



Submitting QRS (Questionnaires, Ratings and Scales) Controlled Terminology (CT) to CDISC

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Reasons for submitting QRS CT

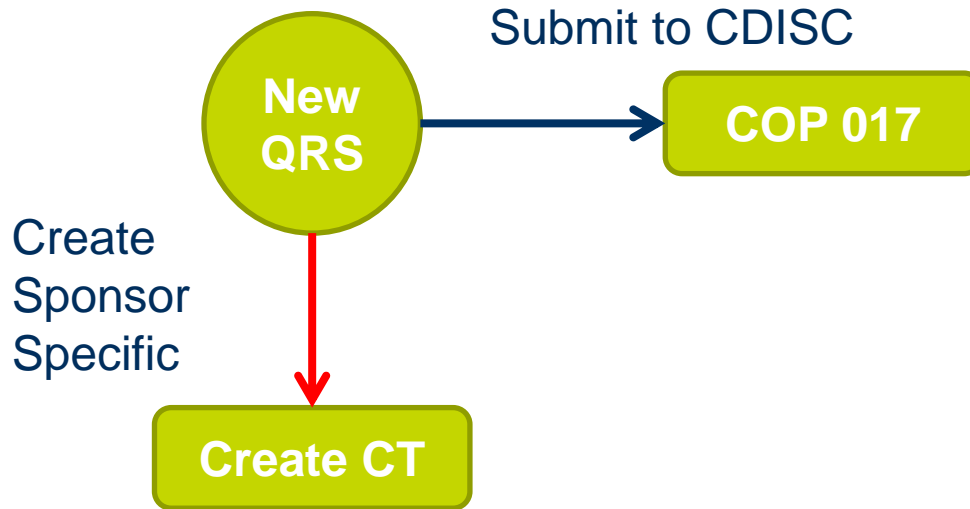
- Appeal to a higher power
 - FDA and PMDA wants it
- Self Interest
 - Good Metadata Management Practice
- Altruistic Reasons
 - Contributing to CDISC and open standards
- Fame and Immortality
 - Create a standard that will be used all over the world by numerous researchers

FDA considers this good terminology management practice.

Good Metadata Management Practice

- If the sponsor creates a sponsor specific version of QRS CT for an instrument CDISC may release official CDISC CT for that QRS instrument in the future. If there are inconsistencies the sponsor will be required to migrate to the new version. This process will have to be managed by the sponsor. Resulting in the potential for:
 - Multiple studies with differing versions of the CT
 - Increased work for the Study Data Standardization Plan (SDSP) creation and maintenance

QRS CT Workflow: Getting Started



- Check if CT exists, if not:
 - review “CDISC Operational Procedure (COP 017) - CDISC SDTM Questionnaires Supplements 30JUN2013 V1.0” section 3.2. Sponsor Clinical Development Plans
 - https://www.cdisc.org/system/files/all/article/application/pdf/cdisc_cop_017_cdisc_sdtmig_questionnaire_supplements_v1_2013_06_28.pdf
 - Create QRS Standard Request Form

Why Create a QRS supplement?

- What are the benefits of creating a QRS supplement?
 - drafting the controlled terminology
 - defining instrument-specific standardized values for
 - Result variables
 - Qualifier
 - Timing
 - populating the SDTM QRS Domain, along with providing examples of use(e.g. how to handle skipped questions).
- <http://cdisc.org/qrs>

QRS Standard Request Form

CDISC QRS Sub-Team - Questionnaires, Ratings and Scales Standard Request Form

Date of QRS Request: 19-JUN-2016

Therapeutic Area: All

Select the domain type of QRS Measure: Functional Test Questionnaire Clinical Classification

QRS: Treatment Satisfaction Questionnaire for Medication Version 1.4 (TSQM V1.4)

QRS Reference: Provide a reference to the Questionnaire, Rating or Scale being requested. Please include a web site URL or other documentation that can be used to obtain more detailed information on the QRS. A sample CRF would also be appreciated.

Treatment Satisfaction Questionnaire for Medication - 14 Items Version 1.4 (TSQM V1.4) (Copyright 2004, Quintiles. All Rights Reserved).

<http://www.quintiles.com/landing-pages/treatment-satisfaction-questionnaire-for-medication-tsgm>



Atkinson 2004 TSQM 14 Development.pdf



JCP_32_1_2011_11_02_TRUJOLS_201286

QRS Public Domain Copyright Verification

- COP 017 section 4.2 the QRS Implementer confirms if the QRS instrument is Public Domain or Copyrighted using
 - QRS Public Domain Copyright Verification Document

CDISC Questionnaires, Ratings, and Scales Public Domain/Copyright Verification Document

Date of Document: <18Apr2015>

Questionnaires, Ratings, and Scales: <Brief Psychiatric Rating Scale-Anchored (BPRS-A)>

Questionnaires, Ratings, and Scales Terminology Publication Release Package: <P9>

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Insert the signed CDISC Copyright letter or other author verification here



BLCS - CDISC
Copyright Letter.pdf

Public Domain

- COP 017 section 4.4 a
 - QS Public Domain_Copyright Verification Document.
 - Statement from instrument owner available on website or an email confirmation.
 - If no notice is displayed and the work was published before March 1, 1989, you can presume not copyrighted.
 - If after this date assume that it is copyrighted and obtain permission for use.
 - A final search needs to be performed on The United States Public Copyright catalog to determine if it was registered at the following site.
<http://cocatalog.loc.gov/cgi-bin/Pwebrecon.cgi?DB=local&PAGE=First>
- CDISC is looking to get permissions from WHO to work with all QRS instruments. The QRS team is also reaching out to EORTC for the use of their instruments.



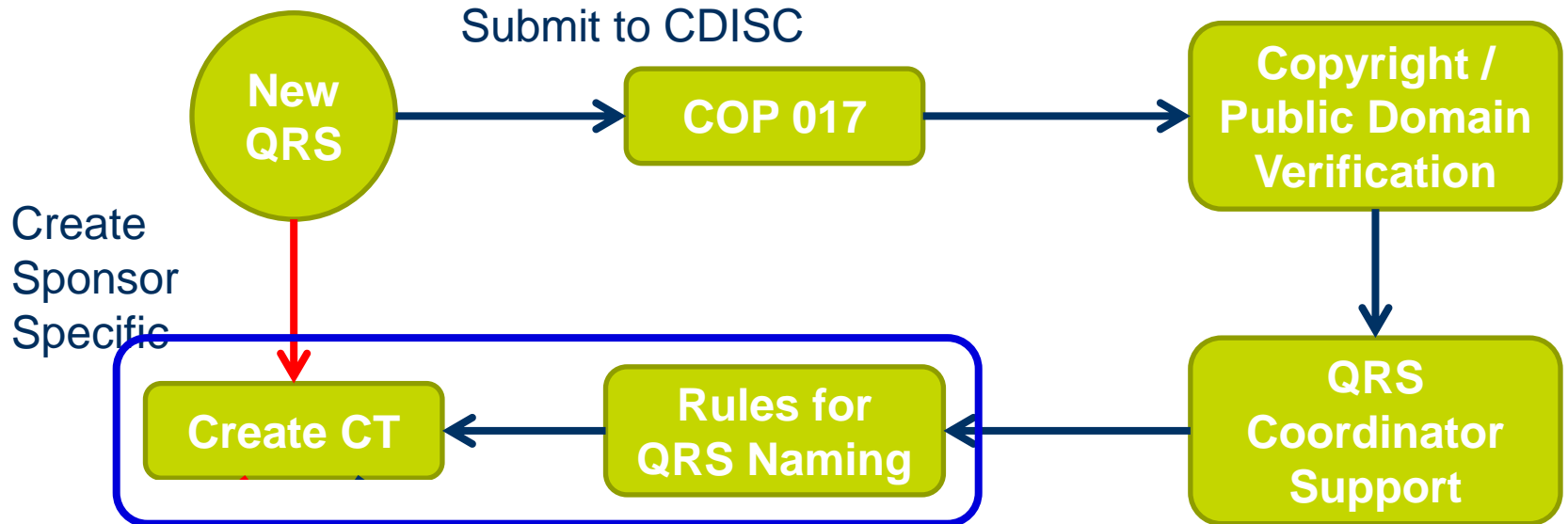
Copyright

- COP 017 section 4.4 b
 - Update and send the CDISC QRS Copyright Letter
 - Follow up every 2 weeks / 1 month until resolution
 - If process is stuck request teleconferences to clarify the mission of CDISC
 - Inform and discuss any issues with the QRS Coordinator for guidance
 - Document if permission is denied
- CDISC working with MAPI Research Trust to streamline copyright requests
- <http://mapi-trust.org/>

Timelines of Contact

#	First Email	Final Email	Emails Instrument Owner	Emails QRS Coordinator
1	Mon 07MAR2016 18:11	Sat 31JAN2017 14:57		17
2	Wed 18MAY2016 17:21	Tue 11OCT2016 01:21 Permission received Thu 16JUN2016 19:27	7	6
3	Fri 15JUL2016 16:13	Permission received Thu 02FEB2017 07:37	3,2,4,2 Total: 11 Web form	5, ,6,3 Total: 14
4	Wed 16NOV2016 00:16	Fri 18NOV2016 17:39 Permission Received Thu 17NOV2016 20:49	4	4
5	Wed 07DEC2016 00:20	Thurs 02FEB2017 07:37	6 Web form	4

QRS CT Workflow: Create CT



- COP 017 section 5.2 documentation needed
 - Rules for QRS Naming
 - QRS Terminology Spreadsheet Example
 - Instrument journal and CRF

QRS--CAT Codelist Rules

- Submission Value (QRS--CAT)
 - Upper case, unique, most commonly name used for the instrument and version number if available
- Synonym
 - Upper case, 6 character, assigns a version number that should start at 01 (or 1 if space is an issue)
- Definition
 - Sentence case. The full name of the instrument including version if available, followed by the acronym in brackets. The copyright information and relevant citation.

CDISC Submission Value	Synonym	CDISC Definition
BPI	BPI1	Brief Pain Inventory (BPI) (copyright 1991 Charles S. Cleeland, PhD, Pain Research Group, All Right Reserved).
TSQM V1.4	TSQM01	Treatment Satisfaction Questionnaire for Medication - Version 1.4 (TSQM V1.4) (Copyright 2004, Quintiles. All Right Reserved)

QRS Instruments CRF

TSQM (Version 1.4)

Treatment Satisfaction Questionnaire for Medication

Instructions: Please take some time to think about your level of satisfaction or dissatisfaction with the medication you are taking in this clinical trial. We are interested in your evaluation of the effectiveness, side effects, and convenience of the medication *over the last two to three weeks, or since you last used it*. For each question, please place a single check mark next to the response that most closely corresponds to your own experiences.

1. How satisfied or dissatisfied are you with the ability of the medication to prevent or treat your condition?

- ₁ Extremely Dissatisfied
- ₂ Very Dissatisfied
- ₃ Dissatisfied
- ₄ Somewhat Satisfied
- ₅ Satisfied
- ₆ Very Satisfied
- ₇ Extremely Satisfied

2. How satisfied or dissatisfied are you with the way the medication relieves your symptoms?

QRS--TESTCD/TEST Codelist Rules

- **QRS--TESTCD:** 8 characters, upper case, begins with QRS--
Synonym. If the instrument has numbered questions, follow the numbering, including alphanumeric, if not numbered assigned 01, 02 etc.
- **QRS--TEST:** 40 characters limit, title case, begins with the QRS--Synonym, followed by a hyphen. Use lower case for: a, an, and, as, at, but, by, for, in, nor, of, on, or, per, to, the.
- **Definition:** The instrument long name including version number if available, followed by a hyphen between two spaces. The verbatim text including punctuation, instructions removed.

--TESTCD	--TEST	CDISC Definition
Synonym & Numbering	Synonym & -Text (or Shortened Text)	Full Instrument Name - Verbatim Text
TSQM01&01	TSQM01 & -Med to Prevent/Treat Condition	Treatment Satisfaction Questionnaire for Medication - How satisfied or dissatisfied are you with the ability of the medication to prevent or treat your condition

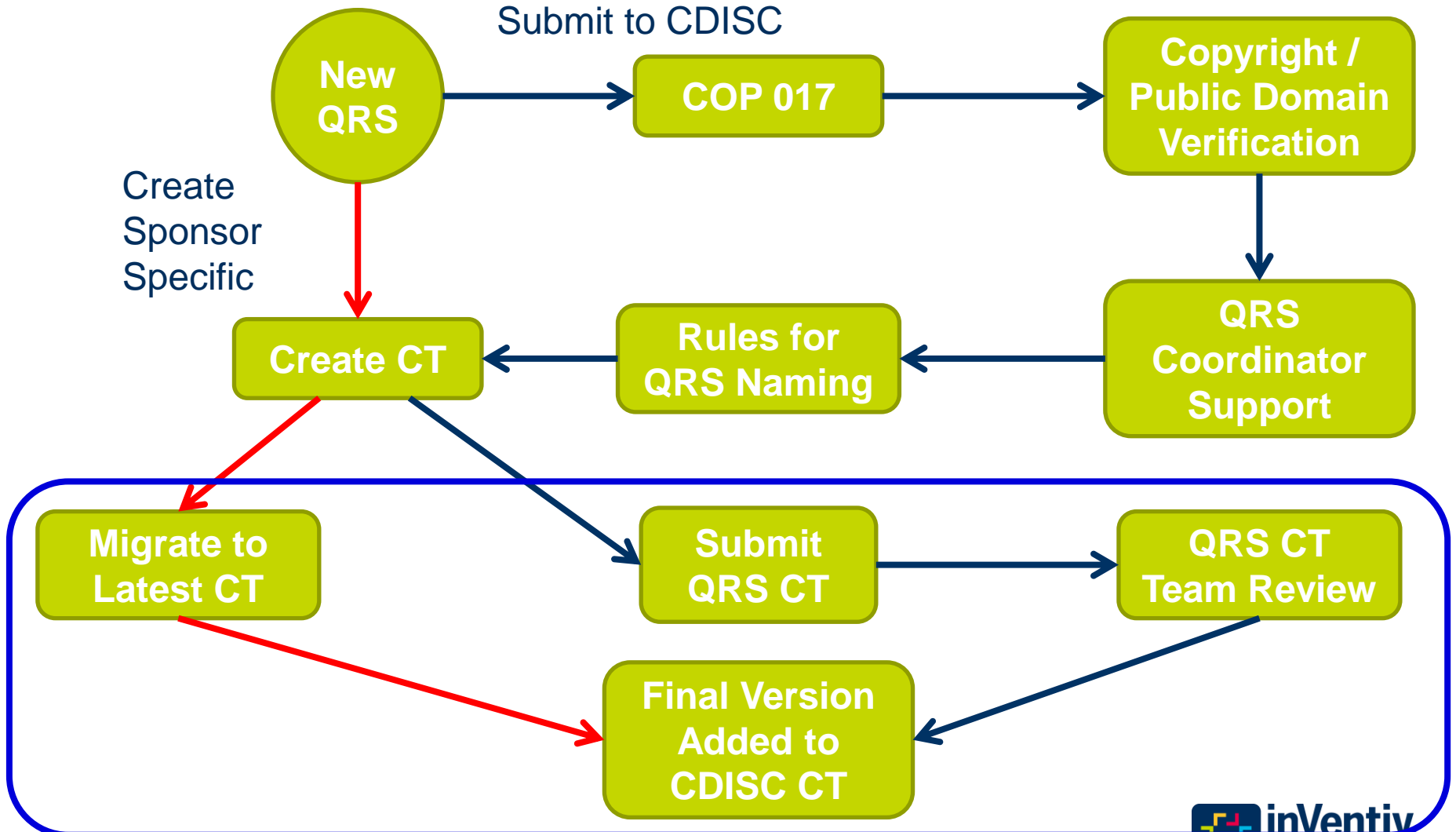
QRS--TESTCD/TEST/SCAT Examples

--TESTCD	--TEST	CDISC Definition
Synonym & Numbering	Synonym & -Text (or Shortened Text)	Full Instrument Name - QRS--SCAT: Verbatim Text
FAC071&01	FAC071&-I Have a Lack of Energy	Functional Assessment of Chronic Illness Therapy-Fatigue Version 4 - Physical Well-Being: I have a lack of energy.
FAMS01&01	FAMS01&-Trouble Meeting Needs of Family	Functional Assessment of Multiple Sclerosis - Mobility: Because of my physical condition, I have trouble meeting the needs of my family.

<u>PHYSICAL WELL-BEING</u>		Not at all	A little bit	Some-what	Quite a bit	Very much
GPI	I have a lack of energy	0	1	2	3	4

- QRS--SCAT is sometimes added after the instrument long name before the verbatim text.
- This is not in controlled terminology, but assists in creating the supplement examples.

QRS CT Workflow: Submitting QRS CT



Finalize the QRS Terminology Spreadsheet

- **CODELIST NAME:** The codelist name is the synonym followed by TN and TC. The codelist description is the instrument long name and version ended with “Test Name/Code”.
 - Codelist Name: **TSQM01TN/TSQM01TC**
 - Codelist Description: **Treatment Satisfaction Questionnaire for Medication Version 1.4 Test Name/Code**
 - Codelist Extensible: No

Submitting QRS CT

Fill in the following fields as appropriate. For multiple term submissions, please click on and download the Excel file [CDISC Controlled Terminology Multiple Term Request Spreadsheet](#) and add on your name and request date to the end of the file name. Email this completed file to NciEvsCdiscHelp@mail.nih.gov. In addition, please submit a CDISC New Term Request form indicating "File emailed separately" in Additional Information.

Term Information:

Vocabulary:

Request Type:

CDISC Code List:

Note to user: CDASH and SDTM Terminology are the same and are contained within the SDTM codelists in the drop down list.

Enter Term or Codelist Request Information: *

- <https://ncitermform.nci.nih.gov/ncitermform/?version=cdisc>

Webform Question	Response
Vocabulary	CDISC Terminology
Request Type	Create New Codelist
CDISC Code List	New
Enter Term or Codelist Request Information	QRS Instrument Type and Name e.g. Questionnaire: Treatment Satisfaction Questionnaire for Medication (TSQM) V1.4
Additional Information	File emailed separately



Submitting QRS CT

- Send the QRS Terminology Spreadsheet with the instrument short name, your name and the request date on the file.
- Attach the QRS Standard Request Form and CDISC QRS Copyright Letter (if applicable)
- Email
 - NciEvsCdiscHelp@mail.nih.gov
 - Steve Kopko skopko@cdisc.org
 - Dana Booth dbooth@cdisc.org
 - Roberta Rosenberg Roberta.E.Rosenberg@pfizer.com

QRS CT Status Tracking

- QRS CT submissions can be tracked at the CT QRS page (access needed)
 - <https://wiki.cdisc.org/display/TER/QRS+%28Questionnaires%2C+Ratings%2C+and+Scales%29+Terminology+Team>
- Therapeutic Area requests are dealt with before Sponsor requests,

QRS (Questionnaires, Ratings, and Scales) Terminology Team

Created by Jordan Li, last modified on Feb 02, 2017

- › QS Tracking
- › CC Tracking
- › FT Tracking

The following list contains instruments where copyright permission has been denied; CAT terminology has been created for the instruments.

- › [Copyright Permission Rejected_CAT ONLY](#)

Potential Process Improvements

- If CDISC did not have to request permission to create CT for an instrument an administrative burden would be removed.
- If CDISC releases the draft CT (including rejected permission requests) on the CDISC wiki during the review and approval rounds it would be so users do not have to create multiple versions of the same CT.
- Additional dedicated volunteers join the QRS CT to move the backlog forward
 - If a company has a metadata and codelist team members it is their interest to provide resources at 4 hours a week



Submit and Volunteer

- Once you have submitted a number of QRS CT and feel comfortable with the process, consider volunteering to join the QRS CT team.
 - Contact
- Chris Gemma cgemma@cdisc.org
- Dana Booth dbooth@cdisc.org
- Roberta Rosenberg Roberta.E.Rosenberg@pfizer.com

- QRS sub-team
- Gary Cunningham gcunningham@thegriessergroup.com
- Steve Kopko skopko@cdisc.org

QRS Documentation Status 2017-04-04

Document	Hyperlink	Hyperlink status	Document Status
COP 017 - CDISC SDTM Questionnaire Supplements	https://www.cdisc.org/system/files/all/article/application/pdf/cdisc_cop_017_cdisc_sdtmig_questionnaire_supplements_v1_2013_06_28.pdf	Active	Latest version
CDISC Copyright Letter	https://www.cdisc.org/system/files/members/standard/QRS/Reference/CDISC%20QRS%20Copyright%20Letter.docx	Active	Newer version not released, updated text and CDISC contact changed
QRS FAQs	https://www.cdisc.org/system/files/members/standard/QRS/Reference/QRS%20FAQs.doc	Active	Newer version not released. Updated frequently.
QRS Naming Rules	https://www.cdisc.org/system/files/all/standard/terminology/Rules%20for%20QRS%20Naming.docx	Active	Out of date, version 2015-05-28
Rules for QRS Naming	https://www.cdisc.org/system/files/members/standard/QRS/Reference/QRS%20Naming%20Rules.docx	Active	Latest version 2016-10-02, replaces “QRS Naming Rules”
QRS Public Domain Copyright Verification Document	https://www.cdisc.org/system/files/members/standard/QRS/Reference/QRS%20Public%20Domain_Copyright%20Verification%20Document.docx	Active	Latest version
QRS Standard Request Form	https://www.cdisc.org/system/files/members/standard/QRS/Reference/QRS%20Standard%20Request%20Form.docx	Active	Latest version
QRS Sub-Team - QRS Supplement QC Checklist v1	https://www.cdisc.org/system/files/members/standard/QRS/Reference/QRS%20Sub-Team%20-%20QRS%20Supplement%20QC%20Checklist%20v2.doc	Active, link name out of date	Latest version 2015-05-28
Functional Tests Supplement Example	https://www.cdisc.org/system/files/members/standard/QRS/Reference/Functional%20Tests%20Supplement%20Example.docx	Active	Contact QRS Coordinator for the latest version
Questionnaires Supplement Example	https://www.cdisc.org/system/files/members/standard/QRS/Reference/Questionnaires%20Supplement%20Example.docx	Active	Contact QRS Coordinator for the latest version
Clinical Classifications Supplement Example	https://www.cdisc.org/system/files/members/standard/QRS/Reference/Clinical%20Classifications%20Supplement%20Example.docx	Active	Contact QRS Coordinator for the latest version
QRS Terminology Spreadsheet Example	https://www.cdisc.org/system/files/members/standard/QRS/Reference/QRS%20Terminology%20Spreadsheet%20Example.xlsx	Active	Latest version 2017-03-03.
QRS Content Guidance Final	https://www.cdisc.org/system/files/members/standard/QRS/Reference/QRS%20Content_Guidance_Final_2013-01-23.docx	Active	Replaced by SDTMIG 3.2 QS section. Will be replaced by SDTMIG 3.3.
QRS Not Granted Table	https://www.cdisc.org/system/files/members/standard/QRS/Reference/QRS%20Instrument%20Documentation%20Table%20Update%20Not%20Granted%202015-09-30.pdf	Inactive	Available on the CDISC Wiki, access needed.
QRS FACIT Item Bank	https://www.cdisc.org/system/files/all/standard/terminology/QRS_FACIT_Item_Bank.xlsx	Active	Contact QRS Coordinator for support

New Slides



Strength through Collaboration

CDISC 2017 Standards Development Plan

Questionnaires, Ratings and Scales (QRS)

Define and support the Questionnaires, Ratings and Scales (QRS) needs of CDISC standards based on the SDTMIG.

QRS Supplements	New Supplements development based on user request and needs.	2017
QRS Process Update	Updating the QRS development process to align with the Foundational Standards development process to include both internal and public reviews of each supplement.	2017

- <https://www.cdisc.org/system/files/all/standard/CDISC2017StandardsDevelopmentPlan.pdf>

QRS Domains (QS, FT, RS) SDTMIG 3.3

Domain Code	Domain Label	Domain Description/Overview
QS	Questionnaire	Questionnaires are named, stand-alone instruments designed to provide an assessment of a concept. Questionnaires have a defined standard structure, format, and content; consist of conceptually related items that are typically scored; and have documented methods for administration and analysis. Most often, questionnaires have as their primary purpose the generation of a quantitative statistic to assess a qualitative concept.
FT	Functional Test	Functional tests are named, stand-alone task based evaluations designed to provide an assessment of a physical or mental ability.
RS	Disease Response and Clin Classification	Assessment of disease response to therapy, or clinical classification, which is often based on published criteria.

I am in SDTMIG 3.2 so what now? FT

? Add the FT data to QS?

- Not QS data.
- It corresponds to the FDA concept of Performance Outcome Measures
 - <https://www.fda.gov/Drugs/DevelopmentApprovalProcess/DrugDevelopmentToolsQualificationProgram/ucm370262.htm#performance>

? Create custom domain:

- The regulatory agencies prefer that we limit the number of custom domains. If you are creating a custom contact the regulatory agency and document in the SDRG.
- FT or X?/Y?/Z?
 - SDTMIG 3.2 section 2.6 Creating a New Domain part 2
 - 2. Check the Submission Data Standards area of the CDISC website (<http://www.cdisc.org/>) for models added after the last publication of the SDTMIG

😊 Create custom domain FT

I am in SDTMIG 3.2 so what now? CC

- ? Add the CC data to QS?
 - Not QS data.
- ? Add the CC data to RS?
 - The RS domain is used for Tumor data
 - The FDA suggested using RS
 - RS is planned to be used in SDTMIG 3.3
 - Contact the regulatory agency and document in the SDRG
- ? Add the CC data to FA?
 - FA can manage the CC data. An FAOBJ would be needed.
 - Would the existing CC CT be used?
- ? Create custom domain:X?/Y?/Z?
 - The regulatory agencies prefer that we limit the number of custom domains. If you are creating a custom contact the regulatory agency and document in the SDRG.

😊 Add the CC data to RS?



FDA and QRS Team

- Ongoing discussions between the FDA and QRS team
 - Logically Skipped Questions
 - QSSTAT = NOT DONE;
 - QSREASND = LOGICALLY SKIPPED ITEM; and
 - QSORRES, QSSTRESC, and QSSTRESN all set to null
 - Implications to data cleaning prompt on QRS instruments?
 - QSEVAL
 - Who is it?
 - RS vs Physiology Domains for CC

Potential Changes to Existing CT

QRS Name	Short Name (--CAT)	Domain	QS	FT	CC
Alzheimer's Disease Assessment Scale - Cognitive (ADAS-Cog)	ADAS-COG	QS		X	
Baseline Dyspnea Index (BDI)	BDI	QS			X
Eastern Cooperative Oncology Group Performance Status (ECOG)	ECOG	QS			X
Generalized Anxiety Disorder (GAD-7)	GAD-7	QS	X		



QS Questionnaire

1. Named measure
2. Provide an assessment of a question concept
3. Have a defined standard structure, format, and content
4. Consist of conceptually related items that are typically scored
5. Have documented methods for administration and analysis
6. Consist of defined questions with a defined set of potential answers
7. Generation of a quantitative statistic to assess a qualitative concept
8. Completed by the subject or clinician
9. All Patient Reported Outcomes (PRO) are questionnaires, in addition some are Clinician Reported Outcome (CLINPRO)
 - For example: the HAMD-6 self report goes into QS and the HAMD-6 clinician goes into CC.



FT Functional Test

1. Named measure
2. Stand alone task based evaluations
3. Designed to provide an assessment of mobility, dexterity, and/or cognitive ability
4. Have documented methods for administration and analysis
5. Not a subjective measurement
6. Objective/quantitative measurement of the performance of the task by the subject in a specific instance
7. Subject performs specific activities that are evaluated and recorded
8. Completed by the clinician
9. This is normally a Clinician Reported Outcome (CLINPRO)

RS Disease Response and Clin Classification

1. Named measure
2. Subsequent to the observation the physician makes a "Classification of Observation" in evaluating the subject (measures are based on a trained health care professional's observation of a subject's health condition or status with input from associated clinical records review)
3. Often composite scores based on diverse inputs
4. Objective observations exist somewhere else
5. Staging or status or risk score about a condition based solely on objective data from clinical records, or they may involve a clinical judgment or interpretation of the directly observable signs, behaviors, or other physical manifestations related to a condition or subject status
6. Ordinal or categorical score that serves as a surrogate for, or ranking of, disease status or other physiological or biological status
7. Continuum
8. *If the findings are based on one system's morphology or physiology, then this instrument can go into the corresponding morphology/physiology body system domain but if the findings are across multiple systems then this instrument can go into CC. (to be confirmed by FDA)*
9. This is a Clinician Reported Outcome (CLINPRO)

Any Further Questions? Thank You!

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Strength through Collaboration