

QRS “Office Hours”

Dana Booth, SDS QRS Subteam Co-Lead, CDISC

Steve Kopko, SDS QRS Subteam Co-Lead, CDISC



Thursday, 27 AUG 2020

11:00 – 12:30 EDT



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** for the entirety of the call
- There will be a Q&A after all of the presentations are finished
- Audio issues? Shut down and restart the GoToWebinar app
- The slides from the presentation and a recording of this webinar will be available in the Members Only section of the CDISC website
 - To access – make sure that you create a login for the CDISC website if you haven't already
 - If you are employed by a CDISC member organization, please ensure you use your employer-issued email address with your employer's domain name, so we can verify membership for the purpose of applying discounts to purchasing event tickets, online courses, and more!



Content Disclaimer

- The purpose of this webinar is to provide examples of implementation and should not be considered official recommendations by CDISC unless otherwise stated in the presentation.
- This webinar is not an authorized CDISC course, is not developed or delivered under CDISC Operating Procedures, and should not replace a published standard. Please refer to the latest published standards for the most authoritative implementation information.



Our Presenters

- Dana Booth, SDS QRS Subteam Co-Lead, CDISC
- Steve Kopko, SDS QRS Subteam Co-Lead, CDISC

QRS “Office Hours”

Dana Booth, SDS QRS Subteam Co-Lead, CDISC

Steve Kopko, SDS QRS Subteam Co-Lead, CDISC



Thursday, 27 AUG 2020

11:00 – 12:30 EDT

QRS Office Hours Webinar

Dana Booth – CDISC Project Manager
Steve Kopko – CDISC SME Consultant

08.27.2020





QRS Updates:

- CDISC invites you to submit comments on one or more of the 18 QRS supplements to the Study Data Tabulation Model Implementation Guide (SDTMIG) during Public Review. All 18 draft supplements are part of the PEDSQL V3.0 Neuromuscular Module.

Timelines and Comment Process

View the draft documents: [PEDSQL 1 - 18 Instruments](#)

Provide comments: [Instructions for Reviewers](#)



QRS Updates :

Dear CDISC Community,

CDISC is pleased to announce the following QRS supplements are now entering the Internal Review period. We strongly encourage organizations that actively use these instruments to review the supplements at this point in the development process.

- [Functional Activities Questionnaire \(FAQ\)](#)
- [Glucose Monitoring System Satisfaction Survey Version: Type 1 Diabetes \(GMSS VERSION TYPE 1 DIABETES\)](#)
- [Hamilton Depression Rating Scale 17-Item \(HAMD 17\)](#)
- [KDIGO AKI Stage \(KDIGO AKI\)](#)
- [Kurtzke Expanded Disability Status Scale \(EDSS\)](#)
- [National Early Warning Score 2 \(NEWS2\)](#)
- [Patient Determined Disease Steps \(PDDS\)](#)
- [Rockport One Mile Walk Test \(ROCKPORT ONE MILE WALK TEST V1.0\)](#)

Reviewers are requested to provide comments via JIRA. Detailed instructions on reviewing the document and using the Wiki and JIRA can be found here: [Instructions for Reviewers.](#)

Internal Review closes **8 September 2020.**



From last time - Suggested representation of CDISC QRS logically skipped items

- CDISC QRS supplements will have a record in *qs.xpt* with
 - original and standardized results that are null (QSORRES/QSSTRESC/QSSTRESN are all missing).
 - a status of NOT DONE (QSSTAT="NOT DONE").
 - reason not done equal "LOGICALLY SKIPPED ITEM" (QSREASND="LOGICALLY SKIPPED ITEM").



Suggested representation of CDISC QRS logically skipped items

- CDISC QRS supplements will have a record in *qs.xpt* with
 - original and standardized results that are null (QSORRES/QSSTRESC/QSSTRESN are all missing).
 - a status of NOT DONE (QSSTAT="NOT DONE").
 - reason not done equal "LOGICALLY SKIPPED ITEM" (QSREASND="LOGICALLY SKIPPED ITEM").



QRS Updates :

Are there know issues with QRS instrument standards implementation?

Issue: How are the --EVAL (evaluator) and --EVALID (evaluator identifier) variables handle with QRS instruments?

The concept of an evaluator or evaluator identifier with a QRS instrument varies widely across many instruments. Many standard QRS instruments do not represent this administration information. In QRS domains the --EVAL variable was overloaded, in the sense that it could represent one of several roles, for example:

- The person who entered their own answers on the instrument
- The person who conducted an interview with the respondent and filled out the instrument
- The person who administered a functional test on the subject (e.g., trained healthcare professional)
- etc.

The QRS subteam has worked on this problem with the FDA representatives and are drafting a resolution of this issues in a Considerations for Questionnaires, Ratings, and Scales document here: [Use of --EVAL and --EVALID variables \(Draft\)](#)

Please follow this guidance with QRS standards as it progresses.



Attendee QRS Questions

- 1) Site worksheet translations; 2) Data that belongs to other domains included within QRS instrument
 - There are no CDISC QRS standard translations to other languages. All QRS supplemented are developed in US English.
 - In general, all collected items on a QRS instrument need to be represented as defined in that instrument's dataset. If the topic of a data item on the instrument also belongs in other topic-based domains, the sponsor's data management practices should define if the data items are also represented in those topic domains. This is more common in clinical classification instruments represented in the RS domain.
- Do you have any recommendations on how/where to map the SOFA questionnaire? some parameters are lab results.
 - Sequential Organ Failure Assessment (SOFA) Score:
<https://www.mdcalc.com/sequential-organ-failure-assessment-sofa-score>
 - <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC6880479/>
 - This instrument consists of composite scores from various topic-based items (e.g., PaO₂, FiO₂, Platelets, ×10³/μL, etc.) and meets the definition of a QRS clinical classification instrument. It is like the National Early Warning Score 2 (NEWS2) instrument.



Attendee QRS Questions

- I would like to hear about the status of response codelists that are being added to Controlled Terminology. Thank you!
 - This proposal was submitted for FDA review that is still ongoing.
- For new questionnaire page in a study which has no CDISC CT what rules to follow for creating study specific test and test codes
 - It is recommended that for Sponsor defined QRS instruments, sponsors follow the QRS Naming Rules: https://www.cdisc.org/system/files/private_media/2020-06/QRS_Naming_Rules_2020-01-28.xlsx. The sponsor's instrument --CAT and Synonym values must be unique from existing CDISC QRS instrument CT values to avoid duplication of CT.

Audience Questions



When is it appropriate to use the record qualifier QSLOC?

Audience Questions

For QS Skipped Item. What about a question 1 was answered, which then causes Question 2 to be logically skipped. And then after the information is collected, the site changes the response to question 1 (which meant that question 2 should have been answered). Should we list question 2 as "skipped" or "logically skipped"



Audience Questions



Any updates on development of psoriasis QRS? example: NAPSI (Nail Psoriasis Severity Index)

Audience Questions

There were multiple Wiki documents that have been mentioned in this presentation, will you please post their names and status on a slide, so people who may not be as familiar with this work can have this point of reference? Thank you!





Upcoming Learning Opportunities

2020 US Virtual Interchange - 7-8 October

- Attendees



- Sponsors and Exhibitors



- Early Bird Rates Available through Friday, August 4

- Sign Up Now and Save!

Events Coming Your Way Soon!



- 2020 US Virtual Interchange
 - Registration Now Open!
 - Presenter, Sponsor and Exhibitor Opportunities Available**
 - Launching NEW Enhanced Virtual Conference Platform
 - 1:1 Virtual Networking
 - F2F Online and On-screen Meetings
 - 3D Exhibitor Experience

**Abstract Submissions Due 24 July

Newly added:

A full schedule of Virtual Courses including:

- ADaM Core Theory & Application
- CDISC for Newcomers
- CDASH Implementation
- CDASH Advanced Topics
- Controlled Terminology
- Define-XML
- ODM Implementation
- SDTM Theory & Application
- SDTM for Medical Devices
- SDTM Advanced Topics
- SEND Implementation

<https://www.cdisc.org/events/interchanges>

Preview Webinar – 1 September

A promotional banner for a CDISC webinar. The background is dark blue with a red header bar at the top containing the CDISC logo. On the left, a cartoon illustration of a man with a beard and glasses, wearing a blue suit and red tie, sits at a desk with a computer monitor. He has his arms raised in a celebratory gesture. The background is filled with various icons representing science, technology, and business, including a beaker, a bar chart, a lightbulb, a hashtag, a speech bubble, a gear, a pie chart, a globe, and a star. The text on the right side of the banner is white and blue.

cdisc

**SIGN UP TODAY FOR A SNEAK PEEK
INTO THE 2020 US VIRTUAL INTERCHANGE**

FREE Pre-conference Webinar

**Tuesday, 1 SEP 2020
11:00 AM - 11:45 AM
(US Eastern Time)**

CDISC 2020 US Interchange
Virtual Conference | 7-8 October 2020

2020 Webinars

Date	Webinar Title
1 SEP	A Sneak Peek at the 2020 US Virtual Interchange
24 SEP	Study Data Tabulation Model Metadata Submission Guidelines (SDTM-MSG): v2.0 Public Review
13 OCT	Controlled Terminology Updates for Q4
22 OCT	Introducing the Next Generation CDISC Library (registration coming soon!)



**CDISC
WEBINARS**

Technology
Digital Media
Great Ideas!

cdisc

www.cdisc.org/events/education/webinars

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

New Virtual Training Methods

- CDISC Provides Many Ways to Begin or Continue Growing Your Standards Knowledge.
 - Popular self-paced training plus new Blended Learning and Virtual Classroom settings.

Blended Learning from CDISC

Online Resources
+ In-Person Instruction
More Personalized Learning


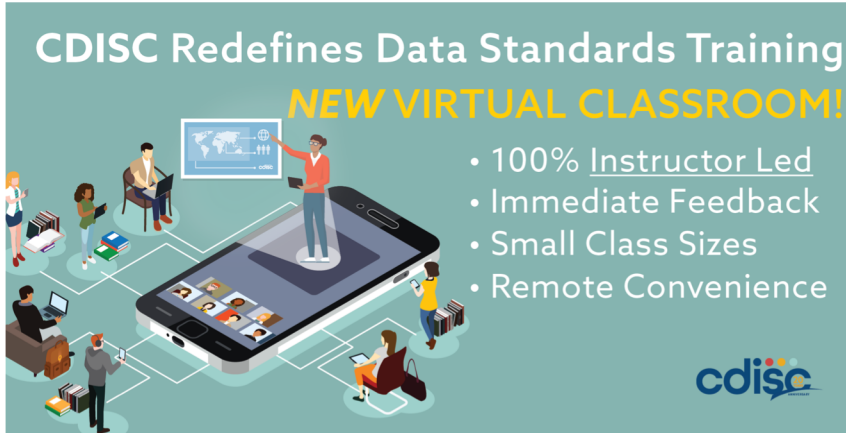


Classes Starting Soon!

CDISC Redefines Data Standards Training

NEW VIRTUAL CLASSROOM!

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





Thank You!

Questions, comments, concerns? Email bklinke@cdisc.org

Don't forget to fill out the feedback survey!

