QRS Office Hours

08.29.2023
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®

<table>
<thead>
<tr>
<th>QSTESTCD=PT01014A and PT01014B</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>14. PRO-CTCAE™ Symptom Term: Hiccups</strong></td>
</tr>
<tr>
<td>a. In the last 7 days, how OFTEN did you have HICCUPS?</td>
</tr>
<tr>
<td>O Never</td>
</tr>
<tr>
<td>b. In the last 7 days, what was the SEVERITY of your HICCUPS at their WORST?</td>
</tr>
<tr>
<td>O None</td>
</tr>
</tbody>
</table>

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

From the Patient-Reported Outcomes Version of the Common Terminology Criteria for Adverse Events (PRO-CTCAE®)
Representing items with conditional branching - PRO-CTCAE®

qs.xpt* - subject never having hiccups

<table>
<thead>
<tr>
<th>Row</th>
<th>USUBJID</th>
<th>QSTESTCD</th>
<th>QSORRES</th>
<th>QSSTRESN</th>
<th>QSSTRESC</th>
<th>QSCBRFL</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>P0001</td>
<td>PT01014A</td>
<td>Never</td>
<td>0</td>
<td>0</td>
<td></td>
</tr>
<tr>
<td>2</td>
<td>P0001</td>
<td>PT01014B</td>
<td>None</td>
<td>0</td>
<td>0</td>
<td>Y</td>
</tr>
</tbody>
</table>

• 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 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.
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.
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.cdscvol@gmail.com