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Amy Palmer, Head of Standards Development, CDISC
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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
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
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
4th February 2021
Introduction

Kit Howard
And then the World Changed…

1,000,000 10,000,000 25,000,000

100,000 75,000,000

100,000,000 cases

COVID-19 Public Review Webinar
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
Extra Version of Controlled Terminology

Published April 2020
Published April 2020
Published May 2020
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

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

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

COVID-19 Public Review Webinar
Stages of the CDISC Standards Development Process

- Scoping
- Concept Modeling
- Standards Development
- Internal Review
- Public Review
- Publication
- Maintenance

Development Team, GGG

Interim TAUG
Stages of the CDISC Standards Development Process

- Scoping
- Concept Modeling
- Standards Development
- Internal Review
- Public Review
- Publication
- Maintenance

Final TAUG

COVID-19 Public Review Webinar
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
2.2 Personal Protective Equipment (PPE)
2.3 Travel
2.4 Contacts
2.5 Smoking
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.

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<th>EROCCUR</th>
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# Personal Protective Equipment (PPE)

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.

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<td>Y</td>
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<td>ER</td>
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<td>2</td>
<td>200</td>
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<td>PPE</td>
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<td>Y</td>
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<td>4</td>
<td>300</td>
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<td>PPE</td>
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<td>Y</td>
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<td>-P14D</td>
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The DI domain is used to represent information about the PPE type and manufacturer.

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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

<table>
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<th>USUBJID</th>
<th>MBSEQ</th>
<th>MBREFID</th>
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<th>MBTSTDTL</th>
<th>MBORRES</th>
<th>MBSTRES</th>
<th>MBSPEC</th>
<th>MBLOC</th>
<th>MBMETHOD</th>
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<td>ABC-01-601</td>
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<td>601001</td>
<td>1</td>
<td>SARS-CoV-2</td>
<td>Severe Acute Resp Syndrome Coronavirus 2</td>
<td>DETECTION</td>
<td>POSITIVE</td>
<td>POSITIVE</td>
<td>ENDOTRACHEAL FLUID</td>
<td>THROAT</td>
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<td>Severe Acute Resp Syndrome Coronavirus 2</td>
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<td>NEGATIVE</td>
<td>NEGATIVE</td>
<td>SWABBED MATERIAL</td>
<td>THROAT</td>
<td>QUANTITATIVE reverse transCRIPtase POLYmerase CHAIN REACTION</td>
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</table>

- 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

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 to 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

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<th>MGRPID</th>
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<th>MBTESTCD</th>
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- 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

- 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
Assisted Ventilation and Oxygen Treatments

Oxygen use represented in CM

Assisted ventilation represented in PR and DI

COVID-19 Public Review Webinar
Questionnaires, Ratings & Scales

Dana Booth
Questionnaires, Ratings and Scales

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<th>Supplement Status</th>
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<td>Supplement in progress</td>
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<td></td>
<td>RASS</td>
<td>RASS0101/RASS01-Score</td>
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<tr>
<td>Riker Sedation-Agitation Scale (SAS)</td>
<td>To be requested</td>
<td></td>
<td>SAS</td>
<td>SAS0101/SAS01-Score</td>
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</tbody>
</table>
QRS- NEWS2 Overview

• NEWS2 should go out for Public Review 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.
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\textsubscript{2} 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**

<table>
<thead>
<tr>
<th>RSTESTCD</th>
<th>RSTEST</th>
<th>RSAT</th>
<th>RSORRES</th>
<th>RSORRESU</th>
<th>RSSTRESP</th>
<th>RSSTRESP</th>
<th>RSSTRESP</th>
<th>RSSTRESP</th>
<th>RSSTAT</th>
<th>RSREASND</th>
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<tbody>
<tr>
<td>NEWS101</td>
<td>NEWS1-Respirations</td>
<td>NEWS2</td>
<td>21-24</td>
<td>breaths/min</td>
<td>2</td>
<td>2</td>
<td></td>
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<tr>
<td>NEWS102</td>
<td>NEWS1-Oxygen Saturation SpO2 Scale 1</td>
<td>NEWS2</td>
<td>&lt;=91</td>
<td>%</td>
<td>3</td>
<td>3</td>
<td></td>
<td></td>
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<td>NEWS103</td>
<td>NEWS1-Oxygen Saturation SpO2 Scale 2</td>
<td>NEWS2</td>
<td></td>
<td></td>
<td>NOT DONE</td>
<td>LOGICALLY SKIPPED ITEM</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
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<td>NEWS104</td>
<td>NEWS1-Air or Oxygen</td>
<td>NEWS2</td>
<td>Room air</td>
<td>0</td>
<td>0</td>
<td></td>
<td></td>
<td></td>
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<td></td>
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<tr>
<td>NEWS104A</td>
<td>NEWS1-Air or Oxygen: Device</td>
<td>NEWS2</td>
<td></td>
<td></td>
<td>NOT DONE</td>
<td>LOGICALLY SKIPPED ITEM</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>NEWS105</td>
<td>NEWS1-Systolic Blood Pressure</td>
<td>NEWS2</td>
<td>81-90</td>
<td>mmHg</td>
<td>3</td>
<td>3</td>
<td></td>
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</table>
Subject Visits (SV) and other items that affect the COVID-19 TAUG are out for review in SDTMIG v3.4

<table>
<thead>
<tr>
<th>Standard/Therapeutic Area</th>
<th>Comments Due</th>
</tr>
</thead>
<tbody>
<tr>
<td>CDASH Model v1.2 and CDASH Implementation Guide v2.2</td>
<td>22 March 2021</td>
</tr>
<tr>
<td>Phase 2: SDTM v2.0, SDTMIG v3.4 and Conformance Rules v2.0</td>
<td>26 February 2021</td>
</tr>
<tr>
<td>TID Therapeutic Area User Guide - Exercise &amp; Nutrition: Hand Grip Strength Assessment</td>
<td>26 February 2021</td>
</tr>
<tr>
<td>Crohn's Disease Therapeutic Area User Guide Work Package 1 - Additional CDASH to SDTM Data Representation</td>
<td>18 February 2021</td>
</tr>
<tr>
<td>ADaM OCCDS v1.1 and Conformance Rules</td>
<td>17 February 2021</td>
</tr>
<tr>
<td>Controlled Terminology Relationships for SDTM v1.4 and SDTMIG v3.2</td>
<td>15 February 2021</td>
</tr>
</tbody>
</table>
The Public Review: Finding the TAUG

COVID-19 Public Review Webinar

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
COVID-19 Therapeutic Area User Guide Home

- 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.

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.

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!

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?
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)?
Is it recommended to use MBTSTDLT 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
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...
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?
Do we need to populate associated persons domains (SDTMIG AP) if any person is associated (taking care of while patient is suffered 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,
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?
is there a standard QS form being designed to collect covid related symptoms? This will especially be useful for asymptomatic patients who may or may not have been tested.
Upcoming Learning Opportunities
New Virtual Training Methods

- Information available at: www.cdisc.org
- Register at: https://learnstore.cdisc.org/
- Contact us at: training@cdisc.org
# 2021 Webinars

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<th>Date</th>
<th>Webinar Title</th>
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<td>23 FEB</td>
<td>What’s Different about SDTM for Clinical and Non-Clinical Trials</td>
</tr>
<tr>
<td>2 MAR</td>
<td>Current and Forthcoming ADaM Publications</td>
</tr>
<tr>
<td>16 MAR</td>
<td>QRS &quot;Office Hours&quot;</td>
</tr>
<tr>
<td>25 MAR</td>
<td>Public Review Webinar: Pancreatic Cancer Therapeutic Area User Guide</td>
</tr>
<tr>
<td>1 APR</td>
<td>Controlled Terminology Updates for Q1 2021</td>
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<tr>
<td>1 JUL</td>
<td>Controlled Terminology Updates for Q2 2021</td>
</tr>
<tr>
<td>Coming Soon</td>
<td>CDASH “Office Hours”; ADaM ”Office Hours”; CDISC Library Update</td>
</tr>
</tbody>
</table>

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Questions/Comments/Concerns

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

Contact general Webinar inbox: cdiscwebinar@cdisc.org

Contact Bernard directly: bklinke@cdisc.org
Thank You!

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