

QRS “Office Hours” Webinar

Presented by

Dana Booth, Consultant, CDISC

Nancy Brucken, Data Standards Engineer, Syneos Health

Steve Kopko, Consultant, CDISC

Karin LaPann, Associate Director Clinical Standards, Takeda Pharmaceutical Company Ltd.

Jordan Li, Biomedical/Clinical Research Information Specialist, National Cancer Institute

11 APR 2019





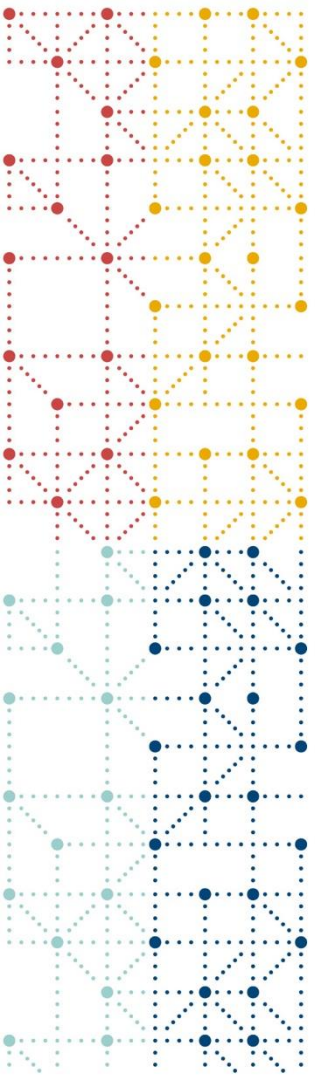
Agenda

1. Presenter Bio
2. Housekeeping
3. Feature Presentation
4. Question & Answer Session
5. Upcoming Learning Opportunities + Resources



Our Presenters

- Dana Booth, Co-Lead SDSQRS Sub-team, Consultant, CDISC
- Nancy Brucken, Co-Lead ADQRS Sub-team, Data Standards Engineer, Syneos Health
- Steve Kopko, Co-Lead SDSQRS Sub-team, Consultant, CDISC
- Karin LaPann, Co-Lead ADQRS Sub-team, Associate Director Clinical Standards, Takeda Pharmaceutical Company Ltd.
- Jordan Li, Lead QRS Terminology Team, Biomedical/Clinical Research Information Specialist, National Cancer Institute



Housekeeping

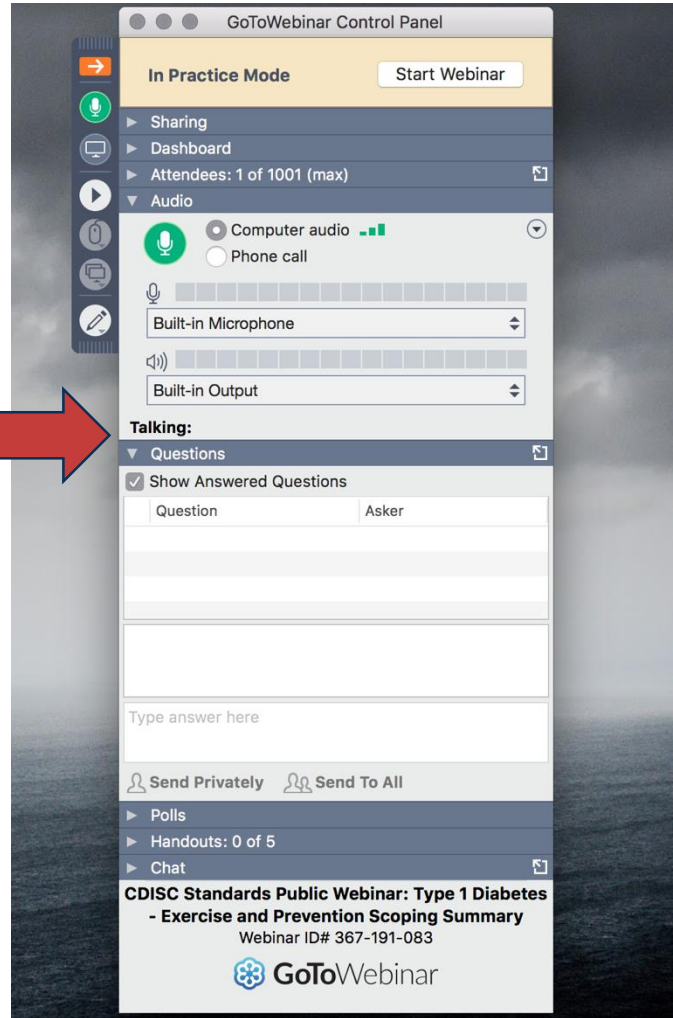


Housekeeping

- You will remain on **mute** for the entirety of the call
- Submit questions via 'Questions' section of toolbar
- Audio issues? Shut down and restart the GoToWebinar app
- Upcoming learning opportunities following Q&A

Submitting Questions

- To send a question, use the “QUESTIONS” function on your GoToWebinar app. (See red arrow)
- You can submit questions at any time during the presentation, we’ll answer them during the Q&A.
- If you have a question for a specific panelist, please indicate the panelist’s name at the beginning of the question
 - Examples:
 - Sam: ‘Question’
 - Anthony: ‘Question’





Content Disclaimer

- The purpose of this webinar is to provide examples of implementation and should not be considered official recommendations by CDISC unless otherwise stated in the presentation.
- This webinar is not an authorized CDISC course, is not developed or delivered under CDISC Operating Procedures, and should not replace a published standard. Please refer to the latest published standards for the most authoritative implementation information.

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First Question



What does “QRS” stand for?



SDS Questionnaires, Ratings and Scales (QRS) Subteam WIKI Home

<https://wiki.cdisc.org/display/QRST/SDS+Questionnaires%2C+Ratings+and+Scales+%28QRS%29+Subteam+Home?src=sidebar>

- ❖ QRS Issues – team documented QRS issues and resolutions
- ❖ QRS Webinars – team documented QRS webinar information
- ❖ QRS Shared Files – team shared files list for team access
- ❖ Meeting Notes – team meeting notes since 2013

What is included in a QRS Supplement?

- ❖ QRS supplements to the SDTMIG include instrument-specific Controlled Terminology and an SDTM example illustrating the use, applicable supplemental qualifiers and item-level mapping instructions for the results. Assumptions for implementing the instrument in SDTM are also included.
- ❖ QRS supplements to the ADaMIG describe how to structure the questionnaire analysis dataset based on data structures described in the ADaMIG. Included in ADaMIG supplements are sample analysis descriptions, scoring for the statistical analysis plan, data checks, and examples of analysis dataset metadata, analysis variable metadata, and value-level metadata. Also included is an example of the final analysis dataset to be used for analysis and regulatory submission.

QRS Webpage

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

All Published QRS Supplements

SDTM Domain/ADaM Dataset		Permission		Search by Name	
Any		Any			
FT		Public Domain			
RS		Granted			
QS		Denied			
ADaM		Author Permission Required			
		No response received			
		Pending			
QRS Name	Short Name (--CAT)	SDTM Domain/ADaM Dataset	Permission	Version	Release Date
12-Item Multiple Sclerosis Walking Scale	MSWS-12	QS	No Response Received		
6 Minute Walk Test	SIX MINUTE WALK	FT	Public Domain	v 1.0	21-May-14
Abnormal Involuntary Movement Scale	AIMS	QS	Public Domain	v 1.0	22-May-13
Acute Physiology and Chronic Health Evaluation II	APACHE II	RS	Public Domain	v 1.0	29-Jun-16

SDTMIG QRS Supplements WIKI Development

<https://wiki.cdisc.org/display/QRSSUPP/SDS+QRS+Supplements+Home>

- ❖ Calendar – SDS QRS meeting and events information
- ❖ QRS Maker – SHARE based application to develop the instrument specific metadata needed for a QRS supplement
- ❖ QRS Supplement Best Practices – documented decisions on how best to handle the specifics in developing QRS supplements
- ❖ QRS template documents used in the development process
 - QRS Supplement Template
 - QRS Review Process Documents
- ❖ Supplements under Development

SDTMIG QRS Supplements WIKI Development

- ❖ Team Review – list of supplements under QRS subteam review
- ❖ Internal Review – list of supplements under CDISC wider internal review
- ❖ Public Review – list of supplements under CDISC public review
- ❖ Published / Archive – list of supplements that are published and archived with source documents



CDISC Definitions QS/FT/RS Domains

Questionnaires (QS)

Questionnaire instruments are stored in the Questionnaires (QS) domain and are **named, standalone instruments** designed to provide an assessment of a concept. Questionnaires often have a defined standard structure, format, and content; consist of conceptually related items that are typically scored; and usually document methods for administration and analysis. **Questionnaires consist of defined questions with a defined set of potential answers.** Most often, the primary purpose of questionnaires is to generate quantitative statistic to assess a qualitative concept.



CDISC Definitions QS/FT/RS Domains

Functional Test (FT)

Functional Test instruments are stored in the Functional Tests (FT) domain and are **named, standalone task-based evaluations, designed to provide an assessment of mobility, dexterity, and/or cognitive ability.** A Functional Test is not a subjective assessment of how the subject generally performs a task. Rather, it is an **objective measurement of the performance of the task by the subject in a specific instance.** Functional Tests have documented methods for administration and analysis and require a subject to perform specific activities that are evaluated and recorded. Most often, Functional Tests are direct, quantitative measurements.



CDISC Definitions QS/FT/RS Domains

Clinical Classifications (RS)

If the instrument is a Rating or Grading Scale in which the intent of the instrument is to evaluate a single body system, it would be stored in the morphology/physiology domain, which represents that body system. Other **Rating or Grading Scales related to multiple body systems and all Composite Score type instruments would be represented as a Clinical Classification in the RS domain.**

Clinical Classifications are **based on a trained healthcare professional's observation of a subject's health condition** or status with input from associated clinical records review. Clinical Classifications may be 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. These physical manifestations may be findings that are typically represented in other SDTM domains, such as labs, vital signs, or clinical events. Therefore, Clinical Classifications are often composite scores based on diverse inputs. This assessment method differs from a more traditional question-and-answer interview commonly seen in Questionnaires.

CDISC Definitions QS/FT/RS Domains

Clinical Classifications (RS)

Decision Summary:

- All PRO instruments that are not functional tests will be implemented as questionnaires.
- The QRS domain determination is not based on use of instrument, but the definitions of the QRS concepts of clinical classification, functional test, and questionnaire.
- The clinical classifications definition on the CDISC QRS web page will be used to determine if an instrument meets that definition.
 - clinician-rated
 - grading or rating scale about multiple body systems or a composite score
 - if the CRF is a rating scale documenting a clinical judgement based on patient information, such as the BPRS-A, it is still considered a clinician-rated rating scale and will be in the RS domain
 - if the instrument is a rating scale and has some patient-reported data and some clinician-reported data, the majority will dictate the domain. Hence the ESRS-A will remain in the RS domain based on the majority of items being symptoms that are clinician-rated.

Clinical Classification Example

- APACHE II -

https://www.cdisc.org/system/files/members/standard/foundational/grs/APACHE%20II%20v1%20Annotated%20CRF_0.pdf

RS=Disease Response and Clin Classification

RSCAT=APACHE II

The APACHE II Severity of Disease Classification System

RSSTRESC/RSSTRESN

Physiologic Variable	High Abnormal Range					Low Abnormal Range					Points
	+4	+3	+2	+1	0	+1	+2	+3	+4		
Temperature - rectal (°C)	RSTESTCD=APCH101	39°-40.9°		38.5°-38.9°	36°-38.4°	34°-35.9°	32°-33.9°	30°-31.9°	≤ 29.9°		
Mean Arterial Pressure - mm Hg	RSTESTCD=APCH102	30-159	110-129		70-109		50-69		≤ 49	RSORRES	
Heart Rate (ventricular response)	RSTESTCD=APCH103	≥ 180	140-179	110-139		70-109		55-69	40-54	≤ 39	
Respiratory Rate (non-ventilated or ventilated)	RSTESTCD=APCH104	≥ 50	35-49		25-34	12-24	10-11	6-9		≤ 5	
Oxygenation: A-aDO ₂ or PaO ₂ (mm Hg)											
a. FIO ₂ ≥ 0.5 record A-aDO ₂	RSTESTCD=APCH105A	350-499	200-349		< 200						
b. FIO ₂ < 0.5 record only PaO ₂	RSTESTCD=APCH105B				PO ₂ > 70	PO ₂ 61-70		PO ₂ 55-60	PO ₂ < 55		
Arterial pH (preferred)	RSTESTCD=APCH106A	7.6-7.69			7.5-7.59	7.33-7.49		7.25-7.32	7.15-7.24	< 7.15	
Serum HCO ₃ (venous mMol/L) (Not preferred, use if no ABGs)	RSTESTCD=APCH106B	≥ 53 1-51.9			32-40.9	22-31.9		18-21.9	15-17.9	< 15	

Questionnaires Available for Internal Review

Comments due April 18th

- [AJCC TNM Staging System 7th Edition \(AJCC V7\)](#)
- [Children's Depression Rating Scale, Revised \(CDRS-R\)](#)
- [Disease Steps \(DISEASE STEPS\)](#)
- [Epworth Sleepiness Scale \(ESS\)](#)
- [Paced Tapping \(PACED TAPPING\)](#)
- [RAND Social Support Survey Instrument \(RAND SOCIAL SUPPORT SURVEY INSTRUMENT\)](#)

Questionnaires Available for Public Review

Comments due May 1st

- [4 Stair Ascend \(4 STAIR ASCEND\)](#)
- [4 Stair Descend \(4 STAIR DESCEND\)](#)
- [Age, Treatment with Systemic Antibiotics, Leukocyte Count, Serum Albumin, and Serum Creatinine as a Measure of Renal Function \(ATLAS\)](#)
- [Combat Exposure Scale \(CES\)](#)
- [Emotion Recognition \(EMOTION RECOGNITION\)](#)
- [Hamilton Anxiety Rating Scale \(HAM-A\)](#)
- [Hospital Anxiety and Depression Scale \(HADS\)](#)
- [Life Events Checklist for DSM-5, Standard Version \(LEC-5 STANDARD VERSION\)](#)
- [Non-Small Cell Lung Cancer Symptom Assessment Questionnaire Version 1.0 \(NSCLC-SAQ v1.0\)](#)
- [PTSD Checklist for DSM-5 \(PCL-5\)](#)
- [Rising From Floor \(RISING FROM FLOOR\)](#)
- [Symptoms of Major Depressive Disorder Scale Version 1.0 \(SMDDS v1.0\)](#)
- [Ten Meter Walk/Run \(TEN METER WALK/RUN\)](#)
- [Veterans Administration Lung Study Group \(VALG\)](#)

Questionnaires Soon to be Published

- Clinical Global Impressions (CGI)
- Patient Global Impressions (PGI)



CDISC ADQRS ADaM Sub-team

Presented by Nancy Brucken and Karin LaPann

CDISC ADaM ADQRS sub-team





What is the Status of ADQRS Supplement Development?

- GDS Short Form to be published in 2019
- Working exclusively on the CDISC wiki for document creation
- Created template on wiki for supplement creation, to facilitate production and consistency for future supplements
- 5 Supplements in the pipeline:
 - GAD-7
 - CHART-SF
 - PAIN INTENSITY (PI) (3 analog scales)
 - HAMD-17
 - CGI/PGI

Do the ADaM supplements have Controlled Terminology?

Here is a sample request to the CDISC CT team

	A	B	C	D	E
1	Please complete all yellow highlighted columns as well as the new codelist metadata in rows 3-5.				
2					
3	New Codelist Name:	GDS02PC			
		GDS02PN			
4	New Codelist Description:	Geriatric Depression Scale Short Form Questionnaire Parameter Code			
		Geriatric Depression Scale Short Form Questionnaire Parameter Name			
5	What variable, TEST/PARM, or NSV will this codelist support?	PARAMC			
		PARAMN			
6					
7	Requested TEST or PARM Name Submission Value (40 Char Max)	Requested TESTCD or PARMCD Submission Value (8 Char Max)	Requested Synonym(s)	Requested Definition (For CDISC-Glossary additions, please include citation)	Request Reason/Use Case/Supplemental Information (See instructions on types of information to include here within the first tab)
8	GDS02 - Total Score	GDS02TS	GDS02 - Total Score	Geriatric Depression Scale Short Form - Total Score.	Controlled terminology for GDSSF Total Score parameter code/name calculated
9					

Finalized Controlled Terminology (CT) for ADaM

After discussion, finalized and published CT (March 2019)

ADaM Terminology.xls [Compatibility Mode]

	A	B	C	D	E	F
	Code	Codelist Code	Codelist Extensible (Yes/No)	Codelist Name	CDISC Submission Value	CDISC Synonym(s)
1						
38	C158114		No	Geriatric Depression Scale Short Form Questionnaire Parameter Code	GDS02PC	Geriatric Depression Scale Short Form Questionnaire Parameter Code
39	C158155	C158114		Geriatric Depression Scale Short Form Questionnaire Parameter Code	GDS02TS	GDS02-Total Score
40	C158115		No	Geriatric Depression Scale Short Form Questionnaire Parameter Name	GDS02PN	Geriatric Depression Scale Short Form Questionnaire Parameter Name
41	C158155	C158115		Geriatric Depression Scale Short Form Questionnaire Parameter Name	GDS02-Total Score	GDS02-Total Score

<https://www.cancer.gov/research/resources/terminology/cdisc>

What do I need to do to Develop ADaM Supplements?

- 1) JOIN THE TEAM AND HELP!!
- 2) Send suggestions for next supplements (must be public domain or have ADaM copyright permissions and be listed on the SDTM QRS site)

The ADaM ADQRS Subteam is comprised of over 17 members:

- 10 ADaM Team members
- 2 SDTM Team members
- 2+ CDISC Team members
- 3+ FDA Team members



CDISC ADQRS ADaM Sub-team

Presented by Jordan Li



<https://www.cdisc.org/standards/terminology>

-- Public Review --

Controlled Terminology Package 38 Public Review

Comments due: 29 Apr 2019

CDISC Controlled Terminology Package 38 is ready for public review. The public review package consists of 14 documents:

- Device
- ECG*
- General*
- Laboratory Terms*
- Microbiology*
- Oncology*
- PK
- Protocol Entities
- SDTM Domain
- SEND*
- SEND Animal Rule
- Units of Measure
- P38 Requests Denied
- Rules for MB and MS

***If there is QRS terminology for public review, the announcement would be made here along with the access WIKI link to download the terminology file.**

An * indicates that **changes to previously existing CDISC Submission Values** are also included on the "Changes to Existing" tab in the document. Please review these changes as they may be submission value changes or term deprecations.

The public review files and comments will be using the CDISC WIKI. Please access the link below and follow the instructions.

<https://wiki.cdisc.org/display/CT/Terminology+Call+for+Public+Review+Package+P38+-+Comments+Due+by+29+April+2019>

CURRENT PUBLIC REVIEWS

SDTM v1.8

Comments Due by: 29 Apr 2019

Controlled Terminology Package 38 Public Review

Comments Due by: 29 Apr 2019

SENDIG-Animal Rule v1.0

Comments Due by: 29 Apr 2019

CDISC Public Webinar: SENDIG Animal Rule Public Review

Considerations for Race and Ethnicity Data in Clinical Trials

Comments Due by: 1 May 2019

QRS Supplements

Comments Due by: 1 May 2019

ADaM Data Structures for Integration

Comments Due by: 21 May 2019

DOWNLOADS

Link(s):

Controlled Terminology Release

QRS Terminology Public Review

QRS terminology typically does not go out for public review because the codelists are non-extensible, and terminology for questionnaires, functional tests and clinical classifications are normally verbatim recreation of the instrument. However please look out for the following items during public review:

- 1) QRS METHOD Terminology (QRSMETHOD): this codelist supports the QSMETHOD, FTMETHOD and RSMETHOD variables. New values added to this codelist will be subjected to public review.
- 2) Major New QRS Decisions: For example, CDISC plans to create controlled terminology for original and standard results for QRS instruments. This type of changes will be communicated to the user community via public review.
- 3) QRS Naming Rule Document: this file contains terminology writing/development rules for QS, FT and CC/RS terminology.

Request for New QRS Terminology and Changes to Existing QRS Terminology

- SEND*
- SEND Animal Rule
- Units of Measure
- P38 Requests Denied
- Rules for MB and MS

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<https://wiki.cdisc.org/display/CT/Terminology+Call+for+Public+Review+Package+P38+-+Comments+Due+by+29+April+2019>

CDISC relies on your input to ensure neutral, consensus-based data standards are developed and adopted by a diverse global community interested in improving research processes and quality for the benefit of all.

Thank you for contributing your time and expertise.

Controlled Terminology is the set of codelists and valid values used with data items within CDISC-defined datasets. Controlled Terminology provides the values required for submission to FDA and PMDA in CDISC-compliant datasets. Controlled Terminology does not tell you *WHAT* to collect; it

Considerations for Race and Ethnicity Data in Clinical Trials

Comments Due by: 1 May 2019

ADaM Data Structures for Integration

Comments Due by: 21 May 2019

DOWNLOADS

Link(s):

Controlled Terminology Release

CONTROLLED TERMINOLOGY RESOURCES

New Term Request Page ←

Multiple Term Request

CT Requests Denied

Publication Schedule

NCI EVS-CDISC New Term Request Page

Please fill out the information on this page and click “submit”. For additional attachments and supporting documents, please use the email in the highlighted red box.

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

NIH NATIONAL CANCER INSTITUTE www.cancer.gov

EVS Enterprise Vocabulary Services

Term Suggestion

Quick Links

Contact Information:

Business Email: *

Name:

Business Phone Number:

Organization:

Privacy Notice: For term submission purposes we request business contact information only, not personal information. Your business email, and any other business contact information that you enter, will be stored in a publicly-accessible web site in support of CDISC term submission tracking. CDISC personnel may contact you.

Term Information:

Vocabulary: CDISC Terminology

Request Type: None

CDISC Code List: Multiple

Enter Term or Codelist Request Information: *

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 Form](#) and add 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.

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

What to Include in a New QRS Term/Codelist Request

For sponsor requests, please submit the following supporting documents if available:

- 1) CRF of the Instrument.
- 2) Scoring Instruction/Manual.
- 3) Reference article from which the instrument is originally created.
- 4) Public Domain/Copyright Information.
 - If copyrighted, please provide copyright holder information.
- 5) Draft terminology.

Send all supporting documents to: NciEvsCdiscHelp@mail.nih.gov, after completing the INFO page:

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

Multiple Term Request File Download

- SEND*
- SEND Animal Rule
- Units of Measure
- P38 Requests Denied
- Rules for MB and MS

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<https://wiki.cdisc.org/display/CT/Terminology+Call+for+Public+Review+Package+P38+-+Comments+Due+by+29+April+2019>

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DOWNLOADS

Link(s):

Controlled Terminology Release

CONTROLLED TERMINOLOGY RESOURCES

New Term Request Page

Multiple Term Request ←

CT Requests Denied

Publication Schedule

Submit New Draft QRS Terminology

Please complete all yellow highlighted columns as well as the new codelist metadata in rows 3-5.

New Codelist Name:		<Requested Codelist Name>			
New Codelist Description:		<Requested Codelist Description>			
What variable, TEST/PARM, or NSV will this codelist support?		<Variable, TEST, PARMCD, or NSV (Non-Standard Variable) supported by requested codelist>			
Requested TEST or PARM Name Submission Value (40 Char Max)	Requested TESTCD or PARMCD Submission Value (8 Char Max)	Requested Synonym(s)	Requested Definition (For CDISC-Glossary additions, please include citation)	Request Reason/Use Case/Supplemental Information (See instructions on types of information to include here within the first tab)	Supplemental Attachment (See instructions on how to attach documents to an Excel worksheet in the first tab)

Exist Codelist - New TEST PARM | Exist Codelist - New Term | Changes to Existing Term | **New Codelist - TEST or PARM** | New (...)

Submit Changes to Existing QRS Terminology

Please complete all yellow highlighted columns.

Changes to Existing Terms:

CT Version Date	Code	Codelist Code	Codelist Extensible (Yes/No)	Codelist Name	CDISC Submission Value (strikethrough the original value and put the change value in red font)	CDISC Synonym(s) (add new synonyms in red font; put a strikethrough on synonyms to be deleted)	CDISC Definition (strikethrough the original value and put the change value in red font)	NCI Preferred Term (strikethrough the original value and put the change value in red font)	Request Reason/Use Case/Supplemental Information (see instructions on types of information to include here within the first tab)	Supplemental Attachment (See instructions on how to attach documents to an Excel worksheet in the first tab)
2017-12-22	C17998	C66768		Outcome of Event	UNKNOWN U	U; Unknown; UNK	Not known, not observed, not recorded, or refused. (NCR) The data is not known, observed or recorded.	Unknown	THIS IS AN EXAMPLE OF HOW TO COMPLETE THE ROW ONLY - New updated information should be present in red font. Removals of existing content should be identified by a strikethrough.	

Exist Codelist - New TEST PARM | Exist Codelist - New Term | **Changes to Existing Term** | New Codelist - TEST or PARM | New (...)

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

- Emotion Recognition (EMOTION RECOGNITION)
- Hamilton Anxiety Rating Scale (HAM-A)
- Hospital Anxiety and Depression Scale (HADS)
- Life Events checklist for DSM-5, Standard Version (LEC-5 STANDARD VERSION)
- Non-Small Cell Lung Cancer Symptom Assessment Questionnaire Version 1.0 (NSCLC-SAQ v1.0)
- PTSD Checklist for DSM-5 (PCL-5)
- Rising From Floor (RISING FROM FLOOR)
- Symptoms of Major Depressive Disorder Scale Version 1.0 (SMDDS v1.0)
- Ten Meter Walk/Run (TEN METER WALK/RUN)
- Veterans Administration Lung Study Group (VALG)

CDISC relies on your input to ensure neutral, consensus-based data standards are developed and adopted by a diverse global community interested in improving research processes and quality for the benefit of all. Public review is a key quality step in the development of a standard.

View draft documents: **QRS Supplements**

You will need to log in or register for the CDISC Wiki to provide comments.

- To register for the Wiki: **Register**. JIRA and Wiki use the same login, please create only one account.
- Instructions for providing comments: **Instructions for Reviewers**

CDISC Wiki is a different login from www.cdisc.org.

CDISC develops SDTM (tabulation) and ADaM (analysis) QRS supplements that provide information on how to structure the data in a standard format for public domain and copyright-approved



QRS Supplements

Comments Due by: 1 May 2019

Considerations for Race and Ethnicity Data in Clinical Trials

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ADaM Data Structures for Integration

Comments Due by: 21 May 2019

QRS IMPLEMENTATION DOCUMENTS

QRS Naming Rules



CDISC QRS Supplement Request Form

FACIT Item Bank

TEAM CHARTER

Team Charter

RELATED STANDARDS

Controlled Terminology

Terminology Rules that Apply to All QS, FT and CC/RS Instruments

A

*Rules that apply to all QS, FT, and CC/RS terminology

1. US English is the strongly preferred language for QRS terminology.

2. If US English version is available, always use US English spelling to code an instrument, unless:

-The instrument explicitly uses both English spellings of a term. For example, if an item on the instrument shows: Diarrhea/Diarrhoea. In this case, TEST NAME and CDISC Definition should include both English spellings of the term.

QSTEST = XXXX01-Diarrhea/Diarrhoea Frequency (if it fits in the 40 character limit)

QS Definition = XXXXXX Instrument – Diarrhea/Diarrhoea frequency.

3. If an instrument absolutely has no US English version, but has other English versions, the QRS Controlled Terminology Team reserves the right to review and develop terminology on a case by case basis.

2019-03-11

General QRS Rules

CC_FT_QS CAT Rules

CC_FT_QS TEST-CD Rules



Rules for --CAT Terminology (QS, FT, CC/RS)

➤ Rules for CAT submission value, synonym and definition creation

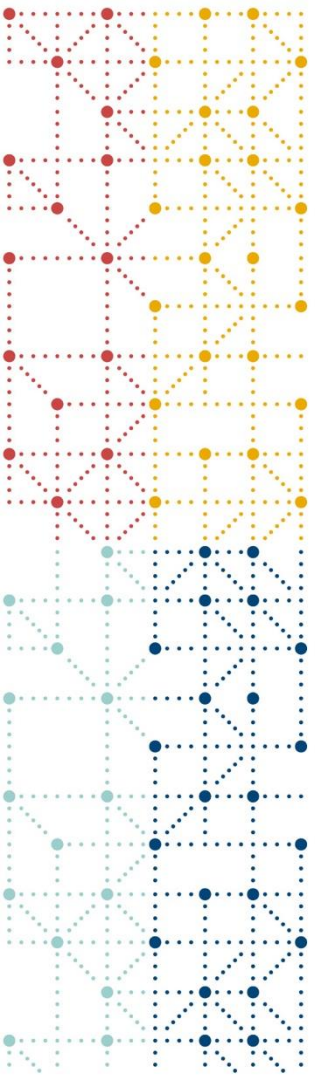
CAT Naming Rules for CC, FT and QS	Examples
<p>Submission Value: A name that uniquely identifies an individual assessment. Where possible, use the most common name that the assessment is known by. This may be an acronym or a complete name of the assessment.</p> <p>If there are multiple versions of an assessment (i.e. version updates), it is important to also include the version number or version name of the assessment in the submission value.</p> <p><i>Upper case text only.</i></p>	<p>EXAMPLES: DAD (i.e. Disability Assessment for Dementia)</p> <p>APACHE II (i.e. Acute Physiology and Chronic Health Evaluation II)</p> <p>FACT-HEP V4 (i.e. Functional Assessment of Cancer Therapy-Hepatobiliary Version 4)</p> <p>TRIGGER-AMBULATION INDEX (no commonly known acronym, hence full name of the assessment is used)</p>
<p>Synonym: A short code name for the assessment used as the basis of the --TESTCD and --TEST. It should be no more than 6 characters but may need to be shortened depending upon how many questions are included in an assessment. A sequence number should be added to the short name. This number represents the chronological order for which the terminology of the instrument is created. The sequence number should start with 01, but may be shortened to 1 to accommodate 8 characters within the --TESTCD value. All assessments should have a sequence number even if there is only one version of the instrument that has been published.</p> <p>Please note: the sequence number is unrelated to the developer/owner/author's version of the instrument.</p> <p><i>Upper case text only.</i></p>	<p>EXAMPLES: DAD01 (i.e. DAD + 01)</p> <p>APCH1 (i.e. APCH + 1)</p> <p>FAC015 (i.e. FAC + 015) more than 100 versions of FACT</p>
<p>Definition: The full name of the assessment including the version if available, is followed by the assessment acronym in parenthesis, followed by: -If copyrighted, include the copyright details and the relevant citation (where available) in parentheses. -If in the public domain, include the reference article citation from which the assessment was originally published in parentheses.</p> <p><i>Sentence case text format.</i></p>	<p>EXAMPLES: Copyrighted Instruments: Negative Symptom Assessment-16 (NSA-16) (Version 2.0, Copyright 2006, Larry Alphas, MD, PhD, All Right Reserved).</p> <p>Public Domain Instruments: Acute Physiology and Chronic Health Evaluation II (APACHE II) (Knaus WA, Draper EA, Wagner DP, Zimmerman JE. APACHE II: a severity of disease classification system. Critical Care Medicine 1985; 13(10):818-29).</p>

Rules for --TEST/CD Terminology (QS, FT, CC/RS)

➤ Rules for TEST-CD submission value, synonym and definition creation

1	A	D	C
<p>TEST-CD Naming Rules for CC, FT and QS</p> <p>TESTCD: A code limited to 8 characters beginning with the --CAT Synonym followed immediately by the item number. Where item numbers are included on the original assessment, the TESTCD should faithfully represent the item with alpha-numeric characters as provided. In the absence of item numbers on the original assessment, sequential numbering is used beginning with 01.</p> <p>TESTCD cannot start with a number, and cannot contain characters other than letters, numbers, or underscores.</p> <p><i>Upper case text only.</i></p>	<p>Additional Notes</p> <p>The numbering of the --TESTCDs should follow item numbering on the CRF as closely as possible. All items should be accounted for consistently in CT and annotation. For example, a questionnaire with items numbered 1-23 on the CRF, should have --TESTCDs = xxxnn01 - xxxnn23.</p> <p>Where questions are numbered, but additional sub-questions are present without numbering:</p> <ul style="list-style-type: none"> • If the sub-questions are conditional to a specific answer to the first question, then the initial question is e.g., xxxnn23 and subsequent questions are e.g., xxxnn23A, xxxnn23B, xxxnn23C etc. • If sub-questions are answered regardless of the initial response, then all questions have a letter appended e.g., xxxnn23A, xxxnn23B ... • Questions that may explain another response (qualifiers) should not be included in the --TESTCD/TESTs and may map to another variable (e.g., --STAT) <p>Where '.' (period) is used in the question numbering on the original CRF (e.g., sub-questions), '_' (underscore) may replace the '.' (period). For example, when a CRF numbers the questions as 1.1, 1.2, 2.1, 2.2, etc., in order to follow the original numbering as closely as possible, the underscore sign will replace the period sign in the --TESTCD (e.g., xxxnn1_1; xxxnn2_2).</p>	<p>Examples:</p> <p>EXAMPLE: DAD0101, APCH101</p> <p>EXAMPLE: Are you currently driving? (VFQ0115) Never Driven or Given Up Driving (VFQ0115A) Main Reason You Gave Up Driving (VFQ0115B)</p> <p>EXAMPLE: How Intense is Your Deep Pain (NPS0110A) How Intense is Your Surface Pain (NPS0110B) (there is no --TESTCD for NPS0110)</p> <p>EXAMPLE: Lacked support from your spouse or partner? (PDQ0128) If you do not have a spouse or partner check here __ (QSSTAT)</p> <p>EXAMPLE: Does [name] only moan, groan or make other sounds that are not understandable? (ED102_5)</p>	
<p>2</p> <p>TEST: A brief description of each question/item's intent. Beginning with the --CAT Synonym, followed by a hyphen, with no spaces before or after the hyphen. Text after the hyphen may be shortened or abbreviated to maintain the 40 character limit as needed, but should faithfully retain the question/item's intent.</p> <p><i>Title case text format after the hyphen (with a few</i></p>	<p>Title Case exceptions - use lower case text for the following words: a, an, and, as, at, but, by, for, in, nor, of, on, or, per, to, the.</p> <p>The following rules are intended primarily to facilitate consistency:</p> <ul style="list-style-type: none"> - Capitalize the first and last words in titles except as part of a name, and capitalize all other major words (nouns, pronouns, verbs, adjectives, adverbs, and some conjunctions). - Lowercase prepositions of 3 characters or less, except when used adverbially or adjectivally ("on" in "The On Button", "to" in "Come To", etc.) or as part of a Latin expression used adjectivally or adverbially (De Facto, In Vitro, etc.). 	<p>EXAMPLE: DAD01-Decide to Wash</p> <p>APCH1-Respiratory Rate</p> <p>CSS04-Preparatory Acts/Behav, Descr</p> <p>ED1-Able to Communicate Clearly</p>	

Note: the Rule Document provides general guidance to help users to create CDISC-compliant QRS terminology; they are recommendations, not mandates.



Audience Questions

Audience Questions

What is the status of ADQRS supplement development?



Audience Questions

Please describe the process for the CDISC QRS team receiving and processing external requests for new QRS Supplement development.



Audience Questions

Could you consider creating results codelist for questionnaires?



Audience Questions

What is the minimum requirements for making a request for a new QRS with all its terminology?



Audience Questions

What SDTM and ADaM standards exist and for which Questionnaires and scales? Where can they be found?



Audience Questions

What is the process for submitting a new instrument for standardization? And about how long does the entire process take?



Audience Questions

How can we now (without to search on internet) where the informations of a QRS has to go? Which domain to use for each QRS?



Audience Questions

Should the ranges related to questionnaires be added in SUPPQS (ie: CDISC SDTM Pain Intensity Questionnaire Supplement (V1.0))?



Audience Questions

Since I have an SDTM QS dataset for my clinical study, how many ADQSxx datasets should I create?



Audience Questions

How do you select questionnaires for ADaM supplement development?



Audience Questions

What do I need to do if I have a questionnaire that I'd like to develop an ADaM supplement for?



Audience Questions

The ADaM supplement only includes a BDS example. What if I need to run a different type of analysis, like correlations, that won't work with a BDS dataset?



Audience Questions

How can/should sponsors best contact QRS team going forward?



Audience Questions

What expectations are there around sponsor implementation of QRS instruments when Controlled Terminology exists for TEST/TESTCDs, but there is no published supplement showing expected response values (e.g. PASI)?



Audience Questions

How should a sponsor handle a vendor collecting ORRES values for a QSTESTCD in a field that allowed for more than 200 characters - how should the extra text be submitted/handled?



Audience Questions

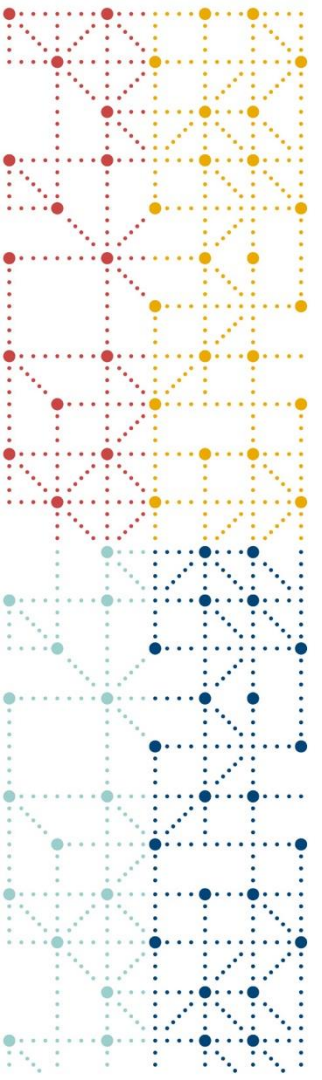
How is team handling British versus American English text differences?



Audience Questions

Is there a way for sponsors to see what is coming next from QRS team (e.g. when psoriasis supplements will be out for review)?





Upcoming Learning Opportunities





2019 Public Courses in North America

Location:	Dates:	Courses Offered:	Discount period ends:	Host:
Bridgewater, NJ	20-24 MAY	SEND, CDASH, SDTM, Define-XML, ADaM	18 FEB 2019	
Seattle, WA	3-7 JUN	CDASH, SDTM, ADaM	4 MAR 2019	 <small>PHARMACEUTICAL COMPANIES of Johnson & Johnson</small>
Gaithersburg, MD	9-13 SEP	CDASH, SDTM, Define-XML, ADaM	10 JUN 2019	 <small>PARTNERS IN RESEARCH</small>

Visit cdisc.org/public-courses for information on additional Public Training even





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Amsterdam, Netherlands	6-10 MAY	SDTM, SDTM-MD, SEND, ADaM, Define-XML, ODM, Controlled Terminology, CDASH, CDISC for Newcomers	TBD	
Frankfurt, Germany	3-7 JUN	SDTM, CDASH, ADaM Primer + Theory & Application, Define-XML	4 MAR	
Brussels Belgium	9-13 SEP	CDASH, SDTM, Define-XML, ADaM Primer + Theory & Application	6 JUN	
Paris, France	7-11 OCT	CDASH, SDTM, Define-XML, ADaM Primer + Theory & Application	8 JUL	

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Location	Dates	Courses Offered:	Discount period ends:	Host:
Osaka, Japan	3-7 JUN	SDTM, CDASH, ADaM Primer + Theory & Application, Define-XML	3 MAR	
Tokyo, Japan	2-6 SEP	SDTM, CDASH, ADaM Primer + Theory & Application, Define-XML	2 JUN	

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2019 Webinars

Date	Webinar Title
16 APR	CDISC Public Webinar: Quarterly Controlled Terminology Updates
18 APR	CDISC Public Webinar: ADaMIG v1.2 & ADaM Integration
19 APR	CDISC Public Webinar: Highlights of Define-XML 2.0 Implementation & FAQ
25 APR	CDISC Public Webinar: Membership Benefits
23 MAY	CDISC Public Webinar: Relative Timing Variables in CRFs
9 JUL	CDISC Public Webinar: Quarterly Controlled Terminology Updates
25 JUL	CDISC Public Webinar: ODM v2.0 Demo Tech

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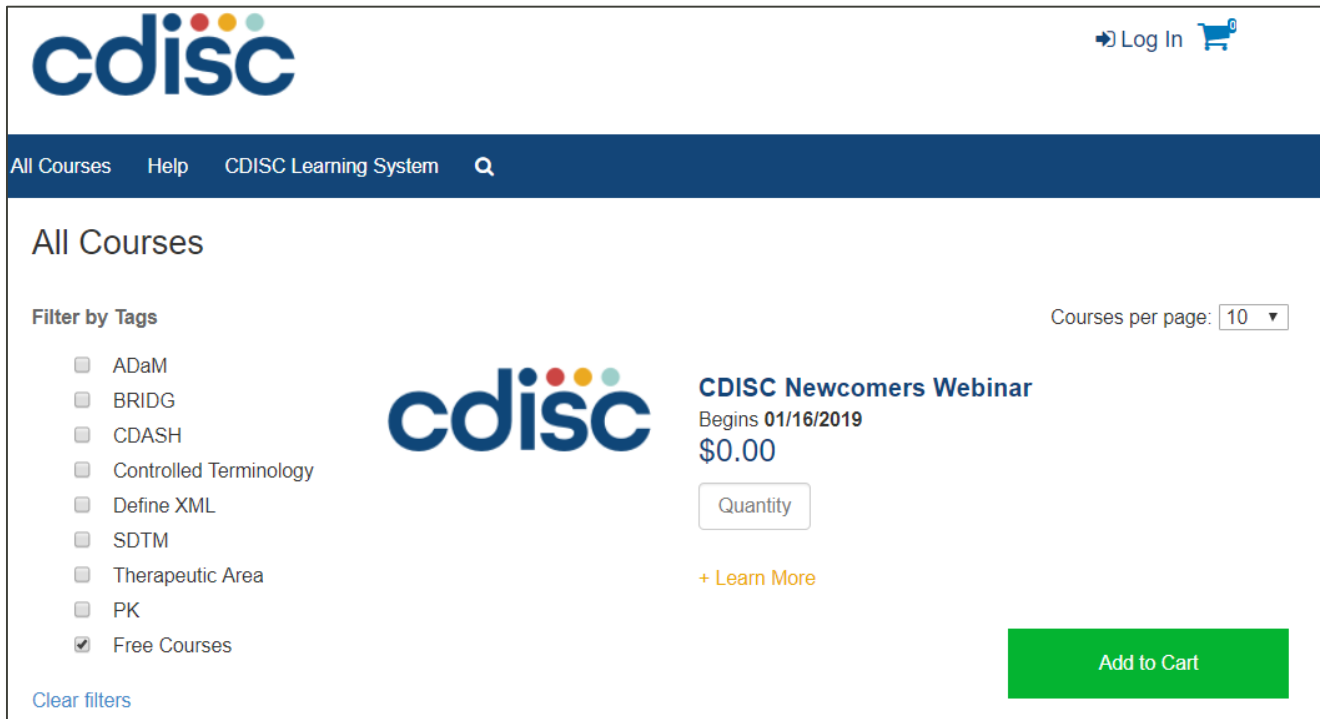


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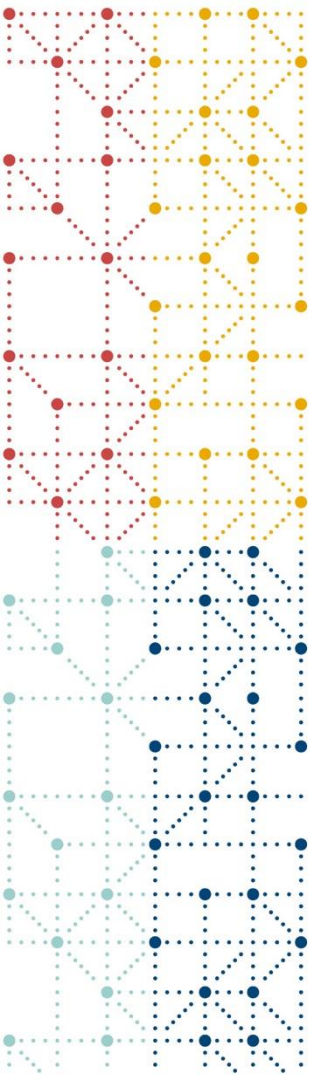


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>50,000	\$50,740	\$59,740	Annual fee + \$59,740

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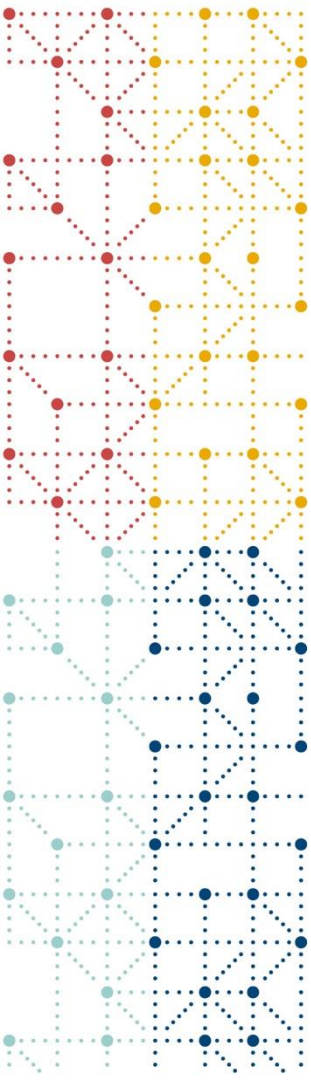
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Any Last Questions?





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