE]	[in_FlagAESerious] <input type="checkbox"/> NOT SUBMITTED
20.	HLGT Code [HLGT Code]	[tx_HLGTCode] AEHLGTCD
21.	HLT Term [HLT Term]	[tx_HLTterm] AEHLT
22.	HLT Code [HLT Code]	[tx_HLTCode] AEHLTCD
23.	PT Term [PT Term]	[tx_PTterm] AEDECOD
24.	PT Code [PT Code]	[tx_PTCode] AEPTCD
25.	LLT Term [LLT Term]	[tx_LLTerm] AELLT
26.	LLT Code [LLT Code]	[tx_LLCode] AELLTCD
27.	Verbatim Comparison [Verbatim Comparison]	[tx_VERBCOMP] NOT SUBMITTED

CM=Concomitant/Prior Medications

CO=Comments

COLCORONA: Concomitant Medications (including natural health products and dietary supplements) (ConMed) - Repeating Form [fm_CM]

#	ConMed #	Medication	Start date	End date	What was the route of administration of the medication?	For what indication was the medication taken?	CM comment
1							

Concomitant Medications (including natural health products and dietary supplements) [fm_CM]

Please enter only one medication per line for each medication ongoing or started from randomization (with the exceptions of concomitant medication taken when necessary (PRN)). Provide the full trade or proprietary name of the drug or therapy; otherwise the generic name may be recorded.

1.	Concomitant Medication identifier (autofilled) [ConMed #]	[in_CMNum] <input type="text"/> CMSPID
2.	What was the term for the medication taken? [Medication]	[tx_CMTRT] <input type="text"/> CMTRT
3.	What was the start date of the medication? [Start date]	[dt_CMStart] <input type="text"/> / <input type="text"/> / <input type="text"/> CMSTDTC
4.	Is the medication still ongoing? [End date]	[rb_CMEndStatus] No, End date: [N:1] <input type="radio"/> [dt_CMStop] <input type="text"/> / <input type="text"/> / <input type="text"/> CMENDTC [N:2] <input type="radio"/> Yes CMENRPT="ONGOING" when "Yes" is checked
5.	What was the route of administration of the medication? [What was the route of administration of the medication?]	[rb_route] [N:1] <input type="radio"/> INHALATION [N:2] <input type="radio"/> INTRALESION [N:3] <input type="radio"/> INTRAMUSCULAR [N:4] <input type="radio"/> INTRAOCULAR CMROUTE [N:5] <input type="radio"/> INTRAPERITONEAL [N:6] <input type="radio"/> INTRAVASCULAR [N:7] <input type="radio"/> NASAL [N:8] <input type="radio"/> ORAL [N:9] <input type="radio"/> RECTAL [N:10] <input type="radio"/> SUBCUTANEOUS [N:11] <input type="radio"/> TOPICAL [N:12] <input type="radio"/> TRANSDERMAL [N:13] <input type="radio"/> VAGINAL [N:14] <input type="radio"/> UNKNOWN [N:15] <input type="radio"/> [tx_routeoth] Other specify: <input type="text"/>
6.	For what indication was the medication taken? [For what indication was the medication taken?]	[tx_indic] <input type="text"/> CMINDC
7.	Comment [CM comment]	[tx_comment] <input type="text"/> COVAL
8.	Medical Coder Name [Medical Coder Name]	[tx_MedCoderName] <input type="text"/> NOT SUBMITTED
9.	Medical Dictionary [Medical Dictionary]	[tx_MedDictionary] <input type="text"/> NOT SUBMITTED
10.	ATC1 Term [ATC1 Term]	[tx_ATC1Term] <input type="text"/> SUPPCM.QVAL when QNAM = "ATC1"

11.	ATC1 Code [ATC1 Code]	[tx_ATC1Code] SUPPCM.QVAL when QNAM = "ATC1CD"
12.	ATC2 Term [ATC2 Term]	[tx_ATC2Term] SUPPCM.QVAL when QNAM = "ATC2"
13.	ATC2 Code [ATC2 Code]	[tx_ATC2Code] SUPPCM.QVAL when QNAM = "ATC2CD"
14.	ATC3 Term [ATC3 Term]	[tx_ATC3Term] SUPPCM.QVAL when QNAM = "ATC3"
15.	ATC3 Code [ATC3 Code]	[tx_ATC3Code] SUPPCM.QVAL when QNAM = "ATC3CD"
16.	ATC4 Term [ATC4 Term]	[tx_ATC4Term] SUPPCM.QVAL when QNAM = "ATC4"
17.	Medical Term Comparaison [Medical Term Comparaison]	[tx_CONMEDCOMP] NOT SUBMITTED
18.	ATC4 Code [ATC4 Code]	[tx_ATC4Code] SUPPCM.QVAL when QNAM = "ATC4CD"
19.	Preferred Name [Preferred Name]	[tx_PrefName] CMDECOD
20.	Preferred Name Code [Preferred Name Code]	[tx_PrefNameCode] SUPPCM.QVAL when QNAM = "PNCD"
21.	Trade Name	[tx_TradeName]

	[Trade Name]	SUPPCM.QVAL when QNAM = "TRDNM"
22.	Trade Name Code [Trade Name Code]	[tx_TradeNameCode] SUPPCM.QVAL when QNAM = "TRDNMCD"