

Using CDISC Standards for COVID-19 Data

A Review of the CDISC COVID-19 TAUG

01 April 2020

Summary

- CDISC is rapidly developing a COVID-19 TAUG during pandemic crisis
 - To support the standardized tabulations (i.e., SDTM) of data collected about COVID-19 in clinical research
 - Very aggressive target to have a provisional standard in 45 days (that's < 10% of the time it usually takes to “quickly” develop a TAUG...)
- Like all CDISC TAUGs, COVID-19 TAUG will primarily use existing foundational standards (CDASH, SDTM, CDISC Controlled Terminology)
 - *This is part of the reason why CDISC should be able to publish this “interim TAUG” so quickly - there won't be much that's **new** - it will mostly be applying existing CDISC standards to represent data that is relevant to COVID-19*
 - *Another reason CDISC will be able to move quickly is that the CDISC teams have experience developing TAUG examples for infectious diseases (e.g., Ebola, TB, Hep-C, Malaria...) so it will mainly be developing and explaining the examples*

CDISC Interim User Guide for COVID-19

From CDISC Wiki

<https://wiki.cdisc.org/display/COVID19/CDISC+Interim+User+Guide+for+COVID-19>

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- ☐ Risk Factors
- ☐ Medical History (MH)
- ☐ Concomitant Medication Use (SU)

MEDICAL HISTORY		
Does the participant have any of the following Risk Factors?	Yes	No
Asthma		
Diabetes		
Hypertension		
Does the participant have any other significant medical history?		
If yes, record condition	Start Date	Ongoing

	STUDYID	DOMAIN	USUBJID	MHSEQ	MHTERM	MHDECOD	MHCAT	MHPRESP	MHOCCUR	MHENRTPT	MHENTPT
• V	COV-19	MH	COV-19-001	1	ASTHMA	Asthma	RISK FACTOR	Y	Y	ONGOING	2020-03-29
• C	COV-19	MH	COV-19-001	2	DIABETES	Diabetes mellitus	RISK FACTOR	Y	N		
• A	COV-19	MH	COV-19-001	3	HYPERTENSION	Hypertension	RISK FACTOR	Y	Y	ONGOING	2020-03-29
• P	COV-19	MH	COV-19-001	4	FREQUENT HEADACHES	Headache	GENERAL HISTORY			ONGOING	2020-03-29
• F	COV-19	MH	COV-19-002	1	ASTHMA	Asthma	RISK FACTOR	Y	N		
	COV-19	MH	COV-19-002	2	DIABETES	Diabetes mellitus	RISK FACTOR	Y	N		
	COV-19	MH	COV-19-002	3	HYPERTENSION	Hypertension	RISK FACTOR	Y	N		

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Signs and Symptoms

Has the participant had any of the following signs or symptoms since the start of acute illness?	Yes	No
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Fever		
Cough		

Cough with Sputum Production		
Cough with Bloody Sputum/Haemoptysis		
Runny Nose		
Ear Pain		
Wheezing		
Chest Pain		
Shortness of Breath		

fections

- Risk Factors
 - Medical History (MH)
 - Substance Use (SU)
- Signs and Symptoms
 - Findings About (FA)
 - FATEST=Occurrence FAOBJ=Cough

STUDYID	DOMAIN	USUBRID	FASEQ	FATESTCD	FATEST	FAOBJ	FACAT	FAORRES	FASTRES	FAEVAL	FAIPI	FAIPNUM	FADTC	FAEVIIX
10V-19	FA	COV-19-001	1	OCCUR	Occurrence Indicator	HISTORY OF FEVER	ADMISSION SIGNS AND SYMPTOMS	Y	Y	INTAKE NURSE	BASLINE		1	2020-04-01 SINCE START OF ACUTE ILLNES
10V-19	FA	COV-19-001	2	OCCUR	Occurrence Indicator	COUGH	ADMISSION SIGNS AND SYMPTOMS	Y	Y	INTAKE NURSE	BASLINE		1	2020-04-01 SINCE START OF ACUTE ILLNES
10V-19	FA	COV-19-001	3	OCCUR	Occurrence Indicator	COUGH WITH SPUTUM PRODUCTION	ADMISSION SIGNS AND SYMPTOMS	Y	Y	INTAKE NURSE	BASLINE		1	2020-04-01 SINCE START OF ACUTE ILLNES
10V-19	FA	COV-19-001	4	OCCUR	Occurrence Indicator	COUGH WITH BLOODY SPUTUM/HAEMOPTYSIS	ADMISSION SIGNS AND SYMPTOMS	N	N	INTAKE NURSE	BASLINE		1	2020-04-01 SINCE START OF ACUTE ILLNES
10V-19	FA	COV-19-001	5	OCCUR	Occurrence Indicator	RUNNY NOSE	ADMISSION SIGNS AND SYMPTOMS	N	N	INTAKE NURSE	BASLINE		1	2020-04-01 SINCE START OF ACUTE ILLNES
10V-19	FA	COV-19-001	6	OCCUR	Occurrence Indicator	EAR PAIN	ADMISSION SIGNS AND SYMPTOMS	N	N	INTAKE NURSE	BASLINE		1	2020-04-01 SINCE START OF ACUTE ILLNES
10V-19	FA	COV-19-001	7	OCCUR	Occurrence Indicator	WHEEZING	ADMISSION SIGNS AND SYMPTOMS	Y	Y	INTAKE NURSE	BASLINE		1	2020-04-01 SINCE START OF ACUTE ILLNES
10V-19	FA	COV-19-001	8	OCCUR	Occurrence Indicator	CHEST PAIN	ADMISSION SIGNS AND SYMPTOMS	Y	Y	INTAKE NURSE	BASLINE		1	2020-04-01 SINCE START OF ACUTE ILLNES
10V-19	FA	COV-19-001	9	OCCUR	Occurrence Indicator	SHORTNESS OF BREATH	ADMISSION SIGNS AND SYMPTOMS	Y	Y	INTAKE NURSE	BASLINE		1	2020-04-01 SINCE START OF ACUTE ILLNES
10V-19	FA	COV-19-002	1	OCCUR	Occurrence Indicator	HISTORY OF FEVER	ADMISSION SIGNS AND SYMPTOMS	Y	Y	INTAKE NURSE	BASLINE		1	2020-04-12 SINCE START OF ACUTE ILLNES
10V-19	FA	COV-19-002	2	OCCUR	Occurrence Indicator	COUGH	ADMISSION SIGNS AND SYMPTOMS	Y	Y	INTAKE NURSE	BASLINE		1	2020-04-12 SINCE START OF ACUTE ILLNES
10V-19	FA	COV-19-002	3	OCCUR	Occurrence Indicator	COUGH WITH SPUTUM PRODUCTION	ADMISSION SIGNS AND SYMPTOMS	N	N	INTAKE NURSE	BASLINE		1	2020-04-12 SINCE START OF ACUTE ILLNES
10V-19	FA	COV-19-002	4	OCCUR	Occurrence Indicator	COUGH WITH BLOODY SPUTUM/HAEMOPTYSIS	ADMISSION SIGNS AND SYMPTOMS	N	N	INTAKE NURSE	BASLINE		1	2020-04-12 SINCE START OF ACUTE ILLNES
10V-19	FA	COV-19-002	5	OCCUR	Occurrence Indicator	RUNNY NOSE	ADMISSION SIGNS AND SYMPTOMS	N	N	INTAKE NURSE	BASLINE		1	2020-04-12 SINCE START OF ACUTE ILLNES
10V-19	FA	COV-19-002	6	OCCUR	Occurrence Indicator	EAR PAIN	ADMISSION SIGNS AND SYMPTOMS	Y	Y	INTAKE NURSE	BASLINE		1	2020-04-12 SINCE START OF ACUTE ILLNES
10V-19	FA	COV-19-002	7	OCCUR	Occurrence Indicator	WHEEZING	ADMISSION SIGNS AND SYMPTOMS	Y	Y	INTAKE NURSE	BASLINE		1	2020-04-12 SINCE START OF ACUTE ILLNES
10V-19	FA	COV-19-002	8	OCCUR	Occurrence Indicator	CHEST PAIN	ADMISSION SIGNS AND SYMPTOMS	Y	Y	INTAKE NURSE	BASLINE		1	2020-04-12 SINCE START OF ACUTE ILLNES
10V-19	FA	COV-19-002	9	OCCUR	Occurrence Indicator	SHORTNESS OF BREATH	ADMISSION SIGNS AND SYMPTOMS	Y	Y	INTAKE NURSE	BASLINE		1	2020-04-12 SINCE START OF ACUTE ILLNES
10V-19	FA	COV-19-003	1	OCCUR	Occurrence Indicator	HISTORY OF FEVER	ADMISSION SIGNS AND SYMPTOMS	Y	Y	INTAKE NURSE	BASLINE		1	2020-04-15 SINCE START OF ACUTE ILLNES
10V-19	FA	COV-19-003	2	OCCUR	Occurrence Indicator	COUGH	ADMISSION SIGNS AND SYMPTOMS	Y	Y	INTAKE NURSE	BASLINE		1	2020-04-15 SINCE START OF ACUTE ILLNES
10V-19	FA	COV-19-003	3	OCCUR	Occurrence Indicator	COUGH WITH SPUTUM PRODUCTION	ADMISSION SIGNS AND SYMPTOMS	Y	Y	INTAKE NURSE	BASLINE		1	2020-04-15 SINCE START OF ACUTE ILLNES
10V-19	FA	COV-19-003	4	OCCUR	Occurrence Indicator	COUGH WITH BLOODY SPUTUM/HAEMOPTYSIS	ADMISSION SIGNS AND SYMPTOMS	Y	Y	INTAKE NURSE	BASLINE		1	2020-04-15 SINCE START OF ACUTE ILLNES
10V-19	FA	COV-19-003	5	OCCUR	Occurrence Indicator	RUNNY NOSE	ADMISSION SIGNS AND SYMPTOMS	Y	Y	INTAKE NURSE	BASLINE		1	2020-04-15 SINCE START OF ACUTE ILLNES
10V-19	FA	COV-19-003	6	OCCUR	Occurrence Indicator	EAR PAIN	ADMISSION SIGNS AND SYMPTOMS	Y	Y	INTAKE NURSE	BASLINE		1	2020-04-15 SINCE START OF ACUTE ILLNES
10V-19	FA	COV-19-003	7	OCCUR	Occurrence Indicator	WHEEZING	ADMISSION SIGNS AND SYMPTOMS	Y	Y	INTAKE NURSE	BASLINE		1	2020-04-15 SINCE START OF ACUTE ILLNES
10V-19	FA	COV-19-003	8	OCCUR	Occurrence Indicator	CHEST PAIN	ADMISSION SIGNS AND SYMPTOMS	Y	Y	INTAKE NURSE	BASLINE		1	2020-04-15 SINCE START OF ACUTE ILLNES
10V-19	FA	COV-19-003	9	OCCUR	Occurrence Indicator	SHORTNESS OF BREATH	ADMISSION SIGNS AND SYMPTOMS	Y	Y	INTAKE NURSE	BASLINE		1	2020-04-15 SINCE START OF ACUTE ILLNES

- Concomitant Medications
- Procedures
 - Mechanical
- Vaccines
- Questionnaires, Ratios, and Scales
 - Clinical Global Impression
 - National Eye Institute Visual Function Index
- Associated Persons
- Personal Protective Equipment
- FDA Guidance for Industry
 - Missed Visits
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☐ Virus Identification in Microbiology Specimen (MB) domain

☐ New terms requested in Package 42 (June 2020)

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Codelist Name: Microorganism						
Codelist Description: Microorganisms, bacteria, fungi and other organisms.						
Codelist Extensible: Yes						
Addition(s) to an existing codelist						
NCI/EVS Request Number	Therapeutic Area Request	Codelist Short Name	TESTCD, PARMCD or Submission Value	TEST or PARM	Synonym(s)	CDISC Definition
CDISC-4219		MICROORG	SARS-CoV-2		Severe Acute Respiratory Syndrome Coronavirus 2, 2019-nCoV, COVID-19 Virus, SARS2	Any viral organism that can be assigned to the species severe acute respiratory syndrome Coronavirus 2.

Codelist Name: Microbiology Test Code/Test Name						
Codelist Description: Terminology relevant to the microbiology test codes/test names of the CDISC Study Data Tabulation Model.						
Codelist Extensible: Yes						
Addition(s) to an existing codelist						
NCI/EVS Request Number	Therapeutic Area Request	Codelist Short Name	TESTCD, PARMCD or Submission Value	TEST or PARM	Synonym(s)	CDISC Definition
CDISC-4219		MBTEST, MBTESTCD	SARSCOV2	Severe Acute Resp Syndrome Coronavirus 2	Severe Acute Resp Syndrome Coronavirus 2; Severe Acute Respiratory Syndrome Coronavirus 2	A measurement of the severe acute respiratory syndrome Coronavirus 2 in a biological specimen.

- ☐ Reference Influenza TAUG V1.1 for relevant Virology and Immunologic Response examples
- ☐ Reference SDTMIG V3.3 Section 6.3.5 for Immunogenicity Specimen Assessments (IS)
- ☐ Assay Kits might use Device Domains to describe and track them, and Biospecimen (BE) for specimen handling - TBD

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Spirometry		
	Result	Unit
FEV1		L
FVC		L
PEF		L/s

Vital Signs

	Result	Unit
Height		in cm
Temperature		C F
Systolic Blood Pressure		mmHg
Diastolic Blood Pressure		mmHg
Respiratory Rate		breaths/min
Pulse		beats/min

- VS_VSORRES_HEIGHT
- VS_VSORRESU_HEIGHT
- VS_VSORRES_TEMP
- VS_VSORRESU_TEMP
- VS_VSORRES_SYSBP
- VS_VSORRES_DIABP
- VS_VSORRES_RESP
- VS_VSORRES_PULSE

- Vital Signs (VS)
- Laboratory Results (LB)
- Biospecimen (BE) handling
- Respiratory Findings (RE)
 - Pulmonary Function tests
 - Results from Imaging

STUDYID	DOMAIN	USUBJID	RESEQ	RETESTCD	RETEST	REORRES	REORRESU	RESTRESC	RESTRESN	RESTRESU	REDAT
COV-19	RE	COV-19-001	1	FEV1	Forced Expiratory Volume in 1 Second	2.73	L	2.73	2.73	L	2020-03-18
COV-19	RE	COV-19-001	2	FVC	Forced Vital Capacity	3.91	L	3.91	3.91	L	2020-03-18
COV-19	RE	COV-19-001	3	PEF	Peak Expiratory Flow	6.11	L/s	6.11	6.11	L/s	2020-03-18

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STUDYID	DOMAIN	USUBJID	HOSEQ	HOTERM	HOSDTC	HOENDTC	HOENRPT	HOENTPT
COV-19	HO	COV-19-001	1	EMERGENCY ROOM	2020-03-20	2020-03-20		
COV-19	HO	COV-19-001	2	INPATIENT HOSPITALIZATION	2020-03-20	2020-03-22		
COV-19	HO	COV-19-001	3	ICU	2020-03-22	2020-03-27		
COV-19	HO	COV-19-001	4	INPATIENT HOSPITALIZATION	2020-03-27		ONGOING	2020-03-29
COV-19	HO	COV-19-002	1	EMERGENCY ROOM	2020-03-20	2020-03-20		
COV-19	HO	COV-19-002	2	ICU	2020-03-20	2020-03-22		
COV-19	HO	COV-19-002	3	INPATIENT HOSPITALIZATION	2020-03-27		ONGOING	2020-03-29

Healthcare Encounters (HO)

Hospitalizations

ICU

Concomitant Medications (CM)

STUDYID	DOMAIN	USUBJID	CMSEQ	CMTRT	CMEVINTX
COV-19	CM	COV-19-001	1	ACETAMINOPHEN	BEFORE HOSPITALIZATION
COV-19	CM	COV-19-002	1	IBUPROFEN	BEFORE HOSPITALIZATION
COV-19	CM	COV-19-003	1	ZINC LOZENGES	BEFORE HOSPITALIZATION
COV-19	CM	COV-19-004	1	ASPIRIN	BEFORE HOSPITALIZATION
COV-19	CM	COV-19-005	1	ACETAMINOPHEN	BEFORE HOSPITALIZATION
COV-19	CM	COV-19-006	1	ACETAMINOPHEN	BEFORE HOSPITALIZATION
COV-19	CM	COV-19-006	2	IBUPROFEN	BEFORE HOSPITALIZATION
COV-19	CM	COV-19-007	1	ACETAMINOPHEN	BEFORE HOSPITALIZATION
COV-19	CM	COV-19-007	2	IBUPROFEN	BEFORE HOSPITALIZATION
COV-19	CM	COV-19-007	3	ASPIRIN	BEFORE HOSPITALIZATION

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COV-19	PR	COV-19-001	1	ABC002	Mechanical Ventilation	INVASIVE VENTILATION	2020-03-10	2020-04-12		DURING HOSPITALIZATION
COV-19	PR	COV-19-002	1		Non-Invasive Ventilation	NON-INVASIVE VENTILATION			P2W	DURING HOSPITALIZATION
COV-19	PR	COV-19-003	1		Intubation/tracheostomy and mechanical ventilation	INVASIVE VENTILATION			P5W	DURING HOSPITALIZATION
COV-19	PR	COV-19-004	1		Prone Ventilation	INVASIVE VENTILATION			P3DT12H	DURING HOSPITALIZATION
COV-19	PR	COV-19-005	1		Tracheostomy and mechanical ventilation	INVASIVE VENTILATION			P3W	DURING HOSPITALIZATION
COV-19	PR	COV-19-006	1		CPAP	NON-INVASIVE VENTILATION	2020-03-10	2020-04-12		DURING HOSPITALIZATION
COV-19	PR	COV-19-006	2		Invasive Ventilation	INVASIVE VENTILATION			P5W	DURING HOSPITALIZATION
COV-19	PR	COV-19-007	1		High-flow Nasal Oxygen	NON-INVASIVE VENTILATION			P1D	DURING HOSPITALIZATION
COV-19	PR	COV-19-007	2		Intubation/tracheostomy and mechanical ventilation	INVASIVE VENTILATION			P2W	DURING HOSPITALIZATION
COV-19	PR	COV-19-007	3		ECMO	INVASIVE VENTILATION			P4D	DURING HOSPITALIZATION

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- ☐ Procedures (PR)
 - ☐ Mechanical Ventilation (may require new terminology in PROCEDUR codelist)
- ☐ Vaccines (reference Vaccines TAUG)

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Clinical Global Impression (CGI)

Questionnaire Supplement to the Study Data Tabulation Model Implementation Guide for Human Clinical Trials

Version 2.1 (Final)

☐ QRS Instruments

- ☐ Clinical Global Impression (CGI) - reference existing QRS Supplement
- ☐ NEWS2 - *will require the development of new RS terminology*

National Early Warning Score 2 (NEWS2)

Physiological Parameters	3	2	1	0	1	2	3
Respiration Rate (BPM)	≤8		9-11	12-20		21-24	≥25
Oxygen Saturations (%)	≤91	92-93	94-95	≥96			
Any Supplemental Oxygen		Yes		No			
Temperature (°C)	≤35		35.1-36.0	36.1-38.0	38.1-39.0	≥39.1	
Systolic Blood Pressure (mmHg)	≤90	19-100	101-110	111-219			≥220
Heart Rate (BPM)	≤40		41-50	51-90	91-110	111-130	≥131
Level of Consciousness				A			V, P or U

<https://www.activ8rlives.com/support/data-collected/cardiovascular-and-respiratory/national-early-warning-score-news/>

National Early Warning Score 2 (NEWS2)

Physiological Parameters	3	2	1	0	1	2	3
Respiration Rate (BPM)	≤8		9-11	12-20		21-24	≥25
Oxygen Saturations (%)	≤91	92-93	94-95	≥96			
Any Supplemental Oxygen		Yes		No			
Temperature (°C)	≤35		35.1-36.0	36.1-38.0	38.1-39.0	≥39.1	
Systolic Blood Pressure (mmHg)	≤90	19-100	101-110	111-219			≥220
Heart Rate (BPM)	≤40		41-50	51-90	91-110	111-130	≥131
Level of Consciousness				A			V, P or U

The NEWS trigger system aligned to the scale of clinical risk.

NEWS Scores	Clinical Risk
0 Aggregate 1 - 4	Low
RED Score* (Individual parameter scoring 3) Aggregate 5 - 6	Medium
Aggregate 7 or more	High

***RED score** refers to an extreme variation in a single physiological parameter (i.e. a score of 3 on the NEWS chart, coloured RED to aid identification and represents an extreme variation in a single physiological parameter). The consensus of the NEWS Development and Implementation Group (NEWSDIG) was that extreme values in one physiological parameter (e.g. heart rate ≥40 beats per minute, or a respiratory rate of ≥8 per minute or a temperature of ≥35°C) could not be ignored and on its own required urgent clinical evaluation.

<https://www.activ8lives.com/support/data-collected/cardiovascular-and-respiratory/national-early-warning-score-news/>

NEWS2 - Clinical Classification

- Data will (most likely) be modeled on Disease Response and Clinical Classification (RS) domain
- Will require the development of new Clinical Classification terminology (probably will look *something like* the following)
 - RSCAT=NEWS2
 - RSTESTCD=NEWS2101

STUDYID	DOMAIN	USUBJID	RSSEQ	RSTESTCD	RSTEST	RSCAT	RSORRE S	RSSTRES C	RSSTRES N	RSDAT
COV-19	RS	COV-19-001	1	NEWS2101	NEWS2-Respiration Rate Score	NEWS2	1	1	1	2020-03-29
COV-19	RS	COV-19-001	2	NEWS2102	NEWS2-Oxygen Saturation Score	NEWS2	3	3	3	2020-03-29
COV-19	RS	COV-19-001	3	NEWS2103	NEWS2-Supplemental Oxygen Score	NEWS2	2	2	2	2020-03-29
COV-19	RS	COV-19-001	4	NEWS2104	NEWS2-Temperature Score	NEWS2	1	1	1	2020-03-29
COV-19	RS	COV-19-001	5	NEWS2105	NEWS2-Systolic Blood Pressure Score	NEWS2	2	2	2	2020-03-29
COV-19	RS	COV-19-001	6	NEWS2106	NEWS2-Heart Rate Score	NEWS2	1	1	1	2020-03-29
COV-19	RS	COV-19-001	7	NEWS2107	NEWS2-Level of Consciousness Score	NEWS2	0	0	0	2020-03-29
COV-19	RS	COV-19-001	8	NEWS2108	NEWS2-Clinical Risk Score	NEWS2	HIGH	10	10	2020-03-29

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 - Missed Visits
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FAMILY MEDICAL HISTORY

Does anyone living with the participant have any of the following Risk Factors?	Yes	No	Relationship
Asthma	X		BIOLOGICAL SON
Diabetes		X	
Hypertension	X		SPOUSE

STUDYID	DOMAIN	APID	RSUBJID	SREL	MHSEQ	MHTERM	MHDECOD	MHCAT
COV-19	APMH	F001	COV-19-001	CHILD	1	ASTHMA	Asthma	RISK FACTOR
COV-19	APMH	F002	COV-19-001	SPOUSE	2	HYPERTENSION	Hypertension	RISK FACTOR
COV-19	APMH	F003	COV-19-002	SPOUSE	1	ASTHMA	Asthma	RISK FACTOR
COV-19	APMH	F003	COV-19-002	SPOUSE	2	DIABETES	Diabetes mellitus	RISK FACTOR
COV-19	APMH	F004	COV-19-002	SPOUSE	3	HYPERTENSION	Hypertension	RISK FACTOR

Associated Persons

- CDASH domains depend on what is collected (e.g., contact tracing, risk factors for people living in the same house as an infected person...)
- Reference separate SDTMIG-AP
- PPE - uses Device Domains (and AP)
- Reference separate SDTMIG-MD and SDTMIG-AP

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Work in Progress...

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- Concomitant Medication Use
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- Cardiac Events/Findings
- Hospitalizations
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 - Dialysis
- Vaccines
- Questionnaires, Ratings and Scales
 - Clinical Global Impression (CGI)
 - National Early Warning Scale 2 (NEWS2)
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 - Changes to Drug Accountability

Cardiovascular
System
Findings (CV)
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SDTMIG V3.3
6.3.10.2

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Environmental Risk Factors (ER) Events Class domain in Ebola TAUG

2.2.1 Environmental Risk Factors

Epidemiological risk factors for exposure to Ebola^[2] are represented in the Environmental Risk Factors (ER) domain. To read more about risk factors for Ebola, see the patient-directed resources listed in Section 1, [Introduction](#).

Example 1

This example shows data about EVD exposure collected by means of a series of questions about pre-specified risk factors.

Rows 1, 2, 4, 6: Show that the subject did not have any of these risk factors (EROCCUR = "N").

Rows 3, 5: Show that the subject had these risk factors. The timing of these risk factors is represented using ERSTDTC and ERENDTC.

er.xpt

Row	STUDYID	DOMAIN	USUBJID	ERSEQ	ERTERM	ERCAT	ERPRESP	EROCCUR	ERDTC	ERSTDTC	ERENDTC
1	CLN-03	ER	ABC-01-201	1	Percutaneous or mucous membrane exposure to blood or body fluids	EVD RISK FACTORS	Y	N	2015-03-10		
2	CLN-03	ER	ABC-01-201	2	Direct skin contact	EVD RISK FACTORS	Y	N	2015-03-10		
3	CLN-03	ER	ABC-01-201	3	Processing blood or body fluids of confirmed EVD subject	EVD RISK FACTORS	Y	Y	2015-03-10	2015-03-02	2015-03-08
4	CLN-03	ER	ABC-01-201	4	Direct contact with dead body	EVD RISK FACTORS	Y	N	2015-03-10		
5	CLN-03	ER	ABC-01-201	5	Direct handling of bats	EVD RISK FACTORS	Y	Y	2015-03-10	2015-03-05	2015-03-05
6	CLN-03	ER	ABC-01-201	6	Household contact	EVD RISK FACTORS	Y	N	2015-03-10		

Summary

- Even though a new “standard” is coming out from CDISC for COVID-19, it will use the existing foundational standards (e.g., SDTMIGs, CDASH/CDASHIG, QRS Supplements, CDISC Controlled Terminology) and *existing rules for applying them*
- Some new terminology may be developed to handle COVID-19 specific data
 - New MBTESTCD and MBTEST controlled terms for SARSCOV2 already in review
 - New controlled term for SARS-CoV-2 microorganism already in review
 - NEWS2 RSCAT, RSTEST/CD terminology may be developed
 - *Possibly some new Disposition (NCOMPLT) terminology for COVID-19-related disposition*
 - *Possibly some new Procedure (PROCEDUR) terminology for ventilation*
- The TAUG will have useful examples based on real-world data that is being provided by the COVID-19 TAUG Task Force (i.e., volunteers from companies doing COVID-19 research)
- If you are following the CDASH standards, and rules for creating new data collection metadata, you will be well-prepared to submit any relevant COVID-19 data using required standards (e.g., SDTM)
 - The main thing you will want to pay attention to is the developing **terminology**

Q&A

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