1. QRS Sub-Team Home on the CDISC Website
2. QRS Sub-Team Home on the CDISC Wiki (Access may be restricted to QRS Sub-Team Members)

Leadership Team

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Team Mission

Primary Objectives

- Define and support the Questionnaires, Ratings and Scales (QRS) needs of CDISC standards based on the SDTMIG
  - Represented in the QS/FT/RS Findings domains
- Focus on developing standard QRS supplements for publication
- Implementations will follow the current appropriate SDTM/SDTMIG published QRS domain models, including any domain assumptions
  - Implementations will follow CDISC COP Standards Development - 001
  - Implementation issues that identify gaps in the current published model will be addressed with the SDS Team for remediation
  - Implementations will be consistent with the SDTMIG, address copyright permission, use controlled terminology, harmonizing on the consistent inclusion of QRS variables and standards/best practices for the specific instrument being implemented
- Process improvements to the QRS implementation process to keep pace with the development of CFAST Therapeutic Area Standards CDISC subject matter experts (i.e. ADaM, Terminology, and CDASH) will be consulted as needed for any input on implementation issues

Scope

The CDISC QRS Sub-Team supports the Questionnaires, Ratings and Scales needs of all CDISC standards (SDTM, CDASH, and ADaM) and all disease /therapeutic area standards. Based on the new instruments that need to be implemented, the sub-team publishes completed QRS Supplements each month. The sub-team manages QRS requests based on CDISC COP 001 – CDISC Standards Development. Supplements have about a 2-4 week implementation cycle after copyright permission is received and QRS terminology is released. All approved Supplements are stored on the CDISC QRS webpage for public access through the CDISC website.

Stakeholders/Constituency

- Regulatory Authorities
- Standards Development Organizations
- Pharmaceutical Sponsors
- Medical Devices, Diagnostics
- Contract Research Organizations & Consultants
- Academic Researchers
- Laboratories
- Instrument Copyright Owners
- Developers of Public Domain Instruments

Collaborations

NCI EVS, SDS, CDASH, ADaM, HL7
RCRIM, CFAST Therapeutic Area standards and CDISC Operations.

Operating Model & Meetings

- There is a need to develop new SDTMIG QRS Supplements for the many existing instruments used in research. Most new disease standards have a potential set of instruments that need to be implemented in the appropriate domain as a Supplement.
- The requests for these new QRS standards are made to the QRS Sub-Team through the TA standards projects and sponsors.
- The QRS Controlled Terminology Team meets regularly to address QRS terminology requests that come from the QRS Sub-Team.
- Other sub-teams teams are convened as needed based on requests.
- Key weekly meetings: 3pm-4:00pm ET 2nd-4th Wed. (US)

Zhao Yang

The QRS sub-team maintains its membership through careful selection of volunteer experts who can contribute to its various sub-teams with their technical or Therapeutic-based subject matter expertise.

2018 Deliverables

Deliverables with Projected Target Dates for Public Review:

- Monthly QRS Supplement Package Updates
- Update the SDTMIG Section 6.3 QS Domain to indicate QRS concepts which currently include QS/FT/RS domain representation
  - Provide consistency revisions in the QS/FT/RS Domain Documents for understandability
- Representing QRS Metadata