QRS Supplements

LPO Support Webinar

03 May 2019

NIH NATIONAL CANCER INSTITUTE

Upon Completion of this Webinar You Should Be Able To

- Describe what a QRS instrument is
- Compare the FDA COA/PRO concepts to CDISC QRS concepts
- Describe the differences between QS, FT and RS SDTM domains
- Explain the use of CDISC Controlled Terminologies with QRS instruments
- Use a QRS Supplement to create data collection instruments or SDTM data
- Briefly explain the QRS Supplement and CT Development Process

QRS: Questionnaires, Ratings and Scales

- Standardized instruments for collecting subjective feedback from
  - Patients (pain scales, QOL)
  - Clinicians (GCI)
  - Caregivers (Parents/ Guardians assessment of how the patient is doing)
- Standardized instruments for assessing the disease state using a set of criteria
  - Staging a cancer
  - Assessing risk for cardiovascular disease
  - Objective measurements for the performance of a task that help us understand how a patient is doing
- Usually these instruments are validated
- FDA has a program for qualifying QRS instruments

https://www.fda.gov/drugs/drug-development-tool-qualification-programs/clinical-outcome-assessment-coa-qualification-program

PRO is One Kind of QRS Instrument for Measuring the Patient Experience

Patient Engagement Should be a Dialogue

Patients

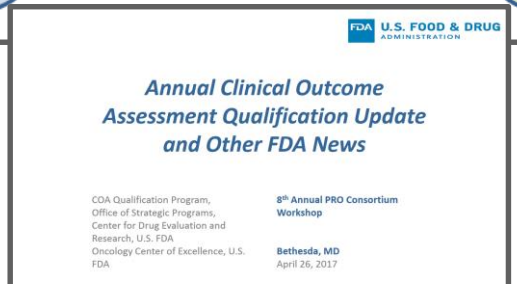
- Experts in how they experience their disease
- Identify what matters most to patients
- Identify areas to make clinical trials more patient-friendly

Patient-centered Scientifically Rigorous Drug Development

Clinicians/ Trialists/ Health Policy Leaders

- Experts in clinical trial design and conduct
- Medical expertise
- Assess feasibility of trial modifications and outcome measures

Slide borrowed from:


U.S. FOOD & DRUG ADMINISTRATION

Annual Clinical Outcome Assessment Qualification Update and Other FDA News

COA Qualification Program, Office of Strategic Programs, Center for Drug Evaluation and Research, U.S. FDA
Oncology Center of Excellence, U.S. FDA

8th Annual PRO Consortium Workshop

Bethesda, MD
April 26, 2017

Side Bar: A Few Words about Collecting eCOA/ePRO

- If you plan to use ePRO/eCOA (or even paper PRO/COA) start the process as far in advance as possible.
  - You might have to research ownership (don't assume it's okay to use just because you can find it through a Google search)
  - You might have to wait for the owner to give permission
  - It might take extra time to build out the form in an ePRO/eCOA device
- Validated instrument has to be validated for the medium in which it is being administered
  - You can't just convert an instrument that has been validated in paper to an electronic version - it has to be validated in the electronic version, too
- ePRO / eCOA vendors can help you with this for many common instruments (i.e., they may have already built the electronic version and may already know if it is validated)

Side Bar: A Few Words about Collecting eCOA/ePRO

- You will need to use CDISC QRS standards:
  - If you are writing a data transfer agreement with a vendor and want to specify that they provide SDTM-conformant data transfers
    - Most of the time we hire ePRO/eCOA vendors to set up the e-version of the instrument for us
  - If you are planning to have the site enter some or all of this data into Rave and you have to set up a data collection screen
    - E.g., What you enter in Rave may be a subset of the information collected in the paper version of the instrument (e.g., a total score)
  - If you are setting up an electronic version of the instrument in another system
  - Or, if you are preparing SDTM data

Questionnaires, Ratings and Scales (QRS) are **Special**

QRS instruments

- Always have a standardized name (and are versioned)
- Are a standardized set of questions (that are conceptually related)
- The entire set of questions are intended to be asked together, in a particular order (and layout), using standard responses (often scored)
- Often (usually) validated (or can be validated) and copyrighted
- People who administer them usually need training on the validated administration method
- There is usually a specific, validated method associated with scoring and/or analyzing results
- *May be developed in-house, but still have to meet the basic criteria for QRS instrument types to be considered QRS*

QRS is NOT just a set of questions that you always ask on the same CRF

QRS is NOT just any standard form that you have developed in-house.
If you would get the same meaning from asking the questions on multiple forms, or in a different order, then it is NOT QRS.

QRS EXAMPLES

- Alzheimers Disease Assessment Scale - Cognitive (ADAS-Cog)
- BODE Index
- Brief Psychiatric Rating Scale - Anchored (BPRS-A)
- Columbia Suicide Severity Rating Scale - Baseline (C-SSRS Baseline)
- Eastern Cooperative Oncology Group Performance Status (ECOG)
- European Quality of Life Five Dimension Three Level Scale (EQ-5D-3L)
- Extended Glasgow Outcome Scale (GOSE)
- Framingham Heart Study Cardiovascular Disease 10-Year Risk Score) FHS CVD 10-YEAR RISK)
- Hamilton Depression Rating Scale 17-Item (HAMD 17)
- Montreal Cognitive Assessment (MOCA)
- Ocular Comfort Index (OCI)
- Pittsburgh Sleep Quality Index (PSQI)
- WHO Clinical Staging of HIV AIDS for Adults and Adolescents

How FDA Categorizes QRS Instruments

- FDA describes these analytical instruments using four categories:
  - Clinician-reported outcome (ClinRO)
    - Example: **Clinical Global Impression** used to indicate the clinician's impression of improvement or severity of participant's illness
  - Observer-reported outcome (ObsRO)
    - Example: TBI **Expanded Disability Rating Sale – Postacute Interview Caregiver Version** used to ask a caregiver their impression of how a post-acute TBI victim is functioning and communicating
  - Patient-reported outcome (PRO)
    - Example: **Faces Pain Scale – Revised** used to assess how much pain someone is in (usually a child) using a visual scale
  - Performance outcome (PerfO)
    - Example: **6 Minute Walk Test** used to measure *how far* someone can *walk* in *six minutes*

How CDISC Categorizes QRS Instruments

- Before FDA published their COA/PRO categories, CDISC had already created SDTM domains for QRS based on the following criteria:
  - Instruments designed to generate a quantitative (numeric) result to measure something that is subjective and not easily measured. Example: **Columbia-Suicide Severity Rating Scale**
    - SDTMIG Domain: Questionnaires (QS)
  - Instruments designed to measure the performance of a physical or mental task. Example: **6 Minute Walk Test**
    - SDTMIG Domain: Functional Tests (FT)
  - Instruments designed to bring together multiple measurements and results to generate a standardized description of a disease state, stage or risk. Example: **Framingham Heart Study Cardiovascular Disease 10-Year Risk Score**
    - SDTMIG Domain: Disease Response and **Clin Classification** (RS)

How CDISC QRS Domains match up with FDA Categories

FDA Categories are more about who completed it (except for PerfO).

	FDA COA			
CDISC SDTM QRS Supplements	ClinRO	ObsRO	PRO	PerfO
QS: designed to generate a quantitative (numeric) result to measure something that is subjective and not easily measured		X	X	
FT: designed to measure the performance of a physical or mental task				X
RS: Staging a disease state, or describing risk of disease	X	X		

CDISC domains are only topic-based. What are the instruments measuring (at a high level)?

SDTM QRS Domains

- Three domains that will handle *any* standardized instrument
  - Functional Tests (FT)
  - Questionnaires (QS)
  - Disease Response and Clin Classifications (RS)
- Domains are published in SDTMIG
- ~293 instruments have some published SDTM Terminolo
- *~182* instruments have published CDISC Supplements

Use these domains for all QRS instruments, *not just those that have published CDISC terminology or Supplements*

If you have an instrument that isn't already in Controlled Terminology, you can submit a New Term Request to add your terminology (should follow QRS naming conventions)

Three CDISC Resources for QRS Domains

1. **QRS SDTMIG Domain sections** (https://www.cdisc.org/standards/foundational/sdtmig/sdtmig-v3-3)
   - **Functional Test** (FT) 6.3.13.1
   - **Questionnaires** (QS) 6.3.13.2
   - Disease Response and **Clin**(ical) **Classification** (RS) 6.3.13.3
2. **Controlled Terminology** (https://www.cancer.gov/research/resources/terminology/cdisc)
   - Codelists for --CAT values - standardized instrument names
   - Codelists for --TESTCD and --TEST values
3. **QRS Supplements** (https://www.cdisc.org/foundational/qrs)

Right now there is more terminology available than Supplements.

Terminology for some QRS instruments has been published even though the QRS team has not yet created an associated supplement.

CDISC Controlled Terminology for QRS

- QSCAT, FTCAT, CCCAT
  - Standardized instrument **names** for **~293** QRS instruments (P37)
  - Naming convention includes a Synonym - a unique, abbreviated (6 character) version of the instrument name including the version
- QSTEST/QSTESTCD, FTTEST/FTTESTCD, RSTEST/RSTESTCD
  - --TESTCD values are prefixed with the 6 character --CAT synonym value, and then a numeric value (total 8 characters max)
  - --TEST values are prefixed with the 6 character --CAT synonym value, and then a brief abbreviation of the question (total 40 characters max)
  - P37 terminology for TESTCD/TEST (total ~242)
    - 22 FT TESTCD/TEST
    - 181 QS TESTCD/TEST
    - 39 Clinical Classifications

What are CDISC QRS ***Supplements***

- "*Supplement*" to the relevant domain section (FT, QS or RS) in SDTMIG showing how to implement that domain for *a specific QRS instrument*
- Supplement Includes
  - Assumptions for the specific instrument
  - Additional instrument-specific examples
- For *some (not all)* instruments there is also an aCRF (sometimes abbreviated)
  - This aCRF is to support the SDTM data, so it is **NOT** a **CDASH** annotation
  - However, these can be helpful in creating data collection instruments because they show where the data will be mapped in SDTM
  - You can use this information to create appropriate Rave metadata (if needed) for data collection

How to Use CDISC QRS Supplements

1. Look for the instrument on the CDISC QRS web page (may or may not exist)
2. Identify which SDTM domain (FT, QS or RS) you need to use for that instrument
   - If there is a Supplement, it will tell you which domain to use
   - Otherwise, reference slide 7 or https://www.cdisc.org/foundational/qrs
3. **Start with** the appropriate SDTMIG domain specification (FT, QS or RS) following all of the relevant rules for the domain (core designations, domain assumptions, etc.)
4. Access the relevant published SDTM Terminology for
   - --CAT, --TESTCD and --TEST
5. If a Supplement exists for that instrument, refer to it for instrument-specific assumptions, to review examples of what the SDTM data should look like for that instrument, and to see the SDTM annotation of the instrument

Walk through of EXAMPLE CDISC Documentation for QRS

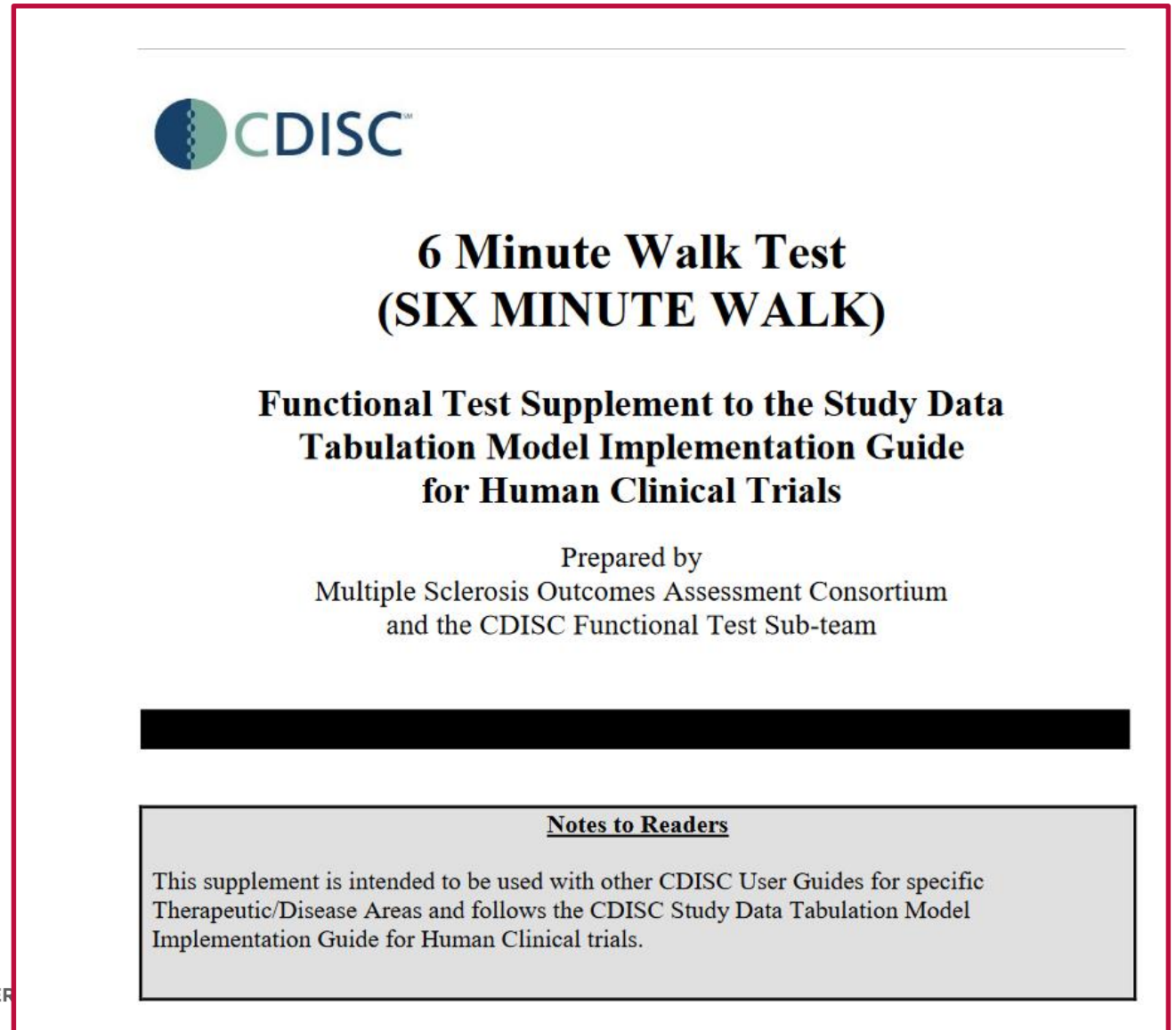
- Example: 6 Minute Walk Test
  - Documentation needed:
    - SDTMIG V3.3 Section 6.3.13.1 Functional Test (FT) Domain
    - CDISC Controlled Terminology
      - FTCAT NCI Codelist C115304
      - FTTESTCD: SIXMW1TC NCI Codelist C115388
      - FTTEST: SIXMW1TN NCI Codelist C115387
    - 6 Minute Walk Test QRS Supplement and aCRF

6 Minute Walk Test	SIX MINUTE WALK	FT	Public Domain	v 1.0	May 21, 2014

https://www.cdisc.org/foundational/qrs

Walk through of EXAMPLE CDISC Documentation for QRS

- Find the 6 Minute Walk Test Supplement



CDISC

6 Minute Walk Test
(SIX MINUTE WALK)

Functional Test Supplement to the Study Data Tabulation Model Implementation Guide for Human Clinical Trials

Prepared by
Multiple Sclerosis Outcomes Assessment Consortium
and the CDISC Functional Test Sub-team

[redacted]

Notes to Readers

This supplement is intended to be used with other CDISC User Guides for specific Therapeutic/Disease Areas and follows the CDISC Study Data Tabulation Model Implementation Guide for Human Clinical trials.

Walk through of EXAMPLE CDISC Documentation for QRS

- Access SDTMIG V3.3 Section 6.3.13.1 Functional Test (FT) Domain

6.3.13.1 Functional Tests

FT – Description/Overview

A findings domain that contains data for named, stand-alone, task-based evaluations designed to provide an assessment of mobility, dexterity, or cognitive ability.

FT – Specification

ft.xpt, Functional Tests — Findings, Version 3.3. One record per Functional Test finding per time point per visit per subject, Tabulation.

Variable Name	Variable Label	Type	Controlled Terms, Codelist or Format[1]	Role	CDISC Notes	Core
STUDYID	Study Identifier	Char		Identifier	Unique identifier for a study.	Req
DOMAIN	Domain Abbreviation	Char	FT	Identifier	Two-character abbreviation for the domain.	Req
USUBJID	Unique Subject Identifier	Char		Identifier	Identifier used to uniquely identify a subject across all studies for all applications or submissions involving the product.	Req
FTSEQ	Sequence Number	Num		Identifier	Sequence number to ensure uniqueness of records within a dataset for a subject. May be any valid number.	Req
FTGRPID	Group ID	Char		Identifier	Optional group identifier, used to link together a block of related records within a subject in a domain.	Perm
FTREFID	Reference ID	Char		Identifier	Optional internal or external identifier.	Perm
FTSPID	Sponsor-Defined Identifier	Char		Identifier	Sponsor-defined identifier. Perhaps preprinted on the CRF as an explicit line identifier or defined in the sponsor's operational database. Example: Line number from the test page.	Perm
FTTESTCD	Short Name of Test	Char	*	Topic	Short character value for FTTEST, which can be used as a column name when converting a dataset from a vertical format to a horizontal format. The value cannot be longer than 8 characters, nor can it start with a number (e.g., "1TEST" is not valid). FTTESTCD cannot contain characters other than letters, numbers, or underscores. Controlled terminology for FTTESTCD is published in separate codelists for each questionnaire. See https://www.cdisc.org/standards/semantics/terminology for values for FTTESTCD. Examples: "W250101", "W25F0102".	Req
FTTEST	Name of Test	Char	*	Synonym Qualifier	Verbatim name of the question used to obtain the finding. The value in FTTEST cannot be longer than 40 characters. Controlled terminology for FTTEST is published in separate codelists for each questionnaire. See https://www.cdisc.org/standards/semantics/terminology for values for FTTEST. Examples: "W2501-25 Foot Walk Time", "W25F-More Than Two Attempts".	Req
FTCAT	Category	Char	(FTCAT)	Grouping Qualifier	Used to specify the functional test in which the functional test question identified by FTTEST and FTTESTCD was included.	Req
FTSCAT	Subcategory	Char		Grouping Qualifier	Used to define a further categorization of FTCAT values.	Perm

Walk through of EXAMPLE CDISC Documentation for QRS

- Access FTCAT NCI Codelist: C115304 to find Six Minute Walk

C115304 FTCAT

NCI Code	CDISC Submission Value	CDISC Synonym	CDISC Definition	NCI Preferred Term
C115791	NHPT	NHPT01	Nine-Hole Peg Test (NHPT) (Copyright 2001, National Multiple Sclerosis Society).	Nine-Hole Peg Functional Test
C150911	PACED TAPPING	PTAP1	Paced Tapping (Rowe KC, Paulsen JS, Langbehn DR, et al. Self-paced timing detects and tracks change in prodromal Huntington disease. Neuropsychology. 2010;24(4):435-442).	Paced Tapping Test Functional Test
C115792	PASAT	PASAT1	Paced Auditory Serial Addition Test (PASAT) (Copyright 2001, National Multiple Sclerosis Society).	Paced Auditory Serial Addition Functional Test
C138334	PUL V1.2	PUL01	Performance of the Upper Limb Module for DMD Version 1.2 (PUL V1.2) (Mayhew A, Mazzone ES, Eagle M, et al. (2013). Development of the Performance of the Upper Limb module for Duchenne muscular dystrophy. Dev Med Child Neurol; 55:1038-45).	Performance of the Upper Limb Module for DMD 1.2 Functional Test
C138335	PUL V2.0	PUL02	Performance of the Upper Limb Module for DMD Version 2.0 (PUL V2.0) (Mayhew A, Mazzone ES, Eagle M, et al. (2013). Development of the Performance of the Upper Limb module for Duchenne muscular dystrophy. Dev Med Child Neurol; 55:1038-45).	Performance of the Upper Limb Module for DMD 2.0 Functional Test
C141687	RISING FROM FLOOR	RISEF1	Rising From Floor (Mcdonald, C. M., Henricson, E. K., Abresch, R. T., Florence, J. M., Eagle, M., Gappmaier, E., et al. (2013). THE 6-MINUTE WALK TEST AND OTHER ENDPOINTS IN DUCHENNE MUSCULAR DYSTROPHY: LONGITUDINAL NATURAL HISTORY OBSERVATIONS OVER 48 WEEKS FROM A MULTICENTER STUDY. Muscle & Nerve, 48(3), 343-356. http://doi.org/10.1002/mus.23902).	Rising From Floor Test Functional Test
C115793	SDMT	SDMT01	Symbol Digit Modalities Test (SDMT) (Copyright 1973 by Western Psychological Services).	Symbol Digit Modalities Functional Test
C115789	SIX MINUTE WALK	SIXMW1	6 Minute Walk Test (6MWT) (Goldman MD, Marrie RA, Cohen JA. Evaluation of the six-minute walk in multiple sclerosis subjects and healthy controls. Multiple Sclerosis 2008; 14: 383-390).	6 Minute Walk Functional Test
C115794	T25FW	T25FW1	Timed 25-Foot Walk (T25FW) (Copyright 2001, National Multiple Sclerosis Society).	Timed 25-Foot Walk Functional Test
C141686	TEN METER WALK/RUN	TENMW1	Ten Meter Walk/Run (Mcdonald, C. M., Henricson, E. K., Abresch, R. T., Florence, J. M., Eagle, M., Gappmaier, E.,	Ten Meter Walk/Run Test Functional Test

Walk through of EXAMPLE CDISC Documentation for QRS

- Access SIXMW1TN NCI Codelist: C115387 to find Six Minute Walk Test Name (long version of the questions) values

SIXMW1TN (6 Minute Walk Functional Test Test Name)

NCI Code: C115387, Codelist extensible: No

C115387 SIXMW1TN

NCI Code	CDISC Submission Value	CDISC Synonym	CDISC Definition	NCI Preferred Term
C115800	SIXMW1-Distance at 1 Minute	SIXMW1-Distance at 1 Minute	6 Minute Walk Test - Distance at 1 minute.	6MWT - Distance at 1 Minute
C115801	SIXMW1-Distance at 2 Minutes	SIXMW1-Distance at 2 Minutes	6 Minute Walk Test - Distance at 2 minutes.	6MWT - Distance at 2 Minutes
C115802	SIXMW1-Distance at 3 Minutes	SIXMW1-Distance at 3 Minutes	6 Minute Walk Test - Distance at 3 minutes.	6MWT - Distance at 3 Minutes
C115803	SIXMW1-Distance at 4 Minutes	SIXMW1-Distance at 4 Minutes	6 Minute Walk Test - Distance at 4 minutes.	6MWT - Distance at 4 Minutes
C115804	SIXMW1-Distance at 5 Minutes	SIXMW1-Distance at 5 Minutes	6 Minute Walk Test - Distance at 5 minutes.	6MWT - Distance at 5 Minutes
C115805	SIXMW1-Distance at 6 Minutes	SIXMW1-Distance at 6 Minutes	6 Minute Walk Test - Distance at 6 minutes.	6MWT - Distance at 6 Minutes

Note: the CT *represents* the question (it is *not usually* the actual question)

Walk through of EXAMPLE CDISC Documentation for QRS

- Access SIXMW1TC NCI Codelist: C115388 to find Six Minute Walk Test Code (short version of the questions) values

SIXMW1TC (6 Minute Walk Functional Test Test Code)

NCI Code: C115388, Codelist extensible: No

C115388 SIXMW1TC

NCI Code	CDISC Submission Value	CDISC Synonym	CDISC Definition	NCI Preferred Term
C115800	SIXMW101	SIXMW1-Distance at 1 Minute	6 Minute Walk Test - Distance at 1 minute.	6MWT - Distance at 1 Minute
C115801	SIXMW102	SIXMW1-Distance at 2 Minutes	6 Minute Walk Test - Distance at 2 minutes.	6MWT - Distance at 2 Minutes
C115802	SIXMW103	SIXMW1-Distance at 3 Minutes	6 Minute Walk Test - Distance at 3 minutes.	6MWT - Distance at 3 Minutes
C115803	SIXMW104	SIXMW1-Distance at 4 Minutes	6 Minute Walk Test - Distance at 4 minutes.	6MWT - Distance at 4 Minutes
C115804	SIXMW105	SIXMW1-Distance at 5 Minutes	6 Minute Walk Test - Distance at 5 minutes.	6MWT - Distance at 5 Minutes
C115805	SIXMW106	SIXMW1-Distance at 6 Minutes	6 Minute Walk Test - Distance at 6 minutes.	6MWT - Distance at 6 Minutes

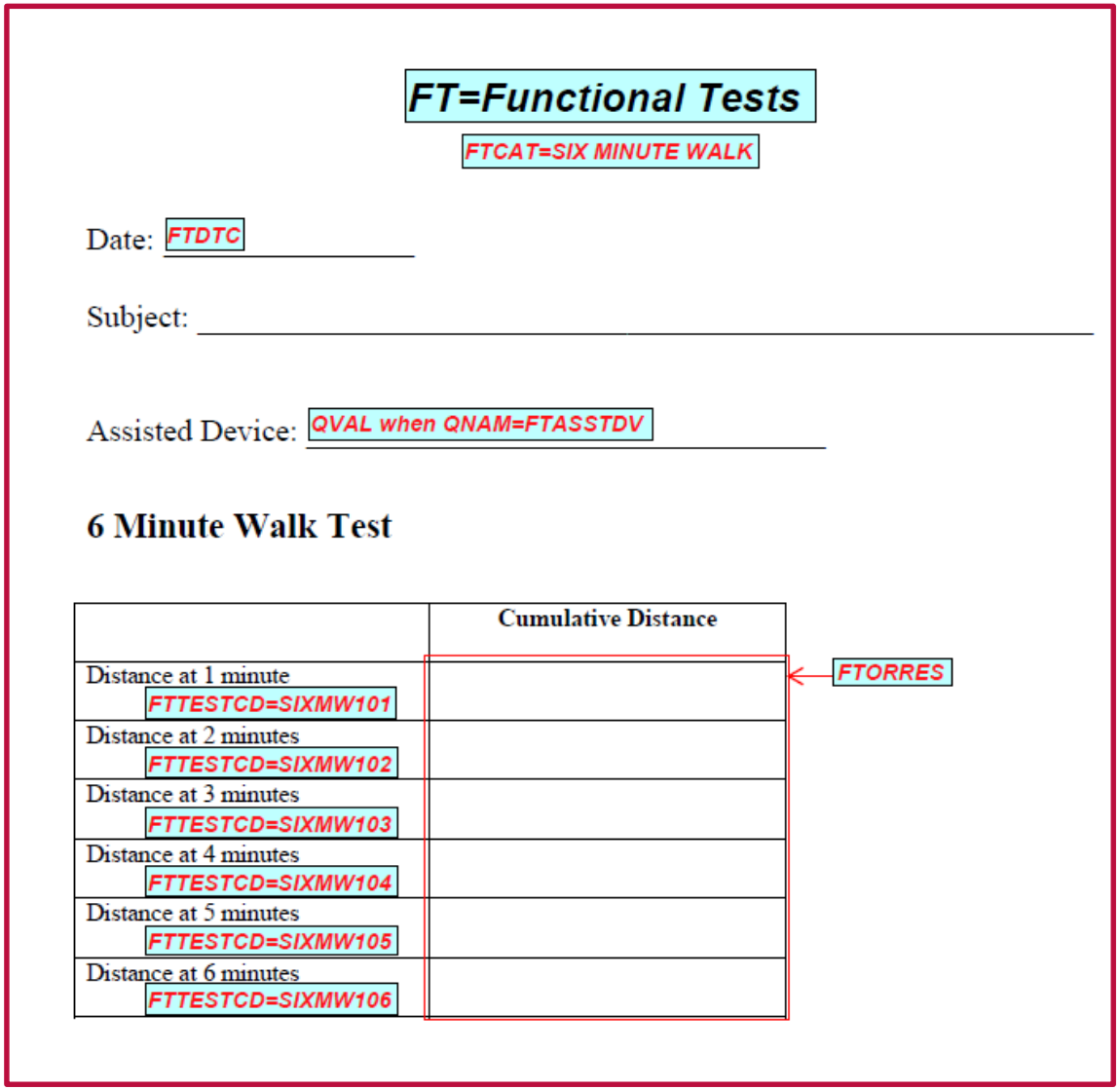
Walk through of EXAMPLE CDISC Documentation for QRS

- Reference the 6 Minute Walk Test aCRF

The aCRF for each QRS Supplement is **not** a CDASH publication - it is the SDTM annotation for submission. (You can use a similar approach to create data collection metadata for Rave.)

You should always obtain permission to use copyrighted instruments before you use them.

You should **never modify** a validated instrument - use them as published.



Walk through of EXAMPLE CDISC Documentation for QRS

- Example SDTM Data for 6 Minute Walk Test:

ft.xpt

Row	STUDYID	DOMAIN	USUBJID	FTSEQ	FTGRPID	FTTESTCD	FTTEST	FTCAT	FTORRES	FTORRESU	FTSTRESC	FTSTRESN
1	STUDYX	FT	MS01-01	1	1	SIXMW101	SIXMW1-Distance at 1 Minute	SIX MINUTE WALK	101	m	101	101
2	STUDYX	FT	MS01-01	2	1	SIXMW102	SIXMW1-Distance at 2 Minutes	SIX MINUTE WALK	201	m	201	201
3	STUDYX	FT	MS01-01	3	1	SIXMW103	SIXMW1-Distance at 3 Minutes	SIX MINUTE WALK	299	m	299	299
4	STUDYX	FT	MS01-01	4	1	SIXMW104	SIXMW1-Distance at 4 Minutes	SIX MINUTE WALK	396	m	396	396
5	STUDYX	FT	MS01-01	5	1	SIXMW105	SIXMW1-Distance at 5 Minutes	SIX MINUTE WALK	493	m	493	493
6	STUDYX	FT	MS01-01	6	1	SIXMW106	SIXMW1-Distance at 6 Minutes	SIX MINUTE WALK	597	m	597	597

ft.xpt (cont)

Row	FTSTRESU	FTBLFL	VISITNUM	FTDTC
1 (cont)	m	Y	1	2014-03-10
2 (cont)	m	Y	1	2014-03-10
3 (cont)	m	Y	1	2014-03-10
4 (cont)	m	Y	1	2014-03-10
5 (cont)	m	Y	1	2014-03-10
6 (cont)	m	Y	1	2014-03-10

Note: the CT *represents* the question, so nobody would be able to reproduce the copyrighted instrument merely by accessing the controlled terminology.

Walk through of EXAMPLE CDISC Documentation for QRS

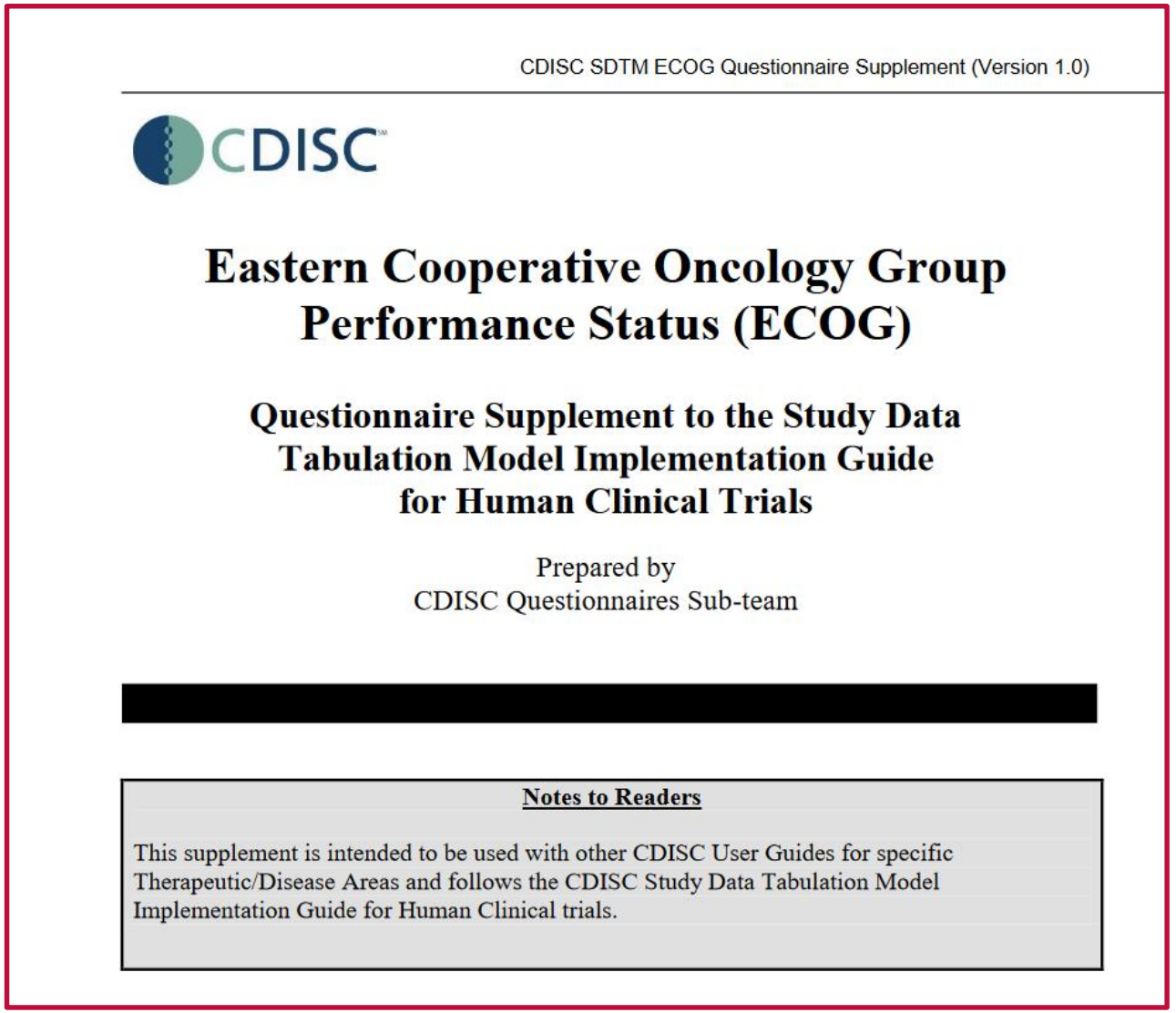
- Example: ECOG
  - Documentation needed:
    - SDTMIG V3.3 Section 6.3.13.2 Questionnaires (QS) Domain
    - CDISC Controlled Terminology
      - QSCAT NCI Codelist C100129
      - QSTESTCD: ECOG1TC NCI Codelist C101815
      - QSTEST: ECOG1TN NCI Codelist C101816
    - ECOG QRS Supplement and aCRF

Eastern Cooperative Oncology Group Performance Status	ECOG	QS	Public Domain	v 1.0	June 26, 2013

https://www.cdisc.org/foundational/qrs

Walk through of EXAMPLE CDISC Documentation for QRS

- Find the ECOG Supplement



CDISC SDTM ECOG Questionnaire Supplement (Version 1.0)

CDISC

Eastern Cooperative Oncology Group Performance Status (ECOG)

Questionnaire Supplement to the Study Data Tabulation Model Implementation Guide for Human Clinical Trials

Prepared by
CDISC Questionnaires Sub-team

[redacted]

Notes to Readers

This supplement is intended to be used with other CDISC User Guides for specific Therapeutic/Disease Areas and follows the CDISC Study Data Tabulation Model Implementation Guide for Human Clinical trials.

Walk through of EXAMPLE CDISC Documentation for QRS

- Access SDTMIG V3.3 Section 6.3.13.2 Questionnaires (QS) Domain

6.3.13.2 Questionnaires

QS – Description/Overview

A findings domain that contains data for 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.

QS – Specification

qs.xpt, Questionnaires — Findings, Version 3.3. One record per questionnaire per question per time point per visit per subject, Tabulation.

Variable Name	Variable Label	Type	Controlled Terms, Codelist or Format[1]	Role	CDISC Notes	Core
STUDYID	Study Identifier	Char		Identifier	Unique identifier for a study.	Req
DOMAIN	Domain Abbreviation	Char	QS	Identifier	Two-character abbreviation for the domain.	Req
USUBJID	Unique Subject Identifier	Char		Identifier	Identifier used to uniquely identify a subject across all studies for all applications or submissions involving the product.	Req
QSSEQ	Sequence Number	Num		Identifier	Sequence number given to ensure uniqueness of subject records within a domain. May be any valid number.	Req
QSGRPID	Group ID	Char		Identifier	Used to tie together a block of related records in a single domain for a subject.	Perm
QSSPID	Sponsor-Defined Identifier	Char		Identifier	Sponsor-defined reference number. Perhaps preprinted on the CRF as an explicit line identifier or defined in the sponsor's operational database. Example: Question number on a questionnaire.	Perm
QSTESTCD	Question Short Name	Char	*	Topic	Topic variable for QS. Short name for the value in QSTEST, which can be used as a column name when converting the dataset from a vertical format to a horizontal format. The value in QSTESTCD cannot be longer than 8 characters, nor can it start with a number (e.g., "1TEST" is not valid). QSTESTCD cannot contain characters other than letters, numbers, or underscores. Controlled terminology for QSTESTCD is published in separate codelists for each questionnaire. See https://www.cdisc.org/standards/semantics/terminology for values for QSTESTCD. Examples: "ADCCMD01", "BPR0103".	Req
QSTEST	Question Name	Char	*	Synonym Qualifier	Verbatim name of the question or group of questions used to obtain the measurement or finding. The value in QSTEST cannot be longer than 40 characters. Controlled terminology for QSTEST is published in separate codelists for each questionnaire. See https://www.cdisc.org/standards/semantics/terminology for vaues for QSTEST. Example: "BPR01 - Emotional Withdrawal".	Req
QSCAT	Category of Question	Char	(QSCAT)	Grouping Qualifier	Used to specify the questionnaire in which the question identified by QSTEST and QSTESTCD was included. Examples: "ADAS-COG", "MDS-UPDRS".	Req
QSSCAT	Subcategory for Question	Char	*	Grouping Qualifier	A further categorization of the questions within the category. Examples: "MENTAL HEALTH" , "DEPRESSION", "WORD RECALL".	Perm
QSORRES	Finding in Original Units	Char		Result Qualifier	Finding as originally received or collected (e.g., "RARELY", "SOMETIMES"). When sponsors apply codelist to indicate the code values are statistically meaningful standardized scores, which are defined by sponsors or by valid methodologies such as SF36 questionnaires, QSORRES will contain the decode format, and QSSTRESC and QSSTRESN may contain the standardized code values or scores.	Exp
QSORRESU	Original Units	Char	(UNIT)	Variable Qualifier	Original units in which the data were collected. The unit for QSORRES, such as minutes or seconds or the units associated with a visual analog scale.	Perm
QSSTRESC	Character Result/Finding in Std Format	Char		Result Qualifier	Contains the finding for all questions or sub-scores, copied or derived from QSORRES in a standard format or standard units. QSSTRESC should store all findings in character format; if findings are numeric, they should also be stored in numeric format in QSSTRESN. If question scores are derived from the original finding, then the standard format is the	Exp

Walk through of EXAMPLE CDISC Documentation for QRS

- Access QSCAT NCI Codelist: C100129 to find ECOG

C100129	QSCAT			
NCI Code	**CDISC Submission Value**	**CDISC Synonym**	**CDISC Definition**	**NCI Preferred Term**
C121003	CRQ-SAS FOLLOW-UP ADMINISTRATION VERSION	CRQ02	Chronic Respiratory Questionnaire Self-Administered Standardized Format (CRQ-SAS) Follow-up Administration Version (Copyright 2001 McMaster University, Hamilton, Ontario, Canada. The Chronic Respiratory Questionnaire Self-Administered including the standardized Dyspnea Domain (CRQSAS), Principal authors G.H. Guyatt and Dr. H.J. Schunemann, is the copyright of McMaster University (Copyright 2001, McMaster University).	Chronic Respiratory Questionnaire Self-Administered Standardized Format Follow-Up Administration Version Questionnaire
C105165	DAD	DAD01	Disability Assessment for Dementia (DAD) (copyright 1994 by L. Gauthier I. Gelinas. All rights reserved.).	Disability Assessment for Dementia Questionnaire
C112519	DISEASE STEPS	DS01	Disease Steps (DS) (Hohol MJ, Orav EJ, Weiner HL. Disease steps in multiple sclerosis: a simple approach to evaluate disease progression. Neurology. 1995 Feb;45(2):251-5).	Disease Steps Questionnaire
C119102	DLQI	DLQI1	Dermatology Life Quality Index (DLQI) (Copyright Dermatology Life Quality Index. A Y Finlay, G K Khan, April 1992. www.dermatology.org.uk. This must not be copied without the permission of the authors).	Dermatology Life Quality Index Questionnaire
C141694	DRRI-2	DRRI1	Deployment Risk and Resilience Inventory-2 (DRRI-2) (Vogt, D., Smith, B. N., King, D. W., & King, L. A. (2012). The Deployment Risk and Resilience Inventory-2 (DRRI-2) [Measurement instrument]. Available from http.ptsd.va.gov).	Deployment Risk and Resilience Inventory-2 Questionnaire
C115796	DRS	DRS01	Disability Rating Scale (DRS) (Rappaport et al. (1982) Disability Rating Scale for Severe Head Trauma Patients: Coma to Community. Archives of Physical Medicine and	Disability Rating Scale Questionnaire
C102116	ECOG	ECOG1	Eastern Cooperative Oncology Group (ECOG) Performance Status (Oken MM, Creech RH, Tormey DC, Horton J, Davis TE, McFadden ET, Carbone PP. Toxicity and response criteria of the Eastern Cooperative Oncology Group. Am J Clin Oncol. 1982 Dec;5(6):649-55).	Eastern Cooperative Oncology Group Performance Status Questionnaire
C112520	EDSS	EDSS01	Kurtzke Expanded Disability Status Scale (EDSS) (Kurtzke JF. Rating neurologic impairment in multiple sclerosis: an expanded disability status scale (EDSS). Neurology. 1983 Nov;33(11):1444-52).	Kurtzke Expanded Disability Status Scale Questionnaire
C132533	EPDS	EPDS01	Edinburgh Postnatal Depression Scale (EPDS) (Copyright by Cox, J.L., Holden, J.M., and Sagovsky, R. 1987. Detection of postnatal depression: Development of the 10-item Edinburgh Postnatal Depression Scale. British	Edinburgh Postnatal Depression Scale Questionnaire

Walk through of EXAMPLE CDISC Documentation for QRS

- Example QSTESTCD/QSTEST Controlled Terminology for ECOG:

ECOG1TC (Eastern Cooperative Oncology Group Performance Status Questionnaire Test Code)

NCI Code: C101815, Codelist extensible: No

C101815	ECOG1TC			
NCI Code	CDISC Submission Value	CDISC Synonym	DISC Definition	NCI Preferred Term
C102408	ECOG101	ECOG1-Performa Status		

Only one response, so only one value needed (one for QSTESTCD and one for QSTEST)

ECOG1TN (Eastern Cooperative Onco

NCI Code: C101816, Codelist extensible: No

C101816	ECOG1TN			
NCI Code	CDISC Submission Value	CDISC Synonym	CDISC Definition	NCI Preferred Term
C102408	ECOG1-Performance Status	ECOG1-Performance Status	ECOG Performance Status - Performance Status.	ECOG - Performance Status

Note: the CT *represents* the question, so nobody would be able to reproduce the copyrighted instrument merely by accessing the controlled terminology.

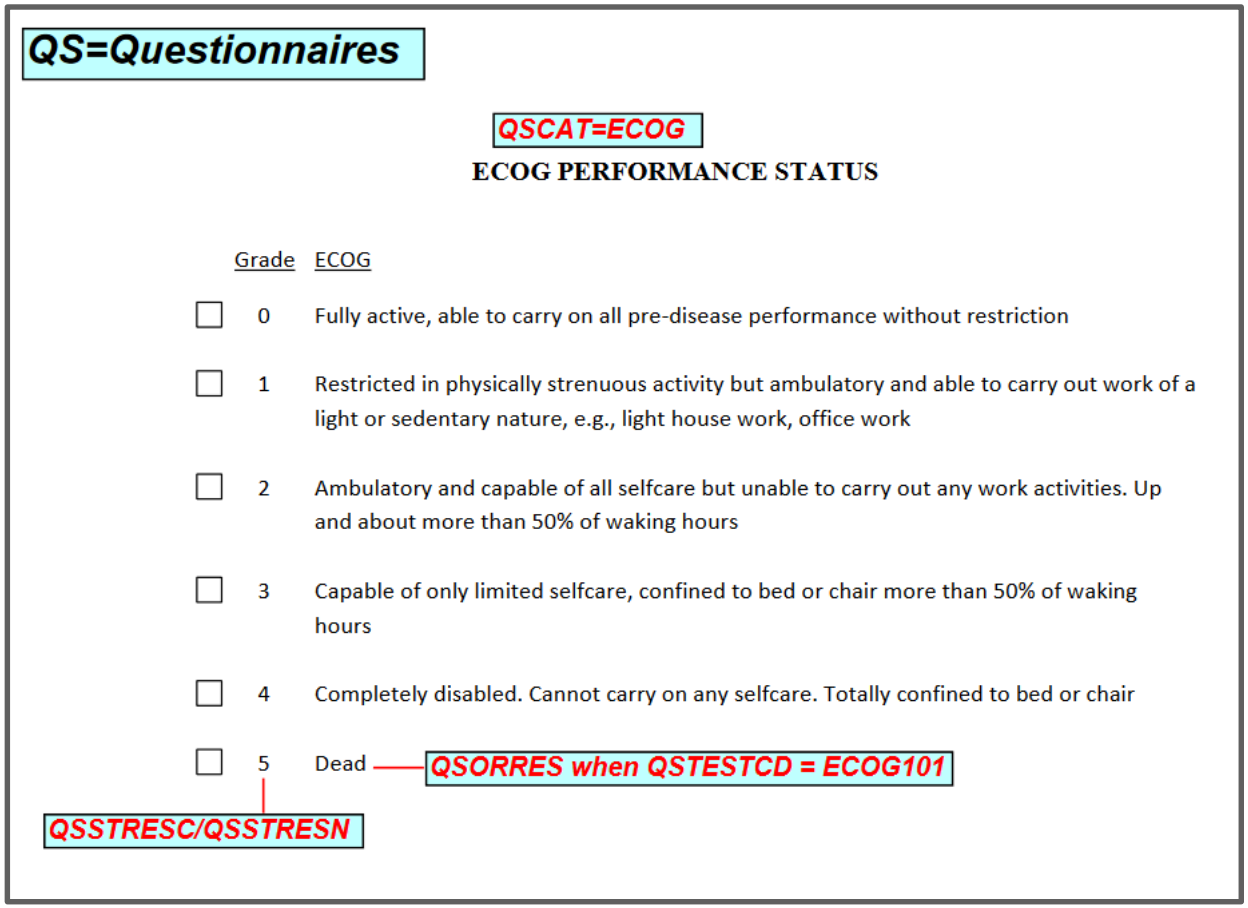
Walk through of EXAMPLE CDISC Documentation for QRS

- Reference the ECOG aCRF

The aCRF for each QRS Supplement is **not** a CDASH publication - it is the SDTM annotation for submission. (You can use a similar approach to create data collection metadata for Rave.)

You should always obtain permission to use copyrighted instruments before you use them.

You should **never modify** a validated instrument - use them as published.



Walk through of EXAMPLE CDISC Documentation for QRS

- Mapping Strategy for SDTM ECOG Data:
  - One record collected for each person, so only one QSTESTCD/QSTEST needed = ECOG101
  - For each text response, there is a corresponding numeric score
  - QS puts the text response in QSORRES and the numeric score into QSSTRESC AND QSSTRESN

QSTESTCD= ECOG101 QSTEST= ECOG1-Performance Status

QSORRES	QSSTRESC	QSSTRESN
Fully active, able to carry on all pre-disease performance without restriction	0	0
Restricted in physically strenuous activity but ambulatory and able to carry out work of a light or sedentary nature, e.g., light house work, office work	1	1
Ambulatory and capable of all selfcare but unable to carry out any work activities. Up and about more than 50% of waking hours	2	2
Capable of only limited selfcare, confined to bed or chair more than 50% of waking hours	3	3
Completely disabled. Cannot carry on any selfcare. Totally confined to bed or chair	4	4
Dead	5	5

Walk through of EXAMPLE CDISC Documentation for QRS

- Example SDTM Data for ECOG (3 patient records):

QS.XPT

ROW	STUDYID	DOMAIN	USUBJID	QSSEQ	QSTESTCD	QSTEST	QSCAT	QSORRES
1	STUDY001	QS	001-001	1	ECOG101	ECOG1-Performance Status	ECOG	Capable of only limited selfcare, confined to bed or chair more than 50% of waking hours
2	STUDY001	QS	001-002	1	ECOG101	ECOG1-Performance Status	ECOG	Fully active, able to carry on all pre-disease performance without restriction
3	STUDY001	QS	001-003	1	ECOG101	ECOG1-Performance Status	ECOG	Restricted in physically strenuous activity but ambulatory and able to carry out work of a light or sedentary nature, e.g., light house work, office work

ROW	QSSTRESC	QSSTRESN	QSBLFL	QSEVAL	VISITNUM	QSDTC
1	3	3	Y	INVESTIGATOR	1	2013-04-09
2	0	0	Y	INVESTIGATOR	1	2013-04-09
3	1	1	Y	INVESTIGATOR	1	2013-04-10

How QRS Standards are Developed

- Request for Supplements come from internal (TA) teams
- CDISC has to research whether or not there is a copyright on an instrument - takes time/resources
  - CDISC has to obtain permission to published terminology and supplements for copyrighted instruments - can take additional time
- Following COP-001, QRS Team develops Supplements in the CDISC Wiki
  - https://wiki.cdisc.org/display/QRSSUPP/SDS+QRS+Supplements+Home
- During public Review period - everyone can review and give feedback
- Terminology
  - Can be requested by anyone (using NCI web page New Term Request)
  - QRS Terminology is published quarterly

What if there is no published terminology or supplement?

- Make sure what you are working with is actually QRS (**see slide 7**) - does it meet all these criteria?
- Determine whether it is FT, QS or RS (**see slide 10** or review the definitions at https://www.CDISC.org/foundational/qrs)
- If there is published terminology, but no Supplement, use the published terminology to prepare your SDTMs
  - There may be --CAT terminology and nothing else - use that to create --TESTCD /--TEST
  - If there is **no** terminology, you can create your own using a similar pattern (follow QRS naming conventions)
- SUBMIT your set of CT terms to CDISC New Term Request (currently no mechanism for receiving external Supplement requests)

Developing your own QRS terminology

- QSCAT, FTCAT or RSCAT (--CAT)
  - Standard name that uniquely identifies the instrument
    - Should be the name that the instrument is commonly known by
    - SDTM rules - character limit is 200 (but most of these would be <50)
  - --CAT Synonym is a short code name for the instrument
    - Should be no more than 6 characters
    - Should include the version number as 0X (e.g., 01, 02) but may be shortened if there are more than 99 questions
    - Will be used to create the --TESTCD and --TEST terminology values that uniquely identify each individual question on the instrument
  - --CAT definition is the full name of the questionnaire include the version, followed by the acronym, the citation and copyright details

Developing your own QRS terminology

- QSTESTCD, FTTESTCD or RSTESTCD (--TESTCD)
  - Create one for each unique question on the instrument
  - Create by beginning with the --CAT 6-character synonym, followed by sequential numbering beginning with “01”
  - SDTM rules
    - Use UPPER CASE
    - Value is limited to 8 characters

Developing your own QRS terminology

- QSTEST, FTTEST or RSTEST (--TEST)
- Create one for each unique question on the instrument (one for each --TESTCD)
- --TEST begins with the --CAT synonym, followed by a hyphen (no spaces on either side of the hyphen), followed by a very short description of the question content
- SDTM Rules
  - Use **title** case (except for the --CAT synonym portion)
  - The entire --TEST value is limited to 40 characters

Key Points

- Preparation of SDTM datasets from QRS instruments starts with the metadata and rules from **one** of three SDTM domains used for QRS instruments:
  - QS - generating a numeric value to describe a qualitative concept
  - FT - measuring performance of a physical or mental task
  - RS - ranking or staging a disease state or risk using multiple inputs
- CDISC has standardized a LOT of QRS instruments, but not all
  - ~293 QRS instruments have at least some published CDISC **Terminology**
  - ~182 QRS instruments have published CDISC **Supplements**

Key Points

- Sponsor is responsible for obtaining a license to use a copyrighted instrument
  - Just because CDISC has permission to publish an aCRF, that doesn't give anyone else permission to use that instrument
- CDISC Controlled Terminology uses standardized **representations** of the questions in an instrument - they are usually abbreviated to fit within the constraints of SDTM data (i.e., 8 character --TESTCD, 40 character --TEST)
  - For data collection: You still have to use the validated instrument *as published* to maintain the validation (i.e., full question)
- If you have to create your own Terminology, submit it to CDISC using the New Term Request form on the NCI website:

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

Q&A

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