

# Public Review Webinar: COVID-19 Therapeutic Area User Guide

Dana Booth, Project Manager, Foundational Standards, CDISC

Kit Howard, Sr. Director, Standards Development & Education, CDISC

Bess LeRoy, Head of Standards Development, CDISC

Jon Neville, Sr. Standards Developer, CDISC

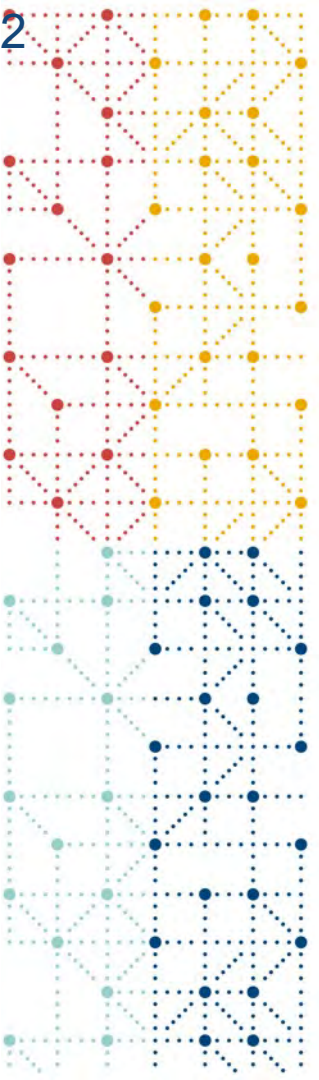
Amy Palmer, Head of Standards Development, CDISC

Alana St. Clair, Project Manager, CDISC

Diane Wold, Sr. Director, Standards Development, CDISC

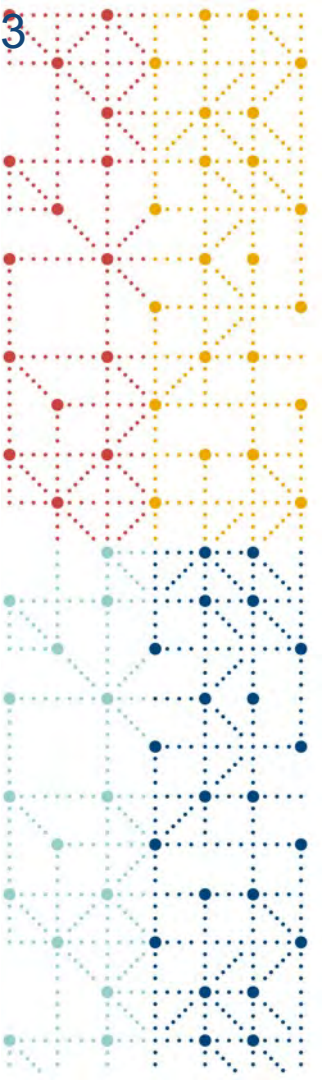


THU 4 FEB  
11:00AM-12:30PM ET



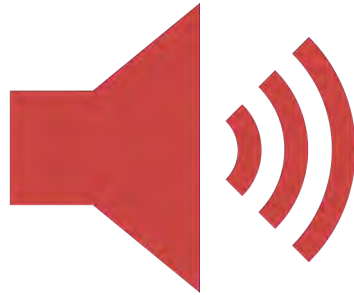
## Today's Agenda

1. Housekeeping
2. Presenter Introductions
3. Feature Presentations
4. Question & Answer Session
5. Upcoming Learning Opportunities & Resources



# Housekeeping

# Housekeeping



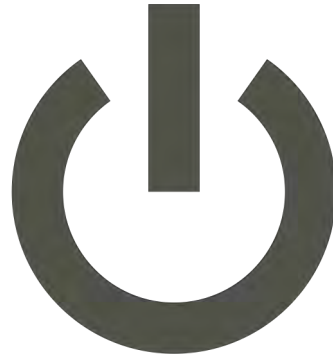
You will remain on **mute**

# Housekeeping



There will be a **Q&A**

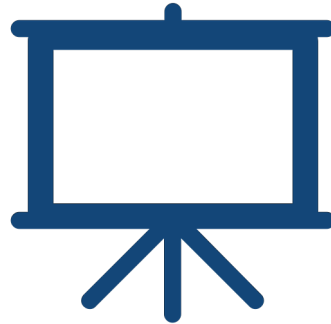
# Housekeeping



## Audio issues?

1. Shut down & restart GoToWebinar
2. Check your local internet connection
3. Send me a note using the Questions tool

# Housekeeping



Webinar slides & recording available  
for **CDISC Members**



# Our Presenters

- Dana Booth, Project Manager, Foundational Standards, CDISC
- Kit Howard, Sr. Director, Standards Development & Education, CDISC
- Bess LeRoy, Head of Standards Development, CDISC
- Jon Neville, Sr. Standards Developer, CDISC
- Amy Palmer, Head of Standards Development, CDISC
- Alana St. Clair, Project Manager, CDISC
- Diane Wold, Sr. Director, Standards Development, CDISC





# COVID-19 Public Review Webinar

COVID-19 Development Team

4<sup>th</sup> February 2021





# Introduction

Kit Howard

# Once Upon a Time...



# And then the World Changed...

1,000,000

10,000,000

25,000,000

100,000

75,000,000



**100,000,000 cases**

# And then the World Changed...



# CDISC Convened a COVID-19 Task Force in March 2020

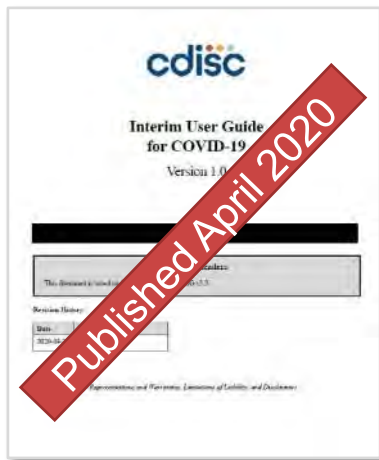
**CDISC**  
(key standards  
development staff)

**Industry  
Stakeholders**

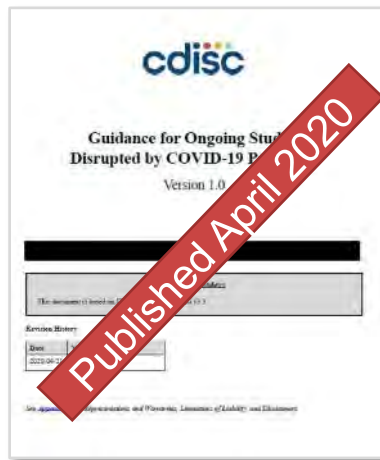
**Regulatory**

**Academia**

**NCI EVS**



COVID-19 Interim  
User Guide



Guidance for Ongoing  
Studies Disrupted by the  
COVID-19 Pandemic



Resources for Public  
Health Researchers

CDISC Submission Value	Code	Code	Code	Code	Code
10-Meter Walk/Run Functional Test	TENWAT01	TENWAT02	TENWAT03	TENWAT04	TENWAT05
10-Meter Walk/Run Functional Test	TENWAT06	TENWAT07	TENWAT08	TENWAT09	TENWAT10
10-Meter Walk/Run Functional Test	TENWAT11	TENWAT12	TENWAT13	TENWAT14	TENWAT15
10-Meter Walk/Run Functional Test	TENWAT16	TENWAT17	TENWAT18	TENWAT19	TENWAT20
10-Meter Walk/Run Functional Test	TENWAT21	TENWAT22	TENWAT23	TENWAT24	TENWAT25
10-Meter Walk/Run Functional Test	TENWAT26	TENWAT27	TENWAT28	TENWAT29	TENWAT30
10-Meter Walk/Run Functional Test	TENWAT31	TENWAT32	TENWAT33	TENWAT34	TENWAT35
10-Meter Walk/Run Functional Test	TENWAT36	TENWAT37	TENWAT38	TENWAT39	TENWAT40
10-Meter Walk/Run Functional Test	TENWAT41	TENWAT42	TENWAT43	TENWAT44	TENWAT45
10-Meter Walk/Run Functional Test	TENWAT46	TENWAT47	TENWAT48	TENWAT49	TENWAT50
10-Meter Walk/Run Functional Test	TENWAT51	TENWAT52	TENWAT53	TENWAT54	TENWAT55
10-Meter Walk/Run Functional Test	TENWAT56	TENWAT57	TENWAT58	TENWAT59	TENWAT60
10-Meter Walk/Run Functional Test	TENWAT61	TENWAT62	TENWAT63	TENWAT64	TENWAT65
10-Meter Walk/Run Functional Test	TENWAT66	TENWAT67	TENWAT68	TENWAT69	TENWAT70
10-Meter Walk/Run Functional Test	TENWAT71	TENWAT72	TENWAT73	TENWAT74	TENWAT75
10-Meter Walk/Run Functional Test	TENWAT76	TENWAT77	TENWAT78	TENWAT79	TENWAT80
10-Meter Walk/Run Functional Test	TENWAT81	TENWAT82	TENWAT83	TENWAT84	TENWAT85
10-Meter Walk/Run Functional Test	TENWAT86	TENWAT87	TENWAT88	TENWAT89	TENWAT90
10-Meter Walk/Run Functional Test	TENWAT91	TENWAT92	TENWAT93	TENWAT94	TENWAT95
10-Meter Walk/Run Functional Test	TENWAT96	TENWAT97	TENWAT98	TENWAT99	TENWAT100

Extra Version of  
Controlled Terminology

# CDISC Convened a COVID-19 Task Force in March 2020

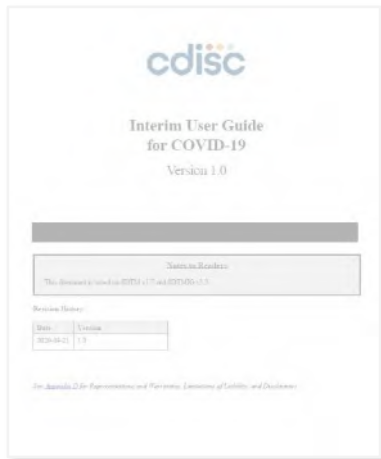
CDISC  
(key standards  
development staff)

Industry  
Stakeholders

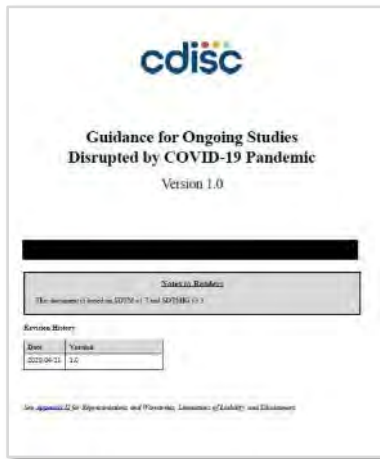
Regulatory

NCI EVS

Based on FDA Guidance



COVID-19 Interim  
User Guide



Guidance for Ongoing  
Studies Disrupted by the  
COVID-19 Pandemic

*Contains Nonbinding Recommendations*

## Conduct of Clinical Trials of Medical Products During the COVID-19 Public Health Emergency

### Guidance for Industry, Investigators, and Institutional Review Boards

March 2020  
Updated on January 27, 2021

For questions on clinical trial conduct during the COVID-19 pandemic, please email [Clinicaltrialconduct-COVID19@fda.hhs.gov](mailto:Clinicaltrialconduct-COVID19@fda.hhs.gov).

U.S. Department of Health and Human Services  
Food and Drug Administration  
Center for Drug Evaluation and Research (CDER)  
Center for Biologics Evaluation and Research (CBER)  
Center for Devices and Radiological Health (CDRH)  
Oncology Center of Excellence (OCE)  
Office of Good Clinical Practice (OGCP)

CDISC Submission Value	CC
TENM017C	10-Meter Walk Scale
TENM017D	10-Meter Walk Scale
TENM017E	10-Meter Walk Scale
TENM017F	10-Meter Walk Scale
TENM017G	10-Meter Walk Scale
TENM017H	10-Meter Walk Scale
TENM017I	10-Meter Walk Scale
TENM017J	10-Meter Walk Scale
TENM017K	10-Meter Walk Scale
TENM017L	10-Meter Walk Scale
TENM017M	10-Meter Walk Scale
TENM017N	10-Meter Walk Scale
TENM017O	10-Meter Walk Scale
TENM017P	10-Meter Walk Scale
TENM017Q	10-Meter Walk Scale
TENM017R	10-Meter Walk Scale
TENM017S	10-Meter Walk Scale
TENM017T	10-Meter Walk Scale
TENM017U	10-Meter Walk Scale
TENM017V	10-Meter Walk Scale
TENM017W	10-Meter Walk Scale
TENM017X	10-Meter Walk Scale
TENM017Y	10-Meter Walk Scale
TENM017Z	10-Meter Walk Scale
TENM018	10-Meter Walk Scale
TENM019	10-Meter Walk Scale
TENM020	10-Meter Walk Scale
TENM021	10-Meter Walk Scale
TENM022	10-Meter Walk Scale
TENM023	10-Meter Walk Scale
TENM024	10-Meter Walk Scale
TENM025	10-Meter Walk Scale
TENM026	10-Meter Walk Scale
TENM027	10-Meter Walk Scale
TENM028	10-Meter Walk Scale
TENM029	10-Meter Walk Scale
TENM030	10-Meter Walk Scale
TENM031	10-Meter Walk Scale
TENM032	10-Meter Walk Scale
TENM033	10-Meter Walk Scale
TENM034	10-Meter Walk Scale
TENM035	10-Meter Walk Scale
TENM036	10-Meter Walk Scale
TENM037	10-Meter Walk Scale
TENM038	10-Meter Walk Scale
TENM039	10-Meter Walk Scale
TENM040	10-Meter Walk Scale
TENM041	10-Meter Walk Scale
TENM042	10-Meter Walk Scale
TENM043	10-Meter Walk Scale
TENM044	10-Meter Walk Scale
TENM045	10-Meter Walk Scale
TENM046	10-Meter Walk Scale
TENM047	10-Meter Walk Scale
TENM048	10-Meter Walk Scale
TENM049	10-Meter Walk Scale
TENM050	10-Meter Walk Scale

ersion of  
terminology



# CDISC Convened a COVID-19 Task Force in March 2020

CDISC  
(key standards  
development staff)

Industry  
Stakeholders

Regulatory

Academia

NCI EVS

A	B	C	D	E	F
CRF Item	Domain	SDTM Variable	SDTM Value	CDASH Variable If Different from SDTM	Notes
Suspected or proven acute novel Coronavirus (nCoV) infection as main cause for admission	HO	HOINDC	SUSPECTED COVID-19; CONFIRMED COVID-19; Not COVID-19		
					Other subject met all criteria.
	IE	IEF			Criteria that were not met are CDASH and SDTM, although all criteria can be provided.
	IC	ICFT	Coronavirus Infection as main cause for admission		
	IF	IFECAT	INCLUSION		
	IE	IEORRES	Y; N		Typically, only criteria that were not met are entered in CDASH and SDTM, although worksheets with all criteria can be provided to the site.

Variables from Annotated ISARIC-WHO COVID-19 Core CRFs w/ CDASH Mappings

ISARIC-WHO COVID-19 Core CRFs w/ SDTM Annotations

a	b	c	d	e	f
CRF Item	Domain	SDTM Variable	SDTM Value	CDASH Variable If Different from SDTM	Notes
10-Meter Walk/Run Functional Test Code					TENMKT0C
10-Meter Walk/Run Functional Test Code					TENMKT01
10-Meter Walk/Run Functional Test Code					TENMKT02
10-Meter Walk/Run Functional Test Code					TENMKT03
10-Meter Walk/Run Functional Test Code					TENMKT04
10-Meter Walk/Run Functional Test Name					TENMKT1N
10-Meter Walk/Run Functional Test Name					TENMKT1C
10-Meter Walk/Run Functional Test Name					TENMKT1D
10-Meter Walk/Run Functional Test Name					TENMKT1E
10-Meter Walk/Run Functional Test Name					TENMKT1F
10-Meter Walk/Run Functional Test Name					TENMKT1G
10-Meter Walk/Run Functional Test Name					TENMKT1H
10-Meter Walk/Run Functional Test Name					TENMKT1I
10-Meter Walk/Run Functional Test Name					TENMKT1J
10-Meter Walk/Run Functional Test Name					TENMKT1K
10-Meter Walk/Run Functional Test Name					TENMKT1L
10-Meter Walk/Run Functional Test Name					TENMKT1M
10-Meter Walk/Run Functional Test Name					TENMKT1N

COVID-19 Interim User Guide

Guidance for Ongoing Studies Disrupted by the COVID-19 Pandemic

Resources for Public Health Researchers

Extra Version of Controlled Terminology





# Publications

**CDISC**  
(key standards  
development staff)

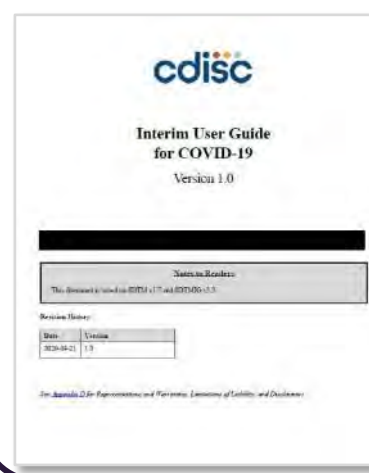
**Industry  
Stakeholders**

**Regulatory**

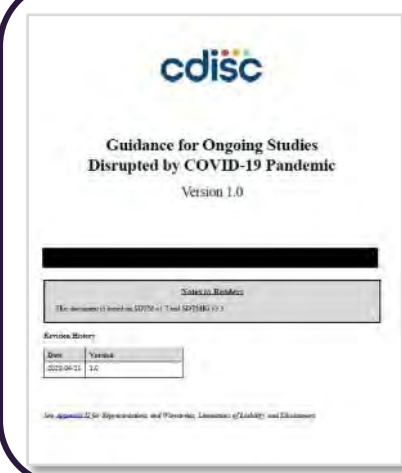
**Academia**

**NCI EVS**

## Informative Content



COVID-19 Interim  
User Guide



Guidance for Ongoing  
Studies Disrupted by the  
COVID-19 Pandemic

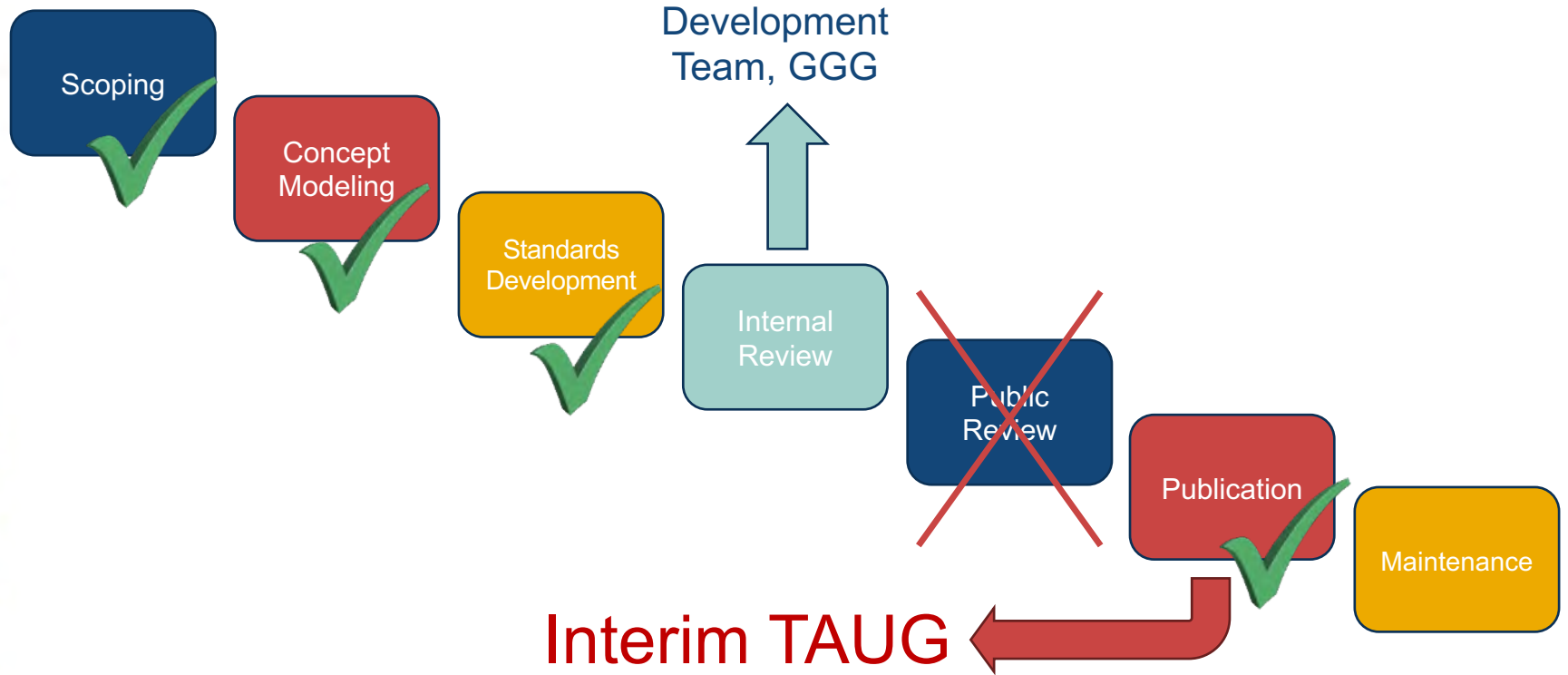


Resources for Public  
Health Researchers  
COVID-19 Public Review Webinar

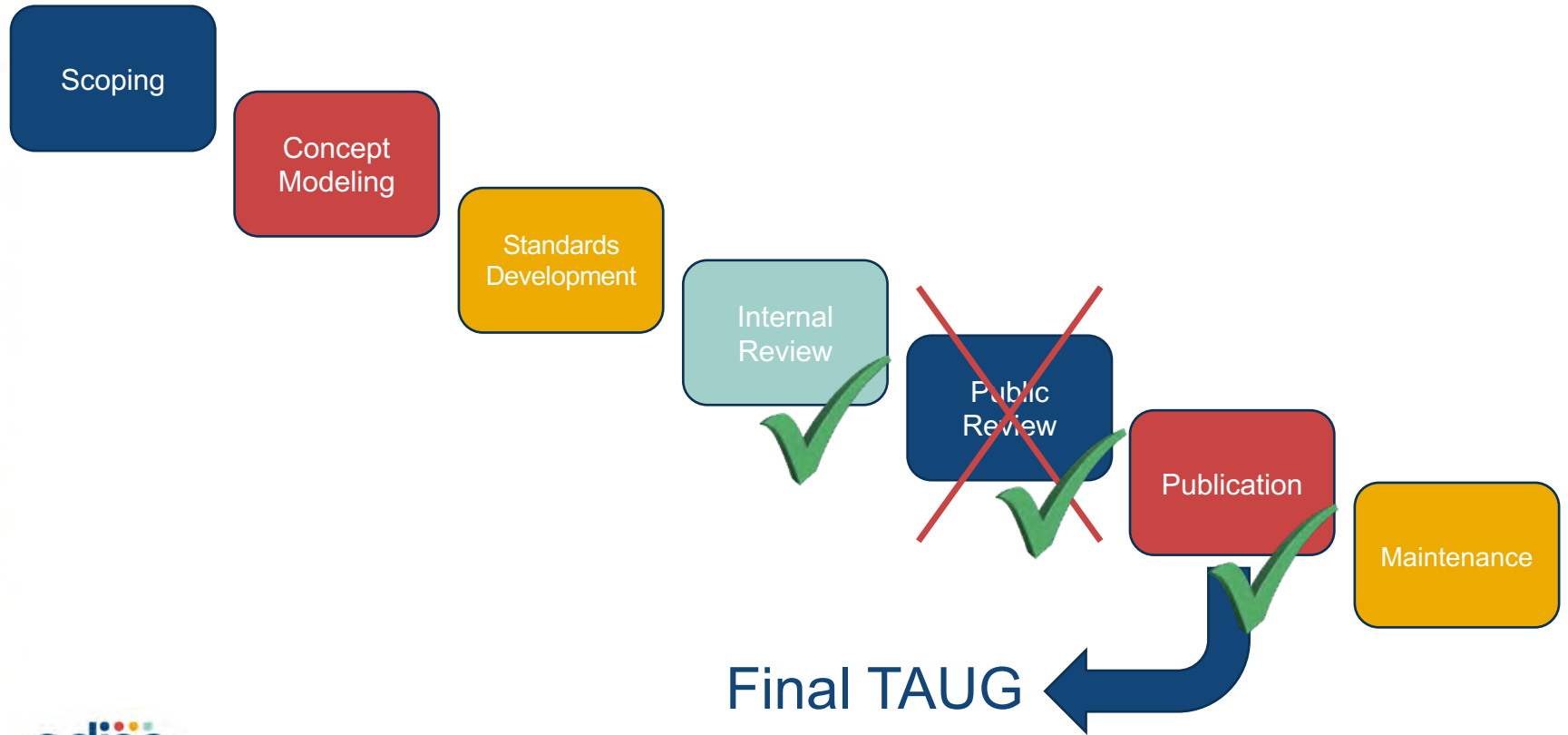
	a	b	c	d	e	f
	Control Elt	Control Elt (Trash)	Control Name	CDISC Submission Value	CC	
1	141587	No	10 Meter Walk/Run Functional Test Test Code	TENMKT02	10 Meter Walk/Run	
2	141428	141587	10 Meter Walk/Run Functional Test Test Code	TENMKT01	TENMKT02	
3	141700	141587	10 Meter Walk/Run Functional Test Test Code	TENMKT03	TENMKT02	
4	141752	141587	10 Meter Walk/Run Functional Test Test Code	TENMKT05	TENMKT02	
5	141701	141587	10 Meter Walk/Run Functional Test Test Code	TENMKT04	TENMKT02	
6	141658	No	10 Meter Walk/Run Functional Test Test Name	TENMKT10	10 Meter Walk/Run	
7	141751	141658	10 Meter Walk/Run Functional Test Test Name	TENMKT11	TENMKT10	
8	141703	141658	10 Meter Walk/Run Functional Test Test Name	TENMKT12	TENMKT10	
9	141698	141658	10 Meter Walk/Run Functional Test Test Name	TENMKT13	TENMKT10	
10	141750	141658	10 Meter Walk/Run Functional Test Test Name	TENMKT14	TENMKT10	
11	141663	No	4 Star Assess Functional Test Test Code	ASTSTR01	4 Star Assess	
12	141743	141663	4 Star Assess Functional Test Test Code	ASTSTR02	ASTSTR01	
13	141706	141663	4 Star Assess Functional Test Test Code	ASTSTR03	ASTSTR01	
14	141737	141663	4 Star Assess Functional Test Test Code	ASTSTR04	ASTSTR01	
15	141662	No	4 Star Assess Functional Test Test Name	ASTSTR05	4 Star Assess	
16	141707	141662	4 Star Assess Functional Test Test Name	ASTSTR06	ASTSTR05	
17	141708	141662	4 Star Assess Functional Test Test Name	ASTSTR07	ASTSTR05	
18	141742	141662	4 Star Assess Functional Test Test Name	ASTSTR08	ASTSTR05	
19	141753	141662	4 Star Assess Functional Test Test Name	ASTSTR09	ASTSTR05	
20	141704	141662	4 Star Assess Functional Test Test Name	ASTSTR10	ASTSTR05	
21	141754	141662	4 Star Assess Functional Test Test Name	ASTSTR11	ASTSTR05	
22	141661	No	4 Star Descend Functional Test Test Code	ASTSTR12	4 Star Descend	
23	141705	141661	4 Star Descend Functional Test Test Code	ASTSTR13	ASTSTR12	
24	141736	141661	4 Star Descend Functional Test Test Code	ASTSTR14	ASTSTR12	
25	141735	141661	4 Star Descend Functional Test Test Code	ASTSTR15	ASTSTR12	
26	141702	141661	4 Star Descend Functional Test Test Code	ASTSTR16	ASTSTR12	
27	141755	141661	4 Star Descend Functional Test Test Code	ASTSTR17	ASTSTR12	
28	141756	141661	4 Star Descend Functional Test Test Code	ASTSTR18	ASTSTR12	
29	141709	No	4 Star Descend Functional Test Test Name	ASTSTR19	4 Star Descend	

Extra Version of  
Controlled Terminology

# Stages of the CDISC Standards Development Process



# Stages of the CDISC Standards Development Process



# Topics Overview

Risk Factors

Bess Leroy

Diagnostics & Virology

Jon Neville

Signs & Symptoms;  
Vaccines

Diane Wold

Vital Signs; Assisted  
Ventilation

Jon Neville & Bess Leroy

Questionnaires, Ratings  
& Scales

Dana Booth



# Risk Factors

Bess LeRoy

# Risk Factors

## 2 RISK FACTORS

2.1 Pre-existing Medical Conditions **MH**

2.2 Personal Protective Equipment (PPE)

2.3 Travel

2.4 Contacts

2.5 Smoking **SU**

2.6 Exposure to Animals

# Environmental and Social Factors (ER) Draft Domain

- The Environmental and Social Factors (ER) domain represents data that was collected to assess the factors that might influence a subject's disease or medical condition via environmental contact or through participation in activities associated with increased or decreased risk.
- Used in COVID-19 Interim User Guide to represent data on travel, contacts, personal protective equipment, and exposure to animals
- This domain went through public review during the TB v2.0 TAUG public review. It also went through public review as part of SDTMIG v3.3 batch 3.
  - Held out from publication due to maturity concerns
  - Unclear if a single observation class (Events) is adequate to cover all use-cases
  - Publicly available on the CDISC Wiki

# Travel

- Row 1:** Shows that subject 100 did travel 14 days prior to symptom onset.
- Row 2:** Shows that subject 100 traveled to the US state of Massachusetts during the dates shown in ERSTDTC and ERENDTC, all within 14 days prior to symptom onset.
- Row 3:** Shows that subject 100 traveled to the US state of New York during the dates shown in ERSTDTC and ERENDTC, all within 14 days prior to symptom onset.
- Row 4:** Shows that subject 101 did travel 14 days prior to symptom onset.
- Row 5:** Shows that subject 101 traveled to the Lombardy region of Italy during the dates shown in ERSTDTC and ERENDTC, all within 14 days prior to symptom onset.
- Row 6:** Shows that subject 101 traveled to Madrid, Spain during the dates shown in ERSTDTC and ERENDTC, all within 14 days prior to symptom onset.
- Row 7:** Shows that subject 102 did not travel 14 days prior to symptom onset.

er.xpt

Row	STUDYID	DOMAIN	USUBJID	ERSEQ	ERGRPID	ERTERM	ERCAT	ERSCAT	ERPRES	EROCCUR	ERDTC	ERSTDTC	ERENDTC	EVINTX	ERCNTRY	ERREGION
1	COV-7	ER	100	1	1	TRAVEL	COVID-19 RISK FACTOR	TRAVEL	Y	Y	2020-02-23			14 DAYS PRIOR TO SYMPTOM ONSET		
2	COV-7	ER	100	2	1	TRAVEL	COVID-19 RISK FACTOR	TRAVEL			2020-02-23	2020-02-11	2020-02-14	14 DAYS PRIOR TO SYMPTOM ONSET	USA	US-MA
3	COV-7	ER	100	3	1	TRAVEL	COVID-19 RISK FACTOR	TRAVEL			2020-02-23	2020-02-14	2020-02-16	14 DAYS PRIOR TO SYMPTOM ONSET	USA	US-NY
4	COV-7	ER	101	1	2	TRAVEL	COVID-19 RISK FACTOR	TRAVEL	Y	Y				14 DAYS PRIOR TO SYMPTOM ONSET		
5	COV-7	ER	101	2	2	TRAVEL	COVID-19 RISK FACTOR	TRAVEL			2020-02-23	2020-02-10	2020-02-13	14 DAYS PRIOR TO SYMPTOM ONSET	ITA	IT-25
6	COV-7	ER	101	3	2	TRAVEL	COVID-19 RISK FACTOR	TRAVEL			2020-02-23	2020-02-13	2020-02-19	14 DAYS PRIOR TO SYMPTOM ONSET	ESP	ES-M
7	COV-7	ER	102	1		TRAVEL	COVID-19 RISK FACTOR	TRAVEL	Y	N	2020-02-23			14 DAYS PRIOR TO SYMPTOM ONSET		



# Personal Protective Equipment (PPE)

## ▼ er.xpt

**Row 1:** Shows that the subject used PPE.

**Rows 2-4:** Show that the subject used an N95 respirator, a gown, and a face shield.

*er.xpt*

Row	STUDYID	DOMAIN	USUBJID	ERSEQ	SPDEVID	ERTERM	ERCAT	ERPRESP	EROCCUR	ERDTC	EREVLINT
1	CVD-4	ER	400	1		Use of Personal Protective Equipment	PPE	Y	Y	2020-04-10	-P14D
2	CVD-4	ER	400	2	100	Use of N95 Respirator	PPE	Y	Y	2020-04-10	-P14D
3	CVD-4	ER	400	3	200	Use of Gown	PPE	Y	Y	2020-04-10	-P14D
4	CVD-4	ER	400	4	300	Use of Face Shield	PPE	Y	Y	2020-04-10	-P14D

The DI domain is used to represent information about the PPE type and manufacturer.

## ▼ di.xpt

*di.xpt*

Row	STUDYID	DOMAIN	SPDEVID	DISEQ	DIPARMCD	DIPARM	DIVAL
1	CVD-4	DI	100	1	DEVTYPE	Device Type	N95 Respirator
2	CVD-4	DI	100	2	MANUF	Manufacturer	Company A
3	CVD-4	DI	200	1	DEVTYPE	Device Type	Gown
4	CVD-4	DI	200	2	MANUF	Manufacturer	Company B
5	CVD-4	DI	300	1	DEVTYPE	Device Type	Face Shield
6	CVD-4	DI	300	2	MANUF	Manufacturer	Company C



# Diagnostics & Virology

Jon Neville



# Diagnostics and Virology Section Overview

- This section includes the following examples:
  - **Virus identification-** testing for the presence of SARS-CoV-2 in a subject sample
  - **Antibody Testing-** detection of IgG and IgM (terminology also exists for testing of SARS-Cov-2 IgA antibody)
  - **Viral load testing**
    - Quantification of SARS-CoV-2 RNA by quantitative PCR
    - Quantification Cycle value
- Sources of input
  - Published literature
  - Task Force member feedback
  - Prior examples from existing CDISC therapeutic-area user guides

# Virus Identification

- The example follows SDTMIG conventions (v3.2-3.3) by representing these data in the MB domain

USUBJID	MBSEQ	MBREFID	MBGPRID	MBTESTCD	MBTEST	MBTSTDTL	MBORRES	MBSTRESC	MBSPEC	MBLOC	MBMETHOD
ABC-01-601	1	60101	1	SARSCOV2	Severe Acute Resp Syndrome Coronavirus 2	DETECTION	POSITIVE	POSITIVE	ENDOTRACHEAL FLUID		QUANTITATIVE REVERSE TRANSCRIPTASE POLYMERASE CHAIN REACTION
ABC-01-722	2	72201	1	SARSCOV2	Severe Acute Resp Syndrome Coronavirus 2	DETECTION	NEGATIVE	NEGATIVE	SWABBED MATERIAL	THROAT	QUANTITATIVE REVERSE TRANSCRIPTASE POLYMERASE CHAIN REACTION

- MBTEST/MBTESTCD represents the name of the virus
- Since we are only interested in detecting the presence of virus (versus quantifying it) MBTSTDTL=DETECTION
- Results are expressed as POSITIVE / NEGATIVE

# Antibody Testing

- As of SDTMIG v3.3, this concept is still represented in MB

DOMAIN	USUBJID	MBSEQ	MBREFID	MBTESTCD	MBTEST	MBTSTDTL	MBORRES	MBSTRESC	MBSPEC
MB	COVID-ABC-011	1	13668	SAR2IGM	SARS-CoV-2 IgM Antibody	DETECTION	POSITIVE	POSITIVE	SERUM
MB	COVID-ABC-011	2	13668	SAR2IGG	SARS-CoV-2 IgG Antibody	DETECTION	NEGATIVE	NEGATIVE	SERUM
MB	COVID-ABC-022	1	23433	SAR2IGGM	SARS-CoV-2 IgG/IgM Antibody	DETECTION	POSITIVE	POSITIVE	SERUM

- Based on the 3 most common antibody detection tests: IgG, IgM, and combination IgG/IgM
- Since we are not quantifying antibodies, the modeling approach is similar to virus detection with regard to MBTEST, MBTSTDTL, and results of POSITIVE / NEGATIVE
- If the assay is designed quantify antibodies, we would use MBTSTDTL=QUANTIFICATION, with numeric results and appropriate units

# Viral Load

Terminology changed from THRESHOLD CYCLE in the interim guide to QUANTIFICATION CYCLE NUMBER

MBGRPID	MBREFID	MBTESTCD	MBTEST	MBTSTDTL	MBORRES	MBORRESU	MBSTRESC	MBSTRESN	MBSTRESU	MBSPEC	MBMETHOD
1	001-02	SAR2RNA	SARS-CoV-2 RNA	VIRAL LOAD	3.9	log 10 copies/mL	3.9	3.9	log 10 copies/mL	SPUTUM	QUANTITATIVE REVERSE TRANSCRIPTASE POLYMERASE CHAIN REACTION
1	001-02	SAR2RNA	SARS-CoV-2 RNA	QUANTIFICATION CYCLE NUMBER	27.43		27.43	27.43		SPUTUM	QUANTITATIVE REVERSE TRANSCRIPTASE POLYMERASE CHAIN REACTION
2	001-03	SAR2RNA	SARS-CoV-2 RNA	VIRAL LOAD	4.7	log 10 copies/mL	4.7	4.7	log 10 copies/mL	SPUTUM	QUANTITATIVE REVERSE TRANSCRIPTASE POLYMERASE CHAIN REACTION
2	001-03	SAR2RNA	SARS-CoV-2 RNA	QUANTIFICATION CYCLE NUMBER	23.11		23.11	23.11		SPUTUM	QUANTITATIVE REVERSE TRANSCRIPTASE POLYMERASE CHAIN REACTION
3	001-04	SAR2RNA	SARS-CoV-2 RNA	VIRAL LOAD	4.5	log 10 copies/mL	4.5	4.5	log 10 copies/mL	SPUTUM	QUANTITATIVE REVERSE TRANSCRIPTASE POLYMERASE CHAIN REACTION
3	001-04	SAR2RNA	SARS-CoV-2 RNA	QUANTIFICATION CYCLE NUMBER	23.22		23.22	23.22		SPUTUM	QUANTITATIVE REVERSE TRANSCRIPTASE POLYMERASE CHAIN REACTION
	001-05	SAR2RNA	SARS-CoV-2 RNA		TARGET NOT DETECTED		TARGET NOT DETECTED			SPUTUM	QUANTITATIVE REVERSE TRANSCRIPTASE POLYMERASE CHAIN REACTION
	001-06	SAR2RNA	SARS-CoV-2 RNA		TARGET NOT DETECTED		TARGET NOT DETECTED			SPUTUM	QUANTITATIVE REVERSE TRANSCRIPTASE POLYMERASE CHAIN REACTION
	001-07	SAR2RNA	SARS-CoV-2 RNA		TARGET NOT DETECTED		TARGET NOT DETECTED			SPUTUM	QUANTITATIVE REVERSE TRANSCRIPTASE POLYMERASE CHAIN REACTION

- The example follows one subject over 6 visits.
- All records: MBTEST= SARS-CoV-2 RNA
- Test may quantify RNA (viral load) and/or quantification cycle; MBTSTDTL distinguishes these, and when both are present, GRPID is used to group both by subject-visit.
- When SARS-CoV-2 RNA isn't detected in the subject sample, MBTSTDTL is null.

# Summary

- All concepts represented in MB (LB is not appropriate for these concepts)
- Pay attention to the value of MBTSTDTL based on what the test is reporting
  - DETECTION, QUANTIFICATION, VIRAL LOAD, QUANTIFICATION CYCLE NUMBER
- Always check controlled terminology. More controlled terminology exists than what is shown in the examples
  - SARS-CoV-2 IgA Antibody
  - “copies/mL” is also valid for viral load



# Signs & Symptoms Vaccines

Diane Wold



# Signs and Symptoms

- Most updates were made to clarify decisions about whether to represent data in an events domain or in the Findings About Events or Interventions (FA) domain.
- In currently published versions of the SDTMIG, advice on criteria for using the FA domain are not completely clear and the application of the criteria in the examples is not always clear. This has led to confusion in the implementation community.
- The version of the SDTMIG currently out for public review updates this advice. The COVID-19 TAUG was prepared using this updated advice, and the updates to the TAUG explain how this advice was applied.

# Added Signs and Symptom Known Issues

- A protocol may specify certain events to be treated as clinical events but indicate that if a clinical event meets certain criteria of duration or seriousness it should be reported as an adverse event.
- **Known Issue:** Should such an event be removed from the CE domain, or be reported in both the CE and AE domains? Consult regulatory authorities for their requirements.
  - If data about clinical events are represented in FA, then splitting of FA into FACE and FAAE datasets may be affected by this issue.
- **Known Issue:** Severity of clinical events may be evaluated using scales other than the Mild/Moderate/Severe scale used for adverse events. If a clinical event meets criteria for reporting as an adverse event, then the way in which the collected severity was mapped to the adverse event severity scale will need to be explained in the cSDRG.

# Vaccine

- The section on Vaccines refers to the TAUG for vaccines and the FDA technical specification *Submitting Study Datasets for Vaccines to the Office of Vaccines Research and Review*.
- The examples in this section address the issue that arises when an investigator's assessment of severity is different from a subject's, an issue discussed in the FDA technical specification.
- The two examples show representation of these two different assessments in the case where the assessments are represented in the Clinical Events domain and the case where the assessments are represented in the FA domain.
- The example involving FA was updated to more clearly explain why the FA domain was used in the example.



# Vital Signs Assisted Ventilation

Jon Neville and Bess LeRoy



# Vital Signs

- This section is based on a CRF that is divided into modules by hospital admission and daily assessments
- Changes from interim guide include the use of the –COLSRT (Collected Summary Result Type) to represent the lowest value in the daily assessments
- Includes urine output volume as a sort of kidney "vital sign" in the LB domain

# 24-hour Urine Output

- Urine output volume is measured every hour over 24 hrs
- Each hour is totaled at the end to arrive at 24 hr fluid output (Row 1)
  - LBDTC/LBENDTC show the 24 hr interval
- Additionally, the investigator collects the LOWEST hourly volume of the 24 individual measurements (Row 2)
  - LBDTC/LBENDTC show which hour within the 24hr period
  - NSV LBCOLSRT (Collected Summary Result Type) indicates this record was lowest
  - LBEVLINT is populated using ISO8601 start datetime/ end datetime format  
 This deviates from the usual period-of-time format used in this variable (i.e, -PT24H) as that would conflict with what's shown in LBDTC/LBENDTC

LBTEST	LBCAT	LBORRES	LBORRESU	LBORNRL0	LBORNRH1	LBSTRESC	LBSTRESN	LBSTRESU	LBOINC	LBSPEC	VISITNUM	VISIT	VISITDY	LBDTC	LBENDTC	LBDY	LBEVLINT	LBCOLSRT
Fluid Output	DAILY ASSESSMENTS	150	mL			150	150	mL	9192-6	URINE	1	1	4	2020-03-10T00:00	2020-03-10T23:59	4		
Fluid Output	DAILY ASSESSMENTS	5	mL			5	5	mL	9188-4	URINE	1	1	4	2020-03-10T07:00	2020-03-10T08:00	4	2020-03-10T00:00/2020-03-10T23:59	LOWEST

# Assisted Ventilation and Oxygen Treatments



Oxygen use  
represented  
in CM



Assisted  
ventilation  
represented  
in PR and DI





# Questionnaires, Ratings & Scales

Dana Booth



# Questionnaires, Ratings and Scales

Full Name and Abbreviation	Copyright Permission Status	Supplement Status	RSCAT	RSTESTCD/RSTEST
National Early Warning Score 2 (NEWS2)	Granted	Supplement in progress	NEWS2	NEWS109/NEWS1-NEWS Total (see supplement for additional RSTESTCD/RSTEST terminology)
Richmond Agitation-Sedation Scale (RASS)	To be requested		RASS	RASS0101/RASS01-Score
Riker Sedation-Agitation Scale (SAS)	To be requested		SAS	SAS0101/SAS01-Score

# QRS- NEWS2 Overview

- NEWS2 should go out for Public Review the by Q2 2021.
- No annotated CRF because copyright permission does not allow for that..
- We will include a copy of the original CRF. They are available at: <https://www.rcplondon.ac.uk/projects/outputs/national-early-warning-score-news-2>, under “NEWS2\_Chart 3\_NEWS observation chart”.
- NEWS2 will be represented in the RS domain as a clinical classification.
- CDISC Controlled Terminology has already been published for the instrument definition, test codes, and test names under the following codelists:
  - Category of Clinical Classification
  - National Early Warning Score 2 Clinical Classification Test Code / Test Name

# QRS- NEWS2 Overview

- Standardized responses are generally 0-3, but Consciousness (RSTESTCD = “NEWS107”) is an exception, having possible values of 0 and 3.
- Also note that RSORRES values are slightly different from the CRF; this was determined with input from subject matter experts.

RSTESTCD	RSTEST
NEWS107	NEWS1-Consciousness

RSORRES	RSSTRESC	RSSTRESN
Alert	0	0
New Confusion	3	3
Verbal Responsive	3	3
Pain Responsive	3	3
Unresponsive	3	3

# QRS- NEWS2 Overview

- NEWS2 includes logically skipped items:
  - Only 1 of the 2 oxygen saturation scales is completed for each subject. (RSTESTCD = “NEWS102” or “NEWS103”).
  - If the subject only receives oxygen from room air (RSTESTCD = “NEWS104”, RSORRES = “Room air”), then the amount of oxygen received in O<sub>2</sub> L/min is missing so RSTESTCD = “NEWS104A” becomes logically skipped.
- For logically skipped items:
  - RSSTAT = “NOT DONE”
  - RSREASND = “LOGICALLY SKIPPED ITEM”
  - RSORRES, RSSTRESC, and RSSTRESN are null (missing)

# QRS- NEWS2 Overview

RSTESTCD	RSTEST	RSCAT	RSORRES	RSORRESU	RSSTRESC	RSSTRESN	RSSTRESU	RSSTAT	RSREASND
NEWS101	NEWS1-Respirations	NEWS2	21-24	breaths/min	2	2			
NEWS102	NEWS1-Oxygen Saturation SpO2 Scale 1	NEWS2	<=91	%	3	3			
NEWS103	NEWS1-Oxygen Saturation SpO2 Scale 2	NEWS2						NOT DONE	LOGICALLY SKIPPED ITEM
NEWS104	NEWS1-Air or Oxygen	NEWS2	Room air		0	0			
NEWS104A	NEWS1-Air or Oxygen: Device	NEWS2						NOT DONE	LOGICALLY SKIPPED ITEM
NEWS105	NEWS1-Systolic Blood Pressure	NEWS2	81-90	mmHg	3	3			

# The Public Review: Finding the TAUG

Log out

My Account

Search



New to CDISC

Standards

Education

Resources

Events

Membership

Members Only

## Foundational

BRIDG

PRM

SEND

CDASH

SDTM

SDTMIG

ADaM

QRS

Medical Devices

PGx

## Data Exchange

CTR-XML

Dataset-XML

Define-XML

LAB

ODM-XML

RDF

SDM-XML

## Terminology

Glossary

Controlled Terminology

## Therapeutic Areas

Alphabetical

By Disease Area

Published User Guides

## In Development

Current Public Reviews

Standards in Development

Real World Data

CDISC 360

## CDISC Library

CDISC Library Archives

# The Public Review: Finding All Public Reviews

Log out

My Account

Search



New to CDISC

Standards

Education

Resources

Events

Membership

Members Only

Home / Public Reviews

## Public Reviews

Subject Visits (SV) and other items that affect the COVID-19 TAUG are out for review in SDTMIG v3.4

Standard/Therapeutic Area

Comments Due

CDASH Model v1.2 and CDASH Implementation Guide v2.2

22 March 2021

Phase 2: SDTM v2.0, SDTMIG v3.4 and Conformance Rules v2.0

26 February 2021

T1D Therapeutic Area User Guide - Exercise & Nutrition: Hand Grip Strength Assessment

26 February 2021

Crohn's Disease Therapeutic Area User Guide Work Package 1 - Additional CDASH to SDTM Data Representation

18 February 2021

ADaM OCCDS v1.1 and Conformance Rules

17 February 2021

Controlled Terminology Relationships for SDTM v1.4 and SDTMIG v3.2

15 February 2021

# The Public Review: Finding the TAUG

Log out

My Account

Search



New to CDISC

Standards

Education

Resources

Events

Membership

Members Only

## Foundational

BRIDG

PRM

SEND

CDASH

SDTM

SDTMIG

ADaM

QRS

Medical Devices

PGx

## Data Exchange

CTR-XML

Dataset-XML

Define-XML

LAB

ODM-XML

RDF

SDM-XML

## Terminology

Glossary

Controlled Terminology

## Therapeutic Areas

Alphabetical

By Disease Area

Published User Guides

## In Development

Current Public Reviews

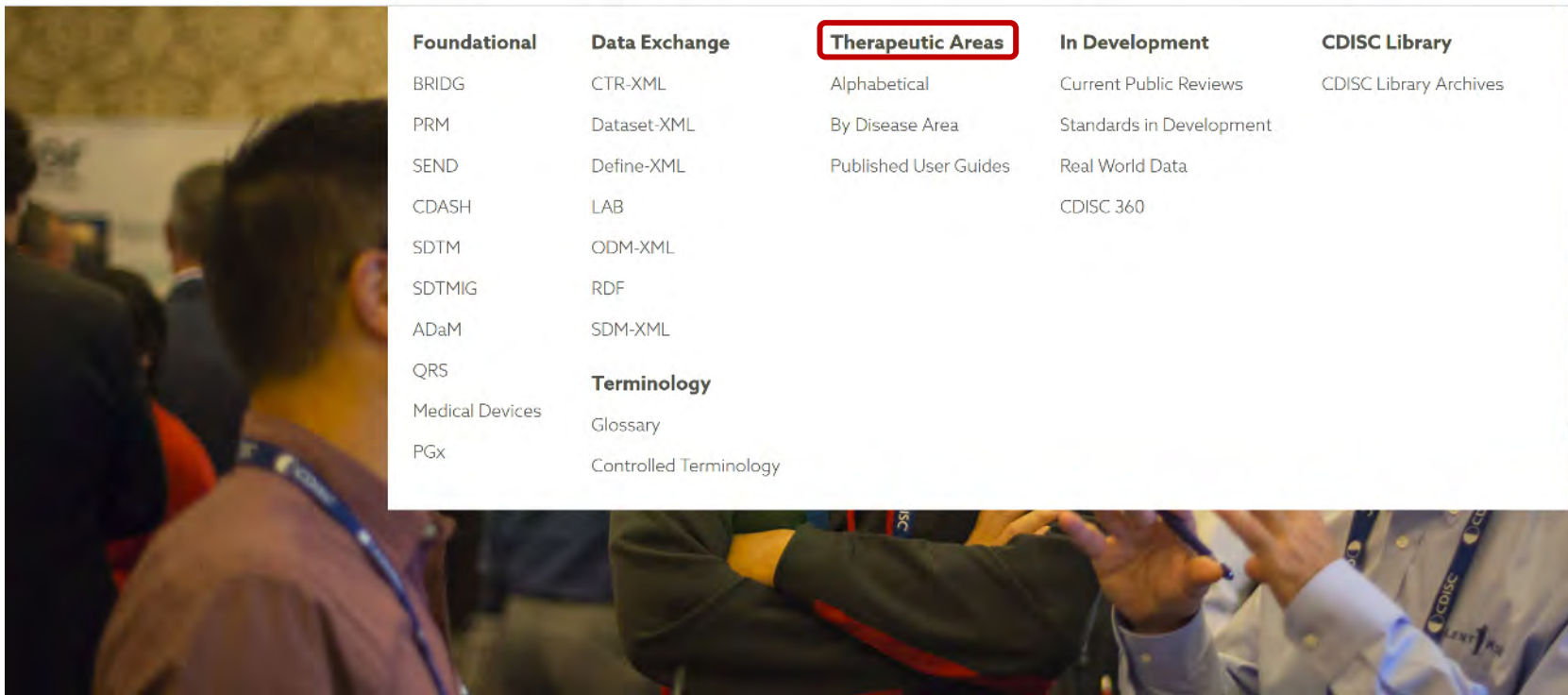
Standards in Development

Real World Data

CDISC 360

## CDISC Library

CDISC Library Archives





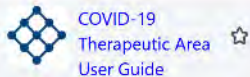
# The Public Review: Finding the TAUG

[Log out](#)[My Account](#)[New to CDISC](#)[Standards](#)[Education](#)[Resources](#)[Events](#)[Membership](#)[Members Only](#)[Home](#) / [Standards](#) / [Therapeutic Areas](#)

## Therapeutic Areas

Therapeutic Area User Guides (TAUGs) extend the Foundational Standards to represent data that pertains to specific disease areas. TAUGs include disease-specific metadata, examples and guidance on implementing CDISC standards for a variety of uses, including global regulatory submissions.

[Acute Kidney Injury](#)[Alzheimer's](#)[Asthma](#)[Breast Cancer](#)[Cardiovascular](#)[CDAD](#)[Colorectal Cancer](#)[COPD](#)[COVID-19](#)[Crohn's Disease](#)[Diabetes](#)[Diabetes - Type 1](#)[Diabetic Kidney Disease](#)[Duchenne Muscular Dystrophy](#)[Dyslipidemia](#)[Ebola](#)[Heart Failure](#)[Hepatitis C](#)[HIV](#)[Huntington's Disease](#)[Influenza](#)[Kidney Transplant](#)[Lung Cancer](#)[Major Depressive Disorder](#)[Malaria](#)[Multiple Sclerosis](#)[Nutrition](#)[Pain](#)[Pancreatic Cancer](#)[Parkinson's Disease](#)[Polycystic Kidney Disease](#)[Post Traumatic Stress Disorder](#)[Prostate Cancer](#)[Psoriasis](#)[QT Studies](#)[Rheumatoid Arthritis](#)[Schizophrenia](#)[Traditional Chinese Medicine - Acupuncture](#)[Traditional Chinese Medicine - Coronary](#)[Artery Disease-Angina](#)[Traumatic Brain Injury](#)[Tuberculosis](#)[Vaccines](#)[Virology](#)



Dashboard

Edit Save for later Watch Share

# COVID-19 Therapeutic Area User Guide Home

Created by Alana St. Clair, last modified on Dec 12, 2020

## PAGE TREE

- [Instructions for Reviewers](#)
- [TAUG-COVID-19 Compiled](#)
- > [TAUG-COVID-19 Sections](#)
- > [SDTM Examples - TAUG CO](#)

### • Read the document

- [TAUG-COVID-19 Compiled](#) — View the entire document as a single web page.
- [TAUG-COVID-19 Sections](#) — Display each section on its own page.
  - > [Jump to a specific section:](#)

### • View the examples

- [SDTM Examples - TAUG COVID-19](#) — This is where all examples used in the document are located.

### • Provide feedback

- [Instructions for Reviewers](#) — This is where to find detailed instructions for how to use JIRA to provide feedback on the document.

### ⓘ Status

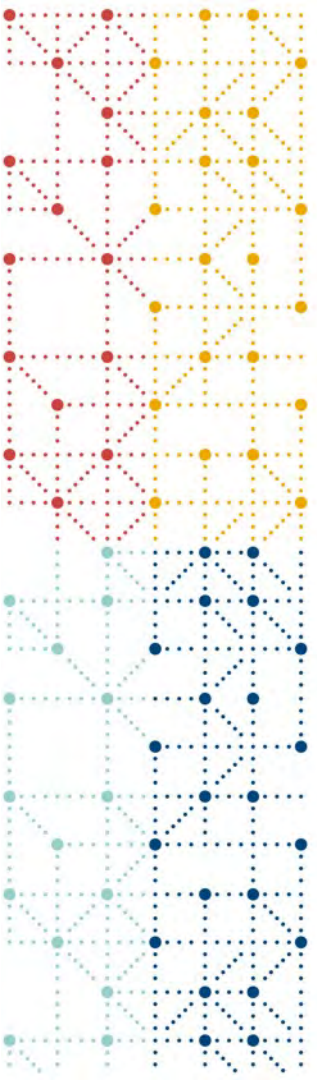
This is a **DRAFT** standard, which means that it is still in development and not yet ready for provisional or general use.

Other resources you may find helpful:

- [Introduction to Therapeutic Area Standards](#) — This provides an overview of what to expect, and what *not* to expect, from a therapeutic area user guide.
- [Reading on the Wiki](#) — This page touches on some of the ways the Wiki edition of the document has been optimized for web use, with which a reader new to the CDISC Wiki may be unfamiliar.
- [TA Specification](#) — This is a spreadsheet that provides information, for newer and proposed domains and variables, on relationships with versions of SDTM and the SDTMIG.

ⓘ TA Specifications were developed to assist FDA in their testing processes, but can also provide implementers with advice on how to adapt the representation of data shown in the TAUG to different versions of the standards. TA Specifications are provided as a resource to reviewers; we are not seeking comment on the TA Specification. However, we would appreciate being informed of inconsistencies in the content of the TA Specification and the TA User Guide.

Comments on this document should be entered into JIRA at: <https://jira.cdisc.org/projects/COVID19>. For more details, see the [Instructions for Reviewers](#).



**Thank You!**



# Public Review Webinar: COVID-19 Therapeutic Area User Guide

Dana Booth, Project Manager, Foundational Standards, CDISC

Kit Howard, Sr. Director, Standards Development & Education, CDISC

Bess LeRoy, Head of Standards Development, CDISC

Jon Neville, Sr. Standards Developer, CDISC

Amy Palmer, Head of Standards Development, CDISC

Alana St. Clair, Project Manager, CDISC

Diane Wold, Sr. Director, Standards Development, CDISC



THU 4 FEB

11:00AM-12:30PM ET

# Audience Questions

ERTERM and ERSCAT variable has same values. Can we have the values of domestic and international travel in ERSCAT variable?



# Audience Questions

Any suggestions for semi -  
quantitative viral count load for MB?



# Audience Questions

Can same MBTESTCD be used one for semi - quantitative viral load ( threshold cycle) results and one for qualitative (detection)?



# Audience Questions



Is it recommended to use MBTSTDTL now?



# Audience Questions

currently many of the changes for COVID19 are creating errors. PMDA has not yet come out with their reco. has CDISC reached out to them?



# Audience Questions



Do we report any COVID related AE at screening stage in MH or AE? Or no need to report it

# Audience Questions

because by this distinguish we can more easily analyse the data regarding from which prospect it is spreading fast



# Audience Questions



in this TAUG, vaccines section seems related to vaccines studies but how to record vaccines done during non-vaccines studies? in CM during study and MH prior study?

# Audience Questions

Does CDISC recommend SV+VE for submitting unscheduled visits or extending SV to include all necessary standard/Non-Standard variables?



# Audience Questions



Will the CDISC Guidance for Ongoing Studies Disrupted by COVID-19 Pandemic Version 1.0 go through public review?

# Audience Questions

Has there been any proof that animals are causing any increases in COVID cases? I find this an interesting question to continue to ask unless we have proven data that shows correlation.



# Audience Questions



did covid 19 TA domains have been added to pinnacle 21 validator or not?



# Audience Questions

The semi qualitative tests are PCR detection of nucleic acid from cycle threshold (ct) . The ct value is not viral load but it is inversely related to the viral load



# Audience Questions



How to record delayed or missed visit due to a vaccination/vaccine shot? in SV? or CO acceptable...

# Audience Questions

does this mean if we'd like to see the use of these NSVs that we should comment as such in the v3.4 review?



# Audience Questions



Do we need to populate associated persons domains (SDTMIG AP) if any person is associated (taking care of while patient is suffering from covid19) with patient who got covid19 and this patient is taking vaccine ?

# Audience Questions

do we include information on which company COVID vaccine patient got, initial shot or booster shot,



# Audience Questions



Yes, but that is only one - so if there is only one NSV from the CDISC Guidance for Ongoing Studies Disrupted by COVID-19 Pandemic Version 1.0 shown does that mean that the others are no longer recommended as a standard?

# Audience Questions

Dana- QRS NEWS2- should we also mention that there is an ADaM supplement under development?



# Audience Questions



is there a standard QS form being designed to collect covid related sympoms? This will especially be useful for asymptomatic patients who may or may not have been tested.





# Upcoming Learning Opportunities

# New Virtual Training Methods

**Blended Learning from CDISC**

Online Resources  
+ In-Person Instruction  
More Personalized Learning

Classes Starting Soon!

**CDISC Redefines Data Standards Training**  
**NEW VIRTUAL CLASSROOM!**

- 100% Instructor Led
- Immediate Feedback
- Small Class Sizes
- Remote Convenience

cdisc

- Information available at: [www.cdisc.org](http://www.cdisc.org)
- Register at: <https://learnstore.cdisc.org/>
- Contact us at: [training@cdisc.org](mailto:training@cdisc.org)



BLEND  
ED LE  
ARNING



VIR  
TUAL  
TRAINING



CLAS  
SROOM  
TRAINING



PRIV  
ATE  
TRAINING



WEBINARS



WORKSHOPS



# 2021 EUROPE INTERCHANGE

With Standards - Science Will Prevail!



Live Stream | 28-30 April

Conference | Trade Show | TechniCon

NEXT GENERATION TECHNOLOGY SOLUTIONS

# TechniCon

30 APRIL 2021  
A VIRTUAL CDISC EVENT

2021



# 2021 JAPAN INTERCHANGE

With Standards - Science Will Prevail!



Live Stream | 10-11 June

Conference | Trade Show



# 2021 CHINA INTERCHANGE

With Standards - Science Will Prevail!



Beijing | 6-7 August

Conference | Trade Show



# 2021 US INTERCHANGE

With Standards - Science Will Prevail!



Washington, DC | 18-22 October

Conference | Trade Show



# 2021 Webinars

Date	Webinar Title
23 FEB	What's Different about SDTM for Clinical and Non-Clinical Trials
2 MAR	Current and Forthcoming ADaM Publications
16 MAR	QRS "Office Hours"
25 MAR	Public Review Webinar: Pancreatic Cancer Therapeutic Area User Guide
1 APR	Controlled Terminology Updates for Q1 2021
1 JUL	Controlled Terminology Updates for Q2 2021
Coming Soon	CDASH "Office Hours"; ADaM "Office Hours"; CDISC Library Update

Visit <https://www.cdisc.org/education/webinars> for information on additional Public Training events.

# Questions/Comments/Concerns



Use CDISC contact form:  
<https://www.cdisc.org/contact>



Contact general Webinar inbox:  
[cdiscwebinar@cdisc.org](mailto:cdiscwebinar@cdisc.org)



Contact Bernard directly: [bklinke@cdisc.org](mailto:bklinke@cdisc.org)



# Thank You!

Please don't forget to fill out the  
feedback survey!

