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 <u>primarily use existing</u> <u>foundational standards</u> (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/C DISC+Interim+User+Guide+for+COVID-19

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- Comorbidities/medical history/coinfections
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 - Assay Kits (TBD)

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- Listing of all COVID-19 Related Impacts as Part of CSR
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Virus Identification in Microbiology Specimen (MB) domain New terms requested in Package 42 (June 2020)

codelist i	Name: Micro	organism				
Codelist [Description:	Microorgan	isms, bacteria, fungi an	d other organisms.		
Codelist E	Extensible: \	/es				
ddition(s)	o an existing (rodolist				
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.
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 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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Personal Protective Equi FDA Guidance for Ongo Missed Visits STUDYID DOMAIN USUBIJD RESEQ RETESTC RETEST REORRES REORRES RESTRESS RESTRESS REDAT • Missed Visits • Listing of all COVI RE COV-19-001 1 FEV1 Forced Expiratory Volume in 1 Second 2.73 L 2.73 L 2020-03-18 • Listing of all COVI RE COV-19-001 2 FVC Forced Vital Capacity 3.91 L 2020-03-18 • Ov-19 RE COV-19-001 3 PEF Peak Expiratory Flow 6.11 L/s 6.11 L/s 2020-03-18	 National Early Warning Scale 2 (N 	EWS2)		Results from	imaging			
• FDA Guidance for Ongo COV-19 RE COV-19-001 1 FEV1 Forced Expiratory Volume in 1 Second 2.73 L 2020-03-18 • Missed Visits COV-19 RE COV-19-001 2 FVC Forced Vital Capacity 3.91 L 2020-03-18 • Listing of all COVI COV-19 RE COV-19-001 3 PEF Peak Expiratory Flow 6.11 L/s 6.11 L/s 2020-03-18								
Missed Visits COV-19 RE COV-19-001 2 FVC Forced Vital Capacity 3.91 L 3.91 L 2020-03-18 • Listing of all COVI COV-19 RE COV-19-001 3 PEF Peak Expiratory Flow 6.11 L/s 6.11 L/s 2020-03-18								
Listing of all COVI COV-19 RE COV-19-001 3 PEF Peak Expiratory Flow 6.11 L/s 6.11 6.11 L/s 2020-03-18								
	50 V 15 ML							
 DISDOSIDOD - INEW 	Disposition - New	COV-19-001	3 PEF	Peak Expiratory Flow	6.11 L/s	6.1	1 6.11 L/s	2020-03-18

- Risk Factors
 - Comorbidities/medical history/coinfections
 - Smoking/Substance Use
- Signs and Symptoms
 - Cough
 - Shortness of Breath
- Virology
 - Rate of Virus Inhibition
 - Virus Identification
 - Viral Genetics
 - Assay Kits (TBD)
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- Hospitalizations
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- Procedures
 - Mechanical Ventilation
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 - Listing of all COVID-19 Related Impacts as Part of CSR
 - Disposition New Controlled Terminology

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

Risk Factors

- Comorbidities/medical history/coinfections
- Smoking/Substance Use

STUDYID	DOMAIN	USUBJID	PRSEQ	SPDEVID	PRTRT	PRCAT	PRSTDTC	PRENDTC	PRDUR	PREVINTX
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	L	Non-Invasive Ventilation	NON-INVASIVE VENTILATION			P2W	DURING HOSPITALIZATION
COV-19	PR	COV-19-003	1	L	Intubation/tracheostomy and mechanical ventilation	INVASIVE VENTILATION			P5W	DURING HOSPITALIZATION
COV-19	PR	COV-19-004	1	L	Prone Ventilation	INVASIVE VENTILATION			P3DT12H	DURING HOSPITALIZATION
COV-19	PR	COV-19-005	1	L	Tracheostomy and mechanical ventilation	INVASIVE VENTILATION			P3W	DURING HOSPITALIZATION
COV-19	PR	COV-19-006	1	L	CPAP	NON-INVASIVE VENTILATION	2020-03-10	2020-04-12		DURING HOSPITALIZATION
COV-19	PR	COV-19-006	2	2	Invasive Ventilation	INVASIVE VENTILATION			P5W	DURING HOSPITALIZATION
COV-19	PR	COV-19-007	1	L	High-flow Nasal Oxygen	NON-INVASIVE VENTILATION			P1D	DURING HOSPITALIZATION
COV-19	PR	COV-19-007	2	2	Intubation/tracheostomy and mechanical ventilation	INVASIVE VENTILATION			P2W	DURING HOSPITALIZATION
COV-19	PR	COV-19-007	3	3	ECMO	INVASIVE VENTILATION			P4D	DURING HOSPITALIZATION

- Controlled Terminology
- Biospecimen Domains
- Respiratory Findings
 - Imaging CT scans, chest x-rays
 - Pulmonary Function Tests
- Hospitalizations
- Concomitant Medication Use
- Procedures
 - Mechanical Ventilation
- Vaccines
- Questionnaires, Ratings and Scales
 - Clinical Global Impression (CGI)
 - National Early Warning Scale 2 (NEWS2)
- Associated Persons
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- FDA Guidance for Ongoing Trials
 - Missed Visits
 - Listing of all COVID-19 Related Impacts as Part of CSR
 - Disposition New Controlled Terminology

□ Procedures (PR)

Mechanical Ventilation (may require new terminology in PROCEDUR codelist)
 Vaccines (reference Vaccines TAUG)

- Risk Factors
 - · Comorbidities/medical history/coinfections
 - Smoking/Substance Use
- Signs and Symptoms
 - Cough
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- Virology
 - Rate of Virus Inhibition
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 - Assay Kits (TBD)
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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			
	≤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 L

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

evaluation. https://www.activ8rlives.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 Clin Classification (RS) domain
- Will require the development of new Clinical Classification terminology (probably will look something like the following)
 - RSCAT=NEWS2
 - RSTESTCD=NEWS2101

							RSORRE	RSSTRES	RSSTRES	
STUDYID	DOMAIN	USUBJID	RSSEQ	RSTESTCD	RSTEST	RSCAT	S	С	Ν	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

Table of Contents								
Risk Factors				FAMI	LY MED	DICAL	HISTORY	
 Comorbidities/medical history/ 	coinfections		Does an	yone living wi	th			
 Smoking/Substance Use 				icipant have a				
 Signs and Symptoms 				following Risk				
Cough				Factors?	·			
 Shortness of Breath 				ractors?			No	Deletionshim
Virology					_	Yes	No	Relationship
 Rate of Virus Inhibition 				Asthr	na	Х		BIOLOGICAL
 Virus Identification 								SON
 Viral Genetics 	Viral Genetics				es		Х	
 Assay Kits (TBD) 				Hypertensi	on	Х		SPOUSE
 Vital Signs 								
 Respiratory Rate 								
 Body Temperature 								
Oxygen Saturation	STUDYID	DOMAIN	APID	RSUBJID	SR	EL	MHSEQ	MHTERM
Labs Controlled Terminology	COV-19	APMH	F001	COV-19-001	CHILD		1	ASTHMA
Controlled Terminology Biospecimen Domains	COV-19	APMH	F002	COV-19-001	SPOUS	E	2	HYPERTENSION
Respiratory Findings	COV-19	APMH	F003	COV-19-002	SPOUS	E	1	ASTHMA
 Imaging – CT scans, chest x-raj 	COV-19	APMH	F003	COV-19-002	SPOUS	E	2	DIABETES
Pulmonary Function Tests Hospitalizations	COV-19	APMH	F004	COV-19-002	SPOUS	E	3	HYPERTENSION

•	Concomitant	Medication	Use

Procedures

Mechanical Ventilation

- Vaccines
- Questionnaires, Ratings and Scales
 - Clinical Global Impression (CGI)
 - National Early Warning Scale 2 (NEWS2)
- Associated Persons
- Personal Protective Equipment (PPE)
- FDA Guidance for Ongoing Trials
 - Missed Visits
 - Listing of all COVID-19 Related Impacts as Part of CSR
 - Disposition New Controlled Terminology

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...)

MHDECOD

Hypertension

Hypertension

Diabetes mellitus

Asthma

Asthma

MHCAT

RISK FACTOR

RISK FACTOR

RISK FACTOR

RISK FACTOR

RISK FACTOR

Reference separate SDTMIG-AP

□ PPE - uses Device Domains (and AP)

Reference separate SDTMIG-MD and

- Risk Factors
 - Comorbidities/medical history/coinfections
 - Smoking/Substance Use
- Signs and Symptoms
 - Cough
 - Shortness of Breath
- Virology
 - Rate of Virus Inhibition
 - Virus Identification
 - Viral Genetics
 - Assay Kits (TBD) Respiratory Rate

Body Temperature

Oxygen Saturation

Vital Signs

Work in Progress...

27 Mar 2020

- Labs
 - Controlled Terminology
 - Biospecimen Domains
- Respiratory Findings
 - Imaging CT scans, chest x-rays
 - Pulmonary Function Tests
- Hospitalizations
- Concomitant Medication Use
- Procedures
 - Mechanical Ventilation
- Vaccines
- Questionnaires, Ratings and Scales
 - Clinical Global Impression (CGI)
 - National Early Warning Scale 2 (NEWS2)
- Associated Persons
- Personal Protective Equipment (PPE)
- FDA Guidance for Ongoing Trials
 - Missed Visits
 - Listing of all COVID-19 Related Impacts as Part of CSR
 - Disposition New Controlled Terminology

Table of Contents Risk Factors

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- Comorbidities/medical history/coinfections
- Smoking/Substance Use
- Epidemiological Risk Factors
- Associated Persons (contacts)
- Personal Protective Equipment (PPE)
- Signs and Symptoms
 - Cough
 - Shortness of Breath
- Labs
 - Controlled Terminology
 - Biospecimen Domains
- Virology
 - Rate of Virus Inhibition
 - Virus Identification
 - Viral Genetics
 - Assav Kits
- Vital Signs
 - Respiratory Rate
 - Body Temperature
 - Oxygen Saturation
- Concomitant Medication Use
- Respiratory Findings
 - Imaging CT scans, chest x-rays
- Cardiac Events/Findings
- Hospitalizations
- Procedures
 - Assisted Ventilation
 - Dialysis
- Vaccines
- Questionnaires, Ratings and Scales
 - Clinical Global Impression (CGI)
 - National Early Warning Scale 2 (NEWS2)
- FDA Guidance for Ongoing Trials
 - Missed Visits
 - Listing of all COVID-19 Related Impacts as Part of CSR
 - Disposition New Controlled Terminology
 - Changes to Drug Accountability

Cardiovascular System Findings (CV) - Reference SDTMIG V3.3 6.3.10.2

Table of Contents • Risk Factors • Comorbidities/medical history/co • Smoking/Substance Use • Signs and Symptoms • Cough • Shortness of Breath • Virology • Rate of Virus Inhibition • Virus Identification • Viral Genetics • Assay Kits (TBD) • Vital Signs • Respiratory Rate	27 Mar 2020	Table of Contents 31 Mar • Risk Factors • Comorbidities/medical history/coinfections • Smoking/Substance Use • Epidemiological Risk Factors • Associated Persons (contacts) • Personal Protective Equipment (PPE) • Signs and Symptoms • Cough • Shortness of Breath • Labs • Controlled Terminology • Biospecimen Domains • Virology • Rate of Virus Inhibition • Virus Identification	2020 Environmental Risk Factors (ER) Events Class domain in Ebola TAUG
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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, <u>Introduction</u>.

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.

61	2171	

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 NCICDISCSupport@nih.gov

