



QRS Office Hours

08.29.2023

The logo for CDISC (Clinical Data Interchange Standards Consortium) features the word "cdisc" in a lowercase, sans-serif font. The letters "c", "d", and "i" are dark blue, while "s", "c", and "e" are light blue. Above the "i" are three small colored dots: red, yellow, and light blue.

Recently Published QRS

- QRS Publishes Supplements 4 times/year – Feb, May, Aug, and Sept
- Brief Psychiatric Rating Scale – Anchored (BPRS-A), 2023-02-27
- Columbia Suicide Severity Rating Scale Screening (C-SSRS SCREENING), 2023-05-29
- Functional Assessment Scale-NACC UDS V3.0 (FAS-NACC UDS V3.0), 2023-02-27
- Glasgow Coma Scale (GCS) the National Institute of Neurological Disorders and Stroke (NINDS) Version 1.0 (GCS NINDS V1.0), 2023-02-27
- Harvey-Bradshaw Index (HBI), 2023-05-29
- Modified Van Assche Index (MVAI), 2023-05-29
- Pain Relief (PR), 2023-05-29
- Patient Health Questionnaire – 9 (PHQ-9), 2023-05-29
- Work Productivity and Activity Impairment Specific Health Problems Questionnaire Version 2.0 (WAPI-SHP V2.0), 2023-02-27
- ADaM Supplement – Craig Handicap Assessment and Reporting Technique – Short Form (CHART-SF), 2023-05-30
- ADaM Supplement – Geriatric Depression Scale Short Form (GDS SHORT FORM), 2023-05-30

Some QRS Supplements in Progress

- To be published this week!:
 - Montreal Classification for Crohn's Disease (MONTREAL CROHN's) Supp V1.0
 - Rutgeerts Score (RUTGEERTS SCORE) Supp V1.0
- Getting ready for public review (may also have FDA review):
 - ASSIGN Risk Score V2.0
 - Chronic Respiratory Questionnaire – Self-Administered Standardized Format First Administration Version (CRQ-SAS FIRST ADMINISTRATION VERSION) Supp V2.0
 - CRQ-SAS FOLLOW-UP ADMINISTRATION VERSION Supp V2.0
 - GDS SHORT FORM Supp V2.0
- Currently under FDA Review:
 - PRO-CTCAE
 - FACT-G V4
 - FACT-HEP V4
 - C-SSRS (3)
 - And more...

QRS Other Updates

- Permission obtained for PROMIS library!
 - CDISC will be developing instrument supplements as well as searchable item libraries for Adult, Pediatric, and Parent Proxy
- Permission obtained for EORTC library!
 - Work to begin soon
- The SDS QRS Supplement template is under review so you'll notice some slight changes to the supplements (improvements in wording for clarity)
- Let us know if you would like to help!! E-mail:
 - volunteer@cdisc.org to sign up
 - dbooth.cdiscvol@gmail.com

QRS Other Updates (Cont.)

- “Logically skipped item” update to “conditional branching” is under review with the representatives we work with at the FDA
- Meanwhile there’s a new supplemental qualifier in use – --CBRFL (Conditional Branching Flag)
 - This will allow for indicating if an item was not done due to conditional branching
 - A new standard variable will be released in SDTMIG v4.0 and the corresponding model SDTM v2.x/3.0.
 - Meanwhile, the CDISC SDS QRS Subteam will use QSCBRFL as a non-standard variable.

Example of items with conditional branching – PRO-CTCAE®

QSTESTCD=PT01014A and PT01014B

14. PRO-CTCAE™ Symptom Term: Hiccups				
a. In the last 7 days, how OFTEN did you have HICCUPS?				
<input type="radio"/> Never	<input type="radio"/> Rarely	<input type="radio"/> Occasionally	<input type="radio"/> Frequently	<input type="radio"/> Almost constantly
b. In the last 7 days, what was the SEVERITY of your HICCUPS at their WORST?				
<input type="radio"/> None	<input type="radio"/> Mild	<input type="radio"/> Moderate	<input type="radio"/> Severe	<input type="radio"/> Very severe

When the PRO-CTCAE® is administered electronically, if the subject answers “Never” for PT01014A, then PT01014B is assigned “None”.

Representing items with conditional branching - PRO-CTCAE®

qs.xpt - subject never having hiccups*

Row	USUBJID	QSTESTCD	QSORRES	QSSTRESC	QSSTRESN	QSCBRFL
1	P0001	PT01014A	Never	0	0	
2	P0001	PT01014B	None	0	0	Y

- *Currently QSCBRFL would be represented as a non-standard variable (suppqual); in the future (SDTMIG v4.0; SDTM v2.x/3.0) it is anticipated to become a new standard variable.*
- *When the PRO-CTCAE is administered electronically, items not done due to conditional branching are assigned values of “None” or “Not at all” for QSORRES; QSSTRESC and QSSTRESN are assigned 0.*

*Note: Due to space constraints, some variables are not shown in the *qs.xpt* table.

QRS Other Updates (Cont.)

- When to Create Sponsor-defined QRS Terminology document is in the works; discussing if it will be part of SDTMIG v4.0. When complete, this will be added to the Resources tab at cdisc.org/qrs.
- QRS administrative metadata supplemental qualifiers are being converted to TESTCDs. These discussions are in early stages while we work through logistics.

QRS Questions Received Ahead of Time

- Q: Should the TNM staging information based on AJCC v7 at the initial cancer diagnosis (no follow-up staging) be mapped to RS?
 - A: Yes; however, please note that there is oncology disease response terminology in addition to standard QRS terminology for AJCC as a clinical classification (supplement in progress). Both are in the RS domain.
- Q: When does a questionnaire need to be put in a custom domain, instead of QS?
 - A: One example would be if you're working with a version of the SDTMIG that doesn't have RS as a QRS domain.
 - A: There are also FAQs on cdisc.org/qrs and the 2nd one addresses MI and FA (for use with VAS/NRS scales).

QRS Questions Received Ahead of Time (cont.)

- Q: How do you define which data to map to QS/RS/FT? Can we consider investigator completed questionnaires as clinical assessment in RS?
 - A: See the [cdisc.org](https://www.cdisc.org) website for definitions of the domains.
 - A: Clinical assessment by an investigator should be in RS if they are doing an assessment of the subject as a whole and providing clinical judgement, not just writing responses to questionnaires a subject has given them.

QRS Questions Received Ahead of Time (cont.)

- Q: Is there any plan to revisit strategy QRS controlled terminology definition? The current strategy is just unmaintainable...
 - A: CDISC Library (available for free) shows relationships between QRS item CT and responses CT. Only public domain (not copyrighted) controlled response CT for QRS is available in the library.
 - A: Need more information please.

QRS Questions Received Ahead of Time (cont.)

- Q: Is CDISC considering standardizing the names of QRS Split datasets for instruments? This could be beneficial in ensuring uniformity.
 - Unfortunately, that is just too big a task for us; however we recommend using the 2-character domain abbreviation and base the rest of the name on the CAT and/or instrument synonym. Since we're moving away from "supp" datasets, we may be able to use more than 2 characters.
 - SDS QRS Subteam will discuss further for potential further guidance in SDTMIG v4.0.



Thank You!

Dana Booth
dbooth.cdiscvol@gmail.com

The logo for CDISC, featuring the word "cdisc" in a dark blue, lowercase, sans-serif font. Above the "i" and "s" are three small colored dots: a red dot above the "i", a yellow dot above the "d", and a light blue dot above the "s".